Sandwell
Metropolitan Borough Council

Health and Adult Social Care Scrutiny Board

Monday 20 January, 2020 at 6.00 pm
in Committee Room 2
at the Sandwell Council House, Oldbury

Agenda

(Open to Public and Press)

1. Apologies for absence.

2. Members to declare:-

   (a) any interest in matters to be discussed at the meeting;
   (b) the existence and nature of any political Party Whip on any matter to be considered at the meeting.

3. To confirm the minutes of the meeting held on 18 November, 2019 as a correct record.

4. NHS Sandwell and West Birmingham Clinical Commissioning Group (SWB CCG) Minor Surgery and Non-Obstetric Ultrasound Scan (NOUS) Service.

5. NHS Sandwell and West Birmingham Clinical Commissioning Group (SWB CCG) Harmonisation of Treatment Policies (Phase 3)

6. Proposed change of location provision of services under General Anaesthesia (GA) for Children in Sandwell General Hospital to Birmingham Dental Hospital in 2022.

7. NHS Sandwell and West Birmingham Clinical Commissioning Group (SWB CCG) listening exercise from 6 January to 14 February 2020 - the future of the Summerfield Urgent Care Centre in West Birmingham and the Parsonage Street Walk-in Centre in Sandwell.

Date of next meeting: 23 March 2020

David Stevens
Interim Chief Executive

Sandwell Council House
Freeth Street
Oldbury
West Midlands

Distribution:
Councillor E M Giles (Chair);
Councillor Piper (Vice-Chair);
Councillors Carmichael, Costigan, Hackett, Hartwell, Jarvis, R Jones, Kausar, Phillips and Tranter.

Agenda prepared by Deb Breedon
Democratic Services Unit - Tel: 0121 569 3896
E-mail: deborah_breedon@sandwell.gov.uk

This document is available in large print on request to the above telephone number. The document is also available electronically on the Committee Management Information System which can be accessed from the Council's web site on www.sandwell.gov.uk

Sandwell
Metropolitan Borough Council

Agenda Item 1

Health and Adult Social Care Scrutiny Board

Apologies for Absence

The Board will receive any apologies for absence from the members of the Board.

Sandwell
Metropolitan Borough Council

Agenda Item 2

Health and Adult Social Care Scrutiny Board

Declaration of Interests

Members to declare:-

(a) any interest in matters to be discussed at the meeting;

(b) the existence and nature of any political Party Whip on any matter to be considered at the meeting.

Sandwell Metropolitan Borough Council

Agenda Item 3

Minutes of the Health and Adult Social Care Scrutiny Board

18th November, 2019 at 5.30pm
at Sandwell Council House, Oldbury

Present: Councillor E M Giles (Chair);
Councillor Piper (Vice-Chair);
Councillors Hartwell, Kauser, Phillips and Tranter.

Apologies: Councillors Carmichael, Costigan, Hackett, Jarvis and R Jones.

In Attendance: Lisa McNally, Director of Public Health;
Deb Ward, Safeguarding Adults Manager;
Michelle Carolan, Chief Officer for Quality CCG;
Karen Emms, Service Manager (Social Work and Reablement);
John Taylor, Chair, Healthwatch Sandwell;
Dave Bradshaw, Healthwatch Sandwell.

20/19 **Minutes**

Resolved that the minutes of the meeting held on 7th October 2019 be approved as a correct record.

21/19 **Sandwell Safeguarding Adults Board Annual Report**

The Board received the Sandwell Safeguarding Adults (SSAB) Annual Report and a presentation from the SSAB Manager. The requirement to provide an annual report was a statutory duty and the presentation highlighted the main messages.

The following comments and responses to questions from the Board were noted: -

- the Care Act defines a person in need of safeguarding as an adult with care and support need;
- work was ongoing with partners around the understanding of safeguarding thresholds. The Board was concerned that having

75% of people feeling safe indicated that 25% did not feel safe. The Council was working positively with them to make a difference to the 25%, looking at safeguarding in different ways to review and update policy and practices, undertake training and identify lead people;

- there had been increased awareness of abuse in Sandwell and this had led to an increase in numbers of reported abuse. The Board requested figures be forwarded to Members for information;
- the Chief Officer for Quality CCG thanked the SSAB Manager for the support given in relation to safeguarding adults. She advised that work was being done to ask relevant questions earlier, to respond earlier, to have earlier intervention and not let matters reach a critical stage. She advised that a designated person would be attending GP surgeries, liaising with relevant services, supporting them in safeguarding matters and creating lots of safe spaces and a support network;
- themes and priorities had been agreed and each of the four Statutory Boards had agreed to lead on an identified work stream within the Prevention of Violence and Exploitation (POVE) umbrella;
- three sub-groups worked to help people to better live their lives:
  - Quality and Excellence
  - Protection
  - Prevention
- it was confirmed that there was provision for male victims of domestic violence (DV) in Sandwell, there was a voluntary sector victims programme, that supported male victims. The Board requested it be advised who commissioned the service;
- the Board was advised that the highest incidents of adult abuse related to neglect and acts of omission, mainly relating to incidents in their own home. The highest level of incidents occurred against young males, violence against women was an issue later on. The Board was advised that most referrals were made by members of the community;
- The Board noted that physical abuse was the main form of abuse against young males and that there were many types of abuse physical, financial, neglect, modern day slavery, etc. The Board requested further information about the types and frequency of abuse in Sandwell;
- it was confirmed that Care Quality Commissioner (CQC) regulated and inspected care homes;
- the Board was advised that the Protection Sub Group (PSG) reviewed policies and procedures locally and regionally, the

SSAB Board Manager and PSG Lead attended the West Midlands Editorial Group to develop and review key policies and the West Midlands policies and procedures were also informed by ADASS group; the ADASS group in turn informed national direction and practice. In addition, there was also learning from SAR action plans in Sandwell to inform practice and policy development.

The Board noted the following comments in response to further questions:

- the referrals made by members of the community came via the Council. Members highlighted the need for people to report their concerns;
- the focus of the safeguarding campaign was to tell people what a concern looked like and what to do about it, raising awareness about safeguarding and training opportunities;
- information would be available in public places, libraries and Public Health would aid the campaign to help get messages out about safeguarding through a number of mechanisms;
- Healthwatch raised a concern that there was not much evidence or information in the Annual report about what had been achieved to respond to the public voice. The SSAB Manager advised that the Annual report was retrospective and that next year it would present what action had been taken and the consequences;
- the Board highlighted that front-line staff and carers were often the greatest asset to observe and to raise the concerns and the service users voice;
- the Director of Public Health highlighted that advice for young males and the way this was provided was potentially a gap in provision. This was something the Council would be interested in looking into with the SSAB Manager to consider awareness of provision for males in domestic violence, including same gender relationships;
- the Board welcomed the increase in safeguarding referrals and thanked the SSAB Manager for her hard work;
- the Board noted that the greatest vulnerability of adults was abuse in their own homes, neglect, and vulnerable young men who may be exposed to abuse and isolation. Members requested a report to highlight the types of abuse and more detail on financial abuse statistics in Sandwell;

The Chair thanked the SSAB Manager and Director of Public Health

for the Annual report and Chief Officer for Quality CCG and officers for their responses to questions. She summarised the requests for further information.

Resolved:

(1) to request the Sandwell Safeguarding Adults Board Manager and Director of Public Health to provide further information to Health and Adult Social Care Scrutiny Board relating to the following requests and enquiries:

- Provide statistics and trend data for the number of domestic abuse reported in Sandwell, is this an increasing trend?
- Provide information relating to male victims of domestic abuse, including who commissions the service and who provides the service in the third sector, what is the victims programme?
- Confirm what are the types of abuse (physical, financial etc) and what percentage of abuse is financial abuse?
- Make a recommendation for safeguarding awareness training as part of the campaign to raise awareness. For Members to learn to recognise and understand more about referrals, how to recognise a concern and what to do about it.
- Make a request for information to clarify how Healthwatch and Voluntary sector are working on services for male victims of abuse.
- Make a request for information about the Community Care Partnership and how the CCG was working with adult safety.

22/19 **Deprivation of Liberty Safeguards (DOLS) mental capacity**

The Board received a report and presentation from the Service Manager, Social Work and Reablement, to illustrate the changes in the law and how this related to the operating model and practice in Sandwell.

The Board noted that the Mental Capacity Law was changing and that the current scheme Deprivation of Liberty Safeguards (DoLS) would cease. The new scheme called Liberty Protection Safeguards (LPS) received royal assent on 17th May 2019 and had an implementation date of 1st October 2020. The Board noted that the Council would still consider 'Best Interest' but one of the biggest changes was that the Council would no longer need to take to court and the responsible body would be able to make decisions.

The Board noted that the Government had changed the age range for deprivation of Liberty from aged 18 to enabling care or treatment of a person, to age 16+, and that there would have to be work carried out with Children's Services to ensure pathways for 16-18 year olds.

The restrictions placed would affect all settings, including home, and it would include all people regardless of where they were residing at the current time. The level of restraint covered a wide range, some individuals would have around the clock restraint, such as belts and straps, others may require a restraint or restriction when moving by transport, including how they were secured for transportation. The Board noted that there would have to be an assessment of how they were restrained.

From October 2020 the new responsible bodies would be the Hospital Manager, the Local Authority and the CCG. The relevant body providing the case would need to be heard by the responsible officer in the organisation they were being restrained by, as well as any person in their own home. The Board was advised that the code of practice would be published in Springtime 2020, which should provide further clarity on who should be making the decision. There would be three key assessments:

- Capacity Assessment to determine if they lack capacity
- Medical Assessment if a person had a mental disorder
- Necessary and Proportionate Assessment to be necessary to prevent harm to the person or likelihood and seriousness of such harm

The Board was advised that when people were defined as not having capacity their wishes and feelings would be considered from previous records made by social workers and other appropriate records. They were advised that social workers talked with people about moving forward and their history could be considered in the assessments.

To carry out LPS the responsible person must be able to demonstrate that they had consulted and included the person, any named person, carers or anyone interested in the person's welfare, any deputy or attorney, the IMCA or appropriate person and the responsible person must, where the person needs advocacy, include them and whether family or friend wants to act as an authorised person.

The Board noted that the pre-authorisation checks needed to happen and that there was a need to think about pre-authorisation process and whether to add to existing roles or to develop a new role. The existing Approved Mental Capacity Professional (AMCP) must meet the person in complex cases, when a person is objecting to a deprivation of liberty. The Local Authority must approve all AMCPs for all the responsible bodies within the area and there were options to consider about how to do that, such as outsource and develop a framework, or to develop the Councils operating structure. The Local Authority had to ensure that it had enough AMCPs to deal with capacity required.

The Board noted that would have to be a process to consider objections to deprivation of liberty, the AMCP role would be crucial to take the person through the process. Currently in Sandwell there were between 900 – 1000 people in deprivation of liberty, less than 10% of these were in residential care, probably in the region of 3-4%.

The Board noted the risk was that the age range was broadening out and that the LA was not sure how many more would need LPS. The Board was advised that this would be monitored and reviewed after one year.

The Board noted that this was quite a responsibility to place on Care Homes. The House of Lords decision had been that the responsible body should decide how Care Homes should be involved in the pathway, but there was further work for the Council to do around this, there were a lot of questions and the code of practice had not yet been published.

The Board noted that with regard to rights to information the legislation was clear, and the Council was working through the elements, the duty to provide care and support plan, to be clear why, how it had to happen and to review the care and support plan every

twelve months for the first two years. After that the support plan would be reviewed every three years.

The Board noted that there was a right to challenge and that CQC and Ofsted would monitor performance.

The Board noted the next steps once the code of practice was received as follows:

- training and workforce strategy – aim to get the right member of staff;
- revised impact assessment - revisit the options paper
- transition arrangements – from the Adult Social Care (ASC) perspective, 1200 people already had deprivation of liberty, all would need to go through the new LPS process and be on the new register. The impact of the addition of the 16 – 18 age group was not currently known, but all would need to go through the LPS process and need to be added to the new register.

The Board noted the importance of getting the right operating model and practice in place.

The Board noted the following comments in response to further questions:

- the greatest risks to the Council would be reputational. Financial risks and getting the options paper right. The operating model and framework was essential and there were some ideas for frameworks being looked at that the team would take through assessment process;
- there was a need to speak to Childrens Social Services as well as Health Organisations about the changes to LPS;
- the Code of Practice would be released in Spring 2020;
- officers were involved in workshops to give some early advice and gather feedback;
- the timescales were to get the Code of Practice in Spring 2020, agree operating model and go live in October 2020. The Government had given a twelve-month period to make the required changes.
- The risk rating for the transition was a low compliant rating, there was a need to do the options rating.

  The Board welcomed the early involvement of scrutiny and was advised that an update and the options paper with potential operating models could be presented to scrutiny at the March meeting.

Recommendations

(1) Requested a report to the Health and Adult Social Care Scrutiny Board in March 2020 to provide an update and to outline the options for operating models and code of practice to the March meeting.

(Meeting ended at 6.53 pm)

Contact Officer: Deb Breedon
Democratic Services Unit
0121 569 3896

Sandwell Metropolitan Borough Council

Agenda Item 4

REPORT TO

HEALTH AND ADULT SOCIAL CARE SCRUTINY BOARD

20 January, 2020

Subject:	SWB CCG Commissioning of Minor Surgery and Non-Obstetric Ultrasound Scan (NOUS) Services
Director:	Angela Poulton, Deputy Chief Officer – Strategic Commissioning and Redesign
Contribution towards Vision 2030:	
Contact Officer(s):	Hazel Barnes, Executive Assistant, SWB CCG - 0121 612 2772

1 PURPOSE OF THE REPORT

1.1 To provide feedback on the outcome of the public engagement undertaken regarding the future commissioning of Minor Surgery and Non-Obstetric Ultrasound Services.

2 BACKGROUND AND MAIN CONSIDERATIONS

2.1 On 17th June 2019 the Committee were advised of the two listening exercises that the CCG were undertaking (Monday 3rd June - Friday 28th June 2019) regarding Minor Surgery and Non-Obstetric Ultrasound (NOUS) services.

2.2 The Minor Surgery contract was coming to the end of its term and following a service evaluation the Strategic Commissioning and Redesign (SCR) Committee agreed that this service would no longer be commissioned for the following reasons:

- The way the service was commissioned does not form part of a joined-up patient journey;

- The CCG could no longer financially sustain this service in the interests of protecting the public purse and using every pound wisely, and;
- The driver to support Primary Care Networks to build on primary care services and enable greater provision of personalised, coordinated and more joined up health and social care for our patients.

2.3 The CCG has the statutory responsibility to ensure Minor Surgery provision for the 19 GP practices (14 of which are Sandwell practices) that did not sign up to the Minor Surgery GP Direct Enhanced Service (DES) during 2018/19.

2.4 With regards to NOUS, the current provider served notice on the CCG saying that this contract does not fit with its strategic priorities requiring the CCG to seek alternative provision for its patients.

2.5 This presented the opportunity for SWB CCG to hold a separate listening exercise in relation to each service to seek views and experiences by engaging with patients, their carers, local communities, general practice and members of the public to help shape Minor Surgery and NOUS services in the future.

2.6 The approach to the engagement was through a variety of methods including:

- Mailings by Post and Electronic
- Public meetings x 3
- Presentations
- Online survey
- Offline survey in paper format with a freepost envelope
- CCG Website
- CCG Twitter
- CCG Facebook

3 OUTCOME OF THE PUBLIC ENGAGEMENT

3.1 Minor Surgery

3.1.1 Based upon the feedback, the factors that matter most about this service to local people are as follows:

- **Venues** - to be given a choice of venues and information on where those are located and how to get to them i.e. transport links and maps of location

- **Appointments** - to be given a choice of times and flexibility such as evenings and weekends
- **Communication and Information** - patients to receive information before the appointment in relation to the procedure either for themselves or the person they are caring for; an explanation as to what is about to happen or be undertaken during the procedure; information to be given as to how to look after yourself following the procedure.
- **Waiting Times** - to be seen quicker especially if in pain.
- **Quality Service** - to receive a high-quality service from trained and competent health care professionals.

3.1.2 The Minor Surgery Listening Exercise Engagement Feedback report is attached in Appendix 1.

3.1.3 The CCG's SCR Committee received the engagement report and gave due consideration to the feedback in prior to agreeing the proposed future Minor Surgery service provision.

3.2 **NOUS**

3.2.1 Based upon the feedback, the factors that matter most about this service to local people are as follows:

- **Venues** - to be given a choice of venues and information on where those are located and how to get to them i.e. transport links and maps of location
- **Appointments** - to be given a choice of times and flexibility such as evenings and weekends
- **Communication and Information** - patients to receive information before the appointment in relation to the scan they are having done and why it is require; an explanation of how the scan will be carried out and how to dress for this; an indication given as to when results can be expected of the scan by the patients' GP.
- **Waiting Times** - to be seen quicker and happy to travel a little further if seen sooner.
- **Double Scanning** - no double scanning, having a scan first in the community, then in the hospital meaning double the cost and wasting time.
- **Quality Service** - to receive a high-quality service from trained and competent health care professionals in this speciality.
- **Results of Scan** - to be received in a timely manner, results to be transferred between community and hospital providers so dependent on where patient needs to go next the results will be there already, patients to take away a copy of their scan results.

3.2.2 The NOUS Listening Exercise Engagement Feedback report is attached in Appendix 2.

3.2.3 The CCG's SCR Committee received the engagement report and gave due consideration to the feedback in prior to agreeing the proposed future commissioning of NOUS service provision.

4 CURRENT STATUS

4.1 Minor Surgery

4.1.1 The contract with the previous provider ceased in September 2019. Based on patient choice, patients requiring the service can choose to be treated by either:

- their GP where they have signed up to the Minor Surgery GP Direct Enhanced Service (DES) in 2019/20
- any provider (NHS or independent sector) listed on the Electronic Referral System.

4.2 NOUS

4.2.1 The contract was due to cease at the end of July 2019 but has been extended to allow time for the commissioning process to complete.

4.2.2 Following the listening exercise, the service specification has been refreshed with the input of Dr Saj Sarwar. The service was put out to tender on 14th October 2019 following a market engagement event that was held on 1st October 2019. The tenders are currently being scored with the process due to end in mobilisation of the successful bidder in May 2020.

5 CONCLUSIONS AND SUMMARY OF REASONS FOR THE RECOMMENDATIONS

5.1 The Health and Scrutiny Committee:

- Note the outcome of listening exercise for Minor Surgery and NOUS, and the issues that matter most to local people who engaged in the process;
- The current service provision commissioned for Minor Surgery by GPs and NHS/independent providers listed on the NHS Electronic Referral System since September 2019; and

- The procurement underway to commission the future NOUS service, and the service to be delivered by the winning bidder to be mobilised by May 2020.

6 BACKGROUND PAPERS

6.1 Minor Surgery and Non-Obstetric Ultrasound Scan (NOUS) Service Listening Exercise Engagement – 17 June 2019

7 APPENDICES:

Appendix 1: Minor Surgery Listening Exercise Engagement Feedback Report
Appendix 2: Non-Obstetric Ultrasound Scan (NOUS) Listening Exercise Engagement Feedback Report

Angela Poulton
Deputy Chief Officer – Strategic Commissioning & Redesign, SWB CCG

NHS
Sandwell and
West Birmingham
Clinical Commissioning Group

Minor Surgery Listening Exercise

Engagement Feedback

Kally Judge
Commissioning Engagement Manager
July 2019

Contents

Appendices

1. Background

NHS Sandwell and West Birmingham Clinical Commissioning Group (SWB CCG) are responsible for commissioning (buying) local health services on behalf of the SWB CCG population. They are a membership organisation consisting of 81 practices with 103 sites and are responsible for 575,684 registered patients across the Sandwell and West Birmingham area.

The CCG commission a number of health care services, one of these services is Minor Surgery with a local organisation who provides community based healthcare services on behalf of the NHS to our organisation as well as other NHS organisations.

This contract is coming to the end of its term and earlier this year the service was reviewed and evaluated by the Commissioners and after careful consideration by the Strategic Commissioning and Redesign Committee (SCR) it was agreed that this service would no longer be commissioned for a number of reasons as stated below;

- The way the service was commissioned does not form part of a joined up patient journey

- The CCG could no longer financially sustain this service in the interests of protecting the public purse and using every pound wisely

- To support Primary Care Networks to build on primary care services and enable greater provision of personalised, coordinated and more joined up health and social care for our patients

This has presented an opportunity for SWB CCG to hold a listening exercise to seek views and experiences by engaging with patients, their carers, their communities, general practice and members of the public to help shape Minor Surgery services in the future.

Earlier this year the NHS Long Term Plan (LTP) was launched and this is a new NHS 10 year plan to improve the quality of patient care and health outcomes.

The CCG is supporting this plan by setting up Primary Care Networks to build on primary care services and enable greater provision of personalised, coordinated and more joined up health and social care for our patients, which means health care services will be commissioned in a different way in the future.

2. Introduction

A Communications and Engagement Plan was developed to ensure that patients, their carers, their communities, general practice and members of the public were effectively informed and involved in sharing their views and experiences on Minor Surgery to help shape services in the future.

In order to support this a range of activities were undertaken in accordance with the following objectives:

- Seeking views on Minor Surgery
- Learning of experiences of Minor Surgery
- Understanding what excellent Minor Surgery should look like
- Understanding what is currently not working well in Minor Surgery
- Understanding how the CCG puts things right in Minor Surgery

Please see **Appendix 1** to view a copy of the Communications and Engagement Plan.

3. Engagement Approach and Methodology

3.1 A four week listening exercise was launched on Monday 3rd June 2019 and closed on Friday 28th June 2019.

The approach to engagement was through a variety of methods including;

- Mailings by Post and Electronic
- Public meetings x 3
- Presentations
- Online survey
- Off line survey in paper format with a freepost envelope
- CCG Website
- CCG Twitter
- CCG Facebook

3.2 Materials

A suite of core documents were developed to support engagement activities including;

- A stakeholder letter informing our stakeholders of the listening exercise

- An information booklet containing a survey with an accompanying freepost envelope to ensure that no cost was incurred to the respondent for completion of the survey

- A presentation to support our listening exercise at public and stakeholder meetings

3.2.1 Activities undertaken

A detailed list of all Communications and Engagement activities can be viewed in the Communications and Engagement Plan. In summary, these activities have included:

3.2.2 Communications and Digital Activities

A questionnaire was developed on a survey monkey link and made available on the SWB CCG website. This survey monkey link was also featured on the stakeholder letters to promote the listening exercise.

Information on the engagement exercise was published on the SWB CCG website including a headline and introduction featured on the Get Involved page under "Current Consultation and Engagement" with a link to the questionnaire: https://sandwellandwestbhamccg.nhs.uk/consultations

Information on the listening exercise was featured on the following:

Websites:

- SWB CCG x 41 hits
- Health Watch Sandwell x hits (unknown)
- Health Watch Birmingham x hits (unknown)
- Sandwell Council of Voluntary Organisations (SCVO) x hits (unknown)
- Birmingham Voluntary Organisations (BVSC) x hits (unknown)

Twitter:

- SWB CCG
    - Tweets x 36
    - Retweets for Minor Surgery x 7
    - Seen by x 732 people
    - Impressions x 537

Facebook

- SWB CCG
    - Posted x 24
    - Likes x 4
    - Potential Reach/Views 320
    - Shares x (unknown)

Regular internal communications and reminders were sent through existing channels to CCG Staff as well as Member Practices consisting of clinical and non-clinical staff in Primary Care.

3.2.3 Postal/electronic mailings and distributions of letters/survey booklets/posters

A potential reach of at least **8841**, that we know of was calculated, as broken down in the table below:

Reach	Audience and distribution format
197	SWB CCG Patient Engagement Membership A stakeholder letter was posted to the SWB CCG Patient Engagement Membership, which included an invitation to the 3 dedicated public meetings including the survey link. This gave recipients of this communication the option of requesting a paper copy survey through the Engagement Team.
932	Nicks News Articles were featured in Nicks News, a weekly communication which is emailed to SWB CCG member practices promoting the listening exercise. Articles featured throughout the period of the listening exercise inviting General Practice to take part. In addition to this posters were also shared through this audience asking them to display the posters in their waiting rooms so that patients and staff were aware of the listening exercise.
293	Alice News Articles were featured in Alice's News, a weekly communication which is emailed to SWB CCG staff promoting the listening exercise. Articles featured throughout the period of the listening exercise inviting Staff to take part in the listening exercise especially as some staff may well be registered patients of SWB CCG.
2,400	Sandwell Council Voluntary Organisation (SCVO) Information was shared through SCVO, a weekly e-bulletin, to promote the listening exercise through their networks. Articles featured throughout the period of the listening exercise inviting the Voluntary Sector to take part in the listening exercise.
5000	Birmingham Voluntary Sector Council (BVSC) Information was shared through BVSC, a weekly e-bulletin, to promote the listening exercise through their networks. Articles featured throughout the period of the listening exercise inviting the Voluntary Sector to take part.

19	<u>Elected Members of Ladywood and Perry Barr Wards</u> Following attendance at Birmingham Overview and Scrutiny Committee (OSC) the Committee had requested that the listening exercise be promoted to elected members. This enabled a further engagement opportunity to promote this listening exercise to their constituents and to also give them the option if they wished the Engagement Team to attend their ward meetings particularly as this covered the West Birmingham patch that the CCG commissions on behalf of.
8841	**TOTAL Mailing and Electronic Engagement**

3.2.4 Engagement activities and reach (events/meetings attended)

- Number of events/meetings attended x 7
- Approximate attendees at event x 78
  (as broken down into below table)

Events/meeting attended	**Attendees**
High Influence Stakeholders x 2 o Sandwell Overview and Scrutiny Committee (OSC) o Birmingham Overview and Scrutiny Committee (OSC)	 12 13
Patient/carer and public groups x 1 o Ladywood and Perry Barr Health and Care Forum	 11
Dedicated Public Meetings x 3 o Public Meeting 1 (04.06.19) o Public Meeting 2 (25.06.19) o Public Meeting 3 (27.06.19)	 13 6 9
Clinical Leads x 1 o Clinical Reference Group	 14
TOTAL Face to Face Engagement	**78**

4. Survey Findings and Participant Responses

Overall 16 surveys were completed.

6 participants completed the survey online, while the remaining 10 participants completed and returned the hard copy survey either by hand or freepost to us.

Q1. Breakdown of respondents by stakeholder group

Participants were asked to select all that applied to the answer choices that best described their relationship to this engagement topic. The majority of participants, 93% were patients registered to a SWB CCG practice as indicated in the table below.

Please note from here on, all questions are displayed in the tables below, answer choices selected by participants, responses by %, responses by no, how many participants answered the question and how many participants skipped the question.

Answers Choices	Responses by %	Responses by No
A patient registered to a SWB CCG practice	93	14
A patient not registered to a SWC CCG practice	0	0
A carer for a patient registered to a SWB CCG practice	0	0
A carer for a patient not registered to a SWB CCG practice	6.5	1
A GP/Staff Member of GP practice	6.5	1
A Health Care Provider	6.5	1
Local Authority	0	0
Voluntary Sector	13	2
Other	0	0
	Answered	15
	Skipped	1

Q5. Are you completing this for yourself or a person you are caring for?

Participants were asked to select one of the answer choices that best described who they were completing the questionnaire for. The majority of participants, 93% were completing the questionnaire for themselves as indicated in the table below:

Answer Choices	Responses by %	Responses by No
For Me	93.33	14
For the Person I am Caring For	6.67	1
	Answered	15
	Skipped	1

Q6. Have you or the person you are caring for had Minor Surgery?

Participants were asked to select one of the answer choices that gave an indication of if they or the person that they cared for had Minor Surgery. More than half of the participants, 64% selected the choice as indicated in the table:

Answer Choices	Responses by %	Responses by No
Yes (please go to question 7)	64	9
No (please go to question 19)	36	5
	Answered	14
	Skipped	2

Q7. When did you or the person you are caring for have Minor Surgery?

Participants were asked to select one of the answer choices either for themselves or the person they were caring for. Half the participants, 50% selected the choice as indicated in the table below:

Answer Choices	Responses by %	Responses by No
0-1 year	50	6
2-3 years	25	3
3-4 years	17	2
4+ years ago	8	1
	Answered	12
	Skipped	4

Q8. Was the appointment offered at a convenient date and time for you/the person you are caring for?

Participants were asked to select one of the answer choices either for themselves or the person they were caring for. The majority of participants, 81% selected the choice as indicated in the table below:

Answer Choices	Responses by %	Responses by No
Yes	82	9
No	18	2
	Answered	11
	Skipped	5

Q9. If no, what was the reason that that the appointment time was not convenient for you/the person you are caring for (please state below).

If participants had selected in Question 8 that the appointment time was convenient to them or the person they were caring for, they were asked to state the reason using free text as listed below"

"Too early 8.30am, OAP, too far way, 3 buses, rush hour. Did not know venue, reception no help."

"No choice given."

Q10. Did you/the person you are caring for be offered a choice of venue where you could have the Minor Surgery?

Participants were asked to select one of the answer choices either for themselves or the person they were caring for. Less than half of participants, 40% were given a choice of where they could have the Minor Surgery as indicated in the table below:

Answer Choices	Responses by %	Responses by No
Yes	40	4
No	60	6
	Answered	10
	Skipped	6

Q11. Did you/the person you are caring for receive any information before the Minor Surgery?

Participants were asked to select one of the answer choices either for themselves or the person they were caring for when asked if they received any information before their Minor Surgery. More than half of the participants, 64% were given information before their Minor Surgery as indicated in the table below:

Answer Choices	Responses by %	Responses by No
Yes (please go to question 12)	64	7
No (please go to question 13)	36	4
	Answered	11
	Skipped	5

Q12. If yes, did you/the person you are caring for find this information useful?

If participants had answered yes to Question 11 for themselves or the person they were caring for they were asked to respond to this question. Whilst 16 participants had completed the survey, 50% of these had skipped the question and the remaining

50% bar one participant had found the information useful as indicated in the table below:

Answer Choices	Responses by %	Responses by No
Yes	87.50	7
No	12.50	1
	Answered	8
	Skipped	8

Q13. If no, would you/ the person you are caring for have found this information useful?

If participants had answered no to Question 11 for themselves or the person they were caring for they were asked to respond to this question. For the majority of participants that had not received any information, 83% they had selected that they would have found it useful to receive information before the Minor Surgery as indicated below:

Answer Choices	Responses by %	Responses by No
Yes	83	5
No	17	1
	Answered	6
	Skipped	10

Q14. Did you/the person you are caring for receive any information after Minor Surgery on how to look after yourself following your procedure?

Participants were asked to select one of the answer choices either for themselves or the person they were caring for. More than half of the participants, 70% had received information following a minor procedure as indicated in the table below:

Answer Choices	Responses by %	Responses by No
Yes	70	7
No	30	3
	Answered	10
	Skipped	6

Q15. How would you/the person you are caring for rate your experience of Minor Surgery?

Participants were asked to select one of the answers choices either for themselves or the person they were caring for. More than half the participants who responded to

the question, 63.63% had rated their experience above good, selecting either very good or excellent as indicated in the table below:

Answers Choices	Responses by %	Responses by No
Poor	18.18	2
Satisfactory	18.18	2
Good	0	0
Very Good	36.36	4
Excellent	27.27	3
	Answered	11
	Skipped	5

Q16. Can you please give details of the reasons for your response/the person you are caring for here?

Participants were invited to use free text in response to Question 15, and 10 participants gave a response which can be viewed in Appendix 4.

The responses received were mixed:

Positive; comments, *a Sunday morning appointment was convenient,* a follow up consultation was undertaken over the telephone, saving time in comparison to a face to face appointment.

Negative; a long wait, rude receptionist.

Q17. What went well for you/the person you are caring for when receiving Minor Surgery?

Participants were invited to use free text, 50% of participants answered this question which can be viewed in Appendix 4.

The responses received were:

Positive; flexibility in getting appointment due to work commitments, attended to quickly, treated well and kept informed, did not wait too long.

Q18. What did not go so well for you/the person you are caring for when receiving Minor Surgery?

Participants were invited to use free text and their responses can be viewed in Appendix 4.

The responses received were mostly:

Negative; waiting around from check in to procedure, surgery not open so had to wait outside in the rain, poor communication and explanation.

Q19. What would you, the person you are caring for like to see in the future for Minor Surgery Services?

Participants were invited to use free text and their responses can be viewed in Appendix 4.

The responses received in summary; to be offered choice of times and venues, better information and communication during care and post-surgery advice, a joined up process, more to be offered in the community.

Q20. Do you/the person you are caring for have any other comments?

Participants were invited to use free text and their responses can be viewed in Appendix 4.

The responses received in summary; for services to be easily accessible services local to where patients are.

Q21. How did you/the person you are caring for find out about this Minor Surgery Listening Exercise?

Participants were invited to select one of the answer choices either for themselves or the person they were caring for as indicated in the table below:

Answer Choices	Responses by %	Responses by No
Poster	0	0
Newspaper	0	0
Social Media	7.14	1
CCG Website	14.29	2
A friend of family member told me	7.14	1
Other (please specify)	71.43*	10
	Answered	14
	Skipped	2

*****As 71.43% (10) participants had selected other, this is broken down further below:

- Optician
- Email
- CCG post
- A doctor from City Hospital sent him
- At CCG meeting at the Handsworth Fire Station
- Sent by GP
- CCG
- Sandwell and West Birmingham Letter
- Information from the CCG
- Email from CCG

5. Engagement by Target Audience

Overall we spoke to 78 people across 7 engagement activities. Activities included hosting or attending dedicated meetings.

Activities and the feedback collated have been summarised and grouped by audience.

Two Overview Scrutiny Committee (OSC) meetings were attended and supported by the SWB CCG Deputy Chief Officer for Strategic Commissioning and Redesign, the SWB CCG SCR Chair and the SWB CCG Engagement Lead.

A presentation was used to engage with Elected Members:

High Influence Stakeholders, Sandwell Overview and Scrutiny Committee

Headline themes included:

- No of practices that carried out Minor Surgery
- Dr shortages affecting patients from getting Minor Surgery
- How many people attending and booked onto our dedicated public meetings
- No of surveys expected to be received in relation to this listening exercise
- Current provider continuing to provide Minor Surgery until a new service is procured to ensure that there is no gap in provision for patients

High Influence Stakeholders, Birmingham Overview and Scrutiny Committee

Headline themes included:

- No of single handed GP practices left in the locality (relating to West Birmingham practices, namely Ladywood and Perry Barr wards)
- Why the contract with the existing provider will be terminated
- Where and how the engagement of this listening exercise has been promoted
- How the diverse population can have their say on this listening exercise
- Sharing of engagement materials with Councillors for the Ladywood and Perry Barr wards
- Super practices
- Benefits to patients for the new commissioned service
- Emerging themes from the first public meeting which had taken place
- Integrated Care Systems
- Self Care
- Attending a future meeting to share engagement report and findings
- Current provider commissioning themselves within the Primary Care Networks (PCNs) that are being formed
- SWB CCG PCNs geographical locations and spread
- Current Minor Surgery Options for patients

- Further travel for patients
- Promotion of location sites and different community understanding

One Clinical Reference Group was attended to make Primary Care aware of the Listening Exercise and how they could take part in it through a verbal update.

SWB CCG Clinical Reference Group at SWB CCG

Headline themes included:

- PCNS may want to provide minor surgery and this should be considered as the CCG explores alternative provision
- PCNs wishing to provide minor surgery require adequate indemnity cover
- 19 practices did not sign up to the Minor Surgery GP Direct Enhanced Service (DES) during 2018/19
- Concerns that some services are not covered by the Minor Surgery DES
- Future provision needs to ensure the same level of access for all, not increase waiting times, should be available and ensure access to good quality services.

Patients their representatives and the general public

Three dedicated public meetings were held to engage with patients, their carers, their communities, general practice and members of the public to help shape Minor Surgery services in the future. These meetings were held in different locations to be representative of the population that CCG commissions on behalf of.

These meetings were supported by the SWB CCG Deputy Chief Officer for Strategic Commissioning and Redesign, the SWB CCG Secondary Care Specialist and representative of the SCR and CCG Governing Body and the SWB CCG Engagement Lead.

A presentation was used; surveys were also available on the day to support these meetings.

Headlines themes included:

- Current contract end date
- Patients wanted to know why current contract is ending
- Why contract required with another provider when it can be provided by GPs
- Enough time for new provider to mobilise service
- Monitoring of quality at Doctors practices for Minor Surgery
- Skills and Qualifications of GPs carrying out Minor Surgery in practice
- GPs to move about to different locations rather than patients having to travel to other locations
- Knowing where to go for Minor Surgery
- Qualified providers
- Screening and follow up for benign results

- What specimen required for suspected cancers
- How the CCG pays the current provider
- Who carries out Minor Surgery

The three public meetings held had the added benefit of attendees taking part in a facilitated workshop to answer three main questions as listed below:

What does excellent Minor Surgery look like?

- To receive a high quality service from trained and competent health care professionals, complaint with legislation, quality assurance of environment, audits to be undertaken of procedures and for the treatment to work
- Parking and Transport; transport links, patient transport and parking
- Patient Circumstances; carer commitments, being sensitive to health needs i.e. diabetes and time of day appointment offered, age of patient to travel to venues and using their bus pass
- Venues; to be given a choice of venues and information on where those are located and how to get to them i.e transport links and maps of location
- Patient Choice; to be offered a choice of where you can have your minor surgery such as your local GP surgery or close to your home and which provider you can choose from
- Accessibility of venue; near to good transport links, venue DDA complaint, have a lift, to be at a safe secure setting
- Appointments; to be given a choice of times and flexibility such as evenings and weekends
- Patient Communication and Information; patients to receive information before the appointment in relation to the procedure either for themselves or the person they are caring for and have all the necessary tests and assessment. An explanation as to what is about to happen or be undertaken during the procedure. Information to be given as to how to look after yourself following the procedure through an information leaflet especially if recovery does not go to plan after the procedure and who to contact for advice and help.
- Referrals and Waiting Times; to be seen quicker especially if in pain or otherwise be seen within a month.
- Follow Ups; especially for removal of lumps, bumps and specimens being tested

What is not working so well now?

- Communication; with the provider and patient, follow up results
- Parking and Transport; transport links, patient transport and parking
- Confidentiality
- Waiting times if in pain
- Lack of information
- Who or Where Health Harmonie Are

How do we put it right?

- Would travel to another venue such as 1 or 2 bus rides away, or within my PCN
- Happy to have local GP carry out Minor Surgery as long as not too far to travel
- Clear information before and during procedure
- Would prefer a quicker service rather than local service

6. Conclusion

Reflecting on all feedback received it can be concluded the following points should be considered when commissioning Minor Surgery in the future as that is what is important to our patients to receive excellent Minor Surgery for them and the persons that they care for:

Venues

To be given a choice of venues and information on where those are located and how to get to them i.e transport links and maps of location

Appointments

To be given a choice of times and flexibility such as evenings and weekends

Communication and Information

Patients to receive information before the appointment in relation to the procedure either for themselves or the person they are caring for. An explanation as to what is about to happen or be undertaken during the procedure. Information to be given as to how to look after yourself following the procedure.

Waiting Times

To be seen quicker especially if in pain.

Quality Service

To receive a high quality service from trained and competent health care professionals.

8. Recommendation

Commissioners to consider the engagement feedback and how this can help shape future Minor Surgery for our population.

To share this report with SWB CCG's SCR as supporting evidence to any future business cases, service specifications and feeding into the decision making process on commissioning and procurement of future Minor Surgery.

SCR to note the contents of this report and approve this so that it can be published on the SWB CCG website, shared with participants and stakeholders who have taken part in this listening exercise to close the engagement loop.

Appendices

Appendix 1

Minor Surgery

Communication & Engagement Action Plan

Minor Surgery service was first commissioned in 2016 for a contract of 3 years duration with a 2 year extension. The service is delivered by Health Harmonie Ltd. The service was commissioned so that there was an equity of provision for minor surgery services across Sandwell and West Birmingham, which historically there were two separate minor surgery services with a different type of service. This Minor Surgery service includes one off procedures using outpatient facilities on the following conditions:

- Carpal Tunnel Syndrome Release
- Excision of ganglions of foot, hand and wrist
- Excision of large painful lipomas, tender sebaceous cysts leading to repeat infection and large/painful infected/irritating warts
- Incision and curettage of meibomian cysts
- Wedge resection or Zadek's procedure for painful in-growing toe nails
- Trigger Finger Release
- Non scalpel vasectomy following pre-operative counselling

The provider also provide services which are commissioned under the Minor Surgery DES on behalf of practices that are not signed up to the DES, where this is clinically appropriate.

This contract is coming to the end of its term and earlier this year the service was reviewed and evaluated by the Commissioners and after careful consideration by the Strategic Commissioning and Redesign Committee (SCR) it was agreed that this service would no longer be commissioned for a number of reasons as stated below;

- The way the service was commissioned does not form part of a joined up patient journey

- The CCG could no longer financially sustain this service in the interests of protecting the public purse and using every pound wisely

- To support Primary Care Networks to build on primary care services and enable greater provision of personalised, coordinated and more joined up health and social care for our patients

This has presented an opportunity for SWB CCG to hold a listening exercise to seek views and experiences by engaging with patients, their carers, their communities, general practice and members of the public to help shape Minor Surgery services in the future.

Earlier this year the NHS Long Term Plan (LTP) was launched and this is a new NHS 10 year plan to improve the quality of patient care and health outcomes.

The CCG is supporting this plan by setting up Primary Care Networks to build on primary care services and enable greater provision of personalised, coordinated and more joined up health and social care for our patients, which means health care services will be commissioned in a different way in the future.

The Communications and Engagement plan will include:

- Patient and Public Engagement meetings
- Information and Survey Listening Exercise Booklet
- An online survey
- An offline survey
- Presentation
- Website article/content
- Social media schedule
- Website article/content
- Communications for General Practice
- Engagement with partners Overview and Scrutiny Committees, Health Watch and the Voluntary Sector

Activities	**Dates**	**Stakeholder/ Audience**	**Method**	***Lead / who's involved***
Public Meeting No 1	04.06.19	Public, Patient/Service Users of SWB CCG	Presentation Qs and As Questionnaire Facilitated Workshop	Angela Poulton (AP) Dr Karl Grindulis (KG) Kally Judge (KJ) Phil Lydon (PL)
Public Meeting No 2	25.06.19	Public, Patient/Service Users of SWB CCG	Presentation Qs and As Questionnaire Facilitated Workshop	(AP) (KG) (KJ)
Public Meeting No 3	27.06.19	Public, Patient/Service Users of SWB CCG	Presentation Qs and As Questionnaire Facilitated Workshop	(AP) (KG) (PL)
Ladywood and Perry Health and Care Forum	11.06.19	Public, Patients/Service Users for SWB CCG	Presentation Questionnaire	(KJ)

Sandwell Overview and Scrutiny Committee (OSC)	17.06.19	Elected Members	Presentation Qs and As	Dr Ian Sykes (IS) (AP) (KJ)
Birmingham Overview and Scrutiny Committee (OSC)	18.06.19	Elected Members	Presentation Qs and As	(IS) (AP) (KJ)
Clinical Reference Group	23.05.19	Clinical Leads	Verbal Update	(KJ)
Nicks News	24.05.19 31.05.19 07.06.19 14.06.19 21.06.19 28.06.19	General Practice Staff	Article Posters Questionnaire	Jack Linstead (JL) (KJ)
Alice's News	24.05.19 31.05.19 07.06.19 14.06.19 21.06.19 28.06.19	CCG Staff	Article Questionnaire	(JL) (KJ)
SWB CCG Website	03.06.19	Public, Patient/Service Users of SWB CCG	Article Questionnaire	(JL) (KJ)
SWB CCG Tweet Plan	03.06.19	Public, Patient/Service Users of SWB CCG	Tweets	(JL) (KJ)
Sandwell Health Watch Engagement	03.06.19	Health Watch Stakeholders	Article Questionnaire	(KJ)
Birmingham Health Watch Engagement	03.06.19	Health Watch Stakeholders	Article Questionnaire	(KJ)

BVSC Voluntary Sector Engagement	03.06.19	Voluntary Sector Stakeholders	Article Questionnaire	(KJ)
SCVO Voluntary Sector Engagement	03.06.19	Voluntary Sector Stakeholders	Article Questionnaire	(KJ)

Timing Plan

Below is an approximate timing plan to give guidance on when actions need to be completed in order to carry out effective engagement for the Minor Surgery Listening Exercise.

Activities	**w/c 20.05.19**	**w/c 27.05.19**	**w/c 03.06.19**	**w/c 10.06.19**	**w/c 17.06.19**	**w/c 24.06.19**
Public Meetings x 3 Public, Patient/Service Users of SWB CCG			X			X
Ladywood and Perry Barr Health and Care Forum				X		
Clinical Leads Engagement	X					
Nicks News General Practice Engagement		X	X	X	X	X
Alice News Staff Engagement			X	X	X	X
Sandwell OSC Elected Members Engagement					X	
Birmingham OSC Elected Members Engagement					X	
Sandwell Health Watch Engagement			X			
Birmingham Health Watch Engagement			X			
BVSC Voluntary Sector Engagement			X			

SCVO Voluntary Sector Engagement			x			
SWB CCG Website			x	x	x	x
SWB CCG Twitter			x	x	x	x

Outcomes:

Patient insights into what excellent Minor Surgery looks like, what the issues are now and how do we fix them

GPs are aware of when Health Harmonie (HH) will stop receiving referrals for Minor Surgery

GPs are aware of pathways and where to refer patients for Minor Surgery once HH contract ceases

Listening Exercise to influence any commissioning and procurement decisions for Minor Surgery use the “You said, We did” approach

Appendix 2.1

Thursday 30th May 2019

Dear Colleague

RE: Minor Surgery Listening Exercise

We are NHS Sandwell and West Birmingham Clinical Commissioning Group (SWB CCG) and are responsible for commissioning (buying) local healthcare services on your behalf. We are a membership organisation consisting of 81 GP Practices and are responsible for 575,684 registered patients across the Sandwell and West Birmingham area.

As your local Clinical Commissioning Group, we have a responsibility under the Health and Social Care Act to inform and consult you on proposed changes and seek your views on how we shape future services.

We currently commission Minor Surgery from an organisation called Health Harmonie that provides community based healthcare services on behalf of the NHS. This contract will soon be coming to an end meaning that Health Harmonie will no longer provide minor surgery to our patients but you will still receive this from the majority of our GP practices and other healthcare providers.

Earlier this year the service was reviewed and evaluated by the Commissioner and after careful consideration the CCG agreed that this service would no longer be commissioned for a number of reasons;

- The way the service was commissioned does not form part of a joined up patient journey
- The CCG could no longer financially sustain this service in the interests of protecting the public purse and using every pound wisely
- To support Primary Care Networks to build on primary care services and enable greater provision of personalised, coordinated and more joined up health and social care for our patients

This has presented an opportunity for SWB CCG to hold a listening exercise as we want to hear about your views and experiences for Minor Surgery Services.

The listening exercise will run from Monday 3rd June 2019 to Friday 28th June 2019 and you can get involved in a number of ways:

Attend one of our public meetings as listed below;

- Tuesday 4th June 2019, 2.00-5.00pm
  Handsworth Fire Station, Rookery Rd, Birmingham B21 9QU

- Tuesday 25th June 2019, 2.00-5.00pm
  Portway Lifestyle Centre, Newbury Lane, Oldbury B69 1HE

- Thursday 27th June 2019, 6.00-9.00pm
  YMCA 38 Carter's Green, West Bromwich B70 9LG

- Complete our online survey at
  https://www.surveymonkey.co.uk/r/SWBMinorSurgery

- Complete a paper copy survey and requesting this by using the number below please

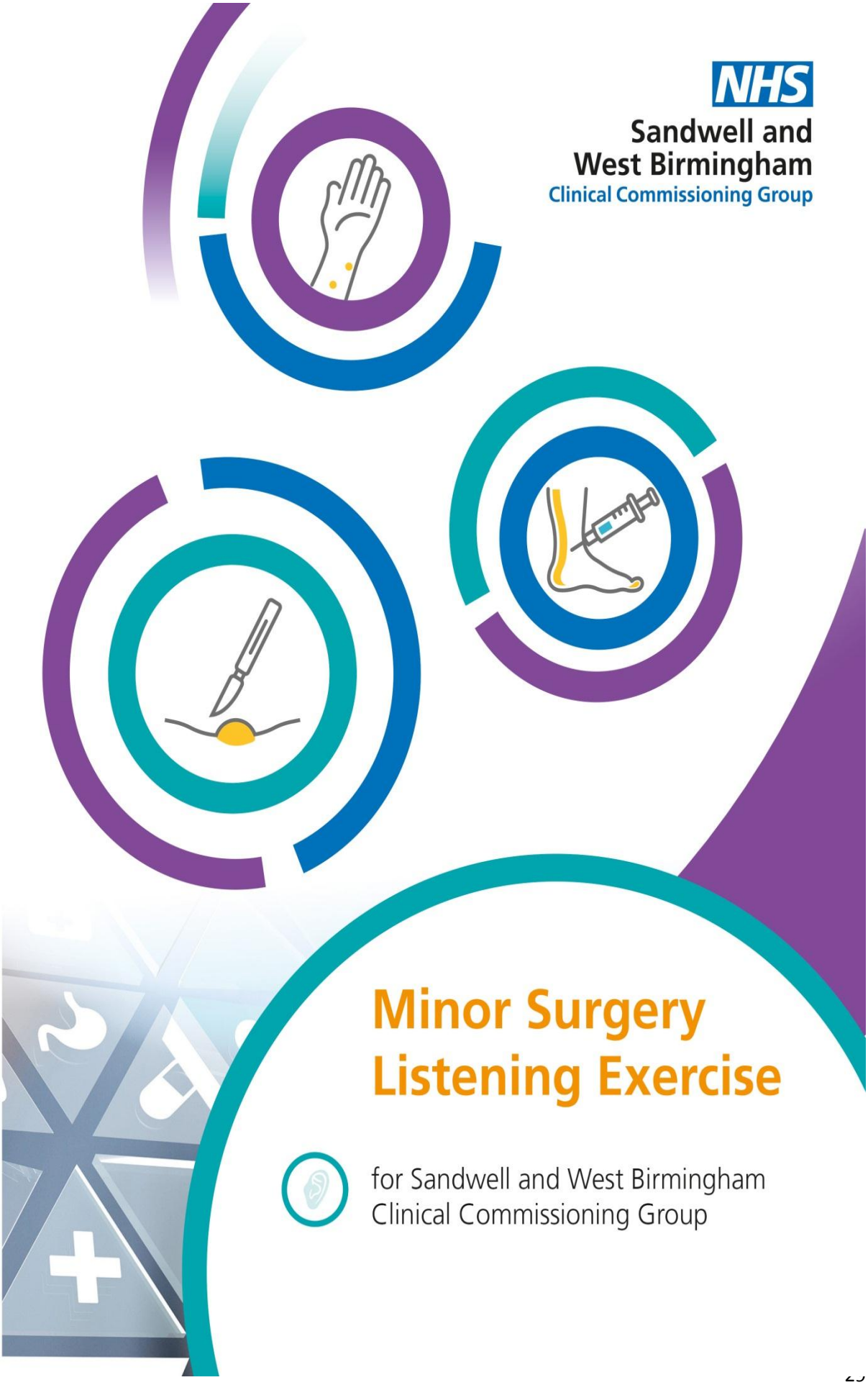
- Alternatively complete the survey in the listening exercise booklet and return it to

  RTHG-KAKC-RTBZ
  Engagement (Freepost)
  Sandwell and West Birmingham Clinical Commissioning Group
  Kingston House
  438 High Street
  West Bromwich
  B70 9LD

We look forward to hearing your views, if you require any further information please contact our Engagement Team on 0121 612 1447 or email swbccg.engagement@nhs.net

Yours sincerely

Dr Karl Grindulis MB ChB FRCP
Secondary Care Specialist for Service Redesign Committee and Governing Body
Sandwell and West Birmingham Clinical Commissioning Group


NHS
Sandwell and
West Birmingham
Clinical Commissioning Group
Minor Surgery
Listening Exercise
for Sandwell and West Birmingham
Clinical Commissioning Group

Contents

About Us

We are NHS Sandwell and West Birmingham Clinical Commissioning Group (SWB CCG) and are responsible for commissioning (buying) local healthcare services on your behalf. We are a membership organisation consisting of 81 GP Practices and are responsible for 575, 684 registered patients across the Sandwell and West Birmingham area.

As your local Clinical Commissioning Group we have a responsibility under the Health and Social Care Act to inform and consult you on proposed changes and seek your views on how we shape future services.

Earlier this year the NHS *Long Term Plan* was launched and this is a new NHS 10 year plan to improve the quality of patient care and health outcomes.

We are supporting this plan by setting up Primary Care Networks to build on primary care services and enable greater provision of personalised, coordinated and more joined up *health* and social *care* for our patients.

About this Listening Exercise

We currently commission Minor Surgery from a company called Health Harmonie, an organisation that provides community based healthcare services on behalf of the NHS.

As the contract is coming to the end of its term, a thorough review and evaluation has been undertaken by the CCG and after careful consideration it has been agreed that this service will no longer be commissioned for a number of reasons:

- The way the service was commissioned does not form part of a joined up patient journey
- The CCG could no longer financially sustain this service in the interests of protecting the public purse and using every pound wisely
- To support Primary Care Networks to build on primary care services and enable greater provision of personalised, coordinated and more joined up health and social care for our patients

This has presented an opportunity to hear your views and experiences regarding Minor Surgery through a listening exercise.

To compliment what is already available we now want to ask patients, their carers, their communities, general practice and members of the public about what Minor Surgery services should look like in the future.

It is important that we commission (buy on your behalf) Minor Surgery services for our patients that:

- Offer choice and flexibility to take into account personal circumstances such as work, study and caring commitments
- Offer a seamless patient journey

- Are fit for purpose
- Offer value for money

What is Minor Surgery?

Minor Surgery is an invasive operative procedure, involving incisions (surgical cut to the skin or flesh) or excisions (removal or cutting out tissue). These surgical procedures can be carried out by GPs in their practice and other healthcare providers. . Patients who have had minor surgery in primary care settings report high levels of patient satisfaction. Furthermore, providing this surgery outside hospital and close to where people live is also highly cost-effective. Some minor procedures require a local anaesthetic which numbs the affected area so that you do not feel any pain when this is performed and can include procedures such as:

- Injections in your joints, muscles and tendons
- Removal of minor lumps and bumps, skin tags, cysts, moles and ingrown toenails

What are the Current Arrangements for Minor Surgery?

Minor Surgery is currently provided by Health Harmonie, some GP Surgeries and the local hospitals.

Where do Health Harmonie currently provide Minor Surgery from?

Health Harmonie provide this from:

Hill Top Medical Centre 15 Hill Top Road, Oldbury, Warley, B68 9DU
(General Surgery)
Swanpool Medical Centre, St Mark's Rd, Tipton DY4 0SZ
(General Surgery)
Great Barr Medical Centre, 379 Queslett Road, Great Barr, B43 7HB
(General & Orthopaedic Surgery)
Soho Road Health Centre, 247-251 Soho Rd, Birmingham B21 9RY
(Orthopaedic Surgery)
Summerfield Health Centre, Winson Green Road, Birmingham, West Midlands, B18 7AL (Orthopaedic Surgery)

What do the Changes mean For Me?

The changes mean that Health Harmonie will no longer provide Minor Surgery from the above five locations.

You will still continue to access and receive Minor Surgery from a wide range of GP locations and other healthcare settings.

Most of our GP Surgeries provide minor surgery under an arrangement known as a Direct Enhanced Service (DES).

Ways to get involved

There are a number of ways you can get involved in our listening exercise;

- Attend one of our events in the area as listed below;

  - **Tuesday 4th June 2019**, 2.00-5.00pm
    Handsworth Fire Station, Rookery Rd, Birmingham B21 9QU

  - **Tuesday 25th June 2019**, 2.00-5.00pm
    Portway Lifestyle Centre, Newbury Lane, Oldbury B69 1HE

  - **Thursday 27th June 2019**, 6.00-9.00pm
    YMCA 38 Carter's Green, West Bromwich, B70 9LG

- Complete our online survey at
  https://www.surveymonkey.co.uk/r/SWBMinorSurgery

- Alternatively complete the survey in this listening exercise booklet and return it to

  RTHG-KAKC-RTBZ
  Engagement (Freepost)
  Sandwell and West Birmingham Clinical Commissioning Group
  Kingston House
  438 High Street
  West Bromwich
  B70 9LD

Further Information

For more information contact our Engagement Team on 0121 612 1447 or email swbccg.engagement@nhs.net

Survey

NHS Sandwell and West Birmingham Clinical Commissioning Group (CCG) is responsible for commissioning (buying) healthcare services for our local population. We want to hear your views and experiences of Minor Surgery so that we can understand:

- What does an excellent Minor Surgery service look like?
- What is not working so well now?
- How do we put it right?

Please let us know your views and experiences by taking the time to complete the survey.

The listening exercise will run from Monday 3rd June 2019 to Friday 28th June 2019.

Section One

Q1. How would you describe yourself (tick all that apply)

☐ A patient registered to a SWB CCG practice

Please tell us the name of your practice here

_____

☐ A patient not registered to a SWB CCG practice

☐ A carer for a patient registered to a SWB CCG practice

Please tell us the name of the practice here

_____

☐A carer for a patient not registered to a SWB CCG practice

☐ A GP/Staff Member of GP Practice

☐ A Health Care Provider

☐ Local Authority

☐ Voluntary Sector

☐ Other

☐ Please tell us the name of your organisation here

_____

Section Two

Q2. Are you completing this for yourself or a person you are caring for?

☐ For Me

☐ For the Person I am Caring For

Q3. Have you or the person you are caring for had Minor Surgery?

☐ Yes (please go to question 4)

☐ No (please go to question 13)

Q4. When did you or the person you are caring for have Minor Surgery?

☐ 0-1 year

☐ 2-3 years

☐ 3-4 year

☐ 4+ years ago

Q5. Was the appointment offered at a convenient date and time for you/ the person you are caring for?

☐ Yes

☐ No (please go to 5a)

Q5a. What was the reason that the appointment time was not convenient for you/the person you are caring for (please state below)

……

……

Q6. Did you/the person you are caring for be offered a choice of venue where you could have the Minor Surgery?

☐ Yes

☐ No

Q7. Did you/the person you are caring for receive any information before the Minor Surgery?

☐ Yes (please go to 7a)

☐ No (please go to 7b)

Q7a. Did you/the person you are caring for find this information useful?

☐ Yes

☐ No

Q7b. Would you/the person you are caring for have found this information useful?

☐ Yes

☐ No

Q8. Did you/the person you are caring for receive any information after Minor Surgery on how to look after yourself following your procedure?

☐ Yes

☐ No

Q9. How would you/the person you are caring for rate your experience of Minor Surgery?

☐ Poor

☐ Satisfactory

☐ Good

☐ Very Good

☐ Excellent

Q10. Can you please give details of the reasons for your response/the person you are caring for here?

……

……

Q11. What went well for you/the person you are caring for when receiving Minor Surgery?

……

……

Q12. What did not go so well for you/the person you caring for when receiving Minor Surgery?

……

……

Q13. What would you/the person you are caring for like to see in the future for Minor Surgery Services?

……

……

Q14. Do you/the person you are caring for have any other comments?

……

……

……

……

Q15. How did you/the person you are caring for find out about this Minor Surgery Listening Exercise?

☐ Poster

☐ Newspaper

☐ Social Media

☐ CCG Website

☐ A friend or family member told me

☐ Other

Please state here

Equalities monitoring

We recognise and actively promote the benefits of diversity and we are committed to treating everyone with dignity and respect regardless of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation. To ensure that our services are designed for the population we serve, we would like you to complete the short monitoring section below. The information provided will only be used for the purpose it has been collected for and will not be passed on to any third parties.

Q16. What are the first four letters of your/the person you are caring for postcode, please specify below:

Q17. What gender are you/the person you are caring for?

☐ Male

☐ Female

☐ Transgender

☐Prefer not to say

Q18. What is your age/the person you are caring for?

☐ 16-24

☐ 25-34

☐ 35-59

☐ 60-74

☐ 75+

Q19. What is your ethnic group/the person you are caring for?

☐ Arab

☐ Asian or Asian British

☐ Black or Black British

☐ Chinese

☐ Gypsy/Romany/Irish traveller

☐ Mixed dual heritage

☐ White or White British

☐ Prefer not to say

☐ Other (please specific)

Q20. Do you look after, or give any help or support to family members, friends, neighbours or others. Please note this is not referring to the person you care for if you have specified carer or if you are completing this survey on behalf of someone else

☐ Long-term physical or mental-ill-health/disability

☐ Problems related to old age

☐ No

☐ Prefer not to say

☐ Other (please specify)

Q21. Are your day-to-day activities limited because of a health condition or illness which has lasted, or is expected to last, at least 12 months? (Please select all that apply)

☐ Yes limited a lot

☐ Yes limited a little

☐ No

Q22. What is your/the person you are caring for sexual orientation?

☐ Bisexual

☐ Heterosexual/straight

☐ Gay

☐ Lesbian

☐ Prefer not to say

☐ Other please specify

Q23. What is your/the person you are caring for status?

☐ Single

☐ Never married or partnered

☐ Living as a couple

☐ Married/civil partnership co-habiting

☐ Not living as a couple

☐ Married (but not living with husband/wife/civil partner)

☐ Separated (still married or in a civil partnership) divorced/dissolved civil partnership)

☐ Widowed/surviving partner/civil partner

☐ Prefer not to say

☐ Other please specify

Q24. What is your/the person you caring for religion and belief?

☐ No religion

☐ Baha

☐ Buddhist

☐ Christian (including Church of England, Catholic, Protestant and all other Christian denominations)

☐ Hindu

☐ Jain

☐ Jewish

☐ Muslim

☐ Sikh

☐ Prefer not to say

☐ Other

What happens next?

Thank you for completing the Minor Surgery Survey, we really appreciate your time.

The Engagement Team will listen to your views at the public meetings, analyse the surveys that you have completed, a report will be developed and presented to the Strategic Commissioning and Redesign (SCR) Committee at the CCG. Our findings will help inform any Minor Surgery services that we buy on behalf of our patients in the future.

A copy of this report will be available shortly, if you would like to view this, it will be available on our website https://sandwellandwestbhamccg.nhs.uk/public-engagement or by contacting the Engagement Team on 0121 612 1447 or email swbccg.engagement@nhs.net

If you have any queries or would like to provide feedback via post, email or telephone, please contact:

Sandwell and West Birmingham CCG
Kingston House
West Bromwich
B70 9LD

Email: **swbccg.engagement@nhs.net**
Tel: **0121 612 1447**

healthcare
without boundaries

Have your say on

Minor Surgery

And

Non Obstetric Ultrasound Services (NOUS)

We will be holding a listening exercise from Monday 3rd June 2019 to Friday 28th June 2019 and will be holding a number of public meetings as listed below;

Tuesday 4th June 2019, 2.00-5.00pm
Handsworth Fire Station, Rookery Rd, Birmingham B21 9QU

Tuesday 25th June 2019, 2.00-5.00pm
Portway Lifestyle Centre, Newbury Lane, Oldbury B69 1HE

Thursday 27th June 2019, 6.00.9.00pm
YMCA 38 Carter's Green, West Bromwich B70 9LG

Appendix 2.4

Minor Surgery Listening Exercise

Feedback Capture Form

Meeting: (Name of Group)		**Date of Meeting:**		**Location:**	
Number of people attending:		**Target audience:**			
Question/ Comments made		**Response given**			
Name of person capturing Feedback:					
Follow Up Actions and By Whom					

Appendix 3

Demographic Data

Participants were given the option to answer the following questions for equality and diversity monitoring purposes.

Q23. What gender are you/the person you are caring for?

Participants were given the option to answer for themselves or the person they were caring for by selecting the choices as indicated in the table below:

Answer Choices	Response by %	Response by No
Male	40	6
Female	60	9
Transgender	0	0
Prefer not to say	0	0
	Answered	15
	Skipped	1

Q24. What is your age/the person you are caring for?

Participants were given the option to answer for themselves or the person they were caring for by selecting the choices as indicated in the table below:

Answer Choices	Response by %	Response by No
16-24	0	0
25-34	0	0
35-59	25	4
60-74	19	3
75+	56	9
	Answered	16

Q25. What is your ethnic group/the person you caring for?

Participants were given the option to answer for themselves or the person they were caring for by selecting the choices as indicated in the table below:

Answer Choices	Responses by %	Response by No
Arab	0	0
Asian or Asian British	0	0
Black or Black British	13	2
Chinese	0	0
Gypsy/Romany/Irish Traveller	0	0
Mixed dual heritage	0	0

White or White British	80	12
Prefer not to say	7	0
Other	0	0
	Answered	15
	Skipped	0

Q26. Do you look after, or give any help or support to family members, friends, neighbours or others? Please note this is not referring to the person you care for if you have specified carer or if you are completing this survey on behalf of someone else.

Participants were given the option to answer for themselves or the person they were caring for and selected the choice as indicated in the table below:

Answer Choices	Responses by %	Responses by No
Long term physical or mental ill health/disability	26.67	4
Problems related to old age	6.67	1
No	60	9
Prefer not to say	0	0
Other (please specify)	6.67	1
	Answered	15
	Skipped	1

Q27. Are your day to day activities limited because of a health condition or illness which has lasted, or is expected to last, at least 12 months? (please select all that apply)

Participants were given the option to answer for themselves or the person they were caring for and selected the choice as indicated in the table below:

Answer Choices	Responses by %	Responses by No
Yes limited a lot	7	1
Yes limited a little	33	5
No	60	9
	Answered	15
	Skipped	1

Q28. What is your/the person you are caring for sexual orientation?

Participants were given the option to answer for themselves or the person they were caring for and selected the choice as indicated in the table below:

Answer Choices	Responses by %	Responses by No
Bisexual	0	0
Heterosexual/straight	85	11
Gay	0	0
Lesbian	0	0
Prefer not to say	15	2
Other (please specify)	0	0
	Answered	13
	Skipped	3

Q29. What is your/the person you are caring for status?

Participants were given the option to answer for themselves or the person they were caring for and selected the choice as indicated in the table below:

Answer Choices	Responses by %	Responses by No
Single	7	1
Never married or partnered	0	0
Living as a couple	21	3
Married/civil partnership co-habitating	57	8
Not living as a couple	0	0
Separated (still married or in a civil partnership) divorced/dissolved civil partnership)	7	1
Widowed/surviving partner/civil partner	7	1
Prefer not to say	0	0
Other (please specify)	0	0
	Answered	14
	Skipped	2

Q30. What is your/the person you care caring for religion and belief?

Participants were given the option to answer for themselves or the person they were caring for and selected the choice as indicated in the table below:

Answer Choices	Response by %	Responses by No
No religion	20	3
Baha	0	0
Buddhist	0	0
Christian	73	0
Hindu	0	0

Jain	0	0
Jewish	0	0
Muslim	0	0
Sikh	0	0
Prefer not to say	7	1
Other (please specify)	0	0
	Answered	15
	Skipped	1

Appendix 4

All free text responses to questions

Paste as appropriate

Q16. Can you please give details of the reasons for your response/the person you are caring for here?

Participants were invited to use free text in response to Question 15, and 10 participants gave a response as stated below:

"The service was swift, but there was a long waiting time during the day."

"Everything went well, staff, venue."

"I am caring for my husband. It was so convenient on a Sunday morning. We did not have to fight any traffic, or wait in a hospital."

"Not kept waiting, clinician explained what he was doing or about to do as it went along."

"Good treatment, but dreadful receptionist. No help, would not get me a taxi."

"It was as expected."

"He felt there was no aftercare advice, the Surgeon was rough and 'rude' and advised patient to see own GP if any problems."

"Prefer not to say."

"Received excellent respect and care throughout."

"I had problematic cyst removed from my leg, it was uneventful, consultation and treatment were done in 2 visits, follow-up was over the phone, which saved us both time as face to face appointment was not necessary."

Q17. What went well for you/the person you are caring for when receiving Minor Surgery?

Participants were invited to use free text, 50% of participants answered this question and their responses are stated below:

"Treated well, informed and kept informed."

"Everything."

"Quickness in getting attention"

"Everything went well, he was treated for hand surgery on a Sunday morning at Summer Hill, Smethwick."

"Exalt surgery, no scar, no pain."

"The timely service as I have to work full time."

"Did not wait too long."

"The time scale – really quick, brilliant surgeon and nice/clean environment."

Q18. What did not go so well for you/the person you are caring for when receiving Minor Surgery?

Participants were invited to use free text and their responses can be seen below:

"Waiting around from check in to procedure."

"N/A."

"Surgery not open, had to wait in the rain, outside, staff dreadful."

"Nothing."

"Poor communication and explanation."

"No complaints."

Q19. What would you, the person you are caring for like to see in the future for Minor Surgery Services?

Participants were invited to use free text and their responses can be seen below:

"Joined up process."

"Best services that we can receive."

"The same service we received before."

"At my surgery – 2 The Slieve or somewhere close."

"Appointments not too far ahead, choice of times and venues."

"More understanding of age, be able to go to my doctor."

"More local venues."

"Better information, communication, care and post-surgery advice."

"Hope all minor surgery services will continue, it eases the hospital."

"I am waiting minor surgery so far everything is ok, given information from pre op about surgery and post-surgery care."

"For this service to be continued."

"More of the same – community based care."

Q20. Do you/the person you are caring for have any other comments?

Participants were invited to use free text and their responses can be seen below:

"No."

"Doctors who like minor surgery and specialise, should float around all surgeries. They should come to us, not for us to undertake horrible journeys."

"None."

"Asking for better service."

"Lots of people are not happy to attend hospital for some treatment."

"As long as there is a good service which is easily accessible, I don't mind it not being based at my own surgery."

NHS
Sandwell and
West Birmingham
Clinical Commissioning Group

Non Obstetric Ultrasound Scan (NOUS) Listening Exercise Engagement Feedback

Kally Judge
Commissioning Engagement Manager
July 2019

Contents

Appendices

1. Background

NHS Sandwell and West Birmingham Clinical Commissioning Group (SWB CCG) are responsible for commissioning (buying) local health services on behalf of the SWB CCG population. They are a membership organisation consisting of 81 practices with 103 sites and are responsible for 575,684 registered patients across the Sandwell and West Birmingham area.

The CCG commission a number of health care services, one of these services is Non Obstetric Ultrasound Scanning (NOUS) (scans for people who are not pregnant), with a local organisation who provides community based healthcare services on behalf of the NHS to our organisation as well as other NHS organisations.

This organisation has served notice on the CCG saying that this contract does not fit with their strategic priorities, meaning the CCG will seek alternative provision for its patients.

This has presented an opportunity for SWB CCG to hold a listening exercise to seek views and experiences by engaging with patients, their carers, their communities, general practice and members of the public to help shape NOUS Services in the future.

Earlier this year the NHS Long Term Plan (LTP) was launched and this is a new NHS 10 year plan to improve the quality of patient care and health outcomes.

The CCG is supporting this plan by setting up Primary Care Networks to build on primary care services and enable greater provision of personalised, coordinated and more joined up health and social care for our patients, which means health care services will be commissioned in a different way in the future.

2. Introduction

A Communications and Engagement Plan was developed to ensure that patients, their carers, their communities, general practice and members of the public were effectively informed and involved in sharing their views and experiences on NOUS to help shape services in the future.

In order to support this a range of activities were undertaken in accordance with the following objectives:

- Seeking views on NOUS
- Learning of experiences of NOUS
- Understanding what excellent NOUS should look like
- Understanding what is currently not working well in NOUS
- Understanding how the CCG puts things right in NOUS

Please see **Appendix 1** to view a copy of the Communications and Engagement Plan.

3. Engagement Approach and Methodology

3.1 A four week listening exercise was launched on Monday 3rd June 2019 and closed on Friday 28th June 2019.

The approach to engagement was through a variety of methods including;

- Mailings by Post and Electronic
- Public meetings x 3
- Presentations
- Online survey
- Off line survey in paper format with a freepost envelope
- CCG Website
- CCG Twitter
- CCG Facebook

3.2 Materials

A suite of core documents were developed to support engagement activities including;

- A stakeholder letter informing our stakeholders of the listening exercise

- An information booklet containing a survey with an accompanying freepost envelope to ensure that no cost was incurred to the participant for completion of the survey

- A presentation to support our listening exercise at public and stakeholder meetings

3.2.1 Activities undertaken

A detailed list of all Communications and Engagement activities can be viewed in the Communications and Engagement Plan. In summary, these activities have included:

3.2.2 Communications and Digital Activities

A questionnaire was developed on a survey monkey link and made available on the SWB CCG website. This survey monkey link was also featured on the stakeholder letters encouraging recipients to take part in the survey.

Information on the engagement exercise was published on the SWB CCG website including a headline and introduction featured on the Get Involved page under

"Current Consultation and Engagement" with a link to the questionnaire: https://sandwellandwestbhamccg.nhs.uk/consultations

Information on the listening exercise was featured on the following:

Websites:

- SWB CCG x 41 hits
- Health Watch Sandwell x hits (unknown)
- Health Watch Birmingham x hits (unknown)
- Sandwell Council of Voluntary Organisations (SCVO) x hits (unknown)
- Birmingham Voluntary Organisations (BVSC) x hits (unknown)

Twitter:

- SWB CCG
    - Tweets x 36
    - Retweets for NOUS x 4
    - Seen by x 732 people
    - Impressions x 95,300

Facebook

- SWB CCG
    - Posted x 24
    - Potential Reach 320
    - Likes for NOUS x 2

Regular internal communications and reminders were sent through existing channels to CCG Staff as well as Member Practices consisting of clinical and non-clinical staff in Primary Care.

3.2.3 Postal/electronic mailings and distributions of letters/survey booklets/posters

A potential reach of at least **8841**, that we know of was calculated, as broken down in the table below:

Reach	Audience and distribution format
197	SWB CCG Patient Engagement Membership A stakeholder letter was posted to the SWB CCG Patient Engagement Membership, which included an invitation to the 3 dedicated public meetings including the survey link. This gave recipients of this communication the option of requesting a paper copy survey through the Engagement Team.

932	Nicks News Articles were featured in Nicks News, a weekly communication which is emailed to SWB CCG member practices promoting the listening exercise. Articles featured throughout the period of the listening exercise inviting General Practice to take part. In addition to this posters were also shared through this audience asking them to display the posters in their waiting rooms so that patients and staff were aware of the listening exercise.
293	Alice News Articles were featured in Alice's News, a weekly communication which is emailed to SWB CCG staff promoting the listening exercise. Articles featured throughout the period of the listening exercise inviting Staff to take part in the listening exercise especially as some staff may well be registered patients of SWB CCG.
2,400	Sandwell Council Voluntary Organisation (SCVO) Information was shared through SCVO, a weekly e-bulletin, to promote the listening exercise through their networks. Articles featured throughout the period of the listening exercise inviting the Voluntary Sector to take part in the listening exercise.
5000	Birmingham Voluntary Sector Council (BVSC) Information was shared through BVSC, a weekly e-bulletin, to promote the listening exercise through their networks. Articles featured throughout the period of the listening exercise inviting the Voluntary Sector to take part.
19	Elected Members of Ladywood and Perry Barr Wards Following attendance at Birmingham Overview and Scrutiny Committee (OSC) the Committee had requested that the listening exercise be promoted to elected members. This enabled a further engagement opportunity to promote this listening exercise to their constituents and to also give them the option if they wished the Engagement Team to attend their ward meetings particularly as this covered the West Birmingham patch that the CCG commissions on behalf of.
8841	**TOTAL Mailing and Electronic Engagement**

3.2.4 Engagement activities and reach (events/meetings attended)

- Number of events/meetings attended x 7
- Approximate attendees at event x 78
  (as broken down into below table)

Events/meeting attended	**Attendees**
High Influence Stakeholders x 2 o Sandwell Overview and Scrutiny Committee (OSC) o Birmingham Overview and Scrutiny Committee (OSC)	 12 13
Patient/carer and public groups x 1 o Ladywood and Perry Barr Health and Care Forum	 11
Dedicated Public Meetings x 3 o Public Meeting 1 (04.06.19) o Public Meeting 2 (25.06.19) o Public Meeting 3 (27.06.19)	 13 6 9
Clinical Leads x 1 o Clinical Reference Group	 14
TOTAL Face to Face Engagement	**78**

4. Survey Findings and Participant Responses

Overall 14 surveys were completed.

6 participants completed the survey online, while the remaining 8 participants completed and returned the hard copy survey either by hand or freepost to us.

Q1. Breakdown of respondents by stakeholder group

Participants were asked to select all that applied to the answer choices that best described their relationship to this engagement topic. The majority of participants (93%) were patients registered to a SWB CCG practice as indicated in the table below.

Please note from here on, all questions are displayed in the tables below, answer choices selected by participants, responses by %, responses by no, how many participants answered the question and how many participants skipped the question.

Answers Choices	Responses by %	Responses by No
A patient registered to a SWB CCG practice	93	13
A patient not registered to a SWC CCG practice	0	0
A carer for a patient registered to a SWB CCG practice	0	0
A carer for a patient not registered to a SWB CCG practice	0	0
A GP/Staff Member of GP practice	7	1
A Health Care Provider	7	1
Local Authority	0	0
Voluntary Sector	7	1
Other	7	1
	Answered	14

Q5. Are you completing this for yourself or a person you are caring for?

Participants were asked to select one of the answer choices that best described who they were completing the questionnaire for. All the participants, 100% were completing the questionnaire for themselves as indicated in the table below:

Answer Choices	Responses by %	Responses by No
For Me	100	14
For the Person I am Caring For	0	0
	Answered	14

Q6. Have you or the person you are caring for had NOUS?

Participants were asked to select one of the answer choices that gave an indication of if they or the person that they cared for had NOUS. More than half of the participants, 71% had either had NOUS themself or the person they were caring for as indicated in the table below:

Answer Choices	Responses by %	Responses by No
Yes (please go to question 7)	71	10
No (please go to question 18)	29	4
	Answered	14

Q7. When did you or the person you are caring for have NOUS?

Participants were asked to either answer for themselves or the person they were caring for. Half the respondents, 50% had NOUS within the past year as indicated in the table below:

Answer Choices	Responses by %	Responses by No
0-1 year	50	5
2-3 years	30	3
3-4 years	20	2
4+ years ago	0	0
	Answered	10
	Skipped	4

Q8. Was the appointment offered at a convenient date and time for you/the person you are caring for?

Participants were asked to answer for either themselves or the person they were caring for. The majority of participants, 90% selected the choice as indicated in the table below:

Answer Choices	Responses by %	Responses by No
Yes	90	9
No	10	1
	Answered	10
	Skipped	4

Q9. If no, what was the reason that that the appointment time was not convenient for you/the person you are caring for (please state below).

If participants had selected in Question 8 that the appointment time was convenient to them or the person they were taking care of, they were asked to state the reason, there was one response as indicated below using free text:

"Appointment cancelled due to misleading information."

Q10. Did you/the person you are caring for be offered a choice of venue where you could have the NOUS?

Participants were asked to select one of the answers either for themselves or the person they were caring for. Only a third of respondents, 33% were given a choice of where they could have the NOUS as indicated in the table below:

Answer Choices	Responses by %	Responses by No
Yes	33	3
No	66	6
	Answered	9
	Skipped	5

Q11. Did you/the person you are caring for receive any information before the NOUS?

Participants were asked to select one of the answers either for themselves or the person they were caring for. Almost three quarters, 70% of the participants had received information before the NOUS as indicated in the table below:

Answer Choices	Responses by %	Responses by No
Yes (please go to question 12)	70	7
No (please go to question 13)	30	3
	Answered	10
	Skipped	4

Q12. If yes, did you/the person you are caring for find this information useful?

If participants had answered yes to Question 11 for themselves or the person they were caring for and were asked to respond to this question. Whilst 14 participants had completed the survey, 6 had skipped the question and the following choices had been selected as indicated in the table overleaf:

Answer Choices	Responses by %	Responses by No
Yes	87.50	7
No	12.50	1
	Answered	8
	Skipped	6

Q13. If no, would you/ the person you are caring for have found this information useful?

If participants had answered no to Question 11 for themselves or the person they were caring for they were asked to respond to this question. Of the 30% of respondents that had not received any information before their NOUS 100% of them said they would have found this information useful, as indicated in the table below:

Answer Choices	Responses by %	Responses by No
Yes	100	3
No	0	0
	Answered	3
	Skipped	11

Q14. How would you/the person you are caring for rate your experience of NOUS?

Participants were asked to respond for either themselves or the person they were caring for. The majority of participants, 80% had rated their experience at good or above good as indicated in the table below:

Answers Choices	Responses by %	Responses by No
Poor	20	2
Satisfactory	0	0
Good	10	1
Very Good	10	1
Excellent	60	6
	Answered	10
	Skipped	4

Q15. Can you please give details of the reasons for your response/the person you are caring for here?

Participants were invited to use free text in response to Question 14, and 10 participants gave a response which can be viewed in Appendix 4.

The responses received were mostly:

Positive; appointment was easy to book at the venue of choice, did not have to wait to be seen, near home so useful, fast and efficient, friendly staff that put you at ease.

Q16. What went well for you/the person you are caring for when receiving NOUS?

Participants were invited to use free text and gave their responses which can be viewed in Appendix 4.

The responses received were mostly:

Positive; seen within appointment time, staff very helpful doctors, not kept waiting long, seen on time on the day, staff were efficient and took time to explain what would happen during the scan and how I would be informed afterwards.

Q17. What did not go so well for you/the person you are caring for when receiving NOUS?

Participants were invited to use free text and gave their responses which can be viewed in Appendix 4.

The responses were mostly:

Negative; the results of the scan were not passed onto the hospital, had them all again, lack of communication, poor patient engagement, no choice of location.

Q18. What would you, the person you are caring for like to see in the future for NOUS?

Participants were invited to use free text and gave their responses which can be viewed in Appendix 4.

The responses received in summary; was to provide procedure information in advance, permitting a choice of locations, providing a way to raise concerns, a good quality accessible service, doctors listening to patients, continuation of service.

Q19. Do you/the person you are caring for have any other comments?

Participants were invited to use free text and gave their responses which can be viewed in Appendix 4.

The response received were mostly:

Positive; pleased with the procedure and venue, I would be happy to use the service again, I made the appointment time to suit me, I realise how useful NOUS is if required.

Q20. How did you/the person you are caring for find out about this NOUS Listening Exercise?

Participants were invited to select one of the answer choices either for themself or the person they were caring for as indicated in the table below:

Answer Choices	Responses by %	Responses by No
Poster	8	1
Newspaper	0	0
Social Media	8	0
CCG Website	15	2
A friend of family member told me	8	1
Other (please specify)	61*	8
	Answered	13
	Skipped	1

*****As 61% (8) participants had selected other, this is broken down further below:

- Information, then post from CCG
- I know my doctor treats people with arthritis
- Sandwell and West Birmingham CCG Meeting
- Letter from CCG x 2 participants
- Email from CCG x 3 participants

5. Engagement by Target Audience

Overall we spoke to 78 people across 7 engagement activities. Activities included hosting or attending dedicated meetings.

Activities and the feedback collated have been summarised and grouped by audience.

Two Overview Scrutiny Committee (OSC) meetings were attended and supported by the SWB CCG Deputy Chief Officer for Strategic Commissioning and Redesign, the SWB CCG SCR Chair and the SWB CCG Engagement Lead.

A presentation was used to engage with Elected Members:

High Influence Stakeholders, Sandwell Overview and Scrutiny Committee

Headline themes included:

- How many people attending and booked onto our dedicated public meetings
- No of surveys expected to be received in relation to this listening exercise
- Current provider continuing to provide NOUS until a new service is procured to ensure that there is no gap in provision for patients

High Influence Stakeholders, Birmingham Overview and Scrutiny Committee

Headline themes included:

- Why the contract with the existing provider will be terminated
- Where and how the engagement of this listening exercise has been promoted
- How the diverse population can have their say on this listening exercise
- Sharing of engagement materials with Councillors for the Ladywood and Perry Barr wards
- Super practices
- Benefits to patients for the new commissioned service
- Emerging themes from the first public meeting which had taken place
- Integrated Care Systems
- Self Care
- Attending a future meeting to share engagement report and findings
- Current provider commissioning themselves within the Primary Care Networks (PCNs) that are being formed
- SWB CCG PCNs geographical location and spread
- Current NOUS Options for patients
- Further travel for patients
- Promotion of location sites and different community understanding

One Clinical Reference Group was attended to make Primary Care aware of the Listening Exercise and how they could take part in it through a verbal update by the Engagement Lead.

SWB CCG Clinical Reference Group at SWB CCG

Headline themes included:

- Future provision needs to ensure the same level of access for all, not increase waiting times, should be available and ensure access to a good quality services.

Patients their representatives and the general public

Three dedicated public meetings were held to engage with patients, their carers, their communities, general practice and members of the public to help shape NOUS services in the future. These meetings were held in different locations to be representative of the population that we commission on behalf of.

These meetings were supported by the SWB CCG Deputy Chief Officer for Strategic Commissioning and Redesign, the SWB CCG Secondary Care Specialist and representative of the SCR and CCG Governing Body and the SWB CCG Engagement Lead.

A presentation was used; surveys were also available on the day to support these meetings.

Headline themes included:

- Patients asked why the current contract was ending and why the provider does not wish to carry on providing the service to the CCG
- Patients raised double scanning, why is one undertaken in the community and another undertaken in the hospital, this costs more financially and takes up more time for the patient and the healthcare professionals
- Rowley Regis Hospital is a lovely hospital, why can scans not be carried out there
- Are there any other qualified providers who can provide a scanning service
- What is the cost of an MRI Scan compared to an Ultrasound Scan
- Can Pharmacists undertake scanning?
- Why can't scan results be shared with community and hospital providers
- What scanning equipment is used worldwide, are some models better than others
- Why does it take so long to get scan results back?
- How much staff do Health Harmonie employ to carry out scanning

The three public meetings held had added benefit of attendees taking part in a facilitated workshop to answer three main questions as listed below:

What does excellent NOUS look like?

- To receive a high quality service from trained and competent health care professionals in this area
- Results; sharing these in a timely manner between patient and their the patients' GP, sharing of these results between community and hospital providers, patients to get an idea of when these will be ready, giving patient the option of taking away a copy of their scan
- Parking and Transport; transport links, patient transport, parking and no parking costs
- Patient Information; receiving information before your scan so you know why you need to have a scan, having a leaflet to explain this using pictures in plain English, knowing how to dress for a scan
- Efficient service when you ring up to make an appointment with provider
- Venues; to be given a choice of venues locally or the hospital, information on where those are located and how to get to them i.e. transport links and maps of location
- Appointments; to be give given a choice of times and flexibility such as evenings and weekends
- No double scanning; having a scan first in the community, then in the hospital meaning double the cost and wasting time
- Referrals and Waiting times; to be seen quicker, happy to travel a little further if seen quicker rather than waiting for a closer venue to home

What is not working so well now?

- Received another patient's letter, confidentiality
- Long waiting times to receive a scan
- Recent experience at Tower Hill, the provider did not turn at the venue so I did not get my scan
- Consistency of appointment i.e if you have agreed a date and appointment, then get a different appointment in the post
- Taking too long to get the results back from ultra sound when patients could be in pain. Waiting a month is too long.

How do we put it right?

- For results of scan to be received quicker
- Having one scan done once by the right person
- Would prefer a high quality scan by an experienced radiographer alongside a consultant rather than a low quality scan in isolation.

6. Conclusion

Reflecting on all feedback received it can be concluded the following points should be considered when commissioning NOUS in the future as that is what is important to our patients to receive excellent NOUS for them and the persons that they care for:

Venues

To be given a choice of venues and information on where those are located and how to get to them i.e. transport links and maps of locations.

Appointments

To be given a choice of times and flexibility such as evenings and weekends.

Communication and Information

Patients to receive information before the appointment in relation to the scan they are having done and why it is required. An explanation of how the scan will be carried out and how to dress for this. An indication given as to when results can be expected of the scan by the patients' GP.

Waiting Times

To be seen quicker and happy to travel a little further if seen sooner.

Quality

To receive a high quality service from trained and competent health care professionals in this speciality.

Double Scanning

No double scanning, having a scan first in the community, then in the hospital meaning double the cost and wasting time.

Results of Scan

To be received in a timely manner, results to be transferred between community and hospital providers so dependent on where patient needs to go next the results will be there already, patients to take away a copy of their scan results.

7. Recommendations

- Commissioners to consider the engagement feedback and how this can help shape future NOUS for our population

- To share this report with SWB CCG's SCR as supporting evidence to any future business cases, service specifications and feeding into the decision making process on commissioning and procurement of future NOUS

- SCR to note the contents of this report and approve it so that it can be published on the SWB CCG website, shared with participants and stakeholders who have taken part in this listening exercise to close the engagement loop

Appendices

Appendix 1

NOUS

Communication & Engagement Action Plan

Health Harmonie have recently informed SWBCCG that they no longer wish to provide Non Obstetric Ultrasound Scanning Services (NOUS) to SWB CCG as this does not fit with their strategic objectives. The CCG are seeking alternative provision for its population.

This decision has presented an opportunity for SWB CCG to hold a listening exercise to seek views and experiences by engaging with patients, their carers, their communities, general practice and members of the public to help shape NOUS services in the future.

Earlier this year the NHS Long Term Plan (LTP) was launched and this is a new NHS 10 year plan to improve the quality of patient care and health outcomes.

The CCG is supporting this plan by setting up Primary Care Networks to build on primary care services and enable greater provision of personalised, coordinated and more joined up health and social care for our patients, which means health care services will be commissioned in a different way in the future.

The Communications and Engagement plan will include:

- Patient and Public Engagement meetings
- Information and Survey Listening Exercise Booklet
- An online survey
- An offline survey
- Presentation
- Website article/content
- Social media schedule
- Website article/content
- Communications for General Practice
- Engagement with partners Overview and Scrutiny Committees, Health Watch and the Voluntary Sector

Engagement Activities

Activities	**Dates**	**Stakeholder/ Audience**	**Method**	***Lead / who's involved***
Public Meeting No 1	04.06.19	Public, Patient/Service Users of SWB CCG	Presentation Qs and As Questionnaire Facilitated Workshop	Angela Poulton (AP) Dr Karl Grindulis (KG) Kally Judge (KJ) Phil Lydon (PL)
Public Meeting No 2	25.06.19	Public, Patient/Service Users of SWB CCG	Presentation Qs and As Questionnaire Facilitated Workshop	(AP) (KG) (KJ)
Public Meeting No 3	27.06.19	Public, Patient/Service Users of SWB CCG	Presentation Qs and As Questionnaire Facilitated Workshop	(AP) (KG) (PL)
Ladywood and Perry Health and Care Forum	11.06.19	Public, Patients/Service Users for SWB CCG	Presentation Questionnaire	(KJ)
Sandwell Overview and Scrutiny Committee (OSC)	17.06.19	Elected Members	Presentation Qs and As	Dr Ian Sykes (IS) (AP) (KJ)
Birmingham Overview and Scrutiny Committee (OSC)	18.06.19	Elected Members	Presentation Qs and As	(IS) (AP) (KJ)
Clinical Reference Group	23.05.19	Clinical Leads	Verbal Update	(KJ)
Nicks News	24.05.19 31.05.19 07.06.19 14.06.19 21.06.19 28.06.19	General Practice Staff	Article Posters Questionnaire	Jack Linstead (JL) (KJ)

Alice's News	24.05.19 31.05.19 07.06.19 14.06.19 21.06.19 28.06.19	CCG Staff	Article Questionnaire	(JL) (KJ)
Sandwell Health Watch Engagement	03.06.19	Health Watch Stakeholders	Article Questionnaire	(KJ)
Birmingham Health Watch Engagement	03.06.19	Health Watch Stakeholders	Article Questionnaire	(KJ)
BVSC Voluntary Sector Engagement	03.06.19	Voluntary Sector Stakeholders	Article Questionnaire	(KJ)
SCVO Voluntary Sector Engagement	03.06.19	Voluntary Sector Stakeholders	Article Questionnaire	(KJ)
Website	03.06.19	Public, Patient/Service Users of SWB CCG	Article Questionnaire	(JL) (KJ)
Tweet Plan	03.06.19	Public, Patient/Service Users of SWB CCG	Tweets	(JL) (KJ)

Timing Plan of Engagement Activities

Below is an approximate timing plan to give guidance on when actions need to be completed in order to carry out effective engagement for the NOUS Listening Exercise.

Activities	**w/c 20.05.19**	**w/c 27.05.19**	**w/c 03.06.19**	**w/c 10.06.19**	**w/c 17.06.19**	**w/c 24.06.19**
Public Meetings x 3 Public, Patient/Service Users of SWB CCG			X			X
Ladywood and Perry Barr Health and Care Forum				X		
Clinical Leads Engagement	X					
Nicks News General Practice Engagement		X	X	X	X	X
Alice News Staff Engagement			X	X	X	X
Sandwell OSC Elected Members Engagement					X	
Birmingham OSC Elected Members Engagement					X	
Sandwell Health Watch Engagement			X			
Birmingham Health Watch Engagement			X			
BVSC Voluntary Sector Engagement			X			
SCVO Voluntary Sector Engagement			X			
SWB CCG Website			X	X	X	X
SWB CCG Twitter			X	X	X	X

Outcomes:

- Patient insights into what excellent NOUS looks like, what the issues are now and how do we fix them

- GPs are aware of when Health Harmonie (HH) will stop receiving referrals for NOUS

- GPs are aware of pathways and where to refer patients for NOUS once Health Harmonie contract ceases

- Listening Exercise to influence any commissioning and procurement decisions for NOUS and use the “You said, We did” approach

Appendix 2.1

Thursday 30th May 2019

Dear Colleague

RE: Non Obstetric Ultrasound Scan (NOUS) Listening Exercise

We are NHS Sandwell and West Birmingham Clinical Commissioning Group (SWB CCG) and are responsible for commissioning (buying) local healthcare services on your behalf. We are a membership organisation consisting of 81 GP Practices and are responsible for 575,684 registered patients across the Sandwell and West Birmingham area.

As your local Clinical Commissioning Group, we have a responsibility under the Health and Social Care Act to inform and consult you on proposed changes and seek your views on how we shape future services.

We currently commission NOUS (scanning services) from an organisation called Health Harmonie that provides community based healthcare services on behalf of the NHS. Health Harmonie has recently informed SWB CCG that they no longer wish to provide this service and we now need to look for an alternative provider for our patients. NOUS is also provided by some GP Surgeries and other health care providers.

This has presented an opportunity for SWB CCG to hold a listening exercise as we want to hear about your views and experiences for NOUS.

The listening exercise will run from Monday 3rd June 2019 to Friday 28th June 2019 and you can get involved in a number of ways;

Attend one of our public meetings as listed below:

- Tuesday 4th June 2019, 2.00-5.00pm
  Handsworth Fire Station, Rookery Rd, Birmingham B21 9QU

- Tuesday 25th June 2019, 2.00-5.00pm
  Portway Lifestyle Centre, Newbury Lane, Oldbury B69 1HE

- Thursday 27th June 2019, 6.00.9.00pm
  YMCA 38 Carter's Green, West Bromwich B70 9LG

Complete our online survey at https://www.surveymonkey.co.uk/r/SWBNOUS

- Complete a paper copy survey and requesting this by using the number overleaf please

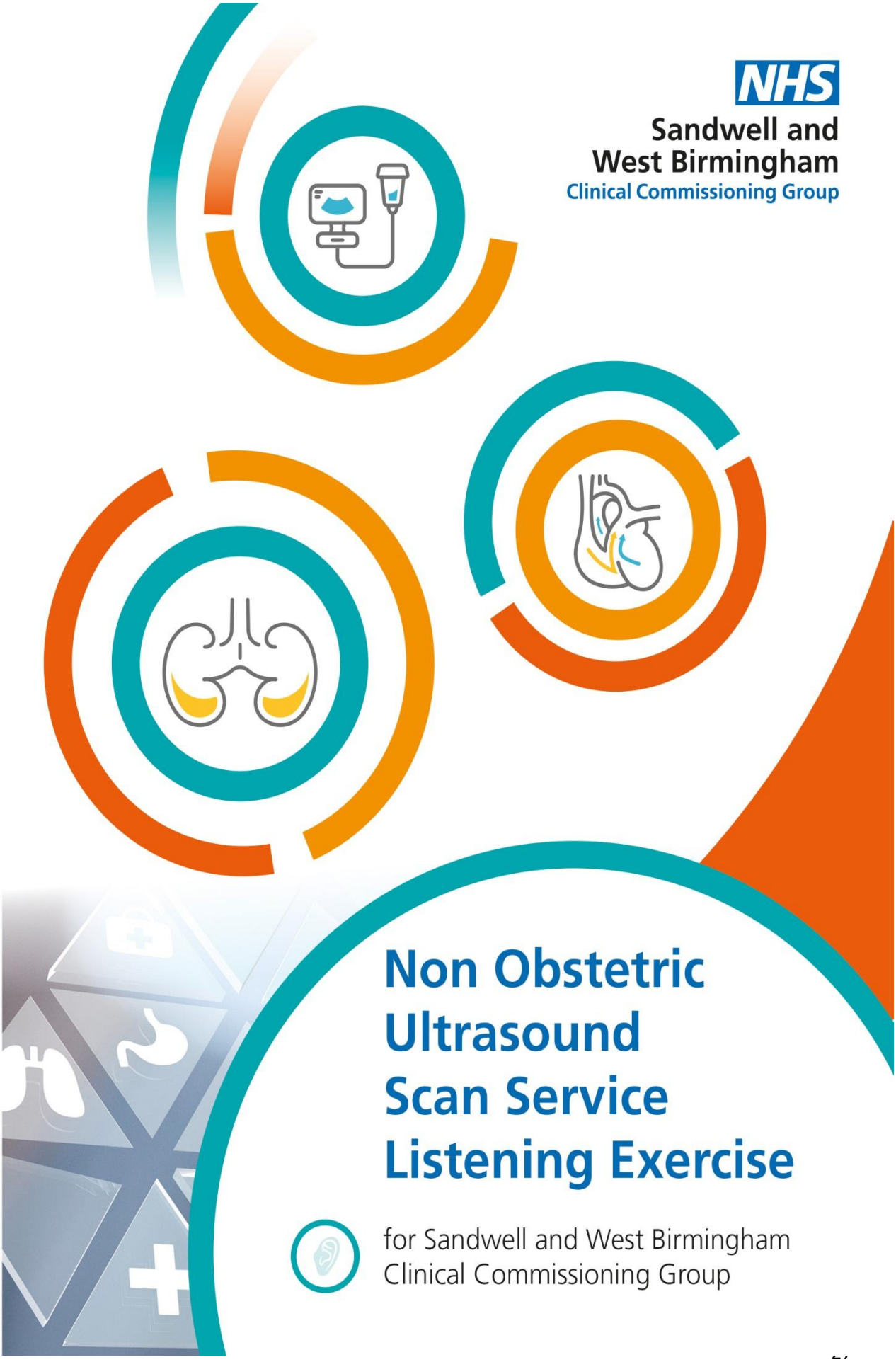
- Alternatively complete the survey in the listening exercise booklet and return it to

  RTHG-KAKC-RTBZ
  Engagement (Freepost)
  Sandwell and West Birmingham Clinical Commissioning Group
  Kingston House
  438 High Street
  West Bromwich
  B70 9LD

We look forward to hearing your views, if you require any further information please contact our Engagement Team on 0121 612 1447 or email swbccg.engagement@nhs.net

Yours sincerely

Dr Karl Grindulis MB ChB FRCP
Secondary Care Specialist for Service Redesign Committee and Governing Body
Sandwell and West Birmingham Clinical Commissioning Group


NHS
Sandwell and
West Birmingham
Clinical Commissioning Group
Non Obstetric
Ultrasound
Scan Service
Listening Exercise
for Sandwell and West Birmingham
Clinical Commissioning Group

Contents

About Us

We are NHS Sandwell and West Birmingham Clinical Commissioning Group (SWB CCG) and are responsible for commissioning (buying) local healthcare services on your behalf. We are a membership organisation consisting of 83 GP Practices and are responsible for 575, 684 registered patients across the Sandwell and West Birmingham area.

As your local Clinical Commissioning Group we have a responsibility under the Health and Social Care Act to inform and consult you on proposed changes and seek your views on how we shape future services.

Earlier this year the NHS *Long Term Plan* was launched and this is a new NHS 10 year plan to improve the quality of patient care and health outcomes.

We are supporting this plan by setting up Primary Care Networks to build on primary care services and enable greater provision of personalised, coordinated and more joined up *health* and social *care* for our patients.

About this Listening Exercise

We currently commission Non Obstetric Ultrasound Service (NOUS) from an organisation called Health Harmonie that provides community based healthcare services on behalf of the NHS.

Health Harmonie have recently informed SWBCCG that they no longer wish to provide this service, SWB CCG will now start to look into alternative provision for our patients. NOUS is also provided by some GP Surgeries and other healthcare providers.

This has presented an opportunity to hear your views and experiences regarding NOUS through a listening exercise.

To compliment what is already available we now want to ask patients, their carers, their communities, general practice and members of the public about what NOUS services should look like in the future.

It is important that we commission (buy on your behalf) NOUS services for our patients that:

- Offer choice and flexibility to take into account personal circumstances such as work, study and caring commitments
- Offer a seamless patient journey
- Are fit for purpose
- Offer value for money

What is Non Obstetric Ultrasound Scan (NOUS)?

Ultrasound is used to create images of soft tissue structures, such as the gallbladder, liver, kidneys, pancreas, bladder, and other organs and parts of the body. Ultrasound can also measure the flow of blood in the arteries to detect blockages. Ultrasound testing is safe and easy to perform

Ultrasounds offer many advantages: they are generally painless and do not require needles, injections, or incisions. Patients are not exposed to ionizing radiation, making the procedure safer than diagnostic techniques such as X-rays and CT scans.

What are the Current Arrangements?

Health Harmonie currently provide NOUS from the following locations at the days and times listed below:

Location	Day	Time
Aston Pride Community Centre	**Tuesday**	**9:00 am – 5:00 pm**
	Wednesday	**9:30 am - 2:30 pm**
Glebefields Health Centre	**Tuesday**	**9:00 am – 4.00 pm**
	Tuesday	**9:00 am – 5:00 pm**
	Thursday	**9:00 am – 5:00 pm**
Great Barr Group practice	**Thursday**	**9:00 am – 12.30 pm**
Great Bridge Surgery	**Wednesday**	**9:00 am – 5:00 pm**
	Thursday	**9:00 am – 5:00 pm**
Handsworth Wood Medical Centre	**Friday**	**8:30 am – 4.30 pm**
Hawes Lane Surgery	**Mondays and Tuesdays**	**9:00 am – 5:00 pm (when Oldbury Health Centre does not have room availability)**
Hill Top Surgery	**Thursday**	**1:30 pm – 5:00 pm**
	Alternate Saturdays	**9:00 am – 4:00 pm**
New Street Surgery	**Monday**	**9:00 am – 5:00 pm**
Nishkam	**Monday**	**9:00 am – 5:00 pm**
	Tuesday	**1:15 pm – 4.45 pm**

	Wednesday	**9:00 pm - 5:00 pm**
Oakham Surgery	**Wednesday**	**9:00 am – 5:00 pm**
	Friday	**9:00 am – 5:00 pm**
Oldbury Health Centre	**Monday**	**9:00 am – 5:00 pm**
	Wednesday	**9:00 am – 5:00 pm**
	Thursday	**9:00 am – 5:00 pm**
	Friday x 2	**9:00 am - 5:00 pm**
Soho Health Centre	**Monday**	**8:30 am – 5:00 pm**
	Tuesday x 2	**8:30 am – 12:30 pm**
	Wednesday x 2	**9:00 am – 5:00 pm**
	Friday x 2	**9:00 am – 5:00 pm**
Spires health Centre	**Tuesday**	**9:00 am – 4:30 pm**
	Thursday	**9:00 am – 4.30 pm**
Tower Hill Partnership	**Tuesday**	**9:45 am – 5:00 pm**
	Wednesday	**9:00 am – 5:00 pm**

What do the changes Mean for Me?

The changes mean that Health Harmonie will no longer provide NOUS from the above locations and the CCG is looking into alternative provision for our patients.

Ways to get involved

There are a number of ways you can get involved in our listening exercise;

- Attend one of our events in the area as listed below;

  - **Tuesday 4th June 2019**, 2.00-5.00pm
    Handsworth Fire Station, Rookery Rd, Birmingham B21 9QU

  - **Tuesday 25th June 2019**, 2.00-5.00pm
    Portway Lifestyle Centre, Newbury Lane, Oldbury B69 1HE

  - **Thursday 27th June 2019**, 6.00-9.00pm
    YMCA 38 Carter's Green, West Bromwich, B70 9LG

- Complete our online survey at
  https://www.surveymonkey.co.uk/r/SWBNOUS

- Alternatively complete the survey in this listening exercise booklet and return it to

  RTHG-KAKC-RTBZ
  Engagement (Freepost)
  Sandwell and West Birmingham Clinical Commissioning Group
  Kingston House
  438 High Street
  West Bromwich
  B70 9LD

Further Information

For more information contact our Engagement Team on 0121 612 1447 or email swbccg.engagement@nhs.net

Survey

NHS Sandwell and West Birmingham Clinical Commissioning Group (CCG) is responsible for commissioning (buying) healthcare services for our local population. We want to hear your views and experiences of NOUS so that we can understand:

- What does an excellent NOUS service look like?
- What is not working so well now?
- How do we put it right?

Please let us know your views and experience by taking the time to complete the survey.

The listening exercise will run from Monday 3rd June 2019 to Friday 28th June 2019.

Section One

Q1. How would you describe yourself (tick all that apply)

☐ A patient registered to a SWB CCG practice

Please tell us the name of your practice here
_____

☐ A patient not registered to a SWB CCG practice

☐ A carer for a patient registered to a SWB CCG practice

Please tell us the name of the practice here
_____

☐A carer for a patient not registered to a SWB CCG practice

☐ A GP Practice/Staff Member of GP Practice

☐ A Health Care Provider

☐ Local Authority

☐ Voluntary Sector

☐ Other

☐ Please tell us the name of your organisation here

_____

Section Two

Q2. Are you completing this for yourself or a person you are caring for?

☐ For Me

☐ For the Person I am Caring For

Q3. Have you or the person you are caring for had a Non Obstetric Ultrasound Scan (NOUS)?

☐ Yes (please go to question 4)

☐ No (please go to question 12)

Q4. When did you or the person you are caring for have NOUS?

☐ 0-1 year

☐ 2-3 years

☐ 3-4 year

☐ 4+ years ago

Q5. Was the appointment offered at a convenient date and time for you/the person you are caring for?

☐ Yes

☐ No (please go to 5a)

Q5a. What was the reason that the appointment time was not convenient for you/the person you are caring for? (please state below)

……

……

Q6. Did you/the person you are caring for be offered a choice of venue where you could have the NOUS?

☐ Yes

☐ No

Q7. Did you/the person you caring for receive any information before the NOUS?

☐ Yes (please go to 7a)

☐ No (please go to 7b)

Q7a. Did you/the person you are caring find this information useful?

☐ Yes

☐ No

Q7b. Would you/the person you are caring for have found this information useful?

☐ Yes

☐ No

Q8. How would you/the person you are caring for rate your experience of NOUS?

☐ Poor

☐ Satisfactory

☐ Good

☐ Very Good

☐ Excellent

Q9. Can you please give details of the reasons for your response/the person you are caring for here?

……

……

Q10. What went well for you/the person you are caring for when receiving NOUS?

……

……

Q11. What did not go so well for you/the person you are caring for when receiving NOUS?

……

……

Q12. Do you/the person you are caring for have any other comments?

……

……

……

……

Q13. How did you/the person you are caring for find out about this NOUS Listening Exercise?

☐ Poster

☐ Newspaper

☐ Social Media

☐ CCG Website

☐ A friend or family member told me

☐ Other

Please state here

Equalities monitoring

We recognise and actively promote the benefits of diversity and we are committed to treating everyone with dignity and respect regardless of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation. To ensure that our services are designed for the population we serve, we would like you to complete the short monitoring section below. The information provided will only be used for the purpose it has been collected for and will not be passed on to any third parties.

Q14. What are the first four letters of your/the person you are caring for postcode, please specify below;

Q15. What gender are you/the person you are caring for?

☐ Male

☐ Female

☐ Transgender

☐Prefer not to say

Q16. What is your age/the person you are caring for?

☐ 16-24

☐ 25-34

☐ 35-59

☐ 60-74

☐ 75+

Q17. What is your ethnic group/the person you are caring for?

☐ Arab

☐ Asian or Asian British

☐ Black or Black British

☐ Chinese

☐ Gypsy/Romany/Irish traveller

☐ Mixed dual heritage

☐ White or White British

☐ Prefer not to say

☐ Other (please specific)

Q18. Do you look after, or give any help or support to family members, friends, neighbours or others. Please note this is not referring to the person you care for if you have specified carer or if you are completing this survey on behalf of someone else

☐ Long-term physical or mental-ill-health/disability

☐ Problems related to old age

☐ No

☐ Prefer not to say

☐ Other (please specify)

Q19. Are your day-to-day activities limited because of a health condition or illness which has lasted, or is expected to last, at least 12 months? (Please select all that apply)

☐ Yes limited alot

☐ Yes limited a little

☐ No

Q20. What is your/the person you are caring for sexual orientation?

☐ Bisexual

☐ Heterosexual/straight

☐ Gay

☐ Lesbian

☐ Prefer not to say

☐ Other please specify

Q21. What is your/the person you are caring for status?

☐ Single

☐ Never married or partnered

☐ Living as a couple

☐ Married/civil partnership co-habiting

☐ Not living as a couple

☐ Married (but not living with husband/wife/civil partner)

☐ Separated (still married or in a civil partnership) divorced/dissolved civil partnership)

☐ Widowed/surviving partner/civil partner

☐ Prefer not to say

☐ Other please specify

Q22. What is your/the person you caring for religion and belief?

☐ No religion

☐ Baha

☐ Buddhist

☐ Christian (including Church of England, Catholic, Protestant and all other Christian denominations)

☐ Hindu

☐ Jain

☐ Jewish

☐ Muslim

☐ Sikh

☐ Prefer not to say

☐ Other

What happens next?

Thank you for completing the NOUS Survey, we really appreciate your time.

The Engagement Team will listen to your views at the public meetings, analyse the surveys that you have completed, a report will be developed and presented to the Strategic Commissioning and Redesign (SCR) Committee at the CCG. Our findings will help inform any NOUS services that we buy on behalf of our patients in the future.

A copy of this report will be available shortly, if you would like to view this, it will be available on our website https://sandwellandwestbhamccg.nhs.uk/public-engagement or by contacting the Engagement Team on 0121 612 1447 or email swbccg.engagement@nhs.net

If you have any queries or would like to provide feedback via post, email or telephone, please contact:

Sandwell and West Birmingham CCG
Kingston House
West Bromwich
B70 9LD

Email: **swbccg.engagement@nhs.net**
Tel: **0121 612 1447**

healthcare
without boundaries

Have your say on

Minor Surgery
And
Non Obstetric Ultrasound Services (NOUS)

We will be holding a listening exercise from Monday 3rd June 2019 to Friday 28th June 2019 and will be holding a number of public meetings as listed below;

Tuesday 4th June 2019, 2.00-5.00pm
Handsworth Fire Station, Rookery Rd, Birmingham B21 9QU

Tuesday 25th June 2019, 2.00-5.00pm
Portway Lifestyle Centre, Newbury Lane, Oldbury B69 1HE

Thursday 27th June 2019, 6.00.9.00pm
YMCA 38 Carter's Green, West Bromwich B70 9LG

Appendix 2.4

NOUS Listening Exercise
Feedback Capture Form

Meeting: (Name of Group)		**Date of Meeting:**		**Location:**	
Number of people attending:		**Target audience:**			
Question/ Comments made		**Response given**			
Name of person capturing Feedback:					
Follow Up Actions and By Whom					

Appendix 3

Demographic Data

Participants were given the option to answer the following questions for equality and diversity monitoring purposes.

Q22. What gender are you/the person you are caring for?

Participants were given the option to answer for themselves or the person they were caring for by selecting the choices as indicated in the table below:

Answer Choices	Response by %	Response by No
Male	21	3
Female	79	11
Transgender	0	0
Prefer not to say	0	0
	Answered	14

Q23. What is your age/the person you are caring for?

Participants were given the option to answer for themselves or the person they were caring for by selecting the choices as indicated in the table below:

Answer Choices	Response by %	Response by No
16-24	0	0
25-34	0	0
35-59	29	4
60-74	21	3
75+	50	7
	Answered	14

Q24. What is your ethnic group/the person you caring for?

Participants were given the option to answer for themselves or the person they were caring for by selecting the choices as indicated in the table below:

Answer Choices	Responses by %	Response by No
Arab	0	0
Asian or Asian British	0	0
Black or Black British	15	2
Chinese	0	0
Gypsy/Romany/Irish Traveller	0	0
Mixed dual heritage	0	0
White or White British	85	11

Prefer not to say	0	0
Other	0	0
	Answered	13
	Skipped	1

Q25. Do you look after, or give any help or support to family members, friends, neighbours or others? Please note this is not referring to the person you care for if you have specified carer or if you are completing this survey on behalf of someone else.

Participants were given the option to answer for themselves or the person they were caring for and selected the choice as indicated in the table below:

Answer Choices	Responses by %	Responses by No
Long term physical or mental ill health/disability	14.29	2
Problems related to old age	21.43	3
No	57.14	8
Prefer not to say	0	0
Other (please specify)	7.14	1
	Answered	14

Q26. Are your day to day activities limited because of a health condition or illness which has lasted, or is expected to last, at least 12 months? (Please select all that apply)

Participants were given the option to answer for themselves or the person they were caring for and selected the choice as indicated in the table below:

Answer Choices	Responses by %	Responses by No
Yes limited a lot	7	1
Yes limited a little	43	6
No	50	7
	Answered	14

Q27. What is your/the person you are caring for sexual orientation?

Participants were given the option to answer for themselves or the person they were caring for and selected the choice as indicated in the table below:

Answer Choices	Responses by %	Responses by No
Bisexual	0	0
Heterosexual/straight	77	10
Gay	0	0

Lesbian	0	0
Prefer not to say	15	2
Other (please specify)	8	1
	Answered	13
	Skipped	1

Q28. What is your/the person you are caring for status?

Participants were given the option to answer for themselves or the person they were caring for and selected the choice as indicated in the table below:

Answer Choices	Responses by %	Responses by No
Single	0	0
Never married or partnered	0	0
Living as a couple	25	3
Married/civil partnership co-habitating	58	7
Not living as a couple	0	0
Married (but not living with a husband/wife/civil partner)	0	0
Separated (still married or in a civil partnership) divorced/dissolved civil partnership)	8	1
Widowed/surviving partner/civil partner	0	0
Prefer not to say	0	0
Other (please specify)	8	1
	Answered	12
	Skipped	2

Q29. What is your/the person you care caring for religion and belief?

Participants were given the option to answer for themselves or the person they were caring for and selected the choice as indicated in the table below:

Answer Choices	Response by %	Responses by No
No religion	8	1
Baha	0	0
Buddhist	0	0
Christian	75	9
Hindu	0	0
Jain	0	0
Jewish	0	0
Muslim	0	0
Sikh	0	0
Prefer not to say	8	1
Other (please specify)	8	1
	Answered	12
	Skipped	2

Appendix 4

Free text responses

Q15. Can you please give details of the reasons for your response/the person you are caring for here?

Participants were invited to use free text in response to Question 14, and 10 participants gave a response as stated below:

"This was done on a Sunday, very few staff. There was no one to give information, where to go – like a morgue. Doctor didn't introduce self just left us sitting there."

"Went near my home so useful."

"Appointment was easy to book at the venue, I wanted. The venue was easy to go, I didn't have to wait to be seen. Staff were efficient."

"My own doctor gave me the injection. I didn't have to go to hospital."

"I was given a 2 week referral for a ultrascan quickly followed by a second, after this I was given a CT scan and then treatment decided following that."

"Very poor explanation of the process. Non-engagement from the practitioner - she did not speak to me throughout but conversed through the healthcare assistant. If she wanted me to change positions she spoke to the assistant who then spoke to me."

"Fast and efficient. Friendly staff that put you at ease."

"The scan lasted about five minutes and I was given the result immediately."

"When an appointment was finally received the hospital was excellent in their treatment."

"I could not ask for a better service from the staff, from start to finish."

Q16. What went well for you/the person you are caring for when receiving NOUS?

Participants were invited to use free text and gave their responses as below:

"Not a lot, had to wait sometime for attention."

"Seen within appointment time."

"I was seen on time on the day. The staff were efficient and took time to explain what would happen during the scan and how I would be informed afterwards."

"Everything"

"The quickness that it came through. The people who carried out the procedures, their advice following CT then the response of the GP."

"Poor overall experience – I would not recommend the location of where I had my NOUS"

"Everything from start to finish"

"Staff very helpful doctors."

"Not kept waiting long for the appointment or for the scan itself on the day, results quickly available."

Q17. What did not go so well for you/the person you are caring for when receiving NOUS?

Participants were invited to use free text and gave their responses as below:

"The results of the scan were not passed onto the hospital, had them all again."

"Lack of communication. Poor patient engagement. No choice of location."

"N/A."

"Nothing."

Q18. What would you, the person you are caring for like to see in the future for NOUS?

Participants were invited to use free text and gave their responses as below:

"Its continuation, as it provides swift answers for GP to respond to."

"Providing procedure information in advance permitting a choice of locations. Providing a way to raise concerns."

"A good quality accessible service, if based within 4-5 miles of every patient I feel this would be more than satisfactory."

"Them to continue as now."

"Doctors need to listen to patients."

Q19. Do you/the person you are caring for have any other comments?

Participants were invited to use free text and gave their responses as below:

"I was very pleased with the procedure and venue. I would be happy to use the service again."

"I made the appointment to suit me."

“I realise how useful NOUS is if required.”

“Unable to comment because I have not had NOUS.”

“N/A.”

“Have never been informed about NOUS.”

“No.”

Sandwell Metropolitan Borough Council

Agenda Item 6

REPORT TO
HEALTH AND ADULT SOCIAL CARE SCRUTINY BOARD

20 January 2020

Subject:	CCG Harmonisation of Treatment Policies (Phase 3)
Contribution towards Vision 2030:	
Report	Sandwell and West Birmingham Clinical Commissioning Group (SWB CCG)

DECISION RECOMMENDATIONS

That Health and Adult Social Care Scrutiny Board:

1. note the contents of the Executive Summary and the accompanying suite of documents
2. note the engagement process with public, patient and clinicians
3. note Sandwell and West Birmingham CCG's Strategic Commissioning & Redesign Committee's recommendation to CCG's Governing Body to approve all Phase 3 policies
4. note final approval received from CCG's Governing Body on 8th January 2020 for Phase 3 policies and the intention to implement from 1st April 2020
5. note BSOL CCG's Clinical Policies Sub-Group Committee's recommendation to the CCG's Governing Body for approval of Phase 3 policies
6. approve the 13 Phase 3 clinical treatment policies to be implemented from 1st April 2020

1 PURPOSE OF THE REPORT

1.1 A summary report (appendix 1) and supporting documents are attached to provide an overview of Phase 3 Treatment Policies. Members will receive a presentation at the meeting on 20th January 2020 for further detail.

Surjit Tour
Director – Law and Governance and Monitoring Officer

Treatment Policies
Evidence Based Policy Harmonisation Programme - Update

Sandwell HOSC

20th January 2020

Last HOSC update July 2019

- Reviewed Phase 3 Policy development programme.
- Today: to deliver the results of the Phase 3 public and clinical engagement.

What are Evidence Based Clinical Treatment Policies?

- The NHS has finite resources and continually and consistently has to make decisions to ensure:
  - the best evidence-based treatments are undertaken
  - the best possible clinical outcome for patients
  - the best value treatments are commissioned for patients

- This involves reviewing and developing what we are calling Clinical Treatment Policies (sometimes known in the NHS as Procedures of Lower Clinical Value (PLCV) to ensure they reflect contemporary clinical evidence.

Purpose of Harmonised Clinical Treatment Policy Process

- To ensure policies incorporate the most up-to-date published clinical evidence so that we prioritise funded treatments that are proven to have clinical benefit for patients.
- Stop variation in access to NHS funded services across Birmingham, Solihull and the Black Country (sometimes called the ‘postcode lottery’ in the media) and allow fair and equitable treatment for all local patients.
- Ensure access to NHS funded treatment is equal and fair, whilst considering the needs of the overall population and evidence of clinical and cost effectiveness.

NHSE Evidence Based Interventions Programme

- NHSE led clinical policy programme
- SWB CCG has been selected as a Demonstrator Site due to the robust, consistent and evidence based nature of the Harmonised Clinical Treatment Policy Programme.
- Phase 1 included 17 policies implemented from 1st April 2019 (Appendix 1.0)
- SWB CCG has engaged with NHSE in planning of Phase 2 EBI programme.
- NHSE Phase 2 consultation to commence in 2020 (delayed due to purdah period).

Previous Phases 1 & 2 Policy Process

- A joint working group was established across Birmingham, Solihull and Black Country
- Representatives included GPs, Public Health, Medicines Management. Commissioning and clinical lead from each CCG
- CCG focus on an initial 'Phase 1' set of 21 commissioning policies launched November 2017
- Phase 2 – Launched July 2018 – set of 22 commissioning policies, implemented from April 2019
- **This is 'Phase 3' List of 13 policies (Appendix 2)**

Next steps: Engagement Timetable

Date	Activity
Sept - Oct 2019	Clinical Engagement period (six weeks)
Sept – Oct 2019	Public Engagement period (six weeks)
Oct- Nov 2019	Evaluation of survey results and post engagement final report with recommendations
End Nov 2019	Working Group reconvenes and considers engagement feedback. Where appropriate some policies may be revised
Dec 2019	Engagement Report published (You Said/We Did)
Jan 2020	Final Policy Changes and Sign-Off
Feb 2020	Communication to stakeholders
April 2020	Implementation of updated policies.

Clinical Treatment Policies: Engagement

- 13 policies were prepared for review during a six-week patient, public and clinical engagement period from:

  Monday 2nd September until Friday 11th October 2019.

- Clinical engagement targeted:
  - Secondary care clinical and managerial colleagues
  - Primary care colleagues
  - Other key stakeholders
- Public engagement was enabled through:
  - surveys
  - outreach engagement
  - stakeholder briefings
  - website information
  - media.

Clinician Engagement: Approach

- Targeted correspondence to Specialist Clinicians /Medical Directors and Chief Nurses / Private Providers / Contract Managers.
- 260 clinicians were contacted across the region from the following providers:
  - University Hospitals Birmingham NHS Foundation Trust
  - Sandwell and West Birmingham Hospitals NHS Trust;
  - University Hospitals of North Midlands NHS Trust
  - BMI Healthcare
  - Spire Healthcare
  - Birmingham Community Healthcare NHS Foundation Trust
  - Birmingham and Solihull Mental Health NHS Foundation Trust.
  - The Dudley Group NHS Foundation Trust
  - Walsall Healthcare NHS Trust
  - The Royal Wolverhampton NHS Trust

Clinician Engagement: Outcomes

- Clinicians were understanding and supportive of the CCG in undertaking an evidence based review of treatment policies in order to provide equitable access to healthcare provision.
- Clinicians were pleased to be given the opportunity to engage with the policy development process and keen to do so.
- All of the policies received further clinical feedback which supported further review by the Treatment Policy Clinical Development Group, for example clinical feedback regarding the use of Biological Mesh instigated a change in commissioning position.
- Clinicians are keen for these policies to be widely communicated to those in primary care so that the referral pathways and patient expectations could be appropriately managed.

Public Engagement :
Activity and Outcomes

1

Media release

Website information 400 views

5

Stakeholder Events organised

16

Number of Tweets

10,390

Twitter impressions

Outpatient clinics
General and targeted Events

100
+
Conversations

Stakeholder briefing

Emailed to over 500 stakeholder organisations

49 Completed Questionnaires

Pubic Engagement: Approach

Key Communication Messages & Approaches

- Tailored and appropriate language to deliver a consistent message to varied audience groups.
- Services are not being decommissioned, but the criteria for accessing the selected treatments is clinical evidence based.
- Fairness through equitable access to consistent services across Birmingham & Solihull and Sandwell & West Birmingham, with fair decisions based on a shared rationale and clinical evidence. No ‘postcode lottery’.
- Emphasis that the development and refinement of treatment policies for Sandwell & West Birmingham and Birmingham & Solihull is continuous and remains a priority.
- Review of language and use of accessible English in policy documents as well as patient friendly leaflets.
- 2 way approach – inform and listen.

Public Engagement

Community Events:

- Proactive approach to face-to-face and electronic community engagement
- General public & community events organised across Birmingham and The Black Country areas.
- Targeted specialised engagement with affected groups

What happened to the feedback from patients and clinicians?

- Feedback from the engagement has been reviewed by the Treatment Policies Clinical Development Group and has resulted in changes to some of the clinical treatment policies and final commissioning position.

- Engagement Report and 'You Said, We Did' Reports were produced.

- Following the Joint HOSC review, a final suite of new treatment policies will be launched; primary care and local acute providers will be notified and the CCG's treatment policies web page https://sandwellandwestbhamccg.nhs.uk/treatment-policies will be updated.

Key points

- Principles that underpin the development of the proposed policies
- Development of You Said We Did document summarising the feedback and response – policy by policy.
- Full Engagement Report Prepared.

Thank You

Q&A

Appendix 1.0 NHSE EBI Policies Implemented from April 2019.

- Snoring Surgery (in the absence of Obstructive Sleep Apnoea (OSA))
- Dilatation and curettage (D&C) for heavy menstrual bleeding
- Knee arthroscopy for patients with osteoarthritis
- Injections for nonspecific low back pain without sciatica
- Breast reduction
- Removal of benign skin lesions
- Grommets
- Tonsillectomy
- Haemorrhoid surgery
- Hysterectomy for heavy bleeding
- Chalazia removal
- Shoulder decompression
- Carpal tunnel syndrome release
- Dupuytren's contracture release
- Ganglion excision
- Trigger finger release
- Varicose vein surgery

Appendix 2 Policy Scope - Phase 3

Phase 3A - Treatment Policy List

(Birmingham & Black Country CCGs)

- 1. Arthroscopic sub-acromial decompression
- 2. Image guided therapeutic intra-articular joint injections with corticosteroids with/without local anaesthetic.
- 3. Image-guided HIGH VOLUME intra-articular injections (40mls+) of saline with or without corticosteroid and/or local anaesthetic.

Appendix 2 Policy Scope - Phase 3

Phase 3B Treatment Policy List

Sandwell & West Birmingham CCG and Birmingham & Solihull CCG.

1. Liposuction for lymphoedema
2. Liposuction for lipoedema
3. Bariatric Surgery
4. Knee arthroscopy – Acute
5. Non Invasive Ventilation
   - COPD
   - Neuro-dependent
6. Continuous Positive Airway Pressure for Obstructive Sleep Apnoea
7. Biological / Bio-Synthetic Mesh for Hernia Repair Surgery
8. Non-Cosmetic Body Contouring
9. Adenoidectomy
10. Hysteroscopy for Heavy Menstrual Bleeding

Appendix 1

Health and Adult Social Care Scrutiny Board

20th January 2020

Sandwell & West Birmingham CCG

Harmonisation of Clinical Treatment Policies (Phase 3)

Executive Summary

This summary provides an overview of Phase 3 Treatment Policies programme jointly undertaken by Birmingham and Solihull (BSOL) and Sandwell and West Birmingham (SWB) CCGs, the programme methodology followed by the Treatment Policies Clinical Development Group (TPCDG), the clinical and public engagement outcomes, the governance oversight and the policy endorsement process.

This summary will be accompanied by a presentation at the meeting on the 20th January 2020 and a document pack which includes:
Evidence Reviews; Policy Documents; Patient Leaflets; Equality Impact Assessments, Engagement Report and You Said, We Did Report.

The policies included in Phase 3 for Sandwell and West Birmingham CCG (SWB CCG) and Birmingham and Solihull CCG (BSOL CCG) are listed below. It is highlighted that the other three Black Country CCGs (Wolverhampton, Walsall and Dudley) also participated in the Phase 3a policy development.

Phase 3A - Treatment Policy List:

- Subacromial Pain
- Image guided therapeutic intra-articular joint injections with corticosteroids with/without local anaesthetic
- Image-guided HIGH VOLUME intra-articular injections (40mls+) of saline with or without corticosteroid and/or local anaesthetic

Phase 3B - Treatment Policy List:

- Liposuction for Lymphoedema
- Liposuction for Lipoedema
- Bariatric Surgery
- Knee arthroscopy – Acute
- Non-Invasive ventilation
  - Neuromuscular
  - COPD
- Continuous Positive Airway pressure for Obstructive Sleep Apnoea

- Biological / Biosynthetic Mesh for use in Hernia Repair Surgery
- Non-Cosmetic Body Contouring
- Adenoidectomy
- Hysteroscopy for Heavy Menstrual Bleeding

High Level Process undertaken by the TPCDG

- Review and evaluation of Evidence Reviews
- Assessment and evaluation of expert clinical stakeholder feedback
- Evaluation and consideration of NICE Guidance and other regulatory and clinical guidance papers
- Full review and drafting of the initial policies
- Engagement with Sandwell and Birmingham and Solihull Overview and Scrutiny Committees

Public & Clinical Engagement Overview

A joint Public and Clinical Engagement exercise was undertaken from 2nd September- 11th October 2019 for both Phase 3a and 3b proposed policies.

- Clinical engagement: 260 primary and secondary care clinical and managerial colleagues were contacted and asked to review and comment on the draft policies, evidence reviews, draft patient leaflets and draft equality impact assessments. Clinical review was also requested from specific clinical groups, national health organisations and charities including ENT UK, the British Hernia Society and the Royal College of Surgeons.

- Public engagement consisted of:

    - A series of public events, facilitated meetings, promotional activities, website articles, social media and questionnaires were used to approach and engage with members of the public, patients and key patient support groups and charities.

- A reader panel of 38 members was recruited to consider the draft patient leaflets prior to the engagement. The panel provided feedback on whether the leaflets were easy to read, easy to understand and if they would benefit from imagery.

- A media release regarding the public and patient engagement was issued to local media to publicise and create awareness around the clinical treatment polices.

- A stakeholder briefing including information on the policies under review and how to feedback into the engagement process with links to additional

information on the website, which was sent to over 500 CCG stakeholder organisations. 88 organisations covering all policies were also sent the briefing.

.

Key Responses of Engagement Process

- Most respondents strongly agreed with the principles that underpinned the development of the proposed policies.

- A total of 49 questionnaire responses were completed online.
    - Over 80% of respondents strongly agreed that procedures and treatments should be offered to patients consistently and fairly.
    - 80% of all respondents strongly agreed that it should not matter where you live in accessing the provision of NHS healthcare services across the county and equally the eligibility criteria for an individual should be the same.
    - 97% of respondents agreed or strongly agreed that the clinical treatment policies should be supported by the most up to date clinical guidance and robust clinical evidence.
    - Over 82% strongly agreed or agreed that clinical practices should not be offered if there is limited clinical evidence to support effectiveness.
    - 93% agreed or strongly agreed that treatment should be prioritised to those which provide the greatest benefits.

Consideration of the Engagement Feedback

- Feedback from the engagement was compiled and reviewed by the TPCDG members in a series of presentation and evaluation meetings. The members proceeded on a policy-by-policy basis, considering and reflecting on the feedback received and making a final recommendation as to whether they endorsed the draft policy or if further amendments and updates to the policy were required.

- Two full and detailed ‘You Said, We Did’ reports have been produced which summarise the high-level clinical and public feedback and the responses of the TPCDG to the points raised during the engagement and are attached in the supporting pack.

Key Policy Points for Consideration

- In general, the policies were generally well received by both clinical colleagues and patient groups. Some policies received more feedback than others and this can be attributed, particular from the public perspective, to the clinically rare nature of certain policy areas, which meant that members of the general public often had no frame of reference regarding the illness or intervention and so often felt unable to provide an opinion.

RECOMMENDATIONS

Members of the Health Oversight and Scrutiny Committee are to:

- note the contents of the Executive Summary and the accompanying suite of documents
- the engagement process with public, patient and clinicians
- note Sandwell and West Birmingham CCG's Strategic Commissioning & Redesign Committee's recommendation to CCG's Governing Body to approve all Phase 3 policies
- note final approval received from CCG's Governing Body on 8th January 2020 for Phase 3 policies and the intention to implement from 1st April 2020
- note BSOL CCG's Clinical Policies Sub-Group Committee's recommendation to the CCG's Governing Body for approval of Phase 3 policies
- approve the 13 Phase 3 clinical treatment policies to be implemented from 1st April 2020

Arden&GEM

NHS

Arden and Greater East Midlands Commissioning Support Unit

NHS Birmingham and Solihull Clinical Commissioning Group

and

NHS Sandwell and West Birmingham Clinical Commissioning Group

Harmonised Treatment Policies – Phase 3

Patient, public, stakeholder and clinical engagement report

October 2019

(Updated November 2019)

Contents

1. Executive Summary

The purpose of this report is to highlight the patient, public and clinical engagement activity undertaken to support the proposed policy changes for Phase 3 of the Harmonisation of Clinical Treatment Policies across the Birmingham and Solihull CCG and Sandwell and West Birmingham CCG areas. A six-week patient, public and clinical engagement programme was undertaken from Monday 2 September until Friday 11 October 2019.

Policies
During Phase 3a, Birmingham and Solihull CCG, Sandwell and West Birmingham CCG, Wolverhampton CCG, Dudley CCG and Walsall CCG undertook clinical, patient and public engagement on three policies in Phase 3a. The policies under Phase 3a included:

1. Subacromial Pain
2. Image guided therapeutic intra-articular joint injections with corticosteroids with/without local anaesthetic.
3. Image-guided HIGH VOLUME intra-articular injections (40mls+) of saline with or without corticosteroid and/or local anaesthetic.

As part of the Phase 3b element, nine policies were engaged on across the footprints from NHS Birmingham and Solihull CCG and NHS Sandwell and West Birmingham CCG. This included the following policies:

4. Exogen Bone Healing
5. Non-cosmetic Liposuction for A. Lymphoedema or B. Lipoedema
6. Bariatric Surgery
7. Knee arthroscopy in Acute Knee Injury
8. Non-Invasive Ventilation
    - COPD
    - Neuromuscular
    - Continuous Positive Airway Pressure for Obstructive Sleep Apnoea
9. Biological or Biosynthetic Mesh for use in Hernia Repair Surgery
10. Non-Cosmetic Body Contouring
11. Adenoidectomy
12. Hysteroscopy for Heavy Menstrual Bleeding

Patient leaflet for each policy
As the content of these policies is complex, patient leaflets for each of the policies above were developed. The initial aim was to use them as an engagement tool to aid understanding at events, and then the information leaflets could be shared with patients at the time of consultation with their GP or allied health professional to aid their understanding of the treatment available.

A reader panel of 38 members was recruited to consider the draft patient leaflets before the engagement period began. Through email communication, they were

asked whether the leaflets were easy to read; if the information was easy to understand; and if the leaflets needed images. General feedback received from the reader panel, was that the leaflets were easy to understand.
However, readers felt there was some medical terminology which could be further simplified. Further feedback was received during the engagement process, and this will be taken into consideration when preparing the final draft of the patient leaflets.

Engagement process
The engagement process consisted of a questionnaire, targeted outreach engagement with service user patient groups where possible, and general engagement events. A media release about the public and patient engagement was issued to local media to publicise and create awareness around the clinical treatment polices. The engagement activity was also promoted through direct emails, social media and information on CCG website which all provided a link to the online survey.

As part of the clinical engagement during the consultation, primary and secondary care clinical and managerial colleagues, and other key stakeholders also had the opportunity to review and comment on the draft policies, evidence reviews, draft patient leaflet and draft equality impact assessments.

Questionnaire
The survey questionnaire included a short summary of the clinical treatment policies and how they would facilitate consistent, evidence-based policy development for planned patient care. General questions were asked around the following:

- Offering procedures and treatments consistently and fairly to patients
- Ending the 'postcode lottery' by agreeing the same eligibility criteria for a given treatment regardless of where patients live in Birmingham, Solihull, Sandwell or West Birmingham
- Ensuring that treatment policies are supported by the most up to date clinical guidance and clinical evidence
- Stopping clinical practices that do not offer clinical benefits to patients, or have very limited clinical evidence base for effectiveness.
- Prioritising treatments which provide the greatest benefits to patients.

In addition, for each policy a short summary was provided along with the proposed changes, and people were asked if they had accessed the service; to what extent they agreed/disagreed to the proposed change(s) to the policy; and to indicate the impact the proposed changes may have.

Events
As part of the consultation activity, five stakeholder events across Birmingham, Solihull and Sandwell were arranged where clinical leads would be in attendance to discuss and engage on the draft policies, evidence reviews and draft patient leaflet. However, due to the specialist nature of these draft policies, there was little or no interest from patients, public and stakeholders to attend these events. As a result,

these were cancelled and where possible, patient service user groups were contacted and engaged with.

Outcomes and key points for consideration
A total of 49 questionnaire responses completed online. Over 80% of respondents strongly agreed that procedures and treatments should be offered to patients consistently and fairly. 80% of all respondents strongly agreed that it should not matter where you live in accessing the provision of NHS healthcare services across the county and equally the eligibility criteria for an individual should be the same. 97% of respondents agreed or strongly agreed that the clinical treatment policies should be supported by the most up to date clinical guidance and robust clinical evidence. Over 82% strongly agreed or agreed that clinical practices should not be offered if there is limited clinical evidence to support effectiveness. 93% agree or strongly agree that treatment should be prioritised to those which provide the greatest benefits.

Based on all feedback received, there were some main points for consideration for the image guided intra-articular injections; exogen bone healing, liposuction for lipoedema and lymphoedema and bariatric surgery policies:

- **Image guided intra-articular injections**
  There was a mixed response from healthcare professionals and patients supporting the use of image guided technology. A general theme occurred around the decision-making process about the treatment, feedback indicated that this should be left to the practitioner performing the procedure and the individual patients' condition. Discussions with physiotherapists revealed that although these injections may only be offered once conservative methods have failed, in certain cases, the pain relief as a result of this procedure may help patients in pain and allows the rest period needed in order to start rehabilitation.

- **Exogen Bone Healing**
  Over 50% of respondents do not agree or disagree with the proposed change to policy. This may be due to insufficient evidence in the use of this treatment. Feedback from healthcare professionals stated that the use of this technology for selective patients has avoided operative interventions and surgical risks.

- **Liposuction for Lipoedema and Lymphoedema**
  Healthcare professionals and patient feedback welcomed the proposed change in procedure to support those who suffer with lymphoedema. There was a consensus that further evidence is needed with regard to the use of

  liposuction in patients with lipoedema. However, it was recognised that in some conditions, where the condition is very advanced conservative management is unsuccessful. It was also recognised that those patients who have had liposuction have greatly benefited for the procedure.

- **Bariatric Surgery**
  Although over 50% agree with the proposed policy criteria those comments received by healthcare professionals question the eligibility criteria. Particular concerns were raised that the proposed policy may exclude those who are in drastic need of the surgery and may oppose current NICE guidelines.

2. Background

In July 2017, the three Birmingham and Solihull Clinical Commissioning Groups (now NHS Birmingham and Solihull CCG) established a Treatment Policies Clinical Development Group along with Sandwell and West Birmingham CCG. Membership includes clinical and management stakeholders who have met monthly to discuss and assess the Evidence Reviews and drafted policies.

This clinical and multi-disciplinary group built on the initial Phase 1 and Phase 2 Harmonised Clinical Treatment Policy work. Phase 1 which included the introduction of 45 new treatment policies. The Phase 1 work was completed in early 2017 and several of the policies revised in 2018 taking into account further evidence, guidance and feedback. Full details of Phase 1 Harmonised Treatment Policies can be found here:
https://www.birminghamandsolihullccg.nhs.uk/your-health/treatment-policies
https://sandwellandwestbhamccg.nhs.uk/treatment-policies

In January 2018, the Treatment Policies Clinical Development Group initiated Phase 2 of the Harmonisation Policies Programme resulting in the implementation of 22 policies in February 2019. Full details of Phase 2 Harmonised Treatment Policies can be found here:
https://www.birminghamandsolihullccg.nhs.uk/your-health/treatment-policies
https://sandwellandwestbhamccg.nhs.uk/treatment-policies

This report details the clinical, patient and public engagement undertaken for Phase 3 Harmonised Treatment Policies.

3. Introduction

National clinical evidence is continually changing and therefore NHS Commissioners must periodically review and update all commissioning policies accordingly. This report details the clinical, patient and public engagement undertaken for Phase 3 of the Harmonisation of Treatment Policies.

Preparation for Phase 3 included the following high level process steps:

- Review and evaluation of Evidence Reviews for each draft Clinical Treatment Policy (prepared and presented by clinical colleagues from NHS Solutions for Public Health, Arden & GEM Commissioning Support Unit or by clinical colleagues in Birmingham Local Authorities' Public Health services).

- Assessment and evaluation of expert clinical stakeholder feedback and commentary on both the Evidence Reviews and the ensuing draft Clinical Treatment Policies. Input was sought from multiple clinical stakeholders, including clinical directorates/departments located in local providers such as University Hospitals Birmingham NHS Foundation Trust, Sandwell and West Birmingham NHS Trust, Birmingham Women's and Children's NHS Foundation Trust, The Royal Orthopaedic Hospital Foundation Trust, The Dudley Group NHS Foundation Trust, Walsall Healthcare NHS Trust and The Royal Wolverhampton NHS Trust.

- Evaluation and consideration of NICE Guidance and other regulatory and clinical guidance papers (including relevant Royal College documents) when deliberating and drafting the policies.

- Full review and drafting of the initial policies in preparation for the broader clinical and public engagement detailed in this report.

- Presentation to the Sandwell Health Oversight and Scrutiny Committee (HOSC) in July 2019 and to the Birmingham and Solihull Joint Health Overview and Scrutiny Committee (JHOSC) in September 2019.

Twelve policies were approved for review during a six- week patient, public and clinical engagement period. The list of policies, approach and sample patient facing materials were supported by Birmingham Joint Health Oversight Committee and the Sandwell Health Oversight Committee.

The policies for Birmingham, Solihull, Sandwell and West Birmingham included:

Phase 3A - Treatment Policy List
Subacromial Pain
Image guided therapeutic intra-articular joint injections with corticosteroids with/without local anaesthetic.
Image-guided HIGH VOLUME intra-articular injections (40mls+) of saline with or without corticosteroid and/or local anaesthetic.

Phase 3B - Treatment Policy List
Exogen Bone healing
Liposuction for Lymphoedema
Liposuction for Lipoedema
Bariatric Surgery
Knee arthroscopy – Acute
Non-Invasive ventilation

- Neuromuscular
- COPD
- Continuous Positive Airway pressure for Obstructive Sleep Apnoea

Biological/Biosynthetic Mesh for use in Hernia Repair Surgery
Non-Cosmetic Body Contouring
Adenoidectomy
Hysteroscopy for Heavy Menstrual Bleeding

For the clinical engagement, it was agreed that primary and secondary care clinical and managerial colleagues would have an opportunity, with other key stakeholders, to review and comment on the draft policies, evidence reviews, draft patient leaflet and draft equality impact assessments.

For the broader public engagement, it was agreed that a series of public events, facilitated meetings, promotional activities, website articles, social media and questionnaires would be used to approach and engage with members of the public, patients and key patient support groups and charities.

4. Summary of clinical and public engagement

The six-week period of clinical and public engagement ran from Monday 2 September until Friday 11 October 2019. This engagement covered geographical areas for both NHS Birmingham and Solihull and NHS Sandwell and West Birmingham Clinical Commission Groups (CCGs). For Phase 3a policies, simultaneous engagement was also carried out across the geographical areas of NHS Dudley CCG, NHS Walsall CCG and NHS Wolverhampton CCG.

The public and patient engagement consisted of:

- A patient and public questionnaire
- Targeted outreach engagement
- General engagement events
- Media, social media and website information.

A total of 49 questionnaire responses were obtained online.

The survey covered the following topics:

- The principles underpinning the proposals for the harmonisation of policies.
- People's experiences of the treatments considered in the proposed policies.
- To what extent people agreed with the proposed policies.
- What they considered impact of the proposed policies would be.

Stakeholder engagement consisted of:

- A stakeholder briefing including information on the policies under review and how to feedback into the engagement process with links to additional information on the website was sent to over 500 CCG stakeholder organisations.
- In addition, research was undertaken to identify organisations with a specific interest in the policies being reviewed and a bespoke database compiled (88 organisations covering all policies) and these stakeholders also received the briefing.
- All organisations were asked to both feedback on the harmonisation of policies and encourage their staff, members or communities to attend one of the engagement events.
- Stakeholders were also asked to identify patient or community groups they knew of and inform them of the harmonisation of treatment policies engagement programme
- Stakeholders were asked to pass on information of existing patient and community groups so that engagement officers could attend such meetings.
- During the engagement period several reminder emails were sent to encourage response.

Clinical and health staff engagement consisted of:

Phase 3a

- 74 targeted emails to specialist clinicians for all Phase 3a policies at all NHS providers in Birmingham; Solihull; Sandwell; West Birmingham; Dudley; Walsall; and Wolverhampton.
- 41 targeted emails (across five providers) to Chief Executives, Chief Nurses and Medical Directors at all NHS providers, asking then to encourage clinical staff to respond. Acknowledgements and responses were received from some individuals stating they would encourage staff to feedback.
- Targeted emails to specialist clinicians at independent sector providers across the footprint of the fives CCGs.
- Request from clinical directors / lead clinician from each clinical speciality for access to any patient groups they may have in linked with their department.
- Requests from CCG contract managers to their provider counterparts, to raise the profile of the engagement within their organisations and encourage clinical colleagues to respond.

Phase 3b

- 186 targeted emails to specialist clinicians for all Phase 3b policies at all NHS providers in Birmingham; Solihull; and Sandwell and West Birmingham.
- 12 targeted emails (across three providers) to Chief Execs, Chief Nurses and Medical Directors at all NHS providers across the two CCG footprints, asking them to encourage clinical staff to respond to the engagement.
- Targeted emails to specialist clinicians at independent sector providers across the footprint of the two CCGs.
- Request from clinical directors / lead clinician from each speciality for access to any patient groups they may have in their department.
- Requests from CCG contract managers to their provider counterparts, to raise the profile of the engagement within their organisations and encourage clinical colleagues to respond.

Clinical review was also requested from specific clinical groups, national health organisations and charities such as ENT UK; British Hernia Society; and Royal College of Surgeons.

Reminders were sent at regular intervals throughout the engagement period to remind clinicians, patients and the public of the closing date for feedback.

5. The engagement approach and methodology

As the content of the engagement is complex, it was important that information to allow understanding and therefore meaningful engagement was prepared and shared.

Patient leaflets
For this reason, a patient leaflet on each policy was developed to explain each clinical treatment policy. The purpose of the patient leaflets is twofold; initially to use as an engagement tool to aid understanding of the policy; and eventually should the proposed changes be implemented, the leaflets will be given to patients at the time of consultation with their GP or allied health professional to aid understanding of the treatment available.

Reader panel
A reader panel was recruited to consider the draft patient leaflets. The reader panel was made up of 38 members of the public from across the footprint of the two CCGs. The purpose of the panel was to feedback on the clarity of language and accessibility of content. They were asked the following questions about the leaflets:

- Was the leaflet easy to read?
- Did you understand the information?
- Do you think it needs images?
- Other comments.

Once the policies have been finalised following the engagement period, the patient leaflets will be updated before being designed and finalised.

Reader panel feedback
The general feedback received from the reader panel, noted that the leaflets were easy to understand, however there was some medical terminology which could be further simplified. Further feedback was received during the engagement process, and this will be taken into account when preparing the final draft of the patient leaflets.

Information online
Information to aid understanding was also published on the Birmingham and Solihull CCG website and Sandwell and West Birmingham CCG website. This included a table to explain the content of current policies and the proposed changes.

https://sandwellandwestbhamccg.nhs.uk/consultations

https://www.birminghamandsolihullccg.nhs.uk/get-involved/consultations-surveys-and-events

Questionnaire distribution
To enable wide and inclusive engagement, a questionnaire was developed as an engagement tool to allow people to feedback their views. Over 500 stakeholder organisations across Birmingham, Solihull and Sandwell plus 88 stakeholder organisations with particular interest in the policies under review were emailed and informed of the engagement opportunity, the time period for the engagement, and how to access the questionnaire online or by hardcopy on request. The questionnaires were available at the links above. People were also informed about how to get involved via press releases and social media.

Stakeholder events
Five stakeholder events were arranged across the geographical area to allow members of the public to find out more and have their views heard and targeted outreach engagement with patient and community groups was scoped.

Clinical database
To engage with clinicians and heads of service an extensive database of more than 200 contacts was developed. Clinical stakeholders were asked to feedback on the proposed treatment policies and to inform of any patient groups to contact as part of the engagement process.

5.1. Engagement activity and feedback summary

5 stakeholder events organised.
Engagement with patient and community groups.

49 questionnaire responses.

A media article was provided to the Birmingham, Solihull and Sandwell and West Birmingham local media, however no articles were published.

The media article provided was published on the CCG websites. Total website views of over 400.

Social media SWB CCG:

- **Twitter:** 5 tweets, 10 link clicks, engagement 12, reach 893, retweet 1, like 1,
- **Facebook:** 2 posts, 47 impressions, reach 40, engagement 1, shares 0, 1 link click, likes 0

Social media BSOL CCG:

- **Twitter:** 11 tweets, 37 link clicks, Engagement 164, Reach 9,497, Retweets 9, Likes 9
- **Facebook:** 7 posts, reach 4,671, engagement 176, shares 14, 35 link clicks, likes 52

6. Stakeholder events

The following stakeholder events were organised and publicised in the media, social media on the CCG websites and in the stakeholder emails. Stakeholder reminder emails both clinical and patient and public were reissued several times to encourage people to register their attendance.

Date	Time	Venue
Tuesday 24 September 2019	9.30am-12.30pm	**YMCA** 38 Carter's Green, West Bromwich, B70 9LG
Tuesday 24 September 2019	1.30-5pm	**Nishkam Civic Association** 6 Soho Road, Handsworth, Birmingham, B21 9BH
Thursday 3 October 2019	9.30am-12.30pm	**Midlands Arts Centre (MAC)** Cannon Hill Park, Birmingham, B12 9QH
Thursday 3 October 2019	1.30-5pm	**St Mary and St Margaret Church** Chester Road, Birmingham, B36 9DE
Monday 7 October 2019	9.30am-12.30pm	**Solihull Royal British Legion** 18 Union Solihull B91 3DH

Unfortunately, despite the wide communication undertaken through all communication channels available, apart from the stakeholder event on Monday 7 October where three people registered to attend there was no interest from stakeholders, patients and the public to attend these events. This is most likely because the clinical treatments policies were either widening the scope of the current service provision, providing policies to protect the current service provision or the interventions are for somewhat rare conditions. The three people who registered to attend the event on Monday 7 October were offered a telephone interview to feedback their views which are captured in this report. All other stakeholder events were cancelled.

As we had no interest in the stakeholder events, and hardly any of the clinical services have patient groups, the engagement team continued to try and gain access to more patents by making calls to patient experience teams at the hospitals, contacting ward sisters/managers and physiotherapists, reaching out to Healthwatch and voluntary organisations and issuing reminders to both the clinical and bespoke organisations database.

7. Outreach engagement

7.1 - Wednesday 2 October 2019, engagement with AGE UK
On Wednesday 2 October 2019, public engagement was carried out with AGE UK with approximately 60 members of the public to discuss the clinical treatment policies under review and the proposed changes to the draft policies. A further 8 members of the public who were attending a support group for religious study at the same venue also took part. Due to the complexity of the policies and the supporting documentation, some of the participants collectively agreed to review these before providing comment. To allow more time for consideration, it was agreed that the questionnaires would be completed outside of this engagement session and sent back for review using the freepost address provided.

Initial feedback received suggested that policies were quite a complex subject matter and clinical practices which offer the best clinical evidence of certain treatments should be adhered to; ensuring this exercise was not a cost cutting exercise; and managing patient expectations if a procedure is then stopped. Questions were also raised over the use of physiotherapists and *'are there enough to support this service'* where a policy mentions the conservation management of a condition. Although there was a consensus that the proposed policy changes for MSK related services would be a positive impact upon patients, concerns were also raised over waiting times.

7.1 Thursday 3 October 2019, engagement at physiotherapy sessions
On Thursday 3 October 2019, engagement within hospital physiotherapy sessions for upper limb, lower limb and post-operative knee, with senior MSK physiotherapists and physiotherapists revealed that there have been patients who have had surgical procedures (key hole) in the upper limb and the lower limb and continue to be in pain. It has only been through regular physiotherapy sessions after surgery and continuing to repeat these exercises/movements demonstrated during these sessions at home, which have helped to ease the pain and gain back greater movement within the shoulder with longer term results.

It was also discussed that in certain patients' conditions, continual physiotherapy would be of more benefit that going for surgical intervention. It was also discussed with Senior MSK Physiotherapists where historically treatments or key hole surgery were commonly used (upper limb / lower limb) and where clinical evidence, in some cases, now demonstrates conservative management approach to the condition, is helping to support patient expectations which is vital. It was also discussed that this was especially apparent straight after surgical intervention where patients may expect immediate positive results but the patient will still have to undertake rehabilitation in order to gain the maximum clinical benefit.

It was also discussed that many of the patients now seen through these sessions have not had any surgical intervention and where there has been, it has only been through continual physiotherapy to help strengthen the area which has brought long

term results. During these upper and lower sessions, the interviewer spoke directly to patients, one of whom had knee arthroscopy; she reported that only after six months of conservative management of the condition was surgery finally an option. She reported that the knee now feels much better but again this was aided by attending regular sessions to help strengthen the knee after surgery.

During an upper limb physiotherapy class, based within a hospital setting; a patient also discussed that they have had intra-articular joint injections and that the procedure was *'extremely painful'* and only provided *'short term results'* which eventually wears off with time. They discussed it should only be used as *'a last resort'.* When the interviewer enquired the use of image guided injections versus palpation directed injections the patient felt this should be down to the practitioner performing the procedure and the patient. They discussed in some cases they could see why image guided would be of more benefit than non-image guided but should be dependent on the patients' individual case.

Engagement with physiotherapists on the use of intra-articular joint injections and the eligibility criteria for the proposed draft policy revealed that whilst it may currently state that 'injections are only offered when the patient has failed to respond to conventional pharmacological and non-pharmacological interventions', in certain individual cases, non pharmacological intervention, for example physiotherapy, could only be performed due to the positive effects that the injections may bring. The patient may need that *'pain free window'* to allow them to start the physiotherapy exercises which will help strengthen that area which they may not been able to do without the injection.

7.3 Friday 4 October 2019, 20 Patients with neuromuscular conditions invited to a meeting at Heartlands

On behalf of Birmingham and Solihull CCG and Sandwell and West Birmingham CCG, a letter was sent by a specialist respiratory ventilation physiotherapist based at Heartlands Hospital, inviting 20 patients with neuromuscular conditions to attend a meeting at the hospital to feedback on the non-invasive ventilation policies. Patients who were unable to attend due to travel difficulties were invited to inform the CCG so that transport could be provided for them. Two people followed up the invitation by telephone to find out more about the meeting, however they decided they would prefer not to attend. One person was calling on behalf of her father and explained that although he would not be able to attend, she would go through the information with him available online. A further telephone meeting was offered, should her father wish to feedback verbally. The other person calling, completed the questionnaire over the telephone with the engagement officer.

The actual meeting on Friday 4 October was attended by a patient with muscular dystrophy and her daughter (also the patient's full-time carer). The patient used non-invasive ventilation to help with her condition during the day and night.

The patient and carer told the interviewer that they strongly agreed with the policy for non-invasive ventilation for neuromuscular patients. This was because they felt the

implementation of the policy would help GPs to refer patients for the correct treatment promptly. The patient and carer felt the policy would raise awareness of the respiratory conditions associated with muscular dystrophy and provide guidance on when to refer patients into a specialist respiratory service. They also felt it would allow quicker access to appropriate equipment. The patient told us that she had become very ill needing admission to intensive care followed by a long stay in hospital. Her breathing had become increasingly impaired over a period of time and eventually she had contracted pneumonia. The patient explained that better education is needed for patients with muscular-dystrophy so they know to contact their GP if experiencing breathlessness. The patient also felt that more education and training was also important for GPs so that patients suffering from muscular dystrophy got the specialist respiratory assessment they need in an appropriate and timely manner. The carer and patient hope the new policy if implemented will help with this.

A Policy and Professional Development Officer from Muscular Dystrophy UK also attended this meeting. The officer agreed to cascade information in order for members of the organisation to feedback and provide a statement from the organisation. Please see the statement below:

"Muscular Dystrophy UK (MDUK) support the implementation of the non-invasive ventilation (NIV) policy which Birmingham and Solihull CCG and Sandwell and West Birmingham CCG have developed. MDUK note that the term 'neuromuscular disorders which is known to cause respiratory muscle weakness or upper airway functional impairment' should be included in the policy to explicitly ensure that children and adults who are living with neuromuscular conditions receive appropriate and timely access to NIV. MDUK are confident that this policy will result in high quality care for treatment of respiratory dysfunction for this patient population."

7.4 - Wednesday 9 October 2019, telephone conversation to discuss patient sessions for Bariatric Surgery

On Wednesday 9 October 2019, a telephone conversation took place to discuss feedback from patients attending sessions for 'Bariatric Surgery' on the proposed policy. Patients commented that the new proposed criteria would mean that they would not be considered suitable for Bariatric Surgery. The point was also made that some of the patients required Baratric Surgery in order for them to access further treatments for example, hip surgery and IVF treatment.

7.5 - Friday 11 October 2019, lymphoedema and lipoedema policies feedback

After reviewing the draft proposed policy for liposuction for lymphoedema and lipoedema, the following feedback was received from Anne Dancey, Plastic and Reconstructive Surgeon FRCS(Plast), MBChB(Hons), MMedSci(Hons) and MCh(PASP):

"I think it is an essential piece of work to clarify the position of these 2 distinct groups of patients. I have read through all the supporting documents and think it is a thorough and comprehensive piece of work. I have also been asked to be involved in the creating of the NICE lipoedema guidelines which I suspect will be the key to possible commissioning of liposuction in lipoedema."

7.6 Friday 11 October 2019, Lipoedema patient engagement

As face-to-face outreach was not possible with the service user group, with the assistance of Birmingham Community Healthcare NHS Foundations Trust, a patient agreed to review the supporting documentation and provide her feedback. Her full response is included in Appendix A where she has documented her personal journey living with and managing this condition.

The patient discussed that she welcomed that the "*CCG are actively recognising these conditions, there seems little change in terms of the treatment options available to patients"* and she is in agreement…"*with commentary around conservative treatment and agree that non -surgical options should always be fully explored in the first instance, however for many patients these are little to no use as their condition is too far advanced."*

The patient has had liposuction for her condition as it was at a very advanced stage and over 4 surgical procedures has had 38 litres removed. The benefits of this procedure in the long term has meant that she can return to full time work and have a better 'quality of life' as it has been *"life changing".*

"Given my situation, I am sure you and your team will appreciate why I am so disappointed by the changes to these policies. As the potential for me to be able to complete my treatment and live a Lipoedema free life are now very slim... and indeed gives newly diagnosed patients in the future little hope of a cure."

Outreach engagement summary

The table below summaries the outreach engagement activity and how many people were engaged with:

Organisation	Date	Group	Attendees / survey provided
Sandwell Hospital	3/10	Physiotherapy – Upper limb	8
	3/10	Physiotherapy – Lower limb	8
	3/10	Physiotherapy – Post operative knee	6
Age UK	2/10	Service user support group	60
	2/10	Support group (religious studies)	8

Organisation	Date	Group	Attendees / survey provided
Birmingham Heartlands Hospital	2/10-11/10	Patient groups for Weight Management and Bariatric Dietitian	50
Birmingham Heartland Hospital	3/10	NIV	2
	11/10	Direct liaison with Lipoedema patient feedback received	1

8. Stakeholder feedback received by email

Some feedback from stakeholder was received by email. Below is a summary of their views:

8.1 - Bioventus Global – exogen bone healing
The implementation of these guidelines could result in patients living in Birmingham and Solihull Clinical Commissioning Group and Sandwell and West Birmingham Clinical Commissioning Group areas being disadvantaged due to inequality of service provision. EXOGEN allows patients to involve themselves in their own treatment. As they use the device at home after being taught how to apply the therapy by a clinician on one occasion in a clinical setting.

The therapy is used once a day with each treatment taking 20 minutes. EXOGEN is used as part of a shared decision-making option providing patients who meet the selection criteria a non-invasive option.

Typically, patients may have:

- Undergone other treatment options or
- Where further surgical intervention would pose a significantly high risk to the patient or
- The risk of surgery outweighs the benefit or
- A preferred option for the appropriate patients.

The type of patient considered suitable may have significant comorbidities which with surgical intervention could lead to increased length of stay in hospital, could require a stay on Intensive care unit (ITU) or a high dependency unit (HDU), and could increase risk of mortality.

The conditions relevant to this scope for the EXOGEN ultrasound bone healing system are long bone fractures where there is non-union (failure of healing after 9 months) and delayed healing (no radiological evidence of healing after approximately 3 months).

8.2 - Lipoedema UK

Lipoedema UK are pleased that lipoedema was on the agenda for the CCGs and hope to develop further partnerships with the CCGs and other key stakeholders such as NHS England. Their aim is to move forward the agenda of more accessible and equitable service provision and treatment options for lipoedema patients. They felt this would have a real positive impact for a patients' quality of life, and with earlier intervention and diagnosis, provide long term cost savings for the NHS. They also sent through various materials including case studies and information relating to patients with lipoedema.

8.3 - Spinal Muscular Atrophy UK (SMA)

One of SMA's clinical research correspondents fed back stating it was good to see patients with SMA are included on the restricted list. Non-invasive Ventilation (NIV) is necessary and effective for many patients who have SMA.

They recommend starting NIV for non-sitters (broadly equivalent to SMA Type 1) even if no symptoms are present: "*Ventilation should be started in all symptomatic patients. Some experts recommend using it before documented respiratory failure to palliate dyspnea. This should be judged on individual basis."*

The draft policy suggests that these patients would be able to access domiciliary NIV if they applied separately and on an individual basis. We consider that would mean the process of obtaining the NIV would therefore be slower and not necessarily equitable. Time is of the essence for these children and we therefore suggest you include these patients as a separate eligible group who, with recommendation of their respiratory specialist, are eligible. This would ensure fair access for this particularly vulnerable group and would enable beneficial access to NIV in a timelier way.

In the long run this would also save the time, energy and resources of clinicians who would otherwise need to apply through the individual funding route for patients who are clearly eligible. Infants who have Type 1 SMA should not have to apply for this individually pre-symptomatically if it is warranted and advised in the SMA Standards of Care (SOC) - this should be accepted that this is an indication. They should be a special case which is included in this document. *"Non-invasive positive pressure ventilation (NIV) should be used in all symptomatic non sitter [sic] infants [8, 9, 10, 14, 15], and in non-sitters prior to signs of respiratory failure, to be "prepared" for respiratory failure, prevent/minimize chest wall distortion, and palliate dyspnea."*

SMA propose that the SoC for SMA are read and included as an essential reference. They also suggested that NIV for non-sitters (SMA Type 1 and pre-symptomatic) is considered as a pro-active treatment for respiratory management, and that the CCG

considers separate eligibility for those with SMA Type 1 and pre-symptomatic as reflected in the SoC for SMA. This action would reduce the risk to the individual, offer a better quality of life and decrease the time spent in hospital undergoing treatment for non-sitters (broadly equal to SMA Type1).

8.4 - Lymphoedema Support Network

The Lymphoedema Support Network agree with the policy changes for liposuction for lipoedema and lymphoedema. However, they felt than an IFR for lymphoedema should not be needed as this condition has specific criteria. They stated in the policy, the advice for liposuction for lipoedema states the treatment was 'not generally funded and to apply for an IFR'. However, in the policy for lymphoedema it states the treatment is funded under specific situations as it fits in with NICE guidance and yet patients would still need to apply for IFR. They accept the need for IFR for lipoedema but as lymphoedema has specific criteria an IFR should not be needed.

8.5 - Muscular Dystrophy UK

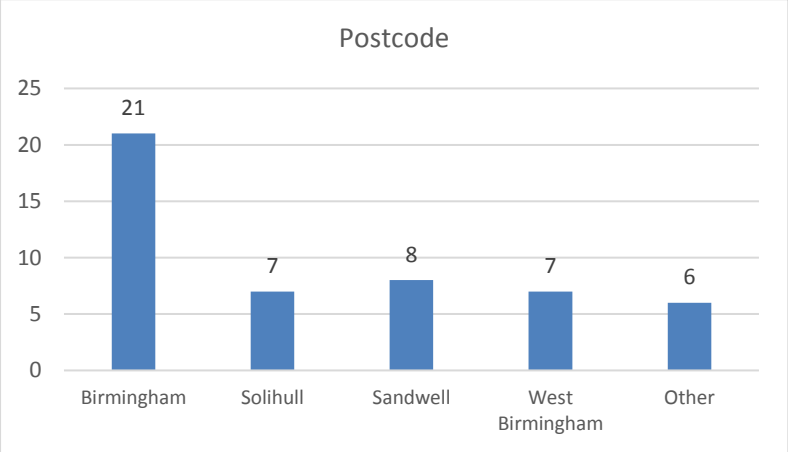
The following statement was received from Muscular Dystrophy UK*: "Muscular Dystrophy UK (MDUK) support the implementation of the non-invasive ventilation (NIV) policy which Birmingham and Solihull CCG & Sandwell & West Birmingham CCG have developed. MDUK note that the term 'neuromuscular disorders which is known to cause respiratory muscle weakness or upper airway functional impairment' should be included in the policy to explicitly ensure that children and adults who are living with neuromuscular conditions receive appropriate and timely access to NIV. MDUK are confident that this policy will result in high quality care for treatment of respiratory dysfunction for this patient population."*

9. Analysis and feedback from the patient and public questionnaire

During the period of 5th September until the 11th October 2019, 49 responses were recorded on the online questionnaire. Respondents were located across the catchment area of both clinical commissioning groups. Further to the responses captured on the questionnaire, additional feedback has been received following outreach with specific individuals (members of the public/and or patients) or directly with healthcare professionals during engagement outreach. These comments have been captured within 'Section 6 Outreach Engagement'.

Survey results: Underlining principles of 'Harmonisation Treatment Policies'

Question 1: Postcode

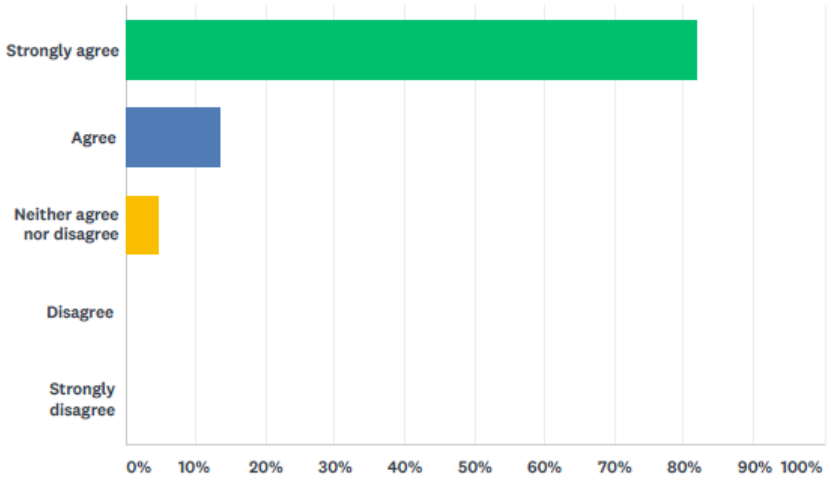


Birmingham	Solihull	Sandwell	West Birmingham	Other	Total
21	7	8	7	6	49
43%	14%	16%	14%	12%	

In order to ensure feedback received was from people who live and receive treatment within the CCG boundary areas, they were asked to provide a postcode when completing the survey. In total, 49 people answered this question with a majority of 43% respondents from Birmingham. Six people who provided their postcode were from other areas outside these localities including Kidderminster, Shropshire; Midhurst, Chichester and Walsall.

Q2 To offer procedures and treatments consistently and fairly to patients.

Answered: 44 Skipped: 5



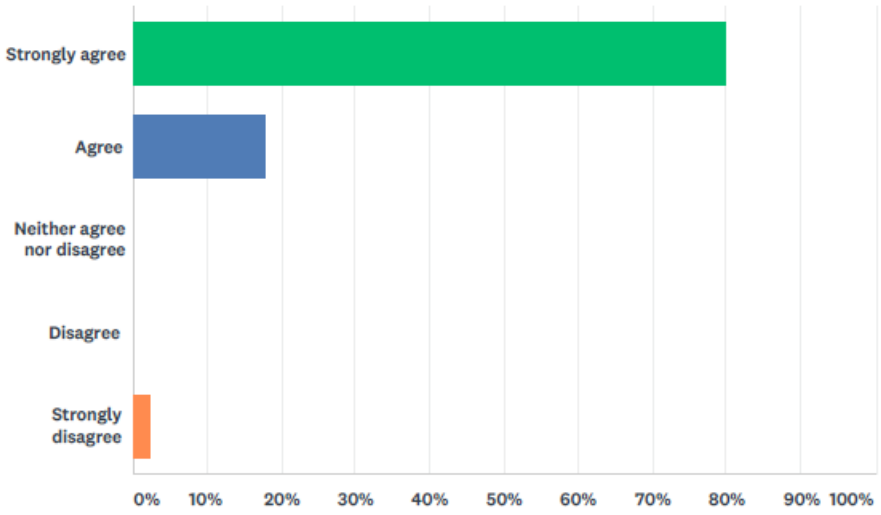
ANSWER CHOICES	RESPONSES	
Strongly agree	81.82%	36
Agree	13.64%	6
Neither agree nor disagree	4.55%	2
Disagree	0.00%	0
Strongly disagree	0.00%	0
TOTAL		44

Analysis:

A strong response has been received in connection to this question, over 80% of responders strongly agreed that procedures and treatments should be offered to patients consistently and fairly.

Q3 To end the 'postcode lottery' by agreeing the same eligibility criteria for a given treatment regardless of where patients live in Birmingham and Solihull and Sandwell and West Birmingham.

Answered: 45 Skipped: 4

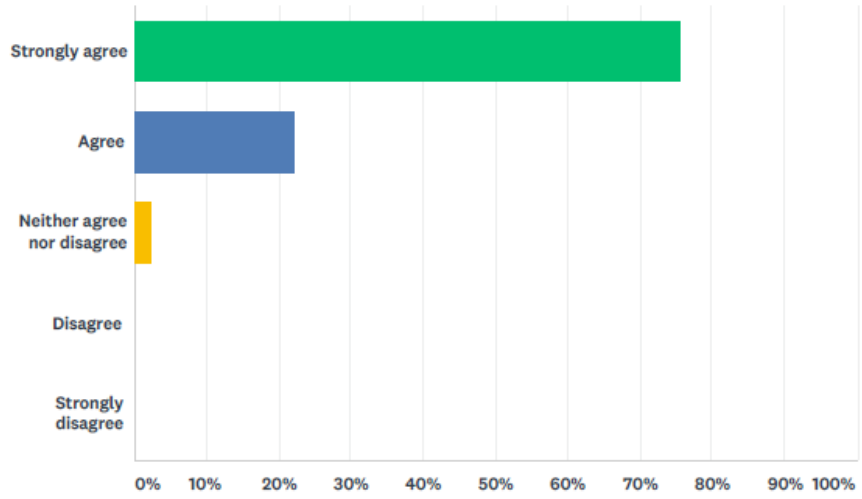


ANSWER CHOICES	RESPONSES	
Strongly agree	80.00%	36
Agree	17.78%	8
Neither agree nor disagree	0.00%	0
Disagree	0.00%	0
Strongly disagree	2.22%	1
TOTAL		45

Analysis:
80% of all responders strongly agreed that it should not matter where you live in accessing the provision of NHS healthcare services across the county, and equally the eligibility criteria for an individual should be the same.

Q4 To ensure that treatment policies are supported by the most up to date clinical guidance and robust clinical evidence.

Answered: 45 Skipped: 4



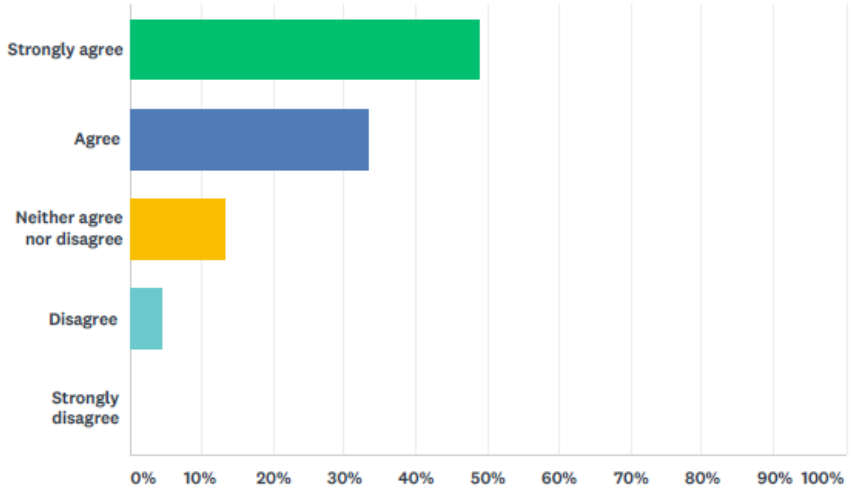
ANSWER CHOICES	RESPONSES	
Strongly agree	75.56%	34
Agree	22.22%	10
Neither agree nor disagree	2.22%	1
Disagree	0.00%	0
Strongly disagree	0.00%	0
TOTAL		45

Analysis:

97% of responders agreed or strongly agreed that up to treatment policies should be supported by the most up to date clinical guidance and robust clinical evidence.

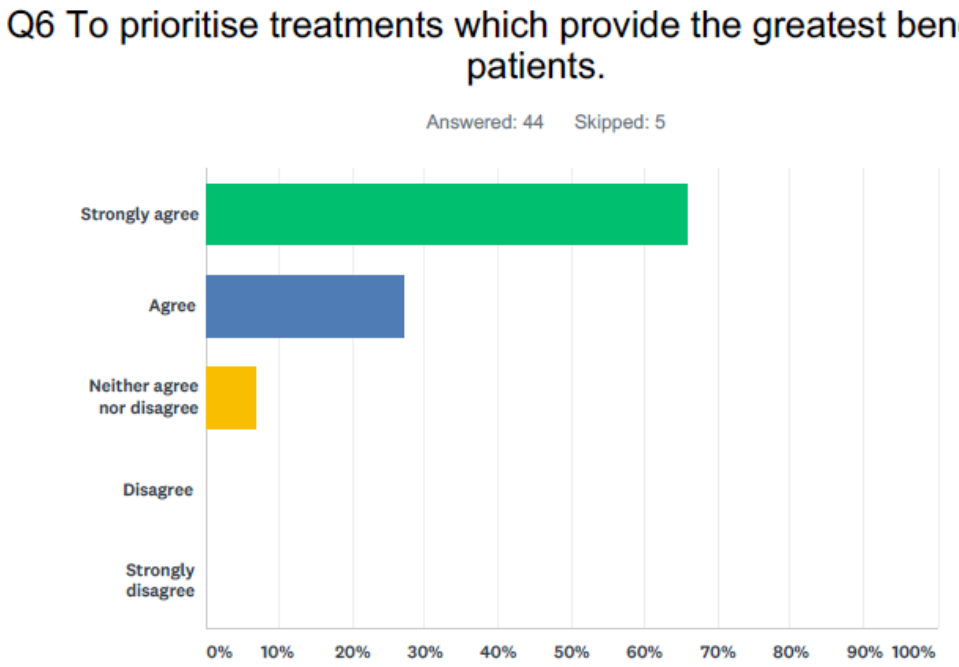
Q5 To stop clinical practices that do not offer clinical benefits to patients, or have very limited clinical evidence base for effectiveness.

Answered: 45 Skipped: 4



ANSWER CHOICES	RESPONSES	
Strongly agree	48.89%	22
Agree	33.33%	15
Neither agree nor disagree	13.33%	6
Disagree	4.44%	2
Strongly disagree	0.00%	0
TOTAL		45

Analysis:
Over 82% strongly agreed or agreed that clinical practices should not be offered if there is limited clinical evidence to support effectiveness.



ANSWER CHOICES	RESPONSES	
Strongly agree	65.91%	29
Agree	27.27%	12
Neither agree nor disagree	6.82%	3
Disagree	0.00%	0
Strongly disagree	0.00%	0
TOTAL		44

Analysis:

93% agree or strongly agree that treatment should be prioritised to those which provide the greatest benefits.

Q7: Do you have any other comments you would like to make about this approach to harmonising the policies for all patients across the area?

Below are the exact responses received for this question:

- Limited resources, needs effective priority
- There are some procedures/interventions that do not have robust evidence but still beneficial in a select group of patients
- It is difficult to produce robust data in situations that vary. i.e. not all cases are the same and just because there are no randomised trial does not mean that the treatment is ineffective. Nice guidelines can be inconsistent when there is little robust data
- No long as there is fairness across all areas

- I feel that these policies when put into practice and prioritised, should stop waste of NHS resource and funding
- If used in rare cases some treatments not seen as large benefit for many can be amazing benefit for the few and if -as in this case- an isolated cost with no infrastructure required then they should be considered in such a capacity
- Sometimes patient feedback is just as important as clinical evidence. If patients have a positive view of a treatment and find it beneficial to their health, even if clinical evidence is limited, the practice shouldn't be discontinued, an example of this is Lymphoedema treatment including raised legs. NHS won't fund electric leg raised due to limited evidence despite many patients finding them beneficial
- Patient input is important, and some equipment or treatment may be more appropriate but may not be under guidelines so should be considered carefully
- Although some treatments have limited value on clinical evidence for some patients the treatment may work well so I think there should be room for some patients to be allowed this treatment
- Important to remember when harmonising policies that that patients are individuals who may have complex needs which require treatment consideration from more than one clinical/surgical area. This means that benefit to the patient will need thorough discussion re the prioritising, effectiveness and eligibility of treatments.
- No, as long as everyone offering these services are all up to date with what is on offer or not. Communication across the board is vital.
- I trust that all the leaflets have been re-written to be readable by the average patient / carer. Those I saw in the recent round of consultation were in far too high a language level and generally uninspiring in appearance (eg irrelevant or no pictures).
- no
- Q5 - To stop clinical practices that do not offer clinical benefits to patients or have very limited clinical evidence base for effectiveness". This statement does not withstand academic scrutiny. For some treatment there is not (yet) robust evidence, and absence of evidence does not mean absence of effectiveness, and so such circumstance when has to rely on plausibility and informed guesses. Whether a treatment confers benefit, is often a post-hoc observation. What is good and what is not good is governed by NICE guidelines, including NICE's observation that these are guidelines, not laws, and that the clinician has a duty to take the particular circumstances, characteristics and wishes of the patient into account. Furthermore, there is the current, DoH and RCGP supported move towards shared (pt-dr) decision making in medicine. To what conclusion the particular medical and psychological circumstances lead, is to be decided by the patient, the GP and the specialist, not by rationing agents. If the CCG resorts to rationing and withholding medically suggested treatment, the CCG must make this explicit to the public/the patient and indemnify drs for adverse outcomes.

- Let us promote general well bring rather than reactive medicine. For this to happen we need more time to be spent with patient, more lifestyle interventions rather than quick fix options.
- Publication of list of operations which will not be offered and taking medicolegal responsibility by the commissioning committee.

Analysis:

45 people answered Q5. There were 16 additional comments overall in response to all questions on the underlying principles. Of these comments 50% mention that although there may be limited clinical evidence to support a specific treatment or procedure, those treatments may still be of benefit to patients and individual cases should still be considered and not be dismissed.

Feedback on the development of the patient leaflets has also been discussed and opportunities to make them more 'patient friendly' and easily understandable to all by the use of non-clinical language.

Survey results for the harmonisation treatment policies

Summary of survey responses: Arthroscopic sub-acromial decompression

Overview:
Subacromial pain in adults is one of the most common causes of non-traumatic shoulder pain and is a normal part of ageing. It also can be known as 'rotator cuff disease', which is thought to be the wear and tear of the rotator cuff tendons.

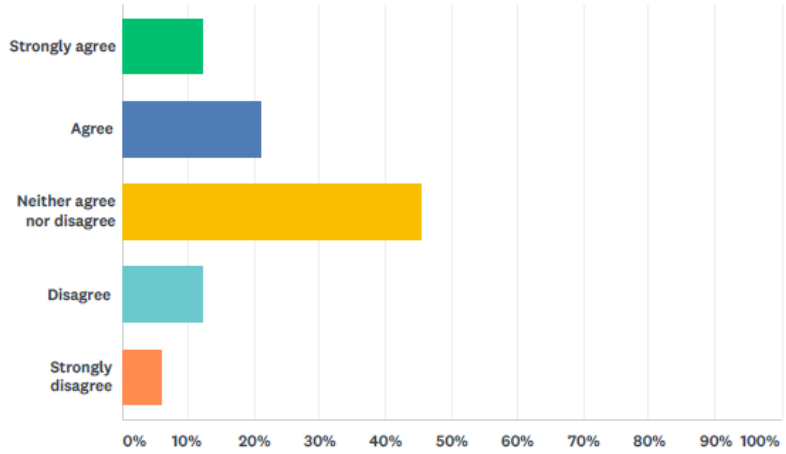
Treatment:
Arthroscopic sub-acromial decompression (ASD) is a series of surgical 'keyhole' procedures to different parts of the shoulder. Due to the lack of evidence for the clinical effectiveness of arthroscopic shoulder decompression (ASD) compared to conservative treatment, ASD for patients with sub-acromial pain is not routinely commissioned.

Proposed Change to policy:
Due to the clinical evidence which fails to demonstrate clinical effectiveness of this intervention in these clinical circumstances the proposed change is not to offer Arthroscopic sub-acromial decompression as a clinical treatment.

Q8: Have you accessed this service?
From the 35 responders who completed this question, 17.14% had accessed this service.

Q9 To what extent do you agree/disagree to the proposed change(s) to this policy?

Answered: 33 Skipped: 16



ANSWER CHOICES	RESPONSES	
Strongly agree	12.12%	4
Agree	21.21%	7
Neither agree nor disagree	45.45%	15
Disagree	12.12%	4
Strongly disagree	6.06%	2
TOTAL		33

Below are the exact responses received from 20 respondents:

- I have not researched or specialised into this field- So difficult to have an opinion.
- For some patients who have tried conservative treatments his may offer some relief
- If you're in pain, real pain, you'll consider anything that helps
- do not fully understand
- The resources could be better used
- There are clinical instances especially in trauma where this might be beneficial in improving function, so it will have to tailored to patient needs
- I do not see patients with shoulder pain
- Has helped some patients
- I feel each case must be looked at and treated on its merit
- Don't treat this
- There may be some people the procedure helps.
- Not qualified to make such a judgement
- I don't think it should be a blanket "no". The surgeon and GP should have the final say
- A family member had keyhole surgery to relieve pain and restricted movement in a shoulder. Treatment very successful. Following a traumatic injury to my

shoulder I was not offered treatment other than physiotherapy; the shoulder still gives pain and still has some restricted movement. Need to be careful that treatment is not seen to be restricted on the criteria of age of patient

- No view either way
- see generic comment about readability etc
- If it's not beneficial it shouldn't be offered.
- Leave the decision to the pt, GP and specialist
- Sometimes, that is the last resort. As a doctor, very difficult to say, sorry you suffer from pain, we will not do anything.
- Patients report benefit and withdrawing assumes that the clinical evidence is absolutely correct - it is often not

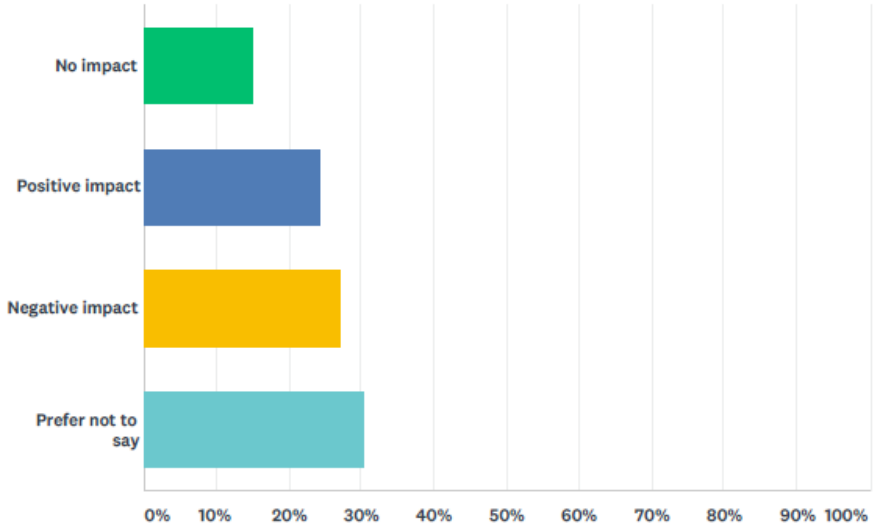
Analysis:
Approximately 45% of responders neither agreed or disagreed with the policy change whilst approx. 33% strongly agreed or agreed that the proposed change to the policy would be of benefit to patients.

In addition, those who provided further comments half of those received mention in some cases this could be of benefit to a patient in pain and an individual need, needs to be assessed.

“Sometimes, that is the last resort. As a doctor, very difficult to say, sorry you suffer from pain, we will not do anything.”

Q10 Please indicate the impact of the proposed change(s).

Answered: 33 Skipped: 16



ANSWER CHOICES	RESPONSES	
No impact	15.15%	5
Positive impact	24.24%	8
Negative impact	27.27%	9
Prefer not to say	30.30%	10
TOTAL		33

Below are the exact responses received from 17 respondents:

- I have not researched or specialised into this field- So difficult to have an opinion...
- see above
- It can only be better than what I am suffering now
- as above
- will make patients unhappy
- Some people tolerate pain better than others, so it comes back to the individual doctor and patient.
- Don’t treat this
- Better use of clinician’s time
- The patient will be happy
- See experience above: Important to widen the scope of NHSE policy on ASD to all causes

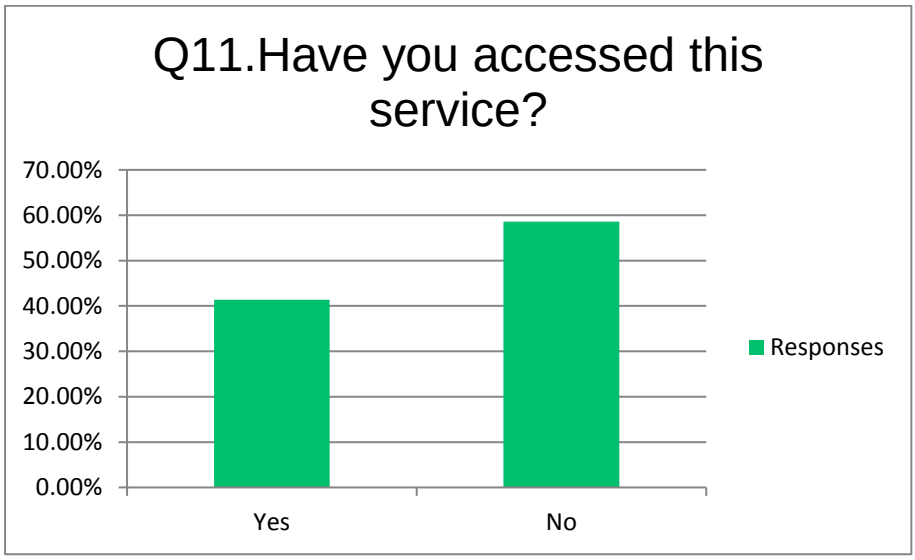
- If a patient has been having this service and it is changed, he or she will think this is just a cost cutting exercise
- If a patient knows that only treatment that is proven to work is offered, surely, they will have more confidence.
- It is not that I prefer not to say, but I don't know
- It will affect patient presenting elsewhere asking for solutions only to be told that you must see GP. No intervention is going to be successful until all clinicians (A/E, walk in centre) all say the same language.
- Breakdown in doctor-patient relationship

Analysis:
From the 33 responders who answered this question, approximately 24% said that the following proposed changes would make a positive impact and approximately 27% said that it would make a negative impact. A slightly higher proportion felt they preferred not to say. Mixed responses were also demonstrated within the additional comments and this may signify that overall responders are neutral on the proposed changes or collectively do not have a strong opinion based on their personal knowledge.

Summary of survey responses: Image guided therapeutic intra-articular joint injections with corticosteroids with/without local anaesthetic

Overview:
Image guided therapeutic intra-articular joint injections are anaesthetic and steroid based injections (corticosteroid injections) used to relieve severe joint pain and inflammation caused by Osteoarthritis. The injections are administered into joints using image guidance from either an x-ray (fluoroscopy) or an ultrasound to identify the correct location to insert the needle. Osteoarthritis is the most common form of arthritis and classed as a chronic musculoskeletal disorder. Knees, hips, feet and small hand joints are the common areas affected by osteoarthritis where joints are unable to repair themselves. However, it can affect most joints and cause severe pain and inflammation resulting in reduced mobility and quality of life.

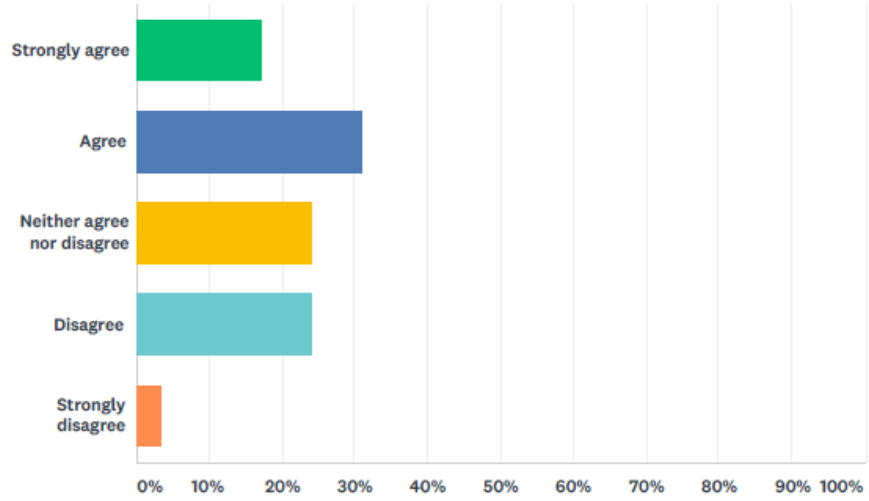
Proposed Change(s):
Image guided injections should only be offered to patients where other treatments have failed and should only be undertaken in the small joints (defined as joint of the hands and feet).



From the 29 responders who completed this question, 41.38% had accessed this service.

Q12 To what extent do you agree/disagree to the proposed change(s) to this policy?

Answered: 29 Skipped: 20



ANSWER CHOICES	RESPONSES	
Strongly agree	17.24%	5
Agree	31.03%	9
Neither agree nor disagree	24.14%	7
Disagree	24.14%	7
Strongly disagree	3.45%	1
TOTAL		29

Below are the additional responses received from respondents:

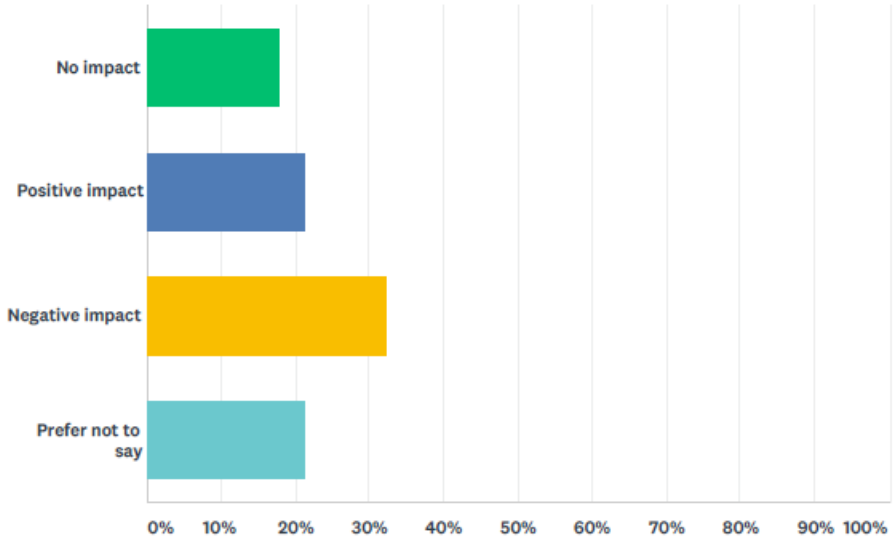
- On the understanding that non-guided injections of large joints will still be made available to patients where this treatment offers pain relief when conservative methods have failed
- Do not fully understand
- Only as last resort
- It is very difficult to administer an injection into the hip especially if the anatomy is also altered and hence safer and also beneficial to inject under imaging guidance. Hence, I would support injections under guidance for hips for this reason. knee joint injections can be done without imaging due to the ease of access. I do not undertake any injections in the ankle or foot to be able to comment.
- Hip injections are difficult to perform without image guidance and for small joints such as hands and wrists it is vital to be sure the injection is in the right place

- Should be done first
- If the practitioner is experienced in this field I would have thought the decision on treatment would be down to him
- I think it is dangerous to insert an injection into large joints without image guidance
- This depends on each individual patient
- Clear evidence
- I have had guided and unguided injections and I think it is the skill of the surgeon that can determine the effectiveness of this treatment
- Important that if this treatment is restricted that GPs and other clinicians are well trained and practised in the delivery of articular large joint injections, which can gift relief to many patients.
- I believe the person delivering image guidance would be more qualified, my husband has had injections given wrongly which has caused more pain and he has needed even more injections to put it right. Would a more careful service of imagery have saved pain time and money.
- see generic comment about readability etc
- Non effective treatment is no treatment and should not be offered.
- Leave the decision to the patient, GP and specialist
- Hip joint injection is difficult to give without guidance as wrong place can be injected.

Analysis:
Approximately 48% of responders either agreed or strongly agreed to the proposed changes; approximately 24% did not have an opinion either way; 28% disagreed to some extent. From the 17 responses received which refer to the responder having preformed this procedure (as a healthcare professional) comments received have been positive for the use of image guidance technology as a way for them to have the reassurance when preforming treatment.
"it is very difficult to administer an injection into the hip especially if the anatomy is also altered and hence safer and also beneficial to inject under imaging guidance. Hence, I would support injections under guidance for hips for this reason. knee joint injections can be done without imaging due to the ease of access."
Responses received from patient/public also support the skill of the practitioner in knowing whether image guided, or non-image guided technology should be used dependent on the condition of the patient.
"I have had guided and unguided injections and I think it is the skill of the surgeon that can determine the effectiveness of this treatment."

Q13 Please indicate the impact of the proposed change(s).

Answered: 28 Skipped: 21



ANSWER CHOICES	RESPONSES	
No impact	17.86%	5
Positive impact	21.43%	6
Negative impact	32.14%	9
Prefer not to say	21.43%	6
TOTAL		28

Below are the additional comments received from respondents:

- Anything that helps is a good thing
- I have had a fractured spine and compressed discs. 3 Injections, 18-month period, 6 months in-between now having a 5 year gap. Area felt much better for 3 weeks however it's a terrible procedure, physio didn't help. Should be used as last resort
- lot of injections done without imaging guidance especially intra-articular in the hip joint might not be accurate and hence will not achieve therapeutic benefit.
- Again, I feel that money saving in some cases would be for the good
- Save multidisciplinary time with no detrimental effect
- Not qualified to comment
- If a surgeon is not skilled in administering the injection without imaging, then it may not be done or done badly. Although I agree in principal that imaging is not always necessary, I imagine some surgeons may feel the need for that backup

- Need to assess future patient outcomes
- Not so precise so may have a negative impact
- Confidence from the patient that the treatment offered is likely to work.
- It is not that I prefer not to say, but I don't know: This is a question for clinical academics to answer
- As stated above.

Analysis:
Approximately 18% of respondents felt that the proposed change would have no impact upon patients; approximately 21% felt the affect would be positive; approximately 32.% felt the effect would be negative.

Additional comments received are very much mixed responses and are very much centred around the assessment of the patients' condition and the skill of the practitioner performing the treatment.

"Although I agree in principal that imaging is not always necessary, I imagine some surgeons may feel the need for that backup"

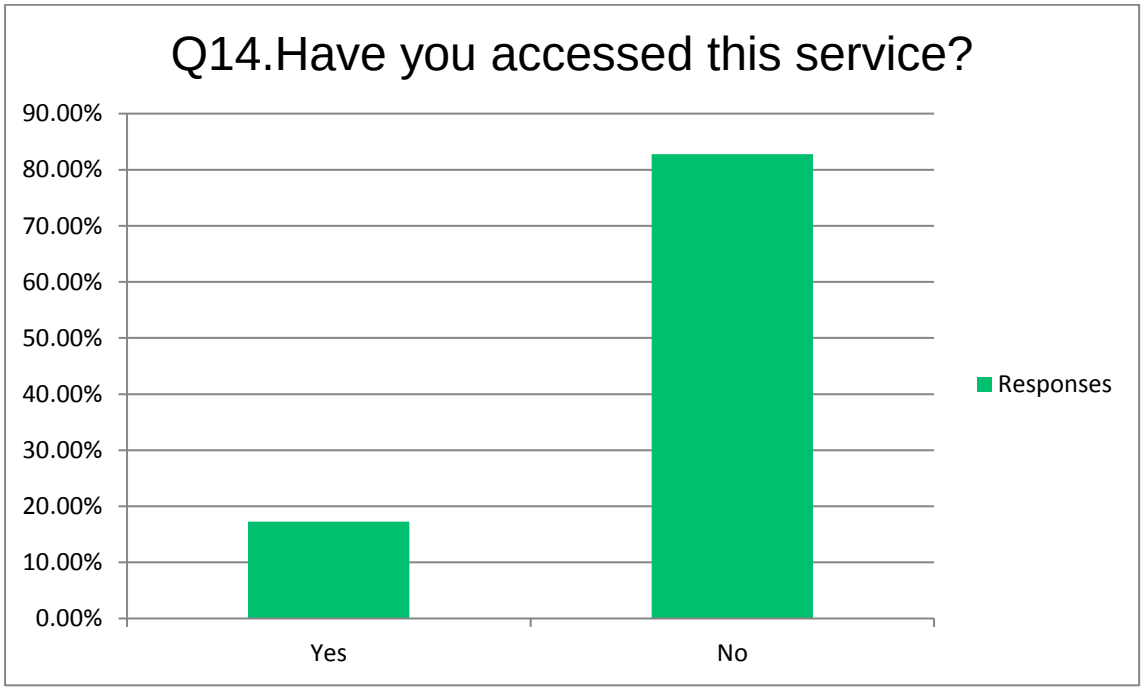
Summary of survey responses: Image-guided high volume intra-articular injections (40mls+) of saline with or without corticosteroid and/or local anaesthetic

In this procedure, high volume injections (10-55mls of saline solution) are injected into joints using imaging guidance through an x-ray (fluoroscopy), ultrasound or computed tomography (CT) to identify the correct location to insert the needle.

Clinical evidence strongly demonstrates that the use of image guidance to administer these injections in large joint is unnecessary for the accurate delivery of the injection and that the use of a high volume injection is not supported by the clinical evidence.

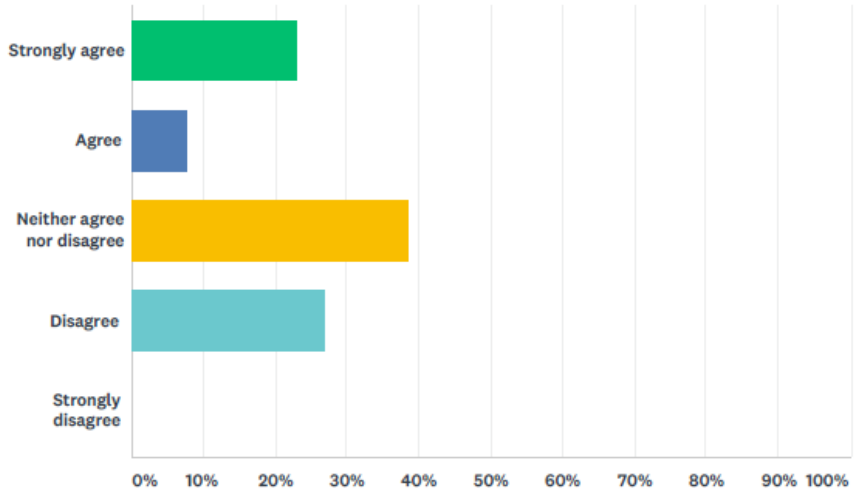
Proposed Change(s):
Currently, there is no policy currently for this clinical treatment. Therefore, it is proposed that a policy is developed stating that due to the limited quality of evidence of clinical and cost effectiveness for image-guided high volume intra-articular injections compared to alternative treatment options, this intervention is not routinely commissioned.

From the 29 responders who completed this question, 17.24% had accessed this service.



Q15 To what extent do you agree/disagree to the proposed change(s) to this policy?

Answered: 26 Skipped: 23

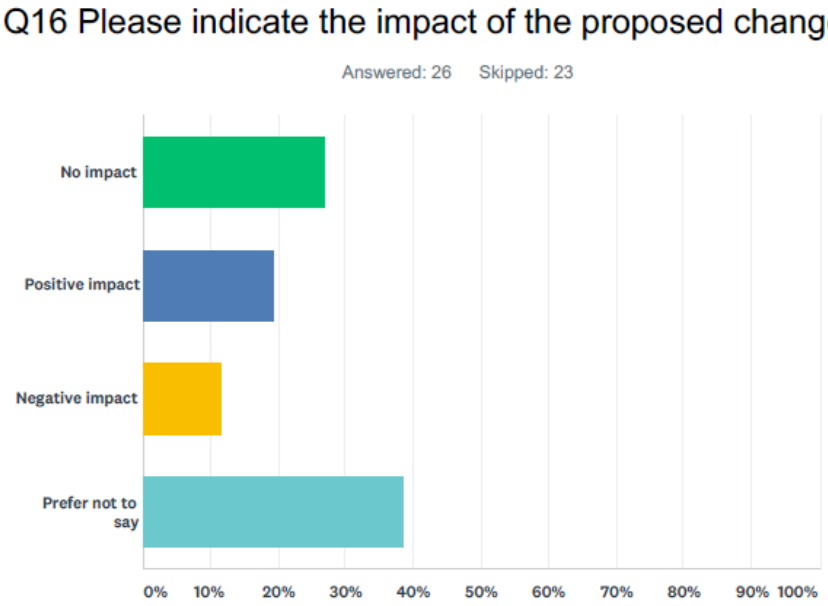


ANSWER CHOICES	RESPONSES	
Strongly agree	23.08%	6
Agree	7.69%	2
Neither agree nor disagree	38.46%	10
Disagree	26.92%	7
Strongly disagree	0.00%	0
TOTAL		26

Below are the exact comments received from the respondents:

- I understand that further research into the use of saline injections is on-going?
- Not enough evidence to go one way or another
- Until there is clinical evidence to either support or stop this procedure then i feel the individual clinical has the say over whether to continue or not.
- Don't treat these patients
- Risky as the procedure could go wrong and the patient could be injured
- Clear evidence for change of policy
- I found the treatment highly effective
- I believe that there are some studies still on-going re this treatment
- Not 100% sure what this means
- see generic comment about readability etc
- As previously, no need to stick things in a patient that are unnecessary.
- Leave the decision to the patientt, GP and specialist

Analysis:
Approximately 31% of respondents agree to some extent. Approximately 38% neither agreed nor disagreed which is reflective within the additional comments received. Where a patient has accessed this service, they have provided further comments that they found this treatment '*highly effective'.* Just over 30% of the comments received refer to not enough clinical evidence in ascertaining whether they agree or disagree with the proposed change due to ongoing clinical study.



ANSWER CHOICES	RESPONSES	
No impact	26.92%	7
Positive impact	19.23%	5
Negative impact	11.54%	3
Prefer not to say	38.46%	10
TOTAL		26

Below are additional comments received from respondents:

- Don't treat these patients
- Stop non beneficial procedures
- See above
- What a saving in money and time not to mention giving the patient more confidence in the treatment that IS being given.
- It is not that I prefer not to say, but I don't know: This is a question for clinical academics to answer.

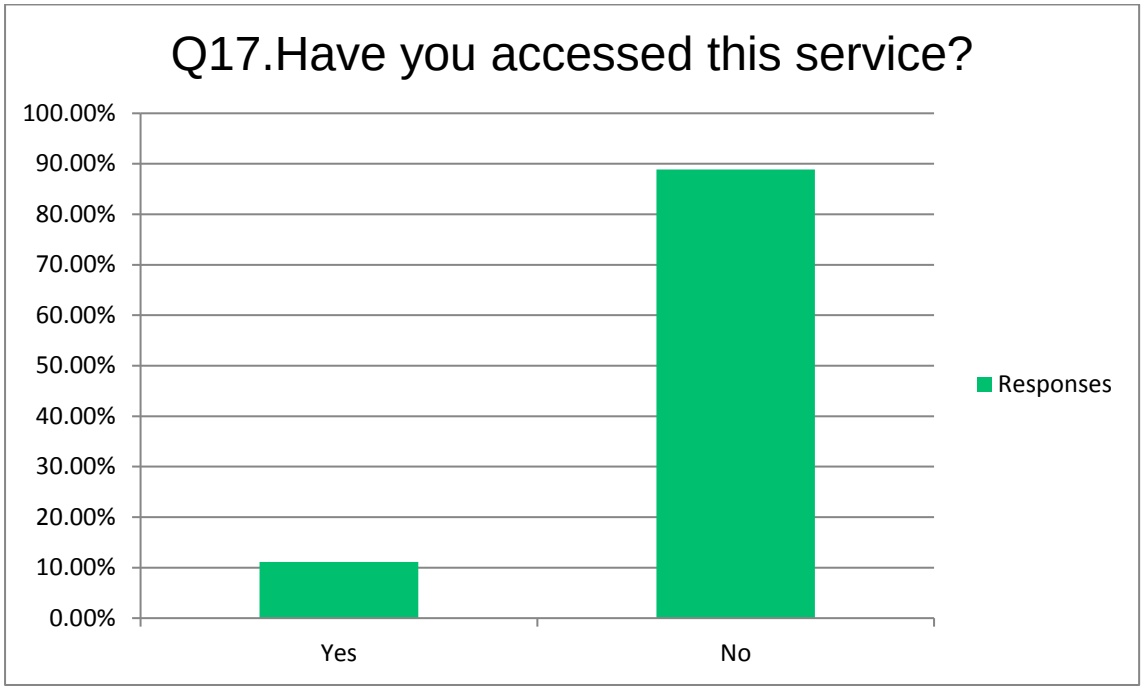
Analysis:
Positive impact approximately 19%; Negative impact approximately 12%; no impact approximately 27%.

Summary of survey responses: The use of EXOGEN ultrasound bone healing system

Overview:
The EXOGEN ultrasound bone healing system sends low-intensity pulsed ultrasound waves through the skin to the fractured bone to potentially help the body to heal the bone. There is a lack of clinical evidence to support the use of the EXOGEN ultrasound bone healing system.

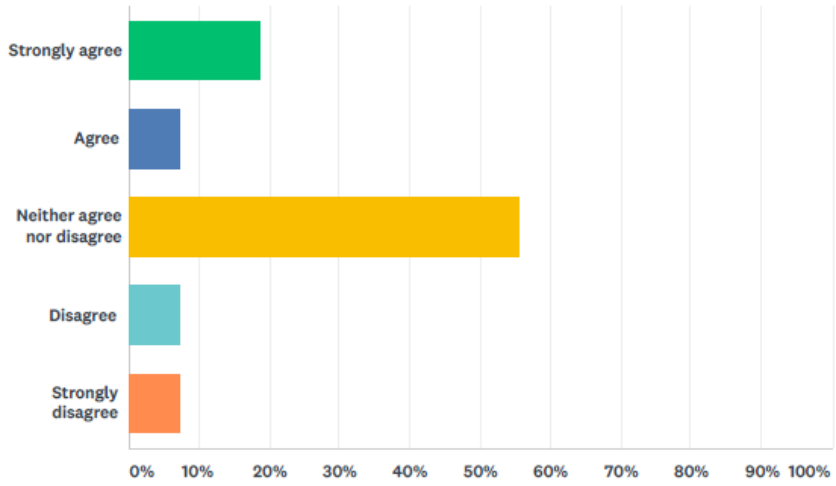
Proposed Change(s):
Currently, there is no policy for this clinical treatment. Therefore, based on the lack of robust clinical evidence to support this clinical treatment it is proposed that a policy is developed stating that the treatment is not routinely commissioned.

From the 27 responders who completed this question, 11.11% had accessed this service.



Q18 To what extent do you agree/disagree to the proposed change(s) to this policy?

Answered: 27 Skipped: 22



ANSWER CHOICES	RESPONSES	
Strongly agree	18.52%	5
Agree	7.41%	2
Neither agree nor disagree	55.56%	15
Disagree	7.41%	2
Strongly disagree	7.41%	2
TOTAL		27

Additional comments received include:

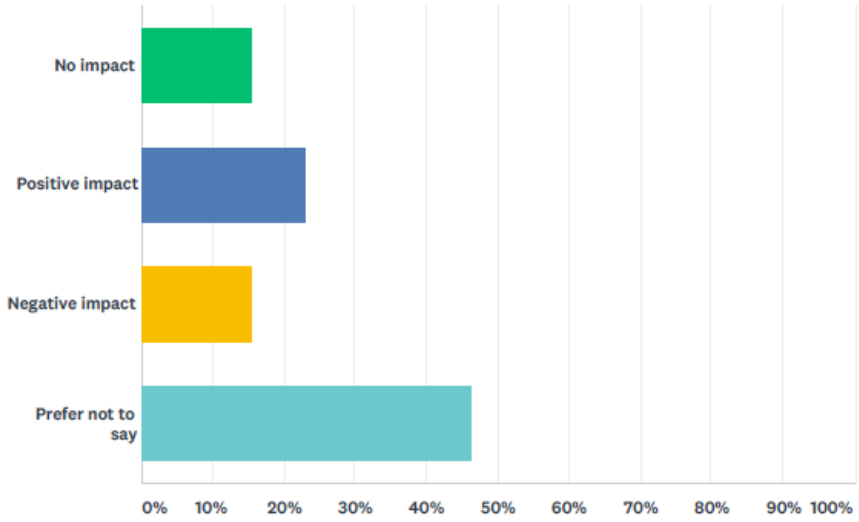
- do not enough to answer
- having used exogen in selective patients, I have seen the clinical benefits to achieve union. We have used this in selective patient when we can avoid operative interventions which might otherwise be necessary and therefore avoid surgical risks in revision operations.
- I have had multiple patients that have had treatment for non-union in which union has taken place with EXOGEN treatment. There is some patient in which the consequences of non-union are severe in which adjunctive treatment with EXOGEN may prevent non-union occurring. there is good evidence of its efficacy in patients with recalcitrant non unions who would otherwise require complex surgery
- I feel if this this is stopped without sufficient evidence then there is no clear way to say whether it works or not

- Evidence presented in non-union if long bones as included in the info reviewed
- lack of evidence for its use
- Not qualified to comment
- I presume that "it is not routinely commissioned" does not mean that it will never be commissioned (or am I incorrect in this assumption?!
- Personal lack of investigation into the efficacy of this treatment
- would leave this up to statistics
- see generic comment about readability etc
- More costs wasted on useless treatments.
- The absence of evidence that it works doesn't mean that it doesn't work - this may well be premature
- Not used so cannot comment.

Analysis:
Approximately 26% agree to some extent with the proposed policy; approximately 15% disagree to some extent; approximately 56% neither agree nor disagree

Q19 Please indicate the impact of the proposed change(s).

Answered: 26 Skipped: 23



ANSWER CHOICES	RESPONSES	
No impact	15.38%	4
Positive impact	23.08%	6
Negative impact	15.38%	4
Prefer not to say	46.15%	12
TOTAL		26

Below are the exact comments received from respondents:

- anything is better than nothing
- Will benefit the use in selective patients and hence a blanket ban would not be beneficial to patients.
- some patient would require bone graft surgery under general anaesthetic without guarantee of good outcome or joint fusion with permanent loss of movement which could be avoided.
- until evidence is produced as to the benefit of a procedure then how do you know the outcome
- This helps me avoid 3-4 operations a year on non-union specific cases
- See above
- More patient confidence in the treatments that are being offered.
- It is not that I prefer not to say, but I don't know: This is a question for clinical academics to answer.

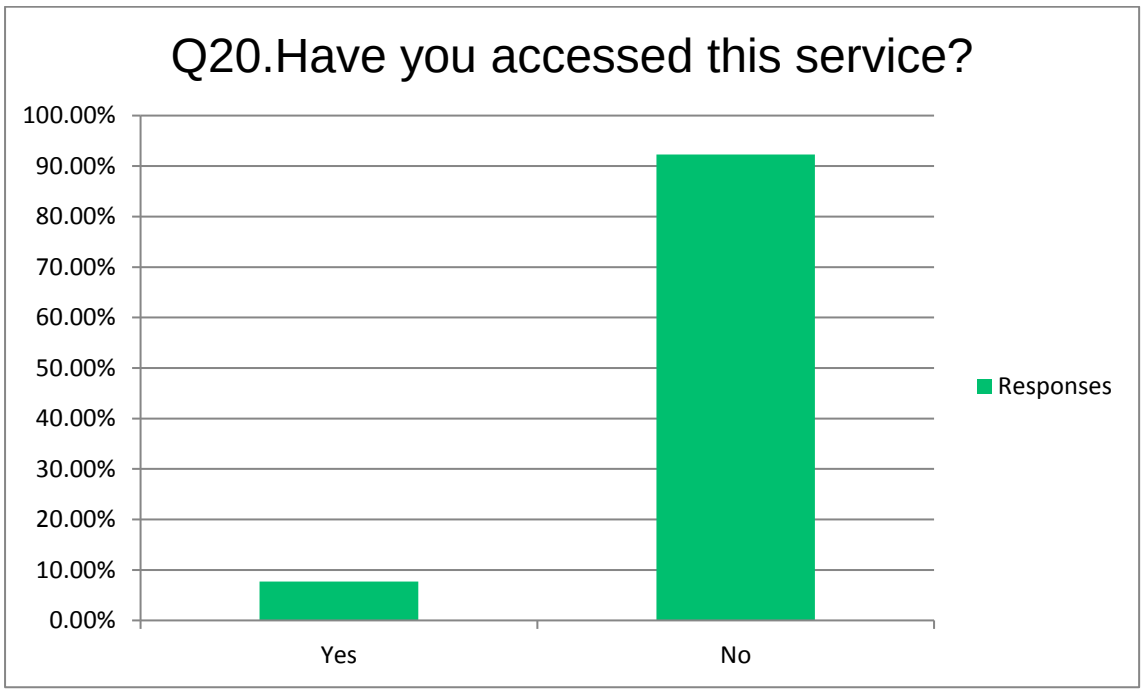
Analysis:
Approximately 23% feel the impact of the proposed policy will be positive; approximately 15% feel the impact will be negative; 15% feel there will be no impact.

Summary of survey responses: The use of liposuction in lymphoedema

Liposuction is normally deemed to be a cosmetic procedure used to remove unwanted body fat. Liposuction carried out for cosmetic reasons is not normally available on the NHS. However, liposuction can sometimes be used by the NHS to treat certain health conditions.

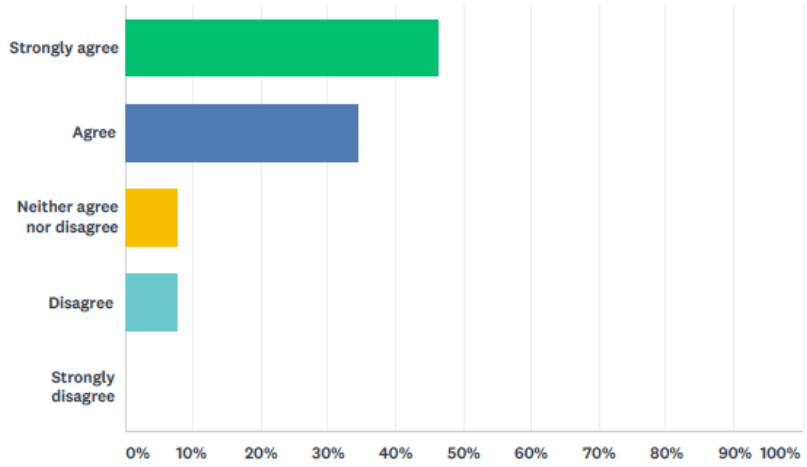
Proposed Change(s):
Currently, there is no policy for this clinical treatment. Therefore, a draft policy will be developed stating that this treatment will be available for patients with lymphoedema who have failed conservative management in line with the current patient pathway for treatment of lymphoedema. Patient selection should only be done by a specialist lymphoedema multi-disciplinary team as part of a lymphoedema service pathway. Clinical evidence strongly supports this intervention for the defined group of patients.

From the 26 responders to this question, 7.29% have accessed this service



Q21 To what extent do you agree/disagree to the proposed change(s) to this policy?

Answered: 26 Skipped: 23



ANSWER CHOICES	RESPONSES	
Strongly agree	46.15%	12
Agree	34.62%	9
Neither agree nor disagree	7.69%	2
Disagree	7.69%	2
Strongly disagree	0.00%	0
TOTAL		26

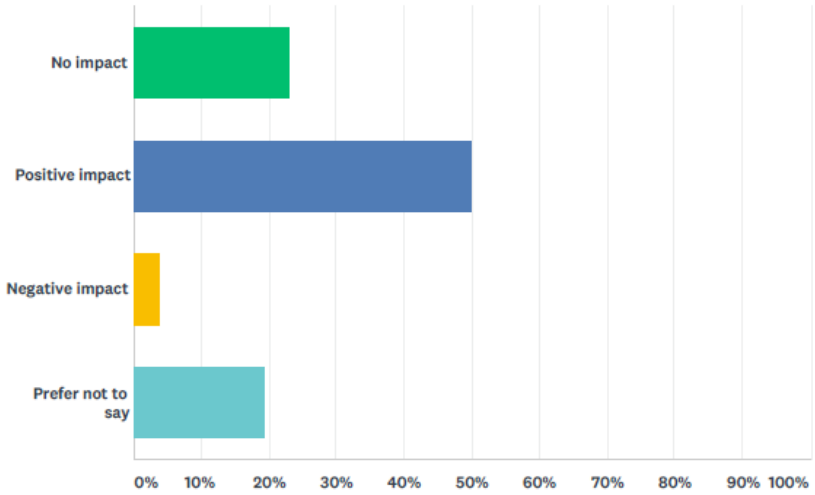
Analysis:

Although a limited amount of responders have accessed this service which is to be expected due to the rarity of this condition, a strong response of over 80% of responders agree or strongly agree with the proposed change.

- if it helps good
- People with this condition do need support after every other avenue has been explored
- Don’t treat
- Patients will benefit
- Can benefit patients who develop lymphoedema following cancer surgery
- Hopefully it will help enormously
- Patients will know that this treatment is necessary if they get it.
- It is not that I prefer not to say, but I don't know: This is a question for clinical academics to answer.

Q22 Please indicate the impact of the proposed change(s).

Answered: 26 Skipped: 23



ANSWER CHOICES	RESPONSES	
No impact	23.08%	6
Positive impact	50.00%	13
Negative impact	3.85%	1
Prefer not to say	19.23%	5
TOTAL		26

Additional comments received from respondents include:

- Studies indicate that Liposuction in lymphoedema where conservative treatments have been exhausted can be beneficial and successful. Clinically in practice I have experience of the positive impact of this procedure on a primary lymphoedema patient. Is new policy going to accept both primary and secondary lymphoedema patients to access this procedure?
- Good to consider a defined group of patients for this service however there is a lack of lymphoedema specialists so there could be delays in assessment and treatment. This needs to be addressed to meet patient needs
- The addition of Liposuction as treatment option for patients with Lymphedema that are no longer responding to traditional treatments such as bandaging, compression wraps, MLD etc would be life changing for those group of patients this procedure is suitable for. Liposuction for Lymphedema is recognised in NICE guidance.
- Any help is better than none
- I personally have lymphedema but under control. I would like to think that if circumstances change then I would like access to treatment.

- Don't treat
- Evidence based change
- If it's an effective treatment
- Lymphoedema can be a distressing ailment and the Patient should be given any help possible to make their condition more tolerable
- Makes treatment options available to wider patient group
- I see people with this terrible condition, and it makes sense to offer treatment if other treatment has failed
- see generic comment about readability etc
- It sounds like a sound policy.
- Leave the decision to the patient, GP and Dr/nurse specialist
- Seeking evidence always best answer.

Analysis:
50% of responders feel that this will have a positive impact upon those with this condition. Additional comments received by those who are healthcare professionals who work within this field believe that once all conservative management treatments have failed that this is a recognised practice supported by NICE guidelines. Comment received from a patient who suffers with this condition also is in agreement of policy.

"Studies indicate that Liposuction in lymphoedema where conservative treatments have been exhausted can be beneficial and successful. Clinically in practice I have experience of the positive impact of this procedure on a primary lymphoedema patient."
"Liposuction for Lymphedema is recognised in NICE guidance."

Summary of survey responses: The use of liposuction in lipoedema

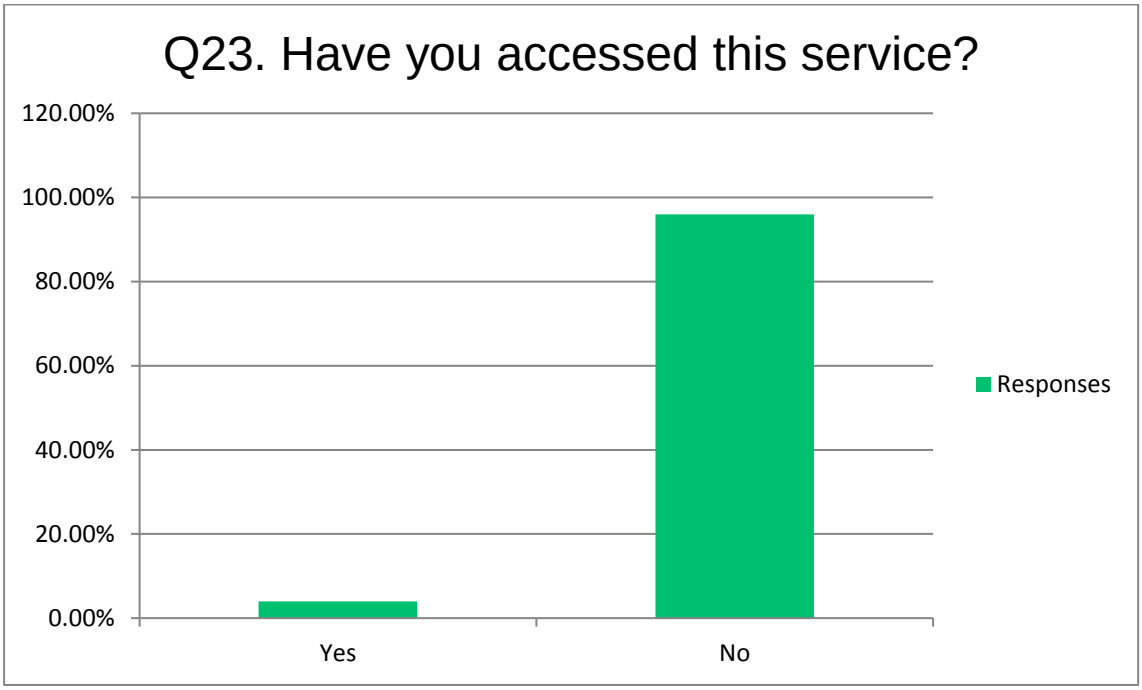
Overview

Lipoedema is a long-term (chronic) condition where there is an abnormal build-up of fat cells in the legs, thighs and buttock areas, and sometimes in the arms. Liposuction is normally deemed to be a cosmetic procedure used to remove unwanted body fat. Liposuction carried out for cosmetic reasons is not normally available on the NHS. However, liposuction can sometimes be used by the NHS to treat certain health conditions.

Proposed Change(s):

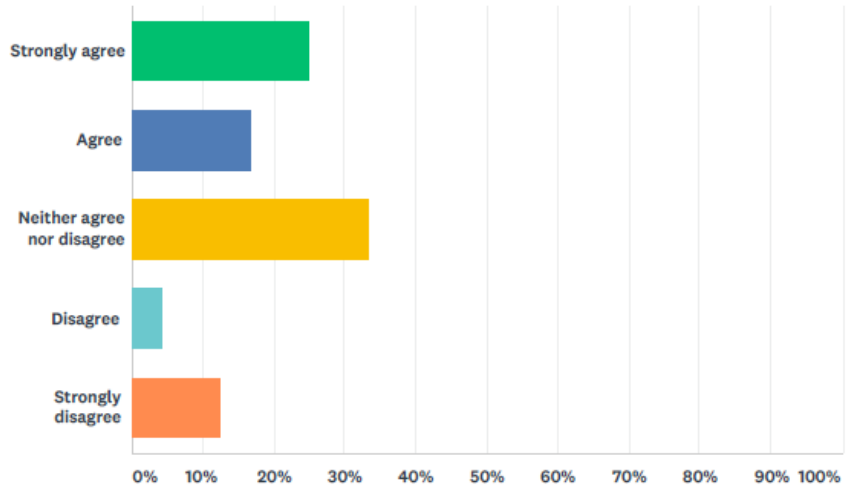
Some research has been undertaken for the use of liposuction in lipoedema, which demonstrated clinical benefit to patients in the study. However, the number of patients in the trials is small. Further research is needed before the CCG may support this intervention. Currently there is no policy for liposuction. Therefore, a draft policy will be developed stating that liposuction is not routinely commissioned for patients diagnosed with Lipoedema

From the 25 responders who answered this question, 4% have accessed the service.



Q24 To what extent do you agree/disagree to the proposed change(s) to this policy?

Answered: 24 Skipped: 25



ANSWER CHOICES	RESPONSES	
Strongly agree	25.00%	6
Agree	16.67%	4
Neither agree nor disagree	33.33%	8
Disagree	4.17%	1
Strongly disagree	12.50%	3
TOTAL		24

Below are additional comments received from respondents:

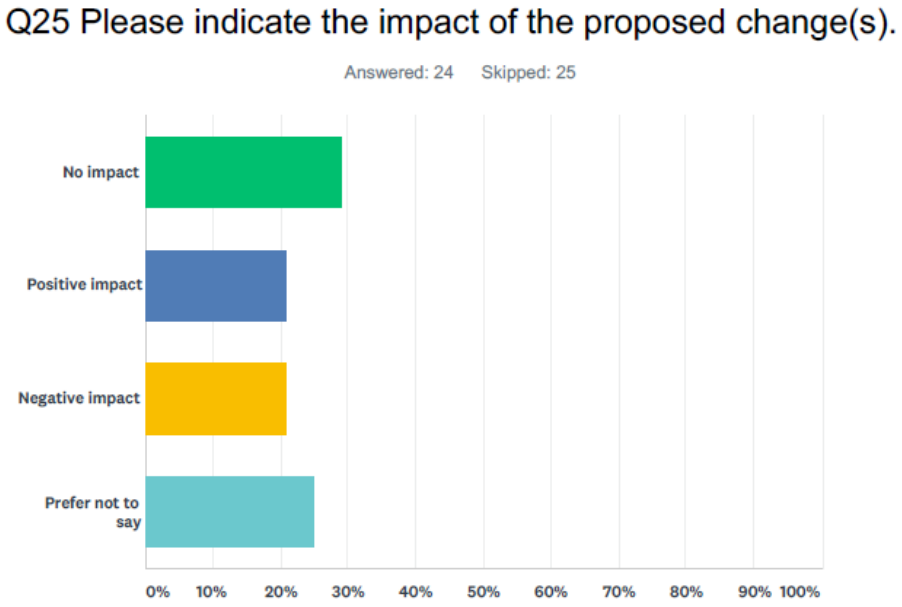
- I am a Nurse Consultant for Lipoedema UK and have been a Clinical Nurse Specialist in lymphoedema and Lipoedema for several years. I have been to the Hanse Clinic as part of my previous role as Director of LymphCare UK and saw the positive results the specialist Tumescent Liposuction had on Women. It was life-changing. The outcomes with improved range of movement, mobility, pain, psychologically and physically were very evident. Circumferential Limb volumes were greatly reduced.

  I have also had a patient on my previous caseload who was struggling to carry on working and interacting with her children. Following a series of Tumescent Liposuction procedures she was able to return to work, play with her children and become more mobile and active. This patient still continues to reap the benefits of this procedure after 9 years. Numerous surveys from Lipoedema UK have highlighted that women are in dire need of services and an option in some cases should be Medical Tumescent Liposuction. There is

currently a postcode lottery of service provision generally for this condition. Women are often mis-diagnosed as obese or suffering for lipoedema and spend several years suffering with the condition prior to being referred to a specialist Lymphoedema service. However, I think this is a positive step to put Lipoedema on the agenda for improving services. I agree that there needs to be more investment into further research and this is a priority moving forward.

- More research and trials should be considered and reviewed
- I am a Lymphedema nurse specialist and Lipoedema UK Nurse consultant and also suffer from this condition myself. This is NOT for a cosmetic purpose but treatment of a now recognised medical condition. Lipoedema does not respond to conservative treatments. Ladies with Lipoedema have fatty doughy abnormal distribution of fat that is not usual obesity fat and is impossible to lose through healthy eating and fat burning exercise. This condition has physical and psychological long term complications. These include significant reduction in mobility often leading to joint problems and orthopaedic surgeries. Some ladies have significant low self-esteem and depressive illness. A complication can be Lymphedema secondary to Lipoedema There is 10 years of evidence from Hanse clinic in Germany that Liposuction is life changing.Lipoedema UK have produced a series of four articles from focus groups women in dire need of liposuction, we will forward these and some other papers via email
- If it helps them only good can come of it
- I feel that there needs to be more evidence gathered before a final decision made
- Don’t treat
- Evidence based decision
- The sooner a trial gets underway the better
- Need for more clinical evidence and therefore option for limited treatments should be left open
- Same as before hopefully it will help
- see generic comment about readability etc
- Not sure if this should be used or not, surely another larger trial should be commissioned.
- If it shown to have clinical benefit, it should be recommended by health care professionals, if medically appropriate. This should be left to the Pt, GP and specialist If the CCG wants to withhold - ration- treatment - the CCG should inform the patient and explain its reasons, as well as indemnify health professionals.

Analysis:
Approximately 42% agree or strongly agree to the proposed policy. 33% neither agree or disagree and this may be reflective of limited clinical evidence available. However, response received by healthcare professionals who work within this area report that patients have benefited greatly from this procedure for significant years after liposuction treatment and it should not be dismissed as not routinely commissioned because of the limited trials.
"Lipoedema There is 10 years of evidence from Hanse clinic in Germany that Liposuction is life changing"



ANSWER CHOICES	RESPONSES	
No impact	29.17%	7
Positive impact	20.83%	5
Negative impact	20.83%	5
Prefer not to say	25.00%	6
TOTAL		24

Below are additional comments received from respondents:

- For those patients who may benefit from this treatment careful assessment could be made following a trail of more conservative treatments
- If it helps - great
- until the evidence is gathered then it's difficult to answer
- Don't treat

- more trials are needed to gauge the effectiveness of the treatment then more Patients can be treated "A chicken and egg situation methinks"
- See above
- Any help would be better than none
- Not sure what the patient will think if they were offered and it was declined due to not enough information. This is a very painful condition to live with.
- If it is shown to have clinical benefit, it should be recommended by health care professionals, if medically appropriate. This should be left to the Patient, GP and specialist .If the CCG wants to withhold - ration- treatment - the CCG should Inform the patient and explain its reasons, as well as indemnify health professionals. This process may undermine trust in health care.

Analysis

Approximately equal weighting in results regarding positive and negative impact have been shown in this question.

Summary of survey responses: Bariatric Surgery

Overview:
Bariatrics is the branch of medicine that deals with causes, prevention and treatment of obesity. Bariatric surgery includes a group of surgical procedures which promote weight loss.

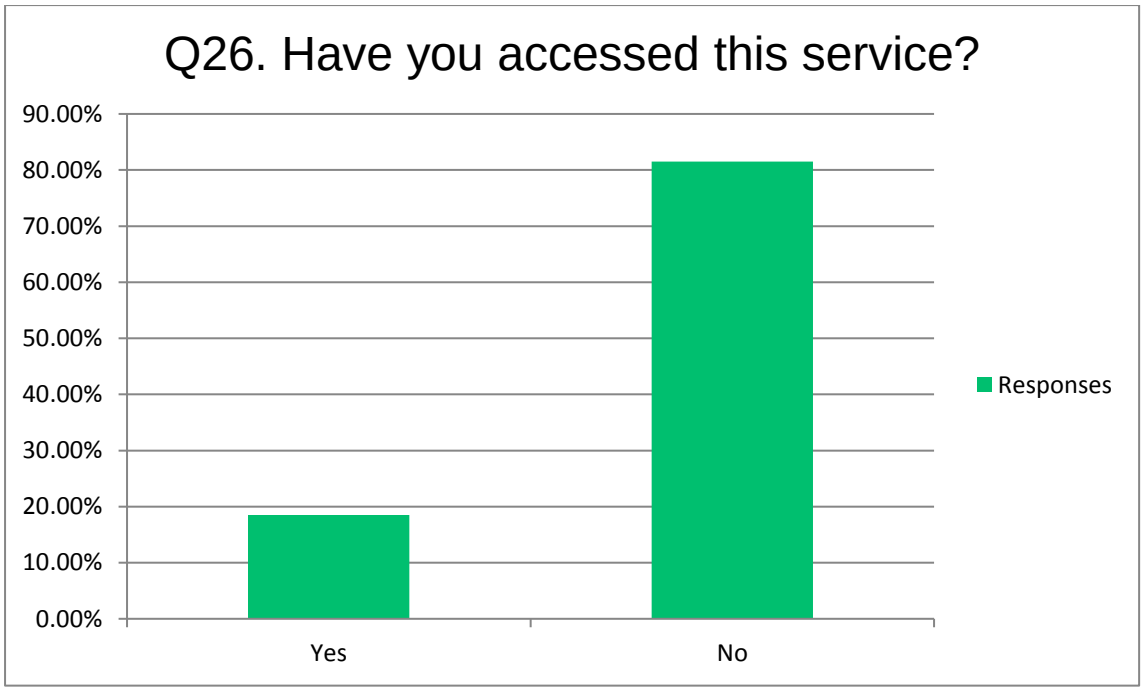
Proposed Change(s):
There is no current policy. Therefore, a draft policy will be developed to state that Patients eligible for surgery must have the following:

- BMI of >35kg/m2

AND
Type 2 diabetes mellitus which has been diagnosed within the last 10 years.
OR

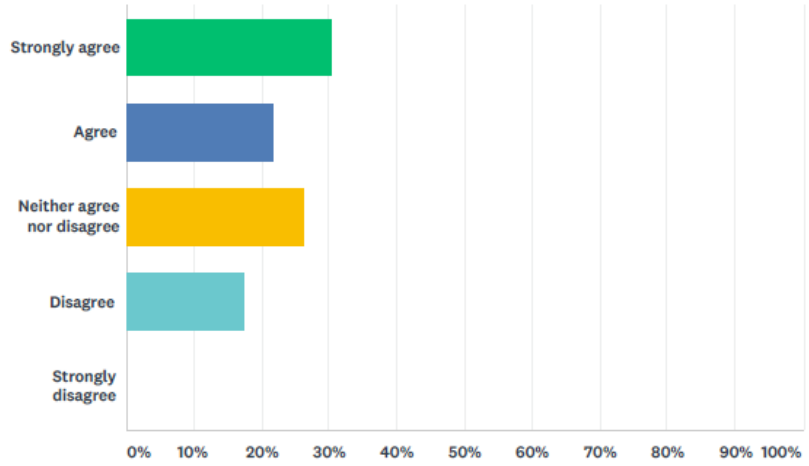
- BMI of >50kg/m2

From the 27 responders who answered this question, 18.52% have accessed the service.



Q27 To what extent do you agree/disagree to the proposed change(s) to this policy?

Answered: 23 Skipped: 26



ANSWER CHOICES	RESPONSES	
Strongly agree	30.43%	7
Agree	21.74%	5
Neither agree nor disagree	26.09%	6
Disagree	17.39%	4
Strongly disagree	0.00%	0
TOTAL		23

Below ar additional comments received from respondents:

- To be used with support for patient in life-style changes and possible emotional support
- Don’t treat
- Obesity is a major problem and some people need this help
- Not qualified to comment
- Obviously, prevention should be the first thing tried but is sometimes difficult to achieve. It seems ludicrous that a Patient of45Kg is deemed "too small" for the surgery so has to put more weight on. The impact on health seems more important to me than the actual weight
- Benefit to patients’ overall health and wellbeing who fall within the eligible groups
- everything must be tried before this costly procedure which we think is self-inflicted
- see generic comment about readability etc
- Sounds reasonable.

- NICE 2014: BMI of 35 or over NICE recommends that all patients with a BMI of 35 or over who have recent-onset type 2 diabetes should be assessed for surgery. Patients must have tried and failed to achieve clinically beneficial weight loss by all other appropriate non-surgical methods and be fit for surgery. You appear to block doctors from fulfilling their medical obligation - and be in breach of the duties of a Dr -GMC
- If patient has BMI 48, do we need to tell them to eat more to hit 50, so that they are eligible
- Limits not based on sound evidence and considerable morbidity at BMI in 40s for some people.

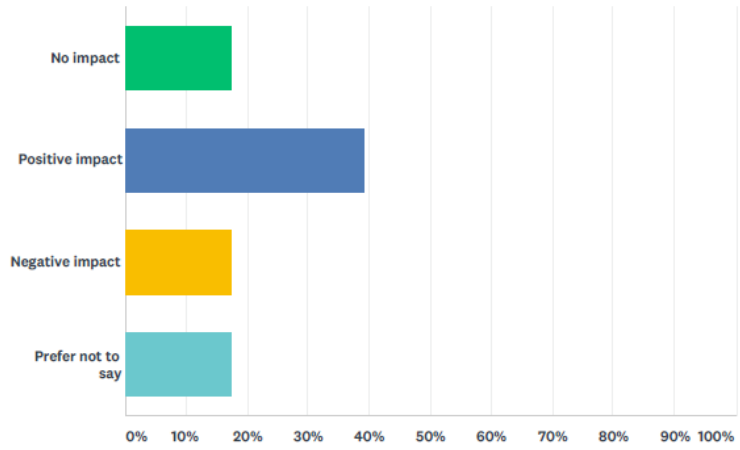
Analysis:
Although over 52% agree with the proposed policy criteria those comments received by healthcare professionals question the eligibility criteria. Particular concerns are also raised that the proposed policy may exclude those who are in drastic need of the surgery and may oppose current NICE guidelines.

"If patient has BMI 48, do we need to tell them to eat more to hit 50, so that they are eligible."

"NICE 2014: BMI of 35 or over NICE recommends that all patients with a BMI of 35 or over who have recent-onset type 2 diabetes should be assessed for surgery. Patients must have tried and failed to achieve clinically beneficial weight loss by all other appropriate non-surgical methods and be fit for surgery. You appear to block doctors from fulfilling their medical obligation - and be in breach of the duties of a Dr-GMC."

Q28 Please indicate the impact of the proposed change(s).

Answered: 23 Skipped: 26



ANSWER CHOICES	RESPONSES	
No impact	17.39%	4
Positive impact	39.13%	9
Negative impact	17.39%	4
Prefer not to say	17.39%	4
TOTAL		23

Below are additional comments received from respondents:

- surgeons do select patients who are suitable for this.
- I find it difficult to answer this question. I feel that the patients' cooperation is very much needed and that they continue with a programme of weight loss there after
- Don't treat
- Once patients have had the surgery they should be able to use the NHS less
- sometimes may defeat the object of the exercise
- Assists general health and well being where all other approaches to weight loos have failed
- Isn't this the normal criteria for this operation so no change
- You have to have limits and boundaries with this type of surgery and everyone knows where they are.
- NICE 2014: BMI of 35 or over NICE recommends that all patients with a BMI of 35 or over who have recent-onset type 2 diabetes should be assessed for surgery. Patients must have tried and failed to achieve clinically beneficial weight loss by all other appropriate non-surgical methods and be fit for surgery. You appear to block doctors from fulfilling their medical obligation - GMC
- It should be decided individually and there should be a range.

Analysis:
Positive impact approximately 39%; negative impact 17%; no impact 17%.

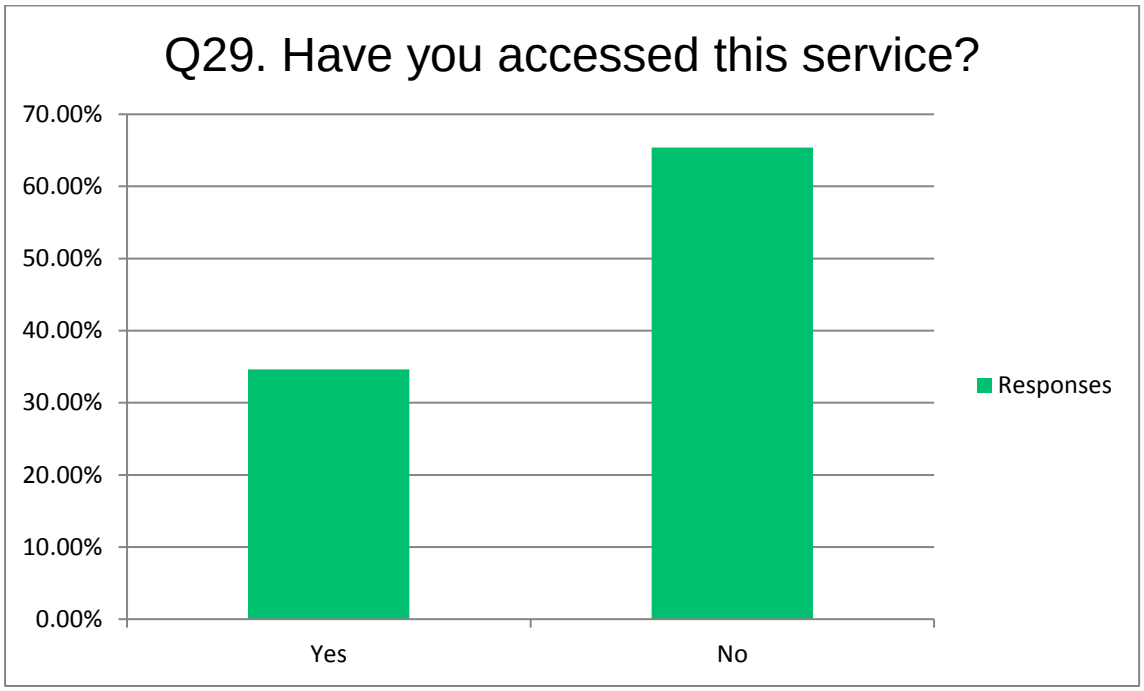
Summary of survey responses: Knee Arthroscopy for Acute Knee Injury

Overview:
Arthroscopic knee surgery is a treatment which may include:

- Arthroscopic lavage (also called arthroscopic washout)
- Arthroscopic debridement (in combination with lavage)
- Arthroscopic partial meniscectomy (APM) which may be performed singly or in combination with the above. The meniscus is a C shaped piece of cartilage that acts as a shock absorber in the knee, meniscectomy is removal of the cartilage.

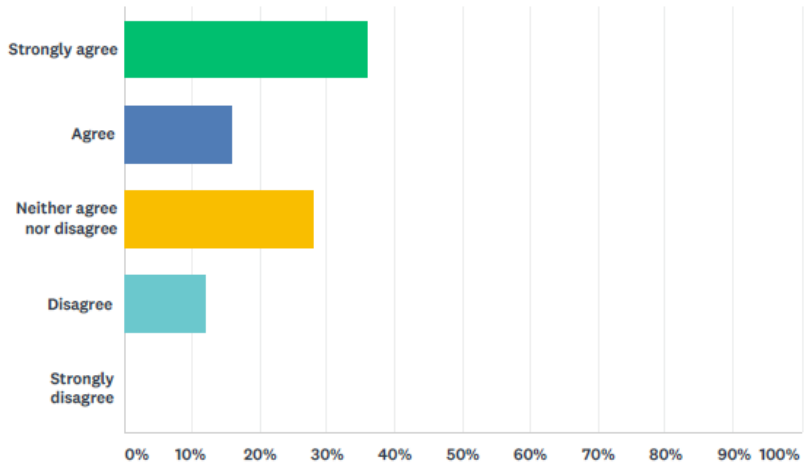
Proposed Change(s):
Clinical evidence strongly demonstrates that knee arthroscopy in acute knee injury provides no greater benefit than conservative treatment immediately following injury. The current policy for knee arthroscopy is for degenerative knee disease only. The proposed draft policy will state that arthroscopy for acute knee injury will only be available for those conditions and individuals where this clinical treatment is likely to be of benefit.

- From the 26 responses to this question, 34.62 have accessed this service.



Q30 To what extent do you agree/disagree to the proposed change(s) to this policy?

Answered: 25 Skipped: 24



ANSWER CHOICES	RESPONSES	
Strongly agree	36.00%	9
Agree	16.00%	4
Neither agree nor disagree	28.00%	7
Disagree	12.00%	3
Strongly disagree	0.00%	0
TOTAL		25

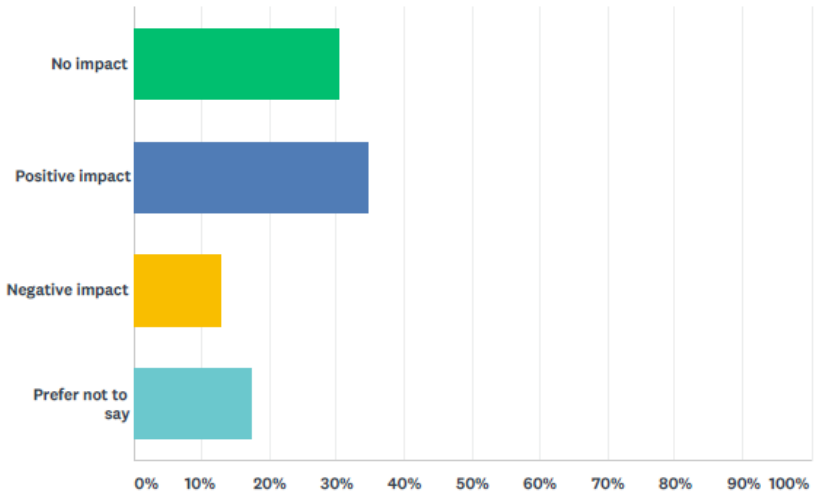
Below are additional comments received from respondents:

- Widens the policy to include acute knee injury when more conservative treatments have failed. However, the policy seems to exclude degenerative knee injury- which may occur across a range of adult age groups. Reconsider this group?
- If it works great
- Because it worked for me. After injury had 6 months of conservative management; leg in brace and other pain management treatments. Then had surgery with supported physio and feels a lot better
- If it is thought to have little benefit, then to carry out this procedure would be wasting funds
- Don't treat
- Evidence based change
- Seems sensible
- If no benefit pointless to proceed
- see generic comment about readability etc
- If it's not beneficial it shouldn't be used.
- Where is the evidence that it does not help in trauma? Leave this to pt, GP and specialist

Analysis:
Approximately 52% of responders agreed or strongly agreed to the proposed policy change. It is noted that within the additional comments the proposed change has been received positively to include acute knee injury, but concerns are raised over degenerative knee injury and subsequent management of this condition. Those who disagree to some extent number approximately 12%; 28% neither agree nor disagree.

Q31 Please indicate the impact of the proposed changes(s).

Answered: 23 Skipped: 26



ANSWER CHOICES	RESPONSES	
No impact	30.43%	7
Positive impact	34.78%	8
Negative impact	13.04%	3
Prefer not to say	17.39%	4
TOTAL		23

Below are additional comments received from respondents:

- Possible negative impact on some group
- anything that helps get movement back good
- Because it worked for me. After injury had 6 months of conservative management; leg in brace, pain management, then had surgery with supported physio and feels much better
- knee arthroscopy is only performed when it is clinically indicated following trauma, especially if there is a locked knee to restore function. Hence this is beneficial.
- If only given to patients who they feel will benefit from th procedure, then funding is surely being saved
- Don’t treat
- If it doesn't help why do it, waste of time and money
- I would think avoiding a painful invasive procedure would be a good thing for a patient.
- I haven't seen the evidence that it is only good in OA

Analysis

Approximately 35% feel the impact will be positive; approximately 13% feel the impact will be negative.

Summary of survey responses: Non-Invasive ventilation for COPD (Chronic Obstructive Pulmonary Disease and Neuromuscular Disorders)

Overview:
A number of chronic neuromuscular disorders, for example muscular dystrophy and motor neurone disease lead to progressive respiratory muscle dysfunction, which in turn can lead to respiratory failure and death. The aim of using Non-Invasive Ventilation (NIV) is not only to obtain satisfactory oxygen levels, but also to expire carbon dioxide.

Proposed Change(s):
Currently there is no policy for this treatment. The proposed draft policy will ensure that in line with the most up to date clinical evidence and clinical expertise, patient with a neuro muscular disorder and a clinical need for home non-invasive ventilation may access this treatment.

The criteria to be eligible for non-invasive ventilation includes:
Non-invasive ventilation at home is restricted. For patients with long term COPD the NHS commissioning organisation (CCG), who is responsible for purchasing healthcare on behalf of the population, will only pay for the use of NIV in the home if:

- The patient has a measured lung capacity of <0.70L

AND

- A measured carbon dioxide level equal to or greater than 6.5kPa

The patient must **also** have ONE of the following:

- A reduced quality of life identified by symptoms consistent with sleep disordered breathing problems

OR

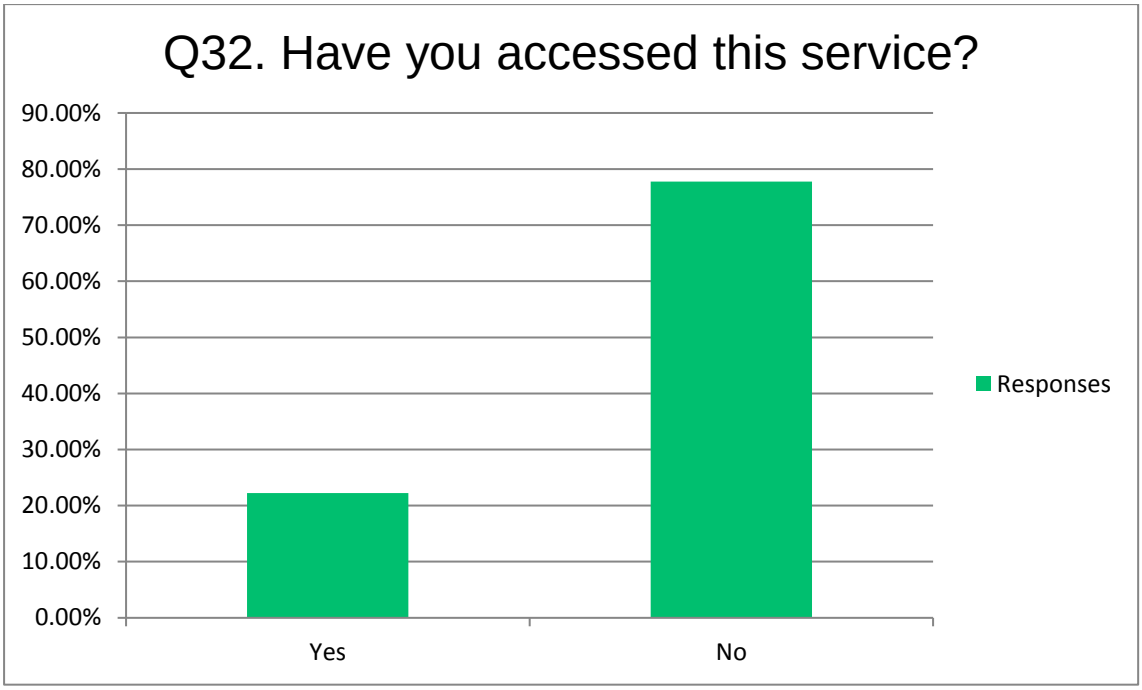
- More than one condition affecting the level of oxygen in the blood which could lead to pulmonary hypertension or heart failure

OR

- Two or more hospital admissions over the past 12 months needing NIV treatment admissions to which the patient has responded well

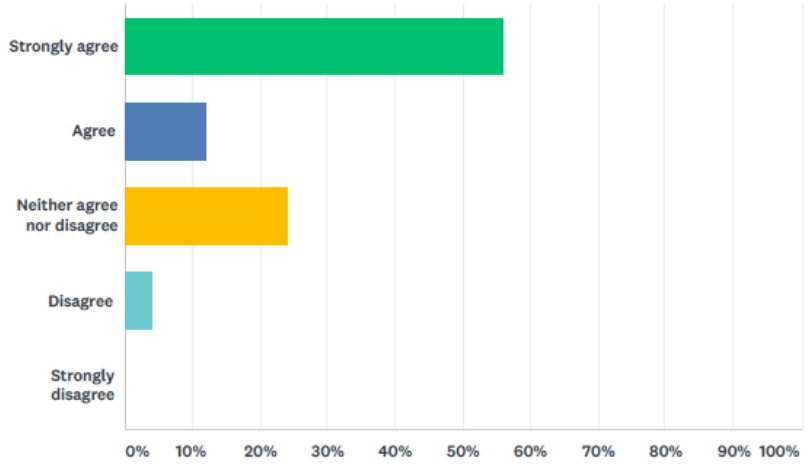
This means the patient's NHS commissioning organisation (CCG), who is responsible for buying healthcare services on behalf of patients, will **only** fund the treatment if an Individual Funding Request (IFR) application has shown exceptional clinical need and the CCG supports this.

From the 27 responders who have responded to this question, 22.22% have accessed the service.



Q33 To what extent do you agree/disagree to the proposed change(s) to this policy?

Answered: 25 Skipped: 24



ANSWER CHOICES	RESPONSES	
Strongly agree	56.00%	14
Agree	12.00%	3
Neither agree nor disagree	24.00%	6
Disagree	4.00%	1
Strongly disagree	0.00%	0
TOTAL		25

Below are the additional comments received from respondents:

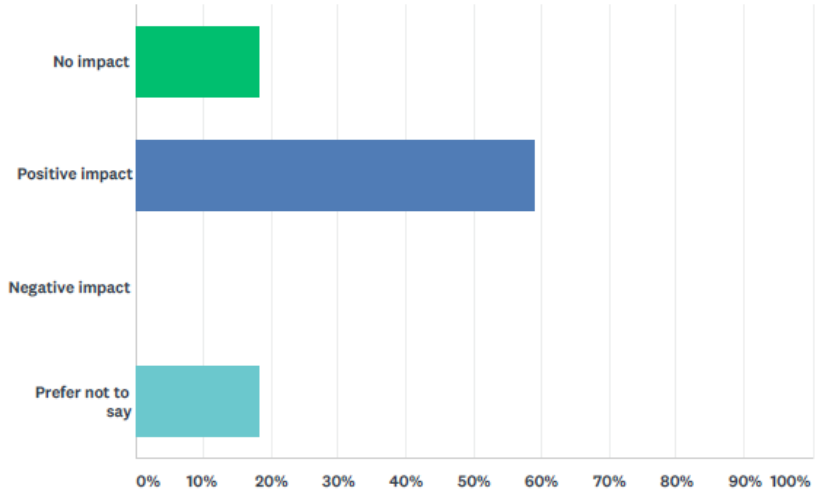
- Do not use this service to be able to comment
- This treatment is vital to patients with respiratory conditions. It offers them a better quality of life which can only have a positive outcome
- Don't treat
- These policies must be put in place in order to speed up process of giving patients their own machinery and make it easier for GPs and walk in centres to know how to refer patients with relevant illness directly to a respiratory specialist instead of putting breathlessness and other symptoms down to asthma/anxiety
- More education and guidelines are needed to prevent Muscular dystrophy patients becoming very ill or dying through lack of knowledge
- This is a needed treatment, provision is long overdue
- Not qualified to comment

- Being unable to breathe ot having difficulty in breathing May make the Patient very anxious. Anything that can alleviate their anxiety and help their breathing can only be a good thing
- Do whatever is best for the patient
- See generic comment about readability etc
- My mother in law had COPD and had this service at home towards the end. It helped her breathe till she died. Obviously but it eased her breathing till she died.
- What is the change?

Analysis:
Approximately 68% of respondents agree to some extent with the proposed this is also reflected in the additional comments.

Q34 Please indicate the impact of the proposed change(s).

Answered: 22 Skipped: 27



ANSWER CHOICES	RESPONSES	
No impact	18.18%	4
Positive impact	59.09%	13
Negative impact	0.00%	0
Prefer not to say	18.18%	4
TOTAL		22

Below are the additional comments received from respondents:

- It ensures a better quality of life
- Don’t treat

- As above, people's quality of life can be drastically improved by these policies being put in place and being used to educate, catch people whose health is declining and speed up treatment and putting long term care (i.e. home machinery in place)
- Will lead to more doctors having the knowledge of what to do in situations they currently have no idea about
- Improvement of quality and quantity of life for patients
- A happier patient
- If no changes made no impact
- Everyone who needs it should have access.
- I do not prefer what to say, but I don't know This should be left to the patient, GP and specialist with regard to NICE guidelines, if any. If the CCG wishes to ration this, it should contact affected patients direct.

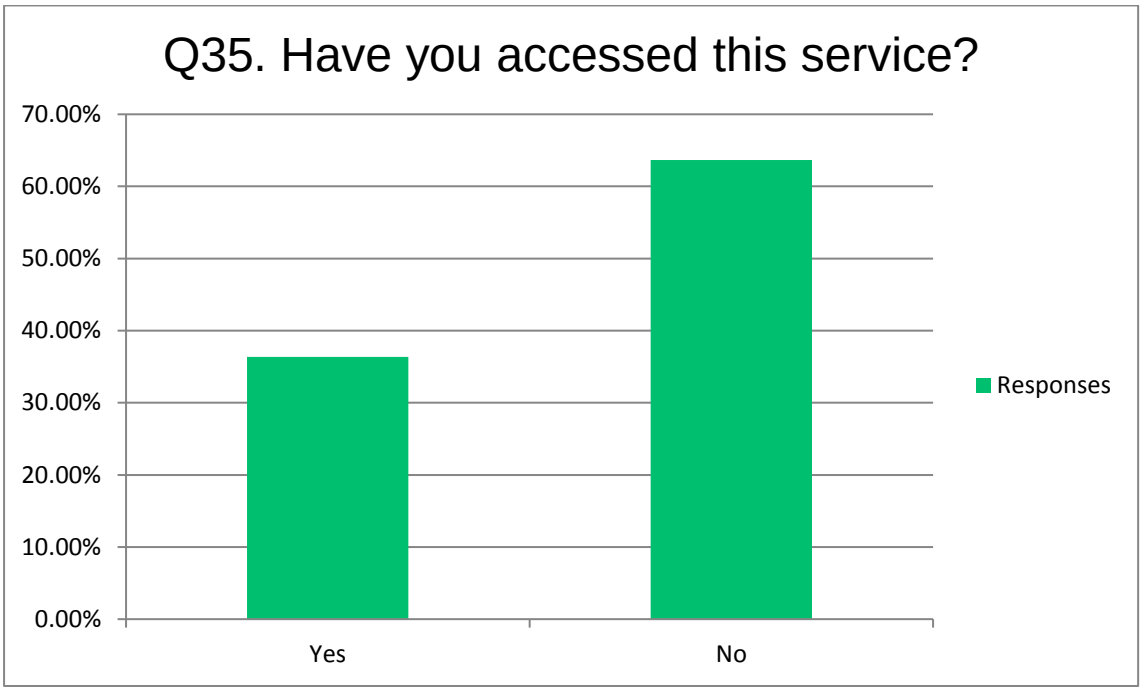
Analysis:
Just under 60% of patients believe that this will have a positive impact upon patients.

Summary Survey: Non-invasive ventilation for sleep apnoea

Overview
Apnoea is defined as a temporary absence or cessation of breathing. Sleep apnoea refers to obstructive sleep apnoea syndrome (OSAS) in which the individual is briefly unable to breathe due to temporary obstruction of the airway in the throat, called the pharynx. In patients with OSAS this may occur many times during a single night's sleep. This can make patients very tired in the daytime and lead to complications of the respiratory system. The non-invasive ventilation treatment for adults with sleep apnoea is continuous airway pressure (CPAP).

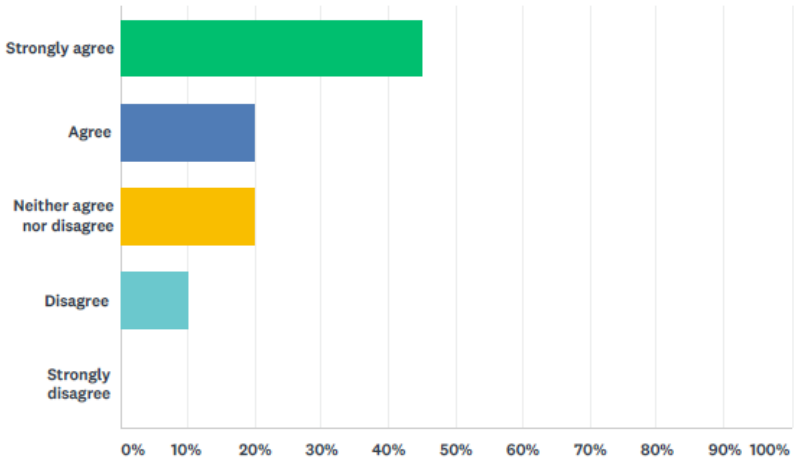
Proposed Change(s):
Currently, there is no policy for this treatment. Therefore, a policy will be drafted to reflect the most up to date clinical evidence and clinical expertise stating that CPAP treatment will be commissioned for patients diagnosed with moderate or severe symptomatic obstructive sleep apnoea/hypopnoea syndrome (OSAS). CPAP will only be recommended for patients with mild OSAHS if the condition is impacting on the patient's ability to carry our activities of daily living and lifestyle advice and any other relevant treatment options have been unsuccessful or are considered inappropriate.

From the 22 responses received, 36.36% have accessed the service.



Q36 To what extent do you agree/disagree to the proposed change(s) to this policy?

Answered: 20 Skipped: 29



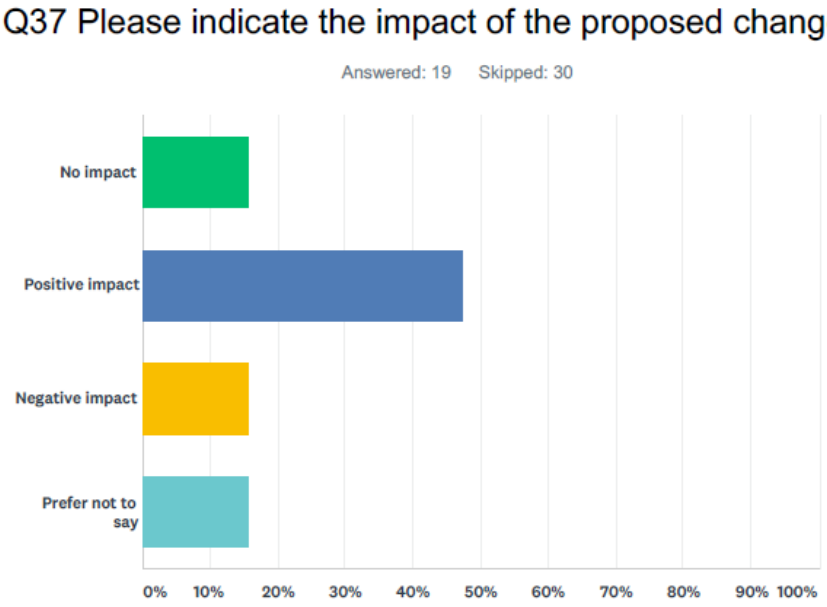
ANSWER CHOICES	RESPONSES	
Strongly agree	45.00%	9
Agree	20.00%	4
Neither agree nor disagree	20.00%	4
Disagree	10.00%	2
Strongly disagree	0.00%	0
TOTAL		20

Below are additional comments provided by the respondents:

- Widens access to a treatment for an increasing common complaint

- Haven't used this to be able to comment
- It offers peace of mind and a better quality of life both for the patient and their partner
- Don’t treat
- As above
- It is not just the Patient who suffers in this condition their partner is often kept awake by the snoring of the Patient (although the machine can be noisy too) Anything that can help the Patient can only be a good thing
- Should work using up to date recommendations
- See generic comment about readability etc
- I was quite a bad case of sleep apnoea, but for mild cases, they may still need a machine, particularly if they are doing jobs where they need to stay sharp.
- This should be left to the patient, GP and specialist with regard to NICE guidelines, if any. If the CCG wishes to ration this against clinical advice of GP and specialists, it should contact affected patients direct and indemnify doctors.

Analysis:
65% of responders agree or strongly agree with the proposed policy which is aligned within the additional comments received who also see this policy is of benefit not only with the patient but their family members.



ANSWER CHOICES	RESPONSES	
No impact	15.79%	3
Positive impact	47.37%	9
Negative impact	15.79%	3
Prefer not to say	15.79%	3
TOTAL		19

Below are additional comments received from respondents:

- Haven't used this service and hence do not have specific info / knowledge to be able to contribute.
- To be able to sleep without the worry that you could stop breathing at any time, brings peace of mind to patient and family
- Don’t treat
- As above
- It could have a negative impact if some people are denied a machine, but I do think maybe weight loss should be explored with some sleep apnoea patients?
- This should be left to the patient, GP and specialist with regard to NICE guidelines, if any. If the CCG wishes to ration this against clinical advice of GP and specialists, it should contact affected patients direct and indemnify Drs.

Analysis:

Approximately 47% of respondents feel the proposed policy will have a positive impact.

Summary of survey responses: Biological Mesh

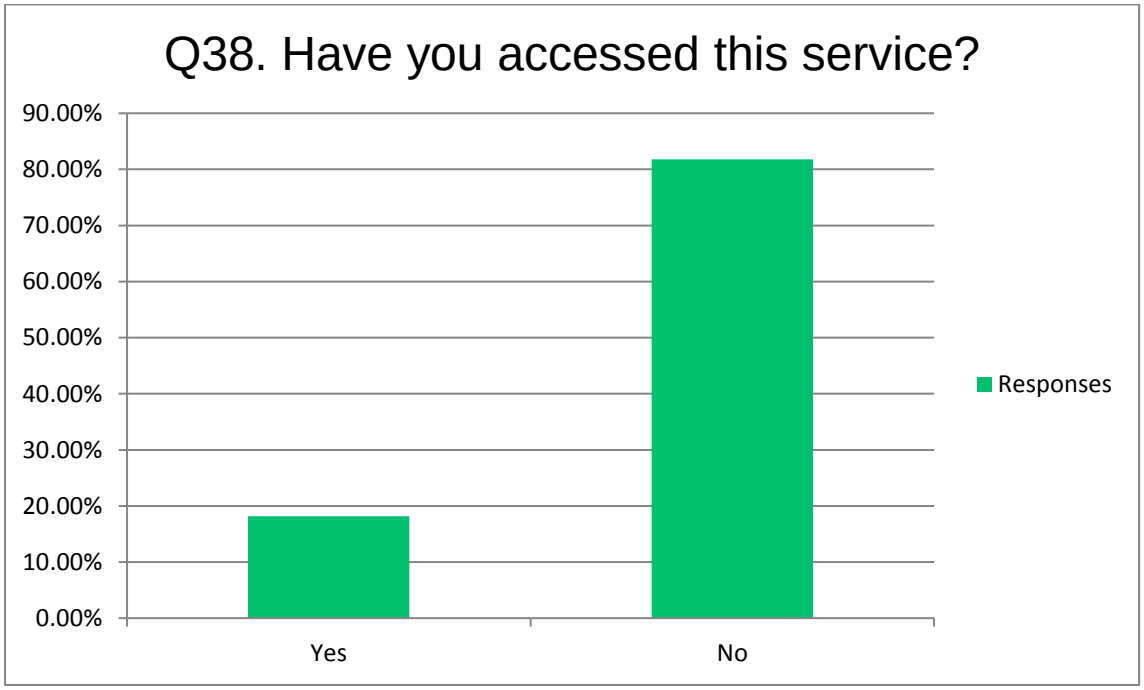
Overview:
Surgical mesh is a screen-like material that is used as a reinforcement for tissue or bone. It can be made of synthetic polymers or biopolymers.
Materials used for surgical mesh include:

- **Non-absorbable synthetic polymers** (polypropylene)
- **Absorbable synthetic polymers** (polyglycolic acid or polycaprolactone)
- **Biologic** (acellular collagen sourced from cows or pigs)
- **Composite** (a combination of any of the three previous materials)

The policy relates to the use of biologic mesh in hernia repair.

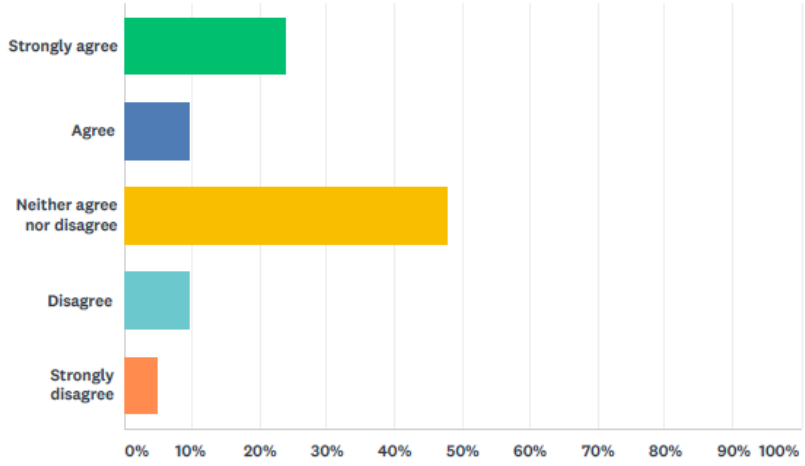
Policy review:
Currently there is no policy for the use of biological mesh in hernia repair meaning it is not commissioned by the NHS as a clinical treatment. Due to the lack of evidence to support biological mesh over standard mesh, a draft policy will be developed stating that the use of biological mesh is not routinely commissioned.

From the 22 responders who answered this question, 18.18% have accessed this service.



Q39 To what extent do you agree/disagree with the decision not to commission biological mesh and therefore not introduce a policy?

Answered: 21 Skipped: 28



ANSWER CHOICES	RESPONSES	
Strongly agree	23.81%	5
Agree	9.52%	2
Neither agree nor disagree	47.62%	10
Disagree	9.52%	2
Strongly disagree	4.76%	1
TOTAL		21

Here are the additional comments received form respondents:

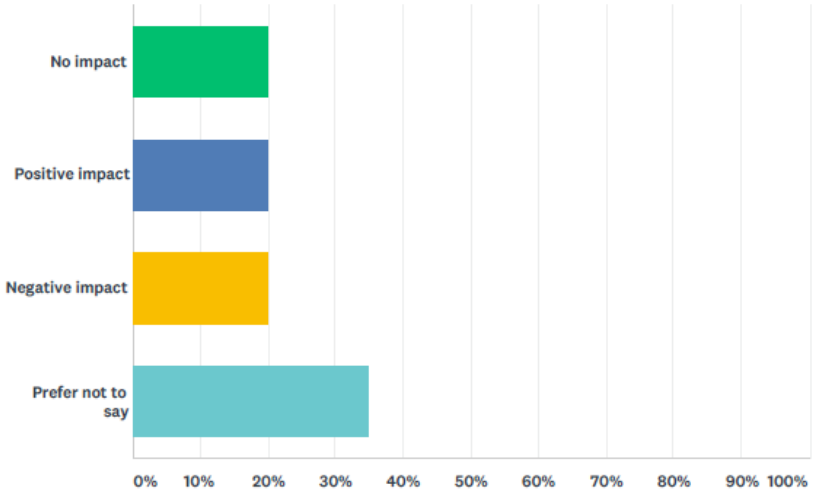
- Some evidence that synthetic polymers have migrated/adhered to surgery sites resulting in difficulties for patients? Further evidence needed and research into safe, viable alternatives
- not clinical experience in this area
- not enough understanding of procedure
- Don't treat
- Evidence based
- As there are other meshes available not using biological mesh should not have much impact
- Hearing all the negative complaints about mesh, patients must be worried about what is used. I also believe as many patients have no problems so a difficult decision
- See generic comment about readability etc
- If ordinary mesh does the job, then why use other types, particularly animal.

- This should be left to the patients, GP and specialist with regard to NICE guidelines, if any. If the CCG wishes to ration this against clinical advice of GP and specialists, it should contact affected patients direct and indemnify Drs.

Analysis:
Approximately 47% of responders neither agree or disagree with the proposed policy change and this may be the lack of clinical evidence. Approximately 33% agree to some extent. Approximately 14% disagree to some extent.

Q40 Please indicate the impact of the proposed change(s).

Answered: 20 Skipped: 29



ANSWER CHOICES	RESPONSES	
No impact	20.00%	4
Positive impact	20.00%	4
Negative impact	20.00%	4
Prefer not to say	35.00%	7
TOTAL		20

Below are additional comments received from respondents:

- No clinical experience in this area
- Not enough understanding
- Don't treat
- There are other meshes available
- Worry would be my first concern; will it work for me or not.

- Less animals need to die in order for us to have hernia repairs.
- This should be left to the patient, GP and specialist with regard to NICE guidelines, if any. If the CCG wishes to ration this against clinical advice of GP and specialists, it should contact affected patients direct and indemnify Drs.

Analysis:
At 20% there is an equal split across all answers in response to patient impact on the proposed policy.

Summary of survey responses: Body Contouring

Overview

The Surgical Procedures included in Body Contouring:

- Full abdominoplasty (tummy tuck)
- Mini abdominoplasty
- Extended abdominoplasty
- Endoscopic abdominoplasty
- Apronectomy (removal of excess tummy skin)
- Arm reduction and lift (Brachioplasty):
- Buttock and/or Thigh lift (Thighplasty):
- Liposuction / Liposculpture / Suction Assisted Lipectomy

Policy relates to the removal of excess skin ONLY in certain clinical circumstances.

Proposed Change(s):
Body Contouring is not routinely commissioned under the current policy. The new proposed policy will enable patients in certain clinical circumstances to access funding for surgery.
The criteria outlined in the proposed new policy includes:

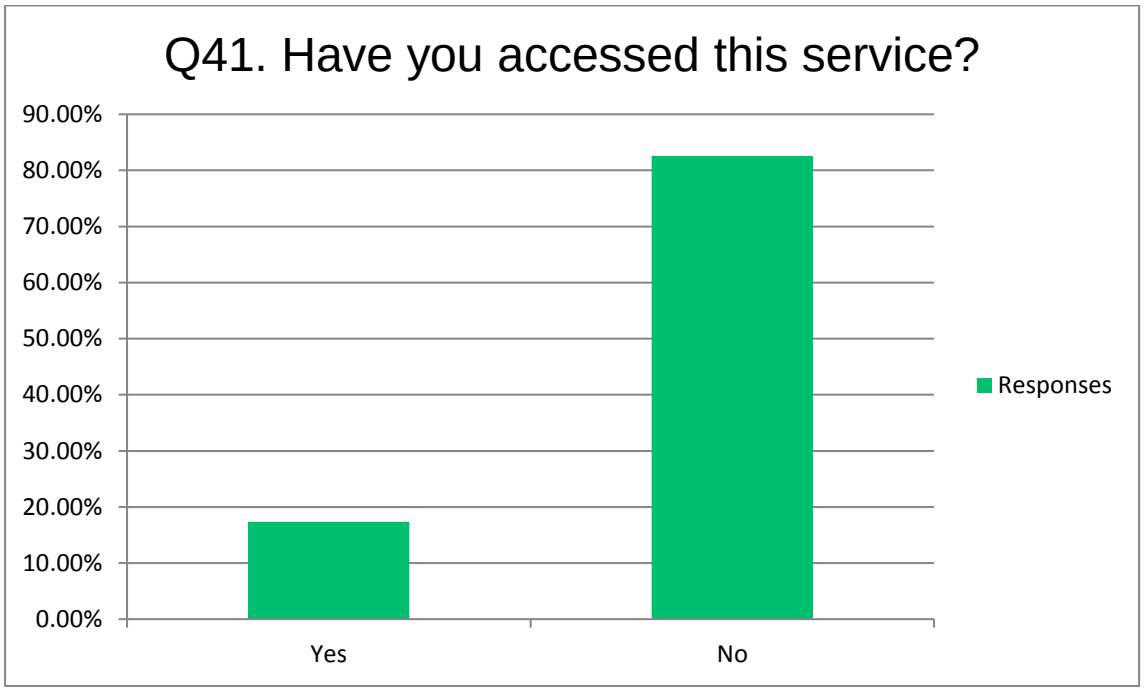
- The patient is 18 or over at the time of application

AND

- fail to resolve, despite appropriate medical treatment for at least 6 months. The patient has lost at least 50% of their original excess weight and maintained for at least two years, both of which have been recorded and documented by a clinician in the patient's medical notes.

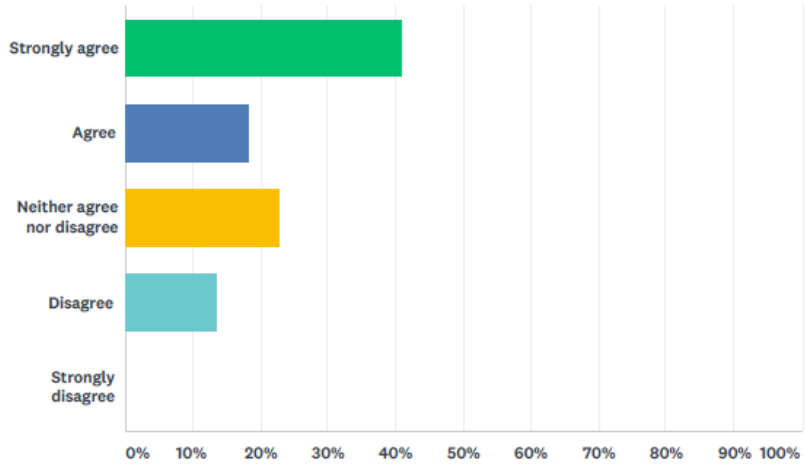
AND the patient has one of the following:

- Skin folds are causing severe functional impairment, which is impacting on the patient's ability to carry out activities of daily living
- From the 23 responses to this question, 17.39% have accessed this service


Q41. Have you accessed this service?
90.00%
80.00%
70.00%
60.00%
50.00%
40.00%
30.00%
20.00%
10.00%
0.00%
Yes
No
Responses

Q42 To what extent do you agree/disagree to the proposed change(s) to this policy?

Answered: 22 Skipped: 27



ANSWER CHOICES	RESPONSES	
Strongly agree	40.91%	9
Agree	18.18%	4
Neither agree nor disagree	22.73%	5
Disagree	13.64%	3
Strongly disagree	0.00%	0
TOTAL		22

Below are additional comments received from respondents:

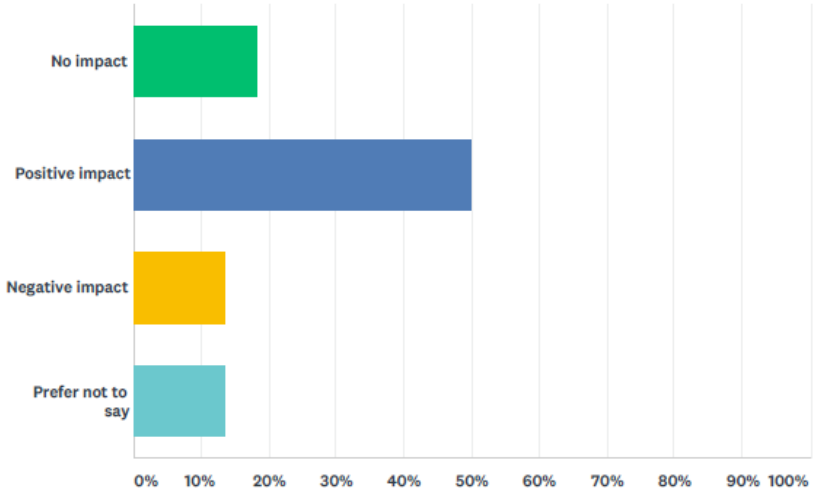
- Positive benefits for those patients who have worked to reduce body mass and maintained lower weight with clinical support. A consequent improvement in quality of life and less impact on their need for further treatment
- If the patient meets the criteria and has followed the rules laid down then yes
- Don't treat
- Improve quality of life for patients
- If a patient has taken positive and sustainable measures to lose and maintain weight loss
- Obviously, prevention of obesity at a much earlier stage should be the 1st thing but often hard to do therefore if a Patient has had the willpower to lose a lot of excess weight, they should not be discouraged by the excess skin which is left (and often with which they are unaware will happen until it does)
- Strict criteria must be monitored
- See generic comment about readability etc

- Surely the mental state of the patient should be assessed also. This loose skin may affect their body image and impinge on their mental health.
- This should be left to the pt, GP and specialist with regard to NICE guidelines, if any. If the CCG wishes to ration this against clinical advice of GP and specialists, it should contact affected patients direct and indemnify Drs.

Analysis:
Approximately 59% of responders strongly agree or agree to the proposed eligibility criteria for this draft policy. Additional comments are also in favour of this policy and also relate to supporting patients at the early stages of obesity to prevent them reaching advance stages.

Q43 Please indicate the impact of the proposed change(s).

Answered: 22 Skipped: 27



ANSWER CHOICES	RESPONSES	
No impact	18.18%	4
Positive impact	50.00%	11
Negative impact	13.64%	3
Prefer not to say	13.64%	3
TOTAL		22

Below are the exact additional comments received from respondents:

- The impact on the patient has to be positive if they have gone through surgery and weight loss etc.
- Don't treat

- Anything that can give a Patient a positive body image after all their hard work in losing weight can only be a good thing
- I thought this was already the case.
- You will probably be saying no to more patients.
- This should be left to the patient, GP and specialist with regard to NICE guidelines, if any. If the CCG wishes to ration this against clinical advice of GP and specialists, it should contact affected patients direct and indemnify Drs.

Analysis:
50% of responders felt this would result in a positive impact upon patients.

Summary of survey responses: Adenoidectomy

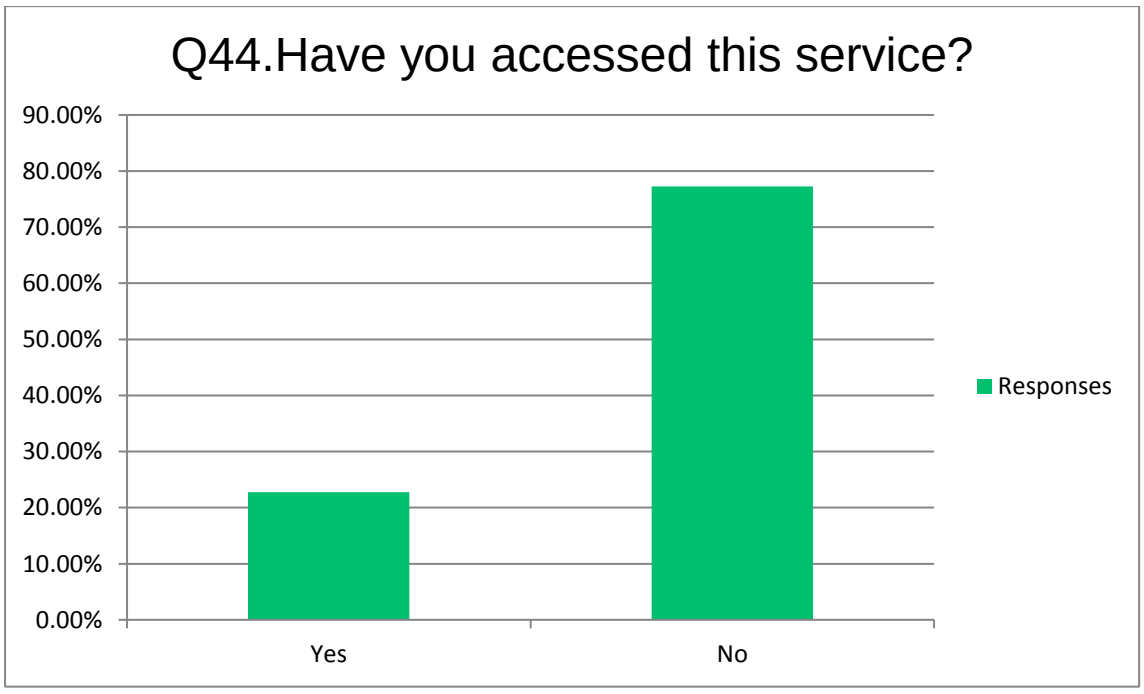
Overview

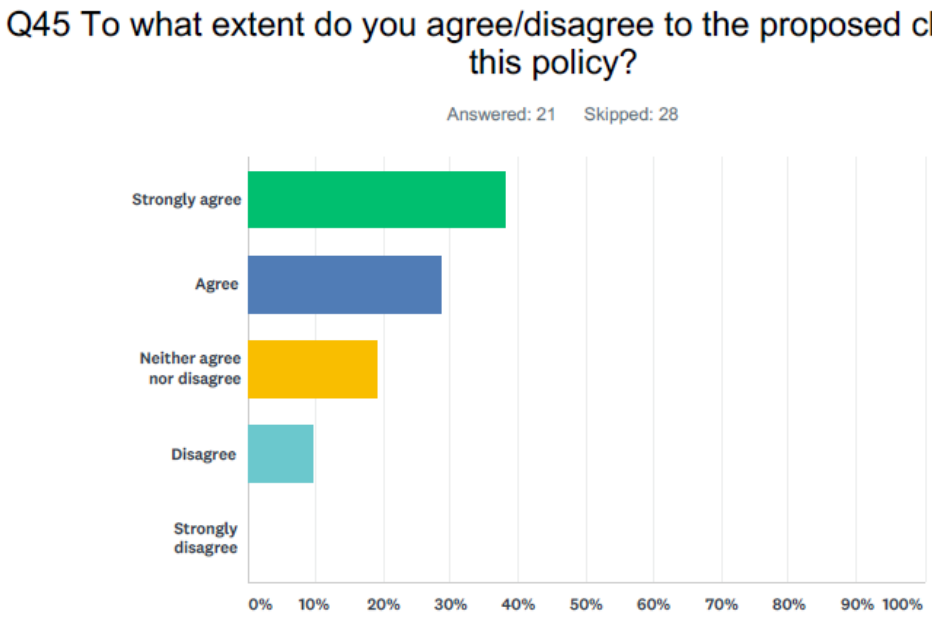
Adenoids are small lumps of tissue at the back of the nose, above the roof of the mouth. Adenoids are part of the immune system, which helps fight infection and protects the body from bacteria and viruses. In most cases only children have adenoids. They start to grow from birth and are at their largest when a child is around three to five years of age. By age seven to eight, the adenoids start to shrink and by the late teens, they're barely visible. By adulthood, in most people they will have disappeared completely. Adenoids can be helpful in young children, but they're not an essential part of an adult's immune system. The adenoids can be removed during an operation called an adenoidectomy.

Proposed Change(s):

The current policy only relates to children. The proposed new policy widens the scope to incorporate the small cohort of adult patients where the adenoids are enlarged. Adenoidectomy will then be available to adults and children when there is documented medical problems caused by obstruction of the airway by enlarged adenoids and all conservative treatments have been exhausted.

From the 22 responses who answered this question, 22.73% have accessed this service.





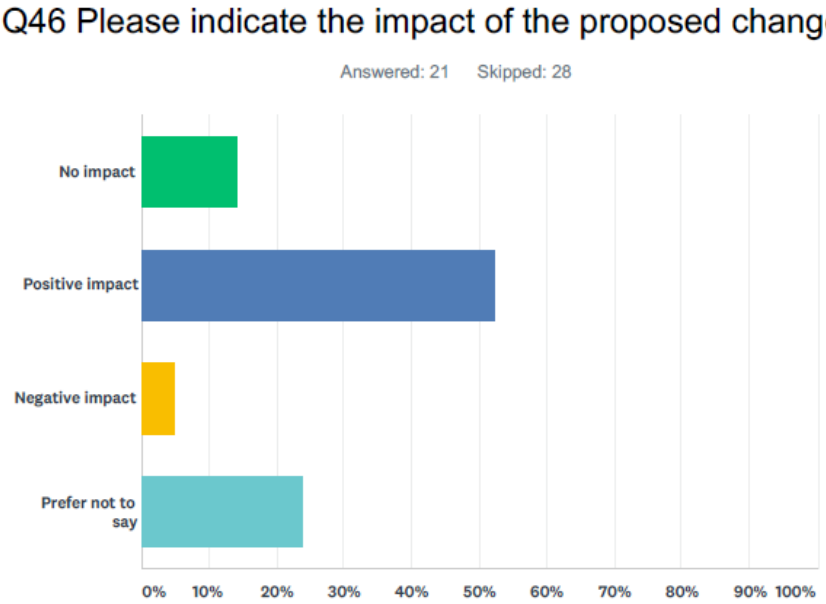
ANSWER CHOICES	RESPONSES	
Strongly agree	38.10%	8
Agree	28.57%	6
Neither agree nor disagree	19.05%	4
Disagree	9.52%	2
Strongly disagree	0.00%	0
TOTAL		21

Below are additional comments received from respondents:

- Positive impact on quality of life for patients
- In both adults I know this can be a problem
- Don't treat
- Enable a small number of patients to have the surgery
- large adenoids can have a negative impact on a patient
- operation only if necessary agree
- See generic comment about readability etc
- As it should be.
- Good
- Some children suffer a lot and suffering can be reduced.

Analysis:
Approximately 67% of respondents agree with the proposed policy and this agreement is reflected in the additional comments provided. It is seen as a positive

improvement to allow adults who may suffer with this condition within the eligibility criteria.



ANSWER CHOICES	RESPONSES	
No impact	14.29%	3
Positive impact	52.38%	11
Negative impact	4.76%	1
Prefer not to say	23.81%	5
TOTAL		21

Below are additional comments received from respondents:

- This condition can cause a lot of discomfort in adults and children, if it continues to bother them I feel it would be positive
- Don't treat
- The Patient should feel a lot better
- Unnecessary operations avoided.
- Good
- Dangerous surgery only for the few likely to benefit

Analysis:
Overall, seen as a positive impact upon children and adults alike suffering with this condition.

Summary survey responses: Hysteroscopy for Heavy Menstrual Bleeding

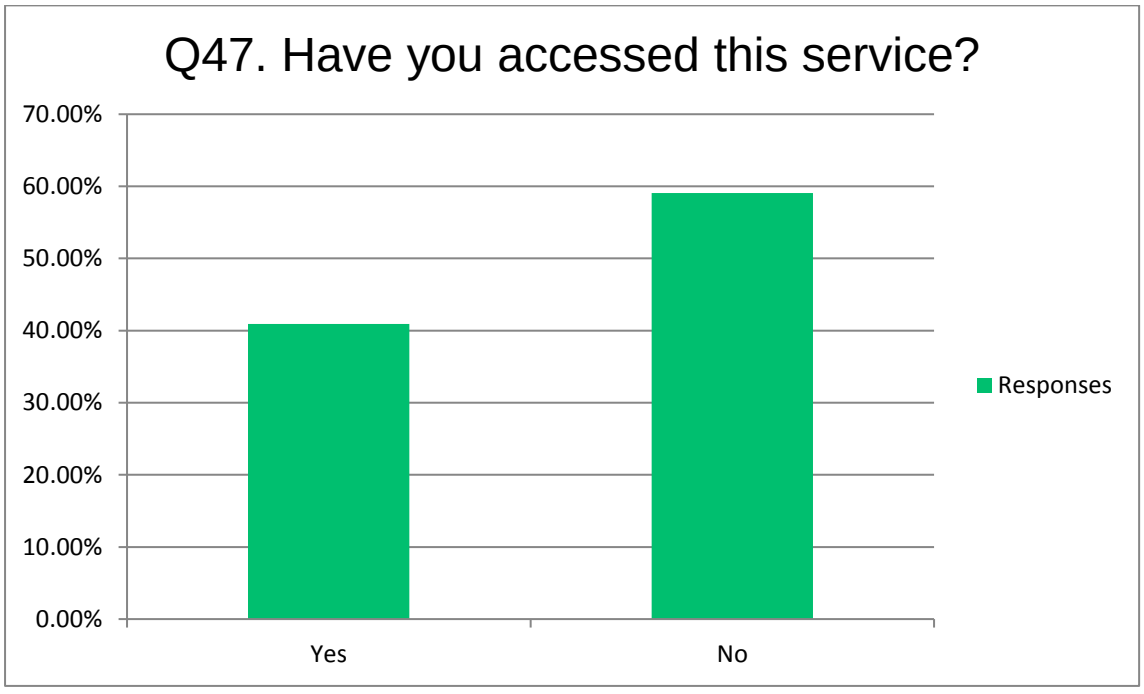
Overview

Heavy Menstrual Bleeding (HMB) is common but can have a big effect on a woman's everyday life**.** HMB does not always have an underlying cause but can result from problems such as fibroids or endometriosis. A hysteroscopy is a procedure used to examine the inside of the womb (uterus). It is carried out using a hysteroscope, which is a narrow telescope with a light and camera at the end. Images are sent to a monitor so the doctor or specialist nurse can see the inside of the womb.

Proposed Change(s):

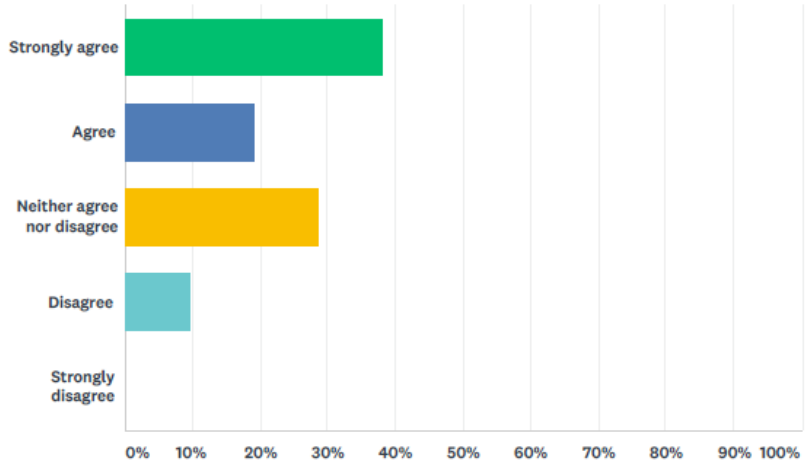
The current policy states that ultrasound scan is the first line treatment for all women and only if this does not enable a clinical diagnosis should hysteroscopy be undertaken. Due to a change in clinical practice following the latest clinical evidence and NICE guidance 88 it is proposed that the new policy will state that in certain clinical circumstances hysteroscopy should be the first line treatment.

From the 22 responses received for this question, 40.91 have accessed this service



Q48 To what extent do you agree/disagree to the proposed change(s) to this policy?

Answered: 21 Skipped: 28



ANSWER CHOICES	RESPONSES	
Strongly agree	38.10%	8
Agree	19.05%	4
Neither agree nor disagree	28.57%	6
Disagree	9.52%	2
Strongly disagree	0.00%	0
TOTAL		21

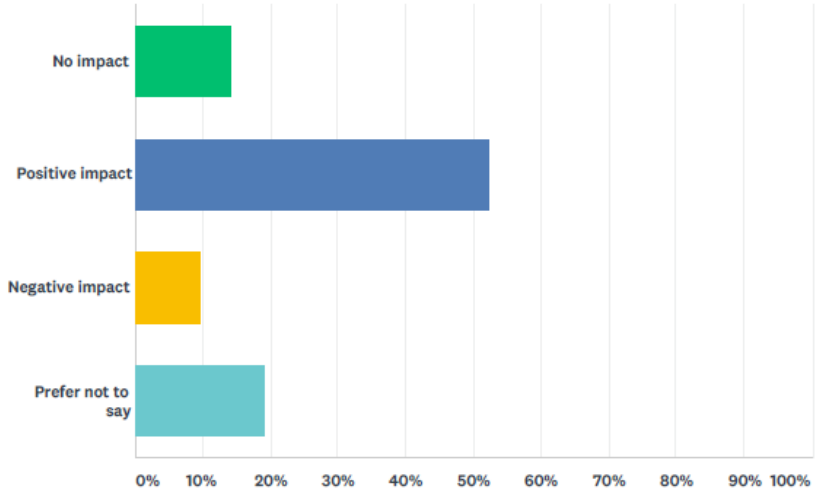
Below are additional comments received from respondents:

- A speedier diagnostic for patients, especially where there is a risk of endometrial pathology
- If it is the first line of action it may save the patient from further treatment
- Don’t treat
- This can impact on the lives of women with this condition
- Evidence based decision
- Sometimes just having a hysteroscopy can reduce the heavy blood loss that a patient experiences in the future
- I had an ultra sound first then a hysteroscopy under sedation. If only a hysteroscopy sedation should be offered as it was the most painful procedure I have ever experienced.
- See generic comment about readability etc
- I don't know enough about it to comment, but if the scope does a better job, then use it first and cut the cost, time etc., of the scan.
- Endometrial polyps can also cause heavy periods. Hysteroscopy helps in those patients.

Analysis:
Approximately 57% of respondents agree with the proposed policy; Approximately 10% disagree. Therefore, there appears to be a general consensus that the proposition of having this procedure in certain clinical circumstances as a first line treatment is a welcomed.

Q49 Please indicate the impact of the proposed change(s).

Answered: 21 Skipped: 28



ANSWER CHOICES	RESPONSES	
No impact	14.29%	3
Positive impact	52.38%	11
Negative impact	9.52%	2
Prefer not to say	19.05%	4
TOTAL		21

Below are additional comments received from respondents:

- It conciliates or highlighting further treatment. Maybe don't treat
- Sometimes can reduce the menstrual flow
- Saves time and I believe more accurate plus any problems they can be done at the same time
- Probably positive in that by using the scope first a patient will get a better diagnosis first time.
- US scanning is not always reliable - I have had 2 cases where it missed endometrial cancer

Analysis:
Approximately 52% of respondents believe the proposed policy will have a positive impact; 10% of respondents feel the impact will be negative.

10. Key points for consideration based on patient, public and stakeholder engagement

Underpinning principles There was a strong and collective result (all questions received 80% or over who strongly agreed or agreed) from all responders when answering the questions on the underpinning principles of the harmonisation treatment programme, for procedures and treatments to be consistently fair, no matter where the patient lives. There was also, strong support for clinical treatments to be supported by the most up to date clinical guidance and robust clinical evidence. Fifty percent of the additional responses received, mention that although there may limited clinical evidence to support a specific treatment or procedure, those treatments may still be of benefit to patients and individual cases should still be considered and not be dismissed.

Image guided intra-articular injections: Approximately 31% of responders either agreed or strongly agreed to the proposed changes in connection to this policy. Mixed responses were received by those who are healthcare professionals and patients alike supporting the use of image guided technology. It is mentioned the decision should be made by the practitioner performing the procedure and the individual patients' condition. Discussions with physiotherapist revealed that although these injections may be only offered once conservative methods have failed, in certain cases, the pain relief that is generated by this procedure may help patients in pain. It gives them the rest period they need so they can start rehabilitation.

Exogen bone healing: Approximately 26% agree with the proposed policy. Approximately 15% agree or disagree. The largest proportion of respondent (approximately 55% neither agree or disagree. Healthcare professional feedback has stated that the use of this technology for selective patients has avoided operative interventions and avoided surgical risks.

Liposuction for Lipoedema and Lymphoedema: Healthcare professional and patient feedback has welcomed the CCG in addressing the need to support those who suffer with these conditions and there is a consensus that further research is needed with regard to the use of liposuction in the management of Lipoedema. However, it is recognised that in some conditions conservative management is futile where the condition is very advanced and those patients who have had liposuction have greatly benefited for the procedure.

Bariatric Surgery: Although over 50% agree with the proposed policy criteria those comments received by healthcare professionals question the eligibility criteria. Particular concerns were also raised that the proposed policy may exclude those who are in drastic need of the surgery and may oppose current NICE guidelines.
Non Invasive Ventilation / Sleep Apnoea: 65% of responders agree or strongly agree with the proposed policy.

Body Contouring: Approximately 59% of responders strongly agree or agree to the proposed eligibility criteria for this draft policy. Additional comments are also in favour of this policy and relate to supporting patients at the early stages of obesity to prevent them reaching advance stages.

Adenoidectomy: Approximately 67% of respondents agree with the proposed policy. It was seen as a positive improvement to allow adults who may suffer with this condition within the eligibility criteria.

Hysteroscopy in Heavy Menstrual Bleeding
Approximately 52% of respondents believe the proposed policy will have a positive impact; 10% of respondents feel the impact will be negative

11. Clinical and stakeholder engagement

11.1 Clinical engagement and feedback on specific policies

Rationale

Clinical engagement was undertaken with specialist clinicians from both NSH and independent sector providers to enable the CCGs to gain a specialist clinical review of the proposed policies from the clinicians who are directly treating patients. The clinical engagement was devised following feedback from clinicians during the Treatment Policy Harmonisation Programme Phases 1 &2, as clinicians submitted feedback following ratification of the final policies and commented that the approach used during the Phase 1 engagement phase to enable them to provide feedback on the draft policies had not reached the treating clinicians. However, following clinical engagement in Phase 2 there was wide clinical support for the clinical engagement phase and so this was replicated for Phase 3.

Methodology

The clinical engagement for the Clinical Treatment Policy Harmonisation Programme Phase 3 was undertaken in a targeted approach, with a database compiled of specialist clinicians, whom were asked to review each of the policies which fell within their area of expertise.

Commissioners and service managers were also asked to review the draft policies where this had been highlighted by the clinical team as an avenue for review, with clinical leaders from the provider trusts being asked to support and encourage their clinical team members to respond.

Contract managers from Birmingham and Solihull CCG, Sandwell and West Birmingham CCG for Phases 3a & 3b and from Dudley CCG, Walsall CCG and Wolverhampton CCG for Phase 3a, were asked to raise awareness of the engagement period with the provider trusts for whom they were responsible to ensure the profile of the engagement with clinicians was sufficient to support the clinical review.

In total 260 clinicians were contacted across the region during the engagement Phase 3a & b to ask for their review of the policy documents relevant to their specialist clinical area.

The engagement was undertaken with clinicians from the following provider trusts:

- University Hospitals Birmingham NHS Foundation Trust
- Sandwell and West Birmingham Hospitals NHS Trust;
- University Hospitals of North Midlands NHS Trust
- The Dudley Group NHS Foundation Trust
- Walsall Healthcare NHS Trust
- The Royal Wolverhampton NHS Trust
- BMI Healthcare
- Spire Healthcare
- Birmingham Community Healthcare NHS Foundation Trust

Clinicians were sent policy packs for policies specific to their clinical area which included:

- DRAFT Policy Document
- Evidence Review Paper or Supporting Guidelines
- DRAFT Equality Impact Analysis
- DRAFT Patient Leaflet.

The policy packs pertaining to each clinician's specialist area were sent by email on the 2nd September 2019, reminders of the closing date of the engagement / thanks to those who had already responded were then sent out to clinicians on the following dates:

- 19th September 2019
- 1st October 2019
- 8th October 2019

11.2 Results of clinical engagement

Prior to the engagement phase contact had been made with the various clinical specialities to gain specialist clinical knowledge in drafting the proposed 12 policies. Specialist clinical input was received in preparing 4 of the policy drafts.

Of the 12 draft policies released during the engagement period, direct clinical feedback was received regarding all of the following 12 draft policies:

Phase 3a

1. Subacromial Pain
2. Image guided therapeutic intra-articular joint injections with corticosteroids with/without local anaesthetic.
3. Image-guided HIGH VOLUME intra-articular injections (40mls+) of saline with or without corticosteroid and/or local anaesthetic.

Phase 3b

4. Exogen Bone Healing System
5. Non-cosmetic Liposuction for A. lymphoedema or B. lipoedema
6. Bariatric Surgery
7. Knee arthroscopy – Acute
8. Non-invasive ventilation
    a. Chronic Obstructive Pulmonary Disease (COPD)
    b. Neuro-Muscular
9. Continuous Positive Airway Pressure for use in Obstructive Sleep Apnoea
10. Biological or biosynthetic mesh for use in surgical hernia repair.
11. Body Contouring
12. Adenoidectomy
13. Hysteroscopy for Heavy Menstrual Bleeding

The clinical engagement responses are summarised in the table below:

DRAFT Policy	Clinical Expertise provided to the TPCDG (*during DRAFT policy formulation phase*)	Clinical Feedback received during the engagement phase		
		Issues raised by clinicians for consideration by the TPCDG	Further Clinical Evidence Submitted	Clinical Support for DRAFT policy received
DRAFT Subacromial Pain	Yes	• UHB Consultant: Thank you. I have been advised by our specialised upper limb experts. Happy with this. • Clinical lead MSK Physio. Community. Firstly, an appraisal of evidence and sense check of final commissioning decision appears sound. i.e: 'Due to the limited quality of evidence of clinical and cost effectiveness, surgery for sub-acromial pain syndrome is not routinely commissioned. This means the patient's NHS commissioning organisation (CCG), who is responsible for buying healthcare services on behalf of patients, will only fund the treatment if an Individual Funding Request (IFR) application has shown exceptional clinical need and the CCG supports this.'	Lewis (2011) Subacromial impingement syndrome: a musculoskeletal condition or a clinical illusion? Physical Therapy Reviews, 16(5), pp. 388 – 398.	Yes

		• However, the evidence cited regarding condition aetiology omits current, non-orthopaedic trends concerning the pathophysiology of subacromial pain syndromes. This is important, as the information given under the heading 'What is Subacromial Pain in Adults?' fails to acknowledge the uncertainty that exists in this area. Instead, the policy asserts the condition is caused thus: Shoulder impingement (pain in the top and outer side of the shoulder) occurs when the tendon rubs or catches on the acromion and the sub-acromial bursa. Pain may start suddenly or come on gradually, and may occur if the tendon is swollen, thickened or torn due to injury, overuse or age-related 'wear and tear'. • This information has been contested for a number of years, and indeed is possibly one of the reasons why the benefits of surgical arthroplasties/decompressions are not significantly better than doing nothing at all (at 12 and 24/12 F/Us). • Rotator cuff tendinopathy/shoulder impingement syndrome appear to be multi-factorial in nature & should be treated as such. Perhaps it would be wise to inform the patient thus: "Previously it was thought that pain occurs when the top of the tendon rubs or catches on the acromion and the sub-acromial bursa, however more recent studies have shown that between 76-91% RC tears occur within the tendon or	Lewis (2016) Rotator cuff related shoulder pain: Assessment, management and uncertainties. Manual Therapy, 23, pp. 57 – 68.	

		on 'under-side' of the tendon. Also, there has shown to be poor correlation between acromial shape and pain. Furthermore, RC tears can continue to develop post SAD. To this end routine SAD surgery for this condition is no longer recommended routinely". Lewis (2011, 2016) • I think that getting this background information right helps both the health practitioner (be it Consultant, GP or physiotherapist) and patient alike make better informed shared-decisions concerning treatment. Also, it doesn't on one-hand provide clarity (i.e. this is how your condition is caused), whilst with the other withdraw care (i.e. 'but we no longer fund surgery for this'), as this is likely to cause frustration and high numbers of IFRs (individual funding requests). • UHB Rheum Consultant - Thank you for passing this on. My comments below apply to surgical decompression and to hydrodilatation. The conclusions of these reviews is expected from recent reviews and trials. My concern is that there will be a significant number of patients with intractable and difficult shoulder pain who will need surgical or radiologic intervention. This is likely to involve more than a handful of patients. To require an individual funding request for each of these is problematic and frustrating for all concerned. I think it would have been useful to have an algorithm that made clear when funding would be likely if patients had failed to respond to standard approaches. As it stands this policy does not acknowledge the real difficulty some patients will have. The current		

		policy does not provide a comprehensive pathway for these patients. • GPSI I have had many of my patients undergo this procedure especially with tears of the rotator cuff. I feel that this procedure does have a place if conservative measures fail. • UHB Consultant Shoulder Surgeon: yes, in agreement with these. I was part of the CSAW (Can Shoulder Arthroscopy Work ?) which showed that SAD is not an effective treatment. This also reflects my practice where for many years now I have not been offering SAD to my patients. I still perform SAD though as part of other procedures eg. during repair of a full thickness rotator cuff tear etc. I refer impingement patients to physio and also consider steroid injection • Dudley Consultant: Re the subacromial pain – This is a highly controversial topic, with the quoted studies also being contested in terms of methodology and interpretation of results. Lets not throw the baby out with the bath water! Not all patients with shoulder pain, have impingement. It is a vastly overdiagnosed (wrongly) condition in any case, as a result of which other causes of shoulder pain can be missed. So, if patients are not referred at all based on the assumption that they have impingement, we will only end up seeing		

		these patients very much later with their condition having become more complex and in need of more invasive, expensive treatment (cuff tears are an example). I would also point out that impingement is not a diagnosis made by imaging alone. No scan in itself can confirm a diagnosis of impingement, it needs other tests also; and most importantly an interpretation of the scan findings in conjunction with clinical findings. Therefore, in my view we may find fewer patients having surgery initially, but we might be storing up bigger problems for later on. A more sensible approach would be to have strict criteria (as for other conditions like Dupuytrens or CTS) that need to be met before surgery is offered. I should add that we as a group of shoulder surgeons have already seen a big reduction in the number of arthroscopic subacromial decompressions being performed, simply through a tighter patient selection process based on the results of the studies quoted. We do not like to operate on patients who are not likely to get a good result from surgery either! • Dudley Consultant: Your list of operations / eligibility criterion does not include chronic cuff tears as an indication for surgery. Recently concluded UKUFF trial has shown the procedure to be clinically and cost effective. There is good evidence to show that cuff tears progress in size and then		

		the concern is they may become irreparable over time. Large irreparable tear is one of the most difficult clinical problems to deal with in younger age. So chronic cuff tear repair surely has to be part of the indications. Subacromial decompression is more often done as an associated procedure alongside other procedures. Patients may be listed for subacromial decompression + other procedure (for eg cuff repair, removal of calcium deposits). If the tear was reported inaccurately on scan and was noted to be too small to repair, or was much bigger than anticipated, patient may end up having an isolated subacromial decompression surgery (despite not being planned for it). These scenarios have to be considered. Isolated subacromial decompression for impingement pain is not a common procedure anyway. However, there are odd indications, just like with other limited clinical value procedures. I am not sure the intention of this document was to address this issue, or the whole list of shoulder operations.		
DRAFT Image guided therapeutic intra-articular joint injections with corticosteroids with/without local anaesthetic.	Yes	• Rheumatology Consultant UHB: We, in rheumatology, do perform standard steroid injections without imaging in outpatient settings but the guidance does not cover steroid injections under imaging to hip, subtalar and sacroiliac joints where it is practically difficult to inject without imaging. • GPSI: **Ultrasound Guided Injections**	https://bjgp.org/content/67/661/378 USGI shoulder injections significantly greater clinical improvement	Yes

		I have injected joints for forty years always on feel alone. I have had a ultrasound machine and now do some injections ultrasound guided like injected Planter Fascia Parthenon, Gluteal Tendinopathy, Ankle Joint, Biceps Tendon etc I feel that ultrasound has a place in small joints and some tendinopathies. In my service I do not apply any additional premium and charge the same whether the injection is blind or US guided **Viscosupplement Injections** I believe that there is a small role in some patients like patients with Arthritis of the knee Grade I or II and Glenohumeral joint osteoarthritis. I have used this injection and we charge the same as for a normal joint injection. The difference is that the preparation (Ostenil) needs three procedures (injections) at weekly intervals. • OTS Clinical Lead: I have read and agree with the comments from all of my colleagues within Secondary Care and have nothing to add. Summary: • Large Osteoarthritic joints do not require US-guided injections (exception: Hip joint) •Small joints (e.g. in the hand and foot) where accuracy is important would benefit from US-guidance • Alternative service model: 3 roomed department with a trained specialist nurse, MSK sonographer and Consultant Rheumatologist with special interest in ultrasound. The	over LMGI - https://www.ncbi.nlm.nih.gov/pubmed/26590864 USGI Carpal Tunnel Syndrome better for several markers - https://bjgp.org/content/67/661/378 USGI shoulder significant improvement in pain and abduction vs LMGI but small and suggests further research - https://www.ncbi.nlm.nih.gov/pubmed/23275390 USGI improves	

		department sees approximately 40-50 patients per week for diagnostic scans and provides a similar sized service for ultrasound guided injections and aspirations. • Dudley Consultant: On behalf of rheumatology I am pleased to feedback. The draft that applies to us is the policy on image guided therapeutic intra-articular injections. I would reassure you that already we would only offer an image-guided injection if a patient has failed to respond to conventional pharmacological and non-pharmacological treatment. My comments are: 1. This policy only discusses injections in relation to osteoarthritis. Therefore this policy needs to be explicit for OA ie the title must be: " Policy for the use of Image Guided Therapeutic Intra-Articular Joint Injections in Osteoarthritis" 2. There is also a small group of patients you have failed to consider, where it is clinically unsafe to inject an (OA) joint without imaging guidance eg the hip. The actual hip joint (not the trochanteric bursa) can only be injected under imaging guidance as it is too deep for a 'blind' injection, and there is a large neurovascular bundle that must be avoided. Injecting the actual hip joint must remain an exclusion to this policy. 3. There are some joints in the foot/ankle eg subtalar, midfoot joints where due to the complex anatomy it is impossible to palpate the joint line 'blindly', making 'blind' injections impossible. Patients here would therefore	efficiency and cost-effectiveness but more research is needed - https://www.ncbi.nlm.nih.gov/pubmed/29511701	

		require imaging guidance for injections, and this must remain an exclusion to the policy. 4. This policy only refers to joints. Infiltration around tendons requires imaging guidance due to the risk of 'blind' injections causing tendon rupture. Infiltrating around tendons must remain an exclusion to this policy. 5. More detail is required as to the evidence which needs to be presented in order to show successful outcome (what outcome measure tools do you require) and how many do you define as adequate, in image guided injections of the small joints? • Dudley GP: My only comment is on the USS guided injections (as my partner in practice is hoping to develop a community based service-conflict of interest here) is that I think the policy should be that "where possible- these USS guided injections of small joints should be offered in the community by primary care". This will hopefully facilitate a shift from mainly secondary care based work more into primary and support the efforts of the MCP. 1. GP: I've gone over the draft and appreciate there is an agenda which has obviously bias the interpretation of evidence. On a purely factual basis, there are some issues with reference duplication which I'm sure will be picked up on - citation 4, 5 and 6 are also 12, 13 and 15.		

		Page 5, Para 2, 2nd sentence is incorrect as the evidence states that USGI results in better pain and functional status at 6 months. Page 5, Para 3, I'm not sure how many DRUJ injections you do but it should be very small and cannot be translated into knee, shoulder, or other joints and represents poor scientific application of evidence. Citation 1 is purely a scoping document and has no additional information to Citation 2 which says exactly the same thing regarding the quote so should be removed. Citation 2 does not separate USGI (ultrasound-guided injection) and LMGI (landmark-guided injection). Citation 3 is regarding the use of hyaluronate suggesting that it is as effective as a steroid which I doubt for a second the CCG would want us to use. Citation 4 states USGI is better than LMGI. Citation 5 states there is no real benefit of steroid injections at all. Citation 6 says USGI is more accurate but doesn't conclude the clinical outcome is any different. Citation 7 says USGI gives maximum benefit. Citation 14 says USGI is better at 6 months. Citation 16 says USGI is better tolerated, more effective at 6 months and more cost-effective. Citation 17 says USGI of the knee is no better than LMGI. Citation 18 is not cited and has no relevance to the document.		

		Citation 19 is not cited and states steroid only has limited benefit in the knee and less for hip and hand.		
DRAFT Image-guided HIGH VOLUME intra-articular injections (40mls+) of saline with or without corticosteroid and/or local anaesthetic.	Yes	• UHB Consultant: Happy with this • Walsall Consultant: I have reviewed the treatment policy of image guided high volume Intra articular injections, and agree with it. • **GPSI: High Volume Injections** I feel that there is a role for HVI especially in Achilles Tendinopathy again we perform these at no additional premium to our tariffs. **Hydro dilatation in Adhesive Capsulitis** This has a role in Adhesive Capsulitis it can stretch the tissues and make it easier to move the joint. Most patients don't need it if treated appropriately in early stages(Freezing stage) The success rate is over 70% for shoulder movement and 90% for improving pain. It is a non-surgical procedure. The alternative is Arthroscopy(Arthrolysis).	No	Yes
DRAFT Exogen Bone healing	No	1. **NICE MTG12 – Review Decision 8th October 2019 – should be included in Evidence Review**	https://www.nice.org.uk/guidance/mtg12.	Yes

		As of this month, the NICE review of the 2013 guidance for EXOGEN has been published. The efficacy and cost-efficiency for EXOGEN have been reconfirmed. ○ https://www.nice.org.uk/guidance/mtg12. ○ Changes to the guidance after review; ▪ Cost consequence has been updated – benefit of EXOGEN has more than doubled to £2,407 per patient – previously this was £1164 per patient. ▪ Details on the device updated to describe new version which includes patient tracker aimed at improving patient compliance. ○ Cost saving referenced does not account for our performance money back guarantee which is also provided with EXOGEN 250. **2. BIOVENTUS Feedback on 'DRAFT Policy Evidence Review for the use of EXOGEN Ultrasound'** 2.1. Discussions on the detail of EXOGEN do not include the Money Back Guarantee that is provided (subject to T&Cs). Should a non-union fracture fail to unite (where the patient has been compliant), Bioventus will provide a refund. • ROH Consultant: Having polled the Clinical Service Leads internally, Mark Brewster (CSL Small Joints) and the small joint (Hand and foot) team are the only team we are aware are using the device at present.		

		They use it for distal radius osteotomy and ulna shortening non-union after 6 months and also for scaphoid non-union after grafting and ORIF also at 6 months. We weren't quite clear from the attachments whether the concern about its use was just for long bone fractures. The indications for its rare use in consultation with commissioners seem reasonable my end. • ROH Consultant: Reading the attached information there appears to be good evidence that Exogen is effective in non unions of long bones but not to promote initial healing or for delayed unions. It therefore appears incongruent with the data attached to this email that it is being taken out of my armamentarium in the treatment of long bone nonunions. In my experience, applications for such treatments on an individual basis tend to be rejected despite being rare cases and appropriate requirement for the intervention		
DRAFT Non-Cosmetic Liposuction for lymphoedema & lipoedema	No	• Lead CNS: Please find enclosed the above policy with tracker changes and comments. I have also taken the liberty of enclosing some useful articles of evidence to the effectiveness of liposuction for lipoedema. If you would like to discuss any of the comments with me in more detail please do not hesitate to contact me. • UHB Consultant: We've had a look at this document as a department. It's not clear to me, or my colleague Darren,	https://www.lipoedema.co.uk/wp-content/uploads/2017/05/WUK_Lipoedema-BPS_Web.pdf	Yes

		exactly what these documents are saying. It seems to say that the CCG with fund liposuction for lymphedema cases where conservative management has failed. I wasn't clear how long conservative management had to be attempted before it was deemed to have failed but I may have missed that. I presumes lipoedema was not funded but I couldn't see where it actually said that. I think in summary this is a good document but the summary could be improved. What we need to know is, in what instances Liposuction for lipoedema and lipoedema is funded. As Darren says most of us would not have the time to fill in IFR's, especially if multiple. It the answer is an IFR I think the CCG might as well say it's not funded rather than putting the work load onto the clinician. • Lymphoedema UK: Liposuction for lipoedema and lymphoedema As discussed I have sought comments from Professor Vaughan Keeley, Dr Kristiana Gordon and other experts in the field. Generally they concur with the advice/comments but are somewhat confused as to why the advice for liposuction for lipoedema says not generally funded and to apply for IFR and the one for lymphoedema was funded under specific situations as in fits in with NICE guidance and yet one still has to apply for IFR. They accept the need for IFR for	https://www.lipoedema.co.uk/wp-content/uploads/2012/08/Early-lipoedema-diagnosis-and-the-RCGP-e-learning-course.pdf https://www.ncbi.nlm.nih.gov/pubmed/24489474 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5055019/ https://www.semanticscholar.org/paper/English-Translation-Liposuction-of-Lipedema-to-Stutz-	

		lipoedema but as lymphoedema has specific criteria an IFR should not be needed.	Wald/a4538d84f421ce4523029bdaffdc10a24ebca1db	
DRAFT Bariatric Surgery	Yes	• I have read through these docs and confirm that I am happy with the content and have no further comments to make.	No	Yes
DRAFT Knee arthroscopy in Acute Knee Injury	Yes	• UHB Consultant in Sport Medicine: The biggest thing that needs clarity is what is meant by "failed physiotherapy" There needs to be a quick route to get IFR approval and this circulated to clinicians - ie within 1-2 weeks There needs to be specific feedback from physiotherapy and pain teams obtained on this given the likely impact on their services • UHB Contract Team Feedback: The draft patient leaflet states that over 35s are automatically excluded. This is at odds with the draft policy, whereby age is an indicator of possible degenerative knee disease, but not an automatic exclusion The exclusion of all patients with degenerative knee disease means that patients who have a degenerative knee disease but then experience an acute injury would be ineligible for treatment. There are patients for whom surgical treatment for the acute injury would greatly improve quality of life and this is not related to underlying disease	https://baskonline.com/professional/wp-content/uploads/sites/5/2018/07/BASK-Meniscal-Surgery-Guideline-2018.pdf https://online.boneandjoint.org.uk/doi/full/10.1302/0301-620X.101B6.BJJ-2019-0126.R1	Yes

		It is unclear from the policy whether patients should only be referred to secondary care following a period of rehab etc. There is a recognised pathway at UHB for acute knee clinic/physio Mr Arbuthnot suggested that all acute knee injuries should be seen by a knee specialist rather than FCP It is confusing to have the definition of degenerative knee disease in the 'eligibility criteria' box. These definitions should be elsewhere. Furthermore the definition of degenerative knee disease is difficult to audit against (patients may be over 35, and may or may not have the following symptoms.) There is an ongoing discussion between clinicians at UHB and yourselves around the definition of locked/locking knee. The definition of functional impairment should include ability to perform one's job. The EIA is unclear. The summary says 'The restriction of this policy may have an impact on those who would wish to receive the treatments for a degenerative condition such as osteoarthritis' but this policy is about acute knee injury The national EBI policy does not have an age limit of 35 but this is stated in the evidence review.	https://cdn.ymaws.com/www.esska.org/resource/resmgr/docs/surveys/Degenerative_Knee_summary.pdf	
DRAFT Policy for Domiciliary NIV/CPAP	Yes	• Lead Consultant Respiratory Ventilation Team: Thank you for your initiative in addressing Domiciliary NIV in the	Dretzke J, et al. The cost-effectiveness of domiciliary non-	Yes

		Birmingham area, for which hopefully our patients will be thankful. Attached are the 2 documents with our comments embedded The most important single point in both documents is the inclusion of CPAP and Bi-Level Ventilation under the umbrella term NIV. The 2018 NCEPOD recommendation is to separate CPAP and NIV (bi-level ventilation, also loosely called BiPAP but BiPAP being a commercial brand the current UK consensus is to call it NIV). The recommendation of the NCEPOD to the NHS Digital and the Association of Clinical Coders is as follows: "Continuous positive airways pressure (CPAP) and non-invasive ventilation (NIV) should be coded separately. They are two distinct treatments given for different conditions and separate coding will reduce clinical confusion and improve reporting of outcomes." • Therefore, it is crucial that to align with the latest (2018) NCEPOD recommendations, the section on Continuous Positive Airways Pressure is EITHER taken out OR the policy is renamed the Policy for the use of domiciliary Continuous Positive Airways Pressure (CPAP) and Non-Invasive Ventilation (NIV). • All other comments are there on the comments list of the attached documents but the two others I would like to highlight are: 1. The ordering of the Neuromuscular conditions should be unambiguous and reflect the order of	invasive ventilation in patients with end-stage chronic obstructive pulmonary disease: a systematic review and economic evaluation. Health technology assessment. 10/2015; 19(81):1-246. doi: 10.3310/hta19810. [PubMed ID: 26470875 PMCID: PMC4781210] https://treat-nmd.org/wp-content/uploads/2019/06/uncat	

		prevalence/clinical relevance. This is why we recommend the ordering on Page 16 of the draft Policy as follows: a. • Motor Neurone Disease b. • Muscular Dystrophies including Duchenne Muscular Dystrophy and Spinal Muscular Atrophy c. • Spinal cord injury d. • Multiple Sclerosis e. • Guillain-Barre Syndrome f. • Post-polio syndrome with respiratory impairment g. • Syringomyelia h. • Tuberculosis infection with residual respiratory insufficiency 2. The only UK-based HTA report (NIHR commissioned) on the cost-effectiveness of Domiciliary NIV in COPD, which included a systematic review is conspicuous by its absence: Dretzke J, et al. The cost-effectiveness of domiciliary non-invasive ventilation in patients with end-stage chronic obstructive pulmonary disease: a systematic review and economic evaluation. Health technology assessment. 10/2015; 19(81):1-246. doi: 10.3310/hta19810. [PubMed ID: 26470875 PMCID: PMC4781210] • SMAUK: In general, it is good to see that patients with SMA are included on the restricted list. Non-invasive Ventilation (NIV) is necessary and effective for many patients who have SMA	egorized-A-Guide-to-the-2017-International-Standards-of-Care-for-SMA_UKEnglish_Digital-v2L.pdf	

		The SoC for SMA are read and included as an essential reference. That NIV for non-sitters (SMA Type 1 and pre-symptomatic) is considered as a pro-active treatment for respiratory management. That the CCG consider separate eligibility for those with SMA Type 1 and pre-symptomatic as reflected in the SoC for SMA. • UHB Paediatric Ventilation Team Section B: What do you mean by 'Neuro-dependant'?? and then the wording is then 'neuromuscular' patients for section B when you arrive at that section. Consider changing to Neuromuscular Also in regards to benefits - improvement of quality of life and longevity of life are also key and hugely important benefits. The list of conditions that are appropriate for NIV does not include Duchenne Muscular Dystrophy or any other paediatric Neuromuscular conditions know to affect ventilation. eg: congential myasthenia, Merosin deficiency, nemaline. Congenital myopathy. Considerations for multiple admissions due to respiratory failure/ chest infections leading to type 2 respiratory failure. In regards to the evidence review - most of the evidence base is around MND - no evidence listed for DMD or SMA although is available.		

		• UHB Sleep Medicine: I have looked through these documents again, and read and concur with the comments of my colleagues My thoughts include: 1) I agree with regards to the confusion between 'NIV' and 'CPAP'. Dr XXX has emphasised the NCEPD recommendations to separate these indications. Clinically the services for each (and frequently the staffing personnel) are different. There is a strong argument for separating a policy for patients with type II respiratory failure (indications COPD, neuromuscular disease, thoracic cage deformity, obesity related respiratory failure, rarely other indications) who will generally require 'NIV' from a policy for obstructive sleep apnoea (OSA) for which the treatment will usually be CPAP, and only very occasionally will NIV be required. • 'CPAP' for OSA falls under the remit of a 'sleep' service. I am hopeful that you have included specialists working within sleep (responsible for a huge workload both numerically and financially) in this proposed policy harmonisation. (eeg and most notably Dr Simon Wharton at Birmingham Heartlands Hospital, as well as people like Dr Syed Huq at the Queen Elizabeth Hospital.) •		

		• The draft policy proposes limiting the use of CPAP in mild OSA to those in whom it causes ‘ severe functional impairment.’ This is later defined as sleeping, eating, walking driving etc. This is a much higher bar than that set by current relevant NICE guidelines: “CPAP is only recommended as a treatment option for adults with mild OSAHS if: they have symptoms that affect their quality of life and ability to go about their daily activities, and lifestyle advice and any other relevant treatment options have been unsuccessful or are considered inappropriate” (my italics.) In my experience a significant proportion of patients with mild sleep apnoea have considerable benefit from the use of CPAP if carefully selected, and I feel that this wording will strongly discourage practitioners from offering appropriate treatment from which patients may benefit. • It is also worth noting that new NICE guidelines for OSA are currently being developed, and the West Midlands policy may require revision in the light of them when published (expected August 2020.) • Long term follow up of patients with OSA is not necessary to ensure adherence once regular usage has been established, although the provision of a service to troubleshoot problems, offer consumables/service machines as necessary and provide a route to clinical		

		review if required is offered in many centres and I think is valued. • I do not see why patient smoking should preclude offering NIV – although as Dr XXX points out, many of these patients will also be receiving oxygen. • I worry the patient leaflets may confuse rather than inform and may benefit from a rewrite. The 'OSAHS' leaflet for example seems to suffer from confusion with obesity related respiratory failure and talks about hypoventilation and hypercapnia which is not appropriate in an OSAHS leaflet. Again, it discussed 'NIV', which is not really appropriate in an OSAHS document.		
DRAFT Policy for the use of Biological Mesh	No	• UHB Consultant Surgeon: Thank you for asking me to comment. I do not use non-synthetic mesh in any of my inguinal, umbilical or incisional hernia repair operations. • UHB Consultant Surgeon: In general, I agree with the findings of the report and have found it to be based on appropriate evidence but would like to make some additional comments. For the vast majority of surgeons undertaking the vast majority of hernia repairs, there is no need for biological or biosynthetic meshes. Medium-weight macroporous (large pore size) polypropylene meshes have shown to provide good outcomes when used appropriately with lower recurrence rates and no increase in chronic pain as compared to non-mesh alternatives.	Köckerling F et al. . What is the evidence for the use of biologic or biosynthetic meshes in abdominal wall reconstruction? Hernia. 2018; 22(2): 249–269.	Yes

		For simple hernias I would not consider the use of biologic or biosynthetic meshes. The descriptions of open and laparoscopic hernia repairs in the draft report are really only applicable to inguinal hernias and I would suggest that this is clarified for the sake of completeness. My personal interest is in complex abdominal wall hernia repairs. This term can be used to describe repairs of very large hernias, mesh infections, contaminated wounds, entero-cutaneous fistulae (uncontrolled holes from the bowel out of the skin) and others. In this context it is not always possible to use a synthetic mesh as the risk of contamination is high although the quality of studies in these cases is limited due to their relative scarcity as discussed in one of the meta-anlalyses[1]. The majority of these patients have had multiple previous operations and often several failed attempts to repair their abdomen. Many have spent long periods of time in hospital due to their problems and months or years of community nursing support prior to definitive surgery. I have moved over the last few years away from biological meshes to almost exclusively using biosynthetic (long-term absorbable) meshes as they are significantly cheaper than true biologics and appear to give me similar outcomes. I also use these meshes in combination with a synthetic mesh as an adjunct to allow closure and protect the bowel where there is a very large hernia defect requiring component separation (division and separation of layers of the abdominal wall).[2] If these meshes were also restricted to use via an IFR it would significant reduce my ability to perform these more complex cases. Some recent studies looking at the	Garcia-Urena MA, Lopez-Monclus J et al. Abdominal Wall Reconstruction Utilising the Combination of Absorbable and Permanent Mesh in a Retromuscular Position: A Multiccenter Prospective Study. World J Surg. 2019 Jan;43(1):149-158 Rognoni C et al. Budget Impact Analysis of a Biosynthetic Mesh for	

		economic benefit of biosynthetic meshes in this complex subgroup of patients would suggest that they may be cost-effective. [3,4] There has been discussion with colleagues in the British Hernia Society and with the GIRFT group regarding accreditation of centres for different grades of hernia repair. If this comes to fruition, then it may be possible to limit these more expensive meshes to centres accredited for complex abdominal wall repair. • I am one of the Colorectal Surgeons over at UHB and I do a lot of work with complex abdominal wall repairs. My colleague, Nigel Suggett forwarded these documents to me and there are a few issues I wanted to highlight about Biological meshes. Please find these points in the email below. The key issue is that complex abdominal wall repairs (these are completely different from your simple and groin herniae) are of various varieties. They cannot all be lumped into the same category. For those of us that get these cases referred to us, we find our use of biologicals are actually fairly limited but steady. I reckon that I might use this about twice a year, but this use is not entirely predictable as some of these might be necessitated as an emergency. In the potentially infected wound, no one will stick a synthetic mesh in because they get infected. Infection of these meshes are very difficult to manage, with often	Incisional Hernia Repair. Clin Ther 2018 Nov; 40(11):1830-1844 Schneeberger S, Phillips S et al. Cost-Utility Analysis of Biologic and Biosynthetic Mesh in Ventral Hernia Repair: When are they Worth it?. J Am Coll Surg 2019 Jan;228(1):66-71	

		disastrous consequences for the patient as well as the cost of management. An example is resecting a tumour in a colostomy that requires excision of the abdominal wall. Unless this is a staged repair (which then costs more to both the trust and the patient), I see no way of using synthetics in that situation. We also use biologics for all repairs after an Abdomino-perineal resection. This is fairly standard practice for a routine cancer operation and I don't think anyone will use synthetics in that scenario. Moreover, I have had to repair a complete perineal prolapse, 6 months after anterior exenteration for gynaecological surgery and radiotherapy. This patient presented as an emergency, very unwell and literally sitting on their small bowel!! The only prospect of a repair was a biological…and all this was happening at about 0200. So, the case for biologicals is that they are not used often in expert hands but use remains steady. We have to be careful they remain available both for the elective and emergency use, but their use needs to be controlled. At UHB-HGS, we have tried to harmonise all the meshes we use in all 4 categories (extraperitoneal, intra-peritoneal, biosynthetics and biologicals) in accordance with both the best evidence we have available to us as well as the difficult cases we encounter in order to save cost. I can provide more of the work we have done on this should you require it.		
	No	•	No	Yes

DRAFT Policy for Non-Cosmetic Body Contouring		• UHB Consultant: Please could you consider my comments regarding the proposal non-cosmetic body contouring surgery. Thank you for making these patients a priority. There are patients who suffer debilitating symptoms as a result of loose skin. I have been involved with a number of cases and I have been trying to get funding in particular for a patient with a chromosomal disorder who is struggling to walk because of her excess skin on her abdomen and surgery has been proposed by a neurologist and myself. This has been rejected despite a number of appeals. I think there should be more emphasis on symptoms and not the amount of weight loss which is arbitrary. There are patients who cannot function after losing less than 50% of excess weight and need an abdominal apron removed to help them exercise and lose further weight. Also, it cannot be stressed how busy we are as surgeons working in acute hospitals and it would be very helpful to have a streamlined form for requests for funding. Perhaps you could do a bespoke one for these patients which has the important information you need. Ultimately, I would like to see a situation with trust whereby the clinician decides on surgery based on these criteria and we can avoid IFRs. Audits could then be done of these cases to demonstrate compliance. • UHB Consultant: It is good and will be good for many patients.		

		I have few notes What is the starting BMI. Is for patients with morbid obesity (BMI more than 35) who were able to lose weight and maintain it As you know, those patients will be referred to us (plastic Surgeons) by their GPs and sometime bariatric surgeon. The referring doctor / surgeon should include in the referring letter that the patient achieved the target weight / the 50% loss of excess weight and maintained for 2 years. It should be documented in the referring letter. Those patients usually have high BMI, so please include in the policy that the patient should be aware of high risks complications as DVT, wound breakdown, …. The surgery will be targeting patients to improve function, so please document in the policy that revision surgery to improve appearance will not be accepted. Those patients will have excess skin in multiple parts. And after removing the excess skin and fat from one site (as abdominplasty), the patient will start noticing the excess skin and tissue in other parts as flanks, buttocks, breasts. If the patient would gain weight again, then surgery will not be repeated.		
DRAFT Policy for Adenoidectomy	Yes		https://www.cochrane.org/CD0	Yes

		• ENT UK We have discussed this at our Executive Meeting and are satisfied that the guidance is reasonable. • ENT Consultant: There is some evidence that topical nasal steroid (e.g. as spray or drops) can be effective in reducing the symptoms of adenoidal hypertrophy. It may be appropriate to states this in the guidance and patient leaflet • https://www.cochrane.org/CD006286/ENT_topical-steroids-for-nasal-airway-obstruction-in-children-with-moderately-to-severely-enlarged-adenoids Cochrane conclusion: "Authors' conclusions: Current evidence suggests that intranasal corticosteroids may significantly improve nasal obstruction symptoms in children with moderate to severe adenoidal hypertrophy, and this improvement may be associated with a reduction in adenoid size. The long-term efficacy of intranasal corticosteroids in these patients remains to be defined.	06286/ENT_topical-steroids-for-nasal-airway-obstruction-in-children-with-moderately-to-severely-enlarged-adenoids	
DRAFT Policy for Hysteroscopy for investigation of Heavy Menstrual Bleeding	No	• SWB Consultant ObGyn: I have looked at the documents and agree with them - they are comprehensive and deal with all points I will also forward to some senior colleagues for their opinion and will let you know • SWB Consultant ObGyn: My colleagues have reviewed this - all in agreement	No	Yes

11.3 Key points for consideration: clinical

Clinicians were generally understanding and supportive of the CCGs in undertaking an evidence-based review of treatment policies in order to provide equitable access to healthcare provision in a robust manner.

Clinicians were pleased to be given the opportunity to engage with the policy development process.

Clinicians would like further clarity and transparency regarding the process which the CCGs follow and how clinical evidence/expert clinical opinion is reviewed.

The 12 policies which received further clinical feedback will require further review by the Treatment Policy Clinical Development Group.

Clinicians were keen to continue to engage with the policy review process.

Clinicians were keen for these policies to be widely communicated to those in primary care so that the referral pathways and patient expectations could be appropriately managed.

11.4 Next Steps: Governance

Each CCG will have a slightly different timetable for governance review and implementation of the policies, but the high level timelines are outlined below:

- October 2019 – Engagement Feedback Evaluation Report prepared and submitted to the TPCDG
- Late October / Early November 2019 – Black Country & Birmingham TPCDG evaluation meetings to review all draft policies in light of the patient and clinical feedback.
- Early / Mid November 2019 – finalisation of polices; patient leaflets and equality impact assessments.
- Late November 2019 – preparation of You Said, We Did Report
- December 2019 & January 2020 –
    - progress of finalised policies through each CCGs internal governance requirements
    - rolling period of communication updates – both feedback to clinicians and governance related e.g. Health Oversight & Scrutiny Committees
- January 2020 – communication of 'finalised policies' to relevant stakeholders.
- December 2019 / January 2020 – provider notification of new policies
- February 2020 – new policies implemented.

12. Appendices

Appendix A – Lipoedema patient feedback received on the policy concerning the treatment of Lymphoedema & Lipoedema

In terms of the survey questions, please see my responses below...
1) Yes
2) Strongly Disagree
3) Negative Impact

Having read the policies and proposed changes, I have to say I am highly disappointed. Although it is good to see that the CCG are actively recognising these conditions, there seems little change in terms of the treatment options available to patients.

I agree with the commentary around conservative treatment and agree that non -surgical options should always be fully explored in the first instance, however for many patients these are little to no use as their condition is too far advanced.

Having read the eligibility criteria section in detail, it appears that the patient pathway for surgical treatment refers to the need to submit an IFR Application, however having discussed this will other patients/ and my GP in much detail I understand that quite often IFRs for Liposuction for treating Lymphoedema & Lipoedema are rejected as the condition is not considered to be rare enough and therefore does no fit the IFR criteria.

With this in mind, I feel the IFR Process would not be a suitable pathway for patients needing surgical intervention, and indeed may only lead to further stress and anxiety going through the process only to receive a rejection outcome.

I note the policy references that there is little research into Liposuction for Lipoedema, however I have seen first hand the successful outcomes of this treatment, both in terms of my own treatment experience and the hundreds of other patients my consultant Miss Anne Dancey has treated.

specific example - please see below:
Having battled with my weight since the point of puberty (aged 15) and having spent hundreds of pounds joining various weight loss groups, exercise classes, gyms etc only to watch my legs and arms continue to balloon I finally received my Lipoedema diagnosis in June 2016 at the Lymphoedema Clinic, Moseley Hall, Birmingham.

Although I was delighted to finally understand the cause of my ever-expanding limbs, I was emotionally devastated to learn that my condition was Chronic and had already advanced to stage 3.... and that the only treatment option was Liposuction, which could only be offered via private healthcare.

My condition was extremely advanced, the lipoedema in my legs had grown to such a point that I was experiencing reduced mobility, constant pain, skin breakdown and buying clothes to fit over my huge limbs was near impossible ... all this and I wasn't even 30 yet!!

I attended an initial consultation with Miss Anne Dancey in July 2016 where she confirmed the diagnosis I had received at Moseley Hall and advised that I had Lipoedema present in my legs from hips to ankles, lower abdomen and buttocks and arms from armpit to elbow.

Following which I worked closely with my GP - Dr C I Elliott and Lymphodema Nurse - Julie Cunneen to compile my evidence in support of Liposuction Treatment, this was finally agreed in line with the current Birmingham CCG Policy and funding was approved for 4 Liposuction Operations to remove the Lipodema from my legs under the care of Miss Anne Dancey and her team in November that year.

I can't begin to tell you what that funding approval meant for me and indeed my family, I had tried everything up to this point including wearing uncomfortable compression garments (day & night) and nothing helped, my mental health was deteriorating, I was losing more and more time from work due to poor mobility and pain and a future life being wheelchair bound was looking more and more likely.. so to finally here that the CCG had approved my surgery was incredible.

Don't get me wrong, the recovery from surgery was long, difficult and painful but was so

surgeries and seeing a total of 38 litres removed from my legs; my mobility has improved significantly, I am able to walk without pain in my knees, I am able to weight bare without fear of my legs giving way and I am more active than ever. I have been able to return to full time work and although this has never been about appearance to me ... I can't deny I was over the moon when I was able to purchase my first pair of skinny jeans and winter boots ....yep the first time ever!!

Unfortunately though, this is not a "Happy Ever After" story for me. As you will have noted from above, my original diagnosis identified Lipoedema in not just my legs, but also in my lower abdomen/buttocks and arms.

However, following the recent merger of CCGs additional funding to complete my treatment has been unavailable and has been reliant upon the outcome of the policy reviews you are currently making.

Despite continuing to wear compression, following a strict low-calorie diet and exercising more than ever my upper body continues to balloon as the Lipoedema continues to grow. The condition is now at its worst in my arms, with huge Lipoedema fat pads visible from my armpit down to my wrists on both arms. This causes significant pain in both arms and I am finding the extreme heaviness in the arms is making some of the most basic day to day tasks impossible for me to complete unaided. So, as you can imagine, I have been pinning all of my hope on these policies being in support of Liposuction and being able to complete the rest of my treatment.

I am not dismissive of the cost of these surgeries and fully appreciate the situation the NHS is currently in, however these conditions (although often considered cosmetic) are chronic like any other condition and have life changing effects on patients both physically and mentally.

The surgical intervention of Liposuction, is most definitely not "cosmetic", believe you me nobody no matter how vain would put themselves through such surgery for cosmetic benefits.. and in fact the outcome of these surgeries often leaves us patients with unsightly, excess skin. What this treatment does provide is an opportunity for sufferers to live a normal & pain free life ....which believe you me is priceless!

Given my situation, I am sure you and your team will appreciate why I am so disappointed by the changes to these policies. As the potential for me to be able to complete my treatment and live a Lipodema free life are now very slim .. and indeed gives newly diagnosed patients in the future little hope of a cure.

If you feel it would help your review process, I am more than happy to share with you photographic evidence of my Liposuction Treatment Journey, where you can visibly see the incredible difference this treatment can make.

Arden and Greater East Midlands
Commissioning Support Unit

NHS Birmingham and Solihull,
NHS Sandwell and West Birmingham,
NHS Dudley
NHS Walsall
NHS Wolverhampton
Clinical Commissioning Groups

Harmonised Treatment Policies – Phase 3a

'YOU SAID, WE DID' SUMMARY REPORT

November 2019

Contents

Treatment Policies Clinical Development Group.

YOU SAID – WE DID Report.

Background

In July 2018 the 5 Birmingham and Black Country CCGs (Birmingham & Solihull CCG; Sandwell & West Birmingham CCG; Dudley CCG; Walsall CCG and Wolverhampton CCG) committed to working together to review 3 orthopaedic treatment policies. The membership of the Birmingham & Solihull and Sandwell and West Birmingham Treatment Policies Clinical Development Group was extended for Phase 3a to include members from Dudley CCG; Walsall CCG and Wolverhampton CCG. Membership of the TPCDG includes clinical and management stakeholders who have met regularly in 2019 to discuss and assess the 3 Evidence Reviews and the related draft policies.

The Treatment Policies Clinical Development Group provides the required governance and oversight of the policy programme by:

- Providing direct clinical input and examination of nationally and, where appropriate, internationally available contemporary evidence research.
- Monitoring project planning, timelines and progress of all treatment policy areas.
- Initial engagement with a range of relevant stakeholders including local provider clinical subject matter experts, council members of the Birmingham and Solihull Councils' Joint Health and Oversight Committee and the Sandwell Council Health Oversight Committee, and patient and public representatives.
- Ensuring the appropriate input, endorsement and sign off of the updated policies.

Public and Clinical Engagement

A core element of the policy harmonisation programme has been the public and clinical engagement period. For a six-week period (*September 2nd – October 11th 2019*) – Birmingham & Solihull, Sandwell & West Birmingham, Dudley, Walsall and Wolverhampton Clinical Commissioning Groups undertook a joint clinical and public consultation exercise. The purpose of the engagement was both to share 3 draft policies (and accompanying literature including draft patient leaflets, Equality Impact Analyses and Evidence Reviews) and gather feedback on the proposals. Upon conclusion of the engagement period – a full summary report of the feedback was prepared and presented to the Treatment Policies Clinical Development Group (TPCDG) for their discussion and consideration. The full summary report is available upon request and will be published on the CCGs' Web Sites following Governing Body adoption in early 2020.

Using the seven commissioning principles to underpin their evaluation and consideration of the feedback – the TPCDG members assessed all the public and clinical feedback received and responded accordingly.

- CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
- CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
- The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
- CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
- CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community;
- CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance; and
- Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered.

The high-level components of these discussions for each of the policies are set out below in the form of a 'You Said -We Did' report.

All of the 3 Policies in Phase 3a received feedback from the public and clinical colleagues.

Policy for the Management of Subacromial Pain.

You Said:

Public Feedback:

1. I have not researched or specialised into this field- So difficult to have an opinion.
2. For some patients who have tried conservative treatments this may offer some relief
3. The resources could be better used
4. There are clinical instances especially in trauma where this might be beneficial in improving function, so it will have to tailored to patient needs
5. Has helped some patients
6. I feel each case must be looked at and treated on its merit
7. Don't treat this
8. There may be some people the procedure helps.
9. Not qualified to make such a judgement
10. Important to widen the scope of NHSE policy on ASD to all causes
11. I don't think it should be a blanket "no". The surgeon and GP should have the final say
12. A family member had keyhole surgery to relieve pain and restricted movement in a shoulder. Treatment very successful. Following a traumatic injury to my shoulder I was not offered treatment other than physiotherapy; the shoulder still gives pain and still has some restricted movement.
13. Need to be careful that treatment is not seen to be restricted on the criteria of age of patient
14. If it's not beneficial it shouldn't be offered.
15. Leave the decision to the patient, GP and specialist

Clinical Feedback:

16. Directorate Lead Consultant Surgeon: Thank you. I have been advised by our specialised upper limb experts. Happy with this.
17. Sometimes, that is the last resort. As a doctor, very difficult to say, sorry you suffer from pain, we will not do anything.
18. Patients report benefit and withdrawing assumes that the clinical evidence is absolutely correct - it is often not
19. Clinical lead MSK Physio. Community. Firstly, an appraisal of evidence and sense check of final commissioning decision appears sound. I.e: 'Due to the limited quality of evidence of clinical and cost effectiveness, surgery for sub-acromial pain syndrome is not routinely commissioned. This means the patient's NHS commissioning organisation (CCG), who is responsible for buying healthcare services on behalf of patients, will only fund the treatment if an Individual Funding Request (IFR) application has shown exceptional clinical need and the CCG supports this.' However, the evidence cited regarding condition aetiology omits current, non-orthopaedic trends concerning the pathophysiology of subacromial pain syndromes. This is important, as the information given under the heading 'What is Subacromial Pain in Adults?' fails to acknowledge the uncertainty that exists

in this area. Instead, the policy asserts the condition is caused thus: Shoulder impingement (pain in the top and outer side of the shoulder) occurs when the tendon rubs or catches on the acromion and the sub-acromial bursa. Pain may start suddenly or come on gradually, and may occur if the tendon is swollen, thickened or torn due to injury, overuse or age-related 'wear and tear'.
This information has been contested for a number of years, and indeed is possibly one of the reasons why the benefits of surgical arthroplasties/decompressions are not significantly better than doing nothing at all (at 12 and 24/12 F/Us).
Rotator cuff tendinopathy/shoulder impingement syndrome appear to be multi-factorial in nature & should be treated as such. Perhaps it would be wise to inform the patient thus:
"Previously it was thought that pain occurs when the top of the tendon rubs or catches on the acromion and the sub-acromial bursa, however more recent studies have shown that between 76-91% RC tears occur within the tendon or on 'under-side' of the tendon. Also, there has shown to be poor correlation between acromial shape and pain. Furthermore, RC tears can continue to develop post SAD. To this end routine SAD surgery for this condition is no longer recommended routinely". Lewis (2011, 2016)
I think that getting this background information right helps both the health practitioner (be it Consultant, GP or physiotherapist) and patient alike make better informed shared-decisions concerning treatment. Also, it doesn't on one-hand provide clarity (i.e. this is how your condition is caused), whilst with the other withdraw care (i.e. 'but we no longer fund surgery for this'), as this is likely to cause frustration and high numbers of IFRs (individual funding requests).

20. Rheumatology Consultant - Thank you for passing this on. My comments below apply to surgical decompression and to hydro-dilatation. The conclusions of these reviews is expected from recent reviews and trials. My concern is that there will be a significant number of patients with intractable and difficult shoulder pain who will need surgical or radiologic intervention. This is likely to involve more than a handful of patients. To require an individual funding request for each of these is problematic and frustrating for all concerned. I think it would have been useful to have an algorithm that made clear when funding would be likely if patients had failed to respond to standard approaches. As it stands this policy does not acknowledge the real difficulty some patients will have. The current policy does not provide a comprehensive pathway for these patients.
21. GPSI I have had many of my patients undergo this procedure especially with tears of the rotator cuff. I feel that this procedure does have a place if conservative measures fail.
22. Consultant Shoulder Surgeon: yes, in agreement with these. I was part of the CSAW (Can Shoulder Arthroscopy Work?) which showed that SAD is not an effective treatment. This also reflects my practice where for many years now I have not been offering SAD to my patients. I still perform SAD though as part of other procedures e.g. during repair of a full thickness rotator cuff tear etc. I refer impingement patients to physio and also consider steroid injection

23. Consultant Surgeon: Re the subacromial pain – This is a highly controversial topic, with the quoted studies also being contested in terms of methodology and interpretation of results. Let's not throw the baby out with the bath water! Not all patients with shoulder pain, have impingement. It is a vastly over diagnosed (wrongly) condition in any case, as a result of which other causes of shoulder pain can be missed. So, if patients are not referred at all based on the assumption that they have impingement, we will only end up seeing these patients very much later with their condition having become more complex and in need of more invasive, expensive treatment (cuff tears are an example). I would also point out that impingement is not a diagnosis made by imaging alone. No scan in itself can confirm a diagnosis of impingement, it needs other tests also; and most importantly an interpretation of the scan findings in conjunction with clinical findings. Therefore, in my view we may find fewer patients having surgery initially, but we might be storing up bigger problems for later on. A more sensible approach would be to have strict criteria (as for other conditions like Dupuytrens or CTS) that need to be met before surgery is offered. I should add that we as a group of shoulder surgeons have already seen a big reduction in the number of arthroscopic subacromial decompressions being performed, simply through a tighter patient selection process based on the results of the studies quoted. We do not like to operate on patients who are not likely to get a good result from surgery either!
24. Consultant Surgeon: Your list of operations / eligibility criterion does not include chronic cuff tears as an indication for surgery. Recently concluded UKUFF trial has shown the procedure to be clinically and cost effective. There is good evidence to show that cuff tears progress in size and then the concern is they may become irreparable over time. Large irreparable tear is one of the most difficult clinical problems to deal with in younger age. So chronic cuff tear repair surely has to be part of the indications. Subacromial decompression is more often done as an associated procedure, alongside other procedures. Patients may be listed for subacromial decompression + other procedure (for e.g. cuff repair, removal of calcium deposits). If the tear was reported inaccurately on scan and was noted to be too small to repair, or was much bigger than anticipated, patient may end up having an isolated subacromial decompression surgery (despite not being planned for it). These scenarios have to be considered. Isolated subacromial decompression for impingement pain is not a common procedure anyway. However, there are odd indications, just like with other limited clinical value procedures. I am not sure the intention of this document was to address this issue, or the whole list of shoulder operations.

We Did:

Public Feedback

1.; 3.; 7; 9.; 10; 14.

The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence.

2.; 5; 6; 8; 11; 15.

The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence. The evidence shows this surgical intervention does not improve the patient's symptoms any more than

physiotherapy and conservative treatments and so the CCGs cannot support surgical intervention when there are no greater benefits for the patients compared to conservative treatment.

4. The policy ensures that any patients who has 'red flag' symptoms with acute shoulder pain, e.g. dislocated shoulder, their care will be determined by an acute care pathway and fall outside of the remit of this policy.
12. Each patient's symptoms will be assessed on an individual basis by a specialist clinician, to ensure that the treatment is tailored to that individual patient. There are some injuries, where symptoms cannot be fully cured despite evidence-based management and management of on-going symptoms will be part of the care package for the patient. The evidence shows this surgical intervention does not improve the patient's symptoms any more than physiotherapy and conservative treatments and so the CCGs cannot support surgical intervention when there are no greater benefits for the patients compared to conservative treatment.
13. This policy for Subacromial Pain does not have any age restrictions attached.

Clinical Feedback

16. The CCGs welcomed the clinical feedback and would like to thank the specialist team for reviewing the clinical policy and for their support in implementing the policy.

17. The CCGs would not want a doctor to say to a patient 'sorry you are in pain we will do nothing'. The CCGs have reviewed the most up to date clinical evidence to determine the most clinically effective treatment for patients with subacromial pain. The treatment pathway the doctor should be offering the patient, should be conservative management, e.g. physiotherapy; pain management etc. The evidence review determined the lack of clinical effectiveness of the surgical intervention over conservative treatment and therefore the CCGs cannot support a surgical intervention which the evidence demonstrates would have no greater benefit to the patient but carries the ensuing risks of surgery.

18. There are varying levels of clinical evidence, the CCGs asked NHS Solutions for Public Health to undertake a rigorous review of the most up to date clinical evidence so they may review the level of evidence available in regard to this surgical intervention. The grade of evidence reviewed was to a high standard. The CCGs want to ensure the best use of the NHS resources available to them and so want to ensure that interventions available to patients are clinically effective above conservative measures, which in Subacromial Pain, the efficacy of surgery has not been demonstrated in the clinical evidence above that of conservative management.

19. The CCGs welcomed the clinical feedback and would like to thank the specialist for reviewing the clinical policy and for their support in implementing the policy. The clinical information provided has been reviewed by the policy development committee and incorporated into the revised policy.

20.; 21; 22. The CCGs welcomed the clinical feedback and would like to thank the specialist for reviewing the clinical policy, the committee discussed at length the issues raised, but the standard of evidence presented in the evidence review was extremely high, to demonstrate that surgical intervention does not have greater benefit for the patient over conservative measures and no further

evidence was submitted to the committee for review which provided evidence of clinical circumstances in which the surgical intervention could be beneficial.

23. The CCGs welcomed the clinical feedback and would like to thank the specialist for reviewing the clinical policy, the committee discussed at length the issues raised, but the standard of evidence presented in the evidence review was extremely high, to demonstrate that surgical intervention does not have greater benefit for the patient over conservative measures and no further evidence was submitted to the committee for review which provided evidence of clinical circumstances in which the surgical intervention could be beneficial. The policy would not stop the patient being referred to a specialist for diagnosis of the cause of the subacromial pain and the committee would encourage GPs to refer patients where a diagnosis is unclear in line with Right Care and GIRFT principles.

24. The purpose of the policy document was to review the surgical intervention of arthroscopic shoulder decompression surgery in any clinical circumstances as an isolated surgical intervention or as an adjunct to another surgical intervention. The clinical evidence does not support the use of arthroscopic shoulder decompression surgery in any clinical circumstances. Other shoulder surgery interventions are not part of this clinical policy and have not been considered in the evidence review only ASD as a stand alone or as an adjunct procedure are covered by this policy.

Policy Outcome

- **The draft policy is endorsed by the TPCDG and will proceed to the next stage of CCG governance for sign off and implementation.**

Policy for the use of Image Guided Therapeutic Intra-Articular Joint Injections.

You Said:

Public Feedback:

1. I have not researched or specialised into this field- So difficult to have an opinion...
2. It can only be better than what I am suffering now
3. will make patients unhappy
4. Some people tolerate pain better than others, so it comes back to the individual doctor and patient.
5. Don't treat this
6. Better use of clinicians time
7. The patient will be happy
8. If a patient has been having this service and it is changed he or she will think this is just a cost cutting exercise
9. If a patient knows that only treatment that is proven to work is offered, surely they will have more confidence.
10. It will affect patient presenting elsewhere asking for solutions only to be told that you must see GP. No intervention is going to be successful until all clinicians (A/E, walk in centre) all say the same language.
11. Breakdown in doctor-patient relationship

Clinical Feedback:

12. It is very difficult to administer an injection into the hip especially if the anatomy is also altered and hence safer and also beneficial to inject under imaging guidance. Hence, I would support injections under guidance for hips for this reason. knee joint injections can be done without imaging due to the ease of access. I do not undertake any injections in the ankle or foot to be able to comment.
13. Hip injections are difficult to perform without image guidance and for small joints such as hands and wrists it is vital to be sure the injection is in the right place
14. Hip joint injection is difficult to give without guidance as wrong place can be injected.
15. Rheumatology Consultant: We, in rheumatology, do perform standard steroid injections without imaging in outpatient settings but the guidance does not cover steroid injections under imaging to hip, subtalar and sacroiliac joints where it is practically difficult to inject without imaging.
16. GPSI: I have injected joints for forty years always on feel alone. I have had a ultrasound machine and now do some injections ultrasound guided like injected Planter Fascia Parthenon, Gluteal Tendinopathy, Ankle Joint, Biceps Tendon etc. I feel that ultrasound has a place in small joints and some tendinopathies. In my service I do not apply any additional premium and charge the same whether the injection is blind or US guided. Viscosupplement Injections I believe that there is a small role in some

patients like patients with Arthritis of the knee Grade I or II and Glenohumeral joint osteoarthritis. I have used this injection and we charge the same as for a normal joint injection. The difference is that the preparation (Ostenil) needs three procedures (injections) at weekly intervals.

17. OTS Clinical Lead: I have read and agree with the comments from all of my colleagues within Secondary Care and have nothing to add.

    Summary:

    •Large Osteoarthritic joints do not require US-guided injections (exception: Hip joint)

    •Small joints (e.g. in the hand and foot) where accuracy is important would benefit from US-guidance

18. Alternative service model: 3 roomed department with a trained specialist nurse, MSK sonographer and Consultant Rheumatologist with special interest in ultrasound. The department sees approximately 40-50 patients per week for diagnostic scans and provides a similar sized service for ultrasound guided injections and aspirations.

19. Rheumatology Consultant: On behalf of rheumatology I am pleased to feedback. The draft that applies to us is the policy on image guided therapeutic intra-articular injections. I would reassure you that already we would only offer an image-guided injection if a patient has failed to respond to conventional pharmacological and non-pharmacological treatment. My comments are:

    a. This policy only discusses injections in relation to osteoarthritis. Therefore, this policy needs to be explicit for OA i.e. the title must be:
    b. “Policy for the use of Image Guided Therapeutic Intra-Articular Joint Injections in Osteoarthritis”
    c. There is also a small group of patients you have failed to consider, where it is clinically unsafe to inject an (OA) joint without imaging guidance eg the hip. The actual hip joint (not the trochanteric bursa) can only be injected under imaging guidance as it is too deep for a ‘blind’ injection, and there is a large neurovascular bundle that must be avoided. Injecting the actual hip joint must remain an exclusion to this policy.
    d. There are some joints in the foot/ankle e.g. subtalar, midfoot joints where due to the complex anatomy it is impossible to palpate the joint line ‘blindly’, making ‘blind’ injections impossible. Patients here would therefore require imaging guidance for injections, and this must remain an exclusion to the policy.
    e. This policy only refers to joints. Infiltration around tendons requires imaging guidance due to the risk of ‘blind’ injections causing tendon rupture. Infiltrating around tendons must remain an exclusion to this policy.

f. More detail is required as to the evidence which needs to be presented in order to show successful outcome (what outcome measure tools do you require) and how many do you define as adequate, in image guided injections of the small joints?

20. GP: My only comment is on the USS guided injections (as my partner in practice is hoping to develop a community based service- conflict of interest here) is that I think the policy should be that “where possible- these USS guided injections of small joints should be offered in the community by primary care”. This will hopefully facilitate a shift from mainly secondary care based work more into primary and support the efforts of the MCP.

21. I've gone over the draft and appreciate there is an agenda which has obviously bias the interpretation of evidence. On a purely factual basis, there are some issues with reference duplication which I'm sure will be picked up on - citation 4, 5 and 6 are also 12, 13 and 15.

    Page 5, Para 2, 2nd sentence is incorrect as the evidence states that USGI results in better pain and functional status at 6 months.
    Page 5, Para 3, I'm not sure how many DRUJ injections you do but it should be very small and cannot be translated into knee, shoulder, or other joints and represents poor scientific application of evidence.
    Citation 1 is purely a scoping document and has no additional information to Citation 2 which says exactly the same thing regarding the quote so should be removed.
    Citation 2 does not separate USGI (ultrasound-guided injection) and LMGI (landmark-guided injection).
    Citation 3 is regarding the use of hyaluronate suggesting that it is as effective as a steroid which I doubt for a second the CCG would want us to use.
    Citation 4 states USGI is better than LMGI.
    Citation 5 states there is no real benefit of steroid injections at all.
    Citation 6 says USGI is more accurate but doesn't conclude the clinical outcome is any different.
    Citation 7 says USGI gives maximum benefit.
    Citation 14 says USGI is better at 6 months.
    Citation 16 says USGI is better tolerated, more effective at 6 months and more cost-effective.
    Citation 17 says USGI of the knee is no better than LMGI.
    Citation 18 is not cited and has no relevance to the document.
    Citation 19 is not cited and states steroid only has limited benefit in the knee and less for hip and hand.
    Evidence that has not been included but should be:

    a. USGI are more clinical + cost-effective - https://bjgp.org/content/67/661/378
    b. USGI shoulder injections significantly greater clinical improvement over LMGI - https://www.ncbi.nlm.nih.gov/pubmed/26590864
    c. USGI Carpal Tunnel Syndrome better for several markers - https://bjgp.org/content/67/661/378

d. USGI shoulder significant improvement in pain and abduction vs LMGI but small and suggests further research - https://www.ncbi.nlm.nih.gov/pubmed/23275390
e. USGI improves efficiency and cost-effectiveness but more research is needed - https://www.ncbi.nlm.nih.gov/pubmed/29511701

We Did:

Public Feedback

1.-11. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence. The clinical evidence demonstrates that the use of image guidance in performing therapeutic injections does not provide a better outcome for the patient with regard to pain relief therefor the patient will be able to access palpated joint injections via their clinical team to gain the same injections as currently are offered.

Clinical Feedback.

12.-17. The CCGs welcomed the clinical feedback and would like to thank the clinician for reviewing the clinical policy and for their support in implementing the policy. As stated in the policy eligibility criteria, the policy relates to joint injections only and joint injections into the spine, hip joint and small joints of the hands and feet are outside of the remit of this policy as the clinical evidence demonstrated greater efficacy of these injections when image-guidance is used.

18.&19. The CCGs welcomed the clinical feedback and would like to thank the clinician for reviewing the clinical policy and for their support in implementing the policy. The feedback regarding clarity of diagnosis was discussed by the policy committee and the policy revised to include all patients with arthritis. As stated in the policy eligibility criteria, the policy relates to joint injections only, not diagnostic scans and not injections into the tendons. Joint injections into the spine, hip joint and small joints of the hands and feet are outside of the remit of this policy as the clinical evidence demonstrated greater efficacy of these injections when image-guidance is used.

20. The CCGs welcomed the clinical feedback and would like to thank the clinician for reviewing the clinical policy and for their support in implementing the policy. It would be by the committee that all primary care treatment options are exhausted before a referral to primary care is made, however unless there is clinical evidence to demonstrate the need for a patient to be reviewed by a specific team, in line with the committee's commitment to offer choice to patients, a specific referral pathway cannot be mandated within the policy.

21. The CCGs welcomed the clinical feedback and would like to thank the clinician for reviewing the clinical policy. The feedback on the clinical evidence was reviewed by the committee and taken into account when reviewing the final policy document. In response to the submitted evidence, this was again reviewed by the committee and the following findings were made:

a. & c. William Wynter Bee and James Thing, 2017. Ultrasound-guided injections in primary care: evidence, costs, and suggestions for change. British Journal of General Practice 2017; 67 (661): 378-379.
DOI: https://doi.org/10.3399/bjgp17X692117
Submitting clinician assertion: USGI are more clinical + cost-effective

Committee Review: The Paper reviews the use of ultrasound guided injections in carpal tunnel and aims to review if U/S guidance can be done more cost effectively in primary care saving on a secondary care referral. In ascertaining that Ultrasound guided injections are more effective than palpated injection, the paper relies on a consensus statement from the American Medical Society for Sports Medicine, where the cohort of patients to be treated under this policy will largely be those affected by arthritis and not a sports injury and a study by Huang et al 2015. Effectiveness of Ultrasound Guidance on Intraarticualr and Periarticular Joint Injections: Systematic Review and Meta-Analysis of randomized Trials. Am J Phys Med Rehabilitation. 2015 Oct;94(10):775-83. doi: 10.1097/PHM.0000000000000260., which found the following conclusion: Intraarticular and periarticular injections using ultrasound guidance significantly improves the accuracy of joint injections, and there is a significant decrease in visual analog scale scores for up to 6 weeks after injection. The effect of ultrasound guidance on the long-term outcome of joint injections is inconclusive. The inconclusive findings in regard to the long-term outcomes of ultra-sound guided injections and the breadth of evidence the committee had already reviewed in developing the policy, this Systematic Review was insufficient evidence to change the policy criteria.

b. Wu T[1], Song HX[2], Dong Y[2], Li JH. 2015. Ultrasound-guided versus blind subacromial-subdeltoid bursa injection in adults with shoulder pain: A systematic review and meta-analysis. Semin Arthritis Rheum. 2015 Dec;45(3):374-8. doi: 10.1016/j.semarthrit.2015.05.011. Epub 2015 May 21. https://www.ncbi.nlm.nih.gov/pubmed/26590864
Submitting clinician's conclusion: USGI shoulder injections significantly greater clinical improvement over LMGI
Committee Review: The author's conclusion within the paper is as follows: Ultrasound-guided corticosteroid injections potentially offer a significantly greater clinical improvement over blind SASD bursitis injections in adults with shoulder pain. The committee reviewed the paper as per the author's conclusion, found that there is a potential, but not a confirmed significantly greater clinical improvement demonstrated by the findings of the paper as per the author's conclusions and therefore the paper did not outweigh the evidence already reviewed by the committee in developing the policy.

d. Sage W[1], Pickup L, Smith TO, Denton ER, Toms AP. 2013 The clinical and functional outcomes of ultrasound-guided vs landmark-guided injections for adults with shoulder pathology--a systematic review and meta-analysis. Rheumatology (Oxford). 2013 Apr;52(4):743-51. doi: 10.1093/rheumatology/kes302. Epub 2012 Dec 28.
Submitting clinician's conclusion: USGI shoulder significant improvement in pain and abduction vs LMGI but small and suggests further research
Committee Review: The author's conclusions in the paper are as follows: There is a statistically significant difference in pain and abduction between LMG and USG steroid injections for adults with shoulder pathology. However, these differences are small and may not represent clinically useful differences. The current evidence base is limited by a number of important methodological weaknesses, which should be considered when interpreting these findings. The cost-effectiveness of the intervention should be considered in the design of

future studies. The committee would agree with this conclusion that whilst there is some statistical significance, these are small and cannot be used in this evidence review to demonstrate clinically useful differences.

e. Daniels EW[1], Cole D[1], Jacobs B[2], Phillips SF[1]. 2018 Existing Evidence on Ultrasound-Guided Injections in Sports Medicine. Orthop J Sports Med. 2018 Feb 22;6(2):2325967118756576. doi: 10.1177/2325967118756576. eCollection 2018 Feb. https://www.ncbi.nlm.nih.gov/pubmed/29511701
Submitting clinician's conclusion: USGI improves efficiency and cost-effectiveness but more research is needed

Committee Review: Again the committee noted that this paper is specifically for sports medicine as opposed to the majority of patients within the cohort of patients requiring joint injections, i.e. patients with arthritis. The committee also noted the author's conclusion: 'While current studies indicate that ultrasound guidance improves efficacy and cost-effectiveness of many injections, these studies are limited and more research is needed'. The committee accepted that there is some evidence to support the use of image guidance in some joint injections, e.g. hip injections, the studies to support use of image guidance in all joint injections are insufficient to outweigh the weight of evidence already reviewed by the committee in demonstrating that image guided therapeutic injections do not provide clinically significant superior outcomes to palpated therapeutic joint injections.

Policy Outcome

- **The draft policy was revised to include all patients with arthritis and is endorsed by the TPCDG and will proceed to the next stage of CCG governance for sign off and implementation.**

Policy for the use of Image Guided High Volume Intra-Articular Injections

You Said:
Public Feedback:

1. On the understanding that non-guided injections of large joints will still be made available to patients where this treatment offers pain relief when conservative methods have failed
2. Do not fully understand
3. Only as last resort
4. Should be done first
5. If the practitioner is experienced in this field I would have thought the decision on treatment would be down to him
6. I think it is dangerous to insert a injection into large joints without image guidance
7. This depends on each individual patient
8. Clear evidence
9. I have had guided and unguided injections and I think it is the skill of the surgeon that can determine the effectiveness of this treatment
10. Important that if this treatment is restricted that GPs and other clinicians are well trained and practised in the delivery of articular large joint injections, which can gift relief to many patients.
11. I believe the person delivering image guidance would be more qualified, my husband has had injections given wrongly which has caused more pain and he has needed even more injections to put it right. Would a more careful service of imagery have saved pain time and money.
12. Non effective treatment is no treatment and should not be offered.
13. Leave the decision to the patient, GP and specialist

Clinical Feedback:

14. Consultant: Happy with this
15. Consultant: I have reviewed the treatment policy of image guided high volume Intra articular injections, and agree with it.
16. GPSI: High Volume Injections
    a. I feel that there is a role for HVI especially in Achilles Tendinopathy again we perform these at no additional premium to our tariffs.

    Hydro-dilatation in Adhesive Capsulitis
    This has a role in Adhesive Capsulitis it can stretch the tissues and make it easier to move the joint. Most patients don't need it if treated appropriately in early stages(Freezing stage)
    The success rate is over 70% for shoulder movement and 90% for improving pain. It is a non-surgical procedure.

The alternative is Arthroscopy(Arthrolysis).
We Did: 1.-13. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence. The clinical evidence demonstrates that the use of image guidance in performing high volume injections does not provide a better outcome for the patient than conservative offered and may cause damage to the patient's joint. Therefore, the high volume injections whether image guided or palpated will not be funded by the CCG. As in the earlier policy, palpated therapeutic injections (small volume of steroid) will still be available to patients if clinically appropriate. 14. & 15. The CCGs welcomed the clinical feedback and would like to thank the clinician for reviewing the clinical policy and for their support in implementing the policy. 16. The policy under consideration relates to high volume joint injections, not to injections into tendons. The committee reviewed the evidence surrounding hydrodilation in adhesive capsulitis as set out in the evidence review which accompanied the draft policy during the engagement phase. The conclusion in the evidence review stated: The systematic review (with meta-analysis) by Saltychev et al (2018) reported that hydrodilatation with corticosteroids has only a small, clinically insignificant effect for pain and ROM (seven RCTs) when treating adhesive capsulitis. Conversely, Catapano et al (2018) reported that the intervention is likely to be effective. However, this conclusion was based on the results from two of five RCTs and three of five RCTs which reported improvements in pain scores and range of movement respectively. The evidence is therefore at best inconsistent. No long term results were reported. Both authors report that the included RCTs were of moderate quality. Therefore, without further submission of supporting evidence to demonstrate the following statistics: 'The success rate is over 70% for shoulder movement and 90% for improving pain. It is a non-surgical procedure.' The policy development committee again reviewed the clinical evidence set out in the evidence review and concluded that there was insufficient clinical evidence to support the use of high volume injections in adhesive capsulitis.
Policy Outcome • **The draft policy is endorsed by the TPCDG and will proceed to the next stage of CCG governance for sign off and implementation.**

Arden and Greater East Midlands
Commissioning Support Unit

NHS Birmingham and Solihull & NHS Sandwell and West Birmingham, Clinical Commissioning Groups

Harmonised Treatment Policies – Phase 3b

'YOU SAID, WE DID' SUMMARY REPORT

November 2019

Contents

Treatment Policies Clinical Development Group: YOU SAID – WE DID Report

Background

In July 2018 the Birmingham and Solihull CCG & Sandwell and West Birmingham CCG committed to working together to develop a further 10 treatment policies to build on the work being undertaken in Phase 3a across Birmingham and the Black Country. The membership of the Birmingham & Solihull and Sandwell and West Birmingham Treatment Policies Clinical Development Group includes clinical and management stakeholders who have met monthly in 2019 to discuss and assess the Evidence Reviews related Draft Policies, Patient Leaflets and Equality Impact Assessments.

The Treatment Policies Clinical Development Group provides the required governance and oversight of the policy programme by:

- Providing direct clinical input and examination of nationally and, where appropriate, internationally available contemporary evidence research.
- Monitoring project planning, timelines and progress of all treatment policy areas.
- Initial engagement with a range of relevant stakeholders including local provider clinical subject matter experts, council members of the Birmingham and Solihull Councils' Joint Health and Oversight Committee and the Sandwell Council Health Oversight Committee, and patient and public representatives.
- Ensuring the appropriate input, endorsement and sign off of the updated policies.

Public and Clinical Engagement

A core element of the policy harmonisation programme has been the public and clinical engagement period. For a six-week period (*September 2nd – October 11th2019*) – Birmingham & Solihull and Sandwell & West Birmingham Clinical Commissioning Groups undertook a joint clinical and public consultation exercise. The purpose of the engagement was both to share 10 draft policies (and accompanying literature including draft patient leaflets, Equality Impact Analyses and Evidence Reviews) and gather feedback on the proposals. Upon conclusion of the engagement period – a full summary report of the feedback was prepared and presented to the Treatment Policies Clinical Development Group (TPCDG) for their discussion and consideration. The full summary report is available upon request and will be published on the CCGs' treatment policies web pages following Governing Body adoption in February 2020.

Using the seven commissioning principles to underpin their evaluation and consideration of the feedback – the TPCDG members assessed all the public and clinical feedback received and responded accordingly.

- CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
- CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
- The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
- CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
- CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community;
- CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance; and
- Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered.

The high level components of these discussions for each of the policies are set out below in the form of a 'You Said -We Did' report.

All of the 10 Policies received feedback from either the public or clinical colleagues.

Policy for the use of Liposuction in Lymphoedema

You Said
Public Feedback:

1. Any help is better than none
2. I personally have lymphoedema but under control. I would like to think that if circumstances change then I would like access to treatment.
3. Don't treat
4. Evidence based change
5. If it's an effective treatment
6. Lymphoedema can be a distressing ailment and the Patient should be given any help possible to make their condition more tolerable
7. Makes treatment options available to wider patient group
8. I see people with this terrible condition, and it makes sense to offer treatment if other treatment has failed
9. see generic comment about readability etc
10. It sounds like a sound policy.
11. Leave the decision to the Patient, GP and Doctor/Nurse specialist
12. Seeking evidence always best answer
13. The addition of Liposuction as treatment option for patients with Lymphedema that are no longer responding to traditional treatments such as bandaging, compression wraps, MLD etc would be life changing for those group of patients this procedure is suitable for. Liposuction for Lymphedema is recognised in NICE guidance.

Clinical Feedback:

14. Studies indicate that Liposuction in lymphoedema where conservative treatments have been exhausted can be beneficial and successful. Clinically in practice I have experience of the positive impact of this procedure on a primary lymphoedema patient. Is new policy going to accept both primary and secondary lymphoedema patients to access this procedure?
15. Good to consider a defined group of patients for this service however there is a lack of lymphoedema specialists so there could be delays in assessment and treatment. This needs to be addressed to meet patient needs

We Did

Public Feedback:

1. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence. There is evidence which shows some clinical interventions do the patient more harm than good and it is the CCG's priority to prevent clinical interventions causing harm to patients. However, liposuction in lymphoedema has been shown to have good success rates.
2. The CCGs welcomed the public feedback. The policy for the use of liposuction in lymphoedema is designed specifically so that when conservative treatment can no longer control the patient's symptoms and the patient is well enough to have liposuction then this may be an option for the patient and her/ his clinician to discuss.
3. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence, which demonstrates that the intervention to be funded has a high rate of improving the patient's quality of life.

   4.; 5; 6. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence and so this policy change is based on up to date evidence.
7. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence and so this policy change is based on up to date evidence which demonstrates that the most effective use of liposuction in patient with lymphoedema is n those patients where conservative treatment is no longer effective.
8. & 10. The CCGs welcomed the public feedback.
9. The CCGs welcomed the public feedback, the patient leaflets will be reviewed in light of this feedback.
11. The CCGs have a finite amount of resources to fund all of the CCG funded services across at area. Therefore, if a service is to increase the clinical options available to a patient, then the CCG have to agree to fund the increase in clinical options, i.e. the liposuction. The policy was drafted with assistance from clinical specialists to ensure that the patients had access. to the most appropriate clinical treatment.
12. & 13. The CCGs welcomed the public feedback.

Clinical feedback:

14. The CCGs welcomed the clinical feedback, the policy will apply to patients with both primary and secondary lymphoedema and the policy has been clarified to reflect this.
15. The CCGs welcomed the clinical feedback, there is currently a bespoke community lymphoedema service commissioned for the patients within Birmingham & Solihull CCG and Sandwell and West Birmingham CCG footprints to meet the patient demand for assessment, conservative management and assessment for suitability for potential liposuction surgery.

Policy Outcome

- **The draft policy with minor amendments following clinical review is endorsed by the TPCDG and will proceed to the next stage of CCG governance for sign off and implementation.**

Policy for the Liposuction in Lipoedema

You Said:

Public Feedback:

1. More research and trials should be considered and reviewed
2. if it helps them only good can come of it
3. I feel that there needs to be more evidence gathered before a final decision made
4. Don't treat
5. Evidence based decision
6. The sooner a trial gets underway the better
7. Need for more clinical evidence and therefore option for limited treatments should be left open
8. Not sure if this should be used or not, surely another larger trial should be commissioned.
9. If it shown to have clinical benefit, it should be recommended by health care professionals, if medically appropriate. This should be left to the Pt, GP and specialist If the CCG wants to withhold - ration- treatment - the CCG should inform the patient and explain its reasons, as well as indemnify health professionals.

Clinical Feedback:

1. I am a Nurse Consultant for Lipoedema UK and have been a Clinical Nurse Specialist in lymphoedema and Lipoedema for several years. I have been to the Hanse Clinic as part of my previous role as Director of LymphCare UK and saw the positive results the specialist Tumescent Liposuction had on Women. It was life-changing. The outcomes with improved range of movement, mobility, pain, psychologically and physically were very evident. Circumferential Limb volumes were greatly reduced. I have also had a patient on my previous caseload who was struggling to carry on working and interacting with her children. Following a series of Tumescent Liposuction procedures she was able to return to work, play with her children and become more mobile and active. This patient still continues to reap the benefits of this procedure after 9 years. Numerous surveys from Lipoedema UK have highlighted that women are in dire need of services and an option in some cases should be Medical Tumescent Liposuction. There is currently a post-code lottery of service provision generally for this condition. Women are often mis-diagnosed as obese or suffering for lipoedema and spend several years suffering with the condition prior to being referred to a specialist Lymphoedema service. However, I think this is a positive step to put Lipoedema on the agenda for improving services. I agree that there needs to be more investment into further research and this is a priority moving forward.

2. I am a Lymphedema nurse specialist and Lipoedema UK Nurse consultant and also suffer from this condition myself. This is NOT for a cosmetic purpose but treatment of a now recognised medical condition. Lipoedema does not respond to conservative treatments. Ladies with Lipoedema have fatty doughy abnormal distribution of fat that is not usual obesity fat and is impossible to loose through healthy eating and fat burning exercise. This condition has physical and psychological long term complications . These include significant reduction in mobility often leading to joint problems and orthopaedic surgeries. Some ladies have significant low self esteem and depressive illness. A complication can be Lymphedema secondary to Lipoedema There is 10 years of evidence from Hanse clinic in Germany that Liposuction is life changing Lipoedema UK have produced a series of four articles from focus groups women in Dire need of Liposuction.

We Did:

Public Feedback

1. The CCGs welcomed the public feedback and agreed then when more research is available the policy development group would review the newly published research for the use of liposuction in patients with lipoedema.
2. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence. There is evidence which shows some improvement in patients with lipoedema who have had liposuction, but the numbers of patients involved in these research studies were very small and cannot be relied on to show that the majority of patients with lipoedema will benefit from liposuction. As new evidence becomes available, which demonstrates the benefits of liposuction in patients with lipoedema, then the CCGs will review this policy.
3. The CCGs welcomed the public feedback and agreed then when more research is available the policy development group would review the newly published research for the use of liposuction in patients with lipoedema.
4. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence, which demonstrates that the clinical intervention to be funded has a high rate of improving the patient's clinical condition.
5. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence and so this policy change is based on up to date evidence.
6. As new evidence becomes available, which demonstrates the benefits of liposuction in patients with lipoedema, then the CCGs will review this policy.
7. The CCGs have a finite amount of resources to fund all of the CCG funded services across the area. Therefore, if a service is to increase the clinical options available to a patient, then the CCG have to agree to fund the increase in clinical options, i.e. the liposuction. There was not enough clinical research on the use of liposuction in lipoedema for the CCG to agree to fund the surgery at this time.
8. The CCGs welcomed the public feedback and agreed then when more research is available the policy development group would review the newly published research for the use of liposuction in patients with lipoedema.
9. The CCGs have a finite amount of resources to fund all of the CCG funded services across the area. Therefore, if a service is to increase the clinical options available to a patient, then the CCG have to agree to fund the

increase in clinical options, i.e. the liposuction. There was not enough clinical research on the use of liposuction in lipoedema for the CCG to agree to fund the surgery at this time.

Clinical Feedback:

1. The CCGs welcomed the clinical feedback, the development of clinical policies is based on review of the most up to date clinical evidence for the area to be reviewed. There is evidence which shows some improvement in patients with lipoedema who have had liposuction, but the numbers of patients involved in these research studies were very small and cannot be extrapolated out to demonstrate a benefit to a larger cohort. The CCG would welcome further research being undertaken. As new clinical evidence becomes available, which demonstrates the benefits of liposuction in patients with lipoedema, then the CCGs will review this policy.
2. The CCGs welcomed the clinical feedback, the policy has been reviewed as it was identified that the CCGs previously only had a policy which relates to cosmetic liposuction which was inappropriate for patients with lipoedema, hence the evidence review was undertaken to review the clinical evidence available to support the use of NHS resources in these clinical circumstances. All clinical evidence which was reviewed by the committee was presented in the engagement phase in the evidence review, and all articles submitted during the clinical engagement were reviewed by the policy development group. However, the level of robust clinical evidence required for the CCG to commission a service was not met at this time. The CCG would be keen to review this policy as new robust clinical evidence is published.

Policy Outcome

- **The draft policy is endorsed by the TPCDG and will proceed to the next stage of CCG governance for sign off and implementation.**

Bariatric Surgery Policy

You Said
Public Feedback:

1. To be used with support for patient in life-style changes and possible emotional support
2. Don’t treat

3. Obesity is a major problem and some people need this help
4. Not qualified to comment
5. Obviously prevention should be the first thing tried but is sometimes difficult to achieve. It seems ludicrous that a Patient of45Kg is deemed "too small" for the surgery so has to put more weight on. The impact on health seems more important to me than the actual weight
6. Benefit to patients overall health and well being who fall within the eligible groups
7. everything must be tried before this costly procedure which we think is self inflicted
8. see generic comment about readability etc
9. Sounds reasonable.
10. Limits not based on sound evidence and considerable morbidity at BMI in 40s for some people

Clinical Feedback:

11. NICE 2014: BMI of 35 or over NICE recommends that all patients with a BMI of 35 or over who have recent-onset type 2 diabetes should be assessed for surgery. Patients must have tried and failed to achieve clinically beneficial weight loss by all other appropriate non-surgical methods and be fit for surgery. You appear to block doctors from fulfilling their medical obligation - and be in breach of the duties of a Dr -GMC
12. If patient has BMI 48, do we need to tell them to eat more to hit 50, so that they are eligible.

We Did:

1. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence. The Bariatric Surgery Policy has been development in line with the service for patients with obesity which has a patient pathway. The final stage of the pathway would be potential surgery, but in earlier stages the patient are supported by a multi-disciplinary team to loose weight.
2. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence, which demonstrates that the clinical intervention to be funded has a high rate of improving the patient's clinical condition.
3. The CCGs welcomed the public feedback.
4. The CCGs welcomed the public feedback.
5. The CCGs welcomed the public feedback. Currently there is only a certain capacity available for bariatric surgery within the local health economy and the CCGs therefore prioritised the patients who could clinically benefit the most from the bariatric surgery.
6. The CCGs welcomed the public feedback.
7. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence. The Bariatric Surgery Policy has been development in line with the service for patients with obesity which has a patient pathway. The final stage of the pathway would

be potential surgery, but in earlier stages the patient are supported by a multi-disciplinary team to loose weight.

8. The CCGs welcomed the public feedback, the patient leaflets will be reviewed in light of this feedback.
9. The CCGs welcomed the public feedback.
10. The CCGs welcomed the public feedback. Currently there is only a certain capacity available for bariatric surgery within the local health economy and the CCGs therefore prioritised the patients who could clinically benefit the most from the bariatric surgery.

Clinical Feedback

11. The CCG will fund all patients who have a BMI of >35 with Type 2 Diabetes onset in the last 10 years for surgery, but the CCG wants to ensure the patient is clinically well enough to undergo surgery, hence the need to be fit for surgery and that the patient has tried other options for weight loss before undergoing a surgical procedure with the ensuing risks of general anaesthesia.
12. If a patient has a BMI of 48, then they may be referred to the Tier 3 Weight Loss service where they will be reviewed by a multidisciplinary weight loss team and provided with an individual care plan. If they meet the criteria for surgery, then the patient will be referred to the Tier 4 service for clinical review. Currently there is only a certain capacity available for bariatric surgery within the local health economy and the CCGs therefore prioritised the patients who could clinically benefit the most from the bariatric surgery.

Policy Outcome

- **The draft policy is endorsed by the TPCDG and will proceed to the next stage of CCG governance for sign off and implementation.**

Policy for the use of Knee Arthroscopy in Acute Knee Injury

You Said:
Public Feedback:

1. Widens the policy to include acute knee injury when more conservative treatments have failed. However, the policy seems to exclude degenerative knee injury- which may occur across a range of adult age groups. Reconsider this group?
2. If it works great
3. Because it worked for me. After injury had 6 months of conservative management; leg in brace and other pain management treatments. Then had surgery with supported physio and feels a lot better
4. If it is thought to have little benefit, then to carry out this procedure would be wasting funds
5. Don't treat
6. Evidence based change
7. Seems sensible
8. If no benefit pointless to proceed
9. If it's not beneficial it shouldn't be used.
10. Where is the evidence that it does not help in trauma? Leave this to Patient, GP and specialist

Clinical Feedback:

11. Consultant in Sport Medicine: The biggest thing that needs clarity is what is meant by "failed physiotherapy". There needs to be a quick route to get IFR approval and this circulated to clinicians - ie within 1-2 weeks. There needs to be specific feedback from physiotherapy and pain teams obtained on this given the likely impact on their services
12. Provider Contract Team Feedback: The draft patient leaflet states that over 35s are automatically excluded. This is at odds with the draft policy, whereby age is an indicator of possible degenerative knee disease, but not an automatic exclusion. The exclusion of all patients with degenerative knee disease means that patients who have a degenerative knee disease but then experience an acute injury would be ineligible for treatment. There are patients for whom surgical treatment for the acute injury would greatly improve quality of life and this is not related to underlying disease. It is unclear from the policy whether patients should only be referred to secondary care following a period of rehab etc. There is a recognised pathway at UHB for acute knee clinic/physio
    Consultant Knee Surgeon suggested that all acute knee injuries should be seen by a knee specialist rather than FCP. It is confusing to have the definition of degenerative knee disease in the 'eligibility criteria' box. These definitions should be elsewhere. Furthermore the definition of degenerative knee disease is difficult to audit against (patients may be over 35, and may

or may not have the following symptoms). There is an ongoing discussion between clinicians at UHB and the CCGs around the definition of locked/locking knee. The definition of functional impairment should include ability to perform one's job. The EIA is unclear. The summary says 'The restriction of this policy may have an impact on those who would wish to receive the treatments for a degenerative condition such as osteoarthritis' but this policy is about acute knee injury. The national EBI policy does not have an age limit of 35 but this is stated in the evidence review.
We Did: 1. The Policy currently under development is for : Knee Arthroscopy In Acute Knee Injury. A review of clinical evidence has determined the pathway of evidence-based treatment for this group of patients with Acute Knee Injury. The CCGs have a separate policy for patient with degenerative knee disease. 2. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence. The clinical evidence reviewed by the policy development group demonstrated that in patients where physiotherapy and other conservative treatments have not worked in the first 3 months, the knee arthroscopy can be clinically effective in patients with acute knee injury. 3. 4. 5. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence. The clinical evidence reviewed by the policy development group demonstrated that in patients where physiotherapy and other conservative treatments have not worked in the first 3 months, the knee arthroscopy can be clinically effective in patients with acute knee injury. 6.7.8.9.The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence, which demonstrates that the clinical intervention to be funded has a high rate of improving the patient's clinical condition. 10. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence, which demonstrates that the clinical intervention to be funded has a high rate of improving the patient's clinical condition, but only when physiotherapy for 3 months has failed. The CCG does not want patients to undergo unnecessary surgery and so wants to ensure that all conservative management options have been tried and have filed before the patient proceeds to surgery. **Clinical Feedback** 11. We have reviewed the patient pathway with the main NHS provider and the planned care surgical knee team currently provides a rapid assessment MDT clinic for patient with acute knee injury who are then seen by physiotherapy within that MDT Clinic and undertake conservative management. Only when this conservative management (including physiotherapy) had failed are patients listed for surgery. 12. The main NHS provider provides a rapid assessment MDT clinic for patient with acute knee injury who are then seen by physiotherapy within that MDT Clinic and undertake conservative management for at least 3 months following the acute knee injury. Only when this conservative management

(including physiotherapy) had failed are patients listed for surgery, these patients, must meet the eligibility criteria for surgery.
In Phase 2 2018 a Knee Arthroscopy in Degenerative Knee Disease was developed and followed a similar engagement phase as has been undertaken in Phase 3. Following implementation of the Knee Arthroscopy in Degenerative Knee Disease Policy which is in line with NHSE EBI Knee Arthroscopy Policy for Degenerative Knee Disease, further discussions are currently being undertaken with providers outside of the Phase 3 engagement to work together to resolve the issues surrounding the Knee Arthroscopy in Degenerative Knee Disease Policy.

Policy Outcome

- **The draft policy is endorsed by the TPCDG and will proceed to the next stage of CCG governance for sign off and implementation.**

Policy for the use of Domiciliary Ventilation in
A. Chronic Obstructive Pulmonary Disease (COPD)
B. Neuro-Muscular Disease (NMD)

You Said:
Public Feedback:

1. Do not use this service to be able to comment
2. This treatment is vital to patients with respiratory conditions. It offers them a better quality of life which can only have a positive outcome
3. Don't treat
4. These policies must be put in place in order to speed up process of giving patients their own machinery and make it easier for GPs and walk in centres to know how to refer patients with relevant illness directly to a respiratory specialist instead of putting breathlessness and other symptoms down to asthma/anxiety
5. More education and guidelines are needed to prevent Muscular dystrophy patients becoming very ill or dying through lack of knowledge
6. This is a needed treatment, provision is long overdue
7. Not qualified to comment

8. Being unable to breathe to having difficulty in breathing May make the Patient very anxious. Anything that can alleviate their anxiety and help their breathing can only be a good thing
9. Do whatever is best for the patient
10. See generic comment about readability etc
11. My mother in law had COPD and had this service at home towards the end. It helped her breathe till she died. Obviously but it eased her breathing till she died.
12. What is the change?

Clinical Feedback:

13. Lead Consultant Respiratory Ventilation Team: Thank you for your initiative in addressing Domiciliary NIV in the Birmingham area, for which hopefully our patients will be thankful. Attached are the 2 documents with our comments embedded. The most important single point in both documents is the inclusion of CPAP and Bi-Level Ventilation under the umbrella term NIV. The 2018 NCEPOD recommendation is to separate CPAP and NIV (bi-level ventilation, also loosely called BiPAP but BiPAP being a commercial brand the current UK consensus is to call it NIV). The recommendation of the NCEPOD to the NHS Digital and the Association of Clinical Coders is as follows: "Continuous positive airways pressure (CPAP) and non-invasive ventilation (NIV) should be coded separately. They are two distinct treatments given for different conditions and separate coding will reduce clinical confusion and improve reporting of outcomes."
    - Therefore it is crucial that to align with the latest (2018) NCEPOD recommendations, the section on Continuous Positive Airways Pressure is EITHER taken out OR the policy is renamed the Policy for the use of domiciliary Continuous Positive Airways Pressure (CPAP) and Non-Invasive Ventilation (NIV).
    - All other comments are there on the comments list of the attached documents but the two others I would like to highlight are:

1. The ordering of the Neuromuscular conditions should be unambiguous and reflect the order of prevalence/clinical relevance. This is why we recommend the ordering on Page 16 of the draft Policy as follows:
    a. • Motor Neurone Disease
    b. • Muscular Dystrophies including Duchenne Muscular Dystrophy and Spinal Muscular Atrophy
    c. • Spinal cord injury
    d. • Multiple Sclerosis
    e. • Guillain-Barre Syndrome

f. • Post-polio syndrome with respiratory impairment

g. • Syringomyelia

h. • Tuberculosis infection with residual respiratory insufficiency

2. The only UK-based HTA report (NIHR commissioned) on the cost-effectiveness of Domiciliary NIV in COPD, which included a systematic review is conspicuous by its absence:

Dretzke J, et al. The cost-effectiveness of domiciliary non-invasive ventilation in patients with end-stage chronic obstructive pulmonary disease: a systematic review and economic evaluation. Health technology assessment. 10/2015; 19(81):1-246. doi: 10.3310/hta19810. [PubMed ID: 26470875 PMCID: PMC4781210]

14. SMAUK:

In general, it is good to see that patients with SMA are included on the restricted list. Non-invasive Ventilation (NIV) is necessary and effective for many patients who have SMA

The SoC for SMA are read and included as an essential reference.

That NIV for non-sitters (SMA Type 1 and pre-symptomatic) is considered as a pro-active treatment for respiratory management.

That the CCG consider separate eligibility for those with SMA Type 1 and pre-symptomatic as reflected in the SoC for SMA.

15. Paediatric Ventilation Team

Section B: What do you mean by 'Neuro-dependant'?? and then the wording is then 'neuromuscular' patients for section B when you arrive at that section. Consider changing to Neuromuscular

Also in regards to benefits - improvement of quality of life and longevity of life are also key and hugely important benefits.

The list of conditions that are appropriate for NIV does not include Duchenne Muscular Dystrophy or any other paediatric Neuromuscular conditions know to affect ventilation. eg: congential myasthenia, Merosin deficiency, nemaline. Congenital myopathy.

Considerations for multiple admissions due to respiratory failure/ chest infections leading to type 2 respiratory failure.

In regards to the evidence review - most of the evidence base is around MND - no evidence listed for DMD or SMA although is available .

We Did:

Public Feedback

1. – 12. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence. The clinical evidence reviewed by the policy development group demonstrated

the strong evidence basis for the use of non-invasive ventilation in clinically appropriate patients who had COPD or Neuromuscular disease. The current pathway is determined through assessment of patients at respiratory centres without an overarching review of the clinical evidence. With leading ventilation specialist, the policy development committee want to ensure provision of non-invasive ventilation in adults for these groups of patients was secured and the process of gaining funding for these patients was streamlined across the footprint of the 2 CCGs.

Clinical Feedback

13., 14. & 15. The CCGs welcomed the clinical feedback, the support of specialist ventilation clinical colleagues has been invaluable in enabling these policies to be developed.
The policy development committee took on board the recommendation to separate the NIV and CPAP policies into two and this was approved by the whole committee following the engagement.
The change ordering of the NMD condition was agreed by the policy development committee, however it was noted by the committee that patients with Spinal Muscular Atrophy have a specialised service commissioned by NHS England and therefore these patients do not fall into the commissioning responsibility of the CCG and therefore have not been included in the policy.

The committee would like to thank the clinician for submitting the following article, which has been taken into consideration: The Dretzke J, et al. The cost-effectiveness of domiciliary non-invasive ventilation in patients with end-stage chronic obstructive pulmonary disease: a systematic review and economic evaluation. Health technology assessment. 10/2015; 19(81):1-246. doi: 10.3310/hta19810. [PubMed ID: 26470875 PMCID: PMC4781210].

The policy development committee also agreed that a separate policy for the use of NIV in children would be beneficial and recommended that such a policy is explored in the next phase of policy development.

Policy Outcome

- **The draft policy has been amended in line with the clinical feedback received regarding clinical assessment of patients and is endorsed by the TPCDG and will proceed to the next stage of CCG governance for sign off and implementation.**

Policy for the use of domiciliary CPAP in Obstructive Sleep Apnoea Hypocapnia Syndrome

You Said:
Public Feedback:

1. Widens access to a treatment for an increasing common complaint
2. Haven't used this to be able to comment

3. It offers peace of mind and a better quality of life both for the patient and their partner
4. Don't treat
5. As above
6. It is not just the Patient who suffers in this condition their partner is often kept awake by the snoring of the Patient (although the machine can be noisy too) Anything that can help the Patient can only be a good thing
7. Should work using up to date recommendations
8. See generic comment about readability etc
9. I was quite a bad case of sleep apnoea, but for mild cases, they may still need a machine, particularly if they are doing jobs where they need to stay sharp.
10. This should be left to the pt, GP and specialist with regard to NICE guidelines, if any. If the CCG wishes to ration this against clinical advice of GP and specialists, it should contact affected patients direct and indemnify drs.
11. To be able to sleep without the worry that you could stop breathing at any time, brings peace of mind to patient and family
12. Don't treat
13. As above
14. It could have a negative impact if some people are denied a machine, but I do think maybe weight loss should be explored with some sleep apnoea patients?
15. This should be left to the pt, GP and specialist with regard to NICE guidelines, if any. If the CCG wishes to ration this against clinical advice of GP and specialists, it should contact affected patients direct and indemnify drs.

Clinical Feedback:

16. UHB Sleep Medicine: I have looked through these documents again, and read and concur with the comments of my colleagues

    My thoughts include:

    - I agree with regards to the confusion between 'NIV' and 'CPAP'. Dr XXX has emphasised the NCEPD recommendations to separate these indications. Clinically the services for each (and frequently the staffing personnel) are different. There is a strong argument for separating a policy for patients with type II respiratory failure (indications COPD, neuromuscular disease, thoracic cage deformity, obesity related respiratory failure, rarely other indications) who will generally require 'NIV' from a policy for obstructive sleep apnoea (OSA) for which the treatment will usually be CPAP, and only very occasionally will NIV be required.

- 'CPAP' for OSA falls under the remit of a 'sleep' service. I am hopeful that you have included specialists working within sleep (responsible for a huge workload both numerically and financially) in this proposed policy harmonisation. (Eg and most notably Dr XXX at Birmingham Heartlands Hospital, as well as people like Dr XXX at the Queen Elizabeth Hospital.)
- The draft policy proposes limiting the use of CPAP in mild OSA to those in whom it causes 'severe functional impairment.' This is later defined as sleeping, eating, walking driving etc. This is a much higher bar than that set by current relevant NICE guidelines: "CPAP is only recommended as a treatment option for adults with mild OSAHS if: they have symptoms that affect their quality of life and ability to go about their daily activities, and lifestyle advice and any other relevant treatment options have been unsuccessful or are considered inappropriate" (my italics.) In my experience a significant proportion of patients with mild sleep apnoea have considerable benefit from the use of CPAP if carefully selected, and I feel that this wording will strongly discourage practitioners from offering appropriate treatment from which patients may benefit.
- It is also worth noting that new NICE guidelines for OSA are currently being developed, and the West Midlands policy may require revision in the light of them when published (expected August 2020.)
- Long term follow up of patients with OSA is not necessary to ensure adherence once regular usage has been established, although the provision of a service to troubleshoot problems, offer consumables/service machines as necessary and provide a route to clinical review if required is offered in many centres and I think is valued.
- I do not see why patient smoking should preclude offering NIV – although as Dr XXX points out, many of these patients will also be receiving oxygen.
- I worry the patient leaflets may confuse rather than inform and may benefit from a rewrite. The 'OSAHS' leaflet for example seems to suffer from confusion with obesity related respiratory failure, and talks about hypoventilation and hypercapnia which is not appropriate in an OSAHS leaflet. Again it discussed 'NIV', which is not really appropriate in an OSAHS document.

We Did:

Public Feedback

1.-15. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence and guidelines including NICE guidelines. The clinical evidence reviewed by the policy development group demonstrated the strong evidence basis for the use of continuous positive airway pressure in the home environment in clinically appropriate patients who had obstructive sleep apnoea. The current

pathway is determined through assessment of patients at sleep medicine centres without an overarching review of the clinical evidence. With leading sleep medicine specialists, the policy development committee want to ensure provision of continuous positive airway pressure devices in adults with obstructive sleep apnoea was secured and the process of gaining funding for these patients was streamlined across the footprint of the 2 CCGs.

Clinical Feedback

16. The CCGs welcomed the clinical feedback, the support of specialist ventilation clinical colleagues has been invaluable in enabling these policies to be developed.
    The policy development committee took on board the recommendation to separate the NIV and CPAP policies into two and this was approved by the whole committee following the engagement.
    Further clinicians were contacted directly following the revised policies being drafted to gain further clinical review before being approved by the policy development committee.
    The committee reviewed the definition of functional impairment, which is a standard definition across all of the CCG policies, to ensure a consistent approach for patients. The committee felt that the definition of functional impairment designated within the policy was not dissimilar from the NICE defined cohort of patients with mild OSA and therefore amending this definition was not required at this present time. However, the committee were grateful for the information pertaining to new guidelines for OSA due to be published in August 2020 and would be mindful of this publication in the next phase of policy development.
    The clinical review of the patient leaflet was also gratefully received and the leaflet has been revised in light of this clinical information.

Policy Outcome

- **The draft policy with minor amendments following the clinical review and separation from the NIV policy, is endorsed by the TPCDG and will proceed to the next stage of CCG governance for sign off and implementation.**

Policy for the use of Biological and Biosynthetic Mesh in Hernia Repair

You Said:
Public Feedback:

1. Some evidence that synthetic polymers have migrated/adhered to surgery sites resulting in difficulties for patients? Further evidence needed and research into safe, viable alternatives
2. not clinical experience in this area

3. not enough understanding of procedure
4. Don't treat
5. Evidence based
6. As there are other meshes available not using biological mesh should not have much impact
7. Hearing all the negative complaints about mesh, patients must be worried about what is used. I also believe as many patients have no problems so a difficult decision
8. See generic comment about readability etc
9. If ordinary mesh does the job, then why use other types, particularly animal.
10. This should be left to the pt, GP and specialist with regard to NICE guidelines, if any. If the CCG wishes to ration this against clinical advice of GP and specialists, it should contact affected patients direct and indemnify drs.

Clinical Feedback:

11. Consultant Surgeon: Thank you for asking me to comment. I do not use non-synthetic mesh in any of my inguinal, umbilical or incisional hernia repair operations.
12. Consultant Surgeon: In general, I agree with the findings of the report and have found it to be based on appropriate evidence but would like to make some additional comments.

For the vast majority of surgeons undertaking the vast majority of hernia repairs, there is no need for biological or biosynthetic meshes. Medium-weight macroporous (large pore size) polypropylene meshes have shown to provide good outcomes when used appropriately with lower recurrence rates and no increase in chronic pain as compared to non-mesh alternatives. For simple hernias I would not consider the use of biologic or biosynthetic meshes.
The descriptions of open and laparoscopic hernia repairs in the draft report are really only applicable to inguinal hernias and I would suggest that this is clarified for the sake of completeness.
My personal interest is in complex abdominal wall hernia repairs. This term can be used to describe repairs of very large hernias, mesh infections, contaminated wounds, entero-cutaneous fistulae (uncontrolled holes from the bowel out of the skin) and others. In this context it is not always possible to use a synthetic mesh as the risk of contamination is high although the quality of studies in these cases is limited due to their relative scarcity as discussed in one of the meta-anlalyses[1]. The majority of these patients have had multiple previous operations and often several failed attempts to repair their abdomen. Many have spent long periods of time in hospital due to their problems and months or years of community nursing support prior to definitive surgery.
I have moved over the last few years away from biological meshes to almost exclusively using biosynthetic (long-term absorbable) meshes as they are significantly cheaper than true biologics and appear to give me similar outcomes. I also use these meshes in combination with a synthetic mesh as an adjunct to allow closure and protect the bowel where there is a very large

hernia defect requiring component separation (division and separation of layers of the abdominal wall).[2] If these meshes were also restricted to use via an IFR it would significant reduce my ability to perform these more complex cases. Some recent studies looking at the economic benefit of biosynthetic meshes in this complex subgroup of patients would suggest that they may be cost-effective.
There has been discussion with colleagues in the British Hernia Society and with the GIRFT group regarding accreditation of centres for different grades of hernia repair. If this comes to fruition then it may be possible to limit these more expensive meshes to centres accredited for complex abdominal wall repair.

13. I am one of the Colorectal Surgeons over at UHB and I do a lot of work with complex abdominal wall repairs. My colleague, XXX forwarded these documents to me and there are a few issues I wanted to highlight about Biological meshes. Please find these points in the email below.
    The key issue is that complex abdominal wall repairs (these are completely different from your simple and groin hernia) are of various varieties. They cannot all be lumped into the same category. For those of us that get these cases referred to us, we find our use of biologicals are actually fairly limited but steady. I reckon that I might use this about twice a year, but this use is not entirely predictable as some of these might be necessitated as an emergency.
    In the potentially infected wound, no one will stick a synthetic mesh in because they get infected. Infection of these meshes are very difficult to manage, with often disastrous consequences for the patient as well as the cost of management. An example is resecting a tumour in a colostomy that requires excision of the abdominal wall. Unless this is a staged repair (which then costs more to both the trust and the patient), I see no way of using synthetics in that situation.
    We also use biologics for all repairs after an Abdomino-perineal resection. This is fairly standard practice for a routine cancer operation and I don't think anyone will use synthetics in that scenario. Moreover, I have had to repair a complete perineal prolapse, 6 months after anterior exenteration for gynaecological surgery and radiotherapy. This patient presented as an emergency, very unwell and literally sitting on their small bowel!! The only prospect of a repair was a biological…and all this was happening at about 0200.
    So, the case for biologicals is that they are not used often in expert hands but use remains steady. We have to be careful they remain available both for the elective and emergency use, but their use needs to be controlled.

    At UHB-HGS, we have tried to harmonise all the meshes we use in all 4 categories (extraperitoneal, intra-peritoneal, biosynthetics and biologicals) in accordance with both the best evidence we have available to us as well as the difficult cases we encounter in order to save cost. I can provide more of the work we have done on this should you require it.

We Did:

Public Feedback

The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence and expert clinical advice in the use of the most up to date, clinically effective surgical interventions. The committee in light of the concerns regarding the use of synthetic mesh in vaginal surgery wanted to ensure that there was evidence to support the use of synthetic mesh in hernia repair and that in line with Right Care and Get It Right First Time (GRIFT) principles patients were being reviewed by the most appropriate surgical team. The committee was satisfied with the standard of evidence available at the present time to demonstrate the safety of synthetic mesh in standard hernia repair, and following clinical input, the committee agreed to endorse the use of biological / biosynthetic mesh in patients where standard / first line surgical repair if hernia had failed or was inappropriate and the patient had been reviewed by a complex abdominal wall MDT.

Clinical Feedback

11 The CCGs welcomed the clinical feedback.

12 & 13. The CCGs welcomed the clinical feedback, and the time the specialist surgeons had taken to review the proposed policy. The clinical information received from the surgical team was extremely pertinent in enabling the committee to understand the clinical complexities of a small cohort patients where first line hernia repair has failed and the use of biological or biosynthetic mesh may be clinically appropriate, once the patient has been reviewed by a specialist multi-disciplinary complex abdominal wall surgical team. Based on the evidence submitted, the committee agreed to fund biological or biosynthetic mesh for a small cohort of patients with non-healed hernias, who have failed first line treatment and who have been reviewed by a complex abdominal wall MDT.

Policy Outcome

- **The draft policy has been amended to enable surgical members of complex abdominal wall MDTs to have access to biological / biosynthetic mesh for patients where first line surgical treatment to repair a hernia has failed and this revised policy is endorsed by the TPCDG and will proceed to the next stage of CCG governance for sign off and implementation.**

Policy for Non-Cosmetic Body Contouring

You Said:

Public Feedback

1. Positive benefits for those patients who have worked to reduce body mass and maintained lower weight with clinical support. A consequent improvement in quality of life and less impact on their need for further treatment
2. If the patient meets the criteria and has followed the rules laid down then yes

3. Don't treat
4. Improve quality of life for patients
5. If a patient has taken positive and sustainable measures to lose and maintain weight loss
6. Obviously, prevention of obesity at a much earlier stage should be the 1st thing but often hard to do therefore if a Patient has had the willpower to lose a lot of excess weight they should not be discouraged by the excess skin which is left (and often with which they are unaware will happen until it does)
7. Strict criteria must be monitored
8. See generic comment about readability etc
9. Surely the mental state of the patient should be assessed also. This loose skin may affect their body image and impinge on their mental health.
10. This should be left to the pt, GP and specialist with regard to NICE guidelines, if any. If the CCG wishes to ration this against clinical advice of GP and specialists, it should contact affected patients direct and indemnify drs.
11. The impact on the patient has to be positive if they have gone through surgery and weight loss etc.
12. Don't treat
13. Anything that can give a Patient a positive body image after all their hard work in losing weight can only be a good thing
14. I thought this was already the case.
15. You will probably be saying no to more patients.
16. This should be left to the pt, GP and specialist with regard to NICE guidelines, if any. If the CCG wishes to ration this against clinical advice of GP and specialists, it should contact affected patients direct and indemnify drs.

Clinical Feedback:

17. Consultant Surgeon:
    Please could you consider my comments regarding the proposal non-cosmetic body contouring surgery.
    Thank you for making these patients a priority. There are patients who suffer debilitating symptoms as a result of loose skin. I have been involved with a number of cases and I have been trying to get funding in particular for a patient with a chromosomal disorder who is struggling to walk because of her excess skin on her abdomen and surgery has been proposed by a neurologist and myself. This has been rejected despite a number of appeals.
    I think there should be more emphasis on symptoms and not the amount of weight loss which is arbitrary. There are patients who cannot function after

losing less than 50% of excess weight and need an abdominal apron removed to help them exercise and lose further weight.
Also, it cannot be stressed how busy we are as surgeons working in acute hospitals and it would be very helpful to have a streamlined form for requests for funding. Perhaps you could do a bespoke one for these patients which has the important information you need.
Ultimately, I would like to see a situation with trust whereby the clinician decides on surgery based on these criteria and we can avoid IFRs. Audits could then be done of these cases to demonstrate compliance.

18. Consultant Surgeon:
It is good and will be good for many patients.
I have few notes
What is the starting BMI. Is for patients with morbid obesity (BMI more than 35) who were able to loss weight and maintain it
As you know, those patient will be referred to us (plastic Surgeons) by their GPs and sometime bariatric surgeon. The referring doctor / surgeon should include in the referring letter that the patient achieved the target weight / the 50% loss of excess weight and maintained for 2 years. It should be documented in the referring letter.
Those patients usually have high BMI, so please include in the policy that the patient should be aware of high risks complications as DVT, wound breakdown, ….
The surgery will be targeting patients to improve function, so please document in the policy that revision surgery to improve appearance will not be accepted. Those patients will have excess skin in multiple parts. And after removing the excess skin and fat from one site (as abdominplasty), the patient will start noticing the excess skin and tissue in other parts as flanks, buttocks, breasts. If the patient would gain weight again, then surgery will not be repeated.

We Did:

Public Feedback

The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence and expert clinical advice in the use of the most up to date, clinically effective surgical interventions. The committee was aware that the currently commissioned policy relating to cosmetic surgery for body contouring meant that patients with a significant amount of excess skin and the resulting medical complications were unable to access surgery for the removal of this skin. The committee was therefore keen to review the evidence in relation to removal of skin where the patient had maintained their weight loss and had significant physical impact from the excessive skin in order to enable these patients to access surgical intervention.

Clinical Feedback

17 & 18. The CCGs welcomed the clinical feedback, the specialist clinical input into the development of policies is essential.
The committee has previously implemented an on-line prior approval process with providers, some providers are using this to streamline the funding application process with good effect.

The committee reviewed the feedback regarding clarification of referral information and will communicate the need for this information to GPs working within the footprints of the CCGs. The committee also agreed to provide clarification in the policy regarding cosmetic surgery to approve appearance and revision surgery.
Policy Outcome • **The draft policy is amended in line with clinical feedback, endorsed by the TPCDG and will proceed to the next stage of CCG governance for sign off and implementation.**

Policy for Adenoidectomy
You Said: **Public Feedback:** 1. Positive impact on quality of life for patients 2. In both adults I know this can be a problem 3. Don't treat 4. Enable a small number of patients to have the surgery 5. large adenoids can have a negative impact on a patient 6. operation only if necessary agree 7. See generic comment about readability etc 8. As it should be. 9. Good 10. Some children suffer a lot and suffering can be reduced 11. This condition can cause a lot of discomfort in adults and children, if it continues to bother them them I fel it would be positive 12. Don't treat 13. The Patient should feel a lot better 14. Unnecessary operations avoided. 15. Good 16. Dangerous surgery only for the few likely to benefit **Clinical Feedback:** 17. ENT UK We have discussed this at our Executive Meeting and are satisfied that the guidance is reasonable.

18. ENT Consultant: There is some evidence that topical nasal steroid (e.g. as spray or drops) can be effective in reducing the symptoms of adenoidal hypertrophy. It may be appropriate to states this in the guidance and patient leaflet

We Did:

Public Feedback

1.-16. The CCGs welcomed the public feedback. The clinical policies are developed based on an evidence review of the most up to date clinical evidence to ensure best practice. The revised policy will enable those with symptoms from enlarged adenoids who have failed conservative treatment to receive clinically appropriate surgical intervention.

Clinical Feedback

17. The CCG welcomed the review provided by ENT UK and would like to thanks the committee for reviewing the proposed policy.
18. The CCG welcomed the clinical feedback and appreciated the submitted piece of robust clinical evidence which enabled a small amendment in the eligibility criteria to be made.

Policy Outcome

- **The draft policy is endorsed by the TPCDG and will proceed to the next stage of CCG governance for sign off and implementation.**

Policy for the use of Hysteroscopy in Heavy Menstrual Bleeding

You Said:

Public Feedback:

1. A speedier diagnostic for patients, especially where there is a risk of endometrial pathology
2. If it is the first line of action it may save the patient from further treatment
3. Don't treat
4. This can impact on the lives of women with this condition
5. Evidence based decision
6. Sometimes just having a hysteroscopy can reduce the heavy blood loss that a patient experiences in the future
7. I had an ultra sound first then a hysteroscopy under sedation. If only a hysteroscopy sedation should be offered as it was the most painful procedure I have ever experienced.
8. See generic comment about readability etc

9. I don't know enough about it to comment, but if the scope does a better job, then use it first and cut the cost, time etc., of the scan.
10. Endometrial polyps can also cause heavy periods. Hysteroscopy helps in those patients.
11. It conciliates or highlighting further treatment. Maybe
12. Don't treat
13. Sometimes can reduce the menstrual flow
14. Saves time and I believe more accurate plus ant problems they can be done at the same time
15. Probably positive in that by using the scope first a patient will get a better diagnosis first time.

Clinical Feedback:

16. US scanning is not always reliable - I have had 2 cases where it missed endometrial cancer
17. Consultant ObGyn: I have looked at the documents and agree with them - they are comprehensive and deal with all points
18. I will also forward to some senior colleagues for their opinion and will let you know - My colleagues have reviewed this - all in agreement

We Did:

Public Feedback

1.-15. The CCGs welcomed the public feedback. The clinical policy has been developed based on an evidence review of the most up to date clinical evidence to ensure best practice in line with NICE Guidance and Right Care to ensure patients who require more invasive investigation may receive this as a first line diagnostic.

Clinical Feedback

16, 17 & 18. The CCG welcomed the clinical feedback. The clinical policy has been developed in line with current clinical evidence and NICE guidelines.

Policy Outcome

- **The draft policy is endorsed by the TPCDG and will proceed to the next stage of CCG governance for sign off and implementation.**

BARIATRIC SURGERY

Rapid Evidence Review: 'Which clinical criteria are associated with the most cost effective use of tier 4 bariatric services?'

First Published: **October 2017**

Revised: **November 2017**

Changes made to revised RER

Page	Section	Original Text	Revised Text
1	Context	between 35 kg/m^2 and 35.9 kg/m^2	between 35 kg/m^2 and 40 kg/m^2
2	Cost Effectiveness	BMI of 35 kg/m^2 to 34.9 kg/m^2	BMI of 35 kg/m^2 to 40 kg/m^2
3	Cost Effectiveness	The reported ICERs	The reported incremental cost effectiveness ratios (ICERs)
21	Schauer 2017	a parallel randomised controlled trial	a parallel randomised controlled trial (the STAMPEDE study)
25	Type 2 diabetes	the remission rate of type 2 diabetes was statistically significantly higher in participants receiving LAGB after two years	the remission rate of type 2 diabetes was statistically significantly higher after two years in participants receiving LAGB
32	Cost Effectiveness	bariatric surgery in general is cost effective, particularly LRYGB and LAGB, which were both approximately US$5,000 6,000 per QALY	bariatric surgery in general is cost effective, particularly LRYGB and LAGB, which were both approximately US$5,000 to US$6,000 per QALY

BARIATRIC SURGERY

Questions to be addressed

The aim of this rapid evidence review is to understand the evidence which will answer the question:

'Which clinical criteria are associated with the most cost effective use of tier 4 bariatric services?'

In order to develop an effective search strategy to find the relevant evidence that will answer this question, two detailed sub-questions were developed:

a) In adults with obesity (BMI at least 35 kg/m^2) with or without associated co-morbidities what is the clinical and cost effectiveness of bariatric surgery compared with non-surgical management?

b) Are there any sub-groups who would benefit more from bariatric surgery than others (defined by, for example, initial BMI status and/or presence of a specific co-morbidity)?

Summary of Evidence

Context

- The risk of developing obesity-related co-morbidities increases as an individual's Body Mass Index (BMI) increases.
- The NICE clinical guideline (CG189) recommends that bariatric surgery should be considered for all patients with a BMI of 40 kg/m^2 or more, or between 35 kg/m^2 and 40 kg/m^2 and other significant disease.
- In the UK, the surgical procedures most commonly used are adjustable gastric banding, sleeve gastrectomy and Roux-en-Y gastric bypass.
- NHS England has transferred commissioning responsibility for tier 4 services to Clinical Commissioning Groups from April 1st 2016. In order to achieve a smooth transition during 2016/17, NHS England continued to negotiate and contract activity whilst CCGs built relationships and planned pathways.
- The information in this review supports evidence based commissioning and planning of weight management pathways for 2017/18.

Clinical Effectiveness

- There was a lack of high-quality randomised controlled trials and trials with long-term follow-up.
- The evidence base covers a wide variety of different non-surgical interventions, making direct comparison difficult due to study heterogeneity.
- A Cochrane systematic review found greater weight loss following bariatric surgery for follow-up periods of one to two years when compared to non-surgical interventions.

November 2017

- There is good quality evidence that bariatric surgery reduces, but does not eliminate the risk of developing diabetes.
- A large, good **quality** study based on the Clinical Practice Research Datalink found that 4.3% of bariatric surgery patients had developed diabetes after seven years, compared to 16.2% of controls.
- There is moderate quality evidence that bariatric surgery reduces metabolic syndrome and weak evidence for improvement in sleep apnoea, however evidence for the benefits relating to hypertension and lipid profiles was inconsistent.

Safety

- The UK National Bariatric Surgery Registry reports that bariatric surgery in the UK is considered safe, with a mortality rate of around one in 1,000.
- Evidence relating to patient safety was generally poor due to inconsistent reporting, different reporting methods between studies and the small number of incidents.
- The short-term follow-up time of studies precludes the possibility of directly comparing the safety of surgery against non-surgical interventions, where individuals not achieving significant weight loss may live with co-morbidities for extended periods of time.

Cost Effectiveness

- There is moderate quality evidence to suggest that bariatric surgery is highly cost effective (less than £20,000 / QALY over a lifetime).
- Cost effectiveness is highly dependent upon the co-morbidity costs avoided, either through remission of existing co-morbidities or a reduction in the risk of developing obesity related co-morbidities in the future.
- Bariatric surgery is highly cost effective for individuals with a BMI 40 kg/m^2 or more and also for those with a BMI of 35 kg/m^2 to 40 kg/m^2 and a significant co-morbidity.
- Bariatric surgery was found to be particularly cost effective for individuals with a BMI of 40 kg/m^2 or more and type 2 diabetes.
- Bariatric surgery is likely to be most cost effective in patients with the most capacity to benefit: younger patients; or those with a higher BMI; or those with an existing obesity-related co-morbidity which is likely to be resolved by significant weight loss resulting from bariatric surgery.

Questions

a. In adults with obesity (BMI at least 35 kg/m^2) with or without associated co-morbidities what is the clinical and cost effectiveness of bariatric surgery compared with non-surgical management?

Clinical effectiveness

Bariatric surgery was found to consistently achieve greater weight-loss than non-surgical interventions.

There is moderate quality evidence that bariatric surgery results in greater weight loss for follow-up periods of one to two years, regardless of the surgical procedure or type of participants included. Weight loss is associated with a reduction in co-morbidities such as type 2 diabetes, metabolic syndrome and sleep apnoea but benefits relating to hypertension and lipid profiles are inconsistent.

Those who do manage to achieve weight loss without surgery are likely to regain weight in the future.

A good quality trial based on Clinical Practice Research Datalink records reported that it was difficult to achieve normal body weight or even just a 5% reduction in initial body weight without surgery. Only a small proportion of individuals who achieve a modest reduction in weight without surgery manage to avoid weight regain two to five years later.

The observed evidence falls in favour of surgical interventions for weight loss and resolution of co-morbidities (particularly type 2 diabetes), It would seem reasonable to conclude that the provision of lifestyle interventions is less clinically effective at dealing with more severe levels of obesity. The risks and benefits of surgery need to be carefully considered given the poor quality of information available in the literature pertaining to patient safety; however, the data provided by the Bariatric Surgery Register goes some way toward countering these concerns.

Cost effectiveness

All of the studies included clearly indicate that bariatric surgery (particularly if performed laparoscopically which is current UK clinical practice) is highly cost effective against both the NICE 'usual' cost effectiveness threshold of £20,000 to £30,000 per QALY, and the 'affordable' NHS threshold estimated by Karl Claxton et al of circa £12,000 per QALY. The reported incremental cost effectiveness ratios (ICERs) are consistently lower than the £20,000 per QALY ceiling by a factor of between four and ten (depending on the estimate considered).

For a mixed population (with and without co-morbidities), there are reliable and authoritative estimates of the lifetime ICER from the recently published UK NIHR cohort study and cost effectiveness analysis by Gulliford et al (2016). Over a lifetime, bariatric surgery resulted in both additional QALYs and was highly cost effective with an ICER of £7129 (95%CI £6775 to £7506) per QALY. The ICER for patients with severe obesity alone was slightly higher but, at £7675 per QALY, it was still well within UK accepted norms. The authors found that bariatric surgery was particularly cost effective in patients with morbid obesity and type 2 diabetes mellitus (T2DM) (£6176 per QALY).

The NIHR report did not find bariatric surgery to be cost saving over the lifetime but this may be because this model included a wider range of costs directly associated with the bariatric surgery pathway as well as a more realistic estimate of diabetes remission and recidivism.

Consistent with these findings, there is evidence from the UK HTA evaluation that bariatric surgery is also highly cost effective over a shorter, 20 year time horizon both for patients with a BMI of more than 40 kg/m^2 and no co-morbidity (ICER less than £5000 per QALY), as well as for patients with a BMI of more than 35 kg/m^2 and T2DM (£1634 per QALY).

b. Are there any sub-groups who would benefit more from bariatric surgery than others (defined by, for example, initial BMI status and/or presence of a specific co-morbidity)?

Individuals with type 2 diabetes who received surgery experienced higher rates of remission than those receiving non-surgical interventions.

Good quality evidence was identified reporting that bariatric surgery resulted in significantly higher remission rates for type 2 diabetes compared to non-surgical interventions.

As noted by NICE in its guidance for preventing ill health and premature death in black, Asian and other minority ethnic groups, these groups are at an equivalent risk of diabetes, other health conditions or mortality at a lower BMI than the white European population. Because of this, it may

prove prudent to examine the possibility of providing weight loss interventions to these groups at a lower threshold BMI value than is currently used for the general population.

Cost effectiveness is highly dependent on the avoidance of healthcare costs associated with co-morbidities. These costs may be avoided either from remission (temporary or otherwise) or avoidance of future incidence of obesity-related co-morbidity.

Patients with the greatest capacity to benefit are likely to be the most cost effective group to treat.

From an economic perspective, bariatric surgery is likely to be most cost effective in patients who are:

- Younger or
- Have a higher BMI or
- Have an existing obesity-related co-morbidity which is likely to be resolved by significant weight loss resulting from bariatric surgery.

Options for commissioners

- To continue to commission bariatric surgery procedures for patients who meet the current NICE eligibility criteria (a BMI of 40 kg /m^2 or more or between 35 kg /m^2 and 40 kg /m^2 and other significant disease).
- To continue to commission bariatric surgery procedures for patients who meet the current NICE eligibility criteria (a BMI of 40 kg/m^2 or more, or between 35 kg/m^2 and 40 kg/m^2 and other significant disease) with priority given to patients based on likely capacity to benefit (e.g. younger patients, patients in whom surgery is likely to prevent or resolve obesity-related co-morbidities, such as type 2 diabetes, sleep apnoea or metabolic syndrome, or those whose weight is such that surgery will achieve improvements in health relatively quickly).
- In addition to points one and two, commissioners may also opt to extend the BMI threshold for surgery for certain ethnic groups who present with higher risk at lower BMI levels, as recommended by NICE.

1 Context

This rapid evidence review is an update of a full review undertaken in July 2016 when a search for evidence back to 2006 was undertaken. The search for this update is therefore from July 2016 to June 22nd 2017.

1.1 Introduction

Obesity is commonly defined as a Body Mass Index (BMI) of 30 kg/m^2 or greater (see Table 1). Individuals living with obesity are at greater risk of a variety of different health conditions. These include type 2 diabetes mellitus (T2DM), non-alcoholic fatty liver disease, hypertension, asthma, gastro-oesophageal reflux disease, depression and a variety of other conditions [1]. The risk of developing obesity-related co-morbidities increases as an individual's BMI increases [2].

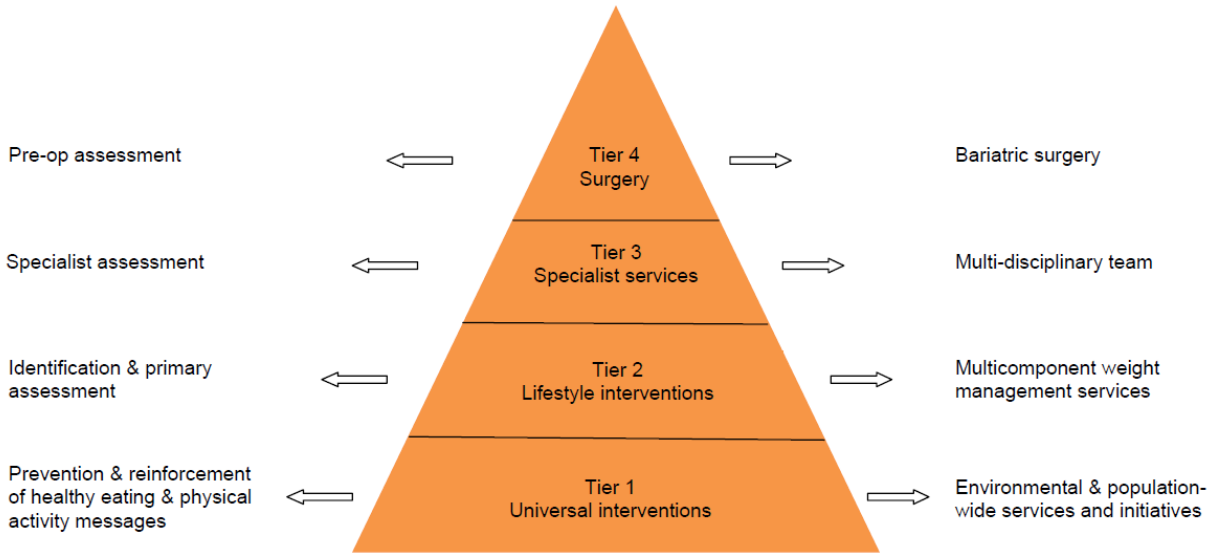
Table 1: NICE BMI Categories

Definition	BMI range (kg/m^2)
Underweight	Under 18.5
Normal	18.5 to less than 25
Overweight	25 to less than 30
Obese	30 to less than 40
Obese I	30 to less than 35
Obese II	35 to less than 40
Morbidly obese	40 and over

Source: NICE. Obesity: identification, assessment and management [1]

In England, obesity is managed through a tiered system (Figure 1), ranging from preventive population-based health promotion strategies (Tier 1) and lifestyle interventions (including diet, exercise, and behavioural) in primary care settings (Tier 2), through to more intensive specialist services provided by multi-disciplinary teams (tier 3) and bariatric surgery (tier 4) [3].

Figure 1: Tiered management of obesity



Source: Department of Health. Developing a specification for lifestyle weight management services. 2013 [3]

1.2 Existing national policies and guidance

In November 2014, NICE published clinical guidance on the identification, assessment and management of obesity (NICE clinical guideline 189), replacing the older section 1.2 in 'Obesity' (NICE clinical guideline 43) [1].

According to the NICE Obesity pathway (Figure 2): "*Bariatric surgery is a treatment option for people with obesity if all of the following criteria are fulfilled:*

- *They have a BMI of 40 kg/m^2 or more, or between 35 kg/m^2 and 40 kg/m^2 and co-morbidity (for example, type 2 diabetes or high blood pressure) that could be improved if they lost weight*
- *All appropriate non-surgical measures have been tried but the person has not achieved or maintained adequate, clinically beneficial weight loss*
- *The person has been receiving or will receive intensive management in a tier 3 service*
- *The person is generally fit for anaesthesia and surgery*
- *The person commits to the need for long-term follow-up*"

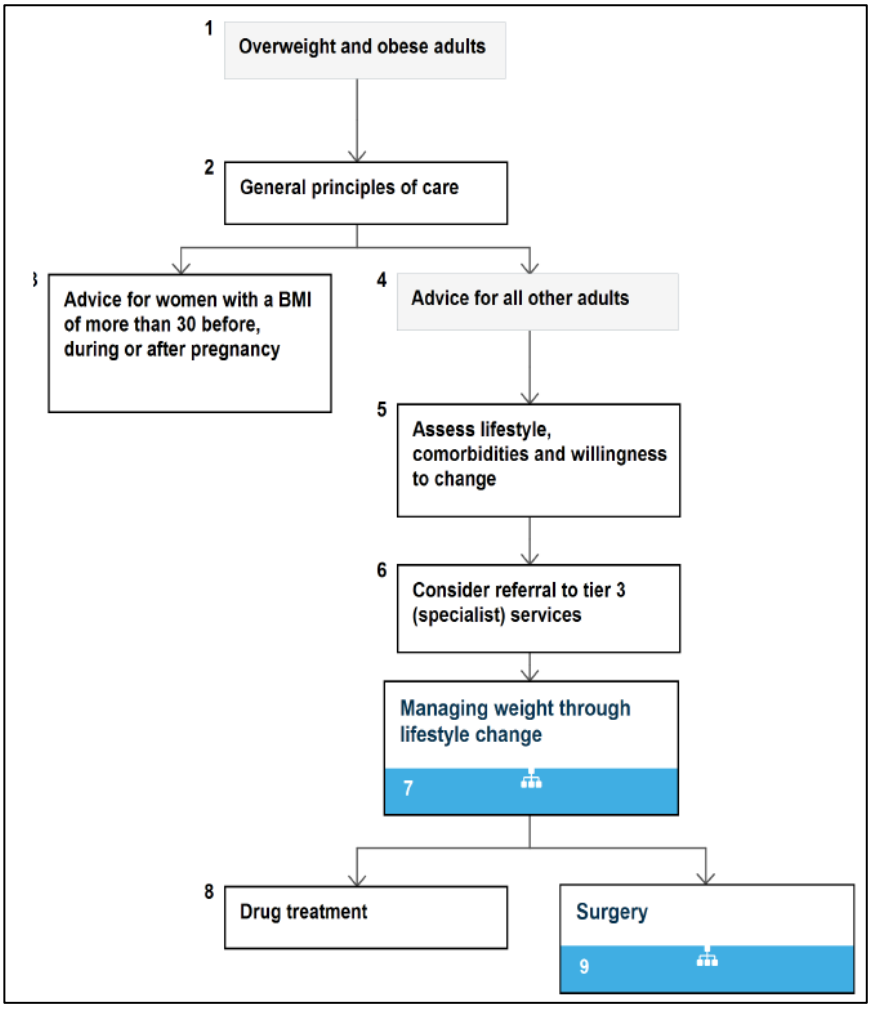
In addition to the criteria listed above, bariatric surgery is the option of choice (instead of lifestyle interventions or drug treatment) for adults with a BMI of more than 50 kg/m^2 when other interventions have not been effective.

To support commissioning of bariatric surgery services, NICE has published a costing template that enables commissioners to complete an economic modelling exercise to assist with decision-making on the thresholds at which this service will be offered [4].

NICE has also published guidance on the following surgical procedures:

- Implantation of a duodenal-jejunal bypass sleeve for managing obesity, which should only be used in the context of research [5]
- Laparoscopic gastric plication for the treatment of severe obesity, with special arrangements for clinical governance, consent and audit or research [6].

Figure 2: NICE pathway for overweight and obese adults



Source: NICE. Overweight and obese adults - NICE Pathways [7]

1.2.1 Non-Surgical Interventions

The commissioning of tier 3 obesity services is a local consideration, aimed at those individuals with either a BMI of 40 kg/m^2 or more or those with a BMI of 35 kg/m^2 or more and an additional co-morbidity. The provision of tier 3 services is variable and indeed absent in many areas [8]. In a recent mapping exercise lead by Public Health England, it was found that 13% of local authorities who responded to a survey commissioned a tier 3 service [9]. Services were primarily split between healthcare settings (GP surgery or hospital, n=21) and community/leisure centre settings (n=20). Programmes tended to be delivered on a one-to-one basis, with referrals originating from GPs, practice nurses or other health professionals. Follow up was reported to last for twelve months or longer.

NICE has published guidance which describes the constituent components of non-surgical weight-management interventions. NICE recommends that programmes are multi-component and address the following areas:

- Behavioural interventions
- Physical activity
- Dietary
- Pharmacological interventions [1].

In addition to this, NICE's public health guidance 'Weight management: lifestyle services for overweight or obese adults' recommends that commissioners ensure that weight management services are multi-component and lead by a multidisciplinary team [10].

According to the NICE obesity pathway (Managing weight through lifestyle change in adults), treatments should be selected based on individual preference, social circumstance and the outcomes of previous interventions. In addition, the individual's level of risk based on BMI, waist circumference and the presence of co-morbidities should be taken into account (see Table 2). The level of intervention should be higher for those with co-morbidities, regardless of waist circumference [11]. NICE also recommends that lower BMI thresholds should be used with black, Asian and other minority ethnic group populations due to the heightened risk of developing type 2 diabetes amongst these groups [12].

In its current form, tier 3 services are often seen as a bridging service prior to patients entering tier 4. In some instances it may even be seen as merely an intermediary step in preparing patients for bariatric surgery [13].

Table 2: NICE Obesity Intervention Risk Matrix

BMI classification	Waist circumference			Comorbidities present
	Low	High	Very high	
Overweight	1	2	2	3
Obesity I	2	2	2	3
Obesity II	3	3	3	4
Obesity III	4	4	4	4

1 = General advice on healthy weight and lifestyle

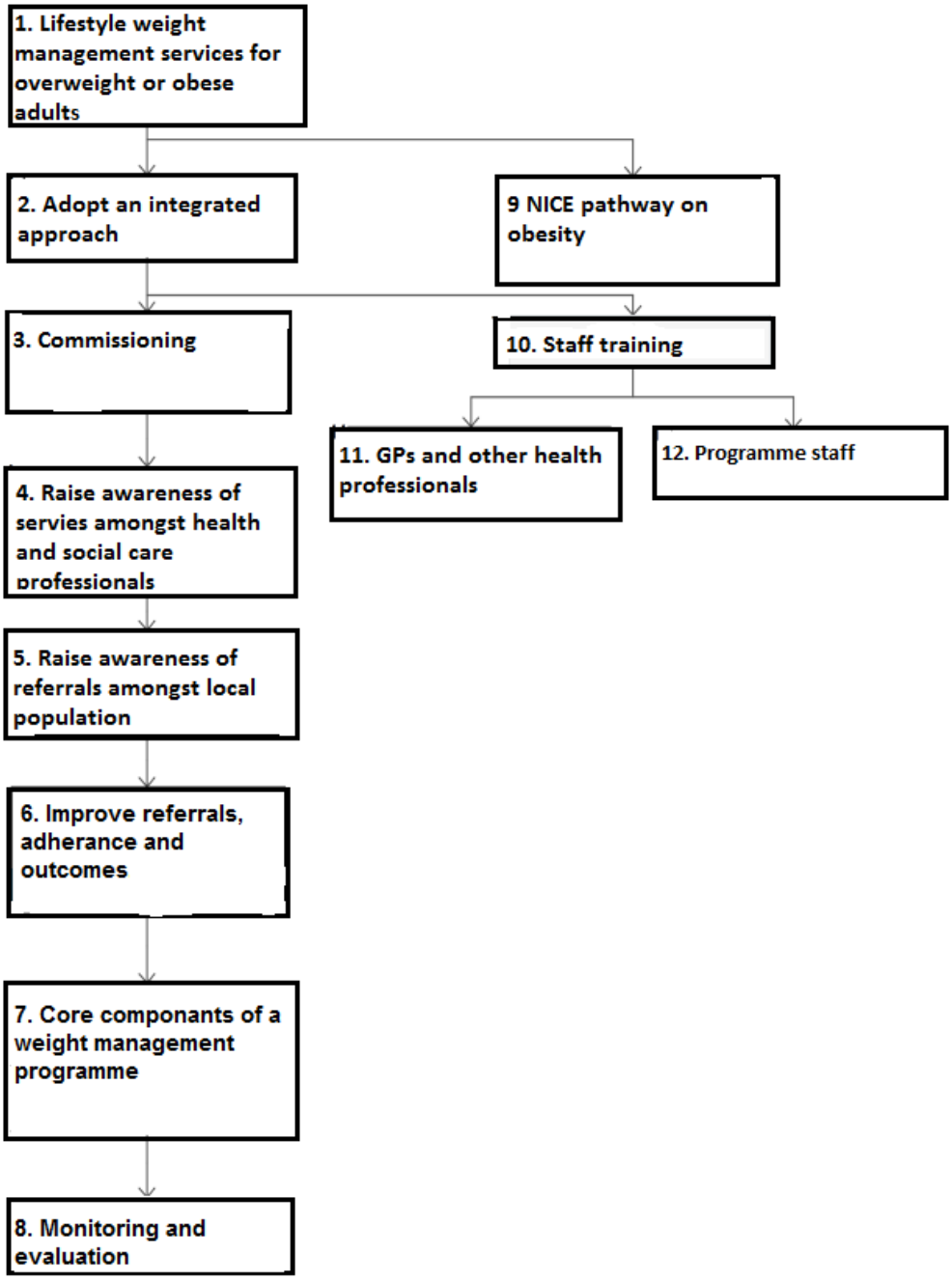
2 = Diet and physical activity

3 = Diet and physical activity; consider drugs

4 = Diet and physical activity; consider drugs; consider surgery

Source: NICE. Managing weight through lifestyle change in adults - NICE Pathways [11]

Figure 3: NICE pathway for managing weight through lifestyle change



Source: NICE. Managing weight through lifestyle change in adults - NICE Pathways [11]

2 Epidemiology

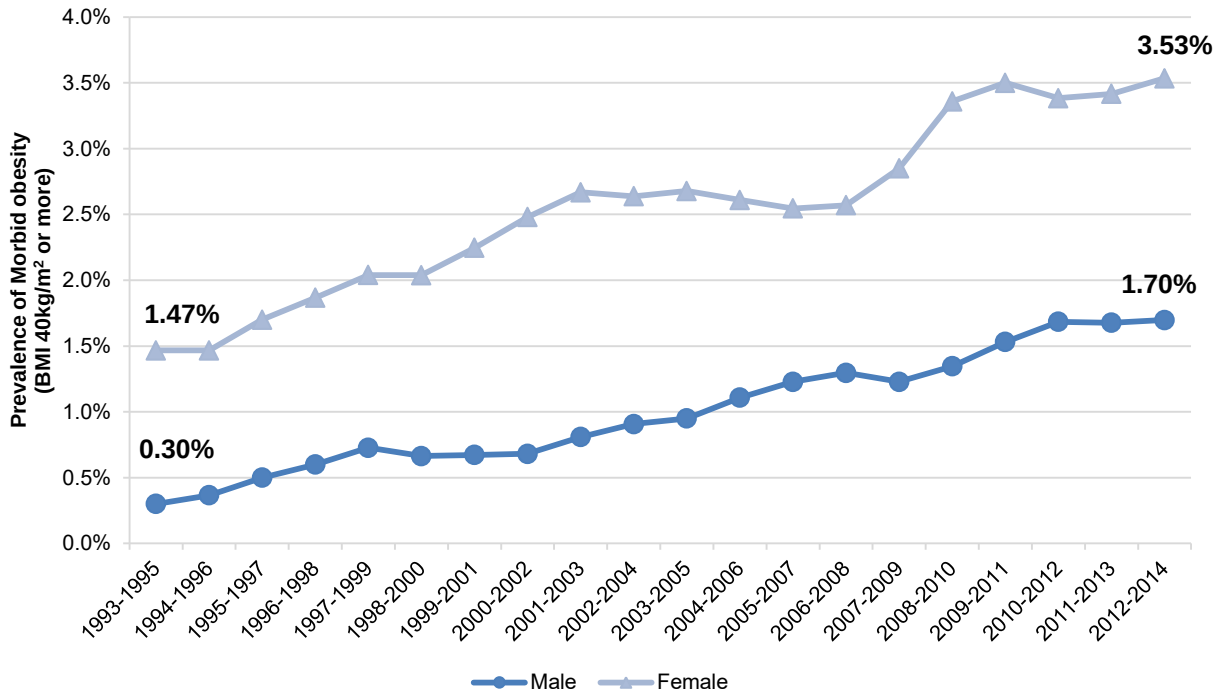
2.1 Obesity

Obesity is a global problem, estimated to have affected over six hundred million adults worldwide in 2014 [14]. In England, in both men and women, more than one in four adults are obese (28.2%) and 2.7% are classed as morbidly obese [15].

The prevalence of obesity in the UK rose between 1993 and 2014, the rate of increase began to slow in 2001 but the overall trend is still continuing to rise. According to the Health Survey for England, 61.7% of adults were overweight or obese in 2014, with more men being obese (65.3%) than women (58.1%) [16, 17]. Over the same time period, the prevalence of morbid obesity has also continued to climb, with a sharp rise in female prevalence between 2007 and 2011 (see Figure 4). Whilst the trend for males appears to have levelled off in recent years, the current level still represents a sizeable increase from that seen in the early 1990's. The number of people classed as obese in the UK is expected to increase by 11 million by 2030, with a likely corresponding increase in those with morbid obesity [18].

According to forecasts produced by the World Health Organisation, 31% of men and 30% of women will be obese by 2020, rising to 36% and 33% respectively by 2030 [19].

Figure 4: Trend in prevalence of morbid obesity among adults in UK from 1993-1995 to 2012-2014 (3 year rolling average)



Source: Health and Social Care Information Centre. Health Survey for England, 2014 [16]

2.2 Co-Morbidities

The health issues associated with being overweight or obese include type 2 diabetes mellitus, cardiovascular disease and musculoskeletal disorders amongst others. People aged 35 to 59 with a BMI measurement of between 40 kg/m^2 and 50 kg/m^2 are five times more likely to die from ischaemic heart disease than those with a BMI of 22.5 kg/m^2 to 25 kg/m^2. Between the same

groups, the risk of dying from stroke was 6.5 times higher and the risk of dying from diabetes was 22.5 times higher. Vascular risk factors also exhibit a strong relationship with BMI; both systolic and diastolic blood pressure increases with BMI [20].

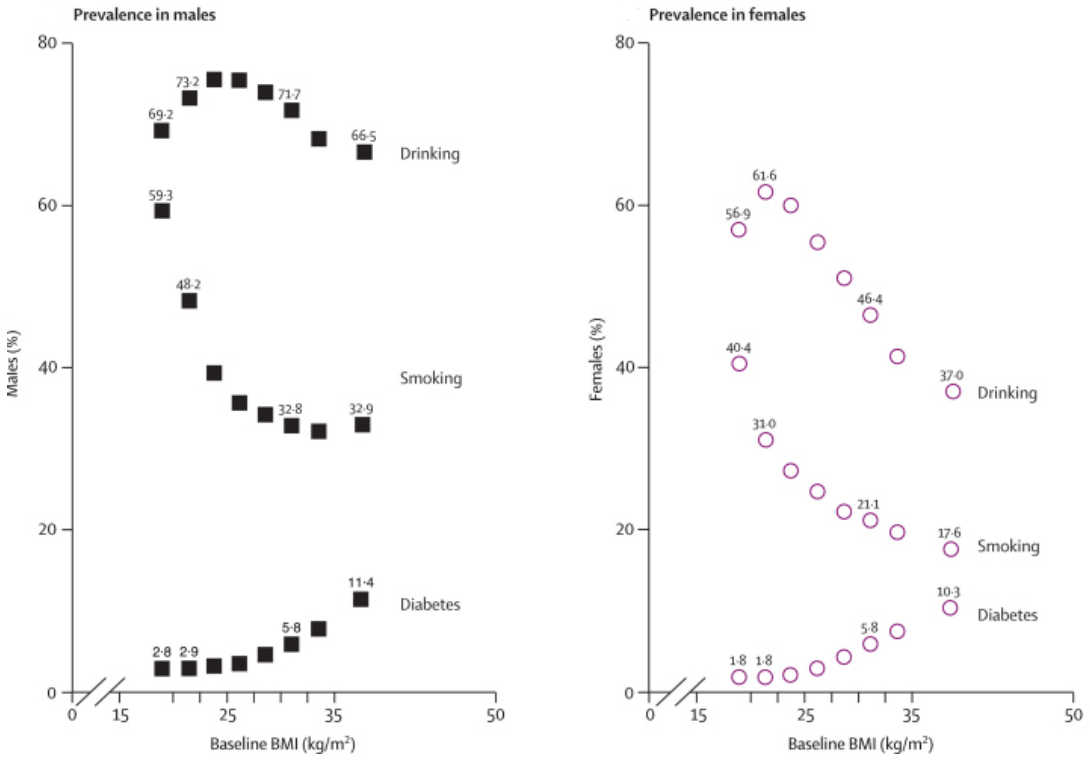
The prevalence of diabetes amongst those with normal weight was around 1.5%, compared to 15% in the severely obese [20]. A table showing the simplified relationship between BMI and health risk is shown below (Table 3). On its own, BMI is a strong predictor of mortality and is strongly associated with diabetes for which sex-specific prevalence may rise more than five-fold from baseline across the BMI range (see Figure 5) [21].

Table 3: Co-Morbidity Risk by BMI Classification

Classification	BMI (kg/m^2)	Risk of Obesity Related Co-Morbidities
Underweight	<18.5	Low risk (but risk of other clinical problems increased)
Normal Range	18.50 – 24.99	Average risk
Overweight	≥25.0	Increased risk
Obese	≥30.0	Medium to high risk
Morbidly Obese	≥40.0	Very high risk

Source: Public Health England Obesity Knowledge and Intelligence team. Severe Obesity [20]

Figure 5: Changes in prevalence of risk factors (drinking, smoking and diabetes) in males and females according to baseline BMI in the range 15–50 kg/m^2



Source: Prospective Studies Collaboration. Body-mass index and cause-specific mortality in 900 000 adults: collaborative analyses of 57 prospective studies. Lancet 2009;373 (9669):1083–96 [21].

3 The Intervention

3.1 Bariatric Surgery

Bariatric surgery includes a group of procedures that promote weight loss. They are usually performed laparoscopically, with decreased time in hospital and a shorter recovery time compared to open procedures. In the UK and Ireland, there were over 18,000 bariatric surgery operations in the three financial years ending 2011, 2012, and 2013; 95.4% of all primary operations were performed laparoscopically over this period [22]. More recently, minimally invasive surgical techniques also include robotic procedures, though their feasibility and safety are debated. Bariatric surgery may be categorised under three headings: restrictive; malabsorptive and combined procedures.

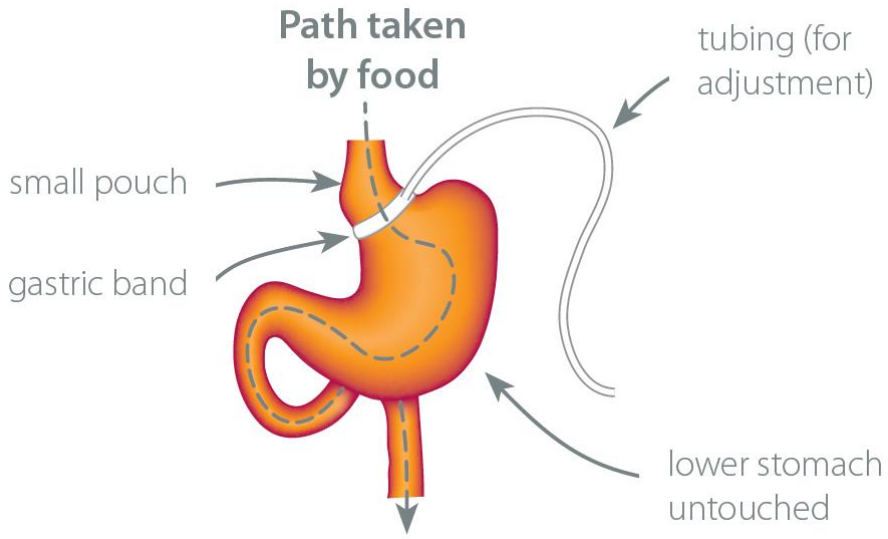
3.1.1 Restrictive procedures

Restrictive procedures, described below, lead to a fixed or adjustable reduction in the size of the upper gastrointestinal tract.

Adjustable gastric banding (AGB)

This procedure places an adjustable silicone band around the upper stomach, creating a small pouch above the band and a narrowing between the pouch and main part of the stomach below it (Figure 6). This restricts the amount of food that can be eaten and reduces hunger sensations by pressing on the surface of the stomach. The band may be tightened or loosened by injecting or removing saline through a portal under the skin that is connected to the band. The procedure is reversible and relatively non-invasive. AGB has replaced the older restrictive gastroplasty (horizontal, vertical, and banded) procedures that are no longer performed in the UK due to poorer performance. Gastric banding made up 22.3% of all bariatric surgery operations in the UK between 2011 and 2013 [22, 23, 24].

Figure 6: Diagrammatic representation of a gastric band in place

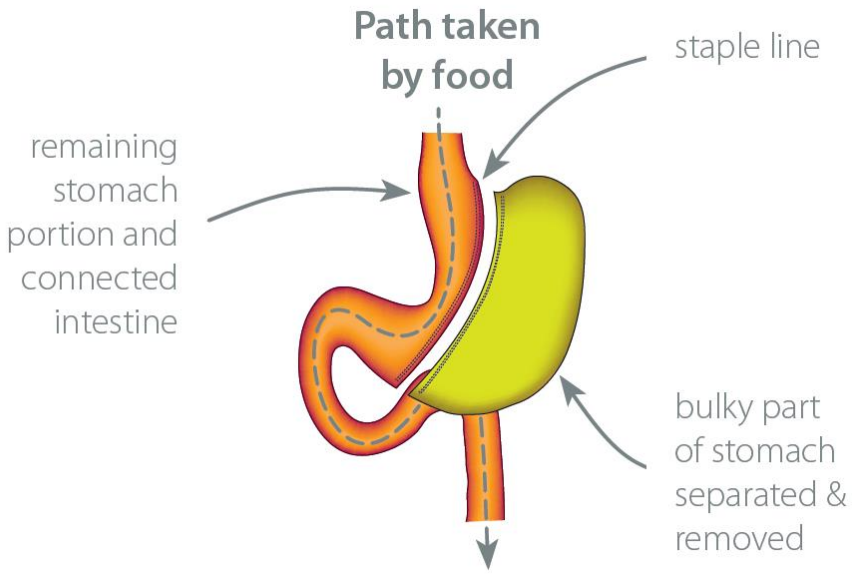


Source: National Bariatric Surgery Register. NSBR Second Registry Report. 2014 [22]

Sleeve gastrectomy (SG)

This procedure divides the stomach vertically to reduce its size by seventy-five percent, whilst keeping the stomach function and digestion unaltered by leaving the pyloric valve intact (see Figure 7). The procedure is not reversible, but is relatively quick to perform and is one of the most commonly performed restrictive procedures. It was initially used as the first of a two-part procedure for patients at high risk from bariatric surgery, followed by a conversion to either a Roux-en-Y gastric bypass or a duodenal switch (see below). However, as some patients achieve significant weight loss with the sleeve gastrectomy alone, it is now also used as a stand-alone procedure. In some patients, the procedure may be followed by a duodenojejunal bypass, which involves bypassing the first part of the small intestine, resulting in food moving directly to the latter part of the small intestine, thereby reducing absorption of calories. SG made up 20.8% of all bariatric surgery operations in the UK between 2011 and 2013 [22]. A further 12 (0.07%) SG procedures were performed in combination with a biliopancreatic diversion with duodenal switch [22].

Figure 7: The basics of a sleeve gastrectomy procedure



Source: National Bariatric Surgery Register. NSBR Second Registry Report. 2014 [22]

Intragastric balloon (IGB)

Intragastric balloon procedures involve placing a silicon balloon endoscopically to float freely inside the stomach, thereby reducing the volume of the stomach, leading to an earlier sensation of satiety. It is typically used either in patients who are at least 40% of their optimal weight, or in morbidly obese patients for whom surgery is high risk. IGB made up 2.1% of all bariatric surgery operations in the UK between 2011 and 2013 [22].

Gastric plication (or gastric imbrication)

A newer procedure that reduces the stomach volume by folding the stomach into itself and stitching it to create a narrow tube shape, similar to that of SG, but without removing any stomach tissue (Figure 6). The Registry report does not present the exact number or proportion of all

bariatric surgery operations that involve gastric plication. However, it is less than the 2.1% procedures labelled as 'other' in the Registry report [22].

3.1.2 Malabsorptive procedures

Malabsorptive procedures bypass a section of the intestine, with less physical restriction of food intake.

Biliopancreatic diversion (without duodenal switch)

This procedure is typically no longer performed in the UK due to risk of postgastrectomy syndrome (including, for example, dumping syndrome, bile reflux, diarrhoea). It involved portions of the stomach being removed through a horizontal gastrectomy (a restrictive procedure), with the small remaining pouch being connected to the final section of the small intestine. This is now replaced with the biliopancreatic diversion with duodenal switch (BDDS) procedure, which may be classed as a combined procedure (see group 3 below).

Jejunoileal bypass (JIB)

This procedure is no longer performed in the UK, where a significant part of the small intestine was detached and set to the side.

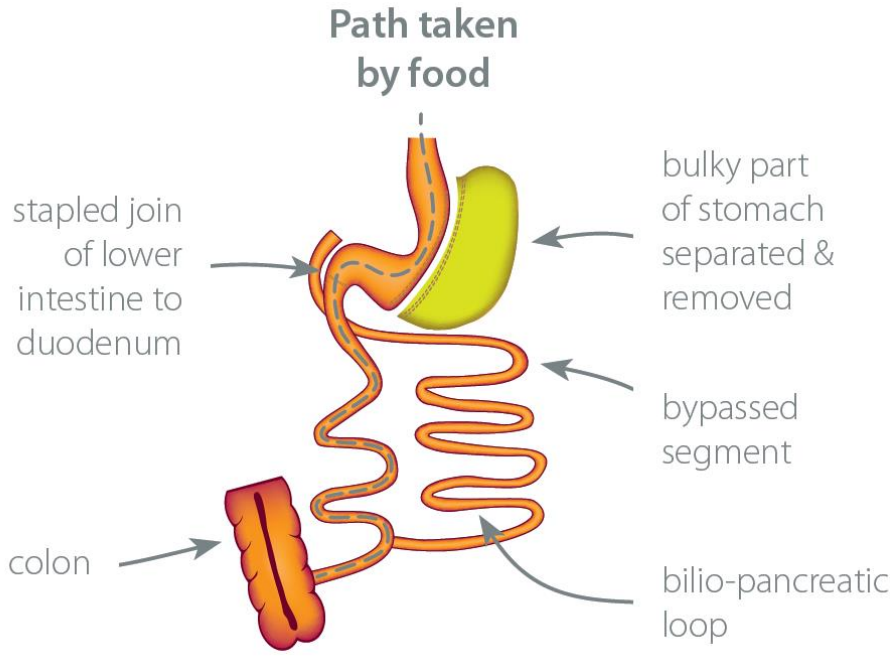
3.1.3 Combined procedures

Combined procedures include both restrictive and malabsorptive components.

Biliopancreatic diversion with duodenal switch (BDDS)

Biliopancreatic diversion with duodenal switch involves an initial restrictive vertical gastrectomy, followed by the malabsorptive component which re-routes a long portion of the small intestine, creating two separate pathways and one common channel (Figure 8). The shorter of the two pathways, the digestive loop, takes food from the stomach to the common channel. The longer pathway, the biliopancreatic loop, carries bile from the liver to the common channel. This procedure reduces the amount of time the body has to capture calories from food in the small intestine, and selectively limits the absorption of fat. The procedure is partially reversible, but there were only 19 BDDS procedures (0.1%), together with a further 12 procedures combined with SG in the UK between 2011 and 2013 [22].

Figure 8: Biliopancreatic diversion with duodenal switch

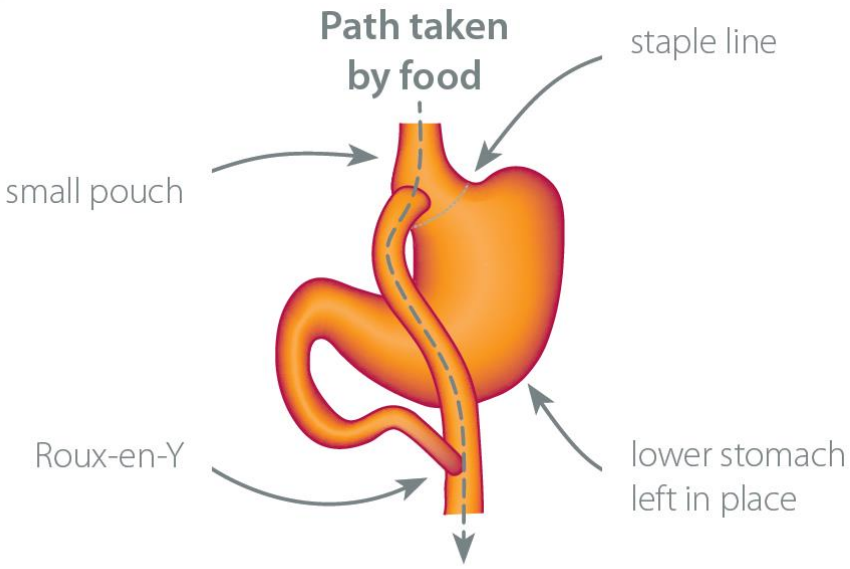


Source: National Bariatric Surgery Register. NSBR Second Registry Report. 2014 [22]

Roux-en-Y gastric bypass (RYGB)

Roux-en-Y gastric bypass has replaced the older banded gastric bypass, and involves creating a small pouch from the stomach which remains attached to the oesophagus at one end, and connected to a section of the small intestine at the other end, thereby bypassing the remaining stomach and the initial loop of small intestine (Figure 9). This procedure reduces intestinal absorption. Adaptations of the procedure have been used to increase malabsorption and increase weight loss. The procedure is technically reversible. Roux en Y gastric bypass comprises 52.1% of bariatric surgery in the United Kingdom [22].

Figure 9: Diagrammatic representation of a Roux-en-Y gastric bypass procedure



Source: National Bariatric Surgery Register. NSBR Second Registry Report. 2014 [22].

3.2 Non-Surgical Interventions

Non-surgical interventions for obesity consist of a wide variety of measures which may be used in varying combinations as part of a multi-component pathway. Generally this comprises dietary intake, physical activity levels and behaviour change and may also include pharmacological interventions [25]. These should be clinically lead and involve multi-disciplinary assessment [13].

In 2014 the Royal College of Surgeons and the British Obesity and Metabolic Surgery Society released commissioning guidance pertaining to tier 3 weight assessments and management clinics [13]. This provides thresholds for GPs referring into a tier 3 service (see Table 3), though it should be noted from the report that these BMI thresholds were chosen purely due to them matching classifications commonly used in research literature:

"The current BMI thresholds for surgery were chosen arbitrarily as the criteria for referral into the clinic since the quoted literature predominantly refers to patients in these groups."

Table 3: Referral Thresholds for tier 3 Services

BMI (kg/m^2)	Co-Morbidity	Comment
≥40	None	
≥35 to <40	Type 2 Diabetes	May be reduced by 2.5 kg/m^2 in Asians
≥35 to <40	Obesity related co-morbidity (e.g. metabolic syndrome, hypertension, obstructive sleep apnoea, depression etc.)	Occasionally patients may be referred who do not meet these thresholds, such as those presenting with weight regain post bariatric surgery

The tier 3 service should be provided via a multidisciplinary team containing a bariatric physician, dietitian, specialist nurse, clinical psychologist and a liaison psychiatry professional. In addition to this there should also be access to a physical therapist.

Non-surgical weight-management interventions (also known as 'Lifestyle Interventions') are commonly split into four categories:

1. Behavioural interventions
2. Physical activity
3. Behaviour change
4. Pharmacological interventions.

Interventions should be seen as multicomponent and incorporate combinations of the interventions described below.

3.2.1 Behavioural interventions

Behavioural interventions are provided with the support of an appropriately trained professional and include various strategies for adults which are incorporated as appropriate. These include (but are not limited to) self-monitoring of behaviour and progress, stimulus control, goal setting, ensuring social support is available, cognitive restructuring (modifying thoughts), reinforcement of changes and providing strategies for dealing with weight regain [1].

3.2.2 Physical Activity

Encouragement should be given to increase levels of physical activity, regardless of whether this will lead to weight-loss. This is due to the general fitness improvements it can bring and the associated reduced risk of cardiovascular disease and type 2 diabetes. This may comprise of 45-60 minutes of moderate-intensity exercise per day, increasing to 60-90 minutes for those who have already lost weight to prevent regaining of excess weight. Suitable activities include brisk walking, gardening, cycling, supervised exercise programmes, swimming, stair-climbing etc [1].

3.2.3 Dietary

Dietary interventions should not be unduly restrictive but should be tailored to individual food preferences and also be nutritionally balanced. As with physical activity, dietary improvements should be encouraged for reasons other than weight loss alone due to the associated health benefits which a balanced diet can bring. The primary requirement for a dietary intervention however is to reduce energy intake to a point below energy expenditure by approximately 600 kcal/day or by reducing fat content. This should be partnered with expert support and intensive follow-up. Low (800-1600 kcal/day) and very low (800 kcal/day or less) calorie diets should be used with some degree of caution due to issues around nutritional completeness [1].

3.2.4 Pharmacological Interventions

Pharmacological interventions should only be considered after behavioural, physical and dietary interventions have been started and evaluated. This applies especially to those service-users who have not achieved their target weight loss or have plateaued. It may also be utilised to maintain weight-loss as opposed to continuing weight loss [1]. Orlistat is the only pharmacological treatment for obesity currently recommended by NICE. This medication is a lipase inhibitor which works through preventing approximately a third of consumed fat from being absorbed, However in addition to the well-documented side effects, there are potential issues related to the heightened risk of kidney problems [26].

4 Findings

We searched Medline, Embase, Cochrane Library, TRIP database and NICE Evidence on the 22nd June 2017 using the strategy detailed in the Search Strategy section. We included the 2014 Second Registry Report of the UK National Bariatric Surgery Registry as a key source for our review.

For the assessment of clinical effectiveness and safety, we identified a recent Cochrane systematic review of randomised controlled trials (RCTs) with a search date in November 2013 [23]. In addition to this, we therefore included only systematic reviews and meta-analyses with search dates after that of the Cochrane review, together with any more recently published randomised controlled trials (RCTs). However, for any comparisons not included in the Cochrane review, we included systematic reviews, meta-analyses, and RCTs published in the last ten years.

For the assessment of cost effectiveness, we identified a 2009 Health Technology Assessment (HTA) with a search date in August 2008 [27]. In addition to the HTA report, we therefore included only economic evaluation studies (cost effectiveness, cost-utility, cost-benefit, cost-consequence studies) published after that date.

We excluded studies of the following procedures no longer in current use (as per the approach taken by the 2014 Cochrane review):

- Jejunoileal bypass
- Horizontal gastroplasty
- Vertical banded gastroplasty or vertical gastroplasty (not banded)
- Banded gastroplasty that is not adjustable
- Banded gastric bypass
- Biliopancreatic diversion (without duodenal switch).

The search was also limited to English language publications and we excluded conference papers, letters, commentary and editorials.

4.1 Evidence of effectiveness

4.1.1 Clinical effectiveness

In addition to the Cochrane systematic review by Colquitt et al, we found three more recently published systematic reviews and five RCTs. Of the systematic reviews, the first, by Hachem et al, was published in 2015 [28]. and the second, by Cheng et al, was published in 2016 [29]. In addition to these, a third review investigating mortality, cardiovascular events and cancer outcomes was published by Zhou et al in 2016 [30].

The review by Hachem et al includes seven trials (n=2,281), one RCT and six non-randomised controlled trials (NRCT) and looks exclusively at quality of life (QoL) outcomes. Because of this it will only be discussed in the quality of life section of this rapid review.

The systematic review and meta-analysis, conducted in China by Cheng et al [29] pooled results from 25 RCTs, comparing surgical to non-surgical interventions in obese patients (BMI > 30 kg/m^2). The review included subgroup analyses, sensitivity analyses and assessment of publication bias. Of the 25 trials included, 12 covered the 'severe obesity' BMI range (BMI > 35 kg/m^2). Whilst this straddles the range being investigated in this rapid review, the majority of studies covered a BMI of more than 40 kg/m^2.

The review by Cheng et al was investigated but not included due to several concerns about the methodology used, particularly the meta-analyses. Chief amongst these is the considerable level

of heterogeneity reported by the authors, an issue previously recognised by Colquitt et al and the reason for the lack of meta-analyses in the Cochrane review. The reasons for this heterogeneity are a combination of differences in surgical procedures, non-surgical interventions and chemical examination techniques. I^2 values (a statistical technique for quantifying heterogeneity) are predominantly above the 50% threshold of substantial heterogeneity as specified by the Cochrane Handbook for Systematic Reviews of Interventions [31]. Although sub-group analyses have been performed by Cheng et al in an effort to counteract heterogeneity, this means a reduction in the power of the analysis for individual sub-groups would be expected. In addition to this, it appears that sub-groups were established post-hoc rather than being pre-specified. This approach constitutes data-dredging according to the Cochrane Handbook for Systematic Reviews of Interventions, a technique which makes it possible to identify false explanations for heterogeneity [32].

Cheng et al's review included the same seven papers included by Colquitt et al which investigated differences between surgical and non-surgical weight-loss interventions. Two of the additional studies included by Cheng et al are included in this rapid review, however an additional eight trials were identified by Cheng et al that were not captured by Colquitt et al. On inspection, these were found to be not relevant to this rapid review for reasons relating to the study design (e.g. not being an RCT), the BMI range, the age of participants, use of surgical procedures that are not used in the UK or a focus on outcomes that are of low relevance.

Similar issues were present in the systematic review and meta-analysis performed by Zhou et al [30]. In this moderate quality study, the authors found substantial heterogeneity amongst the included trials and this is likely to be due to the aforementioned reasons of differences in participants, interventions, outcome definitions and study design. Of the comparisons made which did not show substantial heterogeneity amongst the included RCTs (as measured by I^2 values), statistically significant findings were not identified. The authors also encountered issues with the follow-up time and samples sizes of the included RCTs, ultimately concluding that the evidence from RCTs was inadequate for assessing the long-term effects of bariatric surgery for their selected outcomes. It should be noted that all RCTs included by Zhou which are relevant to this rapid review have been included as part of Colquitt et al's Cochrane review or are discussed as an individual RCT in the body of this rapid review.

For these reasons the findings reported by Cheng et al and Zhou et al have not been incorporated into this rapid review (other than in summary form in Evidence Table 1) and Colquitt et al remains the anchoring paper. It should be noted however that, despite our concerns with the methodology used, Cheng et al and Zhou et al's findings are consistent with those reported by Colquitt et al.

In this section of the report, we provide a brief overview of the methodology of the two systematic reviews before going on to describe their results alongside, where relevant, those from any individual RCTs identified. Detailed findings of the systematic reviews and individual studies are summarised in the evidence tables.

Systematic reviews

Colquitt 2014

The Colquitt study was a well-conducted systematic review published in 2014 which included seven RCTs [33, 34, 35, 36, 37, 38, 39] comparing surgical procedures to non-surgical therapy (n=618) and which followed a rigorous procedure. Five of the seven studies which were included (Dixon 2008 [33], Dixon 2012 [34], Liang 2013 [36], Mingrone 2012 [37] and O'Brien 2006 [38]) had adequate allocation sequence generation, with one of these (O'Brien 2006 [38]) having adequate concealment of allocation.

A small number of limitations were identified with the Cochrane review and are specified in Evidence Table 1. These include how representative the participants of the included studies are, with the majority being female, aged on average between 30 and 50 years, and morbidly obese. This may limit the generalisability of the findings, particularly considering the greater benefit which may be derived from younger adults who have a longer period to accrue benefits. Moreover, participants in the reviewed studies may not fully represent those seen in clinical practice, because many trials focused on low risk patients and, until recently in the UK, much surgery was performed on more unwell and more obese patients with more advanced complications. Lastly, we cannot determine whether study participants underwent tier 3 (or equivalent) non-surgical interventions before surgery.

The authors of the Cochrane review encountered difficulties combining results of these studies for meta-analysis so, instead, discussed the results narratively. The reason for this is the observed heterogeneity in the study characteristics, thought to be caused by variation in the characteristics of the participants, interventions and comparators. These reasons are consistent with those commented on by Cheng et al. The lack of a meta-analysis also precluded the possibility of performing planned sub-group analyses (e.g. whether clinical effectiveness varies by baseline BMI, so as to support a higher BMI threshold to that set by NICE).

Hachem 2015 [28]

This moderately well conducted systematic review by Hachem et al [28] included six studies (five non-randomised controlled trials and one RCT, n=2,281) comparing gastric bypass or gastric banding (both open and laparoscopic) with non-surgical management in obese adults (BMI >30 kg/m^2). In one of the included studies the mean BMI was below 40 kg/m^2 for all treatment arms and a further three studies had a single treatment arm which fell below this threshold. Presence of co-morbidities were not discussed in Hachem et al's review and so these studies fall outside of the scope of this rapid review. Heterogeneity is not discussed in the review and it is unclear if a meta-analysis was intended by the researchers or not. Studies were included if they were English language, published in a peer-reviewed journal and examined QoL outcomes using standardised questionnaires. Most of the included studies reported non-surgical arms with a lower BMI than the surgical participants, potentially introducing some bias into the results. Follow-up times were variable, ranging from one month to ten years; few studies reported both short- and long-term QoL outcomes. The review is included as it provides a greater level of insight into quality of life improvements than the reviews by Colquitt et al or Cheng et al.

Randomised controlled trials

A further five individual RCTs were found comparing the clinical effectiveness and safety of bariatric surgery versus non-surgical interventions. These were published after the search date of the Cochrane review and were not included in the systematic review by Hachem. Two of these RCTs were included by Cheng et al but were deemed relevant to this review.

Halperin 2014 [40]

This single-centre, American RCT was based around the SLIMM-T2D trial and included participants with type 2 diabetes (n=38) who fell into one of two different BMI categories, below 35 kg/m^2 (n=13) or at least 35 kg/m^2 (n=25). Participants were randomised to receive either RYGB (n=19) or an intensive, multidisciplinary, medical diabetes and weight management programme called 'Why WAIT' (n=19). This non-surgical weight-loss intervention comprises a multidisciplinary approach which includes an endocrinologist, dietician, exercise physiologist, mental health provider and a diabetes nurse educator. It also includes regular medication adjustments, group exercise sessions, cognitive-behavioural therapy and group education. Selected participants were free from active cardiovascular or other diseases prohibiting them from engaging in exercise

safely or undergoing a surgical procedure. Participants were also excluded if they had uncontrolled type 2 diabetes (defined as HbA1c levels above 12%), gastrointestinal disease, drug or alcohol misuse, weight loss greater than 3% within the past three months or were participating in other weight reduction programs. Metabolic assessments were performed at baseline and then repeated when 10% weight loss had occurred or at three months if this was not achieved. Final assessments were then performed at twelve months.

The study was limited by a lack of participants with diabetes-related complications, potentially limiting the generalisability of the findings. Despite randomisation, participants in the non-surgical arm had higher baseline HbA1c and fasting glucose levels, affecting the likelihood of achieving remission.

Ding 2015 [41]

This single-centre, American RCT was also based around the SLIMM-T2D trial and included participants with type 2 diabetes (n=40) who fell into one of two different BMI categories, below 35 kg/m^2 (n=15) or at least 35 kg/m^2 (n=25). Participants were randomised to receive either laparoscopic AGB (n=18) or the 'Why WAIT' programme (n=22). Assessments and follow-up were performed as described by Halperin et al, with baseline assessment being followed at 10% weight loss or three months and then at twelve months. This study followed an intention-to-treat methodology inclusive of all randomised participants who had been assessed at least once. The required sample size was calculated to be twenty-two participants per treatment arm in order to achieve 80% power, meaning the study may lack power to some extent. This was due to four surgery patients withdrawing consent and another being found to have severe aortic dilation. The included cohort was thought to be representative of a population with relatively advanced disease but had comparatively few patients with diabetes-related co-morbidities. It may therefore lack generalisability to a population with earlier, milder disease or those with more advanced diabetes-related complications.

Mingrone 2015 [42]

Mingrone et al conducted a single-centre RCT (n=60) in an Italian diabetes unit which allocated participants to receive either medical treatment (n=20), RYGB (n=20) or BPD (n=20). This study follows the same participants as the 2012 trial by Mingrone et al, included in the Cochrane review by Colquitt et al, allowing for a five year follow-up period [37]. Participants had a BMI of more than 35 kg/m^2 and a five year history of type 2 diabetes, exclusions were based on a history of type 1 diabetes, previous bariatric surgery, pregnancy, severe diabetes complications or other disorders and geographic inaccessibility.

Cummings 2016 [43]

Cummings et al undertook a single centre RCT comparing outcomes over 12 months of people aged 25-64 with type 2 diabetes and a BMI of 30 kg/m^2 to 45 kg/m^2. Participants were randomised to either laparoscopic Roux-en-Y gastric bypass (LRYGB) or intensive lifestyle and medical intervention (ILMI). Initially 23 people were randomised to the LRYGB intervention and 20 to the ILMI; however, 11 withdrew before an intervention so data for 15 participants in the LRYGB and 17 in the ILMI groups were gathered over the 12 months. The differences between those who participated and those who withdrew were significantly different in gender, disease severity and hypoglycaemic medication use. This RCT was underpowered with small numbers of participants.

Schauer 2017 [44]

Schauer et al conducted a parallel randomised controlled trial (the STAMPEDE study) in the US. This study follows the same participants as the Schauer 2012 [39] trial included in the Cochrane

review by Colquitt et al. The study reports five year outcomes whereas the 2012 paper reported results after two years of follow up. Participants were randomised to receive either intensive medical therapy alone (n=50), intensive medical therapy with LRYGB (n=50) or intensive medical therapy plus laparoscopic sleeve gastrectomy (LSG, n=50). Following randomisation, eight patients in the medical therapy group and one patient in the LSG group withdrew whilst a further six were lost to follow up and one died after four years. Participants were between 20 to 60 years of age with a diagnosis of type 2 diabetes (glycated haemoglobin level >7.0%) and BMI of 27 kg/m^2 to 43 kg/m^2. Exclusions were based on previous bariatric or complex abdominal surgery, and poorly controlled psychiatric or medical conditions. There was potential bias in the results due to an imbalance of the proportion of people withdrawing from the medical intervention arm of the trial compared to the surgical interventions. The systematic review by Colquitt et al reported that five of the seven RCTs they included were considered to have adequate allocation concealment but Schauer (2012) (and therefore Schauer 2017) was not one of them.

Other studies

Subsequent to these initial findings, two further studies (summarised in evidence table 3) were identified through consultation with clinical experts.

Borisenko 2015 [45]

This study used a modelled population based on an adult, non-smoking, Swedish population aged 41 years with and without type 2 diabetes to investigate outcomes over a lifetime horizon. The study was stratified into BMI categories of 30-34 kg/m^2, 35-39 kg/m^2, 40-50 kg/m^2 and more than 50 kg/m^2. The study outcomes are unlikely to be generalisable to a UK population and the model also reported different proportions of bariatric procedures than are seen within the UK. Post-surgical weight regain is not accounted for in the model and no co-morbidities other than type 2 diabetes are modelled. There were several inconsistencies noted between the values quoted in the abstract and text of this paper compared to what was listed within various tables and supplementary documents. However, despite these drawbacks it was felt that the insight into lifetime risk of events was relevant to this rapid review.

Gulliford 2016 [46]

A recently released Health Services and Delivery Research report by Gulliford et al investigated the effects of bariatric surgery on individuals with a BMI of more than 35 kg/m^2 using a matched cohort design (n=3,045) and Markov analysis. This study was included due to its large size, its direct relevance to the UK population and reflection of UK clinical practice. The Clinical Practice Research Datalink (CPRD) was used as the source of electronic health records (EHRs) for this study. Data held within CPRD, which comprises anonymised longitudinal patients records from UK general practices, are considered to be broadly representative of the UK population. The aim of this study was to use the cohort study data to:

- evaluate weight changes in the absence of bariatric surgery
- report the costs of health-care utilisation associated with obesity
- analyse the realistic impact of bariatric surgery on diabetes incidence and remission, and on clinical depression
- model the realistic cost effectiveness of bariatric surgery over a lifetime from a UK perspective.

In particular, the study provides important insights into the impact of bariatric surgery on diabetes risk and remission, described in more detail below.

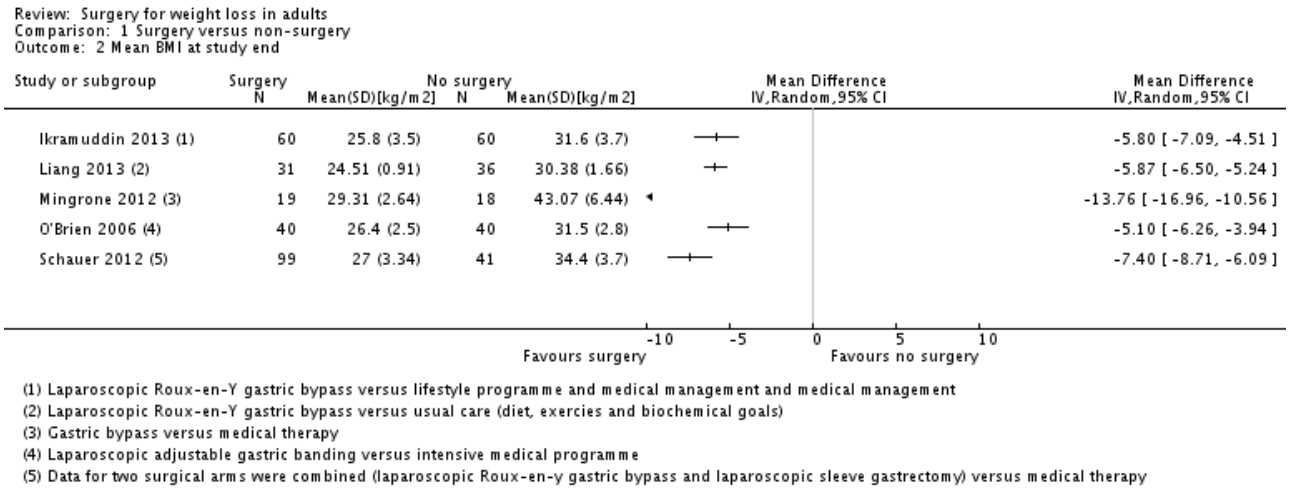
Bariatric surgery outcomes

The findings of the systematic reviews and individual studies are now described for different outcomes of bariatric surgery: weight loss, quality of life, and obesity-related co-morbidities.

Weight loss

In all seven RCTs reviewed by Colquitt et al, the mean BMI was lower following surgery than following non-surgical interventions [23] Five of these studies reported figures at a level of detail which could be analysed as a forest plot (see Figure 10). Of the seven RCTs included by Colquitt, four reported a mean BMI reduction which was greater than non-surgical therapy after either one year (Schauer 2012 [39]) or two years (Dixon 2008 [33], Dixon 2012 [34] and Mingrone 2012 [37]). In addition to this, surgical participants in four studies included by Colquitt et al (Ikramuddin 2013 [35], O'Brien 2006 [38], Schauer 2012 [39] and Dixon 2012 [34]) had significantly lower absolute weight at follow-up than non-surgical participants ($p<0.001$ or 95% confidence interval). The percentage of initial weight lost was reported by five studies included in the Colquitt review (Dixon 2008, Dixon 2012, Mingrone 2012 and O'Brien 2006) and this was routinely greater amongst surgical participants than non-surgical ($p<0.001$).

Figure 10: Forest plot showing surgical vs non-surgical BMI reduction for RCTs included in Colquitt systematic review [23]



Source: Colquitt et al. Surgery for weight loss in adults. Cochrane Database Syst Rev 2014 [23]

Updates for two of the trials included by Colquitt et al were published by Mingrone et al in 2015 [42] and Schauer et al in 2017 [44]. Mingrone et al is a single-centre, Italian RCT including participants (n=60) with a BMI of at least 35 kg/m^2 and type 2 diabetes. Surgical groups saw a reduction in BMI by 12.7 kg/m^2 (RYGB, n=20) and by 14.3 kg/m^2 (BPD, n=20) compared to a reduction by 3.3 kg/m^2 in the fifteen participants receiving medical treatment ($p<0.0001$) after five years.

Schauer et al 2017 [44] reported change in body weight, BMI, waist circumference and waist to hip ratio at five years follow up of an RCT comparing surgery (LRYGB n=49 and, LSG n=47) with medical therapy (n=38). All comparisons showed improvement for all measures after LSG and LRYGB compared to medical intervention ($p<0.05$). The reduction in body weight was greater after LRYGB than LSG ($p<0.01$).

Amongst the other individual studies identified, the RCT by Ding et al (2015)[41] investigated participants (n=45) with a BMI of between 30 kg/m^2 and 45 kg/m^2 and type 2 diabetes for at least one year. Although 37.5% of participants fell outside the BMI range of interest, the study reported a greater degree of weight loss after 12 months in participants who received a surgical (LAGB, n=23) intervention when compared to patients receiving intensive medical diabetes and weight management treatment (n=22) (13.5 kg vs 8.5 kg, p=0.027). The single-centre RCT by Halperin et al [40] compared LRYGB (n=19) against the 'Why WAIT' program (n=19). Findings were stratified by BMI classifications of less than 35 kg/m^2 (n=15) and at least 35 kg/m^2 (n=25), both with type 2 diabetes. Reductions in BMI were statistically significantly greater in the group randomised to surgery (p<0.001) after 12 months. Similarly, body-fat reduced by an average of 22.7 kg in the participants randomised to receive LRYGB, compared to 6.2 kg for those participating in the Why WAIT programme (p<0.001).

Cummings 2016 [43] reported changes in body weight, body fat and lean body mass between participants with diabetes receiving surgery and those receiving ILMI. All measures improved within each group over the 12 month period but they were greater in the surgical group than the ILMI group. Weight loss at one year was 25.8% ± 14.5% in the surgical group compared with 6.4% ± 5.8% (p<0.001) in the ILMI group. Body fat was lower within and between groups at baseline and one year (p<0.05). At 12 months follow up, lean body mass did not significantly decrease amongst participants in the ILMI arm of the trial but did in those who received surgery (p<0.05).

Quality of life

Colquitt identified two RCTs (Dixon 2012 [34] and O'Brien 2006 [38]) which compared validated measures of health-related quality of life between surgical and non-surgical interventions. One of these (O'Brien 2006 [38]) used the short form health survey (SF-36) [47] at a follow-up time-frame of two years between LAGB and a non-surgical group and identified statistically significantly higher scores for the surgical group in five out of eight domains. The second study (Dixon 2012 [34]) reported for the same time-frame and also utilised the SF-36 methodology. In this instance, Dixon (2012) identified statistically significantly greater improvements from baseline which were identified in two of the eight domains for surgical participants. Dixon (2012) also investigated the physical and mental SF-36 domains separately, reporting a statistically significant improvement in LAGB participants (p=0.04) for the physical component score but no statistically significant difference in the mental component summary score (p=0.92).

The systematic review by Hachem et al [28] of six studies (five NRCT and one RCT) reported greater improvements in quality of life in patients undergoing gastric bypass or gastric banding (both open and laparoscopic) than those undergoing non-surgical management. Of the included studies, two NRCTs reported statistically significant improvements when comparing surgical to non-surgical interventions, with the remaining studies commenting on pre- and post-operative differences between the groups. Four out of the six studies (one RCT and three NRCTs) using the SF-36 QoL measure saw improvements in physical QoL after bariatric surgery and three NRCTs out of six studies which used the SF-36 QoL measure saw improvements in mental QoL after bariatric surgery. This review included some studies where the mean BMI was less than 40 kg/m^2 but provides a greater level of insight into quality of life improvements and is included for that reason. Most of the included studies reported non-surgical arms with a lower baseline BMI than the surgical participants, perhaps introducing some bias into the results. Follow-up times were variable, ranging from one month to ten years. Few studies reported both short- and long-term QoL outcomes and most used a generic QoL measure, such as SF-36, which may not accurately capture weight-related changes. Various different questionnaires were used by the included trials, this combined with inconsistent reporting of results made drawing comparisons difficult. This was compounded by the fact that few studies made statistical comparisons between groups to identify

significant differences. In addition to these points, Hachem et al faced similar issues to Colquitt et al relating to the heterogeneity of studies which covered differing surgical procedures and non-surgical interventions.

The RCT by Halperin et al reported that the Impact of Weight on Quality of Life Questionnaire (IWQOL) score improved significantly more in RYGB participants than in non-surgical participants ($p<0.01$). However, significant differences were not identified using other QoL frameworks [40, 48].

Whilst not reported in the initial 2012 study by Mingrone et al [37] (included in the Colquitt review [23]), the 2015 follow up paper [42] reports that improvements in QoL (measured using SF-36 methodology) were statistically significantly greater in surgically treated patients than in those receiving medical treatment after five years ($p<0.0001$).

Cummings et al [43] used the EQ5D questionnaire at baseline and 12 months follow up to assess change in quality of life. For both the LRGYB and ILMI groups overall health ratings improved ($p=0.02$, 0.035 respectively) and there were no between group differences ($p=0.34$).

Schauer (2017) [44] reported some quality of life measures at five years follow up which hadn't been available in Colquitt's review [23] of Schauer (2012) [39] reporting two year outcomes. The responses to a RAND 36-item health survey were collected at baseline and at five year follow up. In general health scores, patients receiving LRYGB and LSG but not medical therapy showed significant mean changes within group from baseline to five years (LRYGB $p<0.001$, LSG $p<0.001$, medical therapy $p=0.92$). There were no changes in bodily pain scores within group for the surgical interventions (LRYGB $p=0.77$, LSG $p=0.87$). In the medical therapy group none of the quality of life elements improved significantly from baseline; bodily pain ($p=0.01$) and emotional well-being ($p=0.04$) significantly worsened. Patients in both surgical groups had significant improvements in physical functioning (LRYGB $p=0.002$, LSG $p=0.01$) and energy/fatigue elements (LRYGB $p=0.001$, LSG $p=0.001$) but emotional wellbeing worsened significantly among patients receiving LRYGB ($p=0.03$). There were no differences between baseline and follow up after any intervention for social functioning, limitations due to emotional problems or limitations due to physical health.

Obesity-related co-morbidities

Of the seven RCTs comparing surgical to non-surgical interventions in Colquitt's systematic review, all reported the effects of interventions upon co-morbidities, however the reported co-morbidities varied across the studies. These are discussed in the following sections, with findings from additional studies incorporated where relevant.

Type 2 diabetes

Five of the RCTs included by Colquitt et al (Dixon 2008 [33], Ikramuddin 2013 [35], Liang 2013 [36], Mingrone 2012 [37] and Schauer 2012 [39]) reported outcomes related to type 2 diabetes for which the evidence was of moderate quality (see Table 4). One study (Dixon 2008) found that the remission rate of type 2 diabetes was statistically significantly higher after two years in participants receiving LAGB (73% vs 13% for conventional therapy, $p<0.001$). In addition to this, a larger proportion of LAGB participants no longer needed diabetes medication (83% vs 15% in conventional therapy), though this was not tested for statistical significance. Ikramuddin (2013) reported that HbA1c levels dropped to below 6% in 44% of participants receiving LRYGB after 12 months, whereas HbA1c levels fell to this level in 9% of those receiving a lifestyle programme with medical management (NICE recommends a target of 6.5% for adults with type 2 diabetes). In the same study, a greater proportion of participants experienced diabetes remission in the LRYGB group (90%) as opposed to none of those receiving usual care or usual care plus exenatide (a

diabetes medication) therapy. Mingrone (2012) reported that after two years, 75% of participants receiving gastric bypass experienced diabetes remission compared to none amongst those receiving medical therapy (p<0.001), however, it is unclear if this study used an intention-to-treat methodology. Comparing LRYGB or LSG against intensive medical therapy, Schauer (2012) found that surgery yielded greater proportions of patients achieving a below threshold level of HbA1c (LRYGB 42%, LSG 37% and intensive medical therapy 12%). Schauer (2012) reported that more patients receiving surgery (LRYGB and LSG) stopped taking diabetes medication compared to those receiving medical therapy (78%, 51% and 0% respectively, p<0.05).

Table 4: RCTs of surgery versus non-surgery for diabetes, overview of results from Colquitt et al [23]

Study	Outcome	Surgery	No surgery	P value
Dixon 2008 [33]	Remission of type 2 diabetes at 2-years	22/30 (73%)	4/30 (13%)	RR 5.5 (95% CI 2.2 to 14.0); p < 0.001
	No diabetes medication at baseline	2/29 (6.9%)	4/26 (15.4%)	-
	No diabetes medication at baseline at 2 years	26/29 (89.7%)	8/26 (30.8%)	-
Ikramuddin 2013 [35]	% with fasting glucose <100 mg/dl at 12 months, n (%)	25 (44%)	7 (14%)	OR 5.8 (95% CI 2.1 to 15.9)
	% with HbA1c < 6.0% at 12 months, n (%)	25 (44%)	5 (9%)	OR 7.9 (95% CI 2.7 to 23.4)
	% with HbA1c < 7.0% at 12 months, n (%)	43 (75%)	18 (32%)	OR 6.0 (95% CI 2.6 to 13.9)
Liang 2013 [36]	Diabetes remission at 12 months: LRYGB v no surgery	28/31 (90%)	0/36 (0%)	-
	Diabetes remission at 12 months: LRYGB v no surgery + exenatide	28/31 (90%)	0/34 (0%)	-
Mingrone 2012 [37]	Diabetes remission at 2 years, n/N (%)	15/20 (75%)	0/18 (0%)	p < 0.001
Schauer 2012 [39]	Glycosylated haemoglobin ≤6% at 12 months, n (%): LRYGB	21 (42%)	5 (12%)	p = 0.002
	Glycosylated haemoglobin ≤6% at 12 months, n (%): LSG	18 (37%)	5 (12%)	p = 0.008
	n (%) of patients taking no diabetes medications: LRYGB	38 (78%)	0	p < 0.05
	n (%) of patients taking no diabetes medications: LSG	25 (51%)	0	p < 0.05

The follow up study by Mingrone et al in 2015 [42] noted that type 2 diabetes remission rates peaked at two years follow-up, with a degree of relapse seen at five years. RYGB saw a 75% remission rate at two years, falling to 37% at five years. No medical patients experienced remission and this difference between surgical and non-surgical arms was statistically significant (p<0.0001).

The update by Schauer (2017) [44] reported that, among the 134 patients who completed five years of follow up, two (5%) in the medical therapy group, 14 (28.6%) in the RYGB group and 11 (23.4%) in the LSG group achieved a glycated haemoglobin level of 6.0% or less. The differences

between medical and surgical groups were statistically significant (for RYGB versus medical therapy p=0.003; for LSG versus medical therapy p= 0.02 in favour of surgery). There was no difference in the change of glycated haemoglobin between the two surgical groups (p=0.488). Duration of diabetes of less than eight years was the main predictor of achieving a glycated haemoglobin level of 6% or less (p=0.008).

The number of patients taking no diabetes medication at five years was 22 (45%) in the RYGB group and 11 (25%) in the LSG group (between surgical groups p<0.05 in favour of RYGB). All those who received medical therapy were taking medication at five years.

Halperin et al [40] found that RYGB led to a greater proportion of participants achieving a target HbA1c level than the non-surgical group (58% vs 16%, p=0.03) at 12 months. In addition to this the change from baseline was significantly greater after 12 months in participants receiving RYGB than the non-surgical group.

No significant differences in HbA1c or fasting plasma glucose levels were identified by Ding et al [41] however it should be noted that the population of this study consisted of participants with relatively advanced type 2 diabetes with comparatively few related complications.

Cummings et al [43] found that the primary endpoint of diabetes remission in their study (glycated haemoglobin ≤ 6% and no diabetes medications) at one year was achieved in 60% of participants in the RYGB group and 5.9% who received intense lifestyle and medical interventions (p=0.002). The odds ratio for diabetes remission at one year after RYGB compared with intense lifestyle and medical interventions was 19.8 (95% CI 2.0, 194.65, p=0.003).

Gulliford et al[46] identified that the incidence of diabetes per 1000 person-years was 5.7% (95%CI 4.2 – 7.8) in the surgical group, compared to 28.2% (95%CI 24.4 – 32.7) in the non-surgical cohort. This is an important finding which highlights that patients receiving surgery remain at risk of developing type 2 diabetes in the years following surgery; however this risk is much reduced when compared to those not receiving surgery. In addition to this, the rate of remission amongst surgical participants is substantially higher than amongst non-surgical participants, ranging from 30% to 17% in the five years following surgery. This compares to a range of 4% to 6% remission in non-surgical participants.

Cardiovascular risk and hypertension

Three RCTs reported by Colquitt et al (Dixon 2008 [33], Mingrone 2012 [37] and Ikramuddin 2013 [35]) investigated the differential effects of weight management interventions on hypertension (see Table 5). Two of these (Dixon 2008 and Mingrone 2012) reported greater reductions in the use of hypertension medication at two years amongst those receiving surgery and Mingrone (2012) also reported a greater proportion of surgical patients experiencing a reduction in systolic blood pressure below a threshold of 130mm Hg. Mingrone et al's 2015 [42] follow-up paper was consistent with these findings, reporting that a greater proportion of medically treated participants (73%) required antihypertensive drugs than participants receiving RYGB (58%, P=0.0359).

Table 5: Surgery versus non-surgery for hypertension, overview of results from Colquitt et al[23]

Study	Outcome	Surgery	No surgery	P value
Dixon 2008 [33]	Antihypertensive agents at baseline, n/N (%)	20/29 (70%)	15/26 (57.7%)	
	Antihypertensive agents at 2 years, n/N (%)	6/29 (20.7%)	15/26 (57.7%)	
Ikramuddin 2013 [35]	% with systolic BP < 130 mm Hg at 12 months, n (%)	48 (84%)	44 (79%)	OR 1.7 (95% CI 0.6 to 4.6)
Mingrone 2012 [37]	Reduction/discontinuation of antihypertensive therapy, %	80%	70%	

In contrast to Colquitt and Mingrone's findings, Ding et al [41] identified a statistically significant greater reduction in systolic blood pressure from baseline at 12 months after non-surgical intervention than LAGB (P=0.038). Halperin et al [40] compared RYGB to the 'Why WAIT' programme and found that both systolic (P=0.02) and diastolic (P=0.001) blood pressure were lower at one year in participants receiving RYGB surgery.

Schauer 2017 [44] reported no significant changes in blood pressure between baseline and five years between or within the three intervention groups whereas Cummings et al reported a decrease in systolic blood pressure (but not diastolic) from baseline to 12 months in the surgical group (p=0.003) but not in the lifestyle and medical therapy group (p=0.23).

Metabolic syndrome

Colquitt et al reported on metabolic syndrome, however varying definitions of this were used by the included studies. Four RCTs included by Colquitt et al (Dixon 2008, Dixon 2012, O'Brien 2006 and Schauer 2012) identified reductions in proportions of participants with metabolic syndrome which were greater amongst those receiving a surgical intervention. Dixon (2012) reported the proportion of participants who had metabolic syndrome after two years compared to those with metabolic syndrome at baseline. This was lower (53%) in the laparoscopic adjustable gastric banding group than the conventional therapy group (92%), with the changes from baseline (-47% and -8% respectively) differing significantly between the groups (p=0.005) [34]. This was reinforced in findings by O'Brien (2006) who identified that the proportion of participants with metabolic syndrome after two years was 2.7% in the LAGB group and 24% in the intensive medical programme group despite both starting at a baseline value of 37.5% [38]. This difference was statistically significant (p<0.006). Schauer (2012) identified that a greater proportion of surgical participants experienced resolution of metabolic syndrome when compared to medical therapy alone [39].

Lipids

Lipid normalisation was reported by two studies included by Colquitt et al (Dixon 2008 and Mingrone 2012). Dixon (2008) reported reductions from baseline in the use of lipid-lowering agents after two years follow-up, these reductions being greater amongst those receiving LAGB as opposed to conventional therapy (27.6% vs 3.9%). Mingrone (2012) [37] reported on normalisation of lipids after two years, these being significantly greater in the GB group as opposed to the medical therapy group (100% vs 27.3%, P<0.001). The same direction of change was also identified for HDL cholesterol (100% vs 11.1%, P<0.005) and triglycerides (85.7% vs 0%, P<0.001). One study included by Colquitt (Ikramuddin 2013) et al found no difference in the proportions with LDL cholesterol below 100 mg/dL after one year between those receiving LRYGB with a lifestyle programme as opposed to a lifestyle programme alone [35].

At five years follow up Schauer (2017) [44] found the decrease from baseline in triglyceride levels (RYGB versus medical therapy p=0.03, LSG versus medical therapy p=0.04, RYGB versus LSG p=0.47) and increase in high density lipoproteins (RYGB versus medical therapy p=0.012, LSG versus medical therapy p=0.016, RYGB versus LSG p=0.75) were significantly greater in the two groups receiving a surgical intervention compared to the medical therapy group. Low density lipoproteins did not change either between or within the three intervention groups.

Ding et al reported that a greater proportion of LAGB patients achieved reductions of LDL cholesterol below threshold (p=0.019) than those participating in the 'Why WAIT' programme [41]. In addition to this, a greater reduction in use of lipid-lowering medication was observed in LAGB participants (p=0.029). Similar results were seen by Halperin et al when comparing RYGB against the 'Why WAIT' programme. In this trial, triglycerides were lower at one year in the surgical group (P=0.02) when compared to those receiving the non-surgical intervention (p<0.001), with HDL cholesterol increasing only in the surgical group.

Cummings et al [43] observed a decrease in triglycerides (LRYGB p=0.005 and ILMI p=0.002) and an increase in HDL cholesterol (LRYGB p=0.0004 and ILMI p=0.02) between baseline and 12 months in both the ILMI and surgical groups.

Obstructive sleep apnoea

Colquitt et al identified a single study (Dixon 2012) [34] looking at the effects of LAGB versus conventional weight-loss therapy on obstructive sleep apnoea (OSA). The proportion of participants who achieved mild OSA after two years was greater in the surgical group (27% vs 7%, p=0.04). However, one participant in the non-surgical group achieved remission of OSA, compared to none in the surgical group. Also, the proportions of participants who continued to use continuous positive airway pressure after two years did not differ significantly between the groups in this study. These findings are of some interest as Dixon's findings support the notion that bariatric surgery is more effective at driving weight loss over a two year period, with the surgical group achieving a mean weight loss of 27.8 kg compared to just 5.1 kg amongst the conventional therapy group (p<0.001). Both surgical and non-surgical groups reported a significant reduction in Apnoea-Hypopnea Index (AHI)[1] measurements with a decrease of 25.5 events/hour (reducing from 65.0 events/hour to 39.5 events/hour) in the surgical group and 14.0 events/hour (reducing from 57.2 events/hour to 43.2 events/hour) in the conventional group, however the between-group differences were not statistically significant. A post-hoc analysis showed a statistically significant positive relationship between change in weight and change in AHI (r = 0.45, p<0.001). However, when treatment arms were examined separately, the relationship was present only in the conventional therapy group. Dixon concluded that improvements in AHI tend to come from mild to moderate weight loss, with less benefit being realised as the degree of weight loss increases. This indicates a potentially complex picture around resolution of sleep apnoea from weight loss; additional factors such as age, sex and bony structures may contribute to this. The clinical picture may be further complicated by self-reported measures of quality of life, sleepiness and sleep quality. The large variance in the effects of weight loss on AHI may also indicate the study was under powered. In addition to this, the surgical procedure used (LAGB) is associated with a slower rate of weight loss than other techniques such as gastric bypass. The limited follow-up period of the study was such that a procedure which generates weight loss at a faster rate may have produced more measurable effects.

[1] The Apnoea–Hypopnea Index is an index used to indicate the severity of sleep apnoea. It is represented by the number of apnoea and hypopnea events per hour of sleep.

4.1.2 Safety

All seven studies included in the Colquitt systematic review reported information on complications and additional operative procedures; however, criteria for these differed between studies. No deaths were reported in any of the seven trials included in the review but all reported adverse events from surgery (such as operative interventions, revision surgery, port site infection) and from non-surgical interventions (such as medication intolerance, gastrointestinal problems and operative intervention requirement).

Dixon (2008) reported several adverse events amongst 30 surgical participants receiving LAGB. These included a superficial wound infection (one patient), gastric pouch enlargement requiring revision (two patients), eating difficulties and persistent regurgitation requiring band removal (one patient), post-operative febrile episode (one patient), minor hypoglycaemic episode (one patient), and gastrointestinal tract intolerance to metformin (one patient). Amongst the 30 non-surgical participants receiving conventional therapy minor adverse events associated with their medication were encountered, including gastrointestinal problems (two patients), persistent diarrhoea with metformin (one patient), and vasculitic rash (one patient). Other adverse events included multiple hypoglycaemic episodes (one patient), angina and a transient cerebral ischaemic episode requiring admission to hospital (one patient) and intolerance to very low-calorie meal replacement (two patients) [33].

Dixon (2012) reported 14 adverse events amongst participants receiving LAGB compared to 13 in the conventional therapy group. Serious event frequency was the same (17%) in each group, with both treatment arms reporting five events. Serious events in the surgically treated group were cholecystitis with pancreatitis, pouch dilation requiring repositioning, pneumonia, severe headaches and strangulated umbilical hernia. Serious adverse events in the conventional therapy group were acute abdomen, asthma, cardiac and renal failure, angina and peri-anal abscess and fistula. Minor adverse events were experienced by 40% of the participants in the LAGB group compared with 30% of participants in the conventional therapy group. Five participants in each group were hospitalised during follow-up [34].

Ikramuddin (2013) reported a total of 22 serious adverse events in the surgical group compared with 15 in the non-surgical group. Revision surgery was undertaken on one patient in the surgical intervention group but there were no conversions to other surgical interventions for weight loss [35].

Liang (2013) did not report complications or adverse events in detail but stated that there were no serious adverse events or deaths in any of the three treatment groups [36].

Mingrone (2012) reported no deaths and three surgical participants experiencing late complications compared to two medical participants experiencing persistent diarrhoea due to metformin use [37]. In their 2015 follow-up study, Mingrone et al [42] reported that after five years, there had been five major diabetes complications amongst four participants receiving medical therapy, including a fatal myocardial infarction. This compares with only one complication resulting from surgical intervention in the same time period. Mingrone (2015) also reported a higher incidence of metabolic adverse events amongst the surgical group than the medical treatment group after five years. Two surgical complications were noted, consisting of an intestinal occlusion in a RYGB recipient and an incisional hernia in a BPD patient, although the latter is of less relevance due to BPD not being in common usage in the UK.

A higher proportion of adverse events was noted by O'Brien (2006) [38] among non-surgical therapy participants (58%, n = 31) than in the laparoscopic adjustable gastric banding group (18%, n = 39). Non-surgical adverse events consisted of intolerance to orlistat (26%), acute cholecystitis (13%), the need for operative interventions (13%) and intolerance to very low calorie

diet (3%). Surgical adverse events included operative interventions (13%), laparoscopic revision (prolapse or posterior) (10%), 5 mm port site infection (2.6%), and acute cholecystitis (2.6%).

Schauer (2012) [39] reported that proportionally more patients who underwent L RYGB (22%, n = 11) were hospitalised due to a serious adverse event than patients who underwent sleeve gastrectomy (8%, n = 4) or medical therapy alone (9%, n = 4). Proportionally more patients who underwent LSG (80%, n = 39) and medical therapy alone (81%, n = 35) had a hypoglycaemic episode during the 12 months following surgery than patients who underwent LRYGB (56%, n = 28) [39]. Schauer (2017) [44] updated adverse events reported from this cohort of patients through to five years follow up. Excessive weight gain (5% increase in body weight over baseline) was reported in eight (19%) patients in the medical therapy group but none in either of the groups receiving a surgical intervention. Anaemia was reported by significantly more patients ($p<0.05$) in the LSG group (n=24, 49%) compared to either the LRYGB (n=14, 28%) or medical therapy group (n=7, 16%). Mild anaemia (mean haemoglobin level 11.9 ± 1.5 g/dl) was more common in the two surgical groups than the medical therapy group ($p<0.009$). Hypoglycaemic episodes were reported in significantly fewer patients ($p<0.05$) receiving RYGB (n=32, 64%) than LSG (n=40, 82%) or medical therapy (n=39, 91%).There was one late reoperation converting LSG to LRYGB due to a recurrent gastric fistula.

Amongst the three additional RCTs identified by Ding et al [41] and Halperin et al [40], and Cummings et al [43] the former of these reported four serious adverse events amongst surgical participants (one failed band placement, two prolonged hospital stays and one surgical intervention for syringomyelia) and one non-surgical participant experienced ischaemic heart disease requiring coronary artery bypass surgery [41]. Halperin et al [40] reported that adverse events amongst surgical participants included ischaemic heart disease with coronary artery bypass surgery, a new breast cancer diagnosis, nephrolithiasis, exacerbated depression with suicide attempt and hip arthroplasty (though hip pain preceded enrolment and did not improve following weight loss). Amongst non-surgical participants, three pre-syncope serious adverse events were reported. During the year of follow up Cummings et al reported 64 adverse events in the ILMI group compared to 31 in the LRYGB group. These included 43 hypoglyceamic events in the lifestyle and medical therapy group, four of which were severe (blood glucose <2.2 nmol/l, or 3.3 nmol/l with neuroglycopenic symptoms) versus 16 in the LRYGB group none of which were severe.

As noted by Colquitt et al, deaths and adverse incidents tend to be rare events. The results reported in the papers included here are unlikely to provide a clear indication of the true prevalence of these events. This is further exacerbated by the limited size and duration of the studies identified for inclusion, as well as the variation seen amongst the recording thresholds used. Not all adverse events reported are necessarily causally related to the interventions that participants were enrolled to.

Bariatric surgery performed in the UK is considered to be a relatively safe procedure, particularly considering the high-risk patients often referred for these procedures [49]. Information from the UK Bariatric Surgery Registry confirms this, reporting 11 deaths over the three financial years 2011-2013, an overall post-operative mortality rate of 0.07% for this time period [22]. This compares favourably with studies performed in the USA with mortality rates reported of 0.1% to 0.3% [22]. A recent meta-analysis of 259 studies published worldwide reported an overall 30 day mortality rate of 0.08% in included RCTs and 0.22% for observational studies [22].

4.1.3 Cost effectiveness

Adults with BMI ≥ 40 kg/m^2, no co-morbidity (Evidence Table 4)

We initially found five published studies suitable for inclusion where the costs and/or cost effectiveness had been estimated for patients who had undergone bariatric surgery procedures. The studies either clearly stated that they included patients with a BMI of at least 40 kg/m^2 or BMI of at least 35 kg/m^2 with at least one co-morbidity, or if this was not explicit but the initial BMI was high, we assumed that some of the patients included had co-morbidity.

One of these was a systematic review by Wang and Furnback (2013) [50] of six economic evaluations for the cost effectiveness of bariatric surgery. Five of the included economic evaluations modelled the cost effectiveness over the lifetime; one study used a ten year timeframe. The focus of the review was to identify and discuss the different methodological approaches that have been used in economic evaluation of bariatric surgery. Meta-analysis of these six studies was not possible due to methodological differences as well as heterogeneity between the interventions, country of origin and time horizon. Despite these differences, they found that bariatric surgery in general is cost effective, particularly LRYGB and LAGB, which were both approximately US$5,000 to US$6,000 per QALY over a lifetime time horizon, well within usually accepted cost effectiveness thresholds. None of the studies included in the systematic review were based on UK costs.

These findings were consistent with an economic evaluation by Clegg et al (2003) [51] which was included in the review by Terranova et al (2012) [52]. Clegg et al reported that over a 20 year timeframe the ICER for LRYGB and LAGB was £6289 and £8527 per QALY respectively for patients for patients who meet the current NICE criteria for bariatric surgery. This estimate is however approximately 15 years out of date.

There were two economic evaluations based on longitudinal analysis of observed patients in the USA [53, 54].The first of these matched the study cohort (n=29,820) with patients with similar health profile but no bariatric surgery [53]. They found that bariatric surgery (including open and laparoscopic RYGB and LAGB) did not reduce over health care costs utilised by insured patients over the six post-operative years studied.

The second study by Finkelstein et al 2013 [54] also assessed costs against a matched sample using US health insurance data, including 31,184 observed patients, 9,104 of whom had a diagnosis of type 2 diabetes. They report that bariatric surgery costs are redeemed after approximately two years and that there is an average net cost saving of at least US$60,000 compared to non-surgical management of morbidly obese patients. in people with a BMI of more than 40 kg/m^2 and type 2 diabetes, the time to break even is reduced to less than two years and the potential cost savings are significantly greater (due to reduction in ongoing type 2 diabetes treatment costs).

It is not clear if the net cost savings can be extrapolated beyond five years and if this is at the same rate. We note that these costs are resource utilisation costs and that they do not take into account benefit (in terms of quality or life years) to the patient. Compared to the random matched sample, bariatric surgery was less cost effective. Given that morbid obesity was not an identified diagnosis in this group, it is perhaps inappropriate for them to be identified as a comparator.

Neither of these two USA studies report cost effectiveness of the different techniques in terms, costs and outcomes (quality of life and life years); rather, the focus is on health resource utilisation which may equate to costs to a health care commissioner.

We found one UK prospective economic evaluation of 88 patients in Scotland [55]. Cost effectiveness was not reported but the NHS perspective resource utilisation focus of the study showed that, at the median follow up of two years, bariatric surgery resulted in reduced co-morbidity (including type 2 diabetes, obstructive sleep apnoea and hypertension). The consequence of this improvement in co-morbidity was a net saving of £11,452 per annum for the related medications and nearly £20,000 per annum for hospital admissions and appointments.

Adults with BMI ≥ 35 kg/m^2 and type 2 diabetes mellitus (Evidence Table 5)

We found three studies reporting cost effectiveness for bariatric surgery for adults with a BMI of at least 35 kg/m^2 and a significant co-morbidity. All of these studies focused on patients with type 2 diabetes.

The updated HTA economic evaluation by Picot et al (2012) [56] compared LAGB only to usual diabetes care and reported the QALY gain, incremental costs and the incremental cost effectiveness ratio (ICER) at two to twenty years. The evaluation used outcomes data for the first two years, and then modelled outcomes and costs to 20 years. They found that at two years post-surgery, there was only 1% probability of LAGB being cost effective at £20,000/QALY (assuming that weight loss is gradual over the 2 year period), but that over a 20 year time horizon, LAGB is highly cost effective with an estimated ICER of £1,634/QALY.

The authors noted that the QALY gains identified for laparoscopic AGB are very modest (as usual diabetes care is also associated with QALY gains) and the cost effectiveness of the surgery is highly dependent on the high costs of diabetes care. If the excess weight loss was more modest, the estimated utility per BMI unit would be less. If surgical costs increased (including post-operative costs, ongoing band adjustments etc.) or if the cost of pharmacological diabetes care was reduced, then this would also reduce the cost effectiveness of laparoscopic AGB significantly.

More recently, Hoerger et al (2010) [57] published a Markov model simulation looking at patients aged 45 to 54 years with a BMI 35 kg/m^2 or more and type 2 diabetes. They estimated the cost effectiveness of LRYGB or LAGB in both patients with newly diagnosed (no more than five years after diagnosis) and established (at least ten years after diagnosis) type 2 diabetes, using six years of outcomes data from a large US registry study and then modelled over the lifetime of the patient. They found that both bariatric procedures are highly cost effective over the lifetime for patients with type 2 diabetes (newly diagnosed and established). However, the greatest cost effectiveness was reported for patients with newly diagnosed type 2 diabetes who underwent laparoscopic RYGB. The sensitivity analysis suggests that the cost effectiveness is improved further in patients aged 35 to 44 years.

It also suggests that the cost effectiveness is reduced (by a factor of two) if the initial BMI is only 30 to 35 kg/m^2. Consistent with the UK HTA economic evaluation by Picot et al (2012), Hoerger et al also found that the cost effectiveness of bariatric surgery was highly dependent on the cost of usual diabetes care [56, 57].

A 2006 study by Ackroyd et al (2006) was referenced in a review of cost effectiveness by Terranova et al (2012) [52, 58]. This reported the UK cost per QALY of both LAGB and LRYGB to be under £2000 per QALY over the first five years after operation.

Adults with BMI ≥ 40 kg/m^2 and BMI ≥ 35 kg/m^2 with co-morbidity (mixed population) (Evidence Table 6)

We initially found five published studies suitable for inclusion where the costs and/or cost effectiveness had been estimated for patients who had undergone bariatric surgery procedures. The studies either clearly stated that they included patients with a BMI of at least 40kg/m^2 or BMI

of at least 35 kg/m^2 with one or more co-morbidities, or if this was not explicit but the initial BMI was high, we assumed that some of the patients included had co-morbidity.

One of these was a systematic review by Wang and Furnback (2013) [50] of six economic evaluations for the cost effectiveness of bariatric surgery. Five of the included economic evaluations modelled the cost effectiveness over the lifetime; one study used a ten year timeframe. The focus of the review was to identify and discuss the different methodological approaches that have been used in economic evaluation of bariatric surgery. Meta-analysis of these six studies was not possible due to methodological differences as well as heterogeneity between the interventions, country of origin and time horizon. Despite these differences, they found that bariatric surgery in general is cost effective, particularly LRYGB and LAGB, which were both approximately US$5,000 to US$6,000 per QALY over a lifetime time horizon, well within usually accepted cost effectiveness thresholds. None of the studies included in the systematic review were based on UK costs.

These findings were consistent with an economic evaluation by Clegg et al (2003) which was included in the review by Terranova et al (2012) [51, 52]. Clegg et al reported that over a 20 year timeframe the ICER for LRYGB and LAGB was £6289 and £8527 per QALY respectively for patients for patients who meet the current NICE criteria for bariatric surgery. This estimate is however approximately 15 years out of date.

There were two economic evaluations based on longitudinal analysis of observed patients in the USA [53, 54]. The first of these matched the study cohort (N=29,820) with patients with similar health profile but no bariatric surgery [53]. They found that bariatric surgery (including open and LRYGB and LAGB) did not reduce over health care costs utilised by insured patients over the six post-operative years studied.

The second study by Finkelstein et al 2013 [54] also assessed costs against a matched sample using US health insurance data, including 31,184 observed patients, 9,104 of whom had a diagnosis of type 2 diabetes. They report that bariatric surgery costs are redeemed after approximately two years and that there is an average net cost saving of at least US$60,000 compared to non-surgical management of morbidly obese patients. in people with a BMI of more than 40 kg/m^2 and type 2 diabetes, the time to break even is reduced to less than two years and the potential cost savings are significantly greater (due to reduction in ongoing type 2 diabetes treatment costs).

It is not clear if the net cost savings can be extrapolated beyond five years and if this is at the same rate. We note that these costs are resource utilisation costs and that they do not take into account benefit (in terms of quality or life years) to the patient. Compared to the random matched sample, bariatric surgery was less cost effective. Given that morbid obesity was not an identified diagnosis in this group, it is perhaps inappropriate for them to be identified as a comparator.

Neither of these two USA studies report cost effectiveness of the different techniques in terms, costs and outcomes (quality of life and life years); rather, the focus is on health resource utilisation which may equate to costs to a health care commissioner.

We found one UK prospective economic evaluation of 88 patients in Scotland [55]. Cost effectiveness was not reported but the NHS perspective resource utilisation focus of the study showed that, at the median follow up of two years, bariatric surgery resulted in reduced co-morbidity (including type 2 diabetes, obstructive sleep apnoea and hypertension). The consequence of this improvement in co-morbidity was a net saving of £11,452 per annum for the related medications and nearly £20,000 per annum for hospital admissions and appointments.

Subsequent to these initial findings, two further studies were identified through consultation with clinical experts. Since these two studies include both clinical effectiveness and cost effectiveness findings, they are covered in both sections of this report.

One of the studies (Borisenko et al 2015) was a cost effectiveness model based upon registry data from Sweden, where the case mix did not reflect UK current clinical practice. The model attempted to estimate (based upon two year post-operative outcomes data from the Swedish Obesity Surgery registry) the costs and benefits associated with bariatric surgery compared to optimal medical management (OMM) over a lifetime, as well as the impact of a three year delay to receiving surgery. This included stratifying patients groups (by gender, initial BMI and diagnosis of diabetes) to estimate differential cost effectiveness.

The model estimated that surgery was more likely to result in a lower lifetime absolute risk of diabetes in particular (14% vs 36% OMM, no p-values reported) and that, for the whole cohort, bariatric surgery was highly cost effective (estimated lifetime ICER €2050 per QALY). In addition, bariatric surgery was cost saving at 17 years post-surgery. More detailed subgroup modelling reported that over a lifetime, surgery was cost saving in all patients except for non-diabetic adults with a BMI lower than 35 kg/m^2.

The authors found that the overall lifetime cost of treatment would be increased if patients with diabetes or a BMI greater than 40 kg/m^2 waited for more than three years to receive bariatric surgery. This was due to loss of clinical benefit which resulted in a reduction of 0.6 life years and 1.2 QALYs per patient over a lifetime.

Recurrence of T2DM had been included in the model design, however we noticed some inaccuracies in the published report (including review of the data supplement for further detail about the results) which gave rise to concern about the reliability of the estimated cost effectiveness estimates. In addition we noted (as did the authors) that the case mix was not reflective of UK current clinical practice and that perhaps the reason that the lifetime estimate ICER was so low might be due to:

- Omission of weight regain post bariatric surgery
- Omission of recurrent diabetes post-surgery
- No annual costs of post-surgery support (e.g. ongoing nutritional and psychological support).

Despite these methodological weaknesses and likely overestimate of cost savings and cost effectiveness (in terms of the ICER), this study is consistent with previous studies in finding that bariatric surgery is a highly cost effective intervention with a low cost per QALY.

Most recently, a UK NIHR funded study was published 2016. This was a combination of a matched cohort study (using data from the UK Clinical Practice Research Datalink (CPRD) which comprises anonymised longitudinal patients records from UK general practices and is considered to be highly representative of the UK population overall) and a cost effectiveness model. This study found that, over a lifetime, bariatric surgery resulted in both additional QALYs and was highly cost effective with an ICER of £7129 (95%CI £6775 to £7506) per QALY. The ICER for patients with severe obesity alone was slightly higher at £7675 per QALY, but still well within UK accepted norms. The authors found that bariatric surgery was particularly cost effective in patients with morbid obesity and T2DM (£6176 per QALY).

Unlike the findings of Borisenko et al the authors of the NIHR report [46] did not find bariatric surgery to be cost saving over the lifetime but this may be because the model included a wider range of costs associated with the bariatric surgery care pathway as well as a more realistic estimate of diabetes remission and recidivism.

This study is perhaps the most reliable and authoritative estimate of the lifetime ICER. It is higher than the estimate from some of the other studies but it was based upon UK matched cohort data and UK Bariatric Surgery Registry data and included multivariate sensitivity analyses.

4.2 Evidence Summary Tables

Evidence Table 1: Summary of systematic reviews of bariatric surgery vs non-surgical interventions

Level of Evidence*	Study	Population	Intervention	Comparator	Outcomes	Comments
1a	Colquitt 2014 [23] *(Cochrane Review)* Systematic review of RCTs	"Adults who are overweight or obese as defined by the study" Whilst most studies included BMI ≥ 35 kg/m^2 with co-morbidities and BMI ≥ 40 kg/m^2, some studies also included subjects with BMI < 35 kg/m^2. (n=618, 7 RCTs)	Bariatric Surgery (AGB, RYGB, RYGB plus medical therapy, SG plus medical therapy, RYGB plus lifestyle programme) (n=316)	Non-Surgical Interventions (Conventional therapy, Intensive Medical Programme, Medical Therapy, Lifestyle programme with medical management, Usual care) (n=302) Comparison 1 (2 RCTs): Lap AGB vs Conventional Therapy Group (BMI 30-40 with T2DM, BMI 35-55) Comparison 2 (1 RCT): Lap AGB vs Intensive Medical Programme (BMI 30-35 with co-morbidity) Comparison 3 (1 RCT): Gastric Bypass vs Medical Therapy (BMI ≥35 kg/m^2 with T2DM) Comparison 4 (1 RCT): Lap RYGB/Lap SG plus medical therapy vs medical therapy alone (BMI 27-43	**Apparently meaningful difference (no p-values or 95% CIs reported)** *Note that because results could not be pooled in a meta-analysis they are reported here as apparently meaningful differences even if individual trials identified significant differences* • **Weight Loss** Compared with non-surgical interventions, surgery had a consistent effect on each of the outcome measures related to weight, regardless of the type of procedure • **Quality of Life** Two moderate quality studies reported greater improvements in SF-36 at 2 years for surgical patients than for non-surgical therapy • **Diabetes Remission** Five of the RCTs reported diabetes-related outcomes (patients with diabetes remission, diabetes medication or specified levels of glycosylated haemoglobin) Remission of type 2 diabetes after two years was statistically significantly ($p < 0.001$) higher following laparoscopic adjustable gastric banding (73%) than conventional therapy (13%) (RR 5.5; 95% CI 2.2 to 14.00) At 12 months, 44% of those in the laparoscopic Roux-en-Y gastric bypass group had a glycosylated haemoglobin level of < 6% compared with 9% in the lifestyle programme with medical management group A greater proportion of people with diabetes remission in a laparoscopic Roux-en-Y gastric bypass group (90%) than the usual care group (0%) or usual care and exenatide therapy group (0%)	• Publication bias not assessed due to low numbers of studies • Meta-analysis not performed due to differences in characteristics of participants, interventions and comparators. • Some studies were thought to not be free of selective reporting • No studies were based in the UK • Follow-up periods of 12, 18 and 24 months

Level of Evidence*	Study	Population	Intervention	Comparator	Outcomes	Comments
				kg/m^2 with T2DM) Comparison 5 (1 RCT): LRYGB plus lifestyle programme vs lifestyle programme with medical management (BMI 30-39.9 kg/m^2 with T2DM) Comparison 6 (1 RCT): LRYGB with usual care vs Usual care with pharmacological treatment (BMI >28 kg/m^2 with T2DM)	After two years, 75% of those in the gastric bypass group but none of those in the medical therapy group were classed as having a diabetes remission ($p < 0.001$) Proportionally more participants in the laparoscopic Roux-en-Y gastric bypass plus intensive medical therapy and laparoscopic sleeve gastrectomy plus intensive medical therapy groups achieved a glycosylated haemoglobin level of ≤ 6% at 12 months than patients in the intensive medical therapy alone group (42%, 37% and 12%, respectively; $p = 0.002$ for gastric bypass versus medical therapy alone; $p = 0.008$ for sleeve gastrectomy versus medical therapy alone) A higher proportion of patients in gastric bypass and sleeve gastrectomy groups were taking no diabetes medications than in the medical therapy alone group (78%, 51% and none, respectively; $p < 0.05$ for gastric bypass versus medical therapy alone and for sleeve gastrectomy versus medical therapy alone) • **Hypertension** Improvements from baseline to two years follow-up for those in the laparoscopic adjustable gastric banding group compared to the conventional therapy group in their use of anti-hypertensives (49.3%versus 0%) The proportions of participants with a reduction/discontinuation of antihypertensive therapies were 80% in the laparoscopic adjustable gastric banding group and 70% in the conventional therapy group Another trial found no difference in the proportion of people with systolic blood pressure < 130 mmgHg (odds ratio (OR) 1.7, 95% CI 0.6 to 4.6) • **Lipids** Improvements from baseline to two years follow-up for those in the laparoscopic adjustable gastric banding group compared to the conventional therapy group in their use of lipid-lowering agents	

Level of Evidence*	Study	Population	Intervention	Comparator	Outcomes	Comments
					(27.6% versus 3.9%) The proportion of participants with normalisation of lipids after two years was significantly higher in the gastric bypass group than the medical therapy group, for total cholesterol (100%versus 27.3%; p < 0.001), high density lipoprotein (HDL) cholesterol (100% versus 11.1%; p < 0.005) and triglycerides (85.7%versus 0%; p < 0.001) • **Sleep** The proportion of participants that achieved a diagnosis of 'mild' obstructive sleep apnoea after two years was statistically significantly higher in those treated with laparoscopic adjustable gastric banding (27%) compared with conventional therapy (7%) (p = 0.04) • **Adverse Events** No deaths reported overall several adverse events among people in the laparoscopic adjustable gastric banding group Frequency of serious adverse events was the same (17%) in both LAGB and conventional weight-loss groups Four early serious adverse events in the laparoscopic Roux-en-Y gastric bypass group but no events in the lifestyle programme group No serious adverse events or deaths in any of the LRYGB, no surgery and no-surgery + exenatide groups No operative deaths from gastric bypass, low numbers of late complications. Two participants in the medical therapy group had persistent diarrhoea associated with metformin A higher proportion of adverse events among those people in the non-surgical therapy group (58%, n = 31) than in the laparoscopic adjustable gastric banding group (18%, n =39)	

Level of Evidence*	Study	Population	Intervention	Comparator	Outcomes	Comments
					Comparing LRYGB and LSG (each in addition to intensive medical therapy) with intensive medical therapy alone proportionally more patients who underwent gastric bypass (22%, n = 11) were hospitalised due to a serious adverse event than patients who underwent sleeve gastrectomy (8%, n = 4) or medical therapy alone (9%, n = 4)	
1a-	Hachem 2015 [28]	BMI>30 kg/m^2 7 trials compare surgical to non-surgical interventions (n= 2,281)	Gastric Bypass, Gastric Banding (open and Laparoscopic) (n=746)	Lifestyle intervention, medical treatment, non-seeking surgery (n=1,535)	**Apparently meaningful difference (no p-values or 95% CIs reported)** • Improvements in QoL outcomes were greatest in those undergoing bariatric surgery • 4 out of 6 studies using the SF-36 QoL measure saw improvements in physical QoL after bariatric surgery • 3 out of 6 studies using the SF-36 QoL measure saw improvements in mental QoL after bariatric surgery • One study found a significant change in both the surgical and non-surgical groups from baseline on the WRSM (weight specific QoL measure) on symptom distress and number of symptoms QoL at 1 year	• Systematically reviews 6 nRCT and 1 RCT • Meta-analysis not performed • Heterogeneity not discussed • Not all studies included are BMI >40 kg/m^2 • Most studies' non-surgical arms have lower BMI • Variable follow-up time from 1 month to 10 years • Few studies reported both short- and long-term QoL outcomes • 5 studies did not compare surgical to non-surgical groups but instead compared pre and post-operative data.
1a- (inconclusive)	Cheng 2016 [29]	BMI > 30 kg/m^2 16 trials,	SG, RYGB, LAGB, BPD	Non-Surgical Interventions (Conventional therapy, Intensive	**Apparently meaningful difference (no p-values or 95% CIs reported)** ***Note that due to heterogeneity issues, only results from meta-analyses with an I^2 value ≤50% are reported and sub-group analyses are excluded. Although P values are reported by Cheng et al, they should***	• Meta-analysis performed but I^2 figures reported indicate large degree of heterogeneity between

Level of Evidence*	Study	Population	Intervention	Comparator	Outcomes	Comments
		(n=1,194)	(n=600)	Medical Programme, Medical Therapy, Lifestyle programme with medical management, Usual care) (n=594)	***be interpreted with caution due to methodological concerns*** • Waist circumference (cm) reduced by 14.59 cm (I^2=50%, p<0.00001) • Systolic pressure (mmHg) reduced by 3.5mmHg (I^2=11%, p<0.00001)	studies • Papers selected relevant to this review are also reported by Colquitt et al • Post-hoc sub-group analyses may lead to reduction in power • Different inclusion criteria to Colquitt et al with additional papers which are not relevant to this review included • Publication bias noted in the results • Findings consistent with Colquitt et al
1a- (inconclusive)	Zhou 2016 [30]	BMI > 30 kg/m^2 11 RCTs, (n=890)	RYGB, LAGB, DJBL, BPD-DS, SG, Implantable Gastric Stimulation (n=491)	Non-Surgical Interventions (Lifestyle intervention, medical intervention, gastric stimulation turned off) (n=399)	**All odds ratios reported for pooled RCT effects had confidence intervals which spanned one and so were not classed as significant.**	• Subgroup analyses to identify source of heterogeneity not possible because many studies included a mixed population • All the meta-analyses used the random-effects model • Separate analyses for RCT and non-RCT study designs • No significant publication bias detected for all-cause mortality, other outcomes not assessed due to insufficient data

Level of Evidence*	Study	Population	Intervention	Comparator	Outcomes	Comments
						• Evidence from RCTs is limited because of the relatively short follow-up and small sample sizes • Not all surgical interventions are relevant to UK clinical practice

see Appendix1

Evidence Table 2: Summary of individual RCTs of bariatric surgery vs non-surgical interventions

Level of Evidence*	Study	Population	Intervention	Comparator	Outcomes	Comments
1b	Schauer 2017 [44] Single centre RCT (the STAMPEDE study), USA	BMI 27-43 kg/m2 with T2DM Age 20-60yrs n=134	RYGB (n=49) LSG (n=47)	Medical therapy (n=38)	**Glycated haemoglobin ≤6%** predicted at 5 years if duration of diabetes <8 years at baseline (p<0.007). **Achieving 6% glycated haemoglobin** • Medical therapy group n=2 (5%) • LRYGB n=14 (28.6%) • LSG n=11 (23.4%) LRYGB vs medical therapy p=0.003 in favour of surgery LSG vs medical therapy p= 0.02 in favour of surgery. LRYGB vs LSG p=0.488 **% change in bodyweight** LRYGB vs medical therapy p<0.001 LSG vs medical therapy p<0.001 LRYGB vs LSG p=0.12 **% change in waist cm** RYGB vs medical therapy p<0.001 LSG vs medical therapy p<0.001 RYGB vs LSG p=0.122 **% change waist hip ratio** LRYGB vs medical therapy p<0.001 LSG vs medical therapy p=0.019 LRYGB vs LSG p=0.769 **Number of people taking no diabetes medications at Baseline and 5 years** LRYGB baseline n=0 (0%), 5 years n=22 (45%) LSG baseline n=1(2.1%), 5 years n=11(25%) Medical therapy baseline n=1(2.6%), 5 years n=1(2.5%) LRYGB vs LSG p<0.05 in favour RYGB **Fasting plasma glucose** LRYGB vs medical therapy p<0.003 LSG vs medical therapy p =0.02 LRYGB vs LSG p=0.35 **Decrease in triglyceride levels in favour of surgical groups** LRYGB vs medical therapy p=0.03 LSG vs Medical therapy p=0.04 LRYGB vs LSG p=0.47	• 5 year follow up of Schauer 2012 (2 year follow up reported in Colquitt et al) • BMI overlaps with range of interest but no stratification of results between <35 kg/m^2 and ≥35 kg/m^2 groups. • Large number of comparisons reported. Imputed intention to treat only carried out on primary end point (change in proportion of people with glycated haemoglobin ≤6%)

Level of Evidence*	Study	Population	Intervention	Comparator	Outcomes	Comments
					Increase in HDL cholesterol in favour of surgical groups LRYGB versus medical therapy p=0.012, LSG versus medical therapy p=0.016, LRYGB versus LSG p=0.75. **QoL – within group differences baseline to 5 yrs** **General health scores** LRYGB p<0.001 (sig improved) LSG p<0.001(sig improved) Medical therapy p=0.92 (no change) **Bodily pain** LRYGB p=0.77 (no change) LSG p=0.87 (no change) Medical therapy p=0.01 (sig. worse) **Emotional wellbeing** LRYGB p=0.03 (sig worse) LSG p=0.62 (no change) Medical therapy p=0.04 (sig worse) **Physical functioning** LRYGB p=0.002 (sig improved) LSG p=0.01 (sig improved) Medical therapy p=0.39 (no change) **Energy/fatigue** LRYGB p=0.001 (sig improved) LSG p=0.001 (sig improved) Medical therapy p=0.32 (no change) **No significant statistical difference** Decrease in LDL within groups Decrease in blood pressure within groups Social functioning Limitations due to emotional or physical problems. **Adverse events** **Excessive weight** LRYGB n= 0 (0%) LSG n=0 (0%) Medical therapy 8 (19%) **Anaemia** LRYGB n=14, 28% LSG group n=24, 49% Medical therapy group n=7, 16%	

Level of Evidence*	Study	Population	Intervention	Comparator	Outcomes	Comments
					LRYGB vs LSG p<0.05 (favouring RYGB) LSG vs medical therapy (favouring medical therapy) **Mild anaemia** Surgery vs medical therapy p<0.009 (favouring medical therapy) **Hypoglycaemic episodes** LRYGB n=32, 64% LSG n=40, 82% Medical therapy n=39, 91% Surgery vs medical therapy p<0.05 One conversion LSG to RYGB due to a recurrent gastric fistula.	
1b	Cummings 2016 [43] Single centre RCT USA	Age 25-64 yrs with T2DM BMI 30-45 kg/m2 n=32	RYGB (n=15)	Intensive lifestyle and medical intervention (n=17)	**Statistically significant difference** The odds ratio for diabetes remission at 1 year after LRYGB compared with intense lifestyle and medical interventions was 19.8 (95% CI 2.0, 194.65, p=0.003). • LRYGB cohort had longer diabetes duration than ILMI (p=0.009) • Weight loss greater in RYGB group (p<0.001) • Diabetes remission at 1 year was 60% with RYGB vs 5.9% ILMI (p=0.002) • Reduction in lean body mass was greater in RYGB group than ILMI (p<0.05) • Reduction in body fat was greater in RYGB group than ILMI (p<0.05) **Decrease in triglycerides within groups** LRYGB p=0.005 ILMI p=0.002 **Increase in HDL cholesterol within groups** LRYGB p=0.0004 ILMI p=0.02 **QoL** LRGYB and ILMI showed improvement in overall health ratings (p=0.02, p= 0.035 respectively) with differences between groups (p=0.34).	• BMI overlaps with range of interest in this review but no stratification of results between <35 kg/m^2 and ≥35 kg/m^2 groups. • Short follow up –(1 year) • Small sample size may limit power to detect changes.

Level of Evidence*	Study	Population	Intervention	Comparator	Outcomes	Comments
1b	Ding 2015 [41] Single centre RCT, USA	BMI 30-45 kg/m^2 with T2DM for ≥1yr n=40	LAGB (n=18)	Intensive medical diabetes and weight management programme ('why WAIT' program) (IMDWM) (n=22)	**Statistically Significant Difference** • **Weight loss** LAGB group saw additional weight loss at 12 months (p=0.027) 13.5kg vs 8.5kg in non-surgical group • **Blood Pressure** Systolic blood pressure reduced more from baseline after non-surgical intervention than LAGB (p=0.038) • **Cholesterol** Greater proportion of LAGB patients achieved reductions of LDL cholesterol below threshold (p=0.019) Reduction in use of lipid-lowering medication in LAGB (p=0.029) **Apparently meaningful difference (no p-values or 95% CIs reported** • **Adverse Events** 4 adverse events reported in the LAGB group vs 1 in the IMDWM group **No statistically significant difference** • **Glycaemic control** Proportions achieving target HbA1c and fasting glucose levels were not significantly different • **Waist circumference** • **Use of hypertensives** • **Fitness**	• BMI range overlaps the range of interest (37.5% of participants outside the range of interest) • Gives a clear outline of the non-surgical intervention • Cohort had relatively advanced T2DM but few related complications • Follow-up is fairly short-term, longer term outcomes not evaluated • Results may not generalise to those with milder T2DM or with advanced complications • Only one type of surgical procedure evaluated

Level of Evidence*	Study	Population	Intervention	Comparator	Outcomes	Comments
					(6 minute walk, post exercise heart rate) • **UKPDS risk scores** • **Quality of Life** SF-36, PAID, EQ-5D & Barriers to Being Active measures	
1b	Mingrone 2015 [42] Single centre RCT, Italy	BMI ≥35 kg/m^2 with T2DM n=60	RYGB (n=20), BPD (n=20)	Medical treatment (n=20)	**Statistically Significant Difference** • **T2DM remission** RYGB saw 75% remission at 2 years, reducing to 37% at 5 years due to relapse. BPD saw 95% remission at 2 years, dropping to 63% at 5 years. Zero medical patients saw remission (p<0.0001). • **Weight loss** Surgical groups saw a reduction in BMI of -12.7 (LRYGB) and -14.3 (BPD) compared to -3.3 in the medical treatment group (p<0.0001). • **Quality of Life** Surgical patients scored significantly better than medically treated patients for all sub-domains (p<0.0001) **Apparently meaningful difference (no p-values or 95% CIs reported)** • **T2DM Improvement** 31 out of 38 (82%) participants who relapsed after surgery were able to maintain HbA1c < 7% with little to no use of glucose lowering medication. • **Weight regain** Modest weight regain was observed in surgical groups between years 2 and 5, weight loss was stable in medical group • **Complications** Complications were observed for 4 medical participants and 1 surgical participant.	• BPD no longer performed in the UK • 2 medical participants excluded due to crossing over to surgery because of inadequate glycaemic control. • 5 year follow up period

Level of Evidence*	Study	Population	Intervention	Comparator	Outcomes	Comments
					No statistically significant difference • Blood pressure	
1b	Halperin 2014 [40] Single centre RCT, USA	BMI <35 kg/m^2 and ≥35 kg/m^2, both with T2DM n=38	RYGB (n=19)	'Why WAIT' program (n=19)	**Statistically Significant Difference** • **Resolution of hyperglycaemia** 58% of theL RYGB group reached target HbA1c levels compared to 16% in the medical therapy group (p=0.03) • **Blood Pressure & Lipid Levels** Systolic (p=0.02) and diastolic (p=0.001) blood pressure and triglycerides (p=0.02) were lower at 1 year and high-density lipoprotein cholesterol was increased only in the LRYGB group (p<0.001) • **Cardiometabolic risk** Risk scores for coronary heart disease (p<0.001), fatal coronary heart disease (p<0.001), stroke (p=0.008), and fatal stroke (P=0.009) were all reduced more at 1 year after LRYGB than non-surgical intervention • **Weight Loss** Reduction in BMI at 12 months (p<0.001), waist circumference (p<0.001), fat mass (p<0.001) and lean mass (p<0.04) were all significantly greater in participants receiving surgery • **Patient reported outcomes** IWQOL score improved significantly greater in RYGB participants compared to non-surgical participants (p<0.01). **No statistically significant difference** • Fitness improvement	• Gives a clear outline of the non-surgical intervention • Includes patients with a BMI <35 kg/m^2 which is out of scope of this review • No stratification within the results between <35 kg/m^2 and ≥35 kg/m^2 groups • SLIMM-T2D trial • Wide range of diabetes duration and insulin use duration • Limited applicability to patients with extensive diabetes-related complications • Relatively short 12 month follow-up period • Small sample size may limit power to detect changes. • Adverse events discussed but absolute numbers not given for comparison

see Appendix1

Evidence Table 3: Summary of Additional Papers of Interest Regarding Clinical Effectiveness

<table>
<tr><th>Level of Evidence*</th><th>Study</th><th>Population</th><th>Intervention</th><th>Comparator</th><th>Outcomes</th><th>Comments</th></tr>
<tr><td>1b</td><td>Gulliford 2016 [46]

UK

Matched cohort study using analysis of UK CPRD[2] and Markov model</td><td>n=3,045

Adults with BMI>35kg/m^2

2002-2014</td><td>Bariatric surgery</td><td>n=247,537

(n=278,982 for analysis of probability of attaining normal body weight)

General population control

2008-2014</td><td><u>Primary outcomes:</u>
• Weight changes in the absence of bariatric surgery
• Bariatric surgery and Incidence of type 2 diabetes mellitus
• Bariatric surgery in the management of type 2 diabetes mellitus
• Bariatric surgery and clinical depression

<u>In the absence of bariatric surgery</u>
Annual probability of achieving normal body weight
• Male, obesity: 1 in 210
• Female, obesity: 1 in 124
• Male, morbid obesity: 1 in 1290
• Female, morbid obesity: 1 in 677
Annual probability of achieving 5% weight reduction
• Male, morbid obesity: 1 in 8
• Female, morbid obesity: 1 in 7
Weight regain to value above initial weight in participants who lost 5% body weight:
• At 2 years: 52.7% (95%CI 52.4% to 53.0%)
• At 5 years: 78% (95%CI77.7% to 78.3%)

<u>Diabetes incidence</u> per 1000 person-years (bariatric surgery vs control): 5.7%(95%CI 4.2 to 7.8) vs 28.2%(95%CI 24.4 to 32.7)

<u>Diabetes remission* (n=826) (maximum 5 year follow-up)</u>
<table>
<tr><th rowspan="2">Cohort</th><th colspan="5">Years Follow-Up</th></tr>
<tr><th>1</th><th>2</th><th>3</th><th>4</th><th>5</th></tr>
<tr><td>Surgery</td><td>30%</td><td>25%</td><td>21%</td><td>21%</td><td>17%</td></tr>
<tr><td>No Surgery</td><td>4%</td><td>4%</td><td>3%</td><td>5%</td><td>6%</td></tr>
</table>
Reported as relative rate of remission within report

Depression:
Proportion of people with depression before and after bariatric surgery:
• Pre-surgery: 36%
• Post-surgery year 2: 32%
• Post-surgery year 7: 37%</td><td>UK, NHS perspective

Reflects UK clinical practice and costs

Lifetime horizon

Extensive sensitivity analyses included</td></tr>
</table>

[2] The UK Clinical Practice Research datalink (CPRD) is the world largest primary care database comprising anonymised longitudinal patient records from UK general practices. Electronic health record data are considered to be broadly representative of the UK population.

	Borisenko 2015 [45] Sweden Modelled outcomes over lifetime based on 2 year outcomes from Swedish Obesity Surgery Registry	Modelled population Based on 41 year old non-smoking adults with BMI 30-34, 35-39, 40-50 and >50 kg/m^2 With or without T2DM	Bariatric surgery Gastric bypass (98%) Sleeve gastrectomy (1.6%) Gastric band (0.4%)	Optimal Medical Management (OMM)	Lifetime absolute risk (surgery vs OMM) (no p-values reported) of events: • Diabetes: 14% vs 36% • Nonfatal MI: 22% vs 28% • Fatal MI; 2% vs 3% • Nonfatal stroke: 18% vs 23% • Fatal stroke: 3% vs 4% • TIA: 2% vs 2% • Heart Failure: 15% vs 19% • Pulmonary arterial disease: 10% vs11% Impact of 3 year delay to surgery: Delays in surgery may lead to a loss of clinical benefits: up to 0.6 life years and 1.2 QALYs per patient over a lifetime in those with diabetes or a body mass index >40 kg/m^2.	Recurrence of T2DM has been included in the model Outcomes not generalisable as • % different procedures are different to current UK practice. • Weight regain post bariatric surgery has not been factored in • Other obesity related co-morbidities not modelled

see Appendix1

Evidence Table 4: Cost effectiveness of bariatric procedures in adults with BMI ≥ 40kg/m^2 and no co-morbidity

<table>
<tr><th>Level of Evidence*</th><th>Study</th><th>Population</th><th>Intervention</th><th>Comparator</th><th>Outcomes</th><th>Comments</th></tr>
<tr><td>1b</td><td>Picot 2009 [56]

UK HTA systematic review and economic evaluation</td><td>Adults with BMI ≥40kg/m^2</td><td>LRYGB

LAGB</td><td>Non-surgical management</td><td>Over 20yr time horizon:
<table><tr><td></td><td>QALY gain</td><td>ICER</td></tr><tr><td>LRYGB</td><td>1.52 to 1.98</td><td>£3160 to £4127</td></tr><tr><td>LAGB</td><td>0.92 to 1.88</td><td>£1897 to £3863</td></tr></table></td><td>Modelled over 20yr time horizon

- Costs and outcomes both discounted at 3.5%

- Multi-way sensitivity analysis

ICER is highly dependent on procedure costs (including operating time and LOS). Varying costs and utilities still produced an ICER <£5,000 per QALY.

Assumed from references that gastric bypass and gastric band procedures were laparoscopic</td></tr>
</table>

<table>
<tr>
<td>4</td>
<td>Hernandez 2010 [59]

USA

Markov model</td>
<td>Adults with BMI ≥40 kg/m^2</td>
<td>Lap-RYGB

Lap-AGB</td>
<td>No surgery</td>
<td>
<table>
<tr><td>Age (yrs)</td><td>QALYs gained
(lap-RYGB over lap-AGB)</td></tr>
<tr><td>35-44</td><td>+7.8</td></tr>
<tr><td>45-54</td><td>+6.4</td></tr>
<tr><td>55+</td><td>+4.7</td></tr>
<tr><td>BMI(kg/m^2)</td><td>QALYs gained
(lap-RYGB over lap-AGB)</td></tr>
<tr><td>40</td><td>+2.8</td></tr>
<tr><td>50</td><td>+6.4</td></tr>
<tr><td>60</td><td>+9.6</td></tr>
</table>
</td>
<td>Modelled to 85yrs of age

Assumed no impact on QoL 2yrs (lap-RYGB) and 4yrs (lap-AGB) post-surgery

Focus was on morbidity directly caused by surgical techniques that led to re-operation.

Did not take into account co-morbidity.</td>
</tr>
</table>

**see Appendix1*

Evidence Table 5: Cost effectiveness of bariatric procedures in adults with BMI ≥ 35kg/m^2 and type 2 diabetes mellitus (T2DM)

<table>
<tr><th>Level of Evidence*</th><th>Study</th><th>Population</th><th>Intervention</th><th>Comparator</th><th>Outcomes</th><th>Comments</th></tr>
<tr>
<td>1b</td>
<td>Picot 2012 [56]

(update of Picot et al 2009) [27]

UK HTA systematic review and economic evaluation</td>
<td>T2DM

and

BMI>30 and <40kg/m^2</td>
<td>LAGB</td>
<td>Usual diabetes care</td>
<td>Cost effectiveness:

<table>
<tr><th></th><th>Incremental QALY gain over usual care</th><th>Incremental costs</th><th>ICER</th></tr>
<tr><td>@2yrs</td><td>0.27</td><td>£5359</td><td>£20,159</td></tr>
<tr><td>@5yrs</td><td>0.61</td><td>£3034</td><td>£4,969</td></tr>
<tr><td>@20yrs</td><td>1.10</td><td>£1792</td><td>£1,634</td></tr>
</table>

Sensitivity analysis:

<table>
<tr><th></th><th colspan="2">WTP threshold</th></tr>
<tr><th></th><th>£20k/QALY</th><th>£30k/QALY</th></tr>
<tr><td>@2yrs</td><td>1%</td><td>38%</td></tr>
<tr><td>@20yrs</td><td>100%</td><td>100%</td></tr>
</table>

Non-surgical care is also associated with QALY gains at 2, 5 and 20 yrs respectively:

1.62, 3.74, 11.12 for usual diabetes care compared to 1.70, 4.03 and 11.52 for LAGB.</td>
<td>Population includes class I obesity (BMI>30<35kg/m^2) which out of scope of this review

- one way sensitivity analysis undertaken

- Costs and outcomes discounted at 3.5%

5 and 20yr data modelled (assumed that at 10 yrs, BMI, BP, lipid profile and T2DM relapses)

Cost effectiveness highly dependent on the (high) costs associated with T2DM case (83% total costs are T2DM costs)

QALY gains are modest.

Only LAGB is used – no LRYGB/LSG.</td>
</tr>
</table>

3b	Hoerger 2010 [57] USA Markov model	Adults aged 45-54years BMI≥35kg/m^2 and T2DM - newly diagnosed (nor more than 5 years after diagnosis) - established (at least 10 years after diagnosis)	Bariatric surgery comprising LRYGB LAGB	Usual diabetes care	Newly diagnosed T2DM: LRYGB: $7000/QALY LAGB: $11000/QALY Age 35-44 vs 65-74 years LRYGB: $5k/QALY vs $12k/QALY LAGB: $9-17k/QALY Established T2DM: LRYGB: $12000/QALY LAGB: $13000/QALY Age 45-54 vs 65-74 years LRYGB: $9k/QALY vs $18k/QALY LAGB: $11-18k/QALY Subgroup analyses BMI 30-34 kg/m2 reduces the cost effectiveness by a factor of two (lower BMI loss and lower QoL gain)	Assume (from references) that procedures are laparoscopic Based on 2005 US costs (US$) Model assumptions clearly stated Sensitivity analysis: model highly sensitive to the QoL improvement per BMI unit estimate and cost of treating active diabetes All scenarios were cost effective Younger patients are most cost effective.

4	Ackroyd 2006 [58] in Terranova 2012 [52]	BMI ≥35kg/m^2, with T2DM	Bariatric surgery including LAGB RYGB	Conventional medical therapy or non-surgical management	Over 5 year timeframe (direct costs only) LAGB: £1,929/QALY LRYGB: £1,517/QALY	Based on narrative outcomes from 1 (Ackroyd et al 2006) of 6 studies in review

**see Appendix1*

Evidence Table 6: Cost effectiveness of bariatric procedures in adults with BMI ≥ 40kg/m^2 or BMI ≥ 35kg/m^2 with co-morbidity (mixed population)

Level of Evidence*	Study	Population	Intervention	Comparator	Outcomes	Comments
1b	Gulliford 2016 [46] UK Matched cohort study using analysis of UK CPRD[3] followed by cost effectiveness analysis and Markov model	n=3,045 Adults with BMI>35kg/m^2 With or without co-morbidity 2002-2014	Bariatric surgery	n=247,537 (n=278,982 for analysis of probability of attaining normal body weight) General population control 2008-2014	Lifetime cost effectiveness of bariatric surgery compared to no surgery: • ICER: £7,129 (95%CI £6775 to £7506) per QALY • Incremental cost of bariatric surgery: £15,258 (95%CI 15,184 to 15,330; p<0.001) • Incremental QALY: 2.142(95% CI 2.031 to 2.256) For patents with morbid obesity and T2DM: • ICER: £6176 (95% CI £5894 to £6457) per QALY For patients with severe obesity: • ICER: £7675 (95%CI £7339 to £8037)	NHS perspective Reflects UK clinical practice and costs Lifetime horizon Extensive sensitivity analyses included Comparison is 'no surgery' which may include but is not restricted to NHS funded tier 2 and tier 3 interventions

[3] The UK Clinical Practice Research datalink (CPRD) is the world largest primary care database comprising anonymised longitudinal patient records from UK general practices. Electronic health record data are considered to be broadly representative of the UK population.

<table>
<tr>
<td></td>
<td>Borisenko 2015 [45]

Sweden

Modelled outcomes over lifetime based on 2 year outcomes from Swedish Obesity Surgery Registry</td>
<td>Modelled population

Based on 41 year old non-smoking adults with BMI 30-34, 35-39, 40-50 and >50 kg/m^2

With or without T2DM</td>
<td>Bariatric surgery

Gastric bypass (98%)

Sleeve gastrectomy (1.6%)

Gastric band (0.4%)</td>
<td>Optimal Medical Management (OMM)</td>
<td>Lifetime cost effectiveness of bariatric surgery compared to OMM (for all patients):
• -€8408
• +0.8 LYG
• +4.1 QALYs
• (€2050 per QALY)

For all patients (mixed population), surgery is cost saving at 17years.

Surgery is cost saving vs OMM over lifetime for all subgroups except for non-diabetic adults with a BMI <35 kg/m^2:

Surgery is highly cost effective for all sub-groups (less than £20,000 per QALY)
<table>
<tr><td></td><td colspan="5">ICER, €/QALY</td></tr>
<tr><td></td><td>Moderately obese (BMI 33kg/m^2)</td><td>Severely obese (BMI 37kg/m^2)</td><td>Morbidly obese (BMI 42kg/m^2), best-case</td><td>Morbidly obese (BMI 42kg/m^2), worst-case</td><td>Super obese (BMI 52kg/m^2)</td></tr>
<tr><td>male diabetic patients</td><td>-4406</td><td>-4189</td><td>-3340</td><td>-3343</td><td>-2854</td></tr>
<tr><td>female diabetic patients</td><td>-6740</td><td>-6310</td><td>-4668</td><td>-4803</td><td>-3990</td></tr>
<tr><td>male non-diabetic patients</td><td>449</td><td>-130</td><td>-1026</td><td>-970</td><td>-1484</td></tr>
<tr><td>female non-diabetic patients</td><td>51</td><td>-668</td><td>-1531</td><td>-1509</td><td>-2142</td></tr>
</table>
Impact of 3 year delay to surgery:
Overall lifetime cost of treatment may be increased in patients with diabetes or a body mass index >40 kg/m^2.</td>
<td>Recurrence of T2DM has been included in the model

Concern re accuracy as reported ICER at 2yrs is inconsistent with data in supplement (S5). Also ICER for Moderate obese male is 459 in text but 449 in supplement.

Outcomes not generalisable as
• % different procedures are different to current UK practice.
• Weight regain post bariatric surgery has not been factored in
• No annual cost of post bariatric surgery support included over lifetime period
• Other obesity related co-morbidities not modelled</td>
</tr>
</table>

2c	Weiner 2013 [53] USA Longitudinal analysis of 2002-8 claims	n=29,820 insured patients BMI≥40 or BMI≥35 with co-morbidity hypertension 54.7%, T2DM 24.6% Others 7.4% Post-op observation period 1yr n=29,820 2yr, n=19,564 3yr, n=12,760 4yr, n=7,571 5yr, n=4,584 6yr, n=1,939	n=29,820 Bariatric Surgery including: ORYGB LRYGB LAGB	n=29,820 Matched non-surgical cohort	Total health care cost per year (including inpatient, outpatient and pharmacy costs), mean(SD),US$ (2005), surgery vs non-surgery 1yr pre-op: 8850(12542) vs 9590(21913) yr 1: 8905(18814) vs 9908(22192) yr 2: 9908(19273) vs 9264(21057) yr3: 9211(19263) vs 9041(21243) yr4: 9051(19520) vs9232(19819) yr5: 9386(21137) vs 8966(20270) yr6: 9259(26909) vs8714(27280)	USA costs may not be directly generalisable to UK. Large study: observed costs not modelled. Old data – outcomes may be better than observed in the study. ORYGB (34.5%)is an obsolete comparison now but is included in the surgical cohort. Provider costs not cost effectiveness. Costs also reflect pharmacy inflation Bariatric surgery does not reduce overall health care costs in the long term.

2c	Finkelstein 2013 [54] USA Non randomised case control study of MarketScan data (including 100 insurers)	Adults with BMI≥40, including some T2DM.	LRYGB n=21,533, 30.9% T2DM LAGB n=9,651, 25.4% with T2DM	Morbid obesity (MO), no surgery Matched random sample (same co-morbidity profile but no confirmed diagnosis of morbid obesity)	<u>Compared to diagnosed morbid obesity, no surgery</u> Time to break even (yrs) LABG: 1.5 (CI: 1.45 to 1.55) LRYGB: 2.25 (CI: 2.07 to 2.43) Net cost savings at 5 yrs (US$) LAGB: 78,980 (CI: 100,550 to 62,320) LRYGB: 61,420 (CI: 82,870 to 44,710) <u>For diabetes subset</u> Time to break even (yrs) LAGB: 1.25 (CI: 1.02 to 1.48) LRYGB : 1.75 (CI: 1.49 to 2.01) Net cost savings at 5 yrs (US$) LAGB: 127,590 (CI: 167,590 to 94,840) LRYGB: 103,340 (CI: 146,760 to 65,550)	Time to break even and cost savings are dependent on the comparator – untreated MO population or patients with same co-morbidity profile but no diagnosis of MO. Based on health care resource utilisation only. Does not reflect societal benefits or costs. Does not reflect the benefit (QoL/ADL) to patients. ? post 5 yrs Based on very large case control study outcomes.

2c	Karim 2013 [55] Prospective economic evaluative Single centre, Scotland 2008-11	Adults median age 45 years (25-65 yrs) Median BMI 47.3 (35-64.5) kg/m^2 n=88, some with Co-morbidities T2DM (n=29) Hypertension (n=31) Arthritis (n=20) Ischaemic heart disease (n=3) Obstructive sleep apnoea (n=27)	Bariatric surgery comprising LRYGB (n=19) LAGB (n=36) LSG (n=33)	Pre-surgery median	At median f/up 24 months (12-45 months): • BMI 35.79kg/m^2 (decreased 24% (p<0.05) Co-morbidities resolved/improved • T2DM: 22/29 (75.9%) • Hypertension: 15/31 (48.4) • OSA: 22/27 (81.5%) Medication net savings: £11,452 p.a. (39.5%) Hospital admissions/ outpatient clinics net savings: £18,950 p.a.	UK study Used average costs of resource utilisation from 2005 to April 2012. No breakdown of cost savings per procedure. No control group.

4	Wang and Furnback 2013 [50] Review of cost effectiveness studies (Faria 2013, Song 2013, WangWong 2013, Chang 2011, Maklin 2011, Campbell 2010)	BMI≥35kg/m^2 with co-morbidity Or BMI≥40kg/m^2	Bariatric Surgery including ORYGB LRYGB LAGB LSG	Ordinary treatment (ranging from brief intervention to intensive conservative treatment).	Bariatric surgery is cost effective, despite variation in methodology for forecasting cost effectiveness. Bariatric surgery produced additional life years compared to no surgery (from 78 years to 80-81 years) Cost effectiveness over lifetime (US$ per QALY) compared to no surgery ranged from: • Bariatric surgery(LAGB/LRYGB/LSG): 1,771-13,249 • LRYGB: 5,600 to 6,600 • LAGB: 5,400 to 6,200 • ORYGB: 17,300	Focus on studies that relate directly to bariatric surgery. Excluded papers that focused on long-term resolution of diabetes or other co-morbidities. No meta-analysis possible so outcomes from 6 studies are narrative only.
4	Clegg 2003 [51] in Terranova 2012 [52]	BMI >40 kg/m^2 and ≥35 kg/m^2 with co-morbidity	Bariatric surgery including LAGB RYGB VBG	Conventional medical therapy or non-surgical management	Over 20 year time frame, direct costs only RYGB: £6,289/QALY LAGB: £8,527/QALY VBG: £10,237/QALY	Based on only 1out of 6 studies in the review Costs are 16 years out of date (1999/2000)

**see Appendix1*

5 Discussion and conclusions

5.1.1 Clinical effectiveness of bariatric surgery compared with non-surgical management in adults with obesity (BMI at least 35 kg/m^2)

Bariatric surgery was found to consistently achieve greater weight loss than non-surgical interventions.

All studies included by Colquitt et al [23] found statistically significant differences in weight loss for follow-up periods of one to two years, regardless of the surgical procedure or type of participants included. The quality of the evidence was moderate, with a noted lack of high quality RCTs comparing the long-term effects of surgery to conventional treatment amongst large sample sizes. Colquitt et al's findings were reinforced in RCTs performed by Ding et al [41], Halperin et al [40] and Cummings et al [43] as well as in the follow-up studies by Mingrone et al (2015) [42] and Scahuer et al (2017) [44]. Observed weight loss is also associated with a reduction in co-morbidities such as type 2 diabetes, metabolic syndrome and sleep apnoea but the benefits relating to hypertension and lipid profiles is less clear. With the exception of Gulliford et al's [46] seven year follow up of T2DM cases, there is a lack of longer-term data examining the effects on co-morbidities of surgery compared to non-surgical interventions. The findings pertaining to sleep apnoea provide a complex picture in terms of clinical benefit. Whilst surgery appears to lead to more patients achieving a classification of mild OSA, the benefits in terms of overall AHI improvements and requirement for CPAP do not differ significantly between patients undergoing surgery and those not undergoing surgery despite greater weight loss amongst surgical participants. This means that caution must be applied when communicating the possible benefits of bariatric surgery to patients and that patients must be evaluated carefully prior to making any recommendations around ceasing treatment for obstructive sleep apnoea after surgical intervention.

The available evidence is highly variable in terms of the interventions being investigated.

One fundamental issue with the evidence in this field is the wide variation in the type of non-surgical intervention used as a comparator and the generally poor descriptions of these given in the literature compared to the more precise descriptions of surgical procedures. Colquitt et al reported that a meta-analysis was considered to be inappropriate due to the inherent differences between studies in terms of participants, surgical interventions and non-surgical comparators.

More detailed descriptions of robust lifestyle interventions were provided by Ding et al [41], Halperin et al [40] and Mingrone et al [42], who each described interventions which bore a resemblance to tier 3 services as described by the Royal College of Surgeons. However, even in these instances where a well described lifestyle intervention was applied, surgical interventions still resulted in greater weight-loss, regardless of co-morbidities.

Those who do manage to achieve weight loss without surgery are likely to regain weight in the future.

Realistic outcomes for non-surgical weight loss in adults in the UK general population is reported by Gulliford et al highlighting the difficulty in achieving normal body weight or even just a 5% reduction in initial body weight without surgery. The authors also reported weight regain to a value greater than the initial weight in the participants who initially achieved 5% weight loss without bariatric surgery (52.7% of those who lost 5% of initial body weight at two years, rising to 78% at 5 years). This shows that, even amongst people who achieve a modest weight reduction without surgery, only a small proportion of them manage to avoid weight regain two to five years later.

Considering the weight of the observed evidence in favour of surgical interventions for weight loss and resolution of co-morbidities (particularly type 2 diabetes), it would seem reasonable to conclude that the provision of lifestyle interventions is a less clinically effective approach to dealing with more severe levels of obesity. The risks and benefits of surgery need to be carefully considered given the poor quality of information available in the literature pertaining to patient safety, however the data provided by the Bariatric Surgery Register goes some way toward countering these concerns.

5.1.2 Safety of bariatric surgery compared with non-surgical interventions

A direct comparison of patient safety between bariatric surgery and non-surgical interventions is not possible based on the available evidence.

Adverse incidents appear to be more common in surgical patients but it is difficult to draw firm conclusions due to inconsistent recording, different reporting methods and small numbers of incidences reported in the literature. The sample size of each study is generally small and no statistical comparisons have been made, merely narrative discussions. Whilst safety information related to bariatric surgery is readily available from the UK National Bariatric Surgery Registry, this information does not allow for comparison to the numbers and rates of non-surgical adverse events [22]. The lack of longer term studies precludes the possibility of identifying whether the higher weight loss amongst surgery patients may lead to a measurable and significant reduction in adverse events over longer periods than those observed, compared to a non-surgical cohort with a lesser degree of weight loss and increased time spent living with co-morbidities such as type 2 diabetes and hypertension.

5.1.3 Cost effectiveness of bariatric surgery compared to non-surgical management in adults with obesity (BMI at least 35 kg/m^2)

All of the economic evaluations are weak due to the limited long-term follow-up data available to inform post-trial modelling.

In addition, there was significant heterogeneity between the studies including different:

- Populations (age, initial BMI, number of co-morbidities);
- Bariatric surgery techniques;
- Comparators (surgery or different levels of non-surgical intervention);
- Cost outcomes;
- Duration of model (two year to lifetime estimates);
- Assumptions about the trajectory of weight change (both time period and weight loss);
- Perspective - immediate hospital costs only versus lifetime costs and patient quality of life and life years);
- Evaluation methodology and sensitivity analyses (none, one way or multivariate);
- Country and setting (which affects the generalisability of the findings to UK NHS setting).

There is no single answer to the question of cost effectiveness of bariatric surgery compared to non-surgical management.

For patients with a BMI of more than 40 kg/m^2 and no co-morbidity, there is reliable evidence from the UK HTA evaluation over a 20 year time horizon that bariatric surgery is highly cost effective with the ICER estimated to be less than £5000 per QALY for both LRYGB and LAGB.

For patients with a BMI of more than 35 kg/m^2 and type 2 diabetes, the ICER is estimated to be circa £20,000 per QALY over two years. When this observed data is modelled over the 20 year

time horizon, the ICER is £1634 per QALY, indicating that bariatric surgery (LAGB) is highly cost effective.

Over a lifetime, bariatric surgery results in both additional QALYs and is highly cost effective.

For a mixed population, the most reliable and authoritative estimate of the lifetime ICER was from the recently published cohort study and cost effectiveness analysis by Gulliford et al (2016) [46]. It is higher than the estimates from some of the other studies such as those by Wang and Furnback [50] and Borisinko et al [45]. but it was based upon UK matched cohort data from the UK CPRD and UK Bariatric Surgery Registry data and included multivariate sensitivity analyses.

This study found that over a lifetime, bariatric surgery resulted in both additional QALYs and was highly cost effective with an ICER of £7129 (95%CI £6775 to £7506) per QALY. The ICER for patients with severe obesity alone was slightly higher but, at £7675 per QALY it was still well within UK accepted norms. The authors found that bariatric surgery was particularly cost effective in patients with morbid obesity and T2DM (£6176 per QALY).

Unlike the findings of Borisenko et al, the authors of the NIHR report did not find bariatric surgery to be cost saving over the lifetime but this may be because the model included a wider range of costs associated with bariatric surgery as well as a more realistic estimate of diabetes remission and recidivism.

Significantly, all the studies that we included clearly indicated that bariatric surgery (particularly if performed laparoscopically which is current UK clinical practice) is highly cost effective when using the NICE 'usual' cost effectiveness threshold of £20,000 to £30,000 per QALY, and even against the more recently calculated 'affordable' NHS threshold estimated by Karl Claxton et al of circa £12,000 per QALY [60]. Whilst we have limited data to be able to reliably estimate the actual cost per QALY for bariatric surgery overall or for each bariatric technique, the reported ICERs are consistently lower than the £20,000 per QALY ceiling by a factor of between four and ten (depending on the estimate considered). NHS commissioners can be confident that bariatric surgery (based on the studies identified in this review) is highly cost effective.

In terms of which bariatric surgery procedure is the most cost effective, there is insufficient reliable evidence to clearly identify a single procedure or to reliably differentiate between the cost effectiveness of LRYGB and LAGB (frequently reported in the studies). Reports by Finkelstein et al (2013) [54] are comparably cost effective, with similar estimated cost per QALY over a lifetime (LRYGB: US$6,600 vs LAGB: US$6200), similar time to break even (LRYGB: 2.25 years vs LAGB: 1.5 years for patients without co-morbidity) and similar net cost savings over five years (LRYGB: US$103,340 vs LAGB: US$127,590).

Laparoscopic RYGB appears to offer greater QALY gain which offsets the additional cost of the procedure. Laparoscopic AGB is similarly cost effective, largely because the procedure costs are so much lower.

5.1.4 Sub-groups who might benefit more from bariatric surgery than others (defined by, for example, initial BMI status and/or presence of a specific co-morbidity)

Individuals with type 2 diabetes who received surgery experienced higher rates of remission than those receiving non-surgical interventions.

Colquitt et al reported that all RCTs included in their review that examined type 2 diabetes as an outcome reported significantly higher remission rates amongst those receiving surgery compared to those using conventional therapy or dietary changes. This conclusion is backed by many of the additional studies included in this review. This is of particular interest due to the increasing direct

and indirect costs of type 2 diabetes in the UK, which are estimated by Hex et al [61] to rise to £36 billion by 2036. Mingrone et al noted that although surgery was more effective than medical treatment in achieving long term control of type 2 diabetes in obese patients, continued monitoring of glycaemic control should be investigated due to the potential for relapse amongst some patients. Halperin et al note that LRYGB surgery may be useful in managing type 2 diabetes in patients with less severe obesity (BMI 30-42 kg/m^2). Schauer et al (2017) concluded that their results were consistent with other findings that surgical patients with lower BMIs of 27 kg/m^2 to 34 kg/m^2 and with diabetes had similar improvement in glycaemic control to patients who had a BMI of 35 kg/m^2 and above and this was superior to those who received medical therapy alone.

As noted by NICE in its guidance for preventing ill health and premature death in black, Asian and other minority ethnic groups, these groups are at an equivalent risk of diabetes, other health conditions or mortality at a lower BMI than the white European population [12]. Because of this, it may prove prudent to examine the possibility of providing weight loss interventions to these groups at a lower threshold BMI value than is currently used for the general population.

Bariatric surgery may be more cost effective in patients with a higher BMI.

While there is evidence to suggest that bariatric surgery is more cost effective in patients with a higher BMI, due to their increased capacity to gain through greater weight loss or resolution of existing co-morbidities, we found no evidence to suggest higher clinical effectiveness or safety of bariatric surgical procedures in patients with a higher baseline BMI.

For all procedure types in the 2014 UK National Bariatric Surgery Registry report [22], the percentage excess weight lost was inversely proportional to the baseline BMI. In other words, a greater proportion of their excess weight was lost by patients with lower baseline BMI. However, this may be a misleading target outcome. Moreover, caution must be taken with this Registry evidence, as the report was not a true controlled comparative study. Findings must be verified through formal randomised controlled trials (RCTs).

Cost effectiveness is highly dependent on the avoidance of costs associated with co-morbidities.

We did note that the cost effectiveness of bariatric surgery is very dependent upon the co-morbidity costs avoided. These costs may be avoided either from remission (temporary or otherwise) of an existing co-morbidity such as type 2 diabetes or reduction in incidence of obesity-related co-morbidities in the future. Obesity-related co-morbidities such as type 2 diabetes, hypertension or obstructive sleep apnoea, all require lifelong pharmacological and lifestyle management and are associated with additional complications (such as stroke, deep vein thrombosis, acute myocardial infarction, and amputation).

The difference in QALY gain between surgical and conservative treatment groups was very marginal [27, 56]. This means that bariatric surgery may be less cost effective if pharmacological management costs decrease or surgical costs increase (high complication / readmission rates, introduction of expensive instrumentation). Conversely, improvements in surgical outcomes which reduce complications and increase costs of conservative management (e.g. new drug costs or expensive new devices such as continuous glucose monitors) will lead to bariatric surgery being even more cost effective.

Patients with the greatest capacity to benefit are likely to be the most cost effective group to treat.

Given that cost effectiveness calculations factor in costs, effect size and the duration of effect, the cost per QALY is inherently biased toward patients who:

- Have the greatest capacity to benefit; and
- Have the potential to experience the benefit for a longer duration.

This means that from an economic perspective, bariatric surgery is likely to be most cost effective in patients who are:

- Younger or
- Have a higher BMI or
- Have an existing obesity-related co-morbidity which is likely to be resolved by significant weight loss resulting from bariatric surgery.

6 Search Strategy

Population	Intervention	Comparator	Outcomes	Studies

Adult patients with BMI ≥35 kg/m^2 with obesity-related co-morbidities or ≥40kg/m^2 without co-morbidity	Bariatric surgery (any technique)	Any non-surgical weight loss/weight management intervention	• Clinical effectiveness including
			  ○ Resolution /remission of co-morbidities (e.g. hypertension, diabetes, reduced medication, improved glycaemic control)
			  ○ BMI/weight reduction
			  ○ Quality of life/patient-reported outcome measures
			• Safety/complications
			• Cost-effectiveness
				• Meta-analyses
				• Systematic reviews
				• RCTs
				• Other controlled studies
				• Cohort studies
				• Case series (excluding single patient case reports)
				• Health economic analyses
				• Resource utilisation studies

Search Date: 22nd June 2017

Databases Searched: We searched Medline, Embase, Cochrane, TRIP and NICE Evidence search limited to July 2016 onwards and English language. Conference papers, letters, commentary and editorials were excluded. This rapid evidence review is an update of a full review undertaken in July 2016 when an identical search for evidence back to 2006 was undertaken.

Search string for TRIP and NICE

"bariatric surgery" OR "weight loss surgery" from:2016

Embase search

# ▲	Searches
1	morbid obesity/
2	((morbid* or extreme*) adj2 (obes* or overweight)).ti,ab.
3	((bmi or "body mass index") adj5 (35* or 40* or 45* or 50* or 55* or 60* or 65* or 70*)).ti,ab.
4	1 or 2 or 3
5	health promotion/ or health education/
6	social marketing/
7	counseling/
8	motivational interviewing/
9	(health promot* or health educat* or counsel* or motivational interview* or brief interview* or motivational advice or brief advice or brief intervention*).ti,ab.
10	((psycholog* or psychosocial or psycho-social or behavio?ral) adj3 (program* or service? or intervention?)).ti,ab.
11	5 or 6 or 7 or 8 or 9 or 10
12	exp kinesiotherapy/
13	exp exercise/

14 exp physical activity/
15 eating habit/
16 exp diet therapy/
17 lifestyle/
18 (diet* or nutrition* or healthy eating or healthful eating or eating healthily or healthy lifestyle).ti.
19 (physical activity or exercise? or active lifestyle or walk* or cycl* or run* or jog*).ti.
20 body weight management/
21 weight reduction/
22 ((weight or bmi or body mass index) and (loss or lose or lost or losing or manage* or chang* or reduc*)).ti.
23 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22
24 4 and 11 and 23
25 nutritional counseling/
26 lifestyle modification/
27 weight loss program/
28 ((diet* or nutrition* or healthy eating or healthful eating or eating healthily or healthy lifestyle) adj5 (counsel* or advice* or support or promot*)).ti,ab.
29 ((diet* or nutrition* or healthy eating or healthful eating or eating healthily or healthy lifestyle) adj5 (program* or service? or intervention*)).ti,ab.
30 ((physical activity or exercise? or active lifestyle or walk* or cycl* or run* or jog*) adj5 (counsel* or advice* or support or promot*)).ti,ab.
31 ((physical activity or exercise? or active lifestyle or walk* or cycl* or run* or jog*) adj5 (program* or service? or intervention*)).ti,ab.
32 ((weight loss or weight management or weight reduction or weight change*) adj5 (counsel* or advice* or support or promot*)).ti,ab.
33 ((weight loss or weight management or weight reduction or weight change*) adj5 (program* or service? or intervention*)).ti,ab.
34 ((lifestyle or life style) adj5 (counsel* or advice* or support or promot*)).ti,ab.
35 ((lifestyle or life style) adj5 (program* or service? or intervention*)).ti,ab.
36 ((conventional or standard or medical or nonsurg* or non-surg*) adj2 (therap* or treatment or manage* or intervention?)).ti,ab.
37 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36
38 4 and 37
39 exp bariatric surgery/
40 (bariatric surg* or weight loss surg*).ti,ab.
41 ((gastric or intragastric or intra-gastric) adj2 (bypass* or band* or plication)).ti,ab.
42 (sleeve adj2 (gastrectomy or gastrectomies)).ti,ab.
43 ((roux or jejuno* or ileal) adj3 bypass*).ti,ab.
44 ((biliopancrea* or bilio-pancrea*) adj2 (diversion or bypass*)).ti,ab.
45 39 or 40 or 41 or 42 or 43 or 44
46 38 and 45
47 (2016* or 2017*).dp,dc,yr.
48 46 and 47
49 limit 48 to english language

50	conference*.pt.
51	49 not 50
52	4 and 45
53	47 and 52
54	limit 53 to "reviews (maximizes specificity)"
55	limit 54 to english language
56	55 not 50
57	51 or 56

7 References

1. National Institute for Health and Care Excellence. Obesity: identification, assessment and management (CG189) [Internet]. 2014 [cited 2017 July 2017]; Available from: https://www.nice.org.uk/guidance/cg189/chapter/Introduction.
2. NHS England. Clinical Commissioning Policy: Complex and Specialised Obesity Surgery. 2013
3. Department of Health. Developing a specification for lifestyle weight management services. 2013
4. National Institute for Health and Care Excellence. Costing template: Obesity: identification, assessment and management of overweight and obesity in children, young people and adults (CG189) [Internet]. [cited 2017 July 31st];Available from: https://www.nice.org.uk/guidance/cg189/resources.
5. National Institute for Health and Care Excellence. Implantation of a duodenal–jejunal bypass sleeve for managing obesity (IPG471) [Internet]. [cited 2017 July 31st];Available from: https://www.nice.org.uk/guidance/IPG471
6. National Institute for Health and Care Excellence. Laparoscopic gastric plication for the treatment of severe obesity (IPG432) [Internet]. [cited 2017 July 31st];Available from: https://www.nice.org.uk/guidance/IPG432
7. National Institute for Health and Care Excellence. Overweight and obese adults - NICE Pathways [Internet]. [cited 2017 July 31st];Available from: http://pathways.nice.org.uk/pathways/obesity#path=view%3A/pathways/obesity/overweight-and-obese-adults.xml&content=view-index
8. Public Health England Obesity & Healthy Weight Team. Report of the working group into joined up clinical pathways for obesity.pdf [Internet]. 2014. Available from: https://www.england.nhs.uk/wp-content/uploads/2014/03/owg-join-clinc-path.pdf
9. PHE. National mapping of weight management services. 2015
10. National Institute for Health and Care Excellence. Weight management: lifestyle services for overweight or obese adults (PH53) [Internet]. 2014 [cited 2017 July 31st];Available from: https://www.nice.org.uk/guidance/ph53
11. National Institute for Health and Care Excellence. Managing weight through lifestyle change in adults - NICE Pathways [Internet]. [cited 2017 July 31st];Available from: https://pathways.nice.org.uk/pathways/lifestyle-weight-management-services-for-overweight-or-obese-adults#path=view%3A/pathways/lifestyle-weight-management-services-for-overweight-or-obese-adults/lifestyle-weight-management-services-for-overweight-or-obese-adults-overview.xml&content=view-index
12. National Institute for Health and Care Excellence. BMI: preventing ill health and premature death in black, Asian and other minority ethnic groups (PH46) [Internet]. 2013 [cited 2017 July 31st];Available from: https://www.nice.org.uk/guidance/PH46
13. Royal College of Surgeons. Commissioning guide: Weight assessment and management clinics (Tier 3). 2014.
14. World Health Organisation. Obesity and overweight factsheet [Internet]. WHO [cited 2017 July 31st];Available from: http://www.who.int/mediacentre/factsheets/fs311/en/
15. Public Health England Obesity Knowledge and Intelligence team. Adult Obesity Slide Set [Internet]. 2017 [cited 2017 July 31st];Available from: https://www.noo.org.uk/slide_sets
16. Health and Social Care Information Centre. Health Survey for England, 2014 [Internet]. 2015 [cited 2017 July 31st];Available from: http://www.hscic.gov.uk/catalogue/PUB19295
17. Public Health England Obesity Knowledge and Intelligence team. UK and Ireland prevalence and trends [Internet]. [cited 2017 July 31st];Available from: https://www.noo.org.uk/NOO_about_obesity/adult_obesity/UK_prevalence_and_trends
18. Wang YC, McPherson K, Marsh T, Gortmaker SL, Brown M. Health and economic burden of the projected obesity trends in the USA and the UK. The Lancet 2011;378(9793):815–25
19. World Health Organisation. Nutrition, Physical Activity and Obesity: United Kingdom of Great Britain and Northern Ireland [Internet]. 2013. Available from: http://www.euro.who.int/__data/assets/pdf_file/0020/243335/United-Kingdom-WHO-Country-Profile.pdf?ua=1
20. Public Health England Obesity Knowledge and Intelligence team. Severe Obesity [Internet]. [cited 2017 July31st];Available from: https://www.noo.org.uk/NOO_about_obesity/severe_obesity

21. Prospective Studies Collaboration. Body-mass index and cause-specific mortality in 900 000 adults: collaborative analyses of 57 prospective studies. Lancet 2009;373(9669):1083–96.
22. National Bariatric Surgery Register. NSBR Second Registry Report. 2014
23. Colquitt JL, Pickett K, Loveman E, Frampton GK. Surgery for weight loss in adults. Cochrane Database Syst Rev 2014;8:CD003641
24. National Obesity Observatory. Bariatric surgery for obesity. 2010
25. Gloy VL, Briel M, Bhatt DL, Kashyap SR, Schauer PR, Mingrone G, et al. Bariatric surgery versus non-surgical treatment for obesity: a systematic review and meta-analysis of randomised controlled trials. BMJ 2013;347:f5934
26. Beyea MM, Garg AX, Weir MA. Does orlistat cause acute kidney injury? Ther Adv Drug Saf 2012;3(2):53–7.
27. Picot J, Jones J, Colquitt JL, Gospodarevskaya E, Loveman E, Baxter L, et al. The clinical effectiveness and cost-effectiveness of bariatric (weight loss) surgery for obesity: a systematic review and economic evaluation. Health Technol Assess Winch Engl 2009;13(41):1–190, 215–357, iii–iv.
28. Hachem A, Brennan L. Quality of Life Outcomes of Bariatric Surgery: A Systematic Review. Obes Surg 2016;26(2):395–409.
29. Cheng J, Gao J, Shuai X, Wang G, Tao K, Cheng J, et al. The comprehensive summary of surgical versus non-surgical treatment for obesity: a systematic review and meta-analysis of randomized controlled trials. Oncotarget [Internet] 2016 [cited 2017 Aug 4th];5(0). Available from: http://www.impactjournals.com/oncotarget/index.php?journal=oncotarget&page=article&op=view&path%5B%5D=9581
30. Zhou X, Yu J, Li L, Gloy VL, Nordmann A, Tiboni M, et al. Effects of Bariatric Surgery on Mortality, Cardiovascular Events, and Cancer Outcomes in Obese Patients: Systematic Review and Meta-analysis. Obes Surg 2016;
31. The Cochrane Collaboration. Cochrane Handbook for Systematic Reviews of Interventions: 9.5.2 Identifying and measuring heterogeneity [Internet]. 2011 [cited 2017 Aug 4th];Available from: http://handbook.cochrane.org/chapter_9/9_5_2_identifying_and_measuring_heterogeneity.htm
32. The Cochrane Collaboration. Cochrane Handbook for Systematic Reviews of Interventions: 9.6.6 Interpretation of subgroup analyses and meta-regressions [Internet]. 2011 [cited 2017 Aug 4th];Available from: http://handbook.cochrane.org/chapter_9/9_6_6_interpretation_of_subgroup_analyses_and_meta_regressions.htm
33. Dixon JB, O'Brien PE, Playfair J, Chapman L, Schachter LM, Skinner S, et al. Adjustable gastric banding and conventional therapy for type 2 diabetes: a randomized controlled trial. JAMA 2008;299(3):316–23.
34. Dixon, Schachter LM, O'Brien PE, et al. Surgical vs conventional therapy for weight loss treatment of obstructive sleep apnea: A randomized controlled trial. JAMA 2012;308(11):1142–9.
35. Ikramuddin S, Korner J, Lee W-J, Connett JE, Inabnet WB, Billington CB, et al. Roux-en-Y Gastric Bypass versus Intensive Medical Management for the Control of Type 2 Diabetes, Hypertension and Hyperlipidemia: An International, Multicenter, Randomized Trial. JAMA J Am Med Assoc 2013;309(21):2240–9
36. Liang Z, Wu Q, Chen B, Yu P, Zhao H, Ouyang X. Effect of laparoscopic Roux-en-Y gastric bypass surgery on type 2 diabetes mellitus with hypertension: a randomized controlled trial. Diabetes Res Clin Pract 2013;101(1):50–6.
37. Mingrone G, Panunzi S, De Gaetano A, Guidone C, Iaconelli A, Leccesi L, et al. Bariatric Surgery versus Conventional Medical Therapy for Type 2 Diabetes. N Engl J Med 2012;366(17):1577–85.
38. O'Brien PE, Dixon JB, Strauss BJG, Laurie C. Changes in body composition with weight loss: obese subjects randomized to surgical and medical programs. Obes Silver Spring Md 2007;15(5):1187–98
39. Schauer PR, Kashyap SR, Bhatt DL, Wolski K, Watanabe RM, Abdul-Ghani M, et al. Metabolic Effects of Bariatric Surgery in Patients With Moderate Obesity and Type 2 Diabetes. Diabetes Care 2013;36(8):2175–82
40. Halperin F, Ding S-A, Simonson DC, Panosian J, Goebel-Fabbri A, Wewalka M, et al. Roux-en-Y Gastric Bypass Surgery or Lifestyle With Intensive Medical Management in Patients With Type 2 Diabetes. JAMA Surg 2014;149(7):716–26.

41. Ding S-A, Simonson DC, Wewalka M, Halperin F, Foster K, Goebel-Fabbri A, et al. Adjustable Gastric Band Surgery or Medical Management in Patients With Type 2 Diabetes: A Randomized Clinical Trial. J Clin Endocrinol Metab 2015;100(7):2546–56.
42. Mingrone G, Panunzi S, Gaetano AD, Guidone C, Iaconelli A, Nanni G, et al. Bariatric–metabolic surgery versus conventional medical treatment in obese patients with type 2 diabetes: 5 year follow-up of an open-label, single-centre, randomised controlled trial. The Lancet 2015;386(9997):964–73
43. Cummings DE, Arterburn DE, Westbrook EO, Kuzma JN, Stewart SD, Chan CP, et al.Gastric bypass surgery vs intensive lifestyle and medical intervention for type 2 diabetes: the CROSSROADS randomised controlled trial. Diabetologia. 2016 01 May;59(5):945-53
44. Schauer PR, Bhatt DL, Kirwan JP, Wolski K, Aminian A, Brethauer SA, et al. Bariatric Surgery versus Intensive Medical Therapy for Diabetes - 5-Year Outcomes. N Engl J Med. 2017 Feb 16;376(7):641-51
45. Borisenko O, Adam D, Funch-Jensen P, Ahmed AR, Zhang R, Colpan Z, et al. Bariatric Surgery can Lead to Net Cost Savings to Health Care Systems: Results from a Comprehensive European Decision Analytic Model. Obes Surg 2015;25(9):1559–68.
46. Gulliford MC, Charlton J, Booth HP, Fildes A, Khan O, Reddy M, et al. Costs and outcomes of increasing access to bariatric surgery for obesity: cohort study and cost-effectiveness analysis using electronic health records. Health Serv Deliv Res 2016;4(17):1–120
47. RAND Health. 36-Item Short Form Survey from the RAND Medical Outcomes Study [Internet]. [cited 2017 Aug 18th];Available from: https://www.rand.org/health/surveys_tools/mos/mos_core_36item.htm
48. Manwaring J, Wilfley D. The Impact of Weight on Quality of Life Questionnaire [Internet]. In: Preedy VR, Watson RR, editors. Handbook of Disease Burdens and Quality of Life Measures. Springer New York; 2010 [cited 2017 Aug 18th]. page 209–25.Available from: http://link.springer.com/referenceworkentry/10.1007/978-0-387-78665-0_12
49. National Institute for Health and Care Excellence. Type 2 diabetes in adults: management (NG28) [Internet]. 2015. Available from: https://www.nice.org.uk/guidance/ng28
50. Wang BCM, Furnback W. Modelling the long-term outcomes of bariatric surgery: A review of cost-effectiveness studies. Best Pract Res Clin Gastroenterol 2013;27(6):987–95
51. Clegg A, Colquitt J, Sidhu M, Royle P, Walker A. Clinical and cost effectiveness of surgery for morbid obesity: a systematic review and economic evaluation. Int J Obes Relat Metab Disord J Int Assoc Study Obes 2003;27(10):1167–77.
52. Terranova L, Busetto L, Vestri A, Zappa MA. Bariatric surgery: cost-effectiveness and budget impact. Obes Surg 2012;22(4):646–53.
53. Weiner JP, Goodwin SM, Chang H-Y, Bolen SD, Richards TM, Johns RA, et al. Impact of bariatric surgery on health care costs of obese persons: a 6-year follow-up of surgical and comparison cohorts using health plan data. JAMA Surg 2013;148(6):555–62.
54. Finkelstein EA, Allaire BT, Globe D, Dixon JB. The Business Case for Bariatric Surgery Revisited: A Non-Randomized Case-Control Study. PLOS ONE 2013;8(9):e75498
55. Karim MA, Clifton E, Ahmed J, Mackay GW, Ali A. Economic evaluation of bariatric surgery to combat morbid obesity: a study from the West of Scotland. Asian J Endosc Surg 2013;6(3):197–202
56. Picot J, Jones J, Colquitt JL, Loveman E, Clegg AJ. Weight Loss Surgery for Mild to Moderate Obesity: A Systematic Review and Economic Evaluation. Obes Surg 2012;22(9):1496–506.
57. Hoerger TJ, Zhang P, Segel JE, Kahn HS, Barker LE, Couper S. Cost-Effectiveness of Bariatric Surgery for Severely Obese Adults With Diabetes. Diabetes Care 2010;33(9):1933–9
58. Ackroyd R, Mouiel J, Chevallier J-M, Daoud F. Cost-effectiveness and budget impact of obesity surgery in patients with type-2 diabetes in three European countries. Obes Surg 2006;16(11):1488–503
59. Hernandez LV, Klyve D. Quality-adjusted life expectancy benefits of laparoscopic bariatric surgery: A United States perspective. Int J Technol Assess Health Care 2010;26(3):280–287.
60. Claxton K, Martin S, Soares M, Rice N, Spackman E, Hinde S, et al. Methods for the estimation of the National Institute for Health and Care Excellence cost-effectiveness threshold. Health Technol Assess Winch Engl 2015;19(14):1–503, v–vi.
61. Hex N, Bartlett C, Wright D, Taylor M, Varley D. Estimating the current and future costs of Type 1 and Type 2 diabetes in the UK, including direct health costs and indirect societal and productivity costs. Diabet Med J Br Diabet Assoc 2012;29(7):855–62.

8 Clinician comments after 3 week consultation of the draft evidence review

The consultation period was from the 25th September to the 13th October.

No comments were received. The invitation to comment is below.

From: Barker Rachael (SPH)
Sent: 25 September 2017 16:08
To: 'martin.richardson@heartofengland.nhs.uk'; 'andrew.mckirgan@uhb.nhs.uk'; 'david.rosser@uhb.nhs.uk'; 'amir.khan@walsallhealthcare.nhs.uk'
Subject: BSOL CCGs Review of Bariatric Surgery
Importance: High

Subject: Solihull, Birmingham Cross City and Birmingham South Central CCGs Review of Bariatric Surgery

FAO: Clinicians with an interest in bariatric surgery in the CCG areas

Deadline for submission of comments: 5pm, Friday 13th October

Dear Colleagues,

Solihull, Birmingham Cross City and Birmingham South Central CCGs have commissioned Solutions for Public Health to produce a rapid evidence review on the clinical and cost effectiveness of bariatric surgery compared with non-surgical management.

This review will be considered by CCGs Treatment Policies Clinical Review Group and will inform future commissioning policy.

We have been given your name by the CCGs and we would be very grateful if you would consider either commenting on the attached review or passing it on to an appropriate colleague.

Please do not circulate this draft review beyond your NHS Trust or organisation (including posting to websites) or pass on to individual patients or patient groups as the CCG process does not include patient and public consultation at this draft stage.

In particular, we are keen to receive comments on the following:

1. **Evidence review**

   - Have we included all relevant studies?
   - Have we summarised and appraised the evidence appropriately?

   Please note that the CCGs do not consider evidence from conference posters and abstracts as the information is insufficient for critical appraisal.

2. **Current CCG activity and clinical practice**
   - Is the activity data presented an accurate reflection of current activity?
   - Are you aware of any additional issues which should be taken into account e.g. problems with IFR authorisation, routine coding, recent changes in clinical practice which would render the information out of date, etc? Please provide details.

- Do you have any additional information which should be considered e.g. your local pathways/protocols; audit results, national standards etc?

3. **Clinical opinion**

The CCGs value the opinion of specialist clinicians. This could include:

- Your view of the likely benefit of the procedure in practice;
- Where you feel the intervention should fit within the care pathway (including any criteria for access which you either currently use or would like to see in place);
- The number of patients you consider would benefit from access to the intervention across Solihull, Birmingham Cross City and Birmingham South Central CCGs.

4. **Format for Comments**

Your response should be submitted **in writing by 5pm, Friday 13th October**, preferably sent electronically in Word format or as an email text. We will include all written responses received in the appendix of the evidence review document. The main purpose of the review is to provide an evidence base for discussion by the CCGs Health Policy Committee. Although not a public document, your comments may be available to a wider audience, and may be subject to FOI request.

5. Finally, the CCGs may wish to invite lead clinicians to attend the CCGs Treatment Policies Clinical Review Group to contribute their advice and expertise to the CCGs discussion. The CCGs Treatment Policies Review Group meeting will be on Thursday 2nd November, at Friars Gate from 1.30-3.30pm. If would like to attend please contact Terri-Ann Millington (terri-ann.millington@nhs.net) who will register your interest and provide further details on specific agenda timings.

Please note that CCGs regard it as very important that all information on each topic is circulated in advance of the meetings. You will not have the opportunity to make a formal presentation or table new material at the meeting. May I therefore stress that it is very important that we receive your written input in advance.

We look forward to hearing from you and thank you in advance for your input to this.

Competing Interest

All SPH authors have completed the ICMJE uniform disclosure form (www.icmje.org/coi_disclosure.pdf) and declare: grants from Solihull CCG, Birmingham CrossCity CCG and Birmingham South Central CCG to SPH to undertake the submitted work, no financial relationships with any organisations that might have an interest in the submitted work in the previous three years and no other relationships or activities that could appear to have influenced the submitted work.

Terms of Use

This document has been produced by SPH for Solihull CCG, Birmingham CrossCity CCG and Birmingham South Central CCG. It must not be distributed or accessed or used for commercial purposes without prior written permission from SPH. The purpose of this document is to review and summarise published evidence relating to clinical interventions. The findings may be applicable to the development of commissioning policy, but commissioning policy development is undertaken by NHS commissioners taking into account a wide range of other factors. SPH is not responsible for the development of commissioning policy. Use of this document is subject to agreement that SPH is fully indemnified against any liability that may arise through use of the information within this document.

Appendix 1 – Levels of Evidence

Oxford Centre for Evidence-based Medicine – Levels of Evidence (March 2009)[4]

The CEBM 'Levels of Evidence 1' document sets out one approach to systematising this process for different question types (see our glossary).

Level	Therapy / Prevention, Aetiology / Harm	Prognosis	Diagnosis	Differential diagnosis / symptom prevalence study	Economic and decision analyses
1a	SR (with homogeneity*) of RCTs	SR (with homogeneity*) of inception cohort studies; CDR" validated in different populations	SR (with homogeneity*) of Level 1 diagnostic studies; CDR" with 1b studies from different clinical centres	SR (with homogeneity*) of prospective cohort studies	SR (with homogeneity*) of Level 1 economic studies
1b	Individual RCT (with narrow Confidence Interval"¡)	Individual inception cohort study with > 80% follow-up; CDR" validated in a single population	Validating** cohort study with good" " " reference standards; or CDR" tested within one clinical centre	Prospective cohort study with good follow-up****	Analysis based on clinically sensible costs or alternatives; systematic review(s) of the evidence; and including multi-way sensitivity analyses
1c	All or none§	All or none case-series	Absolute SpPins and SnNouts" "	All or none case-series	Absolute better-value or worse-value analyses " " " "
2a	SR (with homogeneity*) of cohort studies	SR (with homogeneity*) of either retrospective cohort studies or untreated control groups in RCTs	SR (with homogeneity*) of Level >2 diagnostic studies	SR (with homogeneity*) of 2b and better studies	SR (with homogeneity*) of Level >2 economic studies
2b	Individual cohort study (including low quality RCT; e.g., <80% follow-	Retrospective cohort study or follow-up of untreated control patients in an RCT;	Exploratory** cohort study with good" " " reference standards; CDR" after derivation, or	Retrospective cohort study, or poor follow-up	Analysis based on clinically sensible costs or alternatives; limited

[4] Produced by Bob Phillips, Chris Ball, Dave Sackett, Doug Badenoch, Sharon Straus, Brian Haynes, Martin Dawes since November 1998. Updated by Jeremy Howick March 2009.

	up)	Derivation of CDR" or validated on split-sample§§§ only	validated only on split-sample§§§ or databases		review(s) of the evidence, or single studies; and including multi-way sensitivity analyses
2c	"Outcomes" Research; Ecological studies	"Outcomes" Research		Ecological studies	Audit or outcomes research
3a	SR (with homogeneity*) of case-control studies		SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) of 3b and better studies
3b	Individual Case-Control Study		Non-consecutive study; or without consistently applied reference standards	Non-consecutive cohort study, or very limited population	Analysis based on limited alternatives or costs, poor quality estimates of data, but including sensitivity analyses incorporating clinically sensible variations.
4	Case-series (and poor quality cohort and case-control studies§§)	Case-series (and poor quality prognostic cohort studies***)	Case-control study, poor or non-independent reference standard	Case-series or superseded reference standards	Analysis with no sensitivity analysis
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on economic theory or "first principles"

Notes: Users can add a minus-sign "-" to denote the level of that fails to provide a conclusive answer because:

- ***EITHER*** a single result with a wide Confidence Interval
- ***OR*** a Systematic Review with troublesome heterogeneity.

Such evidence is inconclusive, and therefore can only generate Grade D recommendations.

*	By homogeneity we mean a systematic review that is free of worrisome variations (heterogeneity) in the directions and degrees of results between individual studies. Not all systematic reviews with statistically significant heterogeneity need be worrisome, and not all worrisome heterogeneity need be statistically significant. As noted above, studies displaying worrisome heterogeneity should be tagged with a "-" at the end of their designated level.
"	Clinical Decision Rule. (These are algorithms or scoring systems that lead to a prognostic estimation or a diagnostic category.)

“¡	See note above for advice on how to understand, rate and use trials or other studies with wide confidence intervals.
§	Met when all patients died before the Rx became available, but some now survive on it; or when some patients died before the Rx became available, but none now die on it.
§§	By poor quality cohort study we mean one that failed to clearly define comparison groups and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both exposed and non-exposed individuals and/or failed to identify or appropriately control known confounders and/or failed to carry out a sufficiently long and complete follow-up of patients. By poor quality case-control study we mean one that failed to clearly define comparison groups and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both cases and controls and/or failed to identify or appropriately control known confounders.
§§§	Split-sample validation is achieved by collecting all the information in a single tranche, then artificially dividing this into “derivation” and “validation” samples.
” “	An “Absolute SpPin” is a diagnostic finding whose Specificity is so high that a Positive result rules-in the diagnosis. An “Absolute SnNout” is a diagnostic finding whose Sensitivity is so high that a Negative result rules-out the diagnosis.
“¡”¡	Good, better, bad and worse refer to the comparisons between treatments in terms of their clinical risks and benefits.
” ” “	Good reference standards are independent of the test, and applied blindly or objectively to applied to all patients. Poor reference standards are haphazardly applied, but still independent of the test. Use of a non-independent reference standard (where the ‘test’ is included in the ‘reference’, or where the ‘testing’ affects the ‘reference’) implies a level 4 study.
” ” ” “	Better-value treatments are clearly as good but cheaper, or better at the same or reduced cost. Worse-value treatments are as good and more expensive, or worse and the equally or more expensive.
**	Validating studies test the quality of a specific diagnostic test, based on prior evidence. An exploratory study collects information and trawls the data (e.g. using a regression analysis) to find which factors are ‘significant’.
***	By poor quality prognostic cohort study we mean one in which sampling was biased in favour of patients who already had the target outcome, or the measurement of outcomes was accomplished in <80% of study patients, or outcomes were determined in an unblinded, non-objective way, or there was no correction for confounding factors.
****	Good follow-up in a differential diagnosis study is >80%, with adequate time for alternative diagnoses to emerge (for example 1-6 months acute, 1 – 5 years chronic)

Appendix 2 - Abbreviations

- **ADL** activities of daily living
- **AGB** adjustable gastric band
- **BDDS** biliopancreatic diversion with duodenal switch
- **BMI** body mass index
- **BP** blood pressure
- **CI** confidence interval
- **GORD** gastro-oesophageal reflux disease
- **HbA1c** glycated haemoglobin (provides an overall picture of average blood sugar levels over a period of weeks/months)
- **HDL** high-density lipoprotein
- **HR** hazard ratio
- **I^2** a measure of heterogeneity of studies in the meta-analysis. The Cochrane Handbook suggests where I2<40%, heterogeneity is unlikely to be important.
- **ICER** incremental cost-effectiveness ratio
- **ICU** intensive care unit
- **ILMI** Intensive Lifestyle and Medical Intervention
- **Lap** laparoscopic
- **LDL** low-density lipoprotein
- **LSG** Laparoscopic sleeve gastrectomy
- **LOS** length of stay
- **LRYGB** Laparoscopic Roux-en-Y gastric bypass
- **MO** morbid obesity
- **OR** odds ratio
- **OSA** obstructive sleep apnoea
- **p.a.** per annum
- **QALY** quality-adjusted life year
- **QoL** quality of life
- **RR** risk ratio
- **RYGB** Roux-en-Y gastric bypass
- **SG** sleeve gastrectomy
- **T2DM** type 2 diabetes mellitus
- **TG** triglycerides

DRAFT
Policy for Bariatric Surgery in Adults.

Document Details:

Version:	DRAFT v1.
Ratified by (name and date of Committee):	Treatment Policy Clinical Development Group 13.06.2019
Date issued for Public Engagement:	02.09.2019
Equality & Diversity Impact Assessment	

The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decisions are considered within the wider constraints of the CCG's legally responsibility to remain fiscally responsible.

Obesity is commonly defined as a Body Mass Index (BMI) of 30 kg/m2 or greater (see Table 1). Individuals living with obesity are at greater risk of a variety of different health conditions. These include:

- Type 2 diabetes mellitus (T2DM),
- Non-alcoholic fatty liver disease,
- Hypertension,
- Asthma,
- Gastro-oesophageal reflux disease,
- Depression and
- variety of other conditions [1].

The risk of developing obesity-related co-morbidities increases as an individual's BMI increases [2].

Table 1.

Definition	BMI range (kg/m2)
Underweight	Under 18.5
Normal	18.5 to less than 25
Overweight	25 to less than 30
Obese	30 to less than 40
Obese I	30 to less than 35
Obese II	35 to less than 40
Morbidly obese	40 and over

Source: NICE. Obesity: identification, assessment and management [1]

Epidemiology

Obesity is a global problem, estimated to have affected over six hundred million adults worldwide in 2014 [14]. In England, in both men and women, more than one in four adults are obese (28.2%) and 2.7% are classed as morbidly obese [15].

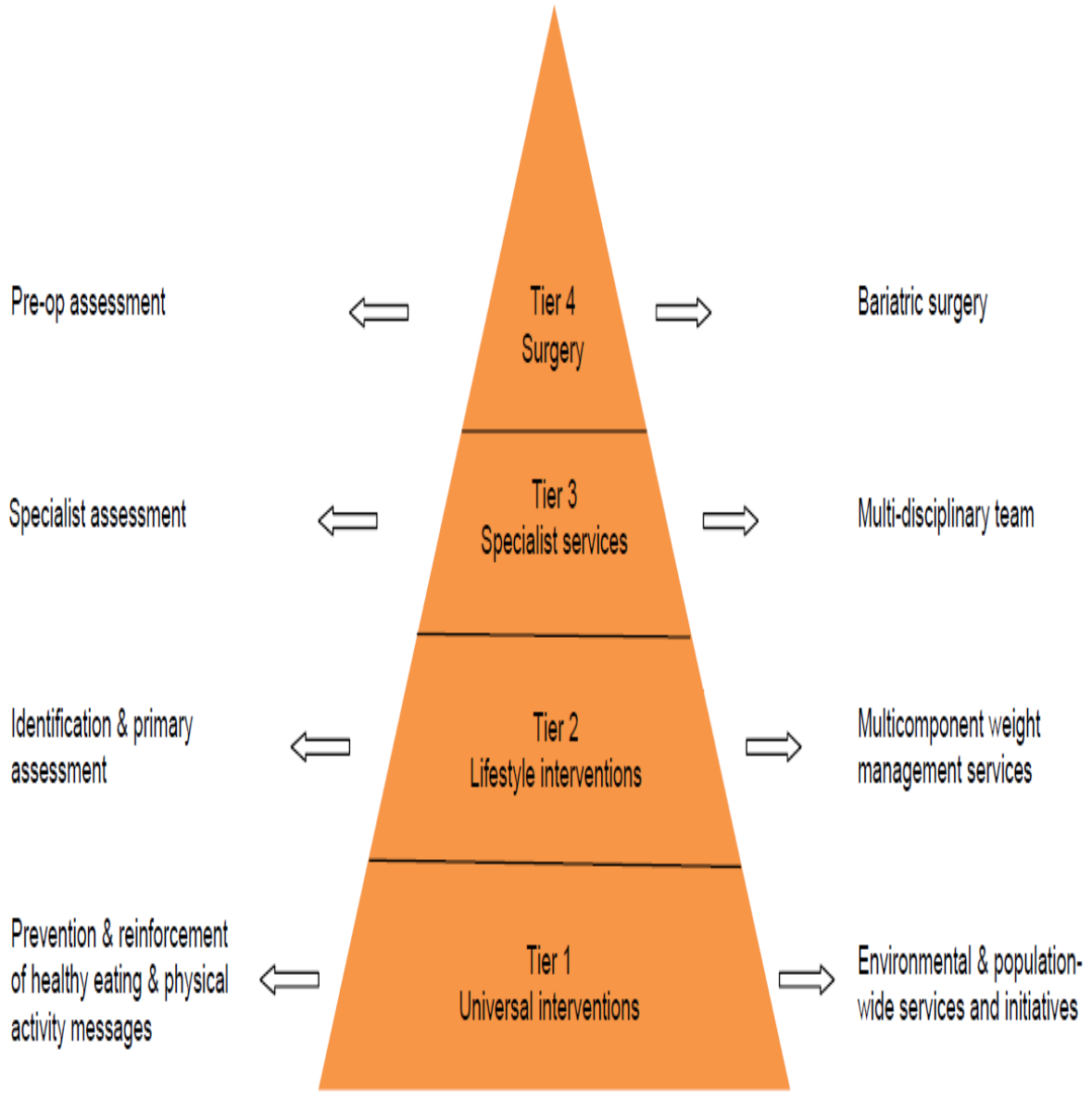
The prevalence of obesity in the UK rose between 1993 and 2014, the rate of increase began to slow in 2001 but the overall trend is still continuing to rise. According to the Health Survey for England, 61.7% of adults were overweight or obese in 2014, with more men being obese (65.3%) than women (58.1%) [16, 17]. Over the same time period, the prevalence of morbid obesity has also continued to climb, with a sharp rise in female prevalence between 2007 and 2011 (see Figure 4). Whilst the trend for males appears to have levelled off in recent years, the current level still represents a sizeable increase from that seen in the early 1990's. The number of people classed as obese in the UK is expected to increase by 11 million by 2030, with a likely corresponding increase in those with morbid obesity [18].

According to forecasts produced by the World Health Organisation, 31% of men and 30% of women will be obese by 2020, rising to 36% and 33% respectively by 2030 [19].

National Guidance

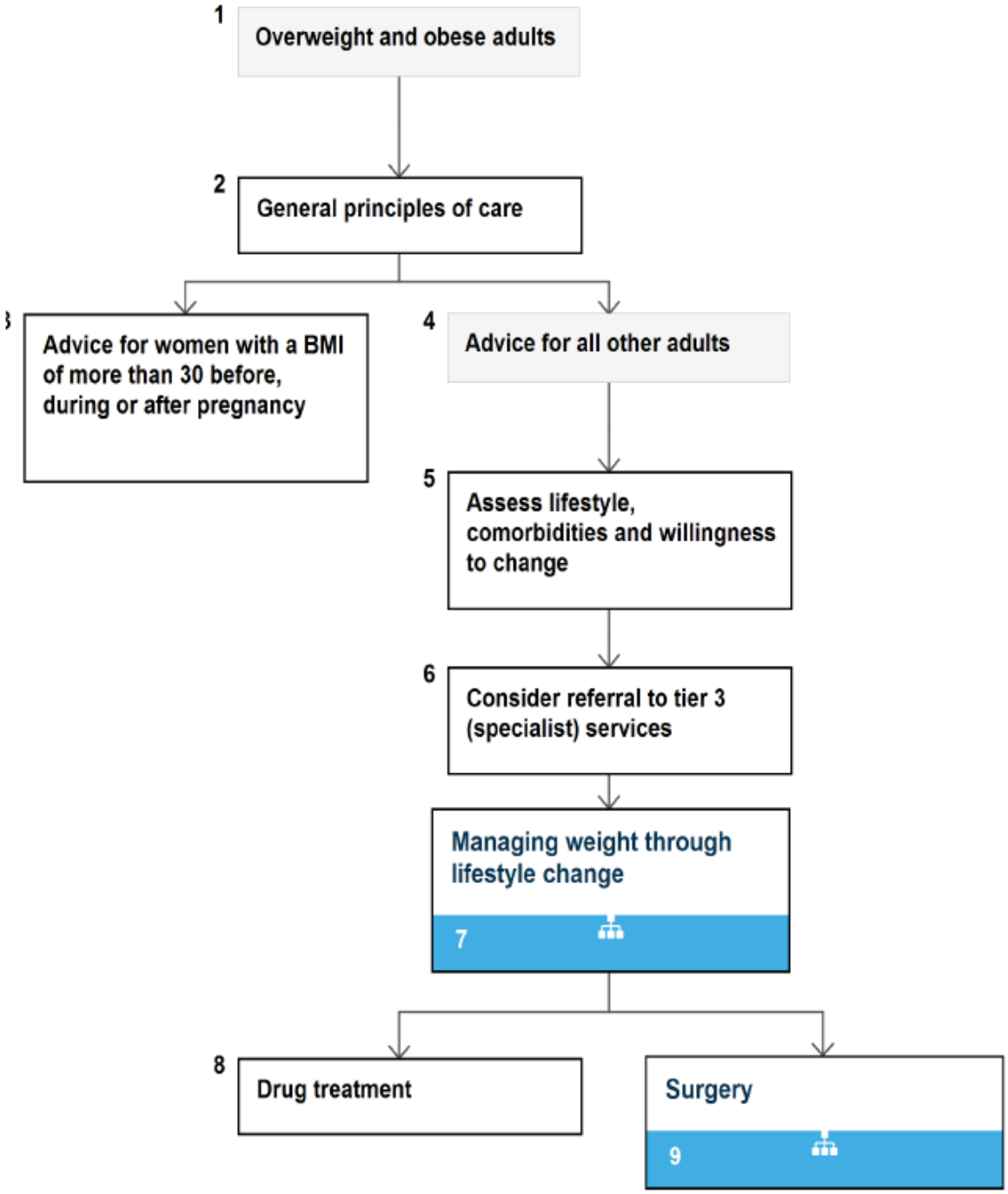
In England, obesity is managed through a tiered system (Figure 1), ranging from preventive population-based health promotion strategies (Tier 1) and lifestyle interventions (including diet, exercise, and behavioural) in primary care settings (Tier 2), through to more intensive specialist services provided by multi-disciplinary teams (tier 3) and bariatric surgery (tier 4) [3].

Figure 1: Tiered management of obesity



In November 2014, NICE published clinical guidance on the identification, assessment and management of obesity (NICE clinical guideline 189). [1]. The proposed NICE pathway is outlined below in Figure 2.

Figure 2: NICE pathway for overweight and obese adults



Co-Morbidities

The health issues associated with being overweight or obese include type 2 diabetes mellitus, cardiovascular disease and musculoskeletal disorders amongst others. People aged 35 to 59 with a BMI measurement of between 40 kg/m2 and 50 kg/m2 are five times more likely to die from ischaemic heart disease than those with a BMI of 22.5 kg/m2 to 25 kg/m2.

Between the same groups, the risk of dying from stroke was 6.5 times higher and the risk of dying from diabetes was 22.5 times higher. Vascular risk factors also exhibit a strong relationship with BMI; both systolic and diastolic blood pressure increases with BMI [20]. The prevalence of diabetes amongst those with normal weight was around 1.5%, compared to 15% in the severely obese [20].

On its own, BMI is a strong predictor of mortality and is strongly associated with diabetes for which sex-specific prevalence may rise more than five-fold from baseline across the BMI range. Table 3 shows a simplified version of the relationship between BMI and health risk.

Table 3: Co-Morbidity Risk by BMI Classification

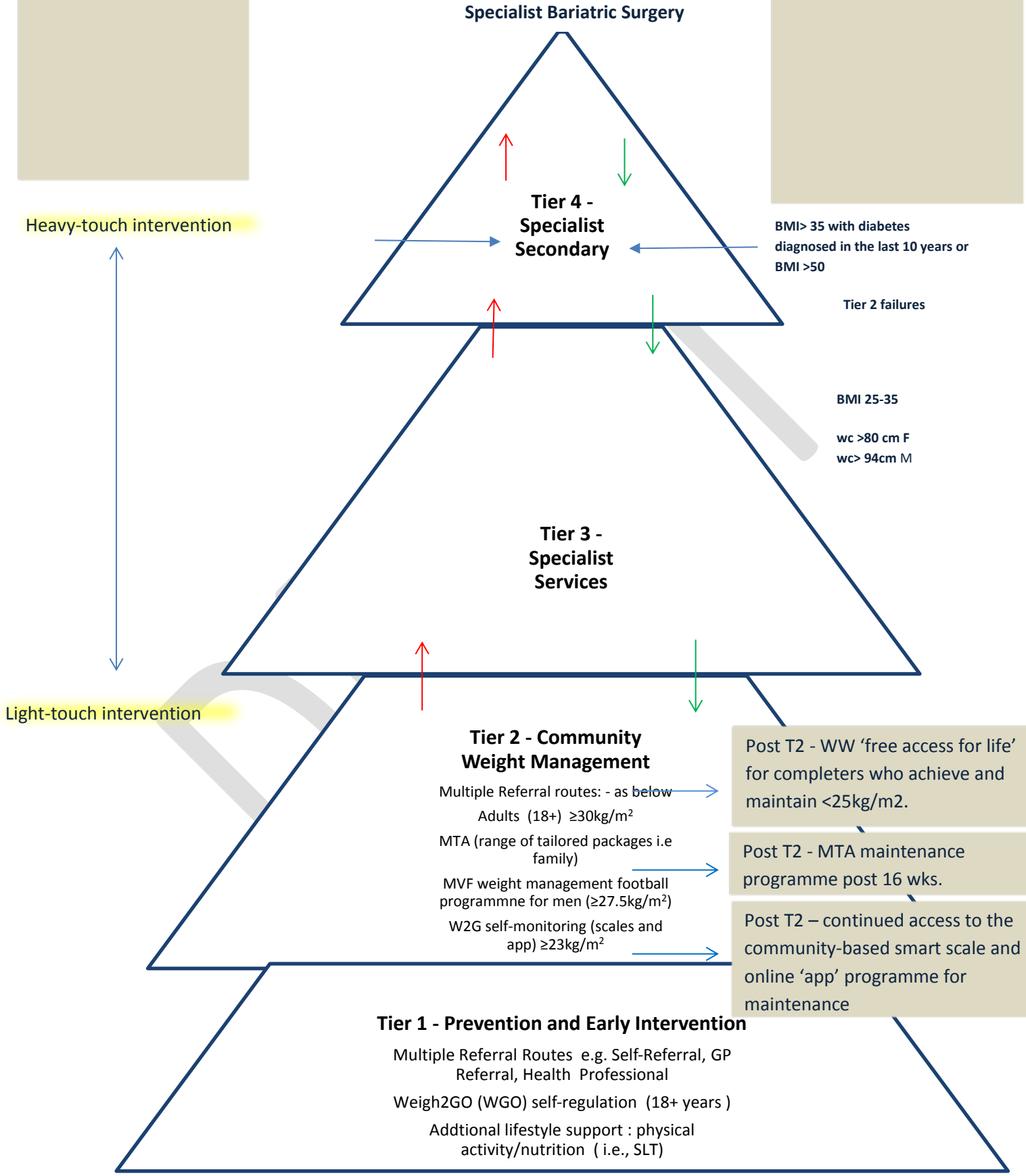
Classification	BMI (kg/m2)	Risk of Obesity Related Co-Morbidities
Underweight	<18.5	Low risk (but risk of other clinical problems increased)
Normal Range	18.50 – 24.99	Average risk
Overweight	≥25.0	Increased risk
Obese	≥30.0	Medium to high risk
Morbidly Obese	≥40.0	Very high risk

Non-Surgical Interventions

Non-surgical interventions for obesity consist of a wide variety of measures which may be used in varying combinations as part of a multi-component pathway. Generally this comprises dietary intake, physical activity levels and behaviour change and may also include pharmacological interventions [25]. These should be clinically led and involve multi-disciplinary assessment [13].

Sandwell and West Birmingham CCG have a designated weight management pathway for service users to follow:

Weight Management Services Pathway 2019



The Tier 3 service should be provided via a multidisciplinary team containing a bariatric physician, dietitian, specialist nurse, clinical psychologist and a liaison psychiatry professional. In addition to this there should also be access to a physical therapist.

Non-surgical weight-management interventions (also known as 'Lifestyle Interventions') are commonly split into four categories:
1. Behavioural interventions
2. Physical activity
3. Behaviour change
4. Pharmacological interventions.

Interventions should be seen as multicomponent and incorporate combinations of the interventions described below.

Behavioural interventions
Behavioural interventions are provided with the support of an appropriately trained professional and include various strategies for adults which are incorporated as appropriate. These include (but are not limited to) self-monitoring of behaviour and progress, stimulus control, goal setting, ensuring social support is available, cognitive restructuring (modifying thoughts), reinforcement of changes and providing strategies for dealing with weight regain [1].

Physical Activity
Encouragement should be given to increase levels of physical activity, regardless of whether this will lead to weight-loss. This is due to the general fitness improvements it can bring and the associated reduced risk of cardiovascular disease and type 2 diabetes. This may comprise of 45-60 minutes of moderate-intensity exercise per day, increasing to 60-90 minutes for those who have already lost weight to prevent regaining of excess weight. Suitable activities include brisk walking, gardening, cycling, supervised exercise programmes, swimming, stair-climbing etc [1].

Dietary
Dietary interventions should not be unduly restrictive but should be tailored to individual food preferences and also be nutritionally balanced. As with physical activity, dietary improvements should be encouraged for reasons other than weight loss alone due to the associated health benefits which a balanced diet can bring. The primary requirement for a dietary intervention however is to reduce energy intake to a point below energy expenditure by approximately 600 kcal/day or by reducing fat content. This should be partnered with expert support and intensive follow-up. Low (800-1600 kcal/day) and very low (800 kcal/day or less) calorie diets should be used with some degree of caution due to issues around nutritional completeness [1].

Pharmacological Interventions

Pharmacological interventions should only be considered after behavioural, physical and dietary interventions have been started and evaluated. This applies especially to those service-users who have not achieved their target weight loss or have plateaued. It may also be utilised to maintain weight-loss as opposed to continuing weight loss [1]. Orlistat is the only pharmacological treatment for obesity currently recommended by NICE. This medication is a lipase inhibitor which works through preventing approximately a third of consumed fat from being absorbed, However in addition to the well-documented side effects, there are potential issues related to the heightened risk of kidney problems [26].

Bariatric Surgery

Bariatric surgery includes a group of procedures that promote weight loss. They are usually performed laparoscopically, with decreased time in hospital and a shorter recovery time compared to open procedures. In the UK and Ireland, there were over 18,000 bariatric surgery operations in the three financial years ending 2011, 2012, and 2013; 95.4% of all primary operations were performed laparoscopically over this period [22]. More recently, minimally invasive surgical techniques also include robotic procedures, though their feasibility and safety are debated. Bariatric surgery may be categorised under three headings: restrictive; malabsorptive and combined procedures.

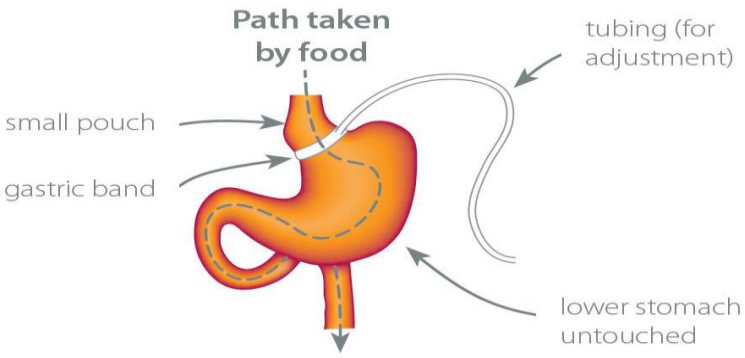
Restrictive procedures

Restrictive procedures, described below, lead to a fixed or adjustable reduction in the size of the upper gastrointestinal tract.

Adjustable gastric banding (AGB)

This procedure places an adjustable silicone band around the upper stomach, creating a small pouch above the band and a narrowing between the pouch and main part of the stomach below it (Figure 6). This restricts the amount of food that can be eaten and reduces hunger sensations by pressing on the surface of the stomach. The band may be tightened or loosened by injecting or removing saline through a portal under the skin that is connected to the band. The procedure is reversible and relatively non-invasive. AGB has replaced the older restrictive gastroplasty (horizontal, vertical, and banded) procedures that are no longer performed in the UK due to poorer performance. Gastric banding made up 22.3% of all bariatric surgery operations in the UK between 2011 and 2013 [22, 23, 24].

Figure 6: Diagrammatic representation of a gastric band in place

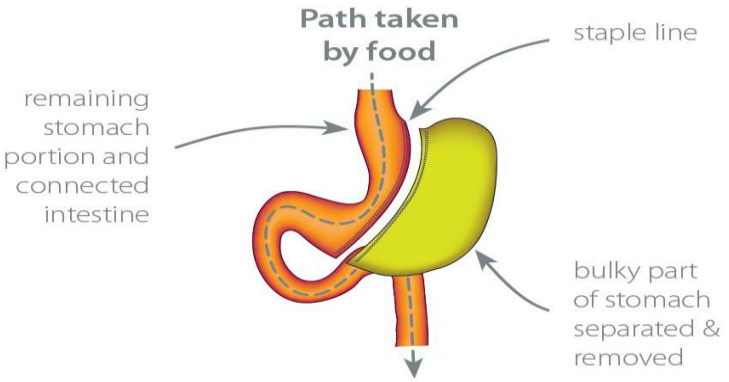


Source: National Bariatric Surgery Register. NSBR Second Registry Report. 2014 [22]

Sleeve gastrectomy (SG)

This procedure divides the stomach vertically to reduce its size by seventy-five percent, whilst keeping the stomach function and digestion unaltered by leaving the pyloric valve intact (see Figure 7). The procedure is not reversible, but is relatively quick to perform and is one of the most commonly performed restrictive procedures. It was initially used as the first of a two-part procedure for patients at high risk from bariatric surgery, followed by a conversion to either a Roux-en-Y gastric bypass or a duodenal switch (see below). However, as some patients achieve significant weight loss with the sleeve gastrectomy alone, it is now also used as a stand-alone procedure. In some patients, the procedure may be followed by a duodenojejunal bypass, which involves bypassing the first part of the small intestine, resulting in food moving directly to the latter part of the small intestine, thereby reducing absorption of calories. SG made up 20.8% of all bariatric surgery operations in the UK between 2011 and 2013 [22]. A further 12 (0.07%) SG procedures were performed in combination with a biliopancreatic diversion with duodenal switch

Figure 7: The basics of a sleeve gastrectomy procedure



Source: National Bariatric Surgery Register. NSBR Second Registry Report. 2014 [22]

Intragastric balloon (IGB)
Intragastric balloon procedures involve placing a silicon balloon endoscopically to float freely inside the stomach, thereby reducing the volume of the stomach, leading to an earlier sensation of satiety. It is typically used either in patients who are at least 40% of their optimal weight, or in morbidly obese patients for whom surgery is high risk. IGB made up 2.1% of all bariatric surgery operations in the UK between 2011 and 2013 [22].

Gastric plication (or gastric imbrication)
A newer procedure that reduces the stomach volume by folding the stomach into itself and stitching it to create a narrow tube shape, similar to that of SG, but without removing any stomach tissue (Figure 6). The Registry report does not present the exact number or proportion of all November 2017 bariatric surgery operations that involve gastric plication. However, it is less than the 2.1% procedures labelled as 'other' in the Registry report [22].

Malabsorptive procedures

Malabsorptive procedures bypass a section of the intestine, with less physical restriction of food intake.

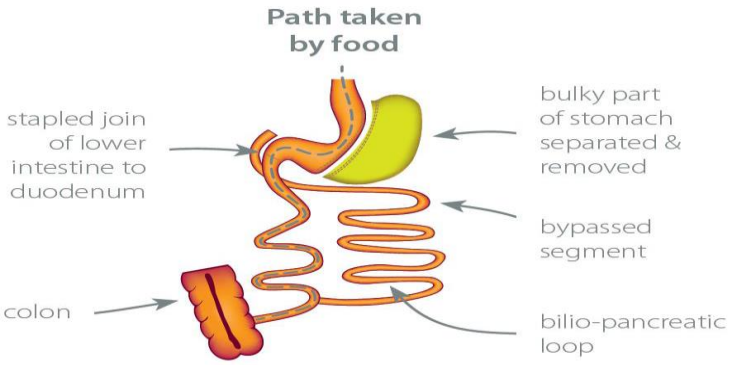
Biliopancreatic diversion (without duodenal switch)
This procedure is typically no longer performed in the UK due to risk of postgastrectomy syndrome (including, for example, dumping syndrome, bile reflux, diarrhoea). It involved portions of the stomach being removed through a horizontal gastrectomy (a restrictive procedure), with the small remaining pouch being connected to the final section of the small intestine. This is now replaced with the biliopancreatic diversion with duodenal switch (BDDS) procedure, which may be classed as a combined procedure (see group 3 below).

Jejunoileal bypass (JIB)
This procedure is no longer performed in the UK, where a significant part of the small intestine was detached and set to the side.

Combined procedures
Combined procedures include both restrictive and malabsorptive components.

Biliopancreatic diversion with duodenal switch (BDDS)
Biliopancreatic diversion with duodenal switch involves an initial restrictive vertical gastrectomy, followed by the malabsorptive component which re-routes a long portion of the small intestine, creating two separate pathways and one common channel (Figure 8). The shorter of the two pathways, the digestive loop, takes food from the stomach to the common channel. The longer pathway, the biliopancreatic loop, carries bile from the liver to the common channel. This procedure reduces the amount of time the body has to capture calories from food in the small intestine, and selectively limits the absorption of fat. The procedure is partially reversible, but there were only 19 BDDS procedures (0.1%), together with a further 12 procedures combined with SG in the UK between 2011 and 2013 [22].

Figure 8: Biliopancreatic diversion with duodenal switch

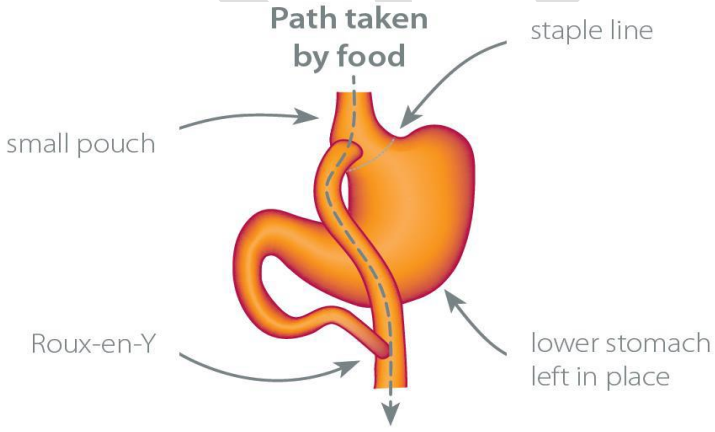


Source: National Bariatric Surgery Register. NSBR Second Registry Report. 2014 [22]

Roux-en-Y gastric bypass (RYGB)

Roux-en-Y gastric bypass has replaced the older banded gastric bypass, and involves creating a small pouch from the stomach which remains attached to the oesophagus at one end, and connected to a section of the small intestine at the other end, thereby bypassing the remaining stomach and the initial loop of small intestine (Figure 9). This procedure reduces intestinal absorption. Adaptations of the procedure have been used to increase malabsorption and increase weight loss. The procedure is technically reversible. Roux en Y gastric bypass comprises 52.1% of bariatric surgery in the United Kingdom [22].

Figure 9: Diagrammatic representation of a Roux-en-Y gastric bypass procedure



Source: National Bariatric Surgery Register. NSBR Second Registry Report. 2014 [22].

Eligibility Criteria: Restricted

Patients eligible for surgery must have the following:

- BMI of >35kg/m2
  AND
  Type 2 diabetes mellitus which has been diagnosed within the last 10 years.
  OR
- BMI of >50kg/m2

The choice of surgery must be undertaken by a specialist bariatric surgeon following a shared decision making discussion with the patient:

- Listen to patients and respond to their concerns and preferences.
- Give patients the information they want or need in a way they can understand.
- Respect patients' right to reach decisions with the doctor about their treatment and care.
- Support patients in caring for themselves to improve and maintain their health.

If the patient is obese and does not meet the above criteria, the patient should be referred to Tier 3 services.

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

This means **(for patients who DO NOT meet the above criteria),** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that request is supported by the CCG.

Guidance

1. National Institute for Health and Care Excellence. Obesity: identification, assessment and management (CG189) [Internet]. 2014 [cited 2017 July 2017]; Available from: https://www.nice.org.uk/guidance/cg189/chapter/Introduction.

2. NHS England. Clinical Commissioning Policy: Complex and Specialised Obesity Surgery. 2013

3. Department of Health. Developing a specification for lifestyle weight management services. 2013

4. National Institute for Health and Care Excellence. Costing template: Obesity: identification, assessment and management of overweight and obesity in children, young people and adults (CG189) [Internet]. [cited 2017 July 31st];Available from: https://www.nice.org.uk/guidance/cg189/resources.

5. National Institute for Health and Care Excellence. Implantation of a duodenal–jejunal bypass sleeve for managing obesity (IPG471) [Internet]. [cited 2017 July 31st];Available from: https://www.nice.org.uk/guidance/IPG471

6. National Institute for Health and Care Excellence. Laparoscopic gastric plication for the treatment of severe obesity (IPG432) [Internet]. [cited 2017 July 31st];Available from: https://www.nice.org.uk/guidance/IPG432

7. National Institute for Health and Care Excellence. Overweight and obese adults - NICE Pathways [Internet]. [cited 2017 July 31st];Available from: http://pathways.nice.org.uk/pathways/obesity#path=view%3A/pathways/obesity/overweight-and-obese-adults.xml&content=view-index

8. Public Health England Obesity & Healthy Weight Team. Report of the working group into joined up clinical pathways for obesity.pdf [Internet]. 2014. Available from: https://www.england.nhs.uk/wp-content/uploads/2014/03/owg-join-clinc-path.pdf

9. PHE. National mapping of weight management services. 2015

10. National Institute for Health and Care Excellence. Weight management: lifestyle services for overweight or obese adults (PH53) [Internet]. 2014 [cited 2017 July 31st];Available from: https://www.nice.org.uk/guidance/ph53

11. National Institute for Health and Care Excellence. Managing weight through lifestyle change in adults - NICE Pathways [Internet]. [cited 2017 July 31st];Available from: https://pathways.nice.org.uk/pathways/lifestyle-weight-management-services-for-overweight-or-obese-adults#path=view%3A/pathways/lifestyle-weight-management-services-for-overweight-or-obese-adults/lifestyle-weight-

management-services-for-overweight-or-obese-adults-overview.xml&content=view-index

12. National Institute for Health and Care Excellence. BMI: preventing ill health and premature death in black, Asian and other minority ethnic groups (PH46) [Internet]. 2013 [cited 2017 July 31st];Available from: https://www.nice.org.uk/guidance/PH46

13. Royal College of Surgeons. Commissioning guide: Weight assessment and management clinics (Tier 3). 2014.

14. World Health Organisation. Obesity and overweight factsheet [Internet]. WHO [cited 2017 July 31st];Available from: http://www.who.int/mediacentre/factsheets/fs311/en/

15. Public Health England Obesity Knowledge and Intelligence team. Adult Obesity Slide Set [Internet]. 2017 [cited 2017 July 31st];Available from: https://www.noo.org.uk/slide_sets

16. Health and Social Care Information Centre. Health Survey for England, 2014 [Internet]. 2015 [cited 2017 July 31st];Available from: http://www.hscic.gov.uk/catalogue/PUB19295

17. Public Health England Obesity Knowledge and Intelligence team. UK and Ireland prevalence and trends [Internet]. [cited 2017 July 31st];Available from: https://www.noo.org.uk/NOO_about_obesity/adult_obesity/UK_prevalence_and_trends

18. 18. Wang YC, McPherson K, Marsh T, Gortmaker SL, Brown M. Health and economic burden of the projected obesity trends in the USA and the UK. The Lancet 2011;378(9793):815–25]

19. World Health Organisation. Nutrition, Physical Activity and Obesity: United Kingdom of Great Britain and Northern Ireland [Internet]. 2013. Available from: http://www.euro.who.int/__data/assets/pdf_file/0020/243335/United-Kingdom-WHO-Country-Profile.pdf?ua=1

20. Public Health England Obesity Knowledge and Intelligence team. Severe Obesity [Internet]. [cited 2017 July31st];Available from: https://www.noo.org.uk/NOO_about_obesity/severe_obesity

21. Prospective Studies Collaboration. Body-mass index and cause-specific mortality in 900 000 adults: collaborative analyses of 57 prospective studies. Lancet 2009;373(9669):1083–96.

22. National Bariatric Surgery Register. NSBR Second Registry Report. 2014

23. Colquitt JL, Pickett K, Loveman E, Frampton GK. Surgery for weight loss in adults. Cochrane Database Syst Rev 2014;8:CD003641

24. National Obesity Observatory. Bariatric surgery for obesity. 2010

25. Gloy VL, Briel M, Bhatt DL, Kashyap SR, Schauer PR, Mingrone G, et al. Bariatric surgery versus non-surgical treatment for obesity: a systematic review and meta-analysis of randomised controlled trials. BMJ 2013;347:f5934

26. Beyea MM, Garg AX, Weir MA. Does orlistat cause acute kidney injury? Therapeutic Advancements in Drug Safety 2012;3(2):53–7.

27. Picot J, Jones J, Colquitt JL, Gospodarevskaya E, Loveman E, Baxter L, et al. The clinical effectiveness and cost-effectiveness of bariatric (weight loss) surgery for obesity: a systematic review and economic evaluation. Health Technology Assessment Winch Engl 2009;13(41):1–190, 215–357, iii–iv.

28. 28. Hachem A, Brennan L. Quality of Life Outcomes of Bariatric Surgery: A Systematic Review. Obes Surg 2016;26(2):395–409.

29. 29. Cheng J, Gao J, Shuai X, Wang G, Tao K, Cheng J, et al. The comprehensive summary of surgical versus non-surgical treatment for obesity: a systematic review and meta-analysis of randomized controlled trials. Oncotarget [Internet] 2016 [cited 2017 Aug 4th];5(0). Available from: http://www.impactjournals.com/oncotarget/index.php?journal=oncotarget&page=article&op=view&path%5B%5D=9581

30. Zhou X, Yu J, Li L, Gloy VL, Nordmann A, Tiboni M, et al. Effects of Bariatric Surgery on Mortality, Cardiovascular Events, and Cancer Outcomes in Obese Patients: Systematic Review and Meta-analysis. Obes Surg 2016;

31. The Cochrane Collaboration. Cochrane Handbook for Systematic Reviews of Interventions: 9.5.2 Identifying and measuring heterogeneity [Internet]. 2011 [cited 2017 Aug 4th];Available from: http://handbook.cochrane.org/chapter_9/9_5_2_identifying_and_measuring_heterogeneity.htm

32. The Cochrane Collaboration. Cochrane Handbook for Systematic Reviews of Interventions: 9.6.6 Interpretation of subgroup analyses and meta-regressions [Internet]. 2011 [cited 2017 Aug 4th];Available from: http://handbook.cochrane.org/chapter_9/9_6_6_interpretation_of_subgroup_analyses_and_meta_regressions.htm

33. Dixon JB, O'Brien PE, Playfair J, Chapman L, Schachter LM, Skinner S, et al. Adjustable gastric banding and conventional therapy for type 2 diabetes: a randomized controlled trial. JAMA 2008;299(3):316–23.

34. Dixon, Schachter LM, O'Brien PE, et al. Surgical vs conventional therapy for weight loss treatment of obstructive sleep apnea: A randomized controlled trial. JAMA 2012;308(11):1142–9.

35. Ikramuddin S, Korner J, Lee W-J, Connett JE, Inabnet WB, Billington CB, et al. Roux-en-Y Gastric Bypass versus Intensive Medical Management for the Control of Type 2 Diabetes, Hypertension and Hyperlipidemia: An International, Multicenter, Randomized Trial. JAMA J Am Med Assoc 2013;309(21):2240–9

36. Liang Z, Wu Q, Chen B, Yu P, Zhao H, Ouyang X. Effect of laparoscopic Roux-en-Y gastric bypass surgery on type 2 diabetes mellitus with hypertension: a randomized controlled trial. Diabetes Res Clin Pract 2013;101(1):50–6.

37. Mingrone G, Panunzi S, De Gaetano A, Guidone C, Iaconelli A, Leccesi L, et al. Bariatric Surgery versus Conventional Medical Therapy for Type 2 Diabetes. N Engl J Med 2012;366(17):1577–85.

38. O'Brien PE, Dixon JB, Strauss BJG, Laurie C. Changes in body composition with weight loss: obese subjects randomized to surgical and medical programs. Obes Silver Spring Md 2007;15(5):1187–98

39. Schauer PR, Kashyap SR, Bhatt DL, Wolski K, Watanabe RM, Abdul-Ghani M, et al. Metabolic Effects of Bariatric Surgery in Patients With Moderate Obesity and Type 2 Diabetes. Diabetes Care 2013;36(8):2175–82

40. Halperin F, Ding S-A, Simonson DC, Panosian J, Goebel-Fabbri A, Wewalka M, et al. Roux-en-Y Gastric Bypass Surgery or Lifestyle With Intensive Medical Management in Patients With Type 2 Diabetes. JAMA Surg 2014;149(7):716–26.

41. Ding S-A, Simonson DC, Wewalka M, Halperin F, Foster K, Goebel-Fabbri A, et al. Adjustable Gastric Band Surgery or Medical Management in Patients With Type 2 Diabetes: A Randomized Clinical Trial. J Clin Endocrinol Metab 2015;100(7):2546–56.

42. Mingrone G, Panunzi S, Gaetano AD, Guidone C, Iaconelli A, Nanni G, et al. Bariatric–metabolic surgery versus conventional medical treatment in obese patients with type 2 diabetes: 5 year follow-up of an open-label, single-centre, randomised controlled trial. The Lancet 2015;386(9997):964–73

43. Cummings DE, Arterburn DE, Westbrook EO, Kuzma JN, Stewart SD, Chan CP, et al.Gastric bypass surgery vs intensive lifestyle and medical intervention for type 2 diabetes: the CROSSROADS randomised controlled trial. Diabetologia. 2016 01 May;59(5):945-53

44. Schauer PR, Bhatt DL, Kirwan JP, Wolski K, Aminian A, Brethauer SA, et al. Bariatric Surgery versus Intensive Medical Therapy for Diabetes - 5-Year Outcomes. N Engl J Med. 2017 Feb 16;376(7):641-51

45. Borisenko O, Adam D, Funch-Jensen P, Ahmed AR, Zhang R, Colpan Z, et al. Bariatric Surgery can Lead to Net Cost Savings to Health Care Systems: Results from a Comprehensive European Decision Analytic Model. Obes Surg 2015;25(9):1559–68.

46. Gulliford MC, Charlton J, Booth HP, Fildes A, Khan O, Reddy M, et al. Costs and outcomes of increasing access to bariatric surgery for obesity: cohort study and cost-effectiveness analysis using electronic health records. Health Serv Deliv Res 2016;4(17):1–120

47. RAND Health. 36-Item Short Form Survey from the RAND Medical Outcomes Study [Internet]. [cited 2017 Aug 18th];Available from: https://www.rand.org/health/surveys_tools/mos/mos_core_36item.htm

48. Manwaring J, Wilfley D. The Impact of Weight on Quality of Life Questionnaire [Internet]. In: Preedy VR, Watson RR, editors. Handbook of Disease Burdens and Quality of Life Measures. Springer New York; 2010 [cited 2017 Aug 18th]. page 209–25.Available from: http://link.springer.com/referenceworkentry/10.1007/978-0-387-78665-0_12

49. National Institute for Health and Care Excellence. Type 2 diabetes in adults: management (NG28) [Internet]. 2015. Available from: https://www.nice.org.uk/guidance/ng28

50. Wang BCM, Furnback W. Modelling the long-term outcomes of bariatric surgery: A review of cost-effectiveness studies. Best Pract Res Clin Gastroenterol 2013;27(6):987–95

51. Clegg A, Colquitt J, Sidhu M, Royle P, Walker A. Clinical and cost effectiveness of surgery for morbid obesity: a systematic review and economic evaluation. Int J Obes Relat Metab Disord J Int Assoc Study Obes 2003;27(10):1167–77.

52. Terranova L, Busetto L, Vestri A, Zappa MA. Bariatric surgery: cost-effectiveness and budget impact. Obes Surg 2012;22(4):646–53.

53. Weiner JP, Goodwin SM, Chang H-Y, Bolen SD, Richards TM, Johns RA, et al. Impact of bariatric surgery on health care costs of obese persons: a 6-year follow-up of surgical and comparison cohorts using health plan data. JAMA Surg 2013;148(6):555–62.

54. Finkelstein EA, Allaire BT, Globe D, Dixon JB. The Business Case for Bariatric Surgery Revisited: A Non-Randomized Case-Control Study. PLOS ONE 2013;8(9):e75498

55. Karim MA, Clifton E, Ahmed J, Mackay GW, Ali A. Economic evaluation of bariatric surgery to combat morbid obesity: a study from the West of Scotland. Asian J Endosc Surg 2013;6(3):197–202

56. Picot J, Jones J, Colquitt JL, Loveman E, Clegg AJ. Weight Loss Surgery for Mild to Moderate Obesity: A Systematic Review and Economic Evaluation. Obes Surg 2012;22(9):1496–506.

57. Hoerger TJ, Zhang P, Segel JE, Kahn HS, Barker LE, Couper S. Cost-Effectiveness of Bariatric Surgery for Severely Obese Adults With Diabetes. Diabetes Care 2010;33(9):1933–9

58. Ackroyd R, Mouiel J, Chevallier J-M, Daoud F. Cost-effectiveness and budget impact of obesity surgery in patients with type-2 diabetes in three European countries. Obes Surg 2006;16(11):1488–503

59. Hernandez LV, Klyve D. Quality-adjusted life expectancy benefits of laparoscopic bariatric surgery: A United States perspective. Int J Technol Assess Health Care 2010;26(3):280–287.

60. Claxton K, Martin S, Soares M, Rice N, Spackman E, Hinde S, et al. Methods for the estimation of the National Institute for Health and Care Excellence cost-effectiveness threshold. Health Technol Assess Winch Engl 2015;19(14):1–503, v–vi.

61. Hex N, Bartlett C, Wright D, Taylor M, Varley D. Estimating the current and future costs of Type 1 and Type 2 diabetes in the UK, including direct health costs and indirect societal and productivity costs. Diabet Med J Br Diabet Assoc 2012;29(7):855–62.

IMAGE-GUIDED HIGH VOLUME INTRA-ARTICULAR INJECTIONS (40MLS+) OF SALINE WITH OR WITHOUT CORTICOSTEROID AND/OR LOCAL ANAESTHETIC FOR THE TREATMENT OF PAINFUL JOINTS

Questions to be addressed

1. In adults with a painful joint, is treatment with image-guided HIGH VOLUME intra-articular injections clinically effective compared to alternative treatment options?
2. In adults with a painful joint, is treatment with image-guided HIGH VOLUME intra-articular injections cost effective compared to alternative treatment options?

Reason for review

NHS Birmingham and Solihull CCG, Sandwell and West Birmingham CCG, in partnership with Walsall CCG, Wolverhampton CCG and Dudley CCG, requested a rapid evidence review of the clinical and cost effectiveness of image-guided HIGH VOLUME intra-articular injections compared to alternative treatment options to inform their decisions on commissioning policy development.

Options for commissioners:

1. The Committee considers that due to the limited quality of evidence of clinical and cost effectiveness for image-guided HIGH VOLUME intra-articular injections compared to alternative treatment options, its use should be considered a low priority.
2. The Committee recommends that, due to the limited quality of evidence of its clinical and cost effectiveness, image-guided HIGH VOLUME intra-articular injections should be offered ONLY to patients who have failed to respond to conventional interventions, including intra-articular corticosteroid injections.
3. The Committee considers that there is sufficient evidence to suggest that image-guided HIGH VOLUME intra-articular injections is at least as effective as alternative treatment options and the costs are comparable, therefore the decision about which approach to proceed with should be made after an informed discussion between the clinician and the individual person about the risks and benefits of each procedure.

Summary

Background

- Pain in the joints affects millions of people worldwide. The causes of joint pain are numerous.
- Joint pain can be related to osteoarthritis or inflammatory joint disorders such as rheumatoid arthritis and psoriatic arthritis. It can also be as a result of traumatic injury, joint surgery or crystal deposition in the joints such as gout or chondrocalcinosis[a]. Other causes of joint pain include sports injuries, general sprains and strains, adhesive capsulitis, unstable shoulder, and bleeding into joint spaces caused by torn ligaments.

[a] Pseudogout, also known as chondrocalcinosis, is a common joint disease caused by deposition of calcium pyrophosphate dihydrate (CPPD) crystals. Most often, it is asymptomatic, but it may simulate gout and osteoarthritis.

- Despite the wide range of conditions and symptoms, different types of joint pain may share similar underlying mechanisms, manifestations, and potential treatments.
- Treatment of joint pain consists of both pharmacologic and non-pharmacologic modalities. First-line therapy generally includes oral analgesia and physiotherapy. If these fail, intra-articular steroid injection may be considered. Image-guided high volume intra-articular injection (hydrodilatation) and arthroscopic capsular release (ACR) are treatment options for adhesive capsulitis (frozen shoulder).

Clinical effectiveness

- We searched for studies that compared image-guided high volume injections to alternative treatment options and the only comparative studies identified were in patients with frozen shoulder. In this rapid evidence review, we report results from two systematic reviews of RCTs and one RCT (published subsequent to the systematic reviews) of the effectiveness of hydrodilatation (also referred to as arthrographic distension) with image-guided high volume injection in patients with adhesive capsulitis (frozen shoulder).
- The systematic review (with meta-analysis) by Saltychev et al (2018) evaluated the evidence on the effectiveness of hydrodilatation (HD) in adults with adhesive capsulitis, frozen shoulder, painful stiff shoulder, or osteoarthritis (presence of pain with restriction of active and passive glenohumeral joint movements). They included 12 RCTs in the review and seven in the meta-analysis. The total number of patients included in the review or meta-analysis was not reported.
    - The meta-analysis of seven of the RCTs showed that for hydrodilatation with corticosteroid versus intra-articular corticosteroids injection alone, there were statistically significant improvements in pain (p=0.00; numbers needed to treat (NNT)[b] = 12) and range of motion (p=0.01; NNT= 12) in favour of hydrodilatation. However, these did not translate to a difference in disability assessment between the two treatment arms (p=0.11).
    - The authors concluded that hydrodilatation has only a small, clinically insignificant effect when treating adhesive capsulitis. These results need to be interpreted with caution as they are from small studies (number of participants ranged from eight to 60) and only a few outcome measures were reported.
- The systematic review conducted by Catapano et al (2018) to determine whether the combined intervention of hydrodilatation and corticosteroid injection expedites restoration of pain-free range of motion (ROM) compared to a control treatment of corticosteroid injection in patients with adhesive capsulitis included six RCTs involving 410 shoulders.
    - Two studies demonstrated statistically significant improvement in pain measured using the VAS with hydrodilatation and corticosteroid injection when compared to corticosteroid injection alone; one study at 12 weeks (p=0.002) and the other at one month (p=0.035).
    - Two studies demonstrated statistically significant improvement in favour of hydrodilatation with corticosteroid injection in ROM at 12 weeks (extension ROM p=0.03; external rotation ROM p=0.010 and abduction ROM p=0.005; internal rotation p=0.027) and one at one month (external rotation, p=0.005).

[b] NNT is the number of patients that need to be treated to achieve one patient with an improvement.

  - Two studies showed no difference between hydrodilatation with corticosteroid injection and corticosteroid injection alone.
  - In contrast to Saltychev et al, and despite considering some of the same studies (reported differently), Catapano et al concluded that combining hydrodilatation with corticosteroid injection potentially expedites recovery of pain-free ROM. These findings need to be interpreted with caution as the results were not consistent across the studies included and no meta-analysis was carried out.
- Gallacher et al carried out an RCT (n=50) to determine whether the Oxford Shoulder Score (OSS)[c] differs between patients with frozen shoulder treated with arthroscopic capsular release (ACR)[d] and hydrodilatation (HD). Patients were randomised to ACR (n=25) or HD (n=25) between June 2013 and December 2013.
  - At six months after the intervention, both groups demonstrated significant improvements in OSS from baseline, but the OSS was significantly higher in the ACR cohort than the HD cohort (p= 0.023). The ACR and HD cohorts showed improvements in external rotation and forward elevation with the improvement in both outcomes being significantly greater in the ACR group (p=0.03 and p=0.023 respectively). Significant improvement in EQ-5D[e] VAS was also noted in each group, but the difference in improvement between the groups at any time point was not significant.
  - The authors concluded that ACR is associated with significantly higher OSS at six months than HD however, significant improvement was observed in both groups. These findings need to be interpreted with caution as the study was small (n=50) so may not have been sufficiently powered to show any differences. In addition the fact that this was a patient-reported outcome measure may have introduced some bias especially as they were not blinded to their treatment.

Safety

- Both systematic reviews reported adverse events associated with hydrodilatation with corticosteroid and corticosteroid only intra-articular injections.
- Saltychev et al (2018) reported that some transient adverse events such as flushing or disturbances in heat regulation, loss of sensation and motor control in the affected arm, loss of sleep, nausea, dizziness, after-pain and hypotensive syncope were observed with both the hydrodilatation with corticosteroid and corticosteroid only groups based on three studies. No absolute numbers or proportions were reported.
- They reported one case of glenohumeral joint infection in a patient treated with hydrodilatation and corticosteroid.
- Catapano et al (2018) reported that side effects were equal among the combined (hydrodilatation with corticosteroid) intervention group and control (corticosteroid only)

[c] The Oxford Shoulder Score (OSS) is a validated patient-reported outcome measure. The OSS questionnaire contains 12 items, each with five potential answers. Patients are asked to rate their symptoms between 1 (minimal symptoms) and 5 (severe symptoms). The combined total gives a minimum score of 12 and a maximum of 60.

[d] Arthroscopic capsular release is an arthroscopic (keyhole) surgery that releases the tightness found in the capsule in cases of frozen shoulder. The aim of capsule release surgery is to restore movement in the shoulder

[e] EuroQol-5D (EQ-5D) is used to measure health-related quality of life; it measures a patient's health across five different domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ-5D has two parts. First, the EQ-5D profile, asks patients to classify their health based on self-assessed levels of problems ("no", "some", "extreme") on the five dimensions. The second is the EQ-VAS, which asks patients to indicate their overall health on a vertical visual analogue scale, ranging from "worst possible" to "best possible" health.

group. They state that approximately 15% of patients in each group described transient loss of sensation, motor control of the arm, flushing, nausea, dizziness, pain and/or discomfort on injection with no further details.

- The RCT by Gallacher et al (2018) reported that there were no complications with either ACR or hydrodilatation.

Cost effectiveness

- No cost effectiveness studies of hydrodilatation compared to alternative treatment options were found. One systematic review attempted to assess the cost-effectiveness of different interventions used for frozen shoulder, including hydrodilatation (referred to arthrographic distension in the review); however, because of the paucity of evidence, the development of an economic model was not feasible (Maund et al 2012).
- Consequently, the authors estimated average treatment costs from the perspective of the UK NHS for the interventions identified in the systematic review.

Equity issues

- It is unknown if there is variation in access to image-guided HIGH VOLUME intra-articular injections compared to alternative treatment options across providers in the NHS Birmingham and Solihull CCG, Sandwell and West Birmingham CCG, and Walsall, Wolverhampton and Dudley CCGs areas, or how access or uptake compares to the rest of England.

1 Context

1.1 Introduction

Pain in the joints affects millions of people worldwide. The causes of joint pain are numerous. Joint pain can be related to osteoarthritis or inflammatory joint disorders such as rheumatoid arthritis and psoriatic arthritis. Joint pain can also be as a result of traumatic injury, joint surgery or crystal deposition in the joints such as gout or chondrocalcinosis[f]. Other causes of joint pain include sports injuries, general sprains and strains, frozen or unstable shoulder, and bleeding into joint spaces caused by torn ligaments [1, 2].

Depending on the individual, pain might be felt in the joint or in the muscles around the joint. Depending on the cause the pain may be diffuse and constant, occurring at rest or while moving. Despite the wide range of underlying conditions and symptoms, joint pain of different aetiology may share similar mechanisms, manifestations, and potential treatments [1]

Treatment of joint pain consists of both pharmacologic and non-pharmacologic modalities. First-line therapy generally includes analgesia and physiotherapy. If these fail, intra-articular steroid injection may be considered. High volume injection intra-articular injection (hydrodilatation) and arthroscopic capsular release (ACR) are considered treatment options for adhesive capsulitis (frozen shoulder) [3].

1.2 Existing national policies and guidance

There is no relevant published NICE Technology Appraisal Guidance (with statutory requirement for NHS organisations to make funding available), Clinical Guidelines or Quality Standards specifically for image-guided HIGH VOLUME intra-articular injections.

2 Epidemiology

Joint pain is one of the leading causes of disability worldwide [4].

A survey carried out by Duncan et al (2011) on the prevalence of arthritis and joint pain in the elderly in Scotland found that 63% of 803 respondents reported joint pain in the previous month. Women reported pain more often than men (68% versus 56%, p=0.001). The individuals who experienced pain were most likely to have knee pain (65%), followed by shoulder pain (31%) then lower back pain (28%), hip pain (25%) and hand pain (24%). Pain was more prevalent in women across all joint areas but the gender difference was only statistically significant for foot (p=0.002), neck (p < 0.0001), ankle (p = 0.01) and lower back pain (p = 0.001) [5].

[f] Pseudogout, also known as chondrocalcinosis, is a common joint disease caused by deposition of calcium pyrophosphate dihydrate (CPPD) crystals. Most often, it is asymptomatic, but it may simulate gout and osteoarthritis.

3 The interventions

Hydrodilatation (HD) also known as arthrographic capsular distension or distension arthrography is a procedure where a high volume injection of saline solution and/or steroids or air is given into the joint usually into the glenohumeral (shoulder) joint. For the purpose of this rapid evidence review we will use the term hydrodilatation (HD). HD is generally carried out with a mixture of contrast medium, long acting anaesthetics, steroids, saline or air. However, because of the inherent compressibility of air, the procedure is more difficult than when saline is used. Dependent upon the contracted state of the joint capsule, HD usually occurs with an injection of between 10ml and 55ml of normal saline [6].

The procedure is performed under imaging guidance, using fluoroscopy, ultrasound or Computed Tomography (CT). HD is felt to provide benefit via two mechanisms: manual stretching of the capsule and thus disruption of adhesions that might be limiting the movements of the glenohumeral joint and causing pain and disability which are characteristic of adhesive capsulitis; and the introduction of cortisone, which provides a potent anti-inflammatory effect and thus prevents further recurrence of adhesion. The risk of complications is thought to be low and treatment success is known after a couple of weeks [6, 7].

4 Findings

We searched Medline, Embase and Cochrane Library on the 19th September 2018 using the search strategy detailed in section 7 below. We also ran a search of TRIP database and NICE Evidence search with similar limits and restricting to Evidence Reviews.

The search was limited to 2008 onwards and English only and we excluded letters, commentary, case reports and conference papers.

4.1 Evidence of effectiveness

We identified three systematic reviews of RCTs [8, 9, 10] of the effectiveness of hydrodilatation with image-guided high volume injection. All three systematic reviews focused on patients with adhesive capsulitis (frozen shoulder). Of the two SRs published in 2018 [8, 9] only one carried out a meta-analysis [8]. The health technology assessment (HTA) published in 2012, attempted to assess cost-effectiveness but without conducting a meta-analysis of pooled results [10]. We have not reported the clinical effectiveness outcomes reported in the HTA by Maund et al 2012 [10] as they have been superseded by the RCTs in the 2018 systematic reviews. However, the information on costs is reported as it is the only one identified. We also identified one relevant RCT published subsequent to these systematic reviews [3].

Earlier systematic reviews which considered the same RCTs as the recent, included systematic reviews with or without meta-analysis were excluded. Individual studies already included in the systematic reviews have not been reported separately. Non-comparative studies were excluded because they add little when there is RCT evidence.

4.1.1 Clinical effectiveness

The systematic review (with meta-analysis) by Saltychev et al (2018) [8] evaluated the evidence on the effectiveness of hydrodilatation with image-guided high volume injection in adults with adhesive capsulitis, frozen shoulder, painful stiff shoulder, or osteoarthritis (presence of pain with restriction of active and passive glenohumeral joint movements). They included 12 RCTs in the review and seven in the meta-analysis. The studies included in the meta-analysis compared hydrodilatation with corticosteroid with corticosteroid injection only. The authors stated that the volume of mixture injected for HD to occur varied from 20ml to 90ml in the studies included. The total number of participants was not provided but patient numbers in the studies varied between eight and 60. It was not clear whether the participants had failed other treatment. The authors report that most of the studies were of moderate quality.

The outcomes reported were change in pain severity, disability level and range of movement (ROM). A statistically significant improvement in pain using VAS[g] was reported for hydrodilatation with corticosteroid versus corticosteroids injection (mean difference (MD): 0.37 (95% CI 0.12 to 0.61), p=0.001; 5 studies, n=not reported). The number of patients that needed to be treated (NNT) in order to get a significant improvement in pain scores was 12. There was no information on the details of the VAS used. A statistically significant improvement in range of movement (ROM) based on pooled results from six studies of hydrodilatation with corticosteroid versus corticosteroids [MD: 0.38 (95% CI 0.07 to 0.69), p=0.01; 6 studies, n=not reported). The number of patients that needed to be treated (NNT) in order to get a significant improvement in range of movement was 12. Importantly, the statistically significant difference between the two treatments for pain and for ROM, did not translate to any between group difference in disability assessment measured using SPADI[h] between hydrodilatation with corticosteroid and corticosteroids alone [MD: 0.20 (95% CI 0.-0.04 to 0.44), p=0.11; 4 studies, n=not reported].

Saltychev et al (2018) concluded that hydrodilatation has only a small, clinically insignificant effect when treating adhesive capsulitis [8]. These results should be interpreted with caution as they are from small studies (number of participants ranged from eight to 60) with only a few outcome measures reported. In addition, the participants were not blinded to their treatment and the assessors were not blinded to the treatment in two of the seven studies included in the meta-analysis.

Catapano et al (2018) [9] conducted a systematic review (no meta-analysis) to determine whether the combined intervention of hydrodilatation and corticosteroid injection(HD) expedites restoration of pain-free ROM compared to a control treatment of intra-articular corticosteroid injection(IAI) in patients with adhesive capsulitis. They included six RCTs (involving 410 shoulders), one of which only used 10ml of injection. The mean age of participants ranged from 51 to 61 years. In most of the studies participants were

[g] VAS: visual analogue score – the details of the score used was not reported.

[h] The Shoulder Pain and Disability Index (SPADI) was developed to measure current shoulder pain and disability in an outpatient setting. The SPADI contains 13 items that assess two domains; a 5-item subscale that measures pain and an 8-item subscale that measures disability.

symptomatic for at least three months. These studies were included in the review by Saltychev et al (2018) [8]. The authors report that the studies were of moderate quality.

Two RCTs (n = 100 shoulders and 90 shoulders respectively) demonstrated statistically significant improvement in pain in favour of treatment with HD compared to IAI: pain (VAS) at 12 weeks (HD 3.29 (SD 0.95) versus IAI 3.57 (SD 1.1), p=0.002), and the other at one month (HD 3.6 (SD 1.3) versus IAI 4.6(SD 1.1), p=0.035).

Three RCTs showed statistically and clinically significant improvement in ROM in favour of treatment with HD compared to IAI:

- at 12 weeks: abduction: (HD 114.4 (SD 30.1) versus IAI 82.7(SD 22.6), p=0.005); internal rotation (HD 55.4^0 (SD 18.2^0) versus IAI 48.4^0 (SD 10.8^0), p=0.027; n= 100 shoulders;
- at 12 weeks: (extension ROM p=0.03; external rotation ROM p=0.010; n= not reported - no detailed results were provided;
- at one month; external rotation (HD 36^0 (SD 9^0) versus IAI 28^0(SD 8^0), p=0.005 n= 90 shoulders;

In contrast, two studies demonstrated no benefit in any outcome measures with HD when compared to IAI alone.

The authors concluded that *"combining hydrodilatation with corticosteroid injection potentially expedites recovery of pain-free ROM"*. The greatest benefit appears to be within the first 3 months of intervention in the RCTs that showed improvement however, long term outcomes were not reported. These findings need to be interpreted with caution as studies were small, and they varied significantly regarding the volume of injection used. In addition, pain scores were reported by patients who were not blinded to their treatment.

Gallacher et al [3] carried out an RCT (n=50) to determine whether the Oxford Shoulder Score (OSS)[i] differs between patients with frozen shoulder treated with arthroscopic capsular release (ACR)[j] and hydrodilatation (HD).

Patients presenting with severe idiopathic frozen shoulder deemed suitable for surgical intervention by a consultant shoulder surgeon at a UK centre were randomised to ACR (n=25) or HD (n=25) between June 2013 and December 2016. Patients had had at least three months' duration of symptoms, and had failed a course of physiotherapy. The average age of the HD and ACR cohorts was 55.2 and 52.6 years, respectively. The primary outcome measure was OSS at six months, with secondary outcomes measures of the EuroQol-5D[k] visual analogue scale, external rotation, complications, and crossover rate also recorded.

---

[i] The Oxford Shoulder Score (OSS) is a validated patient-reported outcome measure. The OSS questionnaire contains 12 items, each with five potential answers. Patients are asked to rate their symptoms between 1 (minimal symptoms) and 5 (severe symptoms). The combined total gives a minimum score of 12 and a maximum of 60.

[j] Arthroscopic capsular release is an arthroscopic (keyhole) surgery that releases the tightness found in the capsule in cases of frozen shoulder. The aim of capsule release surgery is to restore movement in the shoulder

[k] EuroQol-5D (EQ-5D) is used to measure health-related quality of life; it measures a patient's health across five different domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ-5D has two parts. The first, the EQ-5D profile, asks patients to classify their health based on self-assessed levels of problems ("no", "some", "extreme") on the five dimensions. The

Six months after the intervention, 20 patients were available for follow-up in the HD cohort and 19 in the ACR cohort. Both groups demonstrated significant improvements in OSS from baseline, but the OSS was statistically and clinically significantly higher in the ACR cohort than the HD cohort (43.8 (95% CI, 42.2 to 45.2) versus 38.5 (95% CI, 34.6 to 42.4), p= 0.023). The ACR and HD cohorts both showed improvements in external rotation (47° versus 34°) and forward elevation (83° versus 71°), with the improvement in both outcomes being statistically and clinically significantly greater in the ACR group (p=0.03 and p=0.023 respectively). Significant improvement in EQ-5D VAS was also noted in each group, but the difference in improvement between the groups at any time point was not significant (10 versus 19.6 for ACR and HD, respectively, p= 0.053). Before the 6-month follow-up, four patients crossed over from HD to ACR; in contrast, one patient in the ACR cohort crossed over to HD. For the patients that crossed over from the HD group to the ACR group, the authors observed a mean 11.0 point improvement in the OSS at 6 weeks after HD compared with a 20.6 point improvement in the HD group that did not cross over. After ACR, the crossover patients then demonstrated a 28.0 point improvement in OSS from the baseline at 6 months.

Although significant improvement in OSS was observed in both groups, the results suggest that HD is inferior to ACR as it is associated with significantly lower OSS and change in ROM at six months follow-up. There was no difference in health-related quality of life between the two groups. These findings need to be interpreted with caution because the study was small (n=50) and therefore may not have been sufficiently powered to show any differences. It is unclear what criteria would be used to offer patients ACR in every day clinical practice. In addition the pain scores were reported by the patients who were not blinded to their treatment in fact four patients from the HD group crossed over to ACR before treatment was started. It is unclear whether the ROM assessors were blinded to the treatments.

Trials in progress
A search of clinicaltrials.gov did not identify any relevant ongoing trials.

4.1.2 Cost-effectiveness

We identified one HTA which attempted to assess the cost-effectiveness of the different interventions for frozen shoulder.

However, Maund et al [10] were not able to report the cost-effectiveness of the different interventions for frozen shoulder including arthrographic distension due to a lack of reliable clinical effectiveness outcomes to populate a plausible, economic model.

As an alternative, the authors estimated average costs for the interventions from the perspective of the UK NHS, based on NHS reference costs (2008-9) and resource-use estimates obtained from clinical experts.

---

second is the EQ-VAS, which asks patients to indicate their overall health on a vertical visual analogue scale, ranging from “worst possible” to “best possible” health.

Critically none of the resource utilisation costs listed below take into account the relative effectiveness for each intervention. They therefore shed no light on the relative cost effectiveness of any of the treatment options.

The authors estimated that the cost of arthrographic distension derived from NHS reference costs (high volume image-guided injection) was approximately £114.84 (£79.84 to £134.84), depending on the choice of steroid injection. They also reported the costs of other treatments used for frozen shoulder as follows;

- The costs for standard unguided steroid injection varied from £36.16 to £138.51 depending on the practitioner delivering the injection, the type of steroid used and where the practitioner is based (i.e. the setting). These costs suggest that a physiotherapist delivering treatment in a community setting is the cheapest option and a rheumatologist delivering treatment in a hospital setting is the most expensive.
- The estimated costs of standard guided steroid injection ranged from £299.68 to £475.56. These costs were mainly influenced by who delivered the injection; whether it's an orthopaedic surgeon, a rheumatologist or a radiologist.
- Physiotherapy treatment was estimated to cost between £98.75 and £126.75 dependent on setting. The addition of a steroid injection to physiotherapy presented a plethora of scenarios dependent on practitioner, steroid choice and setting; these costs range between £121.43 and £607.31.
- Manipulation under anaesthesia (MUA) was estimated to cost £1446 (£1,213 to £1,522) and capsular release £2,204 (£1,809 to £2,511), both of which included rehabilitation physiotherapy.

Table 1: Summary of systematic reviews of image-guided HIGH VOLUME intra-articular injections compared to alternative treatment options

Study	Patients	Intervention	Comparator	Outcomes
Saltychev et al 2018 [8] Finland Systematic review and meta-analysis of RCTs 12 RCTs in the SR 7 RCTs in the meta-analysis RCTs from different countries No UK studies included Search date – September 2017	Adults with adhesive capsulitis, frozen shoulder, painful stiff shoulder, or osteoarthritis (presence of pain with restriction of active & passive glenohumeral joint movements) Total number of patients not reported	Hydrodilatation Volume = 20 to 90ml Mixture = triamcinolone or methylprednisolone + contrast + normal saline ± local anaesthetic	Placebo, sham, other interventions, or no treatment as reported by individual study.	**PRIMARY OUTCOMES** **Pain** **hydrodilatation + corticosteroid vs corticosteroids (pooled results for 5 studies) –** Mean difference in **VAS** = 0.37 [95% CI 0.12 to 0.61 (p=0.00)], NNT= 12 - The number of patients that needed to be treated (NNT) in order to get a significant improvement in pain scores was 12. **Disability assessment** **hydrodilatation + corticosteroid vs corticosteroids (Pooled results for 4 studies)** Mean difference in **SPADI** = 0.20 [95% CI 0.-0.04 to 0.44 (p=0.11)] **SECONDARY OUTCOMES** **ROM** **hydrodilatation + corticosteroid vs corticosteroids (pooled results for 6 studies)** Mean difference in **ROM** = 0.38 [95% CI 0.07 to 0.69 (p=0.01)], NNT= 12 - The number of patients that needed to be treated (NNT) in order to get a significant improvement in range of movement scores was 12. **ADVERSE EVENTS (3 studies)** Transient flushing or heat regulation disturbances, loss of sensation + motor control in injection arm, loss of sleep, nausea, dizziness, after-pain and hypotensive syncope observed in both arms. One case of GH joint infection with HD + corticosteroid. **No further details provided.**
Catapano et al 2018 [9] Canada Systematic review without meta-analysis of RCTs from different countries 6 RCTs – 5 of the RCTs were also included in the meta-analysis by Saltychev et al 2018 One RCT used a total of 10ml therefore not high volume	Adults with adhesive capsulitis 410 shoulders Mean age 51 to 61 years In most of the studies participants have had symptoms for at least three months	Hydrodilatation with or without corticosteroid	Any	**PAIN - VAS (information on VAS score range for the different studies not reported)** Two of the relevant 5 studies reported statistically significant improvement in pain in favour of hydrodilatation (HD) relative to intra-articular injection (IAI); Three showed no difference At 12 weeks: IAI 3.57 (1.1) vs HD 3.29 (0.95) (p=0.002) Reza et al 2013 (100 shoulders) At 1 month: IAI 4.6(1.1) vs HD 3.6 (1.3) (p=0.035) Yoon et al 2016 (90 shoulders) **ROM** Three of the relevant 5 studies reported statistically significant improvement in ROM pain in favour of HD; Two showed no difference At 12 weeks 1) Extension ROM p=0.03; external rotation ROM p=0.01 (no details were provided Gam et al 1998 2) Abduction: IAI $82.7^0(22.6^0)$ vs HD 114.4^0 (30.1^0) p=0.005; Internal rotation: IAI 48.4^0 (10.8^0) vs HD 55.4^0 (18.2^0) p=0.027 Reza et al 2013 (100 shoulders)

				At 1 month External rotation: IAI $28^0(8^0)$ vs HD 36^0 (9^0) (p=0.005 Yoon et al 2016 (90 shoulders) It is not clear whether assessors were blinded to treatment **ADVERSE EVENTS – number of studies or patients not reported** Approximately 15% of patients in each group described transient loss of sensation, motor control of the arm, flushing, nausea, dizziness, pain and/or discomfort on injection.
Maund et al 2012 [10] UK Systematic review and **cost-effectiveness study** **No UK based studies included** 3 RCTs of arthrographic distension – all the RCTs were included in SR by Saltychev et al 2018	Adults with adhesive capsulitis	Arthrographic distension (with image-guided high volume injection) with or without corticosteroid and/or saline	Any	**Included studies have been considered in the reviews by Saltychev et al 2018 and Catapano et al 2018** **AVERAGE COST ESTIMATES FOR ARTHROGRAPHIC DISTENSION VERSUS ALTERNATIVE OPTIONS BASED ON NHS REFERENCE COSTS AND RESOURCE USE PROVIDED BY CLINICAL EXPERTS IN THE NHS** **£79.84 to £134.84** (Arthrographic distension with image-guided high volume injection) Vs standard unguided steroid injection £36.18 to £138.51 vs image-guided steroid injection £299.68 to £475.56 vs physiotherapy treatment alongside steroid injection £121.43 to £607.31 vs physiotherapy treatment only £98.75 to £126.75 vs Acupuncture £117.75 to £126.75 vs MUA £1,213 to £1,522 vs capsular release £1,809 to £2,511 The figures represent the range which depends on the setting, the professional delivering treatment or the choice of treatment e.g. steroid injection

Abbreviations: ACR – arthroscopic capsular release; EuroQol-5D VAS- EuroQOL-5D visual analogue scale[12]; HD – hydrodilatation; IAI – intra-articular injection; OSS[13] – Oxford Shoulder Score; VAS – visual analogue score; GH – glenohumeral; MUA – manipulation under anaesthesia; ROM – range of motion; SPADI - Shoulder Pain and Disability Index; VAS – visual analogue scale

[12] EuroQol-5D (EQ-5D) is used to measure health-related quality of life; it measures a patient's health across five different domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ-5D has two parts. The first, the EQ-5D profile, asks patients to classify their health based on self-assessed levels of problems ("no", "some", "extreme") on the five dimensions. The second is the EQ-VAS, which asks patients to indicate their overall health on a vertical visual analogue scale, ranging from "worst possible" to "best possible" health.

[13] The Oxford Shoulder Score (OSS) is a validated patient-reported outcome measure. The OSS questionnaire contains 12 items, each with five potential answers. Patients are asked to rate their symptoms between 1 (minimal symptoms) and 5 (severe symptoms). The combined total gives a minimum score of 12 and a maximum of 60.

Table 2: Summary of RCTs of image-guided HIGH VOLUME intra-articular injections compared to alternative treatment options

Study	Patients	Intervention	Comparator	Outcomes
Gallacher et al 2018 [3] UK RCT Single centre	Patients with severe idiopathic frozen shoulder for 3 months and had a failed course of physiotherapy n=50 (39 analysed) Recruited between June 2013 and December 2016 by consultant shoulder surgeon	Hydrodilatation into GH joint (1ml triamcinolone 80mg, 4ml 2% lidocaine, 40ml normal saline) n=25 (20 analysed) Mean age = 55.2 years Patients were unblinded to treatment	Arthroscopic capsular release n=25 (19 analysed) Mean age = 52.6 years Patients were unblinded to treatment	**Oxford shoulder score (OSS) at 6 months** Improvement from baseline with HD : 22.3 (95% CI, 16.6 to 27.5; p <0.01) Improvement from baseline with ACR: 26.5 (95% CI, 23.1 to 29.9; p< 0.01) **OSS at 6 months;** **ACR vs HD**: 43.8 [95% CI 42.2 to 45.2] vs 38.5 [95% CI 34.6 to 42.4], p=0.023 **Difference in improvement in EuroQOL-5D VAS at 6 months** (10 vs 19.6 for ACR and HD, respectively, p=0.053 **Improvement in external rotation at 6 months - ACR vs HD** (47° vs 34°) p=0.03 **Improvement in forward elevation at 6 months - ACR vs HD** (83° vs 71°) p=0.023 **Crossover** < 6-month follow-up, four patients from HD to ACR; one patient from ACR to HD. HD to the ACR group - mean 11.0-point improvement in the OSS at 6 weeks after HD vs 20.6-point improvement in the HD group that did not cross over. In crossover patients a 28.0-point improvement in OSS from the baseline at 6 months after ACR. **The authors found no complications to report**

Abbreviations: ACR – arthroscopic capsular release; EuroQol-5D VAS- EuroQOL-5D visual analogue scale[n]; HD – hydrodilatation; IAI – intra-articular injection; OSS[o] – Oxford Shoulder Score; VAS – visual analogue score; GH – glenohumeral; MUA – manipulation under anaesthesia; ROM – range of motion; SPADI - Shoulder Pain and Disability Index; VAS – visual analogue scale

[n] EuroQol-5D (EQ-5D) is used to measure health-related quality of life; it measures a patient's health across five different domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ-5D has two parts. The first, the EQ-5D profile, asks patients to classify their health based on self-assessed levels of problems ("no", "some", "extreme") on the five dimensions. The second is the EQ-VAS, which asks patients to indicate their overall health on a vertical visual analogue scale, ranging from "worst possible" to "best possible" health.
[o] The Oxford Shoulder Score (OSS) is a validated patient-reported outcome measure. The OSS questionnaire contains 12 items, each with five potential answers. Patients are asked to rate their symptoms between 1 (minimal symptoms) and 5 (severe symptoms). The combined total gives a minimum score of 12 and a maximum of 60.

4.2 Safety

Saltychev et al [8] reported that some transient adverse events such as flushing or disturbances in heat regulation, loss of sensation and motor control in the affected arm, loss of sleep, nausea, dizziness, after-pain and hypotensive syncope were observed with both the hydrodilatation with corticosteroid and corticosteroid only groups from three studies. They stated that one case of glenohumeral joint infection was reported in a patient treated with hydrodilatation and corticosteroid. No further details including the number of patients were provided.

Catapano et al [9] reported that side effects were equal among the combined (hydrodilatation with corticosteroid) intervention group and control (corticosteroid only) group. They stated that approximately 15% of patients in each group described transient loss of sensation, motor control of the arm, flushing, nausea, dizziness, pain and/or discomfort on injection. The authors indicate that these were typically rated as mild and spontaneously resolved completely, lasting only for a short period of time. However, no further details on the number of studies or patients were provided.

In the RCT of 50 patients, no complications were noted in either the ACR or hydrodilatation groups at six months follow-up [3].

4.3 Summary of findings

We identified three systematic reviews of RCTs [8, 9, 10] of hydrodilatation with high volume intra-articular injection for adhesive capsulitis, compared to alternative treatment options. The earliest of these also explored cost-effectiveness [10]. We also found one RCT [3] published subsequent to the systematic reviews. However, we have not reported clinical outcomes from the earliest systematic review as the studies have been superseded by those included in the most recent ones. The main outcomes measures reported include changes in pain scores and range of movement. Change in Oxford Shoulder Scores (OSS) and quality of life was reported.

Pain. Two systematic reviews (one with meta-analysis) reported significant improvements in pain scores using VAS with hydrodilatation with corticosteroid compared with corticosteroids injections alone. The findings from the systematic review (with meta-analysis) by Saltychev et al (2018) [8] was based on pooled results from five RCTs (p=0.00; NNT= 12) while those from Catapano et al (2018) [9] were from two out of five RCTs included in their review; one study at 12 weeks (p=0.002) and the other at one month (p=0.035).

Range of Movement. Significant improvements in range of movement were reported by two systematic reviews and one RCT. The findings reported by Saltychev et al were based on pooled results from six RCTs (p=0.01; NNT= 12) while those by Catapano et al were from two of five RCTs; one at 12 weeks (extension ROM p=0.03; external rotation ROM p=0.010 and abduction ROM p=0.005; internal rotation p=0.027) and one at one month (external rotation, p=0.005) in favour of the hydrodilatation group. Two RCTs included in Catapano et al showed no difference between hydrodilatation with corticosteroid injection and intra-articular corticosteroid injection alone. The RCT by Gallacher et al reported that the ACR and HD cohorts showed improvements in external

rotation and forward elevation with the improvement in both outcomes being significantly greater in the ACR group (p=0.03 and p=0.023 respectively).

Oxford Shoulder Score. The RCT by Gallacher et al reported that both the HD and ACR groups demonstrated significant improvements in OSS from baseline, but the OSS was significantly higher in the ACR cohort than the HD cohort (p= 0.023).

Quality of Life. Significant improvement in EQ-5D[p] VAS was also noted in both the HD and ACR groups in the RCT by Gallacher et al, but the difference in improvement between the groups at any time point was not significant.

These findings need to be interpreted with caution as they are all from small studies which may not have been sufficiently powered to show any meaningful differences. Also many of the outcomes measured were patient-reported; these patients were not blinded to their treatments, so this is likely to have introduced some bias.

Adverse events. Two systematic reviews [8, 9] reported on adverse events associated with hydrodilatation with corticosteroid and corticosteroid only intra-articular injections.

Based on three studies, Saltychev et al [8] reported that some transient adverse events such as flushing or disturbances in heat regulation, loss of sensation and motor control in the affected arm, loss of sleep, nausea, dizziness, after-pain and hypotensive syncope were observed with both the hydrodilatation with corticosteroid and corticosteroid only groups. They stated that there was one case of glenohumeral joint infection in a patient treated with hydrodilatation and corticosteroid. Catapano et al [9] reported similar adverse effects stating that approximately 15% of patients were affected. Neither of the reviews provided any further details

Cost Effectiveness. Maund et al [10] set out to carry out a cost-effectiveness analysis however, were unable to do so due to paucity of evidence. Instead the authors estimated average treatment costs from the perspective of the UK NHS for the interventions identified in the systematic review based on NHS reference costs and resource use provided by clinical advisers.

The costs estimated by the authors do not take into account the relative effectiveness for each intervention. They therefore shed no light on the relative cost effectiveness of any of the treatment options.

[p] EuroQol-5D (EQ-5D) is used to measure health-related quality of life; it measures a patient's health across five different domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ-5D has two parts. First, the EQ-5D profile, asks patients to classify their health based on self-assessed levels of problems ("no", "some", "extreme") on the five dimensions. The second is the EQ-VAS, which asks patients to indicate their overall health on a vertical visual analogue scale, ranging from "worst possible" to "best possible" health.

5 Equity issues

It is unknown if there is variation in access to image-guided HIGH VOLUME intra-articular injections compared to alternative treatment options across providers in the NHS Birmingham and Solihull CCG, Sandwell and West Birmingham CCG, and Walsall, Wolverhampton and Dudley CCGs areas, or how access compares to the rest of England.

6 Discussion and conclusions

Question 1

In adults with a painful joint, is image-guided HIGH VOLUME intra-articular injections clinically effective compared to alternative treatment options?

It is unclear whether treatment for joint pain with an image-guided HIGH VOLUME intra-articular injection is clinically effective compared to alternative treatment options.

Evidence from two systematic reviews of RCTS comparing hydrodilatation with corticosteroids, and corticosteroid injection only, is conflicting. The systematic review (with meta-analysis) by Saltychev et al (2018) reported that hydrodilatation with corticosteroids has only a small, clinically insignificant effect for pain and ROM (seven RCTs) when treating adhesive capsulitis. Conversely, Catapano et al (2018) reported that the intervention is likely to be effective. However, this conclusion was based on the results from two of five RCTs and three of five RCTs which reported improvements in pain scores and range of movement respectively. The evidence is therefore at best inconsistent. No long term results were reported. Both authors report that the included RCTs were of moderate quality.

Evidence from one small RCT suggests that arthrographic capsular release is associated with a higher Oxford Shoulder Score (OSS) than hydrodilatation at six months follow-up. It is not known for how long this effect is likely to be sustained (Gallacher 2018). In addition, the study may not have been sufficiently powered to show any meaningful differences. The pain scores were reported by the patients who were not blinded to their treatment, this could have introduced bias. It is also unclear whether the ROM assessors were blinded to the treatments.

Question 2

In adults with a painful joint, is treatment with image-guided HIGH VOLUME intra-articular injections cost effective compared to alternative treatment options?

It is unclear whether image-guided HIGH VOLUME intra-articular injection is cost-effective compared to alternative treatment options. One study by Maundy et al (2012)[ref] attempted to establish the relative cost-effectiveness of image guided high volume intra-articular injections in painful joints but was unable to do so due to paucity of evidence data on the interventions.

7 Search Strategy

Search date: 19th September 2018

We searched PubMed, Embase and Cochrane Library – limiting to last 10years and English language. We also ran a search of TRIP database and NICE Evidence search with similar limits and restricting to Evidence Reviews. We excluded letters, commentary, case reports and conference papers.

Search terms
Medline:

1. ((arthrograph* or arthroscop* or capsular or joint*) adj5 disten?ion).ti,ab.
2. (hydrodilat* or hydro-dilat*).ti,ab.
3. hvigi.ti,ab.
4. Injections, Intra-Articular/ or *Injections/
5. injection?.ti,ab.
6. (intraarticular or intra-articular).ti,ab.
7. 4 or 5 or 6
8. ((high* or large) adj2 volume*).ti,ab.
9. 7 and 8
10. ((high volume* or large volume) adj5 (inject* or saline or steroid* or corticosteroid* or glucocorticoid* or cortiso* or hydrocortis* or triamcinolone or methylprednisolone or prednisolone or an?esthe*)).ti,ab.
11. 8 or 10
12. exp joints/
13. hip/ or knee/ or elbow/ or shoulder/
14. 12 or 13
15. pain/ or exp back pain/ or chronic pain/
16. 14 and 15
17. exp Arthralgia/
18. arthralgi*.ti,ab.
19. ((sacroiliac or sacro-iliac or facet or zygapophyseal or acromioclavic* or glenohumer* or gleno-humeral or shoulder or acetabul* or hip or tibiofem* or patellofem* or knee* or joint*) adj2 pain).ti,ab.
20. joint diseases/ or exp bursitis/ or femoracetabular impingement/ or patellofemoral pain syndrome/ or shoulder impingement syndrome/
21. exp Tendinopathy/
22. exp OSTEOARTHRITIS/
23. (osteoarthrit* or degenerative arthri*).ti,ab. or arthritis.ti.
24. (frozen shoulder or bursitis or adhesive capsulitis or tennis elbow or tendinopath* or tendinitis).ti,ab.
25. 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24
26. 11 and 25
27. 1 or 2 or 3 or 26
28. limit 27 to (english language and yr="2008 -Current")

Embase:

1. ((arthrograph* or arthroscop* or capsular or joint*) adj5 disten?ion).ti,ab.
2. (hydrodilat* or hydro-dilat*).ti,ab.
3. hvigi.ti,ab.
4. ar.fs. or *Injections/
5. injection?.ti,ab.
6. (intraarticular or intra-articular).ti,ab.
7. 4 or 5 or 6
8. ((high* or large) adj2 volume*).ti,ab.
9. 7 and 8
10. ((high volume* or large volume) adj5 (inject* or saline or steroid* or corticosteroid* or glucocorticoid* or cortiso* or hydrocortis* or triamcinolone or methylprednisolone or prednisolone or an?esthe*)).ti,ab.
11. 9 or 10
12. exp joints/
13. hip/ or knee/ or elbow/ or shoulder/
14. 12 or 13
15. pain/ or exp back pain/ or chronic pain/
16. 14 and 15
17. exp Arthralgia/
18. arthralgi*.ti,ab.
19. ((sacroiliac or sacro-iliac or facet or zygapophyseal or acromioclavic* or glenohumer* or gleno-humeral or shoulder or acetabul* or hip or tibiofem* or patellofem* or knee* or joint*) adj2 pain).ti,ab.
20. exp elbow disease/ or exp shoulder disease/ or exp hip disease/ or exp knee disease/
21. exp Tendinitis/
22. exp OSTEOARTHRITIS/
23. (osteoarthrit* or degenerative arthri*).ti,ab. or arthritis.ti.
24. (frozen shoulder or bursitis or adhesive capsulitis or tennis elbow or tendinopath* or tendinitis).ti,ab.
25. 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24
26. 11 and 25
27. 1 or 2 or 3 or 26
28. limit 27 to (english language and yr="2008 -Current")
29. conference*.pt.
30. 28 not 29

Image-guided HIGH VOLUME intra-articular injections (40mls+) of saline with or without corticosteroid and/or local anaesthetic - Inclusion criteria for identification of relevant studies

Question	Population	Indication	Intervention	Comparator	Outcomes	Studies
In adults with a painful joint, what is the clinical and cost effectiveness of image-guided HIGH VOLUME intra-articular injections compared to alternative treatment options?	Adults with a painful joint	Pain management in degenerative joints	High-volume image guided injection (HVIGI) (40mls+) of saline with or without corticosteroid and/or local anaesthetic.	Any including: Standard volume intra-articular corticosteroid injection (image guided/not image guided) Conservative treatment with lifestyle modification and/or medication and/or physiotherapy	Clinical effectiveness including Pain Function/mobility QoL AE Cost effectiveness Subsequent arthroscopy Subsequent arthroplasty	Standard evidence review in order to be robust enough to influence/change clinical practice. SRMA SR of RCTS RCT SR Prospective cohort studies Retrospective cohort studies Cost effectiveness studies

Inclusion Criteria
Peer reviewed publications
English language

Exclusion Criteria
Abstracts
Letters
Commentaries
Conference papers
Case reports
Papers published more than 10 years ago
Papers published online subsequent to the search date

8 References

1. International Association for the Study of Pain (IASP). Treating people with joint pain. Global year against pain in the joint 2016; Fact sheet no 1. https://s3.amazonaws.com/rdcms-iasp/files/production/public/Content/ContentFolders/GlobalYearAgainstPain2/2016/FactSheets/English/1.%20Patients%20and%20Joint%20Pain.pdf Last accessed 15 October 2018
2. NHS Choices [online] https://www.nhs.uk/conditions/joint-pain/ Last accessed 15 October 2018
3. Gallacher S, Beazley JC et al. A randomized controlled trial of arthroscopic capsular release versus hydrodilatation in the treatment of primary frozen shoulder. Journal of Shoulder & Elbow Surgery. 2018 Aug; 27(8):1401-6.
4. Neogi T. Joint pain epidemiology. Global year against pain in the joint 2016; Fact sheet no 11. https://s3.amazonaws.com/rdcms-iasp/files/production/public/Content/ContentFolders/GlobalYearAgainstPain2/2016/FactSheets/English/11.%20Joint%20Pain%20Epidemiology.pdf Last accessed 15 October 2018
5. Duncan R, Francis RM et al. Prevalence of arthritis and joint pain in the oldest old: findings from the Newcastle 85+ Study. Age and Aging 2011; 40(6):752-5.
6. Georgiannos D, Markopoulos G et al. Adhesive Capsulitis of the Shoulder. Is there Consensus Regarding the Treatment? A Comprehensive Review. The open orthopaedics journal. [Review]. 2017; 11:65-76.
7. Buchbinder R, Green S et al. Arthrographic distension for adhesive capsulitis (frozen shoulder). Cochrane Database of Systematic Reviews 2008, Issue 1. Art. No.: CD007005.
8. Saltychev M, Laimi K et al. Effectiveness of Hydrodilatation in Adhesive Capsulitis of Shoulder: A Systematic Review and Meta-Analysis. Scandinavian Journal of Surgery: SJS. 2018:1457496918772367.
9. Catapano M, Mittal N et al. Hydrodilatation with Corticosteroid for the Treatment of Adhesive Capsulitis: A Systematic Review. Pm & R. [Review]. 2018; 10(6):623-35.
10. Maund E, Craig D et al. Management of frozen shoulder: a systematic review and cost-effectiveness analysis. Health Technology Assessment (Winchester, England). [Research Support, Non-U.S. Gov't Review]. 2012; 16(11):1-264.

4.

9 Clinician comments after 3 week consultation of the draft evidence review

Date	Clinician	Comments	SPH Response
04/12/2018	Mr. Samir Massoud Consultant Trauma & Orthopaedics - University Hospitals Birmingham NHS Foundation Trust Queen Elizabeth Hospital, Queen Elizabeth Medical Centre, Birmingham	In relation to the review of ultrasound guided Hydrodilatation for frozen shoulder, I agree that these are not likely to be more effective than steroid injection alone and are significantly more painful for patients.	Thank you very much for these helpful comments and clinical opinion. We will include them in section 9 of the report so that they are available for discussion with the rest of the rapid evidence review.
10/12/2018	Paresh Jobanputra (Cons Rheumatologist)	My experience in this area is limited. Given what is believed about the natural history of frozen shoulders, the only condition I consider for hydrodilation, a pathway of conservative therapy with or without clinical landmark based injection, perhaps repeated if necessary (either using clinical landmarks or US guidance) and only then considering surgical input seems reasonable.	Thank you very much for these helpful comments and clinical opinion. We will include them in section 9 of the report so that they are available for discussion with the rest of the rapid evidence review.
13/12/2018	Alison Jackson Clinical Team Leader (MSK) Musculoskeletal & Orthotics Good Hope and Solihull Hospitals	**Dear All** **Please see below information which has been compiled by a specialist physiotherapist working in UHB HGS physiotherapy injection service which provides US guided HV injections as well as US guided and blind injections. HGS US guided service has been operational for the delivery of HV shoulder joint injections since 2013: governance evidenced by PGD and relevant inclusion/exclusion criteria.** **Comments** • **Evidence review –** Agree the inclusion of relevant studies and appropriate summaries however additional studies incorporated below with summaries highlighted in yellow. 5. • **Current clinical practice – HV** shoulder joint injections are considered when patients have failed other conservative treatments – hydro, stretches, acupuncture, palpation guided normal volume steroid/local injection – and this is only performed following full consultation with the patient, including information leaflets, consent, explanation of the procedure and its possible complications and intended benefits. Patients in physiotherapy are also always	Thank you for your helpful feedback. We will include them in section 9 of the report so that they are available for discussion with the rest of the rapid evidence review. We deal with the additional studies separately below.

		followed up to review as part of this procedure. **6.** • **Clinical opinion -** Our clinical experience suggests that patients tolerate a guided shoulder distension procedure well and refer to an intense pressure feeling rather than pain. There have been no complications within our physiotherapy service and all have improved. I believe it works well particularly for patients with recalcitrant frozen shoulders, particularly females, in mid 50s and diabetic patients. Pain relief appears to be the most significant feature with variable movement improvement. This then allows tolerance of appropriate rehabilitation/stretching. I believe there are few risk factors, particularly when patients are appropriately screened pre procedure. It is easily performed as an outpatient procedure and patients often continue with their normal day with no restrictions. Cost effectiveness – (page 9 of the BSOL & Black Country HVIGI for joint pain Consultation Draft Nov 18 attachment) – no reference is made to the cost of physio led USG HV intra articular shoulder injection – only to palpation guided and we would encourage you to review this. I believe that physios are best placed to offer this safe, cost effective service as we assess and treat all aspects of the patients presenting problem from assessment to diagnosis, procedure and then rehab afterwards – a seamless service as suggested by Dr Jeremy Lewis's presentation at the 5th biennial Emirates physiotherapy conference in May 2016 "Don't want to be left out in the cold": Non-surgical management of Frozen Shoulder. The patient presents to the right person at the right time in their pathway therefore receiving the most appropriate management located in community or acute care settings.	We did not identify any cost-effectiveness studies on physiotherapy led USG high volume intra articular shoulder injection that met the PICO inclusion criteria.
11/12/2018	Physiotherapists BHH	I agree with the options for the commissioners on page 1 as we only use this for the shoulder joint when patients have failed other conservative treatments – hydro, stretches, acupuncture, palpation guided normal volume steroid/local injection – and this is only performed following full consultation with the patient, including information leaflets , consent, explanation of the procedure and its possible complications and intended benefits. Patients in physiotherapy are also always followed up to review as part of this procedure.	Thank you very much for these helpful comments and the one below. We will include them in section 9 of the report so that they are available for discussion with the rest of the rapid evidence review.

		With regard to clinical effectiveness, safety and cost implications – the following references 1. The effectiveness of ultrasound guided hydrodistension and physiotherapy in the treatment of frozen shoulder/adhesive capsulitis in primary care: a single centre service evaluation. Michael Bryant, Andrew Gough, James Selfe .First Published May 17, 2017 https://doi.org/10.1177/1758573217701063 Conclusions This service evaluation demonstrates that management of frozen shoulder stage II to III, as conducted by physiotherapists in a primary care setting utilizing hydrodistension and a guided exercise programme, represents an effective non-operative treatment strategy. Also details cost effectiveness when comparing with surgery or secondary care guided injection. 2. Analysis of hydrodilatation as part of a combined service for stiff shoulder. Shoulder Elbow 2017 Jul;9 (3): 169-177 7. Rajendranath Sinha,1 Priyesh Patel,1 Nicky Rose,1 John Tuckett,2 Anurag N Banerjee,3 John Williams,1 Stephen Aldridge,1 and Paul Stuart2 8. Conclusions Hydrodilatation results in a significant improvement of symptoms in patients with adhesive capsulitis. An MDT approach has improved the management of the stiff and painful shoulder and markedly reduced the need for surgery – with table of figures over 4 years. 3. Effectiveness of Glenohumeral Joint Dilatation for Treatment of Frozen Shoulder: A Systematic Review and Meta-analysis of Randomized Controlled Trials Wei-Ting Wu, Ke-Vin Chang, Der-Sheng Han, Chung-Hsun Chang, Fu-Sui Yang & Chih-Peng Lin 9. Scientific Reports volume 7, Article number: 10507 (2017) | Download Citation 10. 4. Frozen Shoulder: long term outcome following arthrographic distension. R Clement; A Ray; C Davidson; et al Acta Orthop. Belg 2013,79,368-374. Conclusions Arthrographic distension is safe and effective - including for diabetic patients. They reported long term improvement (12/12s+). The low number of patients requiring a second procedure makes it preferable to MUA.	This service evaluation (not a clinical trial) was not included in the rapid evidence review because it did not meet the PICO inclusion criteria. This paper (not a comparative study) was not included in the rapid evidence review because non-comparative studies add little when there is RCT evidence. (Without a comparator we do not know whether changes observed might have occurred without the treatment.) This systematic review and meta-analysis (Wu et al) was excluded from the rapid evidence review because it has been superseded by a later one (Saltychev et al 2018) which assessed all the trials included in Wu et al and more. This paper (not a comparative study) was not included in the rapid evidence review because non-comparative studies add little when there is RCT evidence. (Without a comparator we do not know whether changes observed might have occurred without the treatment.)

		11. 5. Information on shoulderdoc.co.uk about hydrodistension for frozen shoulder where their own data has " shown good results in selected patients" 12. 6. Dr Jeremy Lewis www.LondonShoulderClinic.com Shine foundation - some details of improvements and cost savings when procedure is performed by physiotherapists. 13. Anecdotally – I have performed 8 of these procedures this year to date. Patients tolerate it well and refer to an intense pressure feeling rather than pain. There have been no complications and all have improved to a varying degree. I believe it works well particularly for patients with recalcitrant frozen shoulders, particularly females, in mid 50s and diabetic patients. Pain relief appears to be the most significant feature with variable movement improvement. This then allows tolerance of appropriate rehabilitation/stretching. I believe there are few risk factors, particularly when patients are appropriately screened pre procedure. It is easily performed as an outpatient procedure and patients often continue with their normal day with no restrictions. There may be equity issues as this is only offered by the physio dept on the GHGH site. Cost effectiveness – page 9 – no reference is made to the cost of physio led USG HV intra articular shoulder injection – only to palpation guided. I believe that physios are best placed to offer this safe, cost effective service as we assess and treat all aspects of the patients presenting problem form assessment to diagnosis, procedure and then rehab afterwards – a seamless service as suggested by Dr Jeremy Lewis's presentation at the 5th biennial Emirates physiotherapy conference in May 2016 " Don't want to be left out in the cold": Non surgical management of Frozen Shoulder –	This article (not a clinical trial) was not included in the rapid evidence review because conference papers and articles not published in peer reviewed journals do not meet the PICO inclusion criteria This article (not a clinical trial) was not included in the rapid evidence review because conference papers and articles not published in peer reviewed journal do not meet the PICO inclusion criteria

Competing Interest
All SPH authors have completed the ICMJE uniform disclosure form (www.icmje.org/coi_disclosure.pdf) and declare: grants from Solihull CCG, Birmingham CrossCity CCG and Birmingham South Central CCG to SPH to undertake the submitted work, no financial relationships with any organisations that might have an interest in the submitted work in the previous three years and no other relationships or activities that could appear to have influenced the submitted work.

Terms of Use
This document has been produced by SPH for Solihull CCG, Birmingham CrossCity CCG and Birmingham South Central CCG. It must not be distributed or accessed or used for commercial purposes without prior written permission from SPH. The purpose of this document is to review and summarise published evidence relating to clinical interventions. The findings may be applicable to the development of commissioning policy, but commissioning policy development is undertaken by NHS commissioners taking into account a wide range of other factors. SPH is not responsible for the development of commissioning policy. Use of this document is subject to agreement that SPH is fully indemnified against any liability that may arise through use of the information within this document.

Image guided therapeutic intra-articular joint injections with corticosteroids with/without local anaesthetic for the treatment of joint pain

Questions to be addressed

1. In adults with a painful joint due to osteoarthritis, is image guided intra-articular corticosteroid injection clinically effective compared to non-image guided intra-articular corticosteroid injection?
2. In adults with a painful joint due to osteoarthritis, is image guided intra-articular corticosteroid injection cost effective compared to non-image guided intra-articular corticosteroid injection?

Reason for review

NHS Birmingham and Solihull CCG and Sandwell and West Birmingham CCG, in partnership with Walsall, Wolverhampton and Dudley CCGs, requested a rapid evidence review of the clinical and cost effectiveness of image guided intra-articular corticosteroid injections compared to non-image guided intra-articular corticosteroid injections to inform their decisions on commissioning policy development.

Options for commissioners:

3. The Committee considers that due to the lack of high quality evidence of clinical and cost effectiveness for image guided intra-articular corticosteroid injections compared to non-image guided intra-articular corticosteroid injections; its use should be considered a low priority.
4. The Committee recommend that image guided intra-articular corticosteroid injections should be offered ONLY to patients who have failed to respond to conventional pharmacological and non-pharmacological interventions due to the limited quality of evidence of its clinical and cost effectiveness.
5. The Committee considers that there is insufficient evidence to suggest that image guided intra-articular corticosteroid injections are more or less effective than non-image guided intra-articular corticosteroid injections and therefore the decision about which approach to proceed with should be made after an informed discussion between the clinician and the individual person about the risks and benefits of each procedure.
6. The Committee recommends that image guided intra-articular corticosteroid injections should be promoted as the treatment of choice because there is sufficient evidence to suggest that it is associated with more injection accuracy which is likely to lead to better clinical outcomes and fewer complications and some evidence to suggest a greater reduction in pain/disability.

Summary

Background

- Osteoarthritis is a chronic musculoskeletal disorder characterised by involvement of all joint structures including the synovial membrane, cartilage and bone.

- Osteoarthritis can affect most joints. The most commonly affected joints are the knees, hips and small joints of the hand.
- People with OA often have joint pain, stiffness, reduced participation in daily activities and poor quality of life.
- OA is a major source of disability owing to pain and loss of function. It is the most common form of joint disease and among the top 10 causes of disability worldwide.
- A range of lifestyle, pharmacological, non-pharmacological, and surgical interventions are used for controlling symptoms and improving function.
- Conventional therapies include the use of analgesics, non-steroidal anti-inflammatory drugs, physical therapy and intra-articular (IA) corticosteroid administration.

Clinical effectiveness

- We identified three studies of image guided intra-articular (IA) corticosteroid injections compared to non-image guided IA corticosteroid injections; one retrospective comparative study and two randomised single-blinded studies.
- Park et al (2015) retrospectively reviewed the medical charts of patients with acromioclavicular[a] (AC) joint degenerative OA who had been treated with ultrasound-guided (US) (n=50) or palpation-guided (n=50) AC joint IA corticosteroid injections between January 2012 and December 2013 at their outpatient clinic.
- The authors reported that the Shoulder Pain and Disability Index (SPADI)[b], Verbal Numeric pain Scale (VNS)[c] at rest (VNSar) and under local pressure (VNSlp), and the arm adduction test (VNSaat) all improved at one, three and six months after the injections in both groups ($p<0.05$).
- They also reported a statistically significantly greater improvement in the VNSlp score and SPDAI at six months and in the VNSaat score at three months and six months for the US-guided group compared with the palpation group ($p<0.05$).
- Given that the study was retrospective and conducted in one centre by a single physician (also one of the assessors), the potential for bias is substantial and therefore the results should be interpreted with caution.
- Nam et al (2013) carried out a randomised, prospective single-blinded clinical study (n=60) on the mid-term benefits and accuracy rate of US-guided versus palpation-guided IA injections for the treatment of distal radioulnar joint[d] (DRUJ) disorder.
- The authors reported that US-guided IA injections showed significantly higher accuracy (100%) than palpation-guided IA injections (75.8%) [$p<0.05$] in DRUJ disorder.
- They found that VNS, Disability of the Arm, Shoulder, and Hand questionnaire (DASH), Modified Mayo Wrist Score (MMWS), and range of movement (ROM) were improved at one, three and six months in both groups ($p<0.05$) but reported no significant difference in clinical outcome measures between the group receiving US-

[a] The acromioclavicular joint, or AC joint, is a joint at the top of the shoulder. It is the junction between the acromion (part of the scapula that forms the highest point of the shoulder) and the clavicle.
[b] The Shoulder Pain and Disability Index (SPADI) was developed to measure current shoulder pain and disability in an outpatient setting. The SPADI contains 13 items that assess two domains; a 5-item subscale that measures pain and an 8-item subscale that measures disability.
[c] Successful treatment (significant pain relief) was defined as > 50% improvement in the VNS score, *a five-point Likert scale of 3 (good) or 4 (excellent)* and 20 point improvement in the SPADI) at one, 3 and 6 months after the injections [14].
[d] The distal radioulnar joint is a joint between the two bones in the forearm; the radius and ulna, at the wrist.

guided injections and that receiving palpation-guided injections. However, they reported a positive correlation between pain/disability improvements and accuracy of IA injections at one, three and six months follow-up.

- These findings may not be generalisable because the palpation-guided IA injection was given by an experienced physician (seven years) which may not always be the case in clinical settings. This may have affected the accuracy rate. In addition, the relatively small number of inaccurate injections means that the study may not have been sufficiently powered to show any difference in results between US-guided and palpation-guided injections.
- Both studies only included patients with BMI of less than 30kg/m^2; this does not necessarily represent the general OA population. The larger amounts of subcutaneous fat – the increased distance between the skin and bone in obese patients – are likely to have an effect on the accuracy of the injection, particularly for palpation-guided injections.
- Sibbitt et al (2011) reported the results from a single-blinded RCT (n=92) which addressed how sonographic needle guidance affects clinical outcomes of IA injection in patients with OA of the knee. Patients' pain was measured using the visual analogue scale (VAS) where 0cm signifies no pain and 10cm unbearable pain.
- The authors reported a significant reduction in pain mean scores (from a mean of 7.5 (±2.0) to 1.4 ±2.1 versus 7.8 ±1.8 to 2.4 ±2.1 with sonographic guidance relative to palpation guidance at two weeks (p=0.025) but this was not sustained at six months follow-up (p=1.0). They also reported superior duration of therapeutic effect in months [4.2± 1.9 versus 3.1± 2.1 (p=0.01)] and lower reinjection rates within 12 months [52% (24/46) versus 74% (34/46) (p=0.03)] with sonographic guidance. The authors also reported a significantly higher responder[e] rate with sonographic guidance of 67% (31/46) versus 33% (15/46) with palpation guidance, p=0.0004.
- These results should be interpreted with caution as participants were not blinded to their treatment and the details on the randomisation methods and concealment were not provided.

Safety

- Two of the three studies identified reported almost identical adverse effect profiles. They report that two and three patients in the US-guided group respectively and one patient (in each study) in the palpation-guided group complained of pain due to steroid-induced synovitis. In both studies skin atrophy and depigmentation were observed in two patients in the palpation group and in none in the US-guided group. There were no severe complications, such as septic arthritis, allergic reactions or ruptured tendons.
- The third study did not report adverse effects.

Cost-effectiveness

- We found one cost-effectiveness study of the use of image guided intra-articular corticosteroid injections compared to non-image guided intra-articular corticosteroid injections conducted in the USA.

[e] Responders were defined as those who had VAS <2cm

- Sibbitt et al (2011) aimed to assess the cost effectiveness of IA injection in patients with OA of the knee based on the results from a single-blinded RCT (n=92) which addressed whether sonographic needle guidance affects clinical outcomes.
- The authors reported a number of data on costs based on the USA Medicare system: cost per year if patient was treated at the physician's office as $173 ± $81 for palpation-guided IA injection compared with $460 ± $207 for sonographic guidance (p=0.0001); cost per year for patients treated in hospital outpatient clinic as $126 ± $58 for palpation-guided IA injection compared with $109 ± $49 for sonographic guidance (p=0.13).
- Cost per responder per year in a physician's office was reported as $531 ± $248 for palpation-guided IA injection compared with $1129 ± $307 for sonographic guidance (p=0.0001) and cost per responder per year in hospital outpatient clinic as $386 ± $180 versus $162 ± $73 respectively (p=0.0001). The authors concluded that the use of sonographic guidance in hospital outpatient clinics modestly reduced the cost per patient per year and cost per responder per year relative to palpation guided injections.
- However it should be noted that the sonographic needle guidance procedure in hospital outpatients is not reimbursed by Medicare so the authors only included $2 per procedure for each mechanical syringe and hence the true costs were missing. The relevance of these results outside of the USA is therefore questionable.

Equity issues

- It is not known whether there is variation in access to image guided intra-articular corticosteroid injections compared to non-image guided intra-articular corticosteroid injections across providers in the NHS Birmingham and Solihull CCG, Sandwell and West Birmingham CCG, and Walsall, Wolverhampton and Dudley CCGs areas, or how access compares to the rest of England.

1 Context

1.1 Introduction

Osteoarthritis (OA) refers to a clinical syndrome of joint pain accompanied by varying degrees of functional limitation and reduced quality of life. It is the most common form of arthritis, and one of the leading causes of pain and disability worldwide. It is a chronic musculoskeletal disorder characterised by involvement of all joint structures including the synovial membrane, cartilage and bone. People with osteoarthritis often have joint pain, reduced mobility, reduced participation in daily activities and poor quality of life [1].

The joints most commonly affected by OA are the knees, hips and small joints of the hand, although most joints can be affected. Pain, reduced function and effects on a person's ability to carry out their day-to-day activities can be important consequences of osteoarthritis. Pain in itself is also a complex biopsychosocial issue, related in part to a person's expectations and self-efficacy (that is, their belief in their ability to complete tasks and reach goals), and is associated with changes in mood, sleep and coping abilities. There is often a poor link between changes visible on an X-ray and symptoms of osteoarthritis: minimal changes can be associated with a lot of pain, or modest structural changes to joints can occur with minimal accompanying symptoms [2].

Contrary to popular belief, OA is not just caused by ageing and does not necessarily deteriorate. It is believed that a variety of traumas may trigger the need for a joint to repair itself which may result in a structurally altered but symptom-free joint. However, in some people, because of either overwhelming trauma or compromised repair, the process cannot fully compensate, resulting in eventual presentation with symptomatic osteoarthritis; this might be thought of as 'joint failure'. This in part explains the extreme variability in clinical presentation and outcome that can be observed between people, and also at different joints in the same person [2].

A range of lifestyle, pharmacological, non-pharmacological, surgical and rehabilitation interventions are effective for controlling symptoms and improving function (NICE 2012). Conventional therapies include the use of simple analgesics, non-steroidal anti-inflammatory drugs, physical therapy and intra-articular (IA) corticosteroid administration [3].

1.2 Existing national policies and guidance

There is no relevant NICE Technology Appraisal Guidance (with statutory requirement for NHS organisations to make funding available), clinical guidelines or quality standards specifically for the use of image guided intra-articular corticosteroid injections compared to non-image guided intra-articular corticosteroid injections. However, NICE published Clinical Guideline (CG177) - Osteoarthritis: care and management in February 2014 [2]. The guidelines made the following recommendations regarding intra-articular injections;

- Intra-articular corticosteroid injections should be considered as an adjunct to core treatments for the relief of moderate to severe pain in people with osteoarthritis.
- Do not offer intra-articular hyaluronan injections for the management of osteoarthritis.

2 Epidemiology

OA is a major source of disability owing to pain and loss of function. It is the most common form of joint disease and among the top 10 causes of disability worldwide [4]. With aging of the population and increasing obesity, OA arises as a major public health problem and an important financial burden for the global economy [5].

In the UK, approximately 8.75 million people aged 45 years and over (33%) have sought treatment for OA. OA is more common in women (60% female, 40% male), and this difference is most apparent for hand and knee OA and among people over 50 years of age [6]. The risk of developing OA increases with age; one third of women and almost a quarter of men between 45 and 64 have sought treatment for OA, this rises to almost half of people aged 75 and over [7]. X-ray studies show that at least 50% of people older than 65 have evidence of OA [1].

The risk of developing OA throughout life increases with rising BMI [8]. People who are overweight or obese are respectively approximately 2.5 and 4.6 times more likely to develop knee OA than those of normal body weight [9]. This, along with the aging population, is contributing to the increasing number of people with OA.

Knee OA is more frequently observed in people with occupations that require squatting and kneeling, hip OA is associated with prolonged lifting and standing. Hand OA is more frequent in people with occupations requiring increased manual dexterity [10]. Genetic factors are thought to account for 60% of hand and hip OA and 40% of knee OA [11].

The total cost of OA to the UK economy is estimated at 1% of annual gross national product. In 1999/2000, 36 million working days were lost because of OA, costing the economy nearly £3.2 billion in lost production [1].

3 The interventions

Intra-articular injections of corticosteroids have been used for several decades in the management of inflammatory and degenerative joint conditions including OA when first-line conservative therapies fail to provide adequate symptom relief [12].

Although osteoarthritis is generally thought to be of degenerative rather than inflammatory origin, there is evidence that an inflammatory component may be prese nt in at least some phases of the disease. Corticosteroids are known as potent anti-inflammatory agents that act through a variety of mechanisms [13].

Traditionally, intra-articular injections have been performed using anatomical landmarks to identify the correct trajectory for needle placement. However, different anatomical-guided injection techniques have yielded inconsistent intra-articular needle positioning due, in large part, to the fact that the physician cannot directly visualize the area of interest, and variations in anatomy are common. Incorrect needle placement has been partially associated with variable clinical outcomes. Furthermore, inaccurate corticosteroid injections may result in complications such as post-injection pain, crystal synovitis,

haemarthrosis, joint sepsis, necrosis, and steroid articular cartilage atrophy, as well as systemic effects, including fluid retention or exacerbation of hypertension or diabetes mellitus. Therefore, identification of methods and proper training to aid in correct needle placement during these procedures is warranted [12, 15]. However, it is controversial whether accuracy of needle placement has a significant impact on clinical outcome [12, 13].

The purpose of guidance during corticosteroid joint injections is to allow visualization, typically in real time, of the target anatomy so that the operator can achieve a more accurate and potentially safer and more effective injection [12, 13].

4 Findings

We searched Medline, Embase and Cochrane Library on the 14th September 2018 using the search strategy detailed in section 7 below. We also ran a search of TRIP database and NICE Evidence search with similar limits and restricting to Evidence Reviews.

The search was limited to 2008 onwards and English language only and we excluded letters, commentary, case reports and conference papers.

4.1 Evidence of effectiveness

We did not find any systematic reviews of the clinical effectiveness of image guided intra-articular corticosteroid injections compared to non-image guided intra-articular corticosteroid injections for patients with osteoarthritis. However we identified three studies; one retrospective comparative study and two randomised single-blinded studies [14, 15, 16] that met the PICO criteria for inclusion. Only comparative studies were included in this review.

> *We also identified one cost-effectiveness study of image guided intra-articular corticosteroid injections compared to non-image guided intra-articular corticosteroid injections conducted in the USA [16].*

4.1.1 Clinical effectiveness

We identified three studies of image guided intra-articular corticosteroid injections compared to non-image guided intra-articular corticosteroid injections; one retrospective comparative study [14] and two randomised single-blinded studies [15, 16].

Park et al [14] retrospectively reviewed the medical charts of patients (n=100) with acromioclavicular (AC) joint degenerative OA who had undergone ultrasound (US) guided or palpation-guided AC joint IA corticosteroid injection between January 2012 and December 2013 at their outpatient clinic. Fifty patients had US guided IA corticosteroid injection and the other 50 had palpation-guided IA corticosteroid injection.

The authors reported that the Shoulder Pain and Disability Index (SPADI), Verbal Numeric pain Scale (VNS)[f] at rest (VNSar) and under local pressure (VNSlp), and the arm adduction test (VNSaat) improved at one, three and six months after the injections compared to before injection in both groups (p<0.05). They also reported a statistically significantly greater improvement in the VNSlp score at six months [baseline scores 6.10 ± 0.93 vs 6.02 ± 0.89; at 6 months: 2.29 ± 1.06 vs 2.83 ± 0.64 (p<0.05)] and SPADI at six months [baseline scores 51.50 ± 6.64 vs 52.88 ± 7.96; at 6 months: 27.44 ± 6.07 vs 30.63 ± 5.59 (p<0.05)] and in the VNSaat score at three months and six months [baseline scores 5.68 ± 0.99 vs 5.64 ± 0.92; at 3 months:2.50 ± 0.71 vs 2.85 ± 0.78 (p<0.05); at 6 months: 2.20 ± 0.98 vs 2.79 ± 1.06 (p<0.05)] for the US-guided group compared with the palpation-guided group. Please refer to table 1 for details.

The authors concluded that US-guided AC joint IA injection for the treatment of symptomatic AC joint OA resulted in better pain and functional status improvement than palpation-guided IA injection at the 6-month follow-up. However, these results need to be interpreted with caution as the treatment was carried out by a single physician in one centre and therefore may not be generalisable. As this is a retrospective chart review, the participants' information and recorded results may not have been accurate. The participants were not randomised, they chose their preferred intervention, and both the participants and the assessors (one of whom was the physician) were not blinded (they were aware of which intervention was used). In addition all the participants had BMIs of less than 30kg/m^2. All of these are likely to have introduced bias to the study.

Nam et al [15] conducted a randomised, prospective single-blinded clinical study (n=60) on the mid-term benefits and accuracy rate of US guided versus palpation guided intra-articular (IA) injections for the treatment of distal radioulnar joint (DRUJ) disorder. Participants were randomly assigned to undergo US-guided or palpation-guided IA injection.

The authors reported that US-guided IA injections showed significantly higher accuracy (100%) than palpation-guided IA injections (75.8%) into the DRUJ (p<0.05). They found that the primary outcome (Disability of the Arm, Shoulder, and Hand questionnaire (DASH)) and the secondary outcomes (VNS[g], Modified Mayo Wrist Score (MMWS), and range of movement (ROM)) all improved at one, three and six months in both groups but observed no significant difference in clinical outcome measures between the group receiving US-guided injections and the group receiving palpation-guided injections. However they observed a positive correlation between pain improvements and accuracy of IA injections at follow-up. DASH scores at baseline were 44.0 ± 8.5 vs 46.3 ± 10.2 for accurate vs inaccurate injections respectively; and scores at 6 months were 15.3 ± 4.1 vs 19.9 ± 2.3 (p<0.05) in favour of accurate injections. This is in contrast to DASH scores for US-guided versus palpation-guided injections with baseline scores of 44.3 ± 8.6 vs

[f] Successful treatment (significant pain relief) was defined as > 50% improvement in the VNS score and 20 point improvement in the SPADI) at one, 3, and 6 months after the injections.
[g] A successful outcome required a five-point Likert scale of 3 (good) or 4 (excellent) and a reduction on the VNS of >50 % and DASH of >15 points at 1, 3, and 6 months after the injection.

44.1 ± 8.9 and six months scores of 16.3 ± 4.1 vs 15.5 ± 4.4 (p=NS[h]). Please refer to table 1 for details.

These results need to be interpreted with caution for a number of reasons. The study was not double-blinded (only the assessors were blinded) and lack of blinding could have resulted in bias, particularly if a difference had been anticipated by patients. The palpation-guided IA injection was given by an experienced physician (seven years) which may not always be the case in clinical settings. This may have affected the accuracy rate. The relatively small number of inaccurate injections means that the study may not have been sufficiently powered to show a difference between the two groups. All the participants had BMIs of less than 30kg/m^2; this is not necessarily representative of the general OA population. The larger amounts of subcutaneous fat in obese patients are likely to have an effect on the accuracy of the injection.

Sibbitt et al (2011) reported the results from a single-blinded RCT (n=92) which addressed how sonographic needle guidance affects clinical outcomes of IA injection in patients with OA of the knee. Patients' pain was measured using the visual analogue scale (VAS) where 0cm signifies no pain and 10cm, unbearable pain.

The authors reported a significant reduction in pain mean scores with sonographic guidance relative to palpation guidance at two weeks (p=0.025) but this was not sustained at six months follow-up (p=1.0) (baseline pain mean scores were 7.5±2.0 versus 7.8±1.8 for the sonographic guidance versus palpation guidance groups respectively; scores at two weeks were 1.4± 2.1 versus 2.4±2.1). They also reported superior duration of therapeutic effect in months [4.2± 1.9 versus 3.1± 2.1 (p=0.01)], lower reinjection rates within 12 months [52% (24/46) versus 74% (34/46) (p=0.03)] and longer time to next procedure (reinjection or referral to surgery) [7.1± 3.2 versus 6.0± 2.8 (p=0.08, not significant)] with sonographic guidance. The authors also reported a significantly higher responder[i] rate with sonographic guidance of 67% (31/46) versus 33% (15/46) with palpation guidance (p=0.0004).

These results should be interpreted with caution as participants were not blinded to their treatment and no details of the randomisation methods used or concealment were provided.

Trials in progress
A search of clinicaltrials.gov identified two trials both of which have been discontinued.

- NCT01032720 – This was a randomised trial to determine if ultrasound-guided knee steroid injections are more effective than sham ultrasound knee steroid injections for the treatment of osteoarthritis. This study, which recruited 33 participants, was terminated in February 2012; no further details are available [17].
- NCT02104726 – This was an open label study to compare relative efficacy of intraarticular steroid injection using anatomic landmarks versus a fluoroscopy guided technique in decreasing knee osteoarthritis pain one month after the procedure. The

[h] NS = not statistically significant
[i] Responders were defined as those who had VAS <2cm

trial, which did not recruit any participants, was withdrawn in July 2016; no further details are available [18].

4.1.2 Cost-effectiveness

We found one cost-effectiveness study of the use of image guided intra-articular corticosteroid injections compared to non-image guided intra-articular corticosteroid injections conducted in the USA.

Sibbitt et al [16] reported the results from an RCT which addressed whether sonographic needle guidance affects clinical outcomes and used these to determine the cost effectiveness of IA injection in patients with OA of the knee.

The authors reported a number of data on costs: cost per year if patient was treated in the physician's office as $173 ± $81 for palpation-guided IA injection compared with $460 ± $207 for sonographic guidance (p=0.0001); cost per year for patients treated in hospital outpatient clinic as $126 ± $58 for palpation-guided IA injection compared with $109 ± $49 for sonographic guidance (p=0.13).

> *Cost per responder per year in a physician's office was reported as $531 ± $248 for palpation-guided IA injection compared with $1129 ± $307 for sonographic guidance (p=0.0001) and cost per responder per year in hospital outpatient clinic as $386 ± $180 for palpation guidance versus $162 ± $73 for sonographic guidance (p=0.0001). The authors concluded that the use of sonographic guidance in hospital outpatient clinics modestly reduced the cost per patient per year and cost per responder per year relative to palpation guided injections.*

These results should be interpreted with caution for the following reasons: very little information was provided and there was no information on the method of randomisation or concealment. The study was conducted in the USA and costings were based on the Medicare reimbursement system which is not universally applicable. The costs not supported by the system were omitted from the costings e.g. sonographic guidance provided in hospital outpatients were not reimbursed and hence the potential cost for this was not reflected in the calculations. This certainly would have skewed the cost difference between the two study arms. It is unclear how relevant these resources and costs are to the NHS in England.

Table 1: Summary of studies of image guided intra-articular corticosteroid injections compared to non-image guided intra-articular corticosteroid injections for patients with osteoarthritis

Study	Patients	Intervention	Comparator	Outcomes
Park et al 2015 [14] Seoul, Republic of Korea Retrospective comparative study (chart review)	Patients with OA of AC joint who had palpation or US guided IA corticosteroid between January 2012 & December 2013 n=100	US guided AC joint IA steroid injection (n=50) mixture of 0.5% lidocaine (1ml) + triamcinolone 20 mg/mL (0.5 ml) + radiographic contrast material (0.5 ml) Men: 11 (22%) Women: 39 (78%) Age: 57.8 ± 8.4 years BMI(kg/m^2): 22.9 ± 1.9 FU: 6.5 ± 2.3 months (Mean±SD)	Palpation (P) guided AC joint IA steroid injection (n=50) mixture of 0.5% lidocaine (1ml) + triamcinolone 20 mg/mL (0.5 ml) + radiographic contrast material (0.5 ml) Men: 12 (24%) Women: 38 (76%) Age: 59.1 ± 8.5 years BMI(kg/m^2): 22.8 ± 2.1 FU: 6.6 ± 2.2 months (Mean±SD)	**Successful (accurate) Injection as determined by the presence of contrast dye in the joint cavity by radiography (US vs P)** 96% (48/50) vs 60.5% (31/50) (p<0.05) **SPADI (US vs P)(Mean±SD)** Baseline 51.50 ± 6.64 vs 52.88 ± 7.96 At one month: 23.88 ± 4.57 vs 25.30 ± 7.56 (p=NS) At 3 months: 25.71 ± 5.01 vs 28.12 ± 6.75 (p=NS) At 6 months: 27.44 ± 6.07 vs 30.63 ± 5.59 (p<0.05) **VNSar (US vs P)** Baseline 5.16 ± 0.79 vs 5.02 ± 0.80 At one month: 2.16 ± 0.96 vs 2.18 ± 0.80 (p=NS) At 3 months: 2.45 ± 0.83 vs 2.56 ± 0.56 (p=NS) At 6 months: 2.47 ± 0.90 vs 2.29 ± 0.75 (p=NS) **VNSlp (US vs P)** Baseline 6.10 ± 0.93 vs 6.02 ± 0.89 At one month: 2.82 ± 0.69 vs 2.94 ± 0.89 (p=NS) At 3 months: 2.52 ± 0.86 vs 2.94 ± 0.89 (p=NS) At 6 months: 2.29 ± 1.06 vs 2.83 ± 0.64 (p<0.05) **VNSaat (US vs P)** Baseline 5.68 ± 0.99 vs 5.64 ± 0.92 At one month: 2.64 ± 0.78 vs 2.94 ± 0.89 (p=NS) At 3 months:2.50 ± 0.71 vs 2.85 ± 0.78 (p<0.05) At 6 months:2.20 ± 0.98 vs 2.79 ± 1.06 (p<0.05) **All (at rest, under local pressure, and the arm adduction test) of the VNS and SPADI after the injection improved significantly from baseline at one, 3, and 6 months in both groups (p<0.05 for each before vs after injection comparison).** Successful treatment (significant pain relief) was defined as > 50% improvement in the VNS score and 20 point improvement in the SPADI) at one, 3 and 6 months after the injections. **Safety – US vs P** Steroid-induced synovitis – 3 vs 1 Skin atrophy and depigmentation – 0 vs 2 No p values reported

Study	Patients	Intervention	Comparator	Outcomes
Nam et al 2013 [15] Seoul, South Korea Randomised, prospective, single-blinded study	Patients with DRUJ disorder n=60 (57 analysed)	US guided IA injection of 0.5ml Omnipaque + 1% lidocaine (0.25ml) + triamcinolone 20mg (0.5ml) into the DRUJ n=28 Mean age: 52.9 years Male: 10 Female: 18	Palpation guided IA injection of 0.5ml Omnipaque + 1% lidocaine (0.25ml) + triamcinolone 20mg (0.5ml) into the DRUJ n=29 Mean age: 54.1 years Male: 11 Female: 18	**Clinical outcome by method of injection guidance** **Primary outcome (US vs P)** **DASH** Baseline 44.3 ± 8.6 vs 44.1 ± 8.9 Score at one month: 21.1 ± 4.5 vs 22.8 ± 4.8 (p=NS) Score at 3 months: 12.8 ± 2.3 vs 14.17 ± 3.5 (p=NS) Score at 6 months: 16.3 ± 4.1 vs 15.5 ± 4.4 (p=NS) **Secondary outcome (US vs P)** **VNS** Baseline 6.5 ± 1.0 vs 6.4 ± 0.9 Score at one month: 2.6 ± 0.8 vs 3.0 ± 0.9 (p=NS) Score at 3 months: 2.7 ± 1.0 vs 3.1 ± 0.8 (p=NS) Score at 6 months: 3.3 ± 1.1 vs 3.5 ± 0.7 (p=NS) **MMWS** Baseline 56.5 ± 6.4 vs 55.3 ± 5.1 Score at one month: 73.6 ± 3.1 vs 72.6 ± 4.1 (p=NS) Score at 3 months: 83.9 ± 3.2 vs 82.2 ± 3.4 (p=NS) Score at 6 months: 80.1 ± 5.0 vs 81.0 ± 4.1 (p=NS) **ROM** Pronation Baseline 63.4 ± 4.5 vs 63.6 ± 5.2 Score at one month: 83.5 ± 3.7 vs 82.1 ± 3.8 (p=NS) Score at 3 months: 82.7 ± 5.7 vs 80.1 ± 4.3 (p=NS) Score at 6 months: 80.3 ± 4.5 vs 79.4 ± 3.8 (p=NS) Supination Baseline 63.5 ± 4.5 vs 63.4 ± 5.9 Score at one month: 82.0 ± 3.4 vs 81.4 ± 3.5 (p=NS) Score at 3 months: 84.7 ± 5.4 vs 83.2 ± 4.3 (p=NS) Score at 6 months: 85.4 ± 5.6 vs 83.7± 4.5 (p=NS) **All outcomes after the injection improved significantly from baseline at one, 3 and 6 months in both groups but there were no significant differences in clinical outcome between the US guided and the palpation guided groups.** A successful outcome required a five-point Likert scale of 3 (good) or 4 (excellent) and a reduction on the VNS of >50 % and DASH of >15 points at 1, 3, and 6 months after the injection.

Study	Patients	Intervention	Comparator	Outcomes
				Successful (accurate) injection as determined by the presence of contrast dye (Omnipaque) in the joint cavity by radiography (US vs P) 100% (28/28) vs 75.8% (22/29) (p<0.05) **Clinical outcome by accuracy of injection** **Primary outcome (Accurate vs Inaccurate)** **DASH** Baseline 44.0 ± 8.5 vs 46.3 ± 10.2 Score at one month: 21.3 ± 4.3 vs 26.6 ± 5.6 (p<0.05) Score at 3 months: 12.8 ± 2.5 vs 18.6 ± 1.4 (p<0.05) Score at 6 months: 15.3 ± 4.1 vs 19.9 ± 2.3 (p<0.05) **Secondary outcome (Accurate vs Inaccurate)** **VNS** Baseline 6.4 ± 1.0 vs 6.6 ± 0.5 Score at one month: 2.6 ± 0.7 vs 4.1 ± 0.4 (p<0.05)) Score at 3 months: 2.8 ± 0.9 vs 3.3 ± 0.9 ((p<0.05) Score at 6 months: 3.3 ± 0.9 vs 4.0 ± 0.0 (p<0.05) **MMWS** Baseline 56.0 ± 6.0 vs 55.3 ± 3.9 Score at one month: 73.4 ± 3.7 vs 70.7 ± 1.5 (p<0.05) Score at 3 months: 83.6 ± 3.2 vs 79.0 ± 1.6 (p<0.05) Score at 6 months: 80.8 ± 4.7 vs 78.4 ± 2.0 (p=NS) **ROM** Pronation Baseline 63.7 ± 4.6 vs 62.1 ± 6.5 Score at one month: 83.3 ± 3.7 vs 78.9 ± 1.3 (p<0.05) Score at 3 months: 86.7 ± 5.7 vs 81.1 ± 1.7 (p<0.05) Score at 6 months: 84.3 ± 4.8 vs 77.4 ± 2.1 (p<0.05)) Supination Baseline 63.6 ± 5.1 vs 62.1 ± 6.5 Score at one month: 82.2 ± 3.4 vs78.4 ± 1.4 (p<0.05) Score at 3 months: 85.9 ± 5.2 vs 80.8 ± 1.3 (p<0.05) Score at 6 months: 83.2 ± 4.6 vs 76.7± 2.5 (p<0.05) **All outcomes after the injection improved significantly from baseline at one, 3, and 6 months in both groups. There was a statistically significant improvement in the VNS, DASH and ROM in the accurate injection group compared with the inaccurate injection group at one, 3 and 6 months but not the MMWS at 6 months.**

Study	Patients	Intervention	Comparator	Outcomes
				Safety – US vs P Steroid-induced synovitis – 2 vs 1 Skin atrophy and depigmentation – 0 vs 2 No p values reported
Sibbitt et al 2011 [16] New York, USA Single-blinded RCT and cost-effectiveness study	Non-effusive knees with OA n=92	Sonographic image guided injection (80mg triamcinolone) enhanced with one-handed mechanical syringe. n=46	Palpation guided anatomic landmark injection (80mg triamcinolone). n=46	**Pre-procedure baseline pain on VAS scores – mean (SD) (P vs US)** 7.8 (1.8) vs 7.5 (2.0) (p=0.45) **Pain at 2 weeks using VAS scores (P vs US)** 2.4 ± 2.1 vs 1.4 ± 2.1 (p=0.025) – 42% difference **Pain at 6 months using VAS scores (P vs US)** 6.3± 2.9 vs 6.3± 2.6 (p=1.0) **Duration of therapeutic effect (months) (P vs US)** 3.1± 2.1 vs 4.2± 1.9 (p=0.01) **Time to next procedure (reinjection or referral to surgery) (P vs US)** 6.0± 2.8 vs 7.1± 3.2 (p=0.08) **Reinjection within 12 months (P vs US)** 74% (34/46) vs 52% (24/46) (p=0.03) **Referral to surgery within 12 months (P vs US)** 7% (3/46) vs 4% (2/46) (p=0.7) **Responders at 2 weeks (P vs US)** 33% (15/46) vs 67% (31/46) p=0.0004 **Cost per year - physician's office (P vs US)** $173 ± $81 vs $460 ± $207 (p=0.0001) **Cost per year – hospital outpatient (P vs US)** $126 ± $58 vs $109 ± $49 (p=0.13) **Cost per responder per year - physician's office (P vs US)** $531 ± $248 vs $1129 ± $307 (p=0.0001) **Cost per responder per year – hospital outpatient (P vs US)** $386 ± $180 vs $162 ± $73 (p=0.0001) Responders were defined as those who had VAS <2cm VAS goes from 0- to 10cm; where 0cm is no pain and 10cm unbearable pain. VAS<2cm is regarded as asymptomatic and significant pain is defined as >5cm

Study	Patients	Intervention	Comparator	Outcomes
				Details of data on those treated in the physicians' office and in hospital outpatients were not provided. Ultrasound guided procedure in hospital outpatients is not reimbursed by Medicare so the authors only included $2 per procedure for each mechanical syringe and hence the true costs were missing.

Abbreviations: AC joint - acromioclavicular joint; BMI – body mass index; DASH - Disability of the Arm, Shoulder and Hand questionnaire; DRUJ - distal radioulnar joint; FU - follow-up; IA - intra-articular; MMWS - Modified Mayo Wrist Score; NS – not significant; OA - osteoarthritis; P – palpation; ROM - range of motion; SD – standard deviation; SPADI - Shoulder Pain and Disability Index; US - ultrasound; VAS - visual analogue scale; VNS - Verbal Numeric pain Scale; VNSar - Verbal Numeric pain Scale at rest; VNSlp - Verbal Numeric pain Scale under local pressure; VNSaat - Verbal Numeric pain Scale arm adduction test

4.2 Safety

The study by Park et al [14] reported that three patients in the US-guided group and one patient in the palpation group complained of pain due to steroid-induced synovitis. Skin atrophy and depigmentation were observed in two patients in the palpation group and none in the US-guided group. There were no severe complications, such as septic arthritis or allergic reactions.

Due to the retrospective nature of the study, it is possible that some of the adverse effects experienced by the patients were not documented.

Nam et al [15] also reported almost identical safety issues “two patients in US-guided group and one patient in the palpation group complained of pain due to steroid-induced synovitis. Skin atrophy and depigmentation were observed in two patients in the palpation group, none in the US-guided group. There were no severe complications, such as septic arthritis, allergic reactions and tendon ruptures”.

4.3 Summary of findings

We did not find any systematic reviews. However, we identified three clinical effectiveness studies, one of which assessed the cost-effectiveness of image guided intra-articular corticosteroid injections compared to non-image guided intra-articular corticosteroid injections in patients with osteoarthritis. The cost-effectiveness study was conducted in the USA.

The retrospective study by Park et al [14] reported statistically significant improvements in patients with OA of the AC joint in all outcome measures at one, three and six months after the injections in both the US and the palpation-guided groups. They also reported a statistically significantly greater improvement in two of the four outcome measures (VNSlp score and SPDAI) at six months and in one of the four measures (VNSaat score) at three months and six months for the US-guided group compared with the palpation group. However, it is unclear what the clinical relevance of the differences observed in these outcome measures is. In addition, given that the participants chose their preferred intervention, the study was retrospective and conducted in one centre by a single physician (also one of the assessors), the potential for bias is substantial and therefore the results should be interpreted with caution.

The randomised prospective single-blinded clinical study by Nam et al [15] reported significantly higher accuracy (100%) with US-guided than with palpation-guided IA injections (75.8%) in patients with DRUJ disorder. They found that all clinical outcome measures were improved at one, three and six months in both the groups receiving US-guided injections and those receiving palpation-guided injections but found no significant difference between the groups. However, they reported a positive correlation between pain improvements and accuracy of IA injections at six months follow-up. These findings may not be generalisable because the palpation-guided IA injection was given by an experienced physician (seven years) which may not always be the case in clinical settings. This may have affected the accuracy rate. In addition, the relatively small number of inaccurate injections means that the study may not have been sufficiently powered to show any difference between the two types of injection guidance.

Both studies only included patients with BMI of less than 30kg/m^2; this does not necessarily represent the general OA population. The distance between the skin and bone in obese patients is likely to have an effect on the accuracy of the injection.

Sibbitt et al [16] reported the results from an RCT as well as the cost effectiveness of IA injection in patients with OA of the knee. The authors reported significant pain reduction with sonographic guidance relative to palpation guidance at two weeks which was not sustained at six months follow-up. They also reported superior duration of therapeutic effect with sonographic guidance compared to palpation guidance and a lower rate of reinjection within 12 months with sonographic guidance. However, there is potential for bias in the results reported because participants were not blinded to the treatment they received.

The authors reported a number of data on costs based on the USA Medicare system: for patients treated in the physician's office they reported a significantly lower cost per patient per year and cost per responder per year for palpation-guided IA injection compared with sonographic guidance. In contrast, for patients treated in hospital outpatient clinic, they reported a significantly lower cost per responder per year with sonographic guidance compared with palpation guidance, but no difference in cost per patient per year for the two groups.

The authors concluded that the use of sonographic guidance in hospital outpatient clinics modestly reduced the cost per patient per year and cost per responder per year relative to palpation guided injections. However it should be noted that the sonographic needle guidance procedure in hospital outpatients is not reimbursed by Medicare so the authors only included $2 per procedure for each mechanical syringe and hence the true costs were missing. The relevance of these results outside of the Medicare system is therefore questionable.

5 Equity issues

It is not known whether there is variation in access to image guided intra-articular corticosteroid injections compared to non-image guided intra-articular corticosteroid injections for patients with osteoarthritis across providers in the NHS Birmingham and Solihull CCG, Sandwell and West Birmingham CCG, and Walsall, Wolverhampton and Dudley CCGs areas, or how access compares to the rest of England.

6 Discussion and conclusions

Question 1

In adults with a painful joint due to osteoarthritis, is image guided intra-articular corticosteroid injection clinically effective compared to non-image guided intra-articular corticosteroid injection?

.

We did not find any high quality evidence to support the clinical effectiveness of image guided intra-articular corticosteroid injections compared to non-image guided intra-articular corticosteroid injections, although some lower quality evidence was found.

Evidence from a low quality study (retrospective chart review) [14] suggests that US guided intra-articular corticosteroid injections for osteoarthritis of the AC joint significantly improves some clinical outcome measures (VNSlp score and SPADI score at six months and VNSaat score at three months and six months)[j] compared to palpation guided intra-articular corticosteroid injections. The clinical relevance of the difference seen in these outcome measures is uncertain. In addition, a moderate quality study (single-blinded RCT) [16] also suggests that sonographic guided intra-articular corticosteroid injections significantly improves pain relative to palpation guided injections in patients with osteoarthritis of the knee after two weeks (although this was not sustained at six months follow-up), reduces reinjection rates within 12 months and increases the time to the next procedure. However, the lack of blinding of the participants to the treatments they received means that there was potential for bias in the results.

These findings conflict with those from a moderate quality prospective single-blinded randomised controlled study [15] which reported no difference in the clinical outcomes measured between US guided and palpation guided IA corticosteroid injections for patients with DRUJ disorder.

Evidence from this study of DRUJ injections [15] suggests that US guided IA corticosteroid injections into the DRUJ have a higher accuracy rate relative to palpation guided IA corticosteroid injections (100% versus 75%; $p<0.05$). The authors also suggest a positive correlation between accuracy and improvement in clinical outcomes measured ($p<0.05$). However, the study may not have been sufficiently powered to show any differences between outcomes for US guided compared to palpation guided injections due to the relatively small number of inaccurate injections in the latter group.

Question 2
In adults with a painful joint due to osteoarthritis, is image guided intra-articular corticosteroid injection cost effectiveness compared to non-image guided intra-articular corticosteroid injection?

We did not find any high or moderate quality evidence to support the cost-effectiveness of image guided intra-articular corticosteroid injections compared to non-image guided intra-articular corticosteroid injections.

> *We found one cost-effectiveness study of sonographic guided versus palpation guided IA corticosteroid injections in patients with osteoarthritis of the knee based on an RCT conducted in the USA. The study based its costs on the Medicare reimbursement system which is unique to the USA. It is therefore unclear how these results relate to the NHS in England.*

.

[j] SPADI - Shoulder Pain and Disability Index; VNSlp - Verbal Numeric pain Scale under local pressure; VNSaat - Verbal Numeric pain Scale arm adduction test

7 Search Strategy

Search date: 14th September 2018

We searched Medline, Embase and Cochrane Library, limited to 2008 onwards and English only. We also ran a search of TRIP database and NICE Evidence search with similar limits and restricting to Evidence Reviews. We excluded letters, commentary, case reports and conference papers.

Search terms
Medline:

1 exp Adrenal Cortex Hormones/
2 Injections, Intra-Articular/
3 1 and 2
4 ((intraarticular or intra-articular or inject*) adj5 (steroid* or corticosteroid* or glucocorticoid*)).ti,ab.
5 ((intraarticular or intra-articular or injection*) adj5 (triamcinolone or methylprednisolone or prednisolone)).ti,ab.
6 3 or 4 or 5
7 (imag* adj5 guid*).ti,ab.
8 (ultraso* or ultra-so* or sonogra* or doppler or fluoroscop*).ti,ab.
9 exp Ultrasonography/
10 7 or 8 or 9
11 6 and 10
12 (imag* adj3 guid* adj5 (steroid* or corticosteroid* or glucocorticoid*)).ti,ab.
13 ((steroid* or corticosteroid* or glucocorticoid*) adj5 imag* adj3 guid*).ti,ab.
14 (imag* adj3 guid* adj5 (triamcinolone or methylprednisolone or prednisolone)).ti,ab.
15 ((triamcinolone or methylprednisolone or prednisolone) adj5 imag* adj3 guid*).ti,ab.
16 11 or 12 or 13 or 14 or 15
17 (comment or editorial or letter or news or "review").pt. or case report.ti.
18 16 not 17
19 limit 18 to (english language and yr="2008 -Current")
20 limit 11 to "reviews (maximizes specificity)"
21 limit 20 to (english language and yr="2008 -Current")
22 19 or 21

Embase

1 exp corticosteroid/ar
2 ((intraarticular or intra-articular or inject*) adj5 (steroid* or corticosteroid* or glucocorticoid*)).ti,ab.
3 ((intraarticular or intra-articular or injection*) adj5 (triamcinolone or methylprednisolone or prednisolone)).ti,ab.
4 1 or 2 or 3
5 (imag* adj5 guid*).ti,ab.
6 (ultraso* or ultra-so* or sonogra* or doppler or fluoroscop*).ti,ab.
7 *exp echography/

8 5 or 6 or 7
9 4 and 8
10 (imag* adj3 guid* adj5 (steroid* or corticosteroid* or glucocorticoid*)).ti,ab.
11 ((steroid* or corticosteroid* or glucocorticoid*) adj5 imag* adj3 guid*).ti,ab.
12 (imag* adj3 guid* adj5 (triamcinolone or methylprednisolone or prednisolone)).ti,ab.
13 ((triamcinolone or methylprednisolone or prednisolone) adj5 imag* adj3 guid*).ti,ab.
14 9 or 10 or 11 or 12 or 13
15 (conference* or comment or editorial or letter or news or "review").pt. or case report.ti.
16 14 not 15
17 limit 16 to (english language and yr="2008 -Current")
18 limit 9 to "reviews (maximizes specificity)"
19 limit 18 to (english language and yr="2008 -Current")
20 17 or 18

Table 2: Inclusion criteria for identification of relevant studies

Question	Population	Indication	Intervention	Comparator	Outcomes	Studies
In adults with a painful joint, what is the clinical and cost effectiveness of image guided intra-articular corticosteroid injections compared to non-image guided intra-articular corticosteroid injections?	Adults with a painful joint (exclude : inflammatory joint conditions - RA, gout, psoriatic arthritis)	Pain management in degenerative joints due to osteoarthritis	Image guided therapeutic intra-articular joint injections with corticosteroids with/without local anaesthetic Exclude: arthrocentesis for any reason	Non image-guided intra-articular joint injections with corticosteroids	Clinical effectiveness including Pain Function/mobility QoL AE Cost effectiveness Subsequent arthroplasty	Standard evidence review in order to be robust enough to influence/change clinical practice. SRMA SR of RCTS RCT SR Prospective cohort studies Retrospective cohort studies Cost effectiveness studies
Inclusion Criteria Peer reviewed publications English language Exclusion Criteria Abstracts Letters Commentaries Conference papers Case reports Papers published more than 10 years ago Papers published online subsequent to the search date						

8 References

1. National Institute for Health and Clinical Excellence (NICE). Final Scope Osteoarthritis: the care and management of osteoarthritis. London, UK :NICE; 2012 https://www.nice.org.uk/guidance/cg177/documents/osteoarthritis-update-final-scope2 Last accessed 27 September 2018
2. National Institute for Health and Clinical Excellence (NICE). Osteoarthritis: the care and management of osteoarthritis. Clinical Guideline 177. London, UK: NICE; 2014
3. Griesser MJ, Harris JD et al. Adhesive capsulitis of the shoulder: a systematic review of the effectiveness of intra-articular corticosteroid injections. J Bone Joint Surg Am 2011; 93: 1727-1733
4. Cross M, Smith E, et al. The global burden of hip and knee osteoarthritis: estimates from the Global Burden of Disease 2010 study. Ann Rheum Dis. 2014; 73(7):1323–30.
5. Ayhan E, Kesmezacar H, Akgun I. Intraarticular injections (corticosteroid, hyaluronic acid, platelet rich plasma) for the knee osteoarthritis. World Journal of Orthopedics 2014; 5(3): 351–361.
6. National Institute for Health and Clinical Excellence (NICE). NICE Clinical Knowledge Summaries (CKS): Osteoarthritis: Prevalence. London, UK: NICE; April 2015.Online. Available: https://cks.nice.org. uk/osteoarthritis#!backgroundsub:2. Last accessed 27 September 2018
7. Arthritis Research UK, Osteoarthritis in General Practice. 2013.
8. Wluka A, Lombard C, and Cicuttini F. Tackling obesity in knee osteoarthritis. Nature Reviews Rheumatology 2013; 9(4): 225-235.
9. Kearns K, Dee A et al. Chronic disease burden associated with overweight and obesity in Ireland: the effects of a small BMI reduction at population level. BMC Public Health 2014; 14(143)
10. Clemence P, Nguyen C et al. Risk factors and burden of osteoarthritis. Annals of Physical and Rehabilitation Medicine 2016 59 (3): 134–138.
11. Spector T and MacGregor A. Risk factors for osteoarthritis: genetics. Osteoarthritis and Cartilage 2004; 12: 39-44.
12. Berkoff DJ, Miller LE, Block JE. Clinical utility of ultrasound guidance for intra-articular knee injections: a review. Clin Interv Aging. 2012; 7:89-95
13. Jüni P, Hari R et al. Intra-articular corticosteroid for knee osteoarthritis. Cochrane Database of Systematic Reviews 2015, Issue 10. Art. No.: CD005328
14. Park KD, Kim TK et al. Palpation versus ultrasound-guided acromioclavicular joint intra-articular corticosteroid injections: a retrospective comparative clinical study. Pain Physician. 2015;18(4):333–341
15. Nam SH, Kim J et al. Palpation versus ultrasound guided corticosteroid injections and short-term effect in the distal radioulnar joint disorder: A randomized, prospective single-blinded study. Clin Rheumatol 2013; 12:1807-1814.
16. Sibbitt WL Jr, Band PA et al. A randomized controlled trial evaluating the cost-effectiveness of sonographic guidance for intra-articular injection of the osteoarthritic knee. J Clin Rheumatol. 2011; 17(8):409–415.
17. Fraenkel L. Ultrasound (US)-Guided Versus Sham Ultrasound Corticosteroid (CS) Knee Injections. https://clinicaltrials.gov/ct2/show/NCT01032720
18. John Hopkins University. "Blind" vs. Fluoroscopy-Guided Steroid Injections for Knee Osteoarthritis. https://clinicaltrials.gov/ct2/show/NCT02104726

19. National Collaborating Centre for Chronic Conditions (UK). Osteoarthritis: National clinical guideline for care and management in adults. London: Royal College of Physicians (UK), 2008
20. Neogi T. The epidemiology and impact of pain in osteoarthritis. Osteoarthritis Cartilage 2013; 21: 1145-1153.

9 Clinician comments after 3 week consultation of the draft evidence review

Date	Clinician	Comments	SPH response
	Jamie Arbuthnot Consultant Trauma & Orthopaedics Good Hope & Solihull Hospital	Can you confirm that this is image guided injections as a treatment rather than as a diagnostic measure please?	Yes, we can confirm that the rapid evidence review relates to image guided injections as a treatment. We will clarify this in the title of the document.
28/11/2018	Mr Andrew M Pearson Executive Medical Director & Consultant Orthopaedic Surgeon The Royal Orthopaedic Hospital NHS Trust	Thank you for sending me the details of this consultation. I have listed some of my personal observations below which you and your team may or may not find helpful in arriving at a decision. 1. Patients should always be managed with pharmacological and lifestyle modifications before referral to secondary care for any type of injection 2. Injections can be used for diagnostic or therapeutic purposes. Particularly in the case of patients with lower back and hip joint pain a hip injection can be useful in differentiating pain arising from the hip and back. 3. Whether image-guidance is required when undertaking a joint injection depends very much on which joint if being injected. For example the knee joint never requires the use of image guidance to be sure that the injection is performed intra-articularly. But in the hip joint it always requires the use of image-guidance to be sure that the injection is in the right place. 4. I see far too many patients in secondary care who have allegedly had joint injections conducted in primary care where the outcome is questionable, but where I have little confidence that the injection actually entered the joint as intended.	Thank you very much for these helpful comments. We will include them in section 9 of the report so that they are available for discussion with the rest of the rapid evidence review. We have clarified in the title that the review relates to injections for treatment rather than diagnostic purposes. We found no studies of the comparative effectiveness of image guided versus palpation guided intra-

		5. I areas where there are important structures nearby, such as the hand, it is important that intra-articular injections are supported by image-guidance. I would be very happy to be involved in any way that I can in order to help further with this consultation	articular injections in the hand.
04/12/2018	Mr. Samir Massoud Consultant Trauma & Orthopaedics - University Hospitals Birmingham NHS Foundation Trust Queen Elizabeth Hospital, Queen Elizabeth Medical Centre, Birmingham	Thanks, The review of injections for arthritis is difficult to comment on because of lack of evidence. As far as I know, ultrasound guided injection of the subacromial space for impingement is much more common than these injections and may be worth investigating as these are fairly simple to do without ultrasound guidance. This would be a more likely source of savings. In my practice, more than 90% of shoulder injections are done in my clinic at the ROH with no ultrasound guidance.	Thank you very much for these helpful comments. This was a review of intra-articular joint injections, and hence injections into the subacromial space were not within scope of this review. We will include your comments in section 9 of the report so that they are available for discussion with the rest of the rapid evidence review.
06/12/2018	Geoff Naylor Clinical Director Planned Care BSOL	Bsol CCG have data suggesting quite a lot of these injections are done by a select few of orthopaedic surgeons mainly in the independent sector on the NHS ECN contract. Not just for the shoulder, but also CMC joint injection injections	Thank you very much for your comment. We will include it in section 9 of the report so that it is available for discussion with the rest of the rapid evidence review.
06/12/2018	William Goude Walsall Healthcare NHS Trust	I agree that making decisions based on 3 low power studies, none of which look at sub acromial or CMCJ injections is not	Thank you very much for these helpful comments and clinical opinion. We will

		possible. My personal practice is to perform the majority of sub acromial injections in the clinic, but if it is an important diagnostic test (e.g if the patient has symptoms from the cervical spine etc as well) I will get the injection ultrasound guided. As upper limb surgeons we are probably confident to perform these injections ourselves in the clinic, but this may not be the case for our juniors or some of our colleagues.	include them in section 9 of the report so that they are available for discussion with the rest of the rapid evidence review. This was a review of intra-articular joint injections, and hence injections into the sub acromial space were not within scope of this review. We found no studies of the comparative effectiveness of image guided versus palpation guided intra-articular injections in the hand/CMCJ.
06/12/2018	Mike Craigen Consultant Orthopaedic and Hand surgeon Trauma & Orthopaedics - University Hospitals Birmingham NHS Foundation Trust	Thank you for your request. I am a hand surgeon managing problems in the elbow wrist and hand and therefore have no experience of high volume intraarticular injections as these would be inappropriate in these areas. As to image guided joint injections this has been my standard practice for all my consultant career, normally using x ray but occasionally using ultrasound. You seem to have found the few studies that are published. The rationale is that if the injection fails to resolve the symptoms one possible explanation is failure to inject into the joint (easy to do in the hand and wrist), a problem avoided if image guidance is used. In addition you don't seem to have made any comment on the complications of injecting steroid outside the joint, including fat necrosis and tendon injury, again a higher risk in the hand due to the number of tendons in close proximity. I would support a recommendation that injections in the hand	Thank you very much for these helpful comments and clinical opinion. We found no studies of the comparative effectiveness of image guided versus palpation guided intra-articular injections in the hand. We will include your comments in section 9 of the report so that they are available for discussion with the rest of the rapid evidence review.

		and wrist should be performed under image guidance although I would prefer under x ray by an specialist in that area would be my preferred choice. I would be happy to provide further input.	
06/12/2018	*Richard Dias* *Clinical Director, Trauma & Orthopaedics* *Consultant Orthopaedic Hand & Upper Limb Surgeon* *Honorary Senior Lecturer, University of Birmingham*	I agree with Samir that subacromial space injections for impingement are easy to do without ultrasound guidance. I suspect it is the physiotherapists that use ultrasound for these injections. I totally agree with Mike Craigen that all injections into the hand and wrist should be done under image guidance. In clinical practice we often see patients who have had blind injections to the small joints of the hand with no benefit at all and the lack of confidence in further injections.	Thank you very much for these helpful comments and clinical opinion. We will include them in section 9 of the report so that they are available for discussion with the rest of the rapid evidence review. This was a review of intra-articular joint injections, and hence injections into the subacromial space were not within scope of this review. We found no studies of the comparative effectiveness of image guided versus palpation guided intra-articular injections in the hand.
06/12/2018	Mr. Rajive Jose Consultant, Hand Surgery Burns & Plastics - University Hospitals Birmingham NHS Foundation Trust Queen Elizabeth Hospital Birmingham,	My practice is the same as Mike Craigen and I echo his comments regarding injections in the hand.	Thank you for your comment. Please see comments above.

06/12/2018	Mr. Mark Brewster Hand Surgery - Consultant Trauma & Orthopaedics - University Hospitals Birmingham NHS Foundation Trust Queen Elizabeth Hospital Birmingham	I must admit that I perform almost all injections without USS or XR I do use XR for CMCJ and STT but all soft tissue injections, wrist joint/TFCC and MCPJs injection I do in the clinic with anatomical guidance only.	Thank you very much for these helpful comments. We will include them in section 9 of the report so that they are available for discussion with the rest of the rapid evidence review.
06/12/2018	Mr. Alastair Marsh Consultant Orthopaedic Trauma Surgeon Clinical Lead Major Trauma Service Trauma & Orthopaedics - University Hospitals Birmingham NHS Foundation Trust Queen Elizabeth Hospital Birmingham	You have done a few though Mike! The important thing is that the joints that are difficult to get into, you do with guidance. Most common reasons for joint injections to not work are wrong joint or not in joint to start with. As a foot and ankle Surgeon I use xray guidance almost always so that I have the confidence that I have placed it where I want it. It also reduced the risk of fat necrosis in the foot and plantar plate rupture around the toes. It allows me to see the joint as well to confirm stability as well.	Thank you very much for these helpful comments and clinical opinion. We will include them in section 9 of the report so that they are available for discussion with the rest of the rapid evidence review. We found no studies of the comparative effectiveness of image guided versus palpation guided intra-articular injections in the ankle or foot.
06/12/2018	Paul Parker University Hospitals Birmingham NHS Foundation Trust	I just guess where the hip is..... Or not.....	
06/12/2018	Seyed A Ali Trauma & Orthopaedic Consultant University Hospitals Birmingham NHS Foundation Trust Selly Oak Hospital	I completely agree with Alastair Marsh. Being a Foot & Ankle Surgeon, I always use X-ray guidance to inject small joints of the foot for reasons mentioned by Alastair. Thank you.	Thank you very much for your helpful comment and clinical opinion. We will include it in section 9 of the report so it is available for discussion with the rest of the rapid evidence review.

			We found no studies of the comparative effectiveness of image guided versus palpation guided intra-articular injections in the ankle or foot.
10/12/2018	Paresh Jobanputra (Rheumatology) University Hospitals Birmingham NHS Foundation Trust	Evidence review: The focus of the review is rather narrow but I suspect the search strategy is sufficiently accurate in terms of the literature for osteoarthritis. However since a large number of injections are done for shoulder pain, and one might argue that much rotator cuff disease is due to AC joint OA, a broader perspective should have been taken to allow the commissioners to make a more informed decision. There are more studies for shoulder pain and several systematic reviews. We should also bear in mind that injections for OA, however they are delivered, have limited efficacy so evidence from systematic reviews of these should have been described to give commissioners a broader perspective. Current clinical practice: I suspect there is considerable practice variation both in primary care and in secondary care. We do not have a local protocol for this but I believe that many hard pressed clinicians are asking for radiology-based injections because of time pressures and also a prevalent belief that the latter are more effective. It would seem appropriate to commission a clear physiotherapy based triage pathway for patients with isolated joint pains such as knee pain, shoulder pain and hand osteoarthritis. Clinical opinion: I suspect that all injections for OA have a large placebo element so a pragmatic approach whereby clinical landmark-based injections done by an experienced practitioner in an appropriate setting, as a first step, is	Thank you very much for these helpful comments and clinical opinion. We will include them in section 9 of the report so that they are available for discussion with the rest of the rapid evidence review. Regarding shoulder pain, separate rapid evidence reviews were carried out on the effectiveness of high volume joint injections and on the effectiveness of subacromial decompression.

		sensible. It seems reasonable to consider an US guided injection in resistant cases especially if these could avoid more invasive therapy. The definition of 'resistant' needs care bearing in mind that, for established OA, injections have limited efficacy. I can only speculate about the number of patients but, given the prevalence of shoulder pain (including AC OA), knee pain (including all grades of OA) and hand pain (DIP and CMC joint disease), I suspect the population burden and consultations in primary care and secondary care are substantial.	
12/12/2018	Michael Waldram SOH Trauma Consultant SOH Trauma Trauma - University Hospitals Birmingham NHS Foundation Trust Queen Elizabeth Hospital, Queen Elizabeth Medical Centre	I have been in Consultant Hand surgery practice for 35 yrs I entirely echo the comments of Mike Craigen	Thank you for your comment. Please see comments above.
12/12/2018	Munawar Shah Walsall Healthcare NHS Trust	I am upper limb consultant for nearly 17 years have been injecting 90% without xray or US however I do have US available to me in clinic and hence use it when required but agree with rest	Thank you very much for these helpful comments. We will include them in section 9 of the report so that they are available for discussion with the rest of the rapid evidence review.

Competing Interest

All SPH authors have completed the ICMJE uniform disclosure form (www.icmje.org/coi_disclosure.pdf) and declare: grants from Solihull CCG, Birmingham CrossCity CCG and Birmingham South Central CCG to SPH to undertake the submitted work, no financial relationships with any organisations that might have an interest in the submitted work in the previous three years and no other relationships or activities that could appear to have influenced the submitted work.

Terms of Use

This document has been produced by SPH for Solihull CCG, Birmingham CrossCity CCG and Birmingham South Central CCG. It must not be distributed or accessed or used for commercial purposes without prior written permission from SPH. The purpose of this document is to review and summarise published evidence relating to clinical interventions. The findings may be applicable to the development of commissioning policy, but commissioning policy development is undertaken by NHS commissioners taking into account a wide range of other factors. SPH is not responsible for the development of commissioning policy. Use of this document is subject to agreement that SPH is fully indemnified against any liability that may arise through use of the information within this document.

January 2019

ARTHROSCOPIC SUBACROMIAL DECOMPRESSION (ASD) IN ADULTS WITH IMPAIRED FUNCTION AND PAIN IN THE AFFECTED SHOULDER JOINT

Questions to be addressed

1. What is the evidence of clinical and cost effectiveness of arthroscopic subacromial decompression, compared to conservative treatment, in adults with impaired function and pain in the affected shoulder joint?

Reason for review

NHS Birmingham and Solihull CCG and Sandwell and West Birmingham CCG, in partnership with Walsall, Wolverhampton and Dudley CCGs, requested a rapid evidence review of the clinical and cost effectiveness of arthroscopic subacromial decompression surgery for adults with functional impairment and pain in the affected shoulder. The review was requested because of recent published evidence, as well as a reported increase in the number of procedures being performed.

Options for commissioners:

1. Due to the lack of evidence for the clinical effectiveness for arthroscopic shoulder decompression (ASD) compared to no treatment, develop a commissioning policy that considers ASD followed by physiotherapy for patients with subacromial pain which has not responded to previous non-operative treatment to be a Low Priority.
2. Due to insufficient volume of evidence demonstrating that ASD is no more effective than either no treatment or physiotherapy alone, continue to routinely commission ASD for patients with subacromial pain who have failed to respond to conservative treatment, including joint injection with corticosteroid, until more evidence is available.

Summary

Refer to glossary in appendix 1 for descriptions of shoulder assessment instruments and outcomes.

Background

- 2.4% of all GP visits in England in 2000 were for shoulder pain. Shoulder impingement syndrome (SIS) is marked by subacromial pain, particularly when the arm is raised [1]. It is due to the impingement of rotator cuff tendons in the subacromial space between the head of the humerus and the inferior surface of the acromion. It is one of the most common types of shoulder pain and accounts for up to 70% of all shoulder pain problems [2].
- Arthroscopic subacromial decompression (ASD) is commonly offered to patients with SIS. It aims to relieve the pain by creating more space for the rotator cuff tendon[3].

- The procedure involves antero-inferior acromioplasty, i.e. the resection of bone spurs under the lateral third of the acromion, as well as the excision of the coracoacromial ligament and the subacromial bursa. If a partial or small full-thickness tear of the rotator cuff is present, it may be mildly debrided or left alone.
- ASD is reported to have increased more than seven-fold between 2000 and 2010 in the NHS in England [4].

Clinical effectiveness

Shoulder Impingement Syndrome (SIS)

- Three randomised controlled trials (RCTs) compared ASD to conservative treatment for patients with SIS and no full thickness tear of the rotator cuff at 12 or 24 months [4,6,7]. Patients with partial thickness rotator cuff tears were not excluded from any of the RCTs. One compared ASD plus physiotherapy to physiotherapy alone (n=140) [7], whereas in the FIMPACT [6] and CSAW [4] RCTs (n=210 and n=313 respectively), there were three treatment arms. Both of these studies compared ASD plus physiotherapy to diagnostic arthroscopy plus physiotherapy. However, in the UK based CSAW RCT, surgery was compared to no treatment at all, whereas in the FIMPACT RCT, the non-operative comparator included a home exercise regime as well as 15 physiotherapy visits.
    - ASD plus physiotherapy versus diagnostic arthroscopy plus physiotherapy. Two RCTs reported no clinically significant difference at either 12-month follow-up [4] or 24 months [6]. This was consistent for all of the outcomes measured: Oxford Shoulder Score (OSS), Constant score, pain, depression and anxiety, health-related quality of life, simple shoulder test and 15D as well as patient satisfaction with the allocated treatment.
    - ASD plus physiotherapy versus no treatment: Although some relatively small differences were seen in favour of ASD plus physiotherapy, there were no clinically important differences for any outcomes measured at 12 months between ASD plus up to four sessions of physiotherapy compared to no treatment at all [4].
    - ASD plus physiotherapy versus physiotherapy only: There were no clinically important differences reported between these two treatment groups at 24-month follow-up [6,7].
- Within each treatment group, all three trials showed clinically significant improvement at 12 or 24 months, when compared to baseline for the OSS, modified Constant score[a] and pain [4,6,7].
- Lack of blinding of patients and assessors may have biased the results in favour of surgery. Despite this, the potential confounding did not result in better outcomes for people receiving ASD compared to those receiving conservative treatment for SIS, even though they have previously failed to respond adequately to conservative management.

[a] The authors refer to the modified Constant Score but it is not clear how it differs from the Constant Score (also called the Constant-Murley Score). Both the CSAW study publication [4] and the CSAW study protocol [19] reference the 1987 Constant-Murley Score publication [13].

Supraspinatus tendon tear.

- The supraspinatus is one for the four rotator cuff muscles; degeneration of the tendon is associated with impingement on the acromion and subacromial pain.
- One RCT [10] allocated 180 patients with a non-traumatic supraspinatus tear to treatment with arthroscopic acromioplasty (ASD) and physiotherapy, or rotator cuff repair, ASD and physiotherapy and the outcomes were compared to patients who had 10 sessions of physiotherapy alone. There were no between group differences for the overall Constant score at 12 months. A statistically significant difference in favour of ASD, with or without the rotator cuff repair, was reported for both the pain and activities of daily living subscores, although there was no difference between surgery and physiotherapy for range of motion, strength or patient satisfaction.

Safety

- Study related complications were reported in two recent RCTs [4, 6]. There were no serious adverse events.
- Six out of the 274 patients in the intention to treat analysis of the CSAW RCT developed frozen shoulder, two in each of the three treatment groups (ASD, arthroscopy only and no treatment) [4]. There was no difference in the incidence of complications between the three treatment groups in the CSAW RCT ($p>0.9999$ for all comparisons)
- Of the 210 patients recruited to the FIMPACT RCT, adverse events were reported for eight patients at 24 month follow-up. Six events were due to frozen shoulder: three had been treated with ASD, one with diagnostic arthroscopy only and two with physiotherapy. There was no difference between the three treatment groups for adverse events [6].

Cost effectiveness

- There are no studies generalisable to the NHS which measure the cost effectiveness of ASD compared to conservative treatment in patients with subacromial shoulder pain.

Equity issues

- There is significant variation in access to ASD elective admissions across the five Birmingham and Black Country CCGs.
- For the period April 2017 to March 2018, patients registered with a GP in Wolverhampton CCG had the highest age standardised rate at 116.7 per 100,000 population. In contrast, Sandwell and West Birmingham CCG had the lowest at 67.4 per 100,000 population. Both CCGs are considered outliers due to age sex standardised rates of elective ASD that are more than 3 standard deviations from the mean of the CCGs. This indicates that there is a high degree of confidence that the variation in access is not due to chance.

Activity and finance

- For the three full years up to and including March 2018, there were 4,794 adult elective admissions for ASD with or without biceps tenotomy and with or without a rotator cuff repair across all of the Birmingham and Black Country CCGs. 2384

(49.7%) of these admissions included a rotator cuff procedure; 2410 (50.2%) were for ASD without a rotator cuff tendon repair.

- The total cost of admissions for these elective ASD procedures during the three year period April 2015 to March 2018 for all Birmingham and Black Country CCGs was £17,963,651 based on the 2018/19 national tariff. For 2017-2018 only, the Birmingham and Black Country CCGs expenditure for elective ASD procedures was £5,702,943.

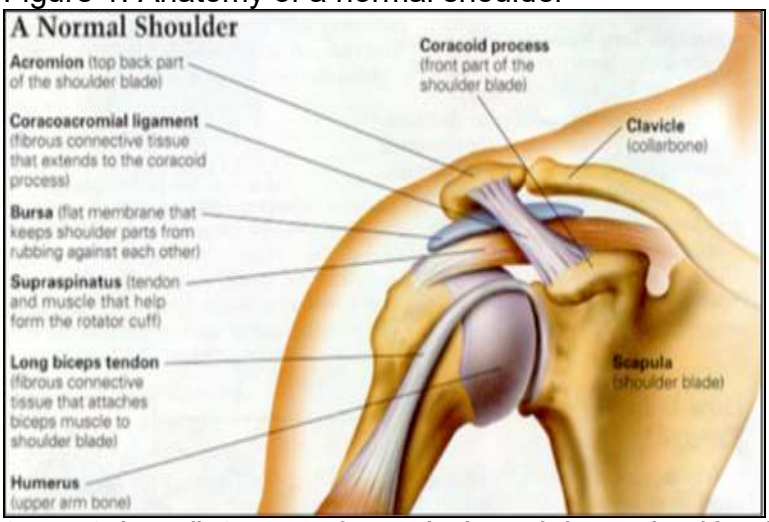
1 Context

1.1 Introduction

Rotator cuff disease (wear and tear of the rotator cuff tendons) is thought to be a continuum ranging from shoulder impingement syndrome (SIS) through to partial and then full thickness rotator cuff tears [1]. It is one of the most common causes of non-traumatic shoulder pain which presents in primary care and is a normal part of aging [2].

The rotator cuff tendons hold the shoulder joint in place and allow people to lift the arm and reach overhead. When the arm is lifted, the rotator cuff tendon passes through a narrow space at the top of the shoulder, known as the subacromial space. The illustration of a healthy shoulder joint below (figure 2) shows the relationship of tendons, ligaments, soft tissue and bony anatomy of the subacromial space.

Figure 1: Anatomy of a normal shoulder



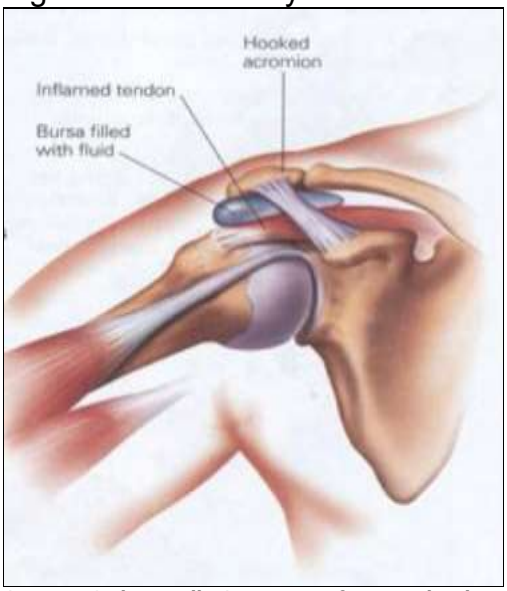
Source: Orthopaedic Surgeons of Long Island Association. Retrieved from http://www.ortho-md.com/procedures/impingement_syndrome.html

Shoulder impingement occurs when the tendon rubs or catches on the acromion and the subacromial bursa. Shoulder impingement can start suddenly or come on gradually. As illustrated in figure 2 below, it may occur if

- the tendon is swollen, thickened or torn due to injury, overuse or age-related "wear and tear"
- the subacromial bursa becomes irritated and inflamed (bursitis)

•the acromion is curved or hooked, rather than flat
•there are bony growths (spurs) on the acromion

Figure 2: Anatomy of a shoulder affected by shoulder impingement syndrome



Source: Orthopaedic Surgeons of Long Island Association. Retrieved from http://www.ortho-md.com/procedures/impingement_syndrome.html

The main problem in shoulder impingement syndrome is of pain in the top and outer side of the shoulder, which is worse when the arm is raised overhead [1]. Pain is associated with dysfunction, affecting usual activities of daily living, sporting activities and ability to work full time. Patients often report a significant reduction in terms of health-related quality of life [3].

1.2 Existing national policies and guidance

There are no relevant NICE guidance or guidelines which consider the use of arthroscopic subacromial decompression or arthroscopic acromioplasty for non-traumatic shoulder pain.

2 Epidemiology

Beard et al (2018) reported that painful shoulders accounted for 2.4% of all GP consultations in the UK [4]. This was for a UK cohort identified in 2000. The incidence of new patients consulting their GP for a shoulder condition was 1.47%. Prevalence increased linearly with age whilst incidence peaked at around 50 years of age and then remained static at around 2%. Just under half (47.9%) of the incident cases consulted once only, while 13.6% were still consulting with a shoulder problem during the third year of follow-up. During the 3 year period following initial presentation, 22.4% of patients were referred to secondary care, 30.8% were prescribed non-steroidal anti-inflammatory drugs and 10.6% were given an injection by the GP [5].

Subacromial pain is thought to be responsible for up to 70% of all shoulder pain [6].

3 The interventions

Shoulder impingement will often improve in a few weeks or months, especially with prescribed shoulder exercises. If the pain persists and is unresponsive to conservative treatment including pain medication, exercises and possibly steroid injections, then surgery may be considered.

The term 'arthroscopic' describes any surgical procedure which is performed using surgical instruments inserted through a small 'keyhole' incision and an endoscope inserted via a separate incision to visualise the area.

Arthroscopic shoulder surgery is not one single surgical procedure; rather it refers to a wide range of procedures to different parts of the shoulder anatomy. These may repair damaged cartilage or torn tendons, remove loose fragments of bone or cartilage, drain excess fluid, or release adhesions.

Arthroscopic subacromial decompression (ASD) which is the focus of this evidence review is the most common surgical procedure in patients with shoulder impingement syndrome (SIS) [3]. The standard procedure is antero-inferior acromioplasty, i.e. the resection of bone spurs under the lateral third of the acromion, as well as the excision of the coracoacromial ligament and the subacromial bursa. If a partial or small full-thickness tear of the rotator cuff is present, it is may be mildly debrided or left alone [3].

Beard et al (2018) highlighted that in the ten years from 2000 to 2010, the number of patients in England who had ASD increased seven-fold from 2,523 to 21,335 [4].

The focus of this evidence review is on the use of arthroscopic subacromial decompression (ASD) compared to conservative treatment for shoulder pain.

For the purpose of this review, we have standardised key terms, even when an alternative term was used in the original publication.

- Physiotherapy (PT). PT will include written information and guidance on exercises to be conducted at home as well as a number of sessions of physiotherapy or supervised exercise therapy. Some studies used the term exercise therapy (ET).

- Diagnostic arthroscopy (DA). DA refers to the arthroscopic investigation of the joint, rotator cuff tendons and subacromial bursa, but does not involve any further intervention. It has been described in studies as a suitable 'sham' ASD or surgical placebo.

- Arthroscopic Subacromial Decompression (ASD). This will refer to the standard procedures described above, including acromioplasty.

- Shoulder impingement syndrome (SIS). SIS will be used to refer to shoulder pain which in various publications has also been referred to as subacromial impingement syndrome or subacromial pain. It may be accompanied by partial thickness/grade I or II tear of the rotator cuff.

4 Findings

4.1 Evidence of effectiveness

The majority of comparative studies for ASD were for subacromial impingement syndrome. We also included studies where the ASD was performed for shoulder pain due to minor rotator cuff tears.

We selected seven publications from four randomised controlled trials (RCTs) all of which compared arthroscopic subacromial decompression with conservative treatment for shoulder pain, and which met the criteria in the PICO table in section 9. Four of the publications reported results from the same RCT population at four different time intervals.

Three RCTs focused on patients with SIS which had persisted for at least three months duration and had failed to respond to conservative treatment including physiotherapy [4, 6, 7]. These were the CSAW trial (n=313) [4], the FIMPACT trial (n=210)[6] and Ketola et al (2009)(n=140)[7]. All of the patients in the CSAW trial had also failed to respond to at least one steroid injection, whereas in the other studies only a proportion of patients had also failed to respond to a steroid injection [4].

The participants in the RCT by Kukkonen et al (2014) were being treated for symptomatic non-traumatic tears of the supraspinatus tendon (one of the four rotator cuff tendons) [10]. In this study, 180 patients were randomised to ASD and physiotherapy (ASD+PT), ASD and rotator cuff repair and physiotherapy (ASD+RC+PT) or physiotherapy alone (PT). The outcomes were reported at 3, 6 and 12 months after baseline.

The four trials reported outcomes using a wide range of assessment scores including

- Shoulder function status: Oxford Shoulder Score (OSS), Constant-Murley Score (CM), Simple Shoulder Test (SST), Shoulder Disability Questionnaire (SDQ)
- Pain: PainDETECT score and visual analogues scores(VAS)
- Anxiety and Depression: HADS Depression score, HADS Anxiety score
- Health related quality of life (HRQoL): EQ-5D
- 15D score

These outcome scores are described in more detail in Appendix 1.

The detailed results of the randomised controlled trials are reported in table 1.

4.1.1 Clinical effectiveness

CSAW RCT [4]. In this RCT, 313 adults in the UK between September 2014 and June 2015 were randomised for treatment with ASD plus physiotherapy (ASD+PT), diagnostic arthroscopy plus physiotherapy (DA+PT) as a sham or placebo ASD or no treatment at all. All of the patients had subacromial pain of at least 3 months' duration and had completed non-operative management that included physiotherapy and at least one steroid injection. Patients with a full thickness rotator cuff tendon tear were excluded, although patients with a partial thickness tear were included. The postoperative physiotherapy comprised advice and between one and four routine treatment sessions. The patients who were allocated to no treatment at all were scheduled to be reassessed by the study investigators three months after randomisation. The patients were assessed at baseline and at 6 and 12 months.

The three treatment arms evaluated whether ASD plus physiotherapy is superior to physiotherapy alone, as well as if physiotherapy is superior to no treatment and if ASD plus physiotherapy is better than no treatment at all.

The primary outcome for the study was the Oxford Shoulder Score (OSS), a 12 question, 0-48 point patient reported outcome score [12]. This was assessed at 6 months after randomisation. Secondary outcomes were the OSS at 12 months, and six different outcome measures for pain and quality of life assessed at six and 12 months after randomisation.

The intention to treat (ITT) analysis showed that at 6 (n=274) and 12 months (n=265), all three groups had a higher mean OSS compared to the baseline. The baseline mean OSS for ASD+PT, DA+PT and no treatment were 25.2, 26.7 and 25.5 respectively. At 6 months, these scores had improved to 32.7, 34.2 and 29.4 respectively, with further improvement reported at 12 months (38.2, 38.4 and 34.3).

Six months after randomisation, the OSS for ASD plus PT (mean difference (MD) 2.8 (95%CI 0.5 to 5.2), p=0.0186) and DA plus PT (MD 4.2 (95%CI 1.8 to 6.6), p=0.0014) were statistically better than no treatment at all. At 12 months, the mean difference in the OSS for ASD plus PT and for DA plus PT when compared to no treatment, were 3.9 (p=0.0193) and 3.6 (p=0.0193) respectively. Although both ASD and the DA plus physiotherapy were statistically better than no treatment at all at both 6 and 12 months, the mean differences reported are lower than the minimal clinically important difference (MCID) of 6 points [12], therefore supporting the authors' conclusion that the '*differences were not clinically important*'.

There was no difference in OSS between ASD plus PT and DA plus PT at 6 months (ASD+PT vs DA+PT: MD -1.3 (95%CI -3.9 to 1.3), p=0.3141) or at 12 months (ASD+PT vs DA+PT: MD 0.3 (95%CI -2.9 to 3.5), p=0.8571).

The Constant-Murley Score[b]. (CS) is a composite functional assessment tool measuring four subscales: Pain (15 points); Activities of daily living (ADL) (20 points); Range of Motion (ROM) (40 points) and Strength (25 points) [13]. The ITT analysis reported that at 6 (n=249) and 12 months (n=227), all three groups had a higher mean CS compared to the baseline. The baseline mean CS for ASD+ET, DA+ET and no treatment were 39.4, 43.1 and 38.3 respectively. At 6 months, these scores had improved to 56.5, 57.6 and 45.4 respectively, with further improvement reported at 12 months (66.2, 64.9 and 56.7).

At 6 months, the mean difference in the modified CS for ASD plus PT and for DA plus PT when compared to no treatment was 9.3 (95%CI 4.1 to 14.6, p=0.0012) and 9.1 (3.1 to 15.2, p=0.0045) respectively. At 12 months, the mean difference in the modified CS for ASD plus PT and for DA plus PT when compared to no treatment was 8.3 (p=0.0067) and 4.9 (p=0.0173) respectively. Although ASD plus PT and the DA plus PT were statistically better than no treatment at 6 and 12 months, the mean differences are lower than the minimal clinically important difference of 11 points [12].

There was no difference in the modified CS between ASD plus PT and DA plus PT at either 6 months (MD 0.3 (95%CI -4.1 to 4.7), p=0.8972) or 12 months (MD 2.7 (95%CI -2.7 to 8.2), p=0.3087).

Pain. At 6 (n=243) and 12 months (n=208), all three groups had a lower mean PainDETECT score [14] compared to baseline. The baseline mean pain score for ASD plus PT, DA plus PT and no treatment were 11.7, 11.0 and 11.9 respectively. At six months, these scores had improved to 8.4, 7.9 and 10.1 respectively, with further improvement reported at 12 months (8.5, 7.3 and 9.8).

At 6 months, the mean difference in the PainDETECT score for ASD plus PT and for DA plus PT when compared to no treatment, was -1.7 (95%CI -3.5 to 0.0), p=0.0559) and -1.9 (-3.7 to 0.0), p=0.0502) respectively. At 12 months, the mean difference in the pain scores for ASD plus PT and DA plus PT when compared to no treatment were -1.5, (p=0.1721) and -1.8 (p=0.1536) respectively). The differences were not statistically or clinically significant.

There was no difference in pain scores between ASD plus PT and DA plus PT at either 6 months (MD 0.1 (95%CI -1.8 to 2.0), p=0.9036) or 12 months (MD 0.4 (95%CI -1.4 to 2.2), p=0.6541).

Depression and anxiety was measured using the HADS (Hospital Anxiety and Depression Scale), a fourteen-item scale; seven of the items relate to anxiety (0-21 points) and seven relate to depression (0-21 points) [15]. The study group reported the depression and anxiety score separately.

Depression. Patients who received either ASD plus PT or DA plus PT had a statistically significantly lower mean depression score at six months compared to the group receiving

[b] The authors refer to the Modified-Constant-Murley Score throughout the study, however it is not clear how this differs from the Constant-Murley Score published in 1987 [13]. Both the publication and the study protocol reference the 1987 publication.

no treatment (MD -1.1 (95% CI -1.8 to -0.4), p-0.0040 and MD -1.3 (95% CI -2.1 to -0.3), p=0.0100 respectively). Although there was a small reduction in HADS depression points for all groups at 12 months when compared to baseline, there was no statistical difference between any of the interventions at 12 months; neither surgical group was better than no treatment at all, and there was no difference in depression score between ASD plus PT and DA plus PT. We noted that the baseline depression scores for ASD plus PT, DA plus PT and no treatment groups were all below 8 points (5.0, 5.0 and 5.7 respectively) and that these are below the cut-off for depression where 8 to 10 points is considered borderline and 11 to 21 points is considered a positive diagnosis of depression.

Anxiety. The outcome for anxiety was similar. At baseline, the mean anxiety scores for all three groups ranged from 6.3 to 6.9, lower than the scores which would indicate anxiety. At 6 and 12 months, there was an improvement in the HADS anxiety scores in all three groups, compared to baseline. There was a statistical improvement in the ASD plus PT group compared to no treatment at 6 months (mean difference -0.8 (95%CI -1.5 to -0.2), p=0.0168) but no difference between ASD plus PT and DA plus PT, or between DA plus PT and no treatment. At 12 months' post randomisation, there was no difference between any of the three groups.

Health related quality of life (HRQoL). The EQ-5D is a standardized instrument designed to measure health-related quality of life (HRQoL) [16]. The EQ-5D consists of two parts: a descriptive system comprising five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression (for which the EQ-5D-3L has 3 levels of severity for each of the 5 dimensions) together with the EQ-VAS which records self-rated health on a vertical visual analogue scale. The study group reported these two elements of the EQ-5D separately.

From a baseline EQ-VAS score ranging from mean 65.8 to 69.7 points across all three groups, the only significant between group difference in self-reported HRQoL was for ASD plus PT versus no treatment (mean difference 6.4 (95%CI 2.2 to 10.7), p=0.0043) at 6 months. This difference was not sustained at 12 months. At 6 months, neither DA plus PT nor no treatment resulted in any significant change to the EQ-VAS score compared to baseline. . At 12 months, there was no between group difference; neither surgical group was better than no treatment at all, and there was no difference in EQ-VAS between ASD plus PT and DA plus PT.

At baseline, the mean **EQ-5D-3L Index** for all three groups ranged from 0.50 to 0.55. At 6 months, there was an improved EQ-5D-3L score for both ASD plus PT and DA plus PT compared to no treatment (ASD+PT vs no treatment: 0.12 (0.04 to 0.21), p=0.0076; DA+PT vs no treatment : 0.12 (0.02 to 0.21), p=0.0154) with no difference between the two surgical intervention groups. At 12 months, there were no between group differences; neither surgical group was better than no treatment at all, and there was no difference in EQ-5D-3L between ASD plus PT and DA plus PT.

FIMPACT RCT. A second, multicentre randomised controlled trial known as FIMPACT was published in July 2018 by Paavola et al (2018) [6]. 210 patients in Finland, aged 35 to 64 years with shoulder impingement syndrome which was unresponsive to conservative treatment, were randomised to three treatment groups between February

2015 and June 2015. These were ASD plus physiotherapy (ASD+PT), diagnostic shoulder arthroscopy plus physiotherapy (DA+PT) or physiotherapy alone. The physiotherapy protocol for the ASD (n=59) and DA (n=63) groups comprised one visit to physiotherapist for instructions on home exercises. Unlike the CSAW trial which offered no treatment at all for the non-operative group, the 71 patients randomised to non-operative received 15 physiotherapy visits as well as instructions for home exercises. Patients were followed up for 24 months.

The primary comparison was for ASD plus PT versus DA plus PT using the primary outcome of shoulder pain at rest and on arm activity measured using a 0-100mm visual analogue score (VAS) where 0 indicated no pain and 100 indicated extreme pain. The MCID was 15 points. No analysis of the comparison between diagnostic arthroscopy and PT was reported.

ASD compared to physiotherapy

Pain. At 24 months, ASD plus one physiotherapy session was statistically better than a course of 15 physiotherapy visits for the two primary outcomes of patient reported perceived pain intensity at rest and during arm activity during the 24 hours preceding the assessment. Both groups reported improvement in pain at rest and during arm activity.

- At baseline, the VAS at rest for ASD plus PT and physiotherapy groups were 41.3 and 41.7 respectively. At 24 months, the VAS at rest for ASD plus PT and physiotherapy groups were 5.3 (95%CI 0.6 to 10.0) and 12.8 (95%CI 8.4 to 17.3). For pain at rest, the mean difference for ASD plus PT versus physiotherapy was -7.5 (-14.0 to -1.0), p=0.023.
- At baseline, the VAS during arm activity for ASD plus PT and physiotherapy groups were 71.2 and 72.4. At 24 months, the VAS during arm activity for ASD plus PT and physiotherapy groups were 16.0 (9.6 to 22.5) and 28.1 (22.1 to 34.1). The mean difference for ASD plus PT versus physiotherapy was -12.0 (-20.9 to -3.2), p=0.008.
- The change from baseline to 24 months for both VAS pain at rest and pain during arm activity scores exceeded the 15 point minimal clinically important difference (MCID) identified by the study group but the statistical significance of the difference was not calculated.
- For both pain at rest and pain during arm activity, the differences between the two groups did not exceed the MCID (15 points on the 0-100 VAS).

The Constant-Murley Score (CSS). In this RCT, ASD plus PT was superior to physiotherapy alone for function assessment using the CMS. The baseline CMS for ASD plus PT and physiotherapy groups were 32.2 and 35.2 respectively. At 24 months, the CMS for ASD plus PT and physiotherapy groups were 79.1 (74.7 to 83.4) and 71.2 (67.0 to 75.3) with a mean difference of 7.7 (95%CI 1.6 to 13.9), p=0.013.

For ASD plus PT compared to a course of physiotherapy sessions, there was no between group difference at 24 months for the simple shoulder test[c] (p=0.12), the 15D[d] score

[c] The simple shoulder test (SST), a measure of impairment of activities of daily living, consists of 12 questions with yes (1) or no (0) response options. The maximum SST score is 12 indicating normal shoulder function, minimum score of 0 points refers to severely diminished shoulder function.

(p=1.00), the proportion of patients able to return to previous leisure activities (p=0.31), the proportion of responders (p=0.23) or patients' satisfaction with treatment (p=0.36).
Although ASD plus minimal physiotherapy showed superiority over 15 sessions of physiotherapy alone for pain and the composite Constant Score, these results should be treated with caution as the they are inconsistent with the findings that showed no difference between these two groups for the Simple Shoulder Test, the 15D and the proportion of patients able to resume previous leisure activities, or who were satisfied with their treatment.

ASD compared to diagnostic arthroscopy.
For the primary comparison of the ASD and diagnostic arthroscopy treatment groups, both with minimal supervised physiotherapy, there was marked improvement in both groups at 24 months compared to baseline for the following outcomes:

- pain at rest
- pain on arm activity
- Constant score
- SST.

However no analysis of the difference in scores over time was reported.

Importantly, at 24 months, there was no statistically significant difference between the ASD group and the diagnostic arthroscopy group for any outcomes, indicating that the ASD procedure provides no clinically relevant benefit over diagnostic arthroscopy for patients with shoulder impingement syndrome, refractory to conservative treatment.

Ketola et al (2009) reported the results of a single centre RCT in Finland for 140 patients who had grade II subacromial impingement, which had failed conservative therapy [7]. Patients were recruited between June 2001 and July 2004 and randomised to receive either ASD plus physiotherapy (n=70) or physiotherapy alone (n=70). The mean number of physiotherapy sessions for each group were 7 and 6 respectively. At 2 years follow-up, 14 patients who were initially allocated to receive treatment with PT elected to receive ASD. The change from baseline for self-reported pain, pain at night, disability and working ability were reported using a 0-10 point VAS. Results were reported two years after randomisation.

There was a significant improvement in self-reported pain which exceeded the MCID[e] for both the ASD+PT group and the PT group, compared to baseline.
There was no difference between ASD plus PT and PT alone for self-reported pain (ASD+PT vs PT: -3.9 vs -3.7, p=0.65). The p-values were not reported for pain at night, disability and working ability; the absolute changes from baseline appear to be similar in the two groups, indicating little or no significant difference between the two groups for these outcomes (changes from baseline for ASD+PT vs PT groups: disability -4.2 vs -3.8; working ability +2.3 vs +2.0; pain at night -4.2 vs -3.8).

[d] The 15D instrument is a health-related quality of life instrument with 15 dimensions. The maximum 15D score is 1 (no problems on any dimension) and the minimum score is 0 (being dead).
[e] The minimal clinically important difference (MCID) is used to determine whether a medical intervention improves perceived outcomes in patients. The MCID for pain measured on a 0-10 VAS was 2 points, based on previous research [22]

Ketola et al (2009) also reported similar change from baseline for the Shoulder Disability Questionnaire (SDQ)[f] for the ASD plus PT and PT groups (change from baseline for ASD+PT vs PT groups: 53.1 vs 50.0, no p-value reported). In addition, they reported no difference in the proportion of pain free patients at two years (ASD+PT vs PT: 0.65 vs 0.64, p=0.90) and similar changes from baseline in the number of painful days reported by both groups (ASD+PT vs PT: -55.0 vs -53.3, no p-value reported).

In 2017, Ketola et al [9] reported the long-term follow-up of 90 of the initial 140 patients recruited (64%) for a mean duration of 12.3 years (range 11.0 to 13.8 years). Outcomes data were available for 44/70 patients who had ASD plus PT and 46/70 patients who were allocated to treatment with PT.

There was no significant difference in the VAS scores between ASD plus PT and PT groups for any of the following outcomes: self-reported pain (p=0.12), change in pain from 5 to 10 years p=0.14, change in pain from 0 to 10 years (p=0.18), pain at night (p=0.19), disability (p=0.41) and working ability (p=0.57).

The between group SDQ scores were similar for ASD plus PT and PT treatment groups (p=0.61) and for the 15D scores (p=0.38). There was no difference between the ASD plus PT and PT groups when asked about the number of painful days that they had experienced during the previous 3 months due to shoulder pain (p=0.32) and the number of days on which NSAIDS were taken during the previous 3 months due to shoulder pain (p=0.47).

ASD for supraspinatus tears.

Participants in the RCT by Kukkonen et al (2014) were being treated for symptomatic non-traumatic tears of the supraspinatus tendon, rather than shoulder impingement syndrome [10]. In this study, 180 shoulders in 173 patients aged over 55 years were randomised to either ASD followed by physiotherapy (ASD+PT, n=59), ASD and rotator cuff repair followed by physiotherapy (ASD+RC+PT, n=59) or physiotherapy alone (PT, n=58). A biceps tenotomy was also performed in 51% and 42% of the ASD+PT and ASD+RC+PT groups respectively. Due to a 7.2% dropout, the outcomes for 167 shoulders were reported at one year follow-up. The physiotherapy regime for all three groups comprised written instructions to patients for exercises to be conducted at home, as well as 10 sessions with a physiotherapist for supervised and progressive exercises.

There was no significant difference at one year between the three treatment groups in the overall Constant score (p=0.34). However, each of the three treatment groups showed a clinically significant improvement[g] in the Constant score from baseline to 12 months (ASD+PT: 59.6 to 77.2; ASD+RC+PT: 58.1 to 77.9; PT alone: 57.1 to 74.1). Although there was no statistical analysis for the significance of the improvement within each group, there was a greater than 10.4 point clinically meaningful improvement in the Constant score one year after starting treatment for all three groups.

[f] The Shoulder Disability Questionnaire (SDQ) evaluates functional status limitation using self-assessment by patients. The scores range from 0 (no functional limitations) to 100 (affirmative answer to all applicable items) [11].
[g] The authors estimated that the smallest clinically significant difference in terms of Constant score is 10.4 points in a cohort of operatively treated rotator cuff tear patients [20]

Analysis of the individual components of the Constant score showed that at one year, the combined surgical groups of patients who had ASD with or without repair of the supraspinatus tendon had statistically better outcomes for pain (p=0.0321) and for activities of daily living (p<0.0001) compared to those who had physiotherapy alone. However, there was no difference between the combined ASD groups and the PT groups for range of movement (p=0.74) or strength (p=0.76). Although patient satisfaction was lower for the group who had physiotherapy alone, the difference was not significant (ASD+PT: 96%, ASD+RC+PT:95%, PT:87%, p=0.14).

For patients with non-traumatic, symptomatic supraspinatus tears, the authors concluded that at one year follow-up, ASD with or without repair of the supraspinatus tendon plus ten sessions of physiotherapy was no better than conservative treatment with ten sessions of physiotherapy alone.

The improvements seen in all groups could have been due to the 10 sessions of physiotherapy that were in the treatment protocol for all three groups or the natural history of the disease, rather than due to surgery. Patients and hospital staff were not blinded to the treatment received which could have introduced bias, reducing the reliability of the results where between group differences were reported (particularly for the self-reported elements of the Constant score: pain and activities of daily living). The study design attempted to limit bias by using an independent study nurse to record the Constant score at all timepoints. This might explain why significant between group differences were reported for pain and activities of daily living but not for ROM and strength, which might be less subjective. The extent to which differences in individual components of the Constant score, a validated composite shoulder instrument, should be interpreted is not clear, particularly when there are no between group differences for the overall Constant score.

4.1.2 Cost effectiveness

We found no studies which evaluated the cost effectiveness of arthroscopic subacromial decompression, compared to conservative treatment, in adults with impaired function and pain in the affected shoulder joint.

Two of the RCTs selected for inclusion in this review (both based in Finland) reported the cost of resources used to deliver the health interventions in the study.

For the 92 patients diagnosed with SIS with complete data at 2 year follow-up, the mean health care costs per patient for ASD plus PT and PT only were €2961 and €1864 respectively [7]. ASD plus PT was €1,097 more expensive than PT alone.

The authors reported that the ICER was €5,431 in order to achieve the one MCID unit (equivalent to 2 points difference for pain measured using a 0-10 point VAS). However, since the change in the mean 2-point MCID unit for ASD plus PT and for PT alone was 1.238 and 1.439 respectively (a difference of 0.2 between the groups), it is not clear that the incremental MCID for ASD plus PT over PT alone can be achieved in practice

regardless of the incremental cost of each treatment option. Costs were based on Euros in Finland in 2004 and are unlikely to be generalisable to the NHS in England in 2018.

In the study of patients with symptomatic supraspinatus tears, at 12 month follow-up, the direct costs of 10 sessions of physiotherapy were significantly less expensive than treatment with ASD plus PT (regardless of whether or not the supraspinatus tendon was repaired) ($p<0.0001$) [10]. The mean cost of ASD plus PT was €4765 (€5709 if supraspinatus was also repaired) compared to €2417 for PT alone. The authors did not specify the dates during which the costs were evaluated, but since the last patient was recruited to the study in December 2012 and the outcomes reported were at 12 month follow-up, it is likely that these costs are the costs associated with treatment in Finland in 2013 and they are unlikely to be generalisable to the NHS in England in 2018.

The authors reported the mean direct cost for patients and the mean indirect societal costs. We have not reported them here as neither are relevant to the NHS setting in England.

Table 1: Summary of randomised controlled trials for use of arthroscopic subacromial decompression compared with conservative treatment for people with shoulder pain with or without a rotator cuff tear.

Study	Patients	Intervention	Comparator	Outcomes
Beard et al 2018 [4] **CSAW trial** Multicentre, randomised, pragmatic parallel group, placebo controlled, three group trial 32 hospitals, 51 surgeons in the UK	n=313 adults Mean age 53.4 yrs With subacromial pain for at least 3 months and with intact rotator cuff based on Consultant clinical diagnosis of tendinopathic pain or partial thickness rotator cuff tear (using local pathways of diagnosis including X rays, MRI scans or ultrasounds)[20]. Completed non-operative management including physiotherapy that includes a remedial exercise programme and at least one steroid injection Recruited Sept 2014 to June 2015 Excluded: full thickness rotator cuff tear Baseline Scores: Mean (SD), n (if reported) **Oxford Shoulder Score**	ASD plus physiotherapy (4 sessions) (ASD+PT) (n=106) 6 pts had surgery to the acromioclavicular joint or the long head of biceps [22] 6 months' post randomisation, 24(23%) pts had not yet received treatment 12 months' post randomisation, 19(18%) pts had not yet received treatment Median time to treatment: 90 days (IQR 58-123)	a. Investigational arthroscopy plus physiotherapy (4 sessions) (DA+PT) (n=103) 6 months' post randomisation, 43 (42%) pts had not received treatment 12 months' post randomisation, 35 (34%) pts had not yet received treatment Median time to treatment: 82 days (IQR56-134) b. No treatment (re-assessment appointment at 3 months only) (n=104) 6 months' post randomisation, 12 (12%) pts had not been reassessed 12 months' post randomisation, *26(25%)*pts had not	**Primary outcome: Oxford Shoulder Score** Mean (SD), n at 6 months ASD+PT: 32.7 (11.6), n=90 DA+PT: 34.2 (9.2), n=94 No treatment: 29.4 (11.9), n=90 Mean difference (95%CI), p value at 6 months ASD vs DA+PT: -1.3(-3.9 to 1.3), 0.3141 ASD+PT vs no treatment: 2.8(0.5 to 5.2), 0.0186[h]= not clinically important DA+PT vs no treatment: 4.2(1.8 to 6.6), 0.0014= not clinically important Mean (SD), n at 12 months ASD+PT: 38.2 (10.3), n=88 DA+PT: 38.4 (9.3), n=93 No treatment: 34.3(11.8), n=84 Mean difference(95%CI), p value at 12 months ASD+PT vs DA+PT: 0.3(-2.9 to 3.5), 0.8571 ASD+PT vs no treatment: 3.9(0.7 to 7.1), 0.0193 DA+PT vs no treatment: 3.6(0.6 to 6.6), 0.0193 • At 6 and 12 months, all groups had better mean OSS compared to baseline. **Modified Constant-Murley Score** Mean (SD), n at 6 months ASD+PT: 56.5 (21.8), n=82 DA+PT: 57.6 (17.7), n=84 No treatment: 45.4(21.3), n=83 Mean difference(95%CI), p value at 6 months ASD+PT vs DA+PT: 0.3(-4.1 to 4.7), 0.8972 ASD+PT vs no treatment: 9.3(4.1 to 14.6), 0.0012 DA+PT vs no treatment: 9.1(3.1 to 15.2), 0.0045 Mean (SD), n at 12 months ASD+PT: 66.2 (19.9), n=76 DA+PT: 64.9 (17.2), n=81 No treatment: 56.7(22.1), n=70

[h] Minimal clinically important difference (MCID) for the OSS is 6 points [12]

	ASD+PT: 25.2 (8.5) n=106 DA+PT: 26.7 (8.8), n=103 No treatment: 25.5 (8.3), n=104 **Constant Score** ASD+PT: 39.4 (13.9) n=102 DA+PT: 43.1 (15.5), n=101 No treatment: 38.3(14.2), n=100 **PainDETECT** ASD+PT: 11.7 (6.6) n=105 DA+PT: 11.0 (5.9) No treatment: 11.9(6.6), n=100 **HADS Depression** ASD+PT: 5.0 (3.8) n=105 DA+PT: 5.0 (3.7) n=102) No treatment: 5.7(4.2), **HADS Anxiety** ASD+PT: 6.3 (4.3) DA+PT: 6.3 (4.2) No treatment: 6.9(4.5) **EQ VAS** ASD+PT: 65.8 (19.4) DA+PT: 69.7 (19.2) No treatment: 64.4(23.2) **EQ-5D-3L** ASD+PT: 0.52 (0.30), n=105 DA+PT: 0.55 (0.29), n=102 No treatment: 0.50 (0.33)		been reassessed Median time to treatment: 217 days (111-262)	Mean difference(95%CI), p value at 12 months ASD+PT vs DA+PT: 2.7(-2.7 to 8.2), 0.3087 ASD+PT vs no treatment: 8.3(2.5 to 14.1), 0.0067 DA+PT vs no treatment: 4.9(0.9 to 8.9), 0.0173 **PainDETECT Score** Mean (SD), n at 6 months ASD+PT: 8.4(7.1), n=81 DA+PT: 7.9 (5.7), n=82 No treatment: 10.1(6.3), n=80 Mean difference(95%CI), p value at 6 months ASD+PT vs DA+PT: 0.1(-1.8 to 2.0), 0.9036 ASD+PT vs no treatment: -1.7(-3.5 to 0.0), 0.0559 DA+PT vs no treatment: -1.9(-3.7 to 0.0), 0.0502 Mean (SD), n at 12 months ASD+PT: 8.5 (7.1), n=67 DA+PT: 7.3(5.7), n=72 No treatment: 9.8(7.6), n=69 Mean difference(95%CI), p value at 12 months ASD+PT vs DA+PT: 0.4(-1.4 to 2.2), 0.6541 ASD+PT vs no treatment: -1.5(-3.7 to 0.7), 0.1721 DA+PT vs no treatment: -1.8(-4.3 to 0.7), 0.1536 **HADS Depression Score** Mean (SD), n at 6 months ASD+PT: 3.6(4.0), n=88 DA+PT: 3.6(3.9), n=91 No treatment: 5.5(4.4), n=89 Mean difference(95%CI), p value at 6 months ASD+PT vs DA+PT: 0.2(-0.8 to 1.2), 0.6738 ASD+PT vs no treatment: -1.1(-1.8 to -0.4), 0.0040 DA+PT vs no treatment: -1.3(-2.2 to -0.3), 0.0100 Mean (SD), n at 12 months ASD+PT: 3.2 (3.5), n=84 DA+PT: 3.5(3.7), n=88 No treatment: 4.4(4.0), n=78 Mean difference(95%CI), p value at 12 months ASD+PT vs DA+PT: -0.1(-0.7 to 0.5), 0.6906 ASD+PT vs no treatment: -0.7(-1.5 to 0.2), 0.1208 DA+PT vs no treatment: -0.5(-1.3 to 0.2), 0.1452

				HADS Anxiety Score Mean (SD), n at 6 months ASD+PT: 5.1(4.0), n=87 DA+PT: 5.6(4.6), n=92 No treatment: 6.7(4.7), n=88 Mean difference(95%CI), p value at 6 months ASD+PT vs DA+PT: -0.1(-1.0 to 0.8), 0.7368 ASD+PT vs no treatment: -0.8(-1.5 to -0.2), 0.0168 DA+PT vs no treatment: -0.6(-1.4 to 0.1), 0.1096 Mean (SD), n at 12 months ASD+PT: 5.2(4.1), n=83 DA+PT: 5.7(4.5), n=87 No treatment: 5.9(4.2), n=81 Mean difference(95%CI), p value at 12 months ASD+PT vs DA+PT: -0.1(-0.9 to 0.6), 0.7474 ASD+PT vs no treatment: -0.1(-1.0 to 0.8), 0.8220 DA+PT vs no treatment: 0.0(-1.0 to 1.1), 0.9215 **EQ VAS** Mean (SD), n at 6 months ASD+PT: 74.2(20.3), n=89 DA+PT: 72.8(20.2), n=93 No treatment: 67.8(22.1), n=89 Mean difference(95%CI), p value at 6 months ASD+PT vs DA+PT: 3.1(-3.5 to 9.7), 0.3393 ASD+PT vs no treatment: 6.4(2.2 to 10.7), 0.0043 DA+PT vs no treatment: 3.4(-1.4 to 8.2), 0.1601 Mean (SD), n at 12 months ASD+PT: 73.7(21.0), n=85 DA+PT: 75.9(20.0), n=91 No treatment: 73.4(22.4), n=82 Mean difference(95%CI), p value at 12 months ASD+PT vs DA+PT: -0.4(-4.4 to 3.7), 0.8530 ASD+PT vs no treatment: 0.0(-4.3 to 4.2), 0.9947 DA+PT vs no treatment: 0.3(-5.1 to 5.7), 0.9050 **EQ-5D-3L Index** Mean (SD), n at 6 months ASD+PT: 0.65(0.29), n=89

				DA+PT: 0.67(0.26), n=93 No treatment: 0.52(0.36), n=89 Mean difference(95%CI), p value at 6 months ASD+PT vs DA+PT: 0.00(-0.09 to 0.08), 0.9308 ASD+PT vs no treatment: 0.12(0.04 to 0.21), 0.0076 DA+PT vs no treatment: 0.12(0.02 to 0.21), 0.0154 Mean (SD), n at 12 months ASD+PT: 0.74(0.28), n=86 DA+PT: 0.73(0.27), n=92 No treatment: 0.66(0.33), n=80 Mean difference(95%CI), p value at 12 months ASD+PT vs DA+PT: 0.04(-0.03 to 0.10), 0.2750 ASD+PT vs no treatment: 0.08(0.00 to 0.16), 0.0517 DA+PT vs no treatment: 0.05(-0.04 to 0.13), 0.2644 Complications (study related) ASD+PT: 2 DA+PT: 2 no treatment: 2 Complications (unrelated) ASD+PT: 1 DA+PT: 2
Paavola et al 2018 [6] FIMPACT Multicentre, three group, randomised, double blind sham controlled trial 3 orthopaedic clinics in Finland	n=210 at first randomisation n=193 after 2nd randomisation (n=17 excluded) Adults aged 35 to 65 years Symptoms of shoulder impingement syndrome (concomitant grade I or II) for more than 3 months, unresponsive to conventional conservative treatment, partial thickness RCT were	ASD within 12 wks after randomisation+ one visit to physiotherapist /home exercises (ASD+PT) (n=59)	a. Diagnostic Arthroscopy within 12 wks after randomisation + one visit to physiotherapist /home exercises (DA+PT) (n=63) b. PT within 2 weeks - 15 physiotherapy sessions +home exercises (n=71)	At 2 years f/up ASD+PT: n=59 DA+PT: n=59 PT: n=68 **For ASD+PT vs Diagnostic Arthroscopy (DA+PT)** **Pain at rest (VAS 0-100)** Mean (95%CI) ASD+PT: 5.3(0.8 to 9.7) DA+PT: 9.9(5.4 to 14.3) ASD+PT vs DA: -4.6(-11.3 to 2.1), p=0.18 **Pain on arm activity (VAS 0-100)** Mean (95%CI) ASD+PT: 15.8(9.4 to 22.2) DA+PT: 24.8(18.4 to 31.2) ASD+PT vs DA: -9.0(-18.1 to 0.2), p=0.054 **Constant-Murley Score** Mean (95%CI) ASD+PT: 77.9(73.7 to 82.3) DA+PT: 73.7(69.5 to 78.0)

	included in the study Recruited 1 Feb 2015 to 25 June 2015 Full or partial thickness tears (grade III/IV) were excluded Baseline, 3,6,12,24 months after randomisation. Data and analysis reported at 24 months only.			ASD+PT vs DA: 4.3(-20. to 10.5), p=0.18 **Simple shoulder test** Mean (95%CI) ASD+PT: 10.3(9.7 to 10.9) DA+PT: 9.9(9.3 to 10.5) ASD+PT vs DA: 0.5(-0.4 to 1.3), p=0.29 **15D score** Mean (95%CI) ASD+PT: 0.92(0.91 to 0.93) DA+PT: 0.92(0.91 to 0.93) ASD+PT vs DA: 0.0(-0.02 to 0.02), p=1.00 **Proportion of pts able to return to previous leisure activities** Mean (95%CI) ASD+PT: 0.82(0.72 to 0.92) DA+PT: 0.77(0.66 to 0.88) ASD+PT vs DA: 0.06(-0.10 to 0.22), p=0.45 **Proportion of responders** Mean (95%CI) ASD+PT: 0.95(0.89 to 1.0) DA+PT: 0.91(0.84 to 0.99) ASD+PT vs DA: 0.04(-0.06 to 0.14), p=0.42 **Pts' satisfaction with treatment Mean** (95%CI) ASD+PT: 88.1(82.9 to 93.3) DA+PT: 87.1(81.9 to 92.3) ASD+PT vs DA: 0.9(-6.6 to 8.3), p=0.82 **For ASD+PT vs PT** **VAS at rest** Mean (95%CI) ASD+PT: 5.3(0.6 to 10.0) ET: 12.8(8.4 to 17.3) ASD+PT vs PT: -7.5(-14.0 to -1.0), p=0.023 **VAS, on arm activity** Mean (95%CI) ASD+PT: 16.0(9.6 to 22.5) ET: 28.1(22.1 to 34.1) ASD+PT vs PT: -12.0(-20.9 to -3.2), p=0.008 **Constant-Murley Score** Mean (95%CI) ASD+PT: 79.1(74.7 to 83.4) ET: 71.2(67.0 to 75.3) ASD+PT vs PT: 7.7(1.6 to 13.9), p=0.013 **Simple shoulder test** Mean (95%CI) ASD+PT: 10.3(9.7 to 10.9) ET: 9.7(9.1 to 10.2) ASD+PT vs PT: 0.7(-0.2 to 1.5), p=0.12

				15D score Mean (95%CI) ASD+PT: 0.91(0.90 to 0.93) ET: 0.91(0.90 to 0.92) ASD+PT vs PT: 0.00(-0.02 to 0.02), p=1.00 **Proportion of pts able to return to previous leisure activities** Mean (95%CI) ASD+PT: 0.82(0.72 to 0.92) ET: 0.76(0.65 to 0.86) ASD+PT vs PT: 0.07(-0.07 to 0.21), p=0.31 **Proportion of responders** Mean (95%CI) ASD+PT: 0.95(0.90 to 1.01) ET: 0.90(0.81 to 0.98) ASD+PT vs PT: 0.06(-0.04 to 0.16), p=0.23 **Pts' satisfaction with treatment Mean** (95%CI) ASD+PT: 88.2(82.8 to 93.5) ET: 84.9(79.9 to 89.8) ASD+PT vs PT: 3.3(-3.9 to 10.5), p=0.36 **Complications and adverse events (n/%)** ASD+PT: 3/5 DA: 2/3 ET: 3/4
Ketola et al 2009 [7] Prospective RCT 1 surgeon	n=140 Grade II subacromial impingement syndrome, symptoms for at least 3 months not relieved by conservative treatment (including NSAIDs, subacromial cortisone injections (59% patients) Mean duration of symptoms was 2.5 years. Recruited between June 2001 and July 2004	Arthroscopic acromioplasty followed by physiotherapy (ASD+PT) (n=70) Mean number of physiotherapy visits =6 Baseline scores (mean VAS 0-10) Self-reported pain: 6.4 Pain at night:	Supervised physiotherapy alone (PT) (n=70) 14 patients crossed over to ASD Mean number of physiotherapy visits =7 Baseline scores (mean VAS 0-10) Self-reported pain: 6.5 Pain at night: 6.4 Disability: 6.5 Working ability: 5.9	At 24 months after randomisation: ASD+ET: n=68 /70 ET: n=66/70 Self-reported pain (VAS 0-10) mean change from baseline ASD+PT vs PT: -3.9 vs -3.7, p=0.65 Disability (VAS 0-10) mean change from baseline ASD+PT vs PT: -4.2 vs -3.8, no p-value reported Working ability (VAS 0-10) mean change from baseline ASD+PT vs PT: +2.3 vs +2.0, no p-value reported Pain at night (VAS 0-10) mean change from baseline ASD+PT vs PT: -4.2 vs -3.8, no p-value reported SDQ score (0-100) mean change from baseline ASD+PT vs PT: -53.1 vs -50.0, no p-value reported Reported painful days, mean change from baseline

	63% female Mean age 47.1 years (23.3 to 60.0) Patients with full thickness rotator cuff tears were excluded	6.2 Disability: 6.3 Working ability: 5.7 Mean SDQ score: 78.0	Mean SDQ score: 82.5	ASD+PT vs PT: -55.0 vs -53.3, no p-value reported Proportion of pain free patients ASD+PT vs PT: 0.65 vs 0.64, p=0.90 Resource utilisation (based on complete data of patients who attended all follow-up visits, n=92) • Mean health care costs per patient ASD+PT vs PT: €2961 vs €1864 • Incremental cost: €1097 • Incremental effectiveness: 0.201 unit (1 unit =2 points on the 0-10 VAS) • For ASD+PT vs PT alone: ICER to achieve the MCID of 2 point reduction on the VAS (0-10) for pain = €5431 Given that observed (n=92) mean incremental effectiveness was 0.201 units, it is not clear that a between group MCID equivalent to a 2 point difference on the 0-10 VAS can be realised.
Ketola et al 2016 [8] RCT MRI of shoulder done at baseline and at 5 years Aim: To find out whether operative treatment (ASD) for shoulder impingement syndrome protects from later rotator cuff rupture and if it has an effect on muscle volume	As above	As above	As above	At 5 year f/up ASD+ET: n=57/70 (81%) ET: 52/70 (74%) Change in muscle volume Supraspinatus: ASD+ET vs PT: -7% vs -4%, p=0.6 Subscapularis ASD vs PT: no data reported, p=0.5 Infraspinatus ASD+ET vs PT: no data reported, p=0.9 % patients with fatty degeneration of the muscles at 5 years ASD+ET vs PT: 65% vs 54%, p=0.3 Number of patients who developed a full thickness tear of the supraspinatus tendon at 5 years: ASD+ET vs PT: 8 vs 7 % patients with thickened coracoacromial ligament at 5 years: ASD+ET vs PT: 44% vs 20%, p=0.02
Ketola et al 2017 [9]	As above	As above	As above	At mean time to final review 12.3 years (11.0 to 13.8), n=90/140 (64% of original group) ASD+PT: n=44/70 (63%) PT: 46/70 (66%) No significant difference between groups for: • Working status, ASD+PT vs PT: 19(43%) vs 14(30%), p=0.40 • Modified job to accommodate shoulder symptoms, ASD+PT vs PT: 4(9%) vs 10(22%), p=0.14 • No sick leave due to shoulder reason in previous year, ASD+PT vs PT: 43(98%) vs 44(96%), p=0.37

				• Retired due to shoulder reasons, ASD+PT vs PT: 1(2%) vs 4(9%), p=0.34 • Contralateral shoulder symptomatic, ASD+PT vs PT: 30(70%) vs 27(60%), p=0.23 • Overall state of heath compared to before treatment 'A lot better', ASD+PT vs PT: 23(56%) vs 24(52%), p=0.96 Self-reported VAS for pain, mean(range): ASD vs PT: 2.8(0 to 10) vs 1.8(0 to 7), p=0.12 Change in VAS for pain from 5 to 10 yrs, mean(range) ASD vs PT: 2.8(0 to 10) vs 1.8(0 to 7), p=0.14 Change in VAS for pain from 0 to 10yrs, mean(range) ASD vs PT: -3.6(-10 to 5) vs -4.5(-10 to 3), p=0.18 VAS for pain at night, mean(range) ASD vs PT: 2.5(0 to 10) vs 1.7(0 to 8), p=0.19 VAS for disability, mean(range) ASD vs PT: 2.5(0 to 9) vs 2.0(0 to 8), p=0.41 VA for working ability, mean(range) ASD vs PT: 7.5(0 to 10) vs 7.2(0 to 10), p=0.57 SDQ score, mean(range) ASD vs PT: 23(0 to 100) vs 17(0 to 100), p=0.61 Painful days per previous 3 months due to shoulder pain, mean(range) ASD vs PT: 18(0 to 90) vs 12(0 to 90), p=0.32 Total days on which NSAIDS were consumed per previous 3 months due to shoulder pain, mean(range) ASD vs PT: 10(0 to 90) vs 7(0 to 85), p=0.47 15D mean score ASD vs PT: 0.906 vs 0.886, p=0.38 Shoulder patients vs general population: 0.896 vs 0.922, p<0.001
Kukkonen et al 2014 [10] RCT 3 hospitals in Finland	n=180 shoulders (n=173 patients) Non-traumatic symptomatic	Acromioplasty and physiotherapy (10 sessions) (ASD+PT)	Physiotherapy only (10 sessions) (PT) n=58	At one year, 167 shoulders available for analysis (7.2% drop out) PT: 55/58 ASD+PT: 57/59 ASD+RC+PT: 55/59 Mean Constant score[i] at baseline and at one year

[i] MCID=10.4 points [20]

<table>
<tr>
<td>Assessment at baseline, 3,6, and 12 months</td>
<td>supraspinatus tendon tear< 75% of tendon insertion

Mean duration of symptoms ranged from 26(SD 9.9) to 28(SD9.7) months.
Recruited between October 2007- December 2012

51% female
Mean age 65 years</td>
<td>n=59

29 patients (51%) also had biceps tenotomy</td>
<td>OR

Rotator cuff repair, acromioplasty and physiotherapy (10 sessions) (ASD+RC+PT)
n=59

23 patients (42%) also had biceps tenotomy</td>
<td>
<table>
<tr><td>Group</td><td>baseline</td><td>At one year</td></tr>
<tr><td>PT</td><td>57.1 (SD16.7)</td><td>74.1(SD 14.2)</td></tr>
<tr><td>ASD+PT</td><td>59.6 (SD 13.3)</td><td>77.2 (SD 13.0)</td></tr>
<tr><td>ASD+RC+PT</td><td>58.1 (SD13.2)</td><td>77.9(SD 12.1)</td></tr>
</table>
Constant sub scores at one year for physiotherapy vs both surgery groups combined
In favour of ASD+PT with or without supraspinatus tendon repair
• Pain, p=0.0321
• Activities of daily living, p<0.0001
No significant difference
• Range of movement, p=0.74
• Strength, p=0.76
• Patient satisfaction: PT(87%), ASD+PT (96%) & ASD+RC+PT (95%), p=0.14

Cost of treatment
<table>
<tr><td>Group</td><td>Mean cost of treatment</td><td>Mean direct cost for the patients</td><td>Mean indirect societal cost</td></tr>
<tr><td>PT</td><td>€2417 (SD 1443)</td><td>€427</td><td>€2130</td></tr>
<tr><td>ASD+PT</td><td>€4765 (SD 896)</td><td>€486</td><td>€4486</td></tr>
<tr><td>ASD+RC+PT</td><td>€5709</td><td>€456</td><td>€5461</td></tr>
<tr><td></td><td>p<0.0001</td><td>p=0.96</td><td>p<0.0001</td></tr>
</table>
Costs not generalisable to UK
</td>
</tr>
</table>

Abbreviations: ASD: arthroscopic subacromial decompression, CI, confidence interval, DA: diagnostic arthroscopy, HrQoL: Health related quality of life, IQR: interquartile range, MCID: minimal clinically important difference, OSS: oxford shoulder score, PT: physiotherapy, pts: patients, RC: rotator cuff, RCT: randomised controlled trial, SD: standard deviation, SDQ, shoulder disability questionnaire, VAS: visual analogue scale, Vs: versus, wks: weeks, yrs: years

Terminology: For the purpose of this review, we have standardised key terms, even when an alternative term was used in the original publication.

- Physiotherapy (PT). PT will include written information and guidance on exercises to be conducted at home as well as a number of sessions of physiotherapy or supervised exercise therapy. Some studies used the term exercise therapy (ET).
- Diagnostic arthroscopy (DA). DA refers to the arthroscopic investigation of the joint, rotator cuff tendons and subacromial bursa, but does not involve any further intervention. It has been described in studies as a suitable 'sham' ASD or surgical placebo.
- Arthroscopic Subacromial Decompression (ASD). The standard procedure is antero-inferior acromioplasty, i.e. the resection of bone spurs under the lateral third of the acromion, as well as the excision of the coracoacromial ligament and the subacromial bursa. If a partial or small full-thickness tear of the rotator cuff is present, it is may be mildly debrided or left alone [3].
- Shoulder impingement syndrome (SIS). SIS will be used to refer to shoulder pain which in various publications has also been referred to as subacromial

4.2 Safety

Adverse events or complications were only reported in two of the randomised controlled trials detailed in table 1.

In the CSAW RCT, six patients out of the 274 in the intention to treat analysis developed frozen shoulder (two in each of the three treatment populations (ASD+PT, DA+PT and no treatment). These were considered to be study related complications. There was no difference between the three treatment groups (p>0.9999 for all comparisons) [4].

Of the 210 patients recruited to the FIMPACT RCT, adverse events were reported for 8 patients at 24 month follow-up. Six events were due to frozen shoulder: three had been treated with ASD, one with diagnostic arthroscopy only and two with physiotherapy. There was no difference between the three treatment groups for adverse events [6].

4.3 Summary of findings

Clinical Effectiveness.

Subacromial impingement syndrome (SIS).

Three well-conducted, randomised controlled trials compared ASD to conservative treatment for patients with SIS which had failed to respond to conservative treatment at 12 or 24 months [4,6,7]. Ketola et al (2009) compared ASD plus PT to PT alone [7], whereas in the FIMPACT [6] and CSAW [4] RCTs, there were three treatment arms. Both the three-arm studies compared ASD plus PT to diagnostic arthroscopy plus PT. However, in the UK based multicentre CSAW RCT, arthroscopic surgery was compared to no treatment at all, whereas in the FIMPACT RCT, the non-operative comparator included a home exercise regime as well as 15 physiotherapy visits.

ASD plus physiotherapy versus diagnostic arthroscopy plus physiotherapy. Two RCTs reported the difference in outcomes between ASD and diagnostic arthroscopy, with restricted physiotherapy support to both groups. There was no clinically significant difference at either 12-month follow-up in the CSAW RCT [4] or 24 months [6] for any of the outcomes measured: OSS, Constant score, pain, depression and anxiety, quality of life, simple shoulder test and 15D. The CSAW study attempted to blind study participants and hospital staff, so that they would not know whether they had had ASD or diagnostic arthroscopy. Subjects were assessed by an independent assessor, and remained clothed in order to conceal the treatment. This may have contributed to the apparent absence of difference in outcomes between the ASD and diagnostic arthroscopy only groups.

ASD plus physiotherapy versus no treatment. There was no clinically important difference for any outcomes measured at 12 months between ASD plus physiotherapy when compared to no treatment at all [4].

ASD plus physiotherapy versus physiotherapy. There was no clinically important difference for any outcomes measured at 24-month follow-up, irrespective of whether the comparator was a mean of 7 sessions [7] or 15 sessions of physiotherapy [6].

It should be noted that the variation in the non-operative treatments from no treatment at all [4] to 15 sessions of structured progressive physiotherapy with prescribed home exercises, should be treated as a potential confounder. In addition, subjects would have been aware of the treatment to which they had been allocated. All of the outcomes measured required some self-reporting, which may be influenced by prior perception that one treatment is better than another. These may have affected the reliability of these results.

Within each treatment group, all three trials showed clinically significant improvement at 12 or 24 months, when compared to baseline for the OSS, (modified) Constant score and pain.

Supraspinatus tear.
There was one RCT where 180 patients with a supraspinatus tear were treated with ASD and physiotherapy, or tendon repair, ASD and physiotherapy and the outcomes were compared to patients who had 10 sessions of physiotherapy alone. All the patients followed the same physiotherapy plan. There were no between group differences in the Constant score at 12 months. Although the surgical procedure is more complex, the results are consistent with the studies that assessed the effectiveness of ASD for the management of shoulder impingement syndrome. It is not clear if the lack of benefit of surgery compared to physiotherapy alone is still apparent in the longer-term.

5 Equity issues

There is significant variation in access to ASD elective admissions across the five Birmingham and Black Country CCGs.

For the period April 2017 to March 2018, patients registered with a GP in Wolverhampton CCG had the highest age and sex standardised rate at 116.7 per 10,000 population. In contrast, Sandwell and West Birmingham CCG had the lowest at 67.4 per 10,000 population. Both CCGs are considered outliers due to age sex standardised rates of elective ASD that are more than 3 standard deviations from the mean of the CCGs. This indicates that there is a high degree of confidence that the variation in access is not due to chance.

6 Activity and financial analysis

This section summarises SUS inpatient admissions for the three years from April 2015 to March 2018 inclusive. Data are presented for activity commissioned by Birmingham and Solihull CCG, Dudley CCG, Sandwell and West Birmingham CCG, Walsall CCG and Wolverhampton CCG (the Birmingham and Black Country CCGs), and show all elective and day case activity for Arthroscopic Subacromial Decompression (ASD) procedures for patients aged eighteen and over.

ASD procedures were defined based on guidance provided in the NHS Digital National Clinical Coding Standards [18], which advises the use of the following codes in combination to identify ASD procedures:

O29.1 Subacromial decompression
AND at least one of
Y76.7 Arthroscopic approach to joint or
W84.4 Endoscopic decompression of joint

In some cases, in addition to these procedures, a tenotomy (T70.2 Tenotomy NEC) is also carried out. These are reported in this section together with ASD procedures without tenotomy.

Further, ASD procedures, with or without tenotomy, may also be carried out in conjunction with rotator cuff procedures, as identified through the procedure codes below. These have been included in reporting shown here, and shown separately to ASD procedures with or without tenotomy, with no rotator cuff procedures.

Rotator cuff procedures:
T79.1 Plastic repair of rotator cuff of shoulder NEC
T79.4 Plastic repair of multiple tears of rotator cuff of shoulder
T79.8 Other specified repair of muscle
T79.9 Unspecified repair of muscle

The procedure code Z54.2 Rotator cuff of shoulder was also used to search for appropriate records.

A dataset of admissions where the combinations of procedures described above were found in either the primary procedure field or any of the subsequent six procedure code fields was produced, containing records for 5,938 admissions for Birmingham and Black Country CCGs between April 2015 and March 2018, and manually reviewed. As a result of this manual review, 1,144 admissions were excluded, as one or more of the procedures shown in Table 2 were present.

Table 2: Procedure codes excluded from analyses after manual review of data

Procedure codes excluded from analyses after manual review of data
O273: Repair of capsule and anterior labrum for stabilisation of glenohumeral joint
O274: Repair of capsule and posterior labrum for stabilisation of glenohumeral joint
O278: Other specified other stabilising operations on joint
T642: Transfer of tendon to tendon NEC
T645: Tenodesis
T658: Other specified excision of tendon
T691: Primary tenolysis
T701: Subcutaneous tenotomy
T709: Unspecified adjustment to length of tendon
T723: Release of constriction of sheath of tendon
T748: Other specified other operations on tendon
T793: Revisional repair of rotator cuff NEC
T794: Plastic repair of multiple tears of rotator cuff of shoulder
W283: Removal of internal fixation from bone NEC
W693: Partial synovectomy
W694: Open biopsy of synovial membrane of joint
W712: Open excision of intra-articular osteophyte
W771: Repair of capsule of joint for stabilisation of joint NEC
W781: Release of contracture of shoulder joint
W784: Limited release of contracture of capsule of joint
W802: Open debridement of joint NEC
W803: Open irrigation of joint NEC
W816: Capsulorrhaphy of joint
W817: Insertion of therapeutic spacer into joint
W833: Endoscopic shaving of articular cartilage
W836: Endoscopic excision of articular cartilage NEC
W847: Endoscopic repair of superior labrum anterior to posterior tear
W891: Endoscopic chondroplasty NEC
Y262: Plastic repair of organ NOC
Y272: Allograft to organ NOC
Y712: Secondary operations NOC
Y713: Revisional operations NOC
Z844: Patellofemoral joint

The main analyses presented here use the categories of ASD procedures with or without tenotomy, with no rotator cuff procedures (ASD +/- T, exc. RC), and ASD procedures with or without tenotomy, with rotator cuff procedures (ASD +/-T, inc. RC).

We attempted to include only admissions which matched the procedures relevant to the evidence selected for inclusion in this evidence review i.e. non elective ASD as the main procedure in adults with a diagnosis SIS or shoulder pain. Despite manual sifting of episodes, there may be some activity included in the dataset that should not be (and some excluded that should not be) due to factors such as coding errors, different permutations of coding for ASD, some of which are not clearly defined, ambiguous

coding, etc. It is unlikely that patients with a full thickness rotator cuff tear, unstable shoulder or frozen shoulder were included as we excluded the main procedures for these, even if they were accompanied by ASD.

We included episodes where the main procure was ASD, but this was accompanied by biceps tenotomy, a rotator cuff repair or acromioclavicular joint procedures for which we have not assessed the evidence. In all cases, these were combined with an ASD procedure.

To provide further contextual information, Table 3 shows a detailed breakdown of admissions by each category and subcategories of these. This shows that over the period April 2015 to March 2018 for all of the Birmingham and Black Country CCGs, there were 4,794 adult elective admissions for ASD procedures, of which 2,410 (50.3%) excluded rotator cuff procedures and 2,384 included rotator cuff procedures. Of those excluding a rotator cuff procedure, 284 included a tenotomy procedure, and of those including a rotator cuff procedure, 732 included a tenotomy.

Table 3: ASD elective admissions by category, all Birmingham and Black Country CCGs, April 2015 to March 2018

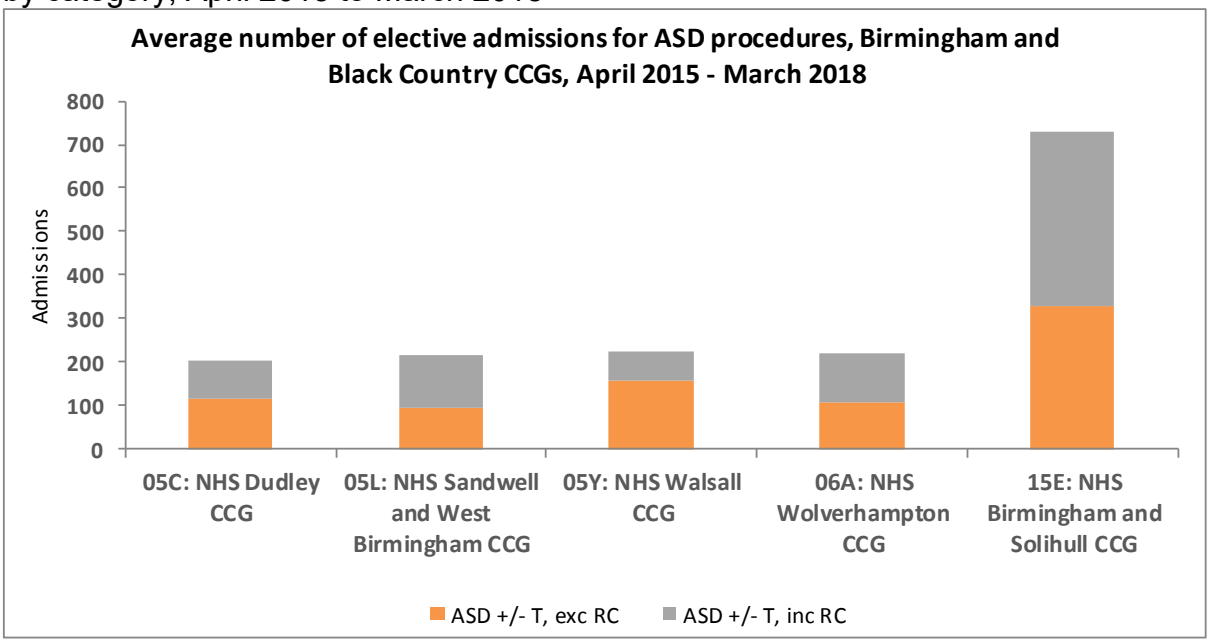
Procedure	Number of admissions
ASD without tenotomy, excluding rotator cuff	2,126
ASD with tenotomy, excluding rotator cuff	284
ASD with or without tenotomy, excluding rotator cuff	2,410
ASD without tenotomy, including rotator cuff	1,652
ASD with tenotomy, including rotator cuff	732
ASD with or without tenotomy, including rotator cuff	2,384
Total	**4,794**

Table 4 shows the number of elective admissions per year by CCG, by category (ASD +/- T, exc. RC and ASD +/- T, inc. RC), as well as the total elective admissions and average number of elective admissions per year by CCG. The highest average number of elective admissions per year over the period April 2015 to March 2018 was for Birmingham and Solihull CCG, with 730 elective admissions. This is also shown in Figure 1.

Table 4: Number of elective admissions for ASD procedures by CCG, by category, April 2015 to March 2018

CCG	2015/16			2016/17			2017/18			All Years			Avg/yr		
	ASD +/- T, exc RC	ASD +/- T, inc RC	Total	ASD +/- T, exc RC	ASD +/- T, inc RC	Total	ASD +/- T, exc RC	ASD +/- T, inc RC	Total	ASD +/- T, exc RC	ASD +/- T, inc RC	Total	ASD +/- T, exc RC	ASD +/- T, inc RC	Total
05C: NHS Dudley CCG	119	70	**189**	115	94	**209**	114	104	**218**	348	268	**616**	116	89	**205**
05L: NHS Sandwell and West Birmingham CCG	105	106	**211**	105	125	**230**	79	128	**207**	289	359	**648**	96	120	**216**
05Y: NHS Walsall CCG	144	85	**229**	166	70	**236**	160	50	**210**	470	205	**675**	157	68	**225**
06A: NHS Wolverhampton CCG	109	130	**239**	108	109	**217**	101	109	**210**	318	348	**666**	106	116	**222**
15E: NHS Birmingham and Solihull CCG	386	409	**795**	334	404	**738**	265	391	**656**	985	1204	**2189**	328	401	**730**
Grand Total	**863**	**800**	**1663**	**828**	**802**	**1630**	**719**	**782**	**1501**	**2410**	**2384**	**4794**	**803**	**795**	**1598**

Figure 3: Average number of elective admissions for ASD procedures by CCG per year, by category, April 2015 to March 2018



Figures 4 and 5 below show the trend in the number of elective admissions for the categories of ASD procedures with or without tenotomy, with no rotator cuff procedures (ASD +/- T, exc. RC), and ASD procedures with or without tenotomy, with rotator cuff procedures (ASD +/-T, inc. RC.

Figure 4: Number of elective admissions for ASD procedures with or without tenotomy with no rotator cuff procedures

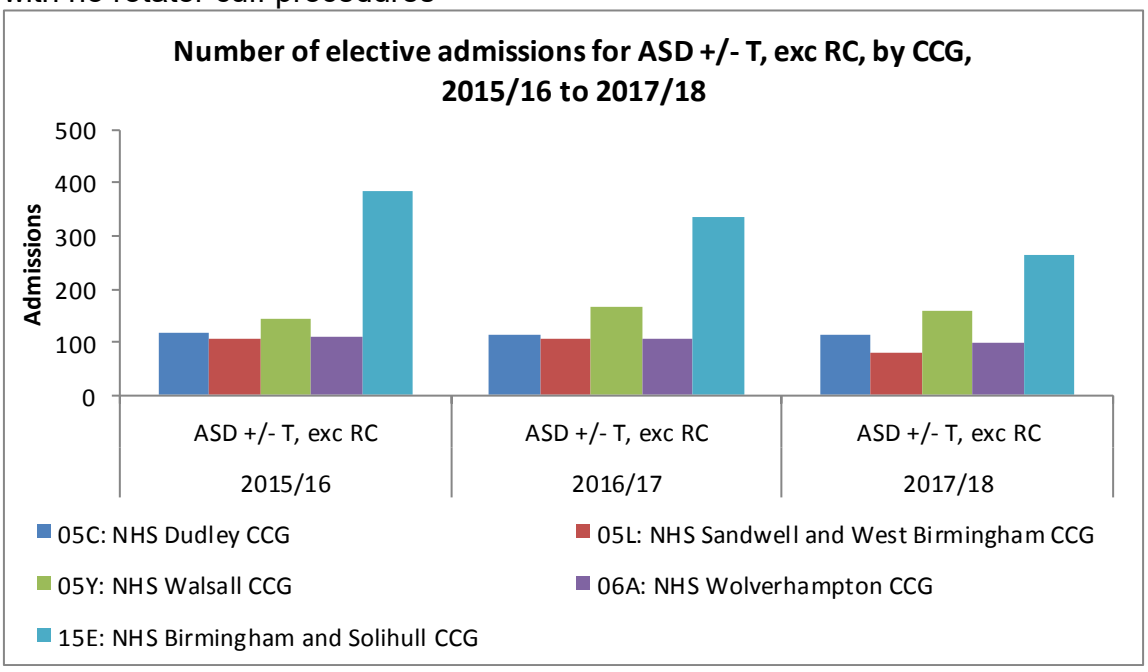


Figure 4 shows that NHS Birmingham and Solihull CCG had the highest number of elective admissions for ASD procedures with or without tenotomy with no rotator cuff procedures in all three years. However, the number of elective admissions per year has declined from 386 in 2015/16 to 285 in 2017/18. NHS Walsall had the second highest number of elective admissions in all three years.

Figure 5: Number of elective admissions for ASD procedures with or without tenotomy with rotator cuff procedures

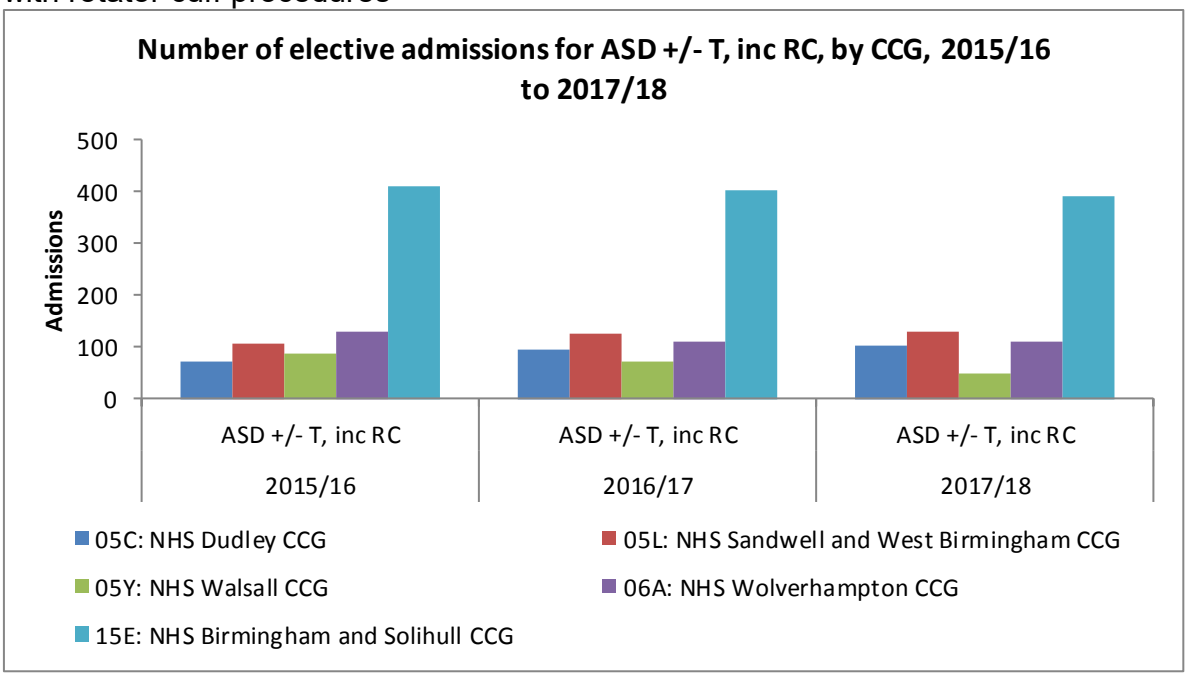


Figure 5 shows that NHS Birmingham and Solihull CCG had the highest number of elective admissions for ASD procedures with or without tenotomy with rotator cuff procedures in all three years. NHS Walsall CCG had a lower number of elective admissions in 2017/18 than in the previous two years.

Figures 6 and 7 below show the trend in the crude elective admission rate per 10,000 population for the categories of ASD procedures with or without tenotomy, with no rotator cuff procedures (ASD +/- T, exc. RC), and ASD procedures with or without tenotomy, with rotator cuff procedures (ASD +/-T, inc. RC).

Figure 6: Crude elective admission rate per 10,000 population for ASD procedures with or without tenotomy with no rotator cuff procedures

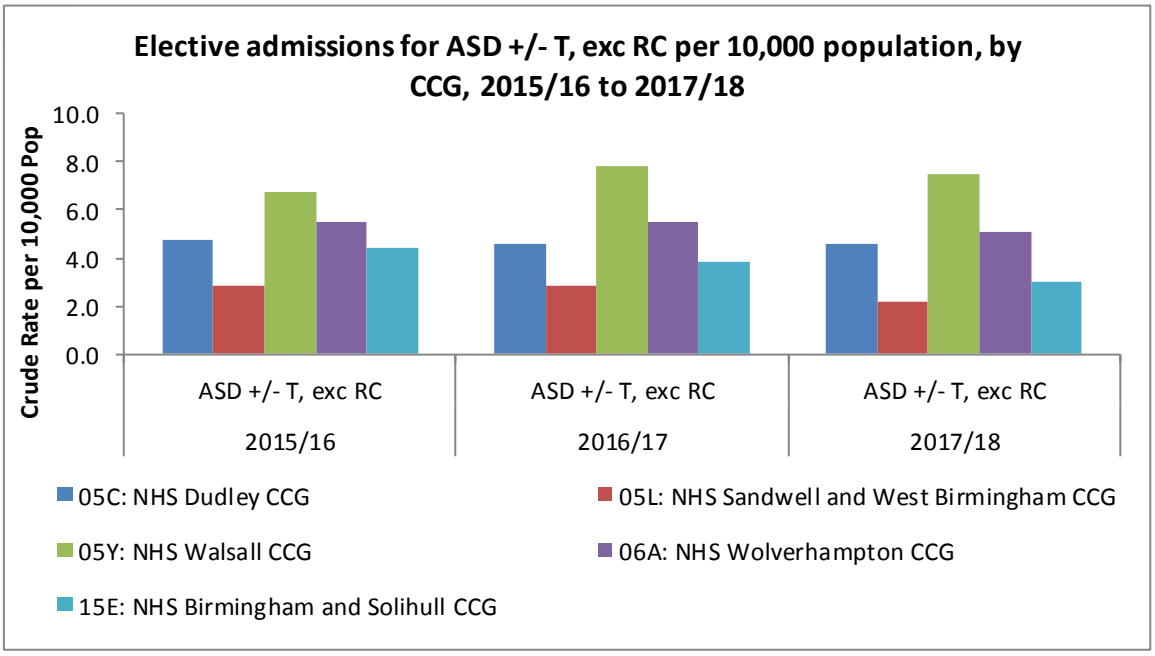


Figure 6 shows that NHS Walsall CCG had the highest crude elective admission rate per 10,000 population for ASD procedures with or without tenotomy, with no rotator cuff procedures in all three years. NHS Sandwell and West Birmingham CCG had the lowest crude elective admission rate per 10,000 population in all three years and the rate decreased over this time period.

Figure 7: Crude elective admission rate per 10,000 population for ASD procedures with or without tenotomy with rotator cuff procedures

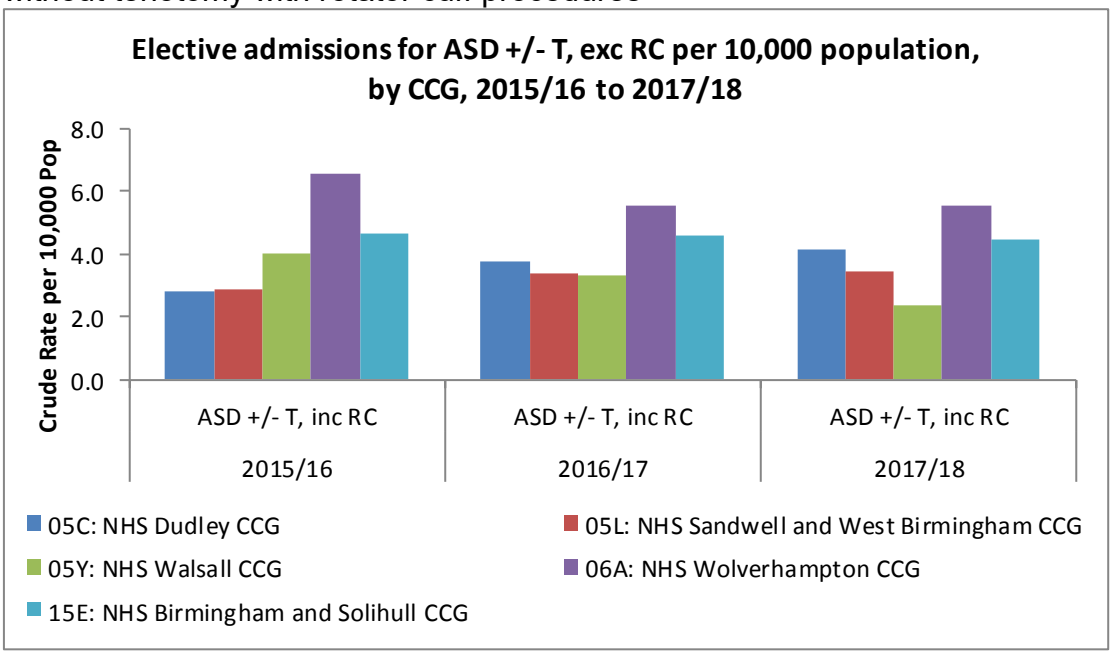


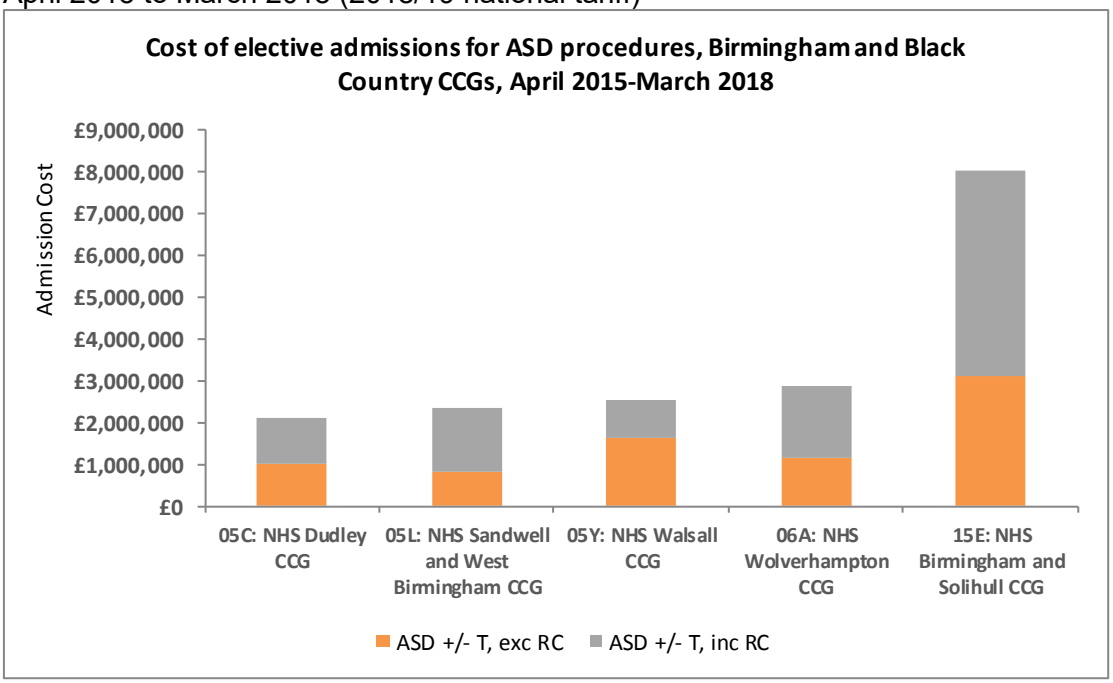
Figure 7 shows that NHS Wolverhampton CCG had the highest elective admission rate for ASD procedures with or without tenotomy, with rotator cuff procedures in all three years. However, the crude elective admission rate was lower in 2017/18 and in 2016/17 than it was in 2015/16.

Table 5 shows the cost of elective admissions per year by CCG, by category, as well as the total national tariff cost, including MFF, for 2018/19 applied to all years of elective admissions and average number of elective admissions per year by CCG. This shows that the total cost of elective admissions for ASD procedures during the period April 2015 to March 2018 for all Birmingham and Black Country CCGs was £17,963,651 based on 2018/19 costs.

Table 5: National tariff cost of elective admissions for ASD procedures by CCG, by category, by financial year, April 2015 to March 2018 (2018/19 national tariff)

CCG	2015/16			2016/17			2017/18			All Years			Avg/yr		
	ASD +/- T, exc RC	ASD +/- T, inc RC	Total	ASD +/- T, exc RC	ASD +/- T, inc RC	Total	ASD +/- T, exc RC	ASD +/- T, inc RC	Total	ASD +/- T, exc RC	ASD +/- T, inc RC	Total	ASD +/- T, exc RC	ASD +/- T, inc RC	Total
05C: NHS Dudley CCG	£329,731	£285,419	**£615,150**	£346,640	£384,478	**£731,118**	£341,532	£428,539	**£770,071**	£1,017,903	£1,098,436	**£2,116,339**	£339,301	£366,145	**£705,446**
05L: NHS Sandwell and West Birmingham CCG	£292,901	£428,327	**£721,228**	£309,804	£529,379	**£839,183**	£244,988	£545,856	**£790,844**	£847,693	£1,503,561	**£2,351,255**	£282,564	£501,187	**£783,752**
05Y: NHS Walsall CCG	£484,769	£378,163	**£862,932**	£589,786	£318,840	**£908,626**	£552,215	£227,916	**£780,130**	£1,626,770	£924,919	**£2,551,689**	£542,257	£308,306	**£850,563**
06A: NHS Wolverhampton CCG	£391,997	£633,876	**£1,025,872**	£401,146	£555,138	**£956,285**	£376,082	£529,609	**£905,692**	£1,169,225	£1,718,624	**£2,887,849**	£389,742	£572,875	**£962,616**
15E: NHS Birmingham and Solihull CCG	£1,201,857	£1,675,283	**£2,877,141**	£1,066,014	£1,657,158	**£2,723,172**	£848,802	£1,607,404	**£2,456,206**	£3,116,674	£4,939,845	**£8,056,519**	£1,038,891	£1,646,615	**£2,685,506**
Grand Total	**£2,701,256**	**£3,401,068**	**£6,102,324**	**£2,713,390**	**£3,444,994**	**£6,158,384**	**£2,363,620**	**£3,339,323**	**£5,702,943**	**£7,778,266**	**£10,185,385**	**£17,963,651**	**£2,592,755**	**£3,395,128**	**£5,987,884**

Figure 8: National tariff cost of elective admissions for ASD procedures by CCG, by category, April 2015 to March 2018 (2018/19 national tariff)



The number of elective admissions for ASD procedures by primary diagnosis is given in Table 6 and Figure 9. These show that 2,095 (44%) admissions related to a primary diagnosis of M754: impingement syndrome of shoulder; 1,996 (42%) admissions related to M751: rotator cuff syndrome; 230 (5%) admissions related to M199: arthrosis, unspecified. Other procedures accounted for the remaining 10%.

Table 6: Number of elective admissions for ASD procedures by primary diagnosis, by category, April 2015 to March 2018

Primary Diagnosis description	ASD +/- T, exc RC	ASD +/- T, inc RC	Total	% of Total
M754: Impingement syndrome of shoulder	1553	542	2095	44%
M751: Rotator cuff syndrome	302	1694	1996	42%
M199: Arthrosis, unspecified	179	51	230	5%
Other	376	97	473	10%
Grand Total	**2410**	**2384**	**4794**	**100%**

Figure 9: Number of elective admissions for ASD procedures by primary diagnosis, by category, April 2015 to March 2018

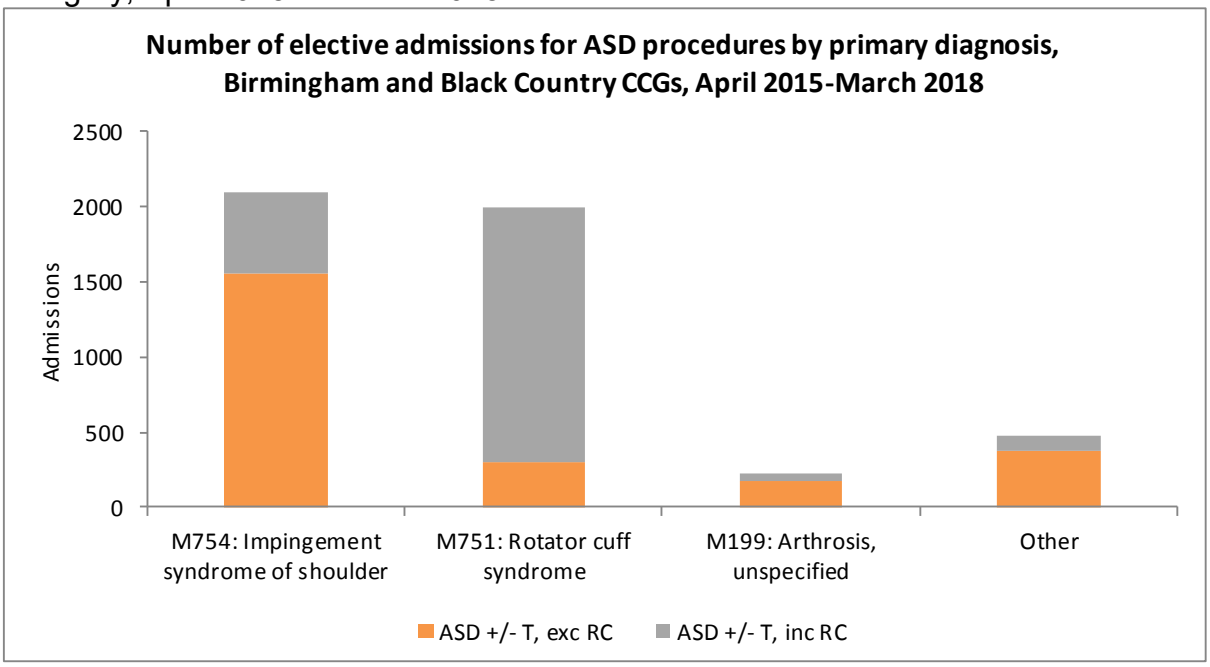
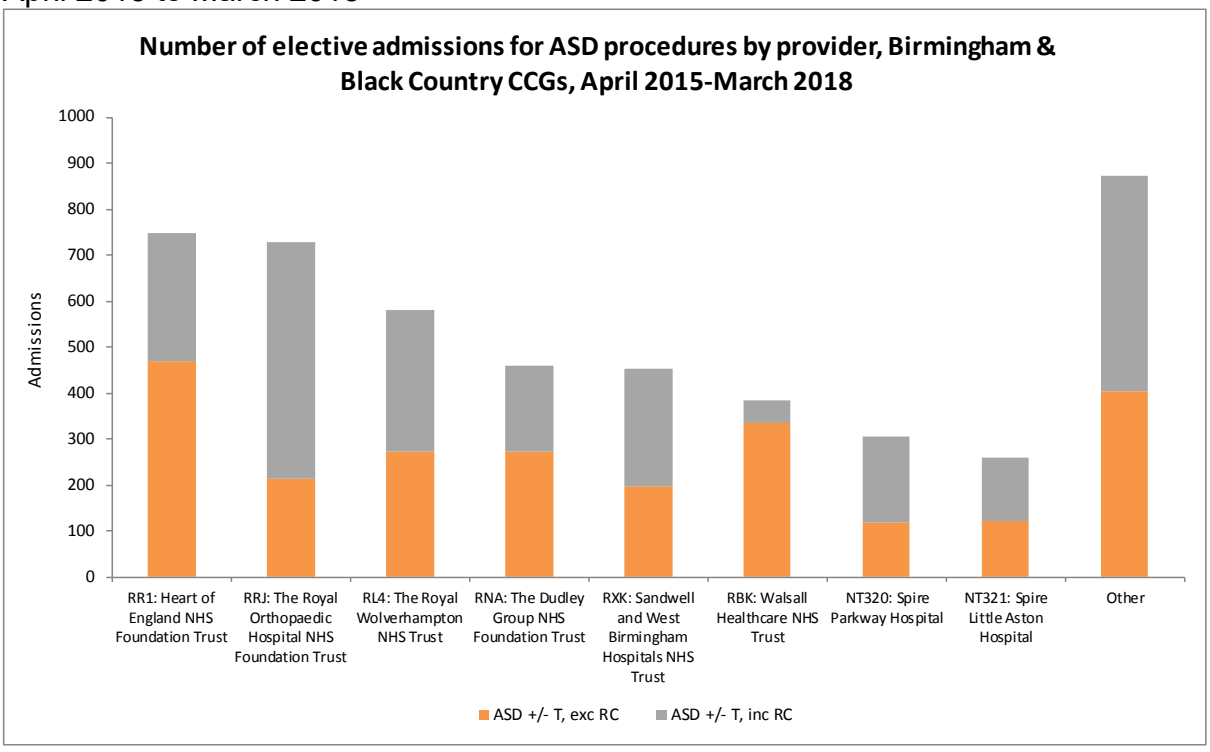


Table 7 and Figure 10 give the number of elective admissions for ASD procedures by provider. This shows that 750 procedures (16%) were carried out at the Heart of England NHS Foundation Trust; 728 procedures (15%) at the Royal Orthopaedic Hospital NHS Foundation Trust; and 581 (12%) at the Royal Wolverhampton NHS Trust on behalf of the Birmingham and Black Country CCGs. These three providers accounted for 43% of all the elective ASD activity commissioned by the CCGs between April 2015 and March 2018.

Table 7: Number of elective admissions for ASD procedures by provider, by category, April 2015 to March 2018

Provider	ASD +/- T, exc RC	ASD +/- T, inc RC	Grand Total	% of Total
RR1: Heart of England NHS Foundation Trust	469	281	750	16%
RRJ: The Royal Orthopaedic Hospital NHS Foundation Trust	216	512	728	15%
RL4: The Royal Wolverhampton NHS Trust	275	306	581	12%
RNA: The Dudley Group NHS Foundation Trust	272	187	459	10%
RXK: Sandwell and West Birmingham Hospitals NHS Trust	198	256	454	9%
RBK: Walsall Healthcare NHS Trust	337	47	384	8%
NT320: Spire Parkway Hospital	118	187	305	6%
NT321: Spire Little Aston Hospital	122	139	261	5%
Other	403	469	872	18%
Grand Total	**2410**	**2384**	**4794**	**100%**

Figure 10: Number of elective admissions for ASD procedures by provider, by category, April 2015 to March 2018

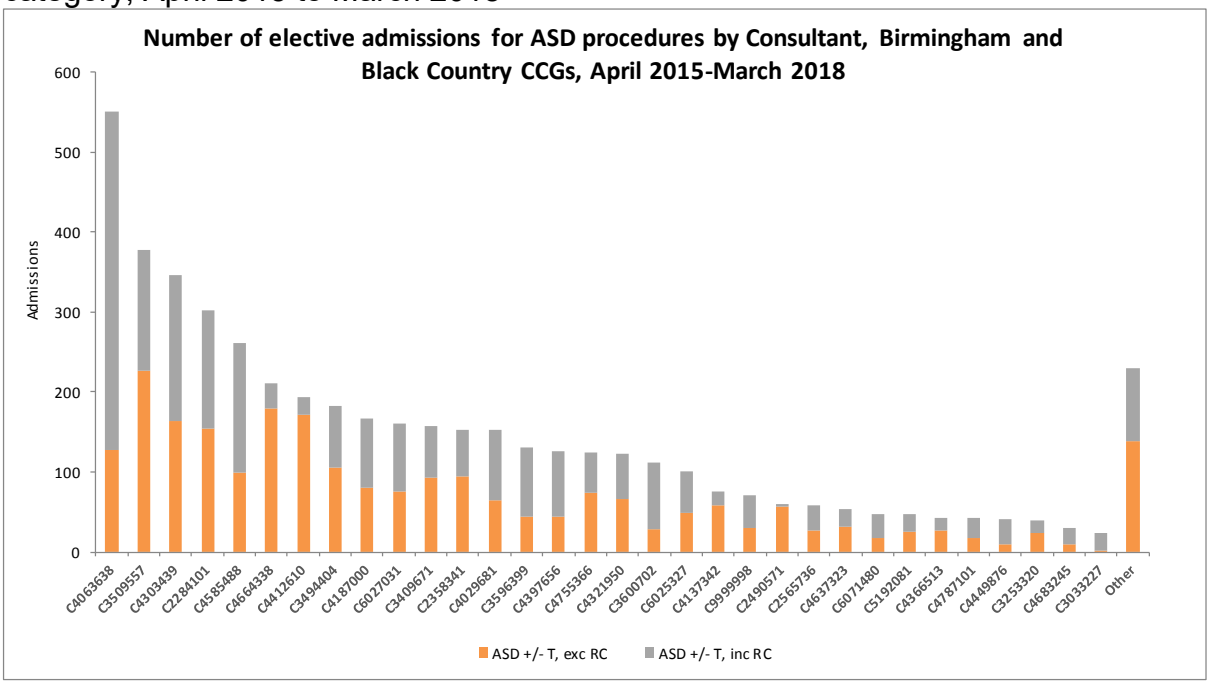


ASD is not a highly specialised shoulder procedure; the operations performed over the three-year period were undertaken by at least 32 different Consultants (Figure 11). The Consultants carrying out the largest number of ASD procedures are identified through the codes listed in Table 8 below. 51% of all the procedures performed over three years were undertaken by the top eight consultant codes, all of whom performed over 150 ASD procedures over the three-year period.

Table 8: Number of elective admissions for ASD procedures by consultant code, by category, April 2015 to March 2018

Consultant Code	ASD +/- T, exc RC	ASD +/- T, inc RC	Total	% of Total
C4063638	127	424	551	11%
C3509557	226	152	378	8%
C4303439	163	183	346	7%
C2284101	155	148	303	6%
C4585488	99	163	262	5%
C4664338	180	31	211	4%
C4412610	171	23	194	4%
C3494404	106	76	182	4%
C4187000	80	87	167	3%
C6027031	75	85	160	3%
C3409671	93	65	158	3%
C2358341	95	57	152	3%
C4029681	64	88	152	3%
C3596399	44	86	130	3%
C4397656	44	82	126	3%
C4755366	74	51	125	3%
C4321950	66	57	123	3%
C3600702	28	83	111	2%
C6025327	49	52	101	2%
C4137342	58	18	76	2%
C9999998	30	41	71	1%
C2490571	57	3	60	1%
C2565736	26	32	58	1%
C4637323	32	21	53	1%
C6071480	17	31	48	1%
C5192081	25	22	47	1%
C4366513	26	17	43	1%
C4787101	18	24	42	1%
C4449876	9	32	41	1%
C3253320	23	16	39	1%
C4683245	9	21	30	1%
C3033227	2	22	24	1%
Other	139	91	230	9%
Grand Total	**2410**	**2384**	**4794**	**100%**

Figure 11: Number of elective admissions for ASD procedures by consultant code, by category, April 2015 to March 2018

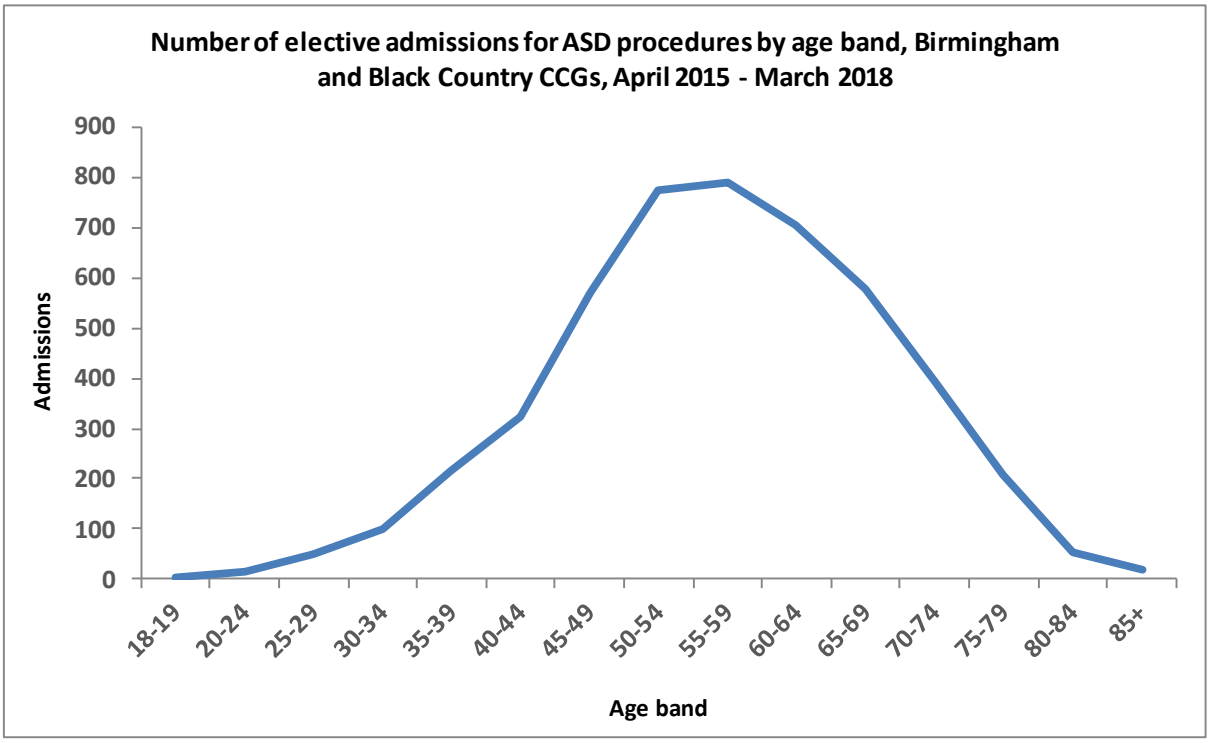


The number of elective admissions for ASD procedures by age band is given in Table 9 and Figure 12. These show that 47% of admissions are for patients aged 50 to 64, with a further 24% of admissions occurring in those aged 45 to 49 or 65 to 69.

Table 9: Number of elective admissions for ASD procedures by age band, April 2015 to March 2018

Age Band	Number of Admissions	% of Admissions	Cumulative % of Admissions
18-19	4	0%	0.1%
20-24	14	0%	0.4%
25-29	50	1%	1.4%
30-34	100	2%	3.5%
35-39	214	4%	8.0%
40-44	322	7%	14.7%
45-49	571	12%	26.6%
50-54	772	16%	42.7%
55-59	788	16%	59.1%
60-64	705	15%	73.8%
65-69	578	12%	85.9%
70-74	394	8%	94.1%
75-79	209	4%	98.5%
80-84	55	1%	99.6%
85+	18	0%	100.0%
Grand total	**4794**	**100%**	**100.0%**

Figure 12: Number of elective admissions for ASD procedures by age band, April 2015 to March 2018



Crude rates of admissions per 10,000 population are given in Table 10. These vary from 5.61 admissions per 10,000 population for Sandwell and West Birmingham CCG, to 10.63 admissions per 10,000 population for Wolverhampton CCG for the period April 2017 to March 2018.

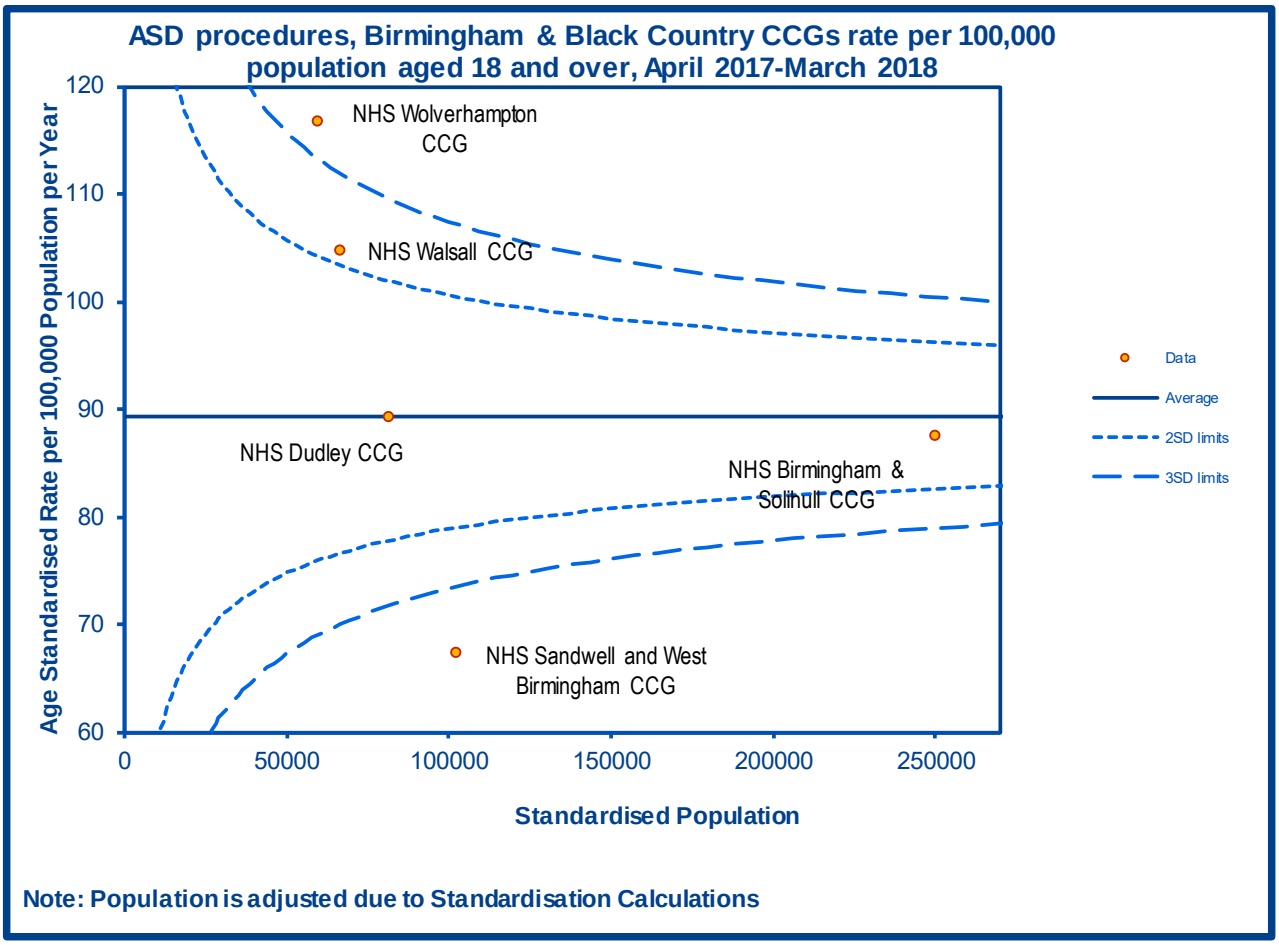
Table 10: Crude elective admission rates per 10,000 population by CCG and financial year, 2015/16 to 2017/18

CCG	2015/16			2016/17			2017/18			All Years		
	ASD +/- T, exc RC	ASD +/- T, inc RC	Total	ASD +/- T, exc RC	ASD +/- T, inc RC	Total	ASD +/- T, exc RC	ASD +/- T, inc RC	Total	ASD +/- T, exc RC	ASD +/- T, inc RC	Total
05C: NHS Dudley CCG	4.77	2.81	7.57	4.61	3.77	8.38	4.57	4.17	8.74	13.95	10.74	24.69
05L: NHS Sandwell and West Birmingham CCG	2.85	2.88	5.72	2.85	3.39	6.24	2.14	3.47	5.61	7.84	9.74	17.58
05Y: NHS Walsall CCG	6.77	4.00	10.77	7.81	3.29	11.10	7.53	2.35	9.88	22.11	9.64	31.75
06A: NHS Wolverhampton CCG	5.52	6.58	12.10	5.47	5.52	10.98	5.11	5.52	10.63	16.09	17.61	33.71
15E: NHS Birmingham and Solihull CCG	4.39	4.66	9.05	3.80	4.60	8.40	3.02	4.45	7.47	11.21	13.71	24.92

Figure 13 below is a funnel plot showing age standardised ASD elective admissions (with or without tenotomy, and with or without rotator cuff procedures) for the period April 2017 to March 2018. The funnel plot methodology calculates standard deviations around the mean of the five CCGs. This shows that Wolverhampton CCG had the highest age standardised rate at 116.7 per 100,000 population, and Sandwell and West Birmingham CCG had the lowest at 67.4 per 100,000 population. The rate for Birmingham and Solihull CCG was 87.5, for Dudley CCG was 89.3 and for Walsall CCG was 104.7 per 100,000 population. Please note that the y-axis starts at 60 in figure 13 below.

The mean is the mean age standardised rate per 100,000 population of the five CCGs, based on elective admissions from April 2017 to March 2018. It should be noted that the mean is reflective of the number of hospital admissions during that year. The ideal age standardised rate per 100,000 population for ASD procedures, taking into account the evidence of clinical and cost effectiveness, is unknown.

Figure 13: Age standardised elective admission rates per 100,000 population by CCG, April 2017 to March 2018



7 Discussion and conclusions

What is the evidence of clinical and cost effectiveness of arthroscopic subacromial decompression, compared to conservative treatment, in adults with impaired function and pain in the affected shoulder joint?

Clinical Effectiveness.

Shoulder Impingement Syndrome.

We found three randomised controlled trials which compared ASD to conservative treatment for patients with SIS (at 24 months in two of the trials and 12 months only in the CSAW RCT). Patients with partial thickness rotator cuff tears were not excluded from these RCTs. The key differences between the study design were that Ketola et al [7] compared ASD plus physiotherapy to physiotherapy alone [7], whereas in the FIMPACT [6] and CSAW [4] RCTs, there were three treatment arms. Both FIMPACT and CSAW included ASD plus physiotherapy and diagnostic arthroscopy plus physiotherapy as two

of the three arms. However, in the UK based multicentre RCT known as CSAW, the third arm was no treatment at all, whereas in the FIMPACT RCT, the non-operative third arm was a home exercise regime as well as 15 physiotherapy visits.

- ASD plus physiotherapy versus diagnostic arthroscopy plus physiotherapy. There was no clinically significant difference between ASD plus physiotherapy treatment compared to diagnostic (sham) arthroscopy plus physiotherapy at either 12-month follow-up in the CSAW RCT [4] or at 24 months (FIMPACT RCT) [6]. This was consistent for all of the outcomes measured: OSS, Constant score, pain, depression and anxiety, quality of life, simple shoulder test,15D and patient satisfaction.

- ASD plus physiotherapy versus no treatment: Although small statistical differences were seen in favour of ASD followed by up to four sessions of physiotherapy, there were no clinically important differences for any outcomes measured at 12 months compared to no treatment at all [4].

- ASD plus physiotherapy versus physiotherapy therapy only: There were no clinically important differences reported between these two treatment groups at 24-month follow-up [6,7] even though the physiotherapy protocol for the FIMPACT RCT was for 15 sessions (compared to just one post-operative session for those being treated with ASD). Both the ASD plus PT and PT only groups in the RCT by Ketola et al [7] had a similar number of physiotherapy sessions (6 and 7 sessions respectively).

Within each treatment group, all three trials showed clinically significant improvements at 12 or 24 months, when compared to baseline for the OSS, the Constant score[j] and for pain [4,6,7].

These RCTs showed that ASD for SIS was no more effective than physiotherapy alone or no treatment at achieving clinically important differences at 12 months and 24 months (OSS, Constant Score and pain). In addition, all three treatment groups achieved clinically important improvements over time compared to baseline. This suggests that the natural history of non-traumatic shoulder impingement syndrome, which has previously failed conservative treatment, is for the painful and disabling symptoms to resolve without intervention.

Supraspinatus tear.

There was one single RCT where 180 patients with a supraspinatus tear were treated with arthroscopic acromioplasty and physiotherapy, or tendon repair, acromioplasty and physiotherapy and the outcomes were compared to patients who had 10 sessions of physiotherapy alone. All the patients followed the same physiotherapy plan. There were no between group differences in the Constant score at 12 months. Although the ASD was performed concomitantly with repair of the supraspinatus tendon, the results are consistent with the results of the RCTs which assessed the effectiveness of ASD for the management of shoulder impingement syndrome.

[j] The authors of the CSAW RCT refer to the modified Constant Score but it is not clear how it differs from the Constant Score (also called the Constant-Murley Score). Both the CSAW study publication [4] and the CSAW study protocol [19] reference the 1987 Constant-Murley Score publication [13].

Cost Effectiveness.
We found no studies generalisable to the NHS which measured the cost effectiveness of ASD compared to conservative treatment in patients with subacromial shoulder pain.

Activity and Variation.
There is significant variation in access to ASD elective admissions across the five Birmingham and Black Country CCGs. For the period April 2017 to March 2018, Wolverhampton CCG had the highest age standardised rate at 116.7 per 100,000 population compared to Sandwell and West Birmingham CCG which had the lowest at 67.4 per 100,000 population. Both CCGs are outliers due to age standardised rates of elective ASD that are more than three standard deviations from the mean of the CCGs. This indicates that there is a high degree of confidence that the variation in access among the five CCGs is not due to chance.

The mean shown on the funnel chart is the mean age standardised rate per 100,000 population of the five CCGs for ASD procedures, based on elective admissions from April 2017 to March 2018. It should be noted that the mean is reflective of the number of hospital admissions during that year. The ideal age standardised rate per 100,000 population for ASD procedures, taking into account the evidence of clinical and cost effectiveness, is unknown, but if the CCGs consider that elective ASD procedures as described in this review are of limited clinical value, then the mean shown on the funnel chart is too high.

Issues that arise from the evidence and data review.

Evidence selection: The search for relevant comparative evidence was initially wide and not restricted to any indication. However, we restricted the selection of papers for inclusion to comparator studies which included a non-operative treatment and ASD as the primary intervention. The only comparator studies which met both the intervention and comparator criteria were for shoulder impingement syndrome or supraspinatus tendon tear.

Data selection: The data in the activity section of this report was selected to most closely match the indications, interventions and comparators in the included RCTs. We allowed inclusion of biceps tenotomy, partial rotator cuff tear repair or acromioclavicular joint surgery if they were combined with ASD only. We excluded any episodes which were associated with non-elective or emergency care. It was clear from the manual sifting of activity data that ASD is commonly coded as an adjunctive procedure with more complex shoulder operations. This, combined with the variation in coding means that the data will not be a completely accurate fit with the evidence to which it relates. However, the data will give an indication of the number and cost of these procedures across the five CCGs.

Indication: Three RCTs reported results for ASD with physiotherapy compared to non-operative management. All patients had a diagnosis of non-traumatic SIS, all had failed to respond to conservative treatment including physiotherapy and oral analgesia. The proportion of patients who had had at least one cortisone injection was not reported in

one study [6], whilst 59% [7] and 100% [4] of participants had had at least one steroid injection in the other two studies. The mean duration of symptoms was reported in two studies: 18 months [6] and 2.5 years [7] but not reported in the CSAW RCT [4]. All three studies excluded patients who had a full thickness tear of the rotator cuff. The proportion of participants who had a partial tear (grade I or II tear of the rotator cuff) was not reported in two of the RCTs. In the CSAW RCT, operative diagnosis was reported; 55/172 patients who received surgery had a partial thickness tear (31/89 allocated to ASD, 22/80 allocated to diagnostic arthroscopy only and 2/24 patients initially allocated to no treatment. The results from all three RCTs are not limited to those patients with isolated impingement syndrome.

Intervention: As described at the start of this review, the standard ASD procedure is antero-inferior acromioplasty and excision of the coracoacromial ligament and the subacromial bursa. All the studies allowed patients with SIS and a partial/small full-thickness tear of the rotator cuff to be included but they did not consistently report the proportion of patients in whom this was repaired. In addition, there was additional variation between studies to the standard ASD procedure as a small number of patients also had surgery to the acromioclavicular joint and to the long head of biceps (tenotomy) [4]. It is uncertain if these adjunct procedures occurred in either of the two Finnish RCTs [6,7]. It is also unclear to what extent these additional procedures might require additional recovery time and if this could affect outcomes such as pain and function.

Physiotherapy: In the three studies of patients with SIS, all patients who were allocated to ASD also received physiotherapy. However, the variation between the PT regimes ranged from one session of physiotherapy for guidance and instructions on home exercises (FIMPACT)[6], to 'up to' 4 physiotherapy appointments (CSAW)[4] and a mean of 6 physiotherapy sessions in the RCT by Ketola et al [7].

Physiotherapy was also the comparator to surgery in two of the RCTs for SIS but the mean number of seven sessions in one RCT [7] was far less than in the FIMPACT RCT where the comparator was 15 sessions as well as home exercises [6].

Uncertainty: Given that all the patients with SIS in these three RCTs had already failed to achieve an adequate response to conservative treatment (which included physiotherapy), it is not clear from these studies if the results warrant further intervention with physiotherapy.

- All three RCTs showed clinically meaningful improvement from baseline after no treatment at 12 months or PT at 24 months for the OSS, Constant score and pain.
- This indicates that some patients' will experience improvement in symptoms over time measured by the OSS, CS and pain scores, without any treatment at all.
- There was no analysis of the comparative effectiveness of the different comparators – no treatment, seven sessions of physiotherapy or 15 sessions of physiotherapy.
- There is insufficient evidence from these studies to justify the incremental costs of 15 sessions of physiotherapy compared to other non-operative alternatives.
- The relative clinical and cost effectiveness between all the non-operative treatment options remains uncertain.

Lack of blinding of patients and assessors may have biased the results in favour of surgery due to perception that no treatment or physiotherapy (which has previously failed) might be an inferior treatment option. All the RCTs attempted to limit the impact of lack of blinding by using independent assessors for data collection, and in some instances insisting that patient's shoulders remained clothed. However, this would not correct for subjective self-reported outcomes for pain, activities of daily living, quality of life and elements of composite scores such as the OSS or the Constant Score. This may have contributed to the observed statistically significant differences between ASD plus PT, compared to no treatment, which were not large enough to meet the MCID for OSS and Constant score at both 6 and 12 months. We noted that the MCIDs reported in the RCTs were referenced, increasing confidence that MCID reflected outcomes which are meaningful to patients.

Despite the lack of blinding to the treatment allocation, the potential bias did not result in clinically significant better outcomes for people receiving ASD compared to those receiving conservative treatment for SIS, even though they had already previously failed to respond adequately to conservative management.

Though not clinically significant, the results of the CSAW and FIMPACT studies [4,6] where ASD was statistically significantly better than no treatment and better than physiotherapy alone but not better than sham ASD (DA), suggests that the reasons why ASD was better than no treatment or than physio was not due to the ASD (otherwise it would also have been better than sham ASD), but due to something else eg placebo effect due to lack of blinding or due to the lack of physio in the no treatment group in CSAW[4].

8 Search Strategy

Search date: 16th August, updated 22nd October 2018

We searched for subacromial decompression on Medline, Embase and Cochrane – limiting to English and 2008 onwards. We also ran a search of TRIP database and NICE Evidence with similar limits and restricting to Evidence Reviews. We excluded letters, commentary, case reports and conference papers.

The search identified publications with any arthroscopic shoulder procedures. The abstracts and titles were then sifted to select those that met the criteria in the PICO table below. Where there was ambiguity in the PICO criteria, the reviewer also referred to the wording of the research question for this evidence review, which specified that the intervention of interest was arthroscopic subacromial decompression.

Medline and Embase

#	Searches
▲	
1	Shoulder Pain/

2 Shoulder Impingement Syndrome/
3 Rotator Cuff Injuries/
4 Osteoarthritis/ and Shoulder Joint/
5 Bursitis/ and Shoulder Joint/
6 ((shoulder* or subacromial or sub-acromial) and (adhesive capsulitis or bursitis)).ti,ab.
7 ((shoulder* or subacromial or sub-acromial) adj5 (pain or osteoarthritis or arthritis or impinge*)).ti,ab.
8 (rotator cuff adj2 (tear? or injur*)).ti,ab.
9 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8
10 Arthroscopy/
11 Therapeutic Irrigation/ and arthroscop*.mp.
12 Debridement/ and arthroscop*.mp.
13 (arthroscop* adj5 (lavage or irrigat* or debride* or decompress* or resurfac*)).ti,ab.
14 (arthroscop* and (lavage or irrigat* or debride* or decompress* or resurfac*)).ti.
15 10 or 11 or 12 or 13 or 14
16 9 and 15
17 (comment or editorial or letter or news or "review").pt. or case report.tw.
18 exp animals/ not humans.sh.
19 17 or 18
20 16 not 19
21 limit 16 to "reviews (maximizes specificity)"
22 20 or 21
23 limit 22 to (english language and yr="2008 -Current")

Inclusion criteria for identification of relevant studies

Population	Indication	Intervention	Comparator	Outcomes	Studies
Adults with impaired function and pain in the affected shoulder joint	Adhesive capsulitis Partial thickness rotator cuff tear Impingement syndrome of the shoulder Osteoarthritis	Arthroscopic subacromial decompression including: arthroscopic lavage, debridement, labral resurfacing [Likely procedure codes: • Diagnostic arthroscopic exam on shoulder +/- biopsy (as sole proc) W8820	Conservative treatment with lifestyle modification and/or medication and/or physiotherapy	Clinical effectiveness including Pain Function/mobility QoL Safety Cost effectiveness Subsequent arthroplasty	SRMA SR of RCTS RCT SR Prospective cohort studies Retrospective cohort studies Cost effectiveness studies

		• Therapeutic arthroscopy of the shoulder W8603 • Resurfacing arthroplasty of shoulder W5060] Exclude : stabilisation procedures including labral(SLAP) tear/tendon repair)			

Inclusion Criteria Peer reviewed publications, English language

Exclusion Criteria Abstracts, Letters, Commentaries, Conference papers, Case reports, Papers published more than 10 years ago

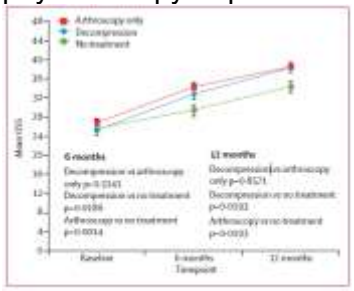
9 References

1. NHS choices. Shoulder Pain. https://www.nhs.uk/conditions/shoulder-pain/
2. Artus M, Holt T and Rees J. The painful shoulder: an update on assessment, treatment, and referral. British Journal of General Practice. 2014;64(626), e593-e595.
3. Chipchase LS, O'Connor DA, Costi JJ, Krishnan J (2000) Shoulder impingement syndrome: preoperative health status. J Shoulder Elbow Surg 9:12–15
4. Beard DJ, Rees JL, Cook JA CSAW Study Group et al. Arthroscopic subacromial decompression for subacromial shoulder pain (CSAW): a multicentre, pragmatic, parallel group, placebo-controlled, three-group, randomised surgical trial. Lancet 2018;391:329-38.
5. Linsell L, Dawson J, Zondervan K, Rose P, Randall T, Fitzpatrick R, Carr A. Prevalence and incidence of adults consulting for shoulder conditions in UK primary care; patterns of diagnosis and referral. Rheumatology (Oxford). 2006;45(2):215-21.
6. Paavola M, Malmivaara A, Taimela S et al. Subacromial decompression versus diagnostic arthroscopy for shoulder impingement: randomised, placebo surgery controlled clinical trial. BMJ 2018;362:k2860
7. Ketola S, Lehtinen J, Arnala I, et al. Does arthroscopic acromioplasty provide any additional value in the treatment of shoulder impingement syndrome? a two-year randomised controlled trial. J Bone Joint Surg Br 2009;91:1326-34

8. Ketola S, Lehtinen J, Rousi T et al. Which patients do not recover from shoulder impingement syndrome, either with operative treatment or with non-operative treatment? Subgroup analysis involving 140 patients at 2 and 5 years in a randomised study. Acta Orthop 2015;86:641-46
9. Ketola S, Lehtinen J, Elo P et al. No difference in long-term development of rotator cuff rupture and muscle volumes in impingement patients with or without decompression. Acta Orthop 2016;87(4):351-55
10. Ketola S, Lehtinen J, Arnala I. Arthroscopic decompression not recommended in the treatment of rotator cuff tendinpathy. Bone Joint J 2017;99-B:799-805
11. Kukkonen J, Joukainen A, Lehtinen J et al. Treatment of non-traumatic rotator cuff tears. Bone Joint J 2014;96-B:75-81
12. Longo UG, Vasta S, Maffulli N, Denaro V. Scoring systems for the functional assessment of patients with rotator cuff pathology Sports Med Arthrosc Rev. 2011;19(3):310-20.doi: 10.1097/JSA.0b013e31820af9b6.
13. Christiansen DH1, Frost P, Falla D, Haahr JP, Frich LH, Svendsen SW. Responsiveness and Minimal Clinically Important Change: A Comparison Between 2 Shoulder Outcome Measures. J Orthop Sports Phys Ther. 2015 Aug;45(8):620-5.
14. Constant CR, Murley AH. A clinical method of functional assessment of the shoulder. Clin Orthop Relat Res 1987;214:160–164
15. Mathieson S, Lin C. PainDETECT Questionnaire Clinimetrics. Journal of Physiotherapy 2013 Vol. 59
16. Stern AF. Questionnaire Review: The Hospitals Anxiety and Depression Score. Occupational Medicine 2014;64:393–394
17. EuroQol Research Foundation 2018. EQ-5D Instruments. https://euroqol.org/eq-5d-instruments/. Accessed 19.11.2018
18. National Clinical Coding Standards OPCS-4 (2017) - NHS Digitalhttps://hscic.kahootz.com/gf2.ti/f/762498/27837541.1/.../-/NCCSOPCS42017.pdf
19. McCormack HM, Horne DJ, Sheather S. Clinical applications of visual analogue scales: a critical review. Psychol Med 1988;18:1007–1019
20. Beard D, Rees J, Rombach I et al. The CSAW Study (Can Shoulder Arthroscopy Work?)—a placebo-controlled surgical intervention trial assessing the clinical and cost effectiveness of arthroscopic subacromial decompression for shoulder pain: study protocol for a randomised controlled trial.Trials. 2015; 16: 210
21. Kukkonen J, Kauko T, Vahlberg T et al Investigating minimal clinically important difference for Constant score in patients undergoing rotator cuff surgery. J Shoulder Elbow Surg 2013;22:1650–1655
22. Salaffi F, Stancati A, Silvestri CA et al. Minimal clinically important changes in chronic musculoskeletal pain intensity measured on a numerical rating scale. Eur J Pain 2004;8:283-91
23. Beard DJ, Carr AJ, Cook JA et al. Can Shoulder Arthroscopy Work? (CSAW) trial – Authors' reply. Lancet. July 28, 2018

10 Clinician comments after three week consultation of the draft evidence review

	Clinician	Comment	SPH response
4 Dec 2018	Samuel Chan, Consultant Shoulder & Elbow Surgeon, Trauma & Orthopaedics, Queen Elizabeth Hospital, University Hospitals Birmingham NHS Foundation Trust	Thank you for the opportunity to contribute my thoughts. With regard to the clinical problem of subacromial impingement and the role of decompression surgery, I agree with the findings of the studies referenced and that the majority do not require surgical decompression, if the problem is isolated to impingement alone. The clinical problem is that there are other structural causes of pain that may be addressed during arthroscopic shoulder surgery including ACJ pathology, long head of biceps pathology and cuff tear pathology. All these other pathologies have been excluded from the referenced studies to allow better definition of subacromial impingement and to try to standardise outcomes. Unfortunately, subacromial impingement as an isolated entity is uncommon, and one which I do not tend to list for surgery without a prolonged trial of physiotherapy +/- steroid injection. In reality, the referenced studies are only relevant to handful of cases per year in my clinical practice. In this cohort of cases, patients with prolonged symptoms are usually keen to try surgical decompression as conservative measures have	Thank you for these helpful comments. All 3 RCTs [4, 6,7] included patients with a partial thickness rotator cuff tear. In the CSAW RCT, 55/172 patients who received surgery had a partial thickness tear (31/89 allocated to ASD, 22/80 allocated to diagnostic arthroscopy only and 2/24 patients initially allocated to no treatment). The results from these RCTs are not limited to those patients with isolated impingement syndrome. We note your comment that isolated subacromial impingement is rare. Whilst coding procedures is not always accurate, we note (table 3 above) that there were 2126 ASD procedures performed without tenotomy or any rotator cuff tear repair) between April 2015 and March 2018. Table 6 indicates that in the 2410 patients who had ASD +/- tenotomy (284/2410 had ASD+tenotomy), the primary diagnosis was M754: Impingement syndrome of the shoulder. No related diagnoses were reported. The only trial to compare ASD to no treatment at all was the CSAW RCT [4]. This did show a statistically significant improvement at both 6 months and 1 year in OSS for both ASD and diagnostic arthroscopy only when compared to no treatment (see below). However, the size of the difference was less than 6 points on the OSS and therefore did not meet the criteria

		failed – and anecdotally, these patients have done well post surgery. On the flip side, patients can present to clinic with imaging showing pathology in the shoulder and are listed accordingly. These patients may not have a cuff tear on long head of biceps pathology intra-operatively and end up only having a subacromial decompression. Unfortunately, any imaging modality is not 100% specific or sensitive. It is difficult to change the treatment algorithm in this group, as if they are symptomatic, I would normally recommend proceeding with arthroscopic surgery. It would be inappropriate to not fund surgery for this cohort of	required to be considered clinically important [12]. All patients had improved OSS at 6 and 12 months (including those who received no treatment). It is not clear to what extent the improvement in OSS observed in the ASD and diagnostic arthroscopy groups might be attributable to post-operative physiotherapy or placebo effect.  Beard et al 2018 [4]. The three RCTs were also at risk of recruiting patients with additional pathology, as you describe in your clinical practice. As stated above, the results apply to patients with subacromial pain with or without a partial rotator cuff tear. We have reviewed the guideline (http://www.bess.org.uk/application/files/2914/8127/3402/Subacromial_Shoulder_Pain.pdf) and note that it recommends that, *"In the absence of a rotator cuff tear, if impingement*

		patients. In light of the CSAW trial, the British Shoulder & Elbow Society have tried to engage with NICE to develop and update the pathway, but unfortunately, there is little inclination to do that at this stage. At the moment, it is probably most helpful to refer you to the Subacromial shoulder pain pathway developed by the British Shoulder & Elbow Society in conjuction with the British Orthopaedic Asssociation: http://www.bess.org.uk/media/Research%20Committee/National%20Guidelines/Subacromial%20Shoulder%20Pain.pdf It is easily accessible and useful for the framework of managing shoulder pain.	*symptoms fail to resolve with conservative treatment, subacromial decompression surgery (acromioplasty) is recommended."* This recommendation appears to conflict with the results from the 3 RCTs which suggest that in patients who have already failed conservative treatment, that ASD plus physiotherapy does not result in a clinically significant difference when compared to diagnostic arthroscopy (12 and 24month follow up)[4,6], physiotherapy only (24 month follow up) [6,7] or no treatment (12 month follow up)[4]. The guideline then explains that *"Subacromial decompression (acromioplasty) surgery aims to excise the bony spur on the antero-inferior surface of the acromion. The operation also involves excision of bursal tissue on the under surface of the acromion and release of the coraco-acromial ligament. The procedure aims to increase the volume of the subacromial space, thereby reducing the mechanical attrition and painful irritation of the rotator cuff tendons."* If increasing the subacromial space is effective, this does not explain why there was no clinically significant different at either 12-month follow-up [4] or 24 months [6] between ASD plus physiotherapy and diagnostic arthroscopy plus physiotherapy. This was consistent for all of the outcomes measured: Oxford Shoulder Score (OSS), Constant score, pain, depression and anxiety, health-related quality of life, simple shoulder test and 15D as well as patient satisfaction with the allocated treatment.

04 Dec. 2018	Mr. Samir Massoud, Consultant Trauma & Orthopaedics, Queen Elizabeth Hospital, University Hospitals Birmingham NHS Foundation Trust	Thanks, Totally agree with the analysis for ASD for shoulder impingement. However, I would caution against including ASD+/ tenotomy and cuff repair in this analysis as the primary procedure in this situation is the cuff repair not ASD. The evidence presented in the supraspinatus tear study indicates similar results at 1 year. However, this is misleading as degenerative cuff tears increase in size with time if not repaired and the results of ASD alone and physiotherapy in that situation are likely to deteriorate in the future whereas the results of cuff repair+ASD will be maintained in the long term. The larger size tears resulting from not repairing the rotator cuff are less likely to heal after future repair, may become irreparable and occasionally lead to patients requiring a muscle transfer or reverse shoulder replacement. The results of all these procedures are not as good as supraspinatus repair. I would be very concerned if this work gives the impression that cuff repairs are not necessary. It is interesting to see, provided the populations treated are similar, what proportion of patients in different practices are treated with ASD+/-tenotomy versus Cuff repair+ASD+/- tenotomy. I am not sure whether you have enough data to	Thank you for these helpful comments. We agree that the Kukkonen et al study focused on the hypothesis that *“rotator cuff repair yields superior results compared with the other treatment modalities”[10].* The study by Kukkonen et al [10] found that a one year follow up, there was no difference in outcome measured using the Constant score between those groups of patients treated with ASD+physiotherapy, ASD+RC repair+physiotherapy or 10 sessions of physiotherapy alone. However the RCT was limited to only 1 year follow up and not designed to establish the proportion of degenerative cuff tears which might become larger or irreparable. The long term outcomes for these patients with a symptomatic but untreated supraspinatus tears<75% was out of scope of this review. In addition, as this is a single, relatively small (n=180) RCT for this population with partial supraspinatus tears, some degree of caution about the interpretation of the results is reasonable. The scope of this review did not include systematic review of the effectiveness of supraspinatus tear repair. The data is available for further analysis should that be agreed. As far as we are aware, outpatient data is less sophisticated than HES and attendance is likely to only be recorded as a T&O outpatient attendance. The existence of an MSK referral hub may be able to provide further insight; this may require clinical audit.

		analyse what proportion of patients seen in outpatients with diagnosis of Shoulder impingement are treated with ASD and what non-operative measures they had prior to surgery. This would give a more accurate picture of current practice.	
14 Dec. 2018	Nigel Featherstone - combined response from UHB/HGS (not already received)	Mr Kalogrinanitis - considered low clinical value and not offered to patients. Mr Cooper - had already been issued by CCG to Shoulder surgeons but recirculating again for comments Mr Spurrier - supports comments by Mr Chen. Isolated impingement is rare, but there is a subset of patients who fail conservative management and do well with decompression surgery. However the majority of decompression surgery patients I have seen have had other pathology to address, which may have gone untreated had decompression not been funded by the relevant commissioner	We note your comment that isolated SIS is rare. However, as stated above the three RCTs did not exclude patients with partial rotator cuff tears. Whilst coding procedures is not always accurate we note (table 3 above) that there were 2126 ASD procedures performed without tenotomy or any rotator cuff tear repair) between April 2015 and March 2018. Table 6 indicates that in the 2410 patients who had ASD +/- tenotomy (284/2410 had ASD+tenotomy), the primary diagnosis was M754: Impingement syndrome of the shoulder

Appendix 1: Glossary of outcome measures used in the trials included in this review.

The Oxford Shoulder Score (OSS) is a patient-based questionnaire used to assess shoulder pain. It is a condition-specific questionnaire, completed unaided by the patient. It consists of 12 questions exploring pain (4 questions) and function (8 questions). Each item is scored from 1 to 5, from least to most difficulty or severity, and combined to produce a single score with a range from 12 (least difficulties) to 60 (most difficulties). [11].
The minimal clinically important difference (MCID) for the OSS in patients with SIS is 6 points [12].

Visual Analogue Scale (VAS) for Pain (VAS 0-100). In the FIMPACT RCT, patients rated the intensity of pain during activity and pain at rest at the actual time of assessment using a Visual Analogue Scale (VAS) (100 mm). Shoulder pain was assessed on a 100 mm scale ranging from 0 (no pain) to 100 (worst imaginable pain).
The MCID for pain measured using VAS(0-100) was 15 points [18].

Visual Analogue Scale (VAS) for Pain (VAS 0-10). In the RCT by Ketola et al [7], patients self-reported pain a Visual Analogue Scale (VAS) ranging from 0 to 10 with 0 indicating a high level of pain and 10 representing no pain.
The MCID for pain measured using VAS(0-10) was 2 points [21].

The Constant-Murley Score, also known as the Constant Score (CS) consists of both objective (range of motion (40 points) and strength (25 points)) and subjective patient reported measurements (pain (15 points), workload and leisure time activities (20 points)), which are summarised in a score between 0 and 100. A higher score indicates better shoulder function.
The total possible score is 100 points, indicating an asymptomatic and healthy person, while the worst score is 0 points.
The MCID for the Constant Score in patients with SIS is 11 points [12].

PainDETECT. The questionnaire consists of seven questions that address the quality of neuropathic pain symptoms; it is completed by the patient and no physical examination is required. The first five questions ask about the gradation of pain, scored from 0 to 5 (never = 0, hardly noticed = 1, slightly = 2; moderately = 3, strongly = 4, very strongly = 5). Question 6 asks about the pain course pattern, scored from –1 to 2, depending on which pain course pattern diagram is selected. Question 7 asks about radiating pain, answered as yes or no, and scored as 2 or 0 respectively. The final score between –1 and 38, indicates the likelihood of a neuropathic pain component. A score of 12 indicates that pain is unlikely to have a neuropathic component (< 15%), while a score of 19 suggests that pain is likely to have a neuropathic component (> 90%). A score between these values indicates that the result is uncertain.

The Simple Shoulder Test (SST) was developed to assess functional impairment of the patient's activities of daily living. The SST consists of 12 questions with yes (1) or no (0) response options. The maximum SST score is 12 indicating normal shoulder function, minimum score of 0 points refers severely diminished shoulder function.
The MCID for the SST in rotator cuff disease is 2 points [6].

The Shoulder Disability Questionnaire (SDQ) was developed to evaluate functional status limitation throughout self-assessment by patients with soft-tissue shoulder disorders. It consists of sixteen items with three answer options: Yes, No and Not Applicable (NA) with the meaning that the activity of the particular item had not been performed in the previous 24 hours. The ratio of the affirmative answers over the number of the applicable items is multiplied by 100 so the result is a percentage between 0 (no functional limitations) and 100 (affirmative answer to all applicable items). The SDQ is reported to have a good responsiveness and it is able to discriminate accurately between self-rated clinically stable and improved subjects [12].

HADS. Depression and anxiety was measured using the HADS (Hospital Anxiety and Depression Scale), a fourteen-item scale; seven of the items relate to anxiety (0-21 points) and seven relate to depression (0-21 points) [15]. Higher scores indicate a greater likelihood of depression or anxiety. For both scales, scores of less than 7 indicate non-cases; scores of 8 to 14 indicate mild to moderate anxiety or depression, whilst scores of 15 or more indicate severe anxiety or depression.

Health related quality of life (HRQoL). The EQ-5D is a standardized instrument designed to measure health-related quality of life (HRQoL) [16]. The EQ-5D consists of two parts: a descriptive system and the EQ-VAS. The descriptive system comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression for which there are 3 levels of severity in the EQ-5D-3L. The EQ-VAS records the patient's self-rated health on a vertical visual analogue scale.

The 15D instrument is a generic health-related quality of life (HRQoL) instrument comprising 15 dimensions concerning breathing, mental function, speech, vision, mobility, usual activity, vitality, hearing, eating, excretion, sleeping, distress, discomfort and symptoms, depression and sexual activity. For each dimension, the respondent must choose one of the five levels that best describes his/her state of health at that moment (the best level being 1 and the worst level being 5). A set of utility or preference weights is used in an addition aggregate formula to generate a single index number, the utility or 15D score. The maximum 15D score is 1 (no problems on any dimension) and the minimum score is 0 (being dead) [6].

Patient satisfaction and responder analysis. Patients' global assessment of satisfaction to the treatment was assessed on a VAS scale ranging from 0 (completely disappointed) to 100 (completely satisfied) with the question: 'Are you satisfied with the treatment you have received?'. In addition, patient satisfaction with the treatment outcome was elicited (using a 5 item scale) at each follow-up time point with the question 'How satisfied are you with the outcome of your treatment?'. Participants who reported very

satisfied or satisfied were categorised as 'Responders' and patients who responded very dissatisfied or dissatisfied were categorised 'Non-responders' [6].

Return to previous leisure activities. At each follow-up, participants were asked to respond to the following question: 'Have you been able to return to your previous leisure activities?' ('yes' or 'no') [6].

Competing Interest
All SPH authors have completed the ICMJE uniform disclosure form (www.icmje.org/coi_disclosure.pdf) and declare: grants from Solihull CCG, Birmingham CrossCity CCG and Birmingham South Central CCG to SPH to undertake the submitted work, no financial relationships with any organisations that might have an interest in the submitted work in the previous three years and no other relationships or activities that could appear to have influenced the submitted work.

Equality Analysis

(Health Inequalities, Human Rights, Social Value)

Policy for the use of Image Guided Therapeutic Intra-Articular Joint Injections.

Before completing this equality analysis it is recommended that you:

- ✓ Contact your equality and diversity lead for advice and support
- ✓ Take time to read the accompanying policy and guidance document on how to complete an equality analysis

NHS Birmingham and Solihull Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group

1. Background

EA Title	Image Guided Therapeutic Intra-Articular Joint Injections.		
EA Author	David King	**Team**	Equality & Diversity Team
Date Started	13/8/2019	**Date Completed**	04/12/2019
EA Version	4	**Reviewed by E&D**	

What are the intended outcomes of this work? Include outline of objectives and function aims

Arthritis refers to a clinical syndrome of joint pain accompanied by varying degrees of functional limitation and reduced quality of life. Arthritis is one of the leading causes of pain and disability worldwide. It is a chronic musculoskeletal disorder characterised by involvement of all joint structures including the synovial membrane, cartilage and bone. People with arthritis often have joint pain, reduced mobility, reduced participation in daily activities and poor quality of life [1].

The joints most commonly affected by arthritis are the knees, hips and small joints of the hand, although most joints can be affected. Pain, reduced function and effects on a person's ability to carry out their day-to-day activities can be important consequences of arthritis. Pain in itself is also a complex biopsychosocial issue, related in part to a person's expectations and self-efficacy (that is, their belief in their ability to complete tasks and reach goals), and is associated with changes in mood, sleep and coping abilities. There is often a poor link between changes visible on an X-ray and symptoms of arthritis: minimal changes can be associated with a lot of pain, or modest structural changes to joints can occur with minimal accompanying symptoms [2].

Contrary to popular belief, arthritis is not just caused by ageing and does not necessarily deteriorate. It is believed that a variety of traumas may trigger the need for a joint to repair itself which may result in a structurally altered but symptom-free joint. However, in some people, because of either overwhelming trauma or compromised repair, the process cannot fully compensate, resulting in eventual presentation with symptomatic arthritis; this might be thought of as 'joint failure'. This in part explains the extreme variability in clinical presentation and outcome that can be observed between people, and also at different joints in the same person [2].

Treatment options

A range of lifestyle, pharmacological, non-pharmacological, surgical and rehabilitation interventions are effective for controlling symptoms and improving function (NICE 2012). Conventional therapies include the use of simple analgesics, non-steroidal anti-inflammatory drugs, physical therapy and intra-articular (IA) corticosteroid administration [3].

NICE published Clinical Guideline (CG177) - Osteoarthritis: care and management in February 2014 [2]. The guidelines made the following recommendations regarding intra-articular injections;

- Intra-articular corticosteroid injections should be considered as an adjunct to core treatments for the relief of moderate to severe pain in people with osteoarthritis.

- Do not offer intra-articular hyaluronan injections for the management of osteoarthritis.

Intra-articular injections of corticosteroids have been used for several decades in the management of inflammatory and degenerative joint conditions when first line conservative therapies fail to provide adequate symptom relief [4].

Traditionally, intra-articular injections have been performed using anatomical landmarks to identify the correct trajectory for needle placement. However, different anatomical-guided injection techniques have yielded inconsistent intra-articular needle positioning due, in large part, to the fact that the physician cannot directly visualize the area of interest, and variations in anatomy are common. Incorrect needle placement has been partially associated with variable clinical outcomes.

Furthermore, inaccurate corticosteroid injections may result in complications such as post-injection pain, crystal synovitis, haemarthrosis, joint sepsis, necrosis, and steroid articular cartilage atrophy, as well as systemic effects, including fluid retention or exacerbation of hypertension or diabetes mellitus. Therefore, identification of methods and proper training to aid in correct needle placement during these procedures is warranted [4, 6].

The purpose of image guidance during corticosteroid joint injections is to allow visualisation, normally of the joint line typically in real time, so that the operator can achieve a more accurate and potentially safer and more effective injection [4, 5]. However clinical evidence demonstrates that visualisation of the joint line with image guidance only provides consistent improvement in injections techniques in the small joints of the hands and feet.

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

Therapeutic image guided intra-articular corticosteroid injections are **Restricted**.

Therapeutic image guided intra-articular corticosteroid injections should only be undertaken in the small joints (defined as joint of the hands & feet)

AND

Therapeutic image guided intra-articular corticosteroid injections should be offered ONLY to patients who have failed to respond to conventional pharmacological and non-pharmacological interventions due to the limited quality of evidence of the clinical and cost effectiveness of this intervention.

Pharmacological and non-pharmalogical interventions are defined as:

- Analgesics/nonsteroidal anti-inflammatory drugs (NSAIDs)
- Domestic exercise programme
- Supervised physiotherapy/manual therapy
- Non-image guided (palpated) steroid injections

N.B. Diagnostic image –guided injections are not within the remit of this policy.

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Activity data:

Number of Procedures	BSOL	Sandwell
	1577	534

Due to limited data collection by the providers service activity data is available by headcount only not protected characteristic.
The Joint Strategic Needs Assessments for Birmingham, Solihull and Sandwell are available via the links below.

Sandwell

Birmingham

Solihull

2. Research

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

Research/Publications	Working Groups	Clinical Experts
1. National Institute for Health and Clinical Excellence (NICE). Final Scope Osteoarthritis: the care and management of osteoarthritis. London, UK :NICE; 2012 https://www.nice.org.uk/guidance/cg177/documents/osteoarthritis-update-final-scope2 a. Last accessed 27 September 2018		

2. National Institute for Health and Clinical Excellence (NICE). Osteoarthritis: the care and management of osteoarthritis. Clinical Guideline 177. London, UK: NICE; 2014

3. Griesser MJ, Harris JD et al. Adhesive capsulitis of the shoulder: a systematic review of the effectiveness of intra-articular corticosteroid injections. J Bone Joint Surg Am 2011; 93: 1727-1733.

4. Berkoff DJ, Miller LE, Block JE. Clinical utility of ultrasound guidance for intra-articular knee injections: a review. Clin Interv Aging. 2012; 7:89-95.

5. Jüni P, Hari R et al. Intra-articular corticosteroid for knee osteoarthritis. Cochrane Database of Systematic Reviews 2015, Issue 10. Art. No.: CD005328

6. Nam SH, Kim J et al. Palpation versus ultrasound guided corticosteroid injections and short-term effect in the distal radioulnar joint disorder: A randomized, prospective single-blinded study. Clin Rheumatol 2013; 12:1807-1814.

7. Arthritis Research UK, Osteoarthritis in General Practice. 2013.

8. Wluka A, Lombard C, and Cicuttini F. Tackling obesity in knee osteoarthritis. Nature Reviews Rheumatology 2013; 9(4): 225-235.

9. Kearns K, Dee A et al. Chronic disease burden associated with overweight and obesity in Ireland: the effects of a small BMI reduction at population level. BMC Public Health 2014; 14(143)

10. Clemence P, Nguyen C et al. Risk factors and burden of osteoarthritis. Annals of Physical and Rehabilitation Medicine 2016 59 (3): 134–138.

11. Spector T and MacGregor A. Risk factors for osteoarthritis: genetics. Osteoarthritis and Cartilage 2004; 12: 39-44.

12. Berkoff DJ, Miller LE, Block JE. Clinical utility of ultrasound guidance for intra-articular knee injections: a review. Clin Interv Aging. 2012; 7:89-95

13. Jüni P, Hari R et al. Intra-articular corticosteroid for knee osteoarthritis. Cochrane Database of Systematic Reviews 2015, Issue 10. Art. No.: CD005328

14. Park KD, Kim TK et al. Palpation versus ultrasound-guided acromioclavicular joint intra-articular corticosteroid injections: a retrospective comparative clinical study. Pain Physician. 2015;18(4):333–341

15. Nam SH, Kim J et al. Palpation versus ultrasound guided corticosteroid injections and short-term effect in the distal radioulnar joint disorder: A randomized, prospective single-blinded study. Clin Rheumatol 2013; 12:1807-1814.

16. Sibbitt WL Jr, Band PA et al. A randomized controlled trial evaluating the costeffectiveness of sonographic guidance for intra-articular injection of the osteoarthritic knee. J Clin Rheumatol. 2011; 17(8):409–415.

17. Fraenkel L. Ultrasound (US)-Guided Versus Sham Ultrasound Corticosteroid (CS) Knee Injections. https://clinicaltrials.gov/ct2/show/NCT01032720

18. John Hopkins University. "Blind" vs. Fluoroscopy-Guided Steroid Injections for Knee Osteoarthritis. https://clinicaltrials.gov/ct2/show/NCT02104726

19. National Collaborating Centre for Chronic Conditions (UK). Osteoarthritis: National clinical guideline for care and management in adults. London: Royal College of Physicians (UK), 2008

20. Neogi T. The epidemiology and impact of pain in osteoarthritis. Osteoarthritis Cartilage 2013; 21: 1145-1153.

3. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

Age: Describe age related impact and evidence. This can include safeguarding, consent and welfare issues:

Age range data is not available for the profile of patients requesting the procedure. Some link may be identified between older patients and increased instances of joint pain, particularly in relation to arthritis.

As the treatment has been restricted, those who meet the criteria will be able to access treatment, who are the group who are deemed to benefit most. It is expected that patients not eligible would receive more suitable alternative treatment.

Disability: Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments:

As with age, pain is itself a life limiting condition and is commonly found as a co morbidity with other conditions. It has not been shown the restricting this treatment will impact on this group negatively since those who would benefit can access it.

Gender reassignment (including transgender): Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment:

No impact identified

Marriage and civil partnership: Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities:

No impact identified

Pregnancy and maternity: Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities:

No impact identified on the basis of available data

3. Impact and Evidence:
Race: Describe race related impact and evidence**.** This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers: No impact identified
Religion or belief: Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues: No impact identified
Sex: Describe any impact and evidence on men and women. This could include access to services and employment: No impact identified
Sexual orientation: Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers: No impact identified
Carers: Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities: No impact identified
Other disadvantaged groups: Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive) No impact identified

4. Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals?	No	This condition is not linked to any identified health inequality
Is there any impact for groups or communities living in particular geographical areas?	No	No impact identified

Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	No	No impact identified
How will you ensure the proposals reduce health inequalities?		

5. FREDA Principles/ Human Rights	Question	Response
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	Yes, this decision has been made in line with clinical recommendation and NICE guidance
Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	No impact of evidence from this policy
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	No discrimination identified
	How will this affect a person's right to freedom of thought, conscience and religion?	N/A
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	Policy will be applied with due regard to this consideration.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	An individual can discuss the impact with their GP and has the option for an IFR request to be made
Right to **Life**	Will or could it affect someone's right to life? How?	No impact of evidence from this policy
Right to **Liberty**	Will or could someone be deprived of their liberty? How?	No impact of evidence from this policy

6. Social Value
Consider how you might use the opportunity to improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.

Marmot Policy Objective	What actions are you able to build into the procurement activity and/or contract to achieve wider public benefits?
Enable all people to have control over their lives and maximise their capabilities	None
Create fair employment and good work for all	None
Create and develop health and sustainable places and communities	None
Strengthen the role and impact of ill-health prevention	None

7. Engagement, Involvement and Consultation

If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:

Engagement Activity	Protected Characteristic/ Group/ Community	Date

For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us …. So we will …..):

As part of the process further targeted engagement is planned with representative groups from among Birmingham and Solihull Patients. In addition, it has been identified that patient and clinician information is key in ensuring that the harmonised treatment policies review delivers effective outcomes. To this end an information briefing sheet on each procedure will be developed to give more information on the procedure, eligibility criteria and signposting to further information sources, such as NHS Choices. These information sheets are also designed to help facilitate discussions between GPs and patients. Information briefing sheets have already been tested for the first and second phases of harmonised treatment policies for Birmingham and Solihull CCG. Due regard will be given to both the accessible information standard and the potential need to translate such leaflets into relevant local languages.

The engagement team used every possible route throughout the engagement period to encourage people to feedback on the proposed policy. Unfortunately, despite the wide communication undertaken through all communication and engagement channels available, 49 questionnaires were completed online and there was little interest from stakeholders, patients and the public to attend any of the five stakeholder events arranged. As a result, the events were cancelled, and the engagement team looked at other routes to encourage engagement with patients directly. A possible reason for the general lack of interest and feedback from stakeholders, patients and the public is most likely because this clinical treatment policy is either widening the scope of the current service provision, providing policies to protect the current service provision or the intervention is for somewhat rare conditions.

Also, in phase 3 of the harmonisation of policies programme clinicians had been integral to the development of the policies from the beginning of the process. It could therefore be argued the proposed policy shared for public engagement was to some extent already informed from a local patient experience and outcomes perspective.

The potential impact on patients was therefore minimal as the treatment is offered based on specific criteria. Feedback from healthcare professionals suggested that image guidance for certain areas such as the hip (which is outside the scope of this policy) or smaller joint areas such as the hands (which are already accommodated for within the policy) was essential, however generally, there were mixed responses supporting the use of image guided technology. Responses also suggest that the decision of making this treatment available should be made by the practitioner performing the procedure based upon the individual patients' condition. Discussions with physiotherapist revealed that although these injections may only be offered once conservative methods have failed, in certain cases, the pain relief provided by this procedure may help patients in pain and give them the rest period needed to start rehabilitation. The therapeutic injections themselves will not be restricted by the policy only the use of image-guidance to deliver the injections. The injections will still be available as palpated injections.

8. Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work:

The restriction of this policy will have limited impact on those who would wish to receive the treatments, as it is the use of image guidance to deliver the therapeutic injection, not the injections itself which is being restricted and this must be balanced against the need to adhere to NICE guidelines and the clinical effectiveness evidence. The opportunity for any exceptional cases to be considered via IFR remains and will ensure treatment is available in an exceptional case.

9. Mitigations and Changes :

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.

None required

10. Contract Monitoring and Key Performance Indicators

Detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract (refer to NHS Standard Contract SC12 and 13):

This policy is not linked to a contract however, prospective providers remain bound by their contracts with the CCG.

11. Procurement

Detail the key equality, health inequalities, human rights, and social value criteria that will be included as part of the procurement activity (to evaluate the providers ability to deliver the service in line with these areas):

N/A

12. Publication

How will you share the findings of the Equality Analysis?

This can include: reports into committee or Governing Body, feedback to stakeholders including patients and the public, publication on the web pages. All Equality Analysis should be recommended for publication unless they are deemed to contain sensitive information.

Publication on the CCG's website.

Following approval all finalised Equality Analysis should be sent to the Communications and Engagement team for publication: bsol.comms@nhs.net

13. Sign Off

The Equality Analysis will need to go through a process of **quality assurance** by the Senior Manager for Equality and Diversity, Senior Manager for Assurance and Compliance or Equality and Human Rights Manager **and** signed-off by a delegated committee

	Name	Date
Quality Assured By:		
Which Committee will be considering the findings and signing off the EA?		
Minute number (to be inserted following presentation to committee)		

Please send to Balvinder Everitt or Michelle Dunne, Equality, Diversity and Inclusion for Quality Assurance.

Once you have committee sign off, please send to Caroline Higgs, Communications & Engagement Team for publication: bsol.comms@nhs.net

Equality Analysis

(Health Inequalities, Human Rights, Social Value)

Policy for Adenoidectomy

Before completing this equality analysis it is recommended that you:

- ✓ Contact your equality and diversity lead for advice and support
- ✓ Take time to read the accompanying policy and guidance document on how to complete an equality analysis

NHS Birmingham and Solihull Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group

1. Background

EA Title	Adenoidectomy		
EA Author	David King	**Team**	Equality and Diversity Team
Date Started	13/08/2019	**Date Completed**	4/12/2019
EA Version	4	**Reviewed by E&D**	

What are the intended outcomes of this work? Include outline of objectives and function aims

Adenoids

Adenoids are small lumps of tissue at the back of the nose, above the roof of the mouth. You can't see a person's adenoids by looking in their mouth.
Adenoids are part of the immune system, which helps fight infection and protects the body from bacteria and viruses.

In most cases only children have adenoids. They start to grow from birth and are at their largest when a child is around three to five years of age. However there is a small group of adults where adenoids remain and may become enlarged.
By age seven to eight, the adenoids start to shrink and by the late teens, they're barely visible. By adulthood, in most people they will have disappeared completely.
Adenoids can be helpful in young children, but they're not an essential part of an adult's immune system.

Adenoids can sometimes become swollen or enlarged. This can happen after a bacterial or viral infection, or after a substance triggers an allergic reaction.
In most cases, swollen adenoids only cause mild discomfort and treatment isn't needed. However, for some, it can cause severe discomfort and interfere with their daily life.

Adenoidectomy

The adenoids can be removed during an adenoidectomy. The operation is usually carried out by an ear, nose and throat (ENT) surgeon and takes around 30 minutes. Afterwards, the patient will need to stay in the recovery ward for up to an hour until the anaesthetic has worn off.

Adenoidectomies are sometimes day cases if carried out in the morning, in which case you / your child may be able to go home on the same day. However, if the procedure is carried out in the afternoon, you / your child may need to stay in hospital overnight.

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

Eligibility Criteria: Restricted

<u>Adenoids may only be removed in the following clinical circumstances:</u>

- Documented medical problems caused by obstruction of the airway by enlarged adenoids **AND** all conservative treatments have been exhausted.

For the purposes of this eligibility criteria, a medical problem is defined as a medical problem that continually impairs sleep and/or breathing, e.g.

- difficulty sleeping – the patient has problems sleeping and may start to snore; in severe cases, some patients may develop sleep apnoea (irregular breathing during sleep and excessive sleepiness during the day) due to enlarged adenoids
- recurrent or persistent problems with the ears – such as middle ear infections (otitis media) or glue ear (where the middle ear becomes filled with fluid)
- recurrent or persistent sinusitis – leading to symptoms such as a constantly runny nose, facial pain and nasal-sounding speech
- All clinical circumstances which meet the above eligibility criteria, must have failed conservative medical treatment, before being eligible for surgical intervention.

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

Activity data 2018/19

Number of Procedures	BSOL	Sandwell
	6,786	2,281

Number of procedures undertaken overall and by CCG

Due to limited data collection by the providers service activity data is available by headcount only not protected characteristic.
The Joint Strategic Needs Assessments for Birmingham, Solihull and Sandwell are available via the links below.

Sandwell

Birmingham

Solihull

This means (for patients who DO NOT meet the above criteria) the CCG will only fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

2. Research

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

Research/Publications	Working Groups	Clinical Experts
Guidance 1. NHS. Adenoids & Adenoidectomy 29.12.2016. https://www.nhs.uk/conditions/adenoids-and-adenoidectomy/ 2. Kamel RH[1], Ishak EA. 1990 Enlarged adenoid and adenoidectomy in adults: endoscopic approach and histopathological study. J Laryngol Otol. 1990 Dec;104(12):965-7. 3. Torretta S[1,2], Guastella C[3], Ibba T[4], Gaffuri M[5], Pignataro L[6] Prevalence of adenoid hypertrophy: A systematic review and meta-analysis. Clin Med. 2019 May 15;8(5). pii: E684. doi: 10.3390/jcm8050684. 4. Torretta S[1,2], Guastella C[3], Ibba T[4], Gaffuri M[5], Pignataro L[6] Surgical Treatment of Paediatric Chronic Rhinosinusitis. https://www.ncbi.nlm.nih.gov/pubmed/31096610 5. Vanneste P[1], Page C[1]. Otitis media with effusion in children: Pathophysiology, diagnosis, and treatment. A review. J Otol. 2019 Jun;14(2):33-39. doi: 10.1016/j.joto.2019.01.005. Epub 2019 Jan 31. https://www.ncbi.nlm.nih.gov/pubmed/31223299 6. Kugelman N[1,2], Ronen O[1,2], Stein N[3,2], Huberfeld O[1,2], Cohen-Kerem R[1,4,2]. Adenoid Obstruction Assessment in Children: Clinical Evaluation Versus Endoscopy and Radiography. Isr Med Assoc J. 2019 Jun;21(6):376-380. https://www.ncbi.nlm.nih.gov/pubmed/31280504 7. Durgut O[1], Dikici O[2]. The effect of adenoid hypertrophy on hearing thresholds in children with otitis media with effusion. Int J Pediatr		

Otorhinolaryngol. 2019 Jun 1;124:116-119. doi: 10.1016/j.ijporl.2019.05.046. https://www.ncbi.nlm.nih.gov/pubmed/31176025 8. Pereira L[1], Monyror J[2], Almeida FT[3], Almeida FR[4], Guerra E[5], Flores-Mir C[6], Pachêco-Pereira CPrevalence of adenoid hypertrophy: A systematic review and meta-analysis. Sleep Med Rev. 2018 Apr;38:101-112. doi: 10.1016/j.smrv.2017.06.001. Epub 2017 Jun 14. https://www.ncbi.nlm.nih.gov/pubmed/29153763		

3. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

Age: Describe age related impact and evidence. This can include safeguarding, consent and welfare issues:

There is an increased normal prevalence of adenoids in those who are under the age of adolescence. In most cases, by adulthood they will have disappeared completely.

Disability: Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments:

No impact identified

Gender reassignment (including transgender): Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment:

No impact identified

Marriage and civil partnership: Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities:

No impact identified

3. Impact and Evidence:
Pregnancy and maternity: Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities: No impact identified
Race: Describe race related impact and evidence**.** This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers: No impact identified
Religion or belief: Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues: No impact identified
Sex: Describe any impact and evidence on men and women. This could include access to services and employment: No impact identified
Sexual orientation: Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers: No impact identified
Carers: Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities: No impact identified
Other disadvantaged groups: Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive) No impact identified

4. Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals?	No	This condition is not linked to a

4. Health Inequalities	Yes/No	Evidence
		health inequality.
Is there any impact for groups or communities living in particular geographical areas?	No	No impact identified
Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	No	No impact identified
How will you ensure the proposals reduce health inequalities? No impact identified		

5. FREDA Principles/ Human Rights	Question	Response
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	Yes, this decision has been made in line with clinical recommendation and NICE guidance.
Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	No evidence of impact from this policy
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	No discrimination identified
	How will this affect a person's right to freedom of thought, conscience and religion?	N/A
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	Policy will be applied with due regard to this consideration.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	An individual can discuss the impact with their GP and has the option for an IFR request to be made
Right to **Life**	Will or could it affect someone's right to life? How?	No evidence of impact from this policy
Right to **Liberty**	Will or could someone be deprived of their liberty? How?	No evidence of impact on this policy

6. Social Value

Consider how you might use the opportunity to improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.

Marmot Policy Objective	What actions are you able to build into the procurement activity and/or contract to achieve wider public benefits?
Enable all people to have control over their lives and maximise their capabilities	None
Create fair employment and good work for all	None
Create and develop health and sustainable places and communities	None
Strengthen the role and impact of ill-health prevention	None

7. Engagement, Involvement and Consultation

If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:

Engagement Activity	Protected Characteristic/ Group/ Community	Date

For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us …. So we will …..):

As part of the process further targeted engagement is planned with representative groups from among Sandwell, Birmingham and Solihull Patients. In addition, it has been identified that patient and clinician information is key in ensuring that the harmonised treatment policy review delivers effective outcomes. To this end an information briefing leaflet on each procedure has been developed to give more information on the procedure, eligibility criteria and signposting to further information sources, such as NHS Choices. These information sheets are also designed to help facilitate discussions between GPs and patients. Information briefing leaflets have already been tested for the Phase 1 and Phase 2 policies in the Harmonised Clinical Treatment Policy Programmes for Birmingham and Solihull CCG and for Sandwell and West Birmingham CCG. Due regard will be given to both the accessible information standard and the potential need to translate such leaflets into relevant local languages.

The engagement team used every possible route throughout the engagement period to encourage people to feedback on the proposed policy. Unfortunately, despite the wide communication undertaken through all communication and engagement channels available, 49 questionnaires were completed online and there was no interest from stakeholders, patients and the public to attend any of the five stakeholder events arranged. As a result, the events were cancelled, and the engagement team looked at other routes to encourage engagement with patients directly. A possible reason for the general lack feedback from stakeholders, patients and the public is most likely due to

7. Engagement, Involvement and Consultation

this clinical treatments policy widening the scope of the current service provision to include adults as opposed to further restricting access for patients.

Also, in Phase 3 of the Harmonised Clinical Treatment Policy Programme clinicians had been integral to the development of the policies from the beginning of the process. It could therefore be argued the proposed policy shared for public engagement was to some extent already informed from a local patient experience and outcomes perspective.

As the scope of this policy was to widen the treatment so it is also available to adults, the potential impact on patients is therefore minimal. Approximately 67% of respondents agreed with the proposed policy and was seen as a positive improvement to allow adults who may suffer with this condition within the eligibility criteria.

8. Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work:

The restriction of this policy will have limited impact on those who would wish to receive the treatments. This must be balanced against the need to adhere to the clinical effectiveness evidence and when all other conservative treatments have been exhausted.

Only when documented medical problems caused by obstruction of the airway which continually impairs sleep and/or breathing by the enlarged adenoids will surgical intervention be necessary.

It is noted that investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

The opportunity for any exceptional cases to be considered via IFR remains.

9. Mitigations and Changes :

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.

None identified

10. Contract Monitoring and Key Performance Indicators

Detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract (refer to NHS Standard Contract SC12 and 13):

This policy is not linked to a contract however, prospective providers remain bound by their contracts with the CCG.

11. Procurement

Detail the key equality, health inequalities, human rights, and social value criteria that will be included as part of the procurement activity (to evaluate the providers ability to deliver the service in line with these areas):

N/A

12. Publication

How will you share the findings of the Equality Analysis?

This can include: reports into committee or Governing Body, feedback to stakeholders including patients and the public, publication on the web pages. All Equality Analysis should be recommended for publication unless they are deemed to contain sensitive information.

Publication on the CCG's website.

Following approval all finalised Equality Analysis should be sent to the Communications and Engagement team for publication: bsol.comms@nhs.net

13. Sign Off

The Equality Analysis will need to go through a process of **quality assurance** by the Senior Manager for Equality and Diversity, Senior Manager for Assurance and Compliance or Equality and Human Rights Manager **and** signed-off by a delegated committee

	Name	Date
Quality Assured By:		
Which Committee will be considering the findings and signing off the EA?		

Minute number (to be inserted following presentation to committee)		

Please send to Balvinder Everitt or Michelle Dunne, Equality, Diversity and Inclusion for Quality Assurance.

Once you have committee sign off, please send to Caroline Higgs, Communications & Engagement Team for publication: bsol.comms@nhs.net

Equality Analysis

(Health Inequalities, Human Rights, Social Value)

Policy for Bariatric Surgery in Adults

Before completing this equality analysis it is recommended that you:

- ✓ Contact your equality and diversity lead for advice and support
- ✓ Take time to read the accompanying policy and guidance document on how to complete an equality analysis

NHS Birmingham and Solihull Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group

1. Background

EA Title	Policy for Bariatric Surgery in Adults		
EA Author	David King	**Team**	
Date Started	4/7/2019	**Date Completed**	4/12/2019
EA Version	4	**Reviewed by E&D**	

What are the intended outcomes of this work? Include outline of objectives and function aims

Obesity is commonly defined as a Body Mass Index (BMI) of 30 kg/m2 or greater (see Table 1). Individuals living with obesity are at greater risk of a variety of different health conditions. These include type 2 diabetes mellitus (T2DM), non-alcoholic fatty liver disease, hypertension, asthma, gastro-oesophageal reflux disease, depression and a variety of other conditions [1]. The risk of developing obesity-related co-morbidities increases as an individual's BMI increases [2].

Table 1.

Definition	BMI range (kg/m2)
Underweight	Under 18.5
Normal	18.5 to less than 25
Overweight	25 to less than 30
Obese	30 to less than 40
Obese I	30 to less than 35
Obese II	35 to less than 40
Morbidly obese	40 and over

Source: NICE. Obesity: identification, assessment and management [1]

Epidemiology

Obesity is a global problem, estimated to have affected over six hundred million adults worldwide in 2014 [14]. In England, in both men and women, more than one in four adults are obese (28.2%) and 2.7% are classed as morbidly obese [15].

The prevalence of obesity in the UK rose between 1993 and 2014, the rate of increase began to slow in 2001 but the overall trend is still continuing to rise. According to the Health Survey for England, 61.7% of adults were overweight or obese in 2014, with more men being obese (65.3%) than women (58.1%) [16, 17]. Over the same time period, the prevalence of morbid obesity has also continued to climb, with a sharp rise in female prevalence between 2007 and 2011 (see Figure 4). Whilst the trend for males appears to have levelled off in recent years, the current level still represents a sizeable increase from that seen in the early 1990's. The number of people classed as obese in

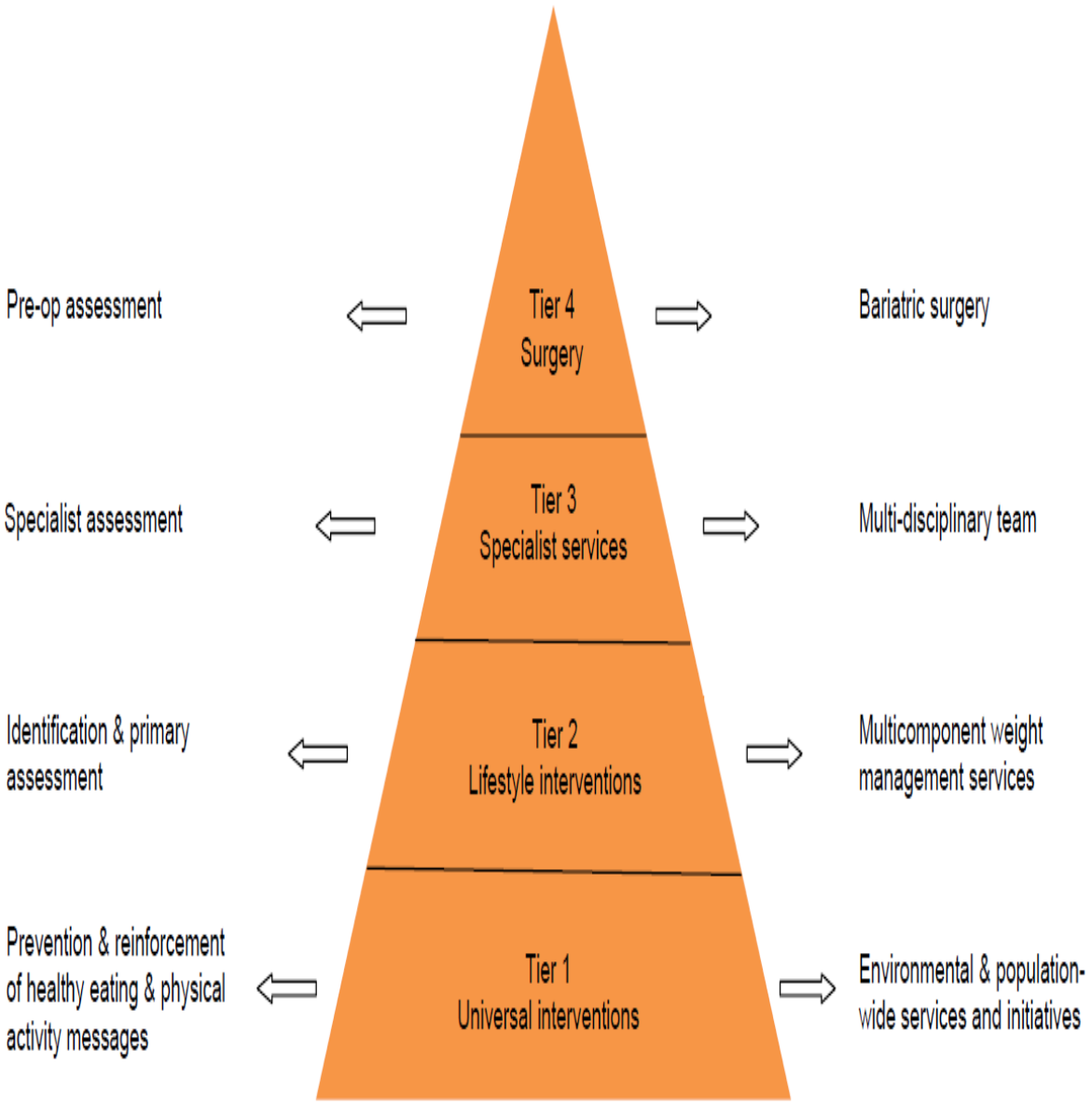
the UK is expected to increase by 11 million by 2030, with a likely corresponding increase in those with morbid obesity [18].

According to forecasts produced by the World Health Organisation, 31% of men and 30% of women will be obese by 2020, rising to 36% and 33% respectively by 2030 [19].

National Guidance

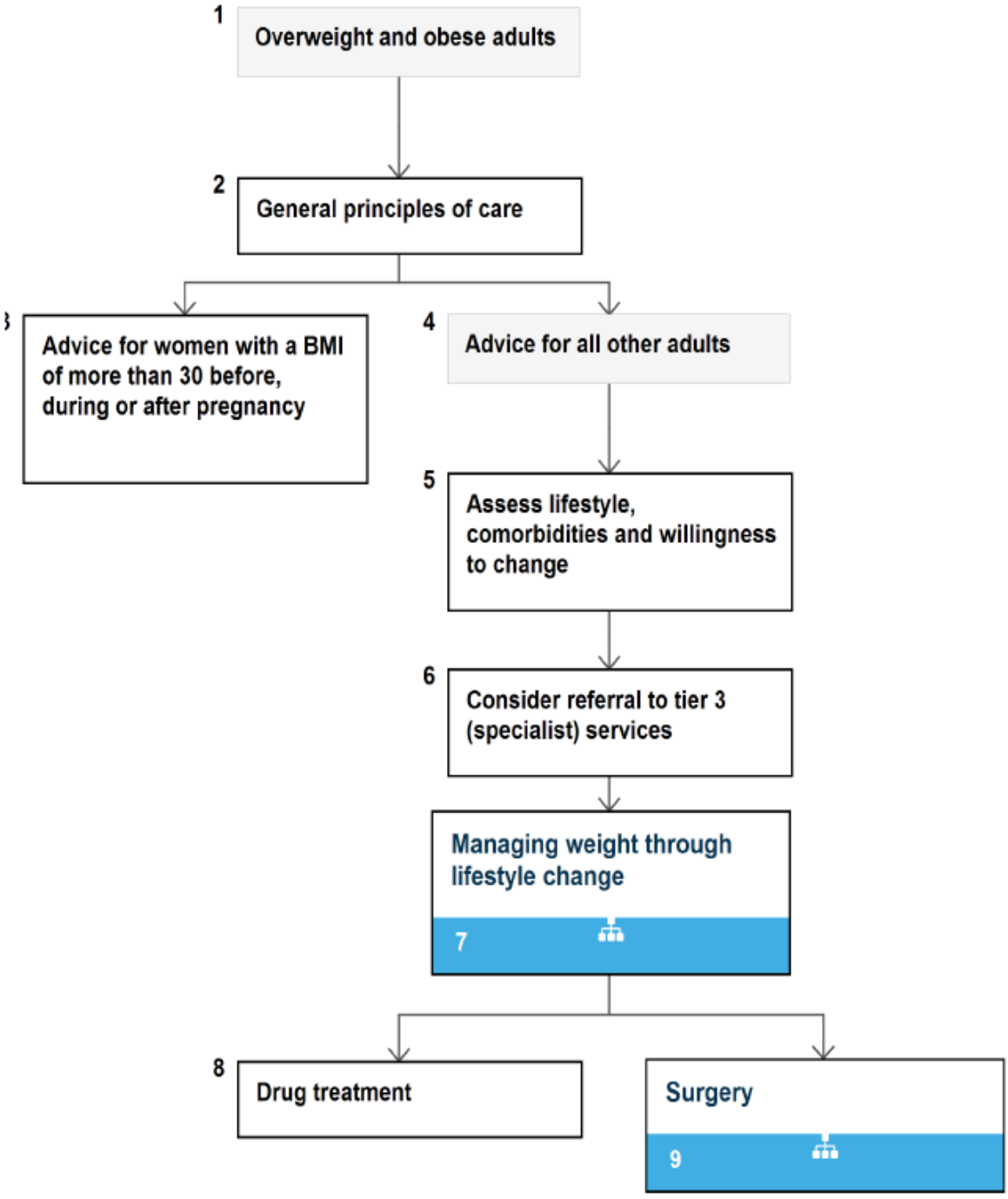
In England, obesity is managed through a tiered system (Figure 1), ranging from preventive population-based health promotion strategies (Tier 1) and lifestyle interventions (including diet, exercise, and behavioural) in primary care settings (Tier 2), through to more intensive specialist services provided by multi-disciplinary teams (Tier 3) and bariatric surgery (Tier 4) [3].

Figure 1: Tiered management of obesity



In November 2014, NICE published clinical guidance on the identification, assessment and management of obesity (NICE clinical guideline 189). [1]. The proposed NICE pathway is outlined below in Figure 2.

Figure 2: NICE pathway for overweight and obese adults



Co-Morbidities

The health issues associated with being overweight or obese include type 2 diabetes mellitus, cardiovascular disease and musculoskeletal disorders amongst others. People aged 35 to 59 with a BMI measurement of between 40 kg/m2 and 50 kg/m2 are five

times more likely to die from ischaemic heart disease than those with a BMI of 22.5 kg/m2 to 25 kg/m2.

Between the same groups, the risk of dying from stroke was 6.5 times higher and the risk of dying from diabetes was 22.5 times higher. Vascular risk factors also exhibit a strong relationship with BMI; both systolic and diastolic blood pressure increases with BMI [20].
The prevalence of diabetes amongst those with normal weight was around 1.5%, compared to 15% in the severely obese [20].
On its own, BMI is a strong predictor of mortality and is strongly associated with diabetes for which sex-specific prevalence may rise more than five-fold from baseline across the BMI range. Table 3 shows a simplified version of the relationship between BMI and health risk.

Table 3: Co-Morbidity Risk by BMI Classification

Classification	BMI (kg/m2)	Risk of Obesity Related Co-Morbidities
Underweight	<18.5	Low risk (but risk of other clinical problems increased)
Normal Range	18.50 – 24.99	Average risk
Overweight	≥25.0	Increased risk
Obese	≥30.0	Medium to high risk
Morbidly Obese	≥40.0	Very high risk

Non-Surgical Interventions

Non-surgical interventions for obesity consist of a wide variety of measures which may be used in varying combinations as part of a multi-component pathway. Generally, this comprises dietary intake, physical activity levels and behaviour change and may also include pharmacological interventions [25]. These should be clinically led and involve multi-disciplinary assessment [13].

The current Tier 3 offer differs across Birmingham and Solihull and is going through a process of harmonisation whereby Tier 3 service are being modelled to accommodate a range of patients in need of clinically-led weight management support. Once finalised, the patient will follow the Tier 3 commissioned pathway.

The Tier 3 service should be provided via a multidisciplinary team containing a bariatric physician, dietitian, specialist nurse, clinical psychologist and a liaison psychiatry professional. In addition to this there should also be access to a physical therapist.

Non-surgical weight-management interventions (also known as ‘Lifestyle Interventions’) are commonly split into four categories:
1. Behavioural interventions
2. Physical activity
3. Behaviour change

4. Pharmacological interventions.

Interventions should be seen as multicomponent and incorporate combinations of the interventions described below.

Behavioural interventions

Behavioural interventions are provided with the support of an appropriately trained professional and include various strategies for adults which are incorporated as appropriate. These include (but are not limited to) self-monitoring of behaviour and progress, stimulus control, goal setting, ensuring social support is available, cognitive restructuring (modifying thoughts), reinforcement of changes and providing strategies for dealing with weight regain [1].

Physical Activity

Encouragement should be given to increase levels of physical activity, regardless of whether this will lead to weight-loss. This is due to the general fitness improvements it can bring and the associated reduced risk of cardiovascular disease and type 2 diabetes. This may comprise of 45-60 minutes of moderate-intensity exercise per day, increasing to 60-90 minutes for those who have already lost weight to prevent regaining of excess weight. Suitable activities include brisk walking, gardening, cycling, supervised exercise programmes, swimming, stair-climbing etc [1].

Dietary

Dietary interventions should not be unduly restrictive but should be tailored to individual food preferences and also be nutritionally balanced. As with physical activity, dietary improvements should be encouraged for reasons other than weight loss alone due to the associated health benefits which a balanced diet can bring. The primary requirement for a dietary intervention however is to reduce energy intake to a point below energy expenditure by approximately 600 kcal/day or by reducing fat content. This should be partnered with expert support and intensive follow-up. Low (800-1600 kcal/day) and very low (800 kcal/day or less) calorie diets should be used with some degree of caution due to issues around nutritional completeness [1].

Pharmacological Interventions

Pharmacological interventions should only be considered after behavioural, physical and dietary interventions have been started and evaluated. This applies especially to those service-users who have not achieved their target weight loss or have plateaued. It may also be utilised to maintain weight-loss as opposed to continuing weight loss [1]. Orlistat is the only pharmacological treatment for obesity currently recommended by NICE. This medication is a lipase inhibitor which works through preventing approximately a third of consumed fat from being absorbed, However, in addition to the well-documented side effects, there are potential issues related to the heightened risk of kidney problems [26].

Bariatric Surgery

Bariatric surgery includes a group of procedures that promote weight loss. They are usually performed laparoscopically, with decreased time in hospital and a shorter recovery time compared to open procedures. In the UK and Ireland, there were over 18,000 bariatric surgery operations in the three financial years ending 2011, 2012, and 2013; 95.4% of all primary operations were performed laparoscopically over this period [22]. More recently, minimally invasive surgical techniques also include robotic procedures, though their feasibility and safety are debated. Bariatric surgery may be categorised under three headings: restrictive; malabsorptive and combined procedures.

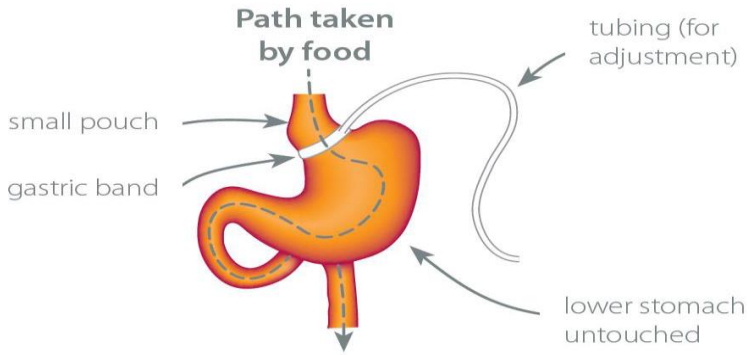
Restrictive procedures

Restrictive procedures, described below, lead to a fixed or adjustable reduction in the size of the upper gastrointestinal tract.

Adjustable gastric banding (AGB)

This procedure places an adjustable silicone band around the upper stomach, creating a small pouch above the band and a narrowing between the pouch and main part of the stomach below it (Figure 6). This restricts the amount of food that can be eaten and reduces hunger sensations by pressing on the surface of the stomach. The band may be tightened or loosened by injecting or removing saline through a portal under the skin that is connected to the band. The procedure is reversible and relatively non-invasive. AGB has replaced the older restrictive gastroplasty (horizontal, vertical, and banded) procedures that are no longer performed in the UK due to poorer performance. Gastric banding made up 22.3% of all bariatric surgery operations in the UK between 2011 and 2013 [22, 23, 24].

Figure 6: Diagrammatic representation of a gastric band in place

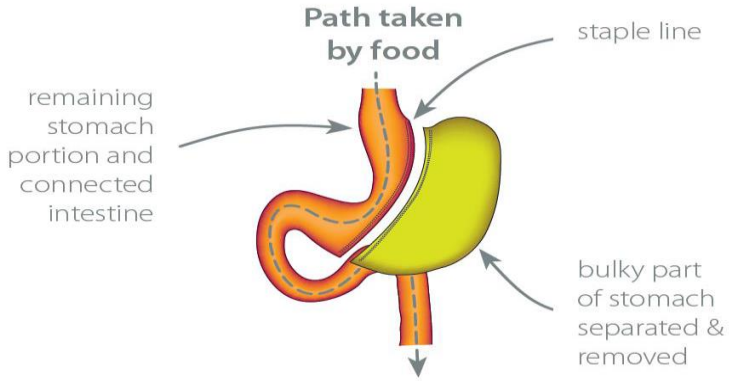


Source: National Bariatric Surgery Register. NSBR Second Registry Report. 2014 [22]

Sleeve gastrectomy (SG)

This procedure divides the stomach vertically to reduce its size by seventy-five percent, whilst keeping the stomach function and digestion unaltered by leaving the pyloric valve intact (see Figure 7). The procedure is not reversible but is relatively quick to perform and is one of the most commonly performed restrictive procedures. It was initially used as the first of a two-part procedure for patients at high risk from bariatric surgery, followed by a conversion to either a Roux-en-Y gastric bypass or a duodenal switch (see below). However, as some patients achieve significant weight loss with the sleeve gastrectomy alone, it is now also used as a stand-alone procedure. In some patients, the procedure may be followed by a duodenojejunal bypass, which involves bypassing the first part of the small intestine, resulting in food moving directly to the latter part of the small intestine, thereby reducing absorption of calories. SG made up 20.8% of all bariatric surgery operations in the UK between 2011 and 2013 [22]. A further 12 (0.07%) SG procedures were performed in combination with a biliopancreatic diversion with duodenal switch

Figure 7: The basics of a sleeve gastrectomy procedure



Source: National Bariatric Surgery Register. NSBR Second Registry Report. 2014 [22]

Intragastric balloon (IGB)

Intragastric balloon procedures involve placing a silicon balloon endoscopically to float freely inside the stomach, thereby reducing the volume of the stomach, leading to an earlier sensation of satiety. It is typically used either in patients who are at least 40% of their optimal weight, or in morbidly obese patients for whom surgery is high risk. IGB made up 2.1% of all bariatric surgery operations in the UK between 2011 and 2013 [22].

Gastric plication (or gastric imbrication)

A newer procedure that reduces the stomach volume by folding the stomach into itself and stitching it to create a narrow tube shape, similar to that of SG, but without removing any stomach tissue (Figure 6). The Registry report does not present the exact number or proportion of all November 2017 bariatric surgery operations that involve gastric plication. However, it is less than the 2.1% procedures labelled as ‘other’ in the Registry report [22].

Malabsorptive procedures

Malabsorptive procedures bypass a section of the intestine, with less physical restriction of food intake.

Biliopancreatic diversion (without duodenal switch)

This procedure is typically no longer performed in the UK due to risk of postgastrectomy syndrome (including, for example, dumping syndrome, bile reflux, diarrhoea). It involved portions of the stomach being removed through a horizontal gastrectomy (a restrictive procedure), with the small remaining pouch being connected to the final section of the small intestine. This is now replaced with the biliopancreatic diversion with duodenal switch (BDDS) procedure, which may be classed as a combined procedure (see group 3 below).

Jejunoileal bypass (JIB)

This procedure is no longer performed in the UK, where a significant part of the small intestine was detached and set to the side.

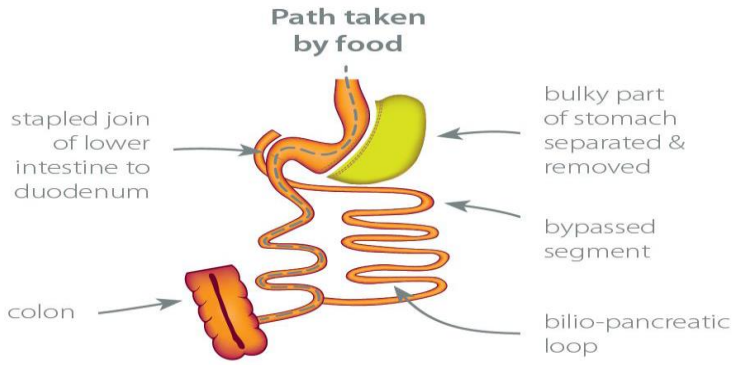
Combined procedures

Combined procedures include both restrictive and malabsorptive components.

Biliopancreatic diversion with duodenal switch (BDDS)

Biliopancreatic diversion with duodenal switch involves an initial restrictive vertical gastrectomy, followed by the malabsorptive component which re-routes a long portion of the small intestine, creating two separate pathways and one common channel (Figure 8). The shorter of the two pathways, the digestive loop, takes food from the stomach to the common channel. The longer pathway, the biliopancreatic loop, carries bile from the liver to the common channel. This procedure reduces the amount of time the body has to capture calories from food in the small intestine, and selectively limits the absorption of fat. The procedure is partially reversible, but there were only 19 BDDS procedures (0.1%), together with a further 12 procedures combined with SG in the UK between 2011 and 2013 [22].

Figure 8: Biliopancreatic diversion with duodenal switch

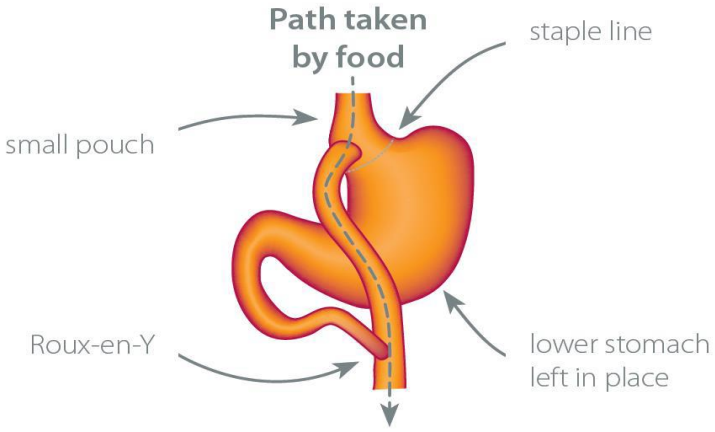


Source: National Bariatric Surgery Register. NSBR Second Registry Report. 2014 [22]

Roux-en-Y gastric bypass (RYGB)

Roux-en-Y gastric bypass has replaced the older banded gastric bypass, and involves creating a small pouch from the stomach which remains attached to the oesophagus at one end, and connected to a section of the small intestine at the other end, thereby bypassing the remaining stomach and the initial loop of small intestine (Figure 9). This procedure reduces intestinal absorption. Adaptations of the procedure have been used to increase malabsorption and increase weight loss. The procedure is technically reversible. Roux en Y gastric bypass comprises 52.1% of bariatric surgery in the United Kingdom [22].

Figure 9: Diagrammatic representation of a Roux-en-Y gastric bypass procedure



A key aim of this policy is to increase capacity and reduce waiting times for patients most in need of surgery, as set out in the criteria.

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

Eligibility Criteria: Restricted

Eligibility Criteria: Restricted

Patients eligible for surgery must have the following:

- BMI of >35kg/m2
  AND
  Type 2 diabetes mellitus which has been diagnosed within the last 10 years.
  OR
- BMI of >50kg/m2

The choice of surgery must be undertaken by a specialist bariatric surgeon following a shared decision making discussion with the patient:

- Listen to patients and respond to their concerns and preferences.
- Give patients the information they want or need in a way they can understand.
- Respect patients' right to reach decisions with the doctor about their treatment and care.
- Support patients in caring for themselves to improve and maintain their health.

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Activity data 2018/19

	BSOL	Sandwell
Number of Procedures	116	61

It is not possible to tell definitively from the data if any of the above procedures would not have been undertaken based on this policy however it is believed that these procedures undertaken represent patients who would receive bariatric surgery under this policy.

Number of procedures undertaken overall and by CCG

Due to limited data collection by the providers service activity data is available by headcount only not protected characteristic.
The Joint Strategic Needs Assessments for Birmingham, Solihull and Sandwell are available via the links below.

Sandwell

Birmingham

Solihull

2. Research

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

Research/Publications	Working Groups	Clinical Experts
Guidance 1. National Institute for Health and Care Excellence. Obesity: identification, assessment and management (CG189) [Internet]. 2014 [cited 2017 July 2017]; Available from: https://www.nice.org.uk/guidance/cg189/chapter/Introduction. 2. NHS England. Clinical Commissioning Policy: Complex and Specialised Obesity Surgery. 2013 3. Department of Health. Developing a specification for lifestyle weight management services. 2013 4. National Institute for Health and Care Excellence. Costing template: Obesity: identification, assessment and management of overweight and obesity in children, young people and adults (CG189) [Internet]. [cited 2017 July 31st];Available from: https://www.nice.org.uk/guidance/cg189/resources. 5. National Institute for Health and Care Excellence. Implantation of a duodenal–jejunal bypass sleeve for managing obesity (IPG471) [Internet]. [cited 2017 July 31st];Available from: https://www.nice.org.uk/guidance/IPG471 6. National Institute for Health and Care Excellence. Laparoscopic gastric plication for the treatment of severe obesity (IPG432) [Internet]. [cited 2017 July 31st];Available from: https://www.nice.org.uk/guidance/IPG432 7. National Institute for Health and Care Excellence. Overweight and obese adults - NICE Pathways [Internet]. [cited 2017 July 31st];Available from: http://pathways.nice.org.uk/pathways/obesity#path=view%3A/pathways/obesity/overweight-and-obese-adults.xml&content=view-index 8. Public Health England Obesity & Healthy Weight Team. Report of the working group into joined up clinical pathways for obesity.pdf [Internet]. 2014. Available from: https://www.england.nhs.uk/wp-content/uploads/2014/03/owg-join-clinc-path.pdf 9. PHE. National mapping of weight management services. 2015 10. National Institute for Health and Care Excellence. Weight management: lifestyle services for overweight or obese adults (PH53) [Internet]. 2014 [cited 2017 July 31st];Available from: https://www.nice.org.uk/guidance/ph53 11. National Institute for Health and Care Excellence. Managing weight through lifestyle change in adults - NICE Pathways [Internet]. [cited 2017 July 31st];Available from: https://pathways.nice.org.uk/pathways/lifestyle-		

weight-management-services-for-overweight-or-obese-adults#path=view%3A/pathways/lifestyle-weight-management-services-for-overweight-or-obese-adults/lifestyle-weight-management-services-for-overweight-or-obese-adults-overview.xml&content=view-index
12. National Institute for Health and Care Excellence. BMI: preventing ill health and premature death in black, Asian and other minority ethnic groups (PH46) [Internet]. 2013 [cited 2017 July 31st];Available from: https://www.nice.org.uk/guidance/PH46
13. Royal College of Surgeons. Commissioning guide: Weight assessment and management clinics (Tier 3). 2014.
14. World Health Organisation. Obesity and overweight factsheet [Internet]. WHO [cited 2017 July 31st];Available from: http://www.who.int/mediacentre/factsheets/fs311/en/
15. Public Health England Obesity Knowledge and Intelligence team. Adult Obesity Slide Set [Internet]. 2017 [cited 2017 July 31st];Available from: https://www.noo.org.uk/slide_sets
16. Health and Social Care Information Centre. Health Survey for England, 2014 [Internet]. 2015 [cited 2017 July 31st];Available from: http://www.hscic.gov.uk/catalogue/PUB19295
17. Public Health England Obesity Knowledge and Intelligence team. UK and Ireland prevalence and trends [Internet]. [cited 2017 July 31st];Available from: https://www.noo.org.uk/NOO_about_obesity/adult_obesity/UK_prevalence_and_trends
18. Wang YC, McPherson K, Marsh T, Gortmaker SL, Brown M. Health and economic burden of the projected obesity trends in the USA and the UK. The Lancet 2011;378(9793):815–25
19. World Health Organisation. Nutrition, Physical Activity and Obesity: United Kingdom of Great Britain and Northern Ireland [Internet]. 2013. Available from: http://www.euro.who.int/__data/assets/pdf_file/0020/243335/United-Kingdom-WHO-Country-Profile.pdf?ua=1
20. Public Health England Obesity Knowledge and Intelligence team. Severe Obesity [Internet]. [cited 2017 July31st];Available from: https://www.noo.org.uk/NOO_about_obesity/severe_obesity

21. Prospective Studies Collaboration. Body-mass index and cause-specific mortality in 900 000 adults: collaborative analyses of 57 prospective studies. Lancet 2009;373(9669):1083–96.
22. National Bariatric Surgery Register. NSBR Second Registry Report. 2014
23. Colquitt JL, Pickett K, Loveman E, Frampton GK. Surgery for weight loss in adults. Cochrane Database Syst Rev 2014;8:CD003641
24. National Obesity Observatory. Bariatric surgery for obesity. 2010
25. Gloy VL, Briel M, Bhatt DL, Kashyap SR, Schauer PR, Mingrone G, et al. Bariatric surgery versus non-surgical treatment for obesity: a systematic review and meta-analysis of randomised controlled trials. BMJ 2013;347:f5934

26. Beyea MM, Garg AX, Weir MA. Does orlistat cause acute kidney injury? Ther Adv Drug Saf 2012;3(2):53–7.
27. Picot J, Jones J, Colquitt JL, Gospodarevskaya E, Loveman E, Baxter L, et al. The clinical effectiveness and cost-effectiveness of bariatric (weight loss) surgery for obesity: a systematic review and economic evaluation. Health Technol Assess Winch Engl 2009;13(41):1–190, 215–357, iii–iv.
28. Hachem A, Brennan L. Quality of Life Outcomes of Bariatric Surgery: A Systematic Review. Obes Surg 2016;26(2):395–409.
29. Cheng J, Gao J, Shuai X, Wang G, Tao K, Cheng J, et al. The comprehensive summary of surgical versus non-surgical treatment for obesity: a systematic review and meta-analysis of randomized controlled trials. Oncotarget [Internet] 2016 [cited 2017 Aug 4th];5(0). Available from: http://www.impactjournals.com/oncotarget/index.php?journal=oncotarget&page=article&op=view&path%5B%5D=9581
30. Zhou X, Yu J, Li L, Gloy VL, Nordmann A, Tiboni M, et al. Effects of Bariatric Surgery on Mortality, Cardiovascular Events, and Cancer Outcomes in Obese Patients: Systematic Review and Meta-analysis. Obes Surg 2016;
31. The Cochrane Collaboration. Cochrane Handbook for Systematic Reviews of Interventions: 9.5.2 Identifying and measuring heterogeneity [Internet]. 2011 [cited 2017 Aug 4th];Available from: http://handbook.cochrane.org/chapter_9/9_5_2_identifying_and_measuring_heterogeneity.htm
32. The Cochrane Collaboration. Cochrane Handbook for Systematic Reviews of Interventions: 9.6.6 Interpretation of subgroup analyses and meta-regressions [Internet]. 2011 [cited 2017 Aug 4th];Available from: http://handbook.cochrane.org/chapter_9/9_6_6_interpretation_of_subgroup_analyses_and_meta_regressions.htm
33. Dixon JB, O'Brien PE, Playfair J, Chapman L, Schachter LM, Skinner S, et al. Adjustable gastric banding and conventional therapy for type 2 diabetes: a randomized controlled trial. JAMA 2008;299(3):316–23.
34. Dixon, Schachter LM, O'Brien PE, et al. Surgical vs conventional therapy for weight loss treatment of obstructive sleep apnea: A randomized controlled trial. JAMA 2012;308(11):1142–9.
35. Ikramuddin S, Korner J, Lee W-J, Connett JE, Inabnet WB, Billington CB, et al. Roux-en-Y Gastric Bypass versus Intensive Medical Management for the Control of Type 2 Diabetes, Hypertension and Hyperlipidemia: An International, Multicenter, Randomized Trial. JAMA J Am Med Assoc 2013;309(21):2240–9
36. Liang Z, Wu Q, Chen B, Yu P, Zhao H, Ouyang X. Effect of laparoscopic Roux-en-Y gastric bypass surgery on type 2 diabetes mellitus with hypertension: a randomized controlled trial. Diabetes Res Clin Pract 2013;101(1):50–6.
37. Mingrone G, Panunzi S, De Gaetano A, Guidone C, Iaconelli A, Leccesi L, et al. Bariatric Surgery versus Conventional Medical Therapy for Type 2 Diabetes. N Engl J Med 2012;366(17):1577–85.

38. O'Brien PE, Dixon JB, Strauss BJG, Laurie C. Changes in body composition with weight loss: obese subjects randomized to surgical and medical programs. Obes Silver Spring Md 2007;15(5):1187–98
39. Schauer PR, Kashyap SR, Bhatt DL, Wolski K, Watanabe RM, Abdul-Ghani M, et al. Metabolic Effects of Bariatric Surgery in Patients With Moderate Obesity and Type 2 Diabetes. Diabetes Care 2013;36(8):2175–82
40. Halperin F, Ding S-A, Simonson DC, Panosian J, Goebel-Fabbri A, Wewalka M, et al. Roux-en-Y Gastric Bypass Surgery or Lifestyle With Intensive Medical Management in Patients With Type 2 Diabetes. JAMA Surg 2014;149(7):716–26.
41. Ding S-A, Simonson DC, Wewalka M, Halperin F, Foster K, Goebel-Fabbri A, et al. Adjustable Gastric Band Surgery or Medical Management in Patients With Type 2 Diabetes: A Randomized Clinical Trial. J Clin Endocrinol Metab 2015;100(7):2546–56.
42. Mingrone G, Panunzi S, Gaetano AD, Guidone C, Iaconelli A, Nanni G, et al. Bariatric–metabolic surgery versus conventional medical treatment in obese patients with type 2 diabetes: 5 year follow-up of an open-label, single-centre, randomised controlled trial. The Lancet 2015;386(9997):964–73
43. Cummings DE, Arterburn DE, Westbrook EO, Kuzma JN, Stewart SD, Chan CP, et al.Gastric bypass surgery vs intensive lifestyle and medical intervention for type 2 diabetes: the CROSSROADS randomised controlled trial. Diabetologia. 2016 01 May;59(5):945-53
44. Schauer PR, Bhatt DL, Kirwan JP, Wolski K, Aminian A, Brethauer SA, et al. Bariatric Surgery versus Intensive Medical Therapy for Diabetes - 5-Year Outcomes. N Engl J Med. 2017 Feb 16;376(7):641-51
45. Borisenko O, Adam D, Funch-Jensen P, Ahmed AR, Zhang R, Colpan Z, et al. Bariatric Surgery can Lead to Net Cost Savings to Health Care Systems: Results from a Comprehensive European Decision Analytic Model. Obes Surg 2015;25(9):1559–68.
46. Gulliford MC, Charlton J, Booth HP, Fildes A, Khan O, Reddy M, et al. Costs and outcomes of increasing access to bariatric surgery for obesity: cohort study and cost-effectiveness analysis using electronic health records. Health Serv Deliv Res 2016;4(17):1–120
47. RAND Health. 36-Item Short Form Survey from the RAND Medical Outcomes Study [Internet]. [cited 2017 Aug 18th];Available from: https://www.rand.org/health/surveys_tools/mos/mos_core_36item.htm
48. Manwaring J, Wilfley D. The Impact of Weight on Quality of Life Questionnaire [Internet]. In: Preedy VR, Watson RR, editors. Handbook of Disease Burdens and Quality of Life Measures. Springer New York; 2010 [cited 2017 Aug 18th]. page 209–25.Available from: http://link.springer.com/referenceworkentry/10.1007/978-0-387-78665-0_12
49. National Institute for Health and Care Excellence. Type 2 diabetes in adults: management (NG28) [Internet]. 2015. Available from: https://www.nice.org.uk/guidance/ng28

50. Wang BCM, Furnback W. Modelling the long-term outcomes of bariatric surgery: A review of cost-effectiveness studies. Best Pract Res Clin Gastroenterol 2013;27(6):987–95
51. Clegg A, Colquitt J, Sidhu M, Royle P, Walker A. Clinical and cost effectiveness of surgery for morbid obesity: a systematic review and economic evaluation. Int J Obes Relat Metab Disord J Int Assoc Study Obes 2003;27(10):1167–77.
52. Terranova L, Busetto L, Vestri A, Zappa MA. Bariatric surgery: cost-effectiveness and budget impact. Obes Surg 2012;22(4):646–53.
53. Weiner JP, Goodwin SM, Chang H-Y, Bolen SD, Richards TM, Johns RA, et al. Impact of bariatric surgery on health care costs of obese persons: a 6-year follow-up of surgical and comparison cohorts using health plan data. JAMA Surg 2013;148(6):555–62.
54. Finkelstein EA, Allaire BT, Globe D, Dixon JB. The Business Case for Bariatric Surgery Revisited: A Non-Randomized Case-Control Study. PLOS ONE 2013;8(9):e75498
55. Karim MA, Clifton E, Ahmed J, Mackay GW, Ali A. Economic evaluation of bariatric surgery to combat morbid obesity: a study from the West of Scotland. Asian J Endosc Surg 2013;6(3):197–202
56. Picot J, Jones J, Colquitt JL, Loveman E, Clegg AJ. Weight Loss Surgery for Mild to Moderate Obesity: A Systematic Review and Economic Evaluation. Obes Surg 2012;22(9):1496–506.
57. Hoerger TJ, Zhang P, Segel JE, Kahn HS, Barker LE, Couper S. Cost-Effectiveness of Bariatric Surgery for Severely Obese Adults With Diabetes. Diabetes Care 2010;33(9):1933–9
58. Ackroyd R, Mouiel J, Chevallier J-M, Daoud F. Cost-effectiveness and budget impact of obesity surgery in patients with type-2 diabetes in three European countries. Obes Surg 2006;16(11):1488–503
59. Hernandez LV, Klyve D. Quality-adjusted life expectancy benefits of laparoscopic bariatric surgery: A United States perspective. Int J Technol Assess Health Care 2010;26(3):280–287.
60. Claxton K, Martin S, Soares M, Rice N, Spackman E, Hinde S, et al. Methods for the estimation of the National Institute for Health and Care Excellence cost-effectiveness threshold. Health Technol Assess Winch Engl 2015;19(14):1–503, v–vi.
61. Hex N, Bartlett C, Wright D, Taylor M, Varley D. Estimating the current and future costs of Type 1 and Type 2 diabetes in the UK, including direct health costs and indirect societal and productivity costs. Diabet Med J Br Diabet Assoc 2012;29(7):855–62.

3. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

3. Impact and Evidence:

Age: Describe age related impact and evidence. This can include safeguarding, consent and welfare issues:

Age range data is not available for the profile of patients requesting the procedure. Some link may be identified between obesity and reduced mobility.

As the treatment has been restricted, those who meet the criteria will be able to access treatment, who are the group who are deemed to benefit most. For patients not eligible alternative less invasive options are available to help reduce their BMI.

Disability: Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments:

As with age obesity is itself a life limiting condition and is commonly found as a co morbidity with other conditions. It has not been shown the restricting this treatment will impact on this group negatively since those who would benefit most can access surgery and for others alternative approaches are better.

It is noted that exercise may be more difficult / impossible for patients with some conditions which reduce mobility. In such case the approach would give due regard to reasonable adjustments.

Gender reassignment (including transgender): Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment:

No impact identified

Marriage and civil partnership: Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities:

No impact identified

Pregnancy and maternity: Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities:

3. Impact and Evidence:

No impact identified on the basis of available data, a link may be made between pregnancy and increased weight during and post birth.

Race: Describe race related impact and evidence**.** This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers:

Patients from BAME backgrounds (including South Asian and African Caribbean) have a higher risk of developing type 2 diabetes at a lower BMI. Therefore the criteria to be considered for Bariatric Surgery could have an adverse impact on people from these communities in the prevention of developing type 2 diabetes.

The TPCDG Committee spent considerable time discussing this issue and how to manage this. The criteria for surgery are in line with NICE recommendation for bariatric surgery, where the threshold for surgery is lower (i.e. BMI>35 as opposed to BMI>50) when the patient has type 2 diabetes to take into consideration the fact that those patient in certain ethnic groups have a higher risk of developing diabetes at a lower BMI.

Religion or belief: Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues:

No impact identified

Sex: Describe any impact and evidence on men and women. This could include access to services and employment:

No impact identified

Sexual orientation: Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers:

No impact identified

Carers: Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities:

No impact identified

Other disadvantaged groups: Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive)

3. Impact and Evidence:
No impact identified

4. Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals?	No	This condition could be linked to a health inequality due to the prevalence of obesity. As the surgical procedures remain available it is not anticipated that a health inequality will be made worse.
Is there any impact for groups or communities living in particular geographical areas?	Yes	A limited link between obesity and areas of high deprivation has been made.
Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	Yes	The ability to access better diet quality and exercise may be reduced for those in low socio economic groups. Due regard to this will need to be given in supporting such patients.
How will you ensure the proposals reduce health inequalities? The intention of the policy is to support patients with very high BMI through a number of interventions with surgery being the final option.		

5. FREDA Principles/ Human Rights	Question	Response

Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	Yes, this decision has been made in line with clinical recommendation and NICE guidance
Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	No evidence of impact from this policy
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	No discrimination identified
	How will this affect a person's right to freedom of thought, conscience and religion?	N/A
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	Policy will be applied with due Regard to this consideration.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	An individual can discuss the impact with their GP and has the option for an IFR request to be made
Right to **Life**	Will or could it affect someone's right to life? How?	No evidence of impact from this policy
Right to **Liberty**	Will or could someone be deprived of their liberty? How?	No evidence of impact from this policy

6. Social Value

Consider how you might use the opportunity to improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.

Marmot Policy Objective	**What actions are you able to build into the procurement activity and/or contract to achieve wider public benefits?**
Enable all people to have control over their lives and maximise their capabilities	None
Create fair employment and good work for all	None

Create and develop health and sustainable places and communities	None
Strengthen the role and impact of ill-health prevention	None

7. Engagement, Involvement and Consultation

If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:

Engagement Activity	Protected Characteristic/ Group/ Community	Date

For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us …. So we will …..):

As part of the process further targeted engagement is planned with representative groups from among Sandwell, Birmingham and Solihull Patients. In addition, it has been identified that patient and clinician information is key in ensuring that the harmonised treatment policies review delivers effective outcomes. To this end an information briefing sheets on each procedure will be developed to give more information on the procedure, eligibility criteria and signposting to further information sources, such as NHS Choices. These information sheets are also designed to help facilitate discussions between GPs and patients. Information briefing sheets have already been tested and uploaded onto the GP systems for the first 45 harmonised treatment policies for Birmingham and Solihull. Due regard will be given to both the accessible information standard and the potential need to translate such leaflets into relevant local languages.

The engagement team used every possible route throughout the engagement period to encourage people to feedback on the proposed policy. Unfortunately, despite the wide communication undertaken through all communication and engagement channels available, 49 questionnaires were completed online and there was no interest from stakeholders, patients and the public to attend any of the five stakeholder events arranged. As a result, the events were cancelled, and the engagement team looked at other routes to encourage engagement with patients directly where possible. A possible reason for the general lack of interest and feedback from stakeholders, patients and the public is most likely because this clinical treatments policy either widening the scope of the current service provision, providing policies to protect the current service provision or the intervention is for somewhat rare conditions.

Also, in phase 3 of the harmonisation of policies programme clinicians had been integral to the development of the policies from the beginning of the process. It could therefore be argued the proposed policy shared for public engagement was to some extent already informed from a local patient experience and outcomes perspective.

As there is currently no policy for the bariatric surgery to promote weight loss, the potential impact on patients was therefore minimal as the treatment will be offered based on specific criteria. Although over 50% agreed with the proposed policy criteria,

7. Engagement, Involvement and Consultation

healthcare professionals questioned the eligibility criteria. Particular concerns were also raised that the proposed policy may exclude those who are in drastic need of the surgery and may oppose current NICE guidelines.

8. Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work:

The restriction of this policy will have limited impact on those who would wish to receive the treatments, this must be balanced against the need to adhere to NICE guidelines and the clinical effectiveness evidence. The opportunity for any exceptional cases to be considered via IFR remains and will ensure treatment is available in an exceptional case.

9. Mitigations and Changes :

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.

Consideration will need to be given to what additional support patients from a low socio economic background will require and how due regard can be given to reasonable adjustments in approach for disabled persons.

10. Contract Monitoring and Key Performance Indicators

Detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract (refer to NHS Standard Contract SC12 and 13):

This policy is not linked to a contract however, prospective providers remain bound by their contracts with the CCG.

11. Procurement

Detail the key equality, health inequalities, human rights, and social value criteria that will be included as part of the procurement activity (to evaluate the providers ability to deliver the service in line with these areas):

N/A

12. Publication

How will you share the findings of the Equality Analysis?

This can include: reports into committee or Governing Body, feedback to stakeholders including patients and the public, publication on the web pages. All Equality Analysis should be recommended for publication unless they are deemed to contain sensitive information.

Publication on the CCG's website.

Following approval all finalised Equality Analysis should be sent to the Communications and Engagement team for publication: bsol.comms@nhs.net

13. Sign Off

The Equality Analysis will need to go through a process of **quality assurance** by the Senior Manager for Equality and Diversity, Senior Manager for Assurance and Compliance or Equality and Human Rights Manager **and** signed-off by a delegated committee

	Name	Date
Quality Assured By:		
Which Committee will be considering the findings and signing off the EA?		
Minute number (to be inserted following presentation to committee)		

Please send to Balvinder Everitt or Michelle Dunne, Equality, Diversity and Inclusion for Quality Assurance.

Once you have committee sign off, please send to Caroline Higgs, Communications & Engagement Team for publication: bsol.comms@nhs.net

Equality Analysis

(Health Inequalities, Human Rights, Social Value)

Policy for the use of Biological Mesh

Before completing this equality analysis it is recommended that you:

- ✓ Contact your equality and diversity lead for advice and support
- ✓ Take time to read the accompanying policy and guidance document on how to complete an equality analysis

NHS Birmingham and Solihull Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group

1. Background

EA Title	Policy for the use of Biological Mesh		
EA Author	David King	**Team**	Equality and Diversity
Date Started	13/08/2019	**Date Completed**	4/12/2019
EA Version	4	**Reviewed by E&D**	

What are the intended outcomes of this work? Include outline of objectives and function aims

Surgical Mesh

Surgical mesh is a screen-like material that is used as a reinforcement for tissue or bone. It can be made of synthetic polymers or biopolymers.

Materials used for surgical mesh include:

- Non-absorbable synthetic polymers (polypropylene)
- Absorbable synthetic polymers (polyglycolic acid or polycaprolactone)
- Biologic (acellular collagen sourced from cows or pigs)
- Composite (a combination of any of the three previous materials e.g. Biosynthetic)

Mesh implants may be used in a number of surgical procedures to provide additional support when repairing weakened or damaged tissue.

Over recent years attention has increased on complications that can occur with the use of this mesh in urogynaecological procedures to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI). These complications may include persistent pain, sexual problems, mesh exposure through vaginal tissues and occasionally injury to nearby organs, such as the bladder or bowel. There has been an acknowledgement from the NHS England Mesh Working Group that there is a lack of comprehensive data on these complications. Work is ongoing to ensure that patients are encouraged to report complications and clinicians report adverse events.

Currently, the use of mesh in urogynaecological procedures to treat pelvic organ prolapse and stress urinary incontinence is not supported across the NHS and a wider NHS England review of the use of mesh in these clinical circumstances, means that at the current time in line with NHSE recommendation, the CCG does not support the use of mesh implants in these urogynaecological procedures.

However, surgical mesh implants (non-biological mesh) are routinely used across the NHS to address the clinical problem of hernia. A hernia may be inguinal, femoral; umbilical; para-umbilical or incisional. These implants typically restore structural domain to the abdominal/pelvic wall and prevent extrusion of visceral contents. Surgery takes place either as an open or laprascopic procedure.

Open surgery
The surgeon makes a single cut (incision) over the hernia. This incision is usually about 6 to 8cm long. The surgeon then places the lump of fatty tissue or loop of bowel back into your abdomen (tummy). A mesh is placed in the abdominal wall, at the weak spot where the hernia came through, to strengthen it. When the repair is complete, your skin will be sealed with stitches. These stitches usually dissolve on their own over the course of a few days after the operation.

If the hernia has become strangulated and part of the bowel is damaged, the affected segment may need to be removed and the 2 ends of healthy bowel rejoined. This is a bigger operation and you may need to stay in hospital for 4 to 5 days.

Laparoscopic (keyhole) surgery
During keyhole surgery, the surgeon usually makes 3 small incisions in your abdomen instead of a single larger incision. A thin tube containing a light source and a camera (laparoscope) is inserted through one of these incisions so the surgeon can see inside your abdomen. Special surgical instruments are inserted through the other incisions so the surgeon can pull the hernia back into place.

There are 2 types of keyhole surgery.

1. Transabdominal preperitoneal (TAPP)

Instruments are inserted through the muscle wall of your abdomen and through the lining covering your organs (the peritoneum).

A flap of the peritoneum is then peeled back over the hernia and a piece of mesh is stapled or glued to the weakened area in your abdomen wall to strengthen it.

2. Totally extraperitoneal (TEP)

This is the newest keyhole technique and involves repairing the hernia without entering the peritoneal cavity.

Once the repair is complete, the incisions in your skin are sealed with stitches or surgical glue.

Evidence Review

A review of the clinical evidence found mixed clinical review, with no strong basis for the use of biological mesh over standard mesh in standard or first line hernia repair operations (inguinal; umbilical; paraumbilical or incisional). The standard of the evidence reviewed comprised mainly of retrospective studies of low to moderate quality, but with hernia reoccurrence being slightly higher following the use of biological mesh, but no significant difference was determined in the occurrence of wound and mesh infection. It is possible due to the nature of the studies that the high rates of reoccurrence could be accounted for due to the more complex nature of the hernia repairs where biological mesh was utilised. Therefore, in light of the currently available low quality evidence, to support the use of biological mesh over standard mesh, in first line or standard hernia repair procedures, the use of biological or bio-synthetic mesh is not routinely commissioned.

However, the use of biological or biosynthetic mesh in hernia repair may be undertaken when first line hernia repair surgery with permanent synthetic mesh or conservative treatment has failed or is inappropriate to use synthetic mesh and the use of biological / biosynthetic mesh has been deemed the most clinically appropriate surgical intervention by a complex abdominal wall repair multidisciplinary team.

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

Eligibility Criteria: Restricted

The use of biological or biosynthetic mesh in standard hernia (inguinal; femoral; umbilical, para-umbilical and incisional) repair is Not Routinely Commissioned.
The use of biological or biosynthetic mesh in hernia repair is only to be undertaken when:

- first line hernia repair surgery with permanent synthetic mesh followed by conservative wound care management has failed

OR

- first line hernia repair surgery with permanent synthetic mesh followed by conservative wound care management is deemed inappropriate

In ALL surgical cases, where the use of biological / biosynthetic mesh is to be considered for use in hernia repair, the patient must be reviewed by a specialist complex abdominal wall repair MDT and the use of biological / biosynthetic mesh must be deemed the most clinically appropriate surgical intervention by a complex abdominal wall repair MDT.

Conservative wound care management is defined as follows:

- Wound care management plan developed for the individual patient by the specialist wound care management team has failed.

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

This means the CCG will <u>only</u> fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Activity data 2018/19 –

This is currently not available, due to the lack of granular coding detail to determine between **synthetic** and **biological / biosynthetic mesh**. The number of IFR requests are <10 per year in 17/18 and 18/19.

Number of procedures undertaken overall and by CCG

Due to limited data collection by the providers service activity data is available by headcount only not protected characteristic.
The Joint Strategic Needs Assessments for Birmingham, Solihull and Sandwell are available via the links below.

Sandwell

Birmingham

Solihull

2. Research

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

Research/Publications	Working Groups	Clinical Experts
Guidance 1. Barber,S. 2018 BRIEFING PAPER: Surgical mesh implants Number CBP 8108, 15 January 2018. House of Commons Library. https://www.baus.org.uk/_userfiles/pages/files/Patients/CBP-8108.pdf 2. RCOG. Use of Vaginal Mesh. (2019) https://www.rcog.org.uk/globalassets/documents/guidelines/safety-alerts/nhs-mesh-letter-extension-of-pause-on-the-use-of-vaginal-mesh-29-march-2019.pdf 3. F. Köckerling, N. N. Alam, S. A. Antoniou, I. R. Daniels, F. Famiglietti, R. H. Fortelny, M. M. Heiss, F. Kallinowski, I. Kyle-Leinhase, F. Mayer, M. Miserez, A. Montgomery, S. Morales-Conde, F. Muysoms, S. K. Narang, A. Petter-Puchner, W. Reinpold, H. Scheuerlein, M. Smietanski, B. Stechemesser, C. Strey, G. Woeste, N. J. Smart. What is the evidence for the use of biologic or biosynthetic meshes in abdominal wall reconstruction? Hernia. 2018; 22(2): 249–269. Published online 2018 Jan 31. doi: 10.1007/s10029-018-1735-y		

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5978919/

4. Biologic versus Synthetic Mesh Reinforcement: What are the Pros and Cons?
James F. FitzGerald, Anjali S. Kumar. Clin Colon Rectal Surg. 2014 Dec; 27(4): 140–148. doi: 10.1055/s-0034-1394155
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4477030/

5. Majumder A[1], Winder JS[2], Wen Y[1], Pauli EM[2], Belyansky I[3], Novitsky YW[4] Comparative analysis of biologic versus synthetic mesh outcomes in contaminated hernia repairs. Surgery. 2016 Oct;160(4):828-838. doi: 10.1016/j.surg.2016.04.041. Epub 2016 Jul 21. https://www.ncbi.nlm.nih.gov/pubmed/27452954

6. Carver DA, Kirkpatrick AW, Eberle TL, *et al.* Performance of biological mesh materials in abdominal wall reconstruction: study protocol for a randomised controlled trial
BMJ Open 2019;9:e024091. doi: 10.1136/bmjopen-2018-024091 .
https://bmjopen.bmj.com/content/9/2/e024091

7. C. S. Seefeldt; J. S. Meyer; J. Knievel; A. Rieger; R. Geißen,R. Lefering; M. M. Heiss (2019) BIOLAP: biological versus synthetic mesh in laparo-endoscopic inguinal hernia repair: study protocol for a randomized, multicenter, self-controlled clinical trial. *Trials*2019**20**:55. https://doi.org/10.1186/s13063-018-3122-5https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-018-3122-5

8. Loes Knaapen, Otmar Buyne, Harry van Goor, Nicholas J (2016) Synthetic vs biologic mesh for the repair and prevention of parastomal hernia. *World J Meta-Anal* 2017 December 26; 5(6): 150-166. DOI: 10.13105/wjma.v5.i6.150.
https://f6publishing.blob.core.windows.net/66e60003-20b2-4ada-9595-26b5152dc122/WJMA-5-150.pdf

9. David A Carver, Andrew W Kirkpatrick, Tammy L Eberle, Chad G Ball (2019)Performance of biological mesh materials in abdominal wall reconstruction: study protocol for a randomised controlled trial

BMJ Open. 2019; 9(2): e024091. Published online 2019 Feb 15. doi: 10.1136/bmjopen-2018-024091 10. Hubert Scheuerlein, Andreas Thiessen, Christine Schug-Pass, Ferdinand Köckerling. (2018) What Do We Know About Component Separation Techniques for Abdominal Wall Hernia Repair? Front Surg. 2018; 5: 24. Published online 2018 Mar 27. doi: 10.3389/fsurg.2018.00024		

3. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

Age: Describe age related impact and evidence. This can include safeguarding, consent and welfare issues:

Although developing a hernia can affect those from birth up to old age, the most common type diagnosed is often associated with ageing, the diaphragm becoming weaker with age and repeated strain/pressure on the stomach.

Disability: Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments:

No impact identified based on available data, however a link can be made with degenerative conditions where the person experiencing is likely to have a disability. Limiting this procedure may have an impact on this group as a result. This should be balanced against the lack of clinical evidence.

Gender reassignment (including transgender): Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment:

No impact identified

3. Impact and Evidence:
Marriage and civil partnership: Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities: No impact identified
Pregnancy and maternity: Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities: Those who are pregnant may have an increased risk of hernias because of the increased pressure pregnancy puts on the abdomen.
Race: Describe race related impact and evidence**.** This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers: No impact identified
Religion or belief: Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues: Biological mesh although restricted can be made from porcine / bovine or human tissues due regard to a patient's faith should be taken into consideration if biological mesh is commissioned.
Sex: Describe any impact and evidence on men and women. This could include access to services and employment: Depending on the type of hernia diagnosed there is a correlation that males and females are more prone to a developing particular type due to the nature of the condition. However, the most common type diagnosed mainly affects men.
Sexual orientation: Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers: No impact identified
Carers: Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities: No impact identified

3. Impact and Evidence:
Other disadvantaged groups: Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive) No impact identified

4. Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals?	No	This condition is not linked to a health inequality.
Is there any impact for groups or communities living in particular geographical areas?	No	No impact identified
Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	No	No impact identified
How will you ensure the proposals reduce health inequalities?		

5. FREDA Principles/ Human Rights	Question	Response
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	Yes, this decision has been made in line with clinical recommendation.
Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	No evidence of impact from this policy
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	No discrimination identified
	How will this affect a person's right to freedom of thought, conscience and religion?	If biological mesh is commissioned due regard to a patient's faith must be taken into consideration. (Regard to use of pork / bovine derived products

		and their unacceptability to those of certain faith groups)
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	Policy will be applied with due regard to this consideration.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	An individual can discuss the impact with their GP and has the option for an IFR request to be made.
Right to **Life**	Will or could it affect someone's right to life? How?	No evidence of impact from this policy
Right to **Liberty**	Will or could someone be deprived of their liberty? How?	No evidence of impact from this policy

6. Social Value

Consider how you might use the opportunity to improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.

Marmot Policy Objective	**What actions are you able to build into the procurement activity and/or contract to achieve wider public benefits?**
Enable all people to have control over their lives and maximise their capabilities	None
Create fair employment and good work for all	None
Create and develop health and sustainable places and communities	None
Strengthen the role and impact of ill-health prevention	None

7. Engagement, Involvement and Consultation

If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:

Engagement Activity	**Protected Characteristic/ Group/ Community**	**Date**

For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us …. So we will …..):

As part of the process further targeted engagement is planned with representative groups from among Sandwell, Birmingham and Solihull Patients. In addition, it has been identified that patient and clinician information is key in ensuring that the

7. Engagement, Involvement and Consultation

harmonised treatment policies review delivers effective outcomes. To this end an information briefing sheets on each procedure will be developed to give more information on the procedure, eligibility criteria and signposting to further information sources, such as NHS Choices. These information sheets are also designed to help facilitate discussions between GPs and patients. Information briefing sheets have already been tested and uploaded onto the GP systems for the first 45 harmonised treatment policies for Birmingham and Solihull. Due regard will be given to both the accessible information standard and the potential need to translate such leaflets into relevant local languages.

The engagement team used every possible route throughout the engagement period to encourage people to feedback on the proposed policy. Unfortunately, despite the wide communication undertaken through all communication and engagement channels available, 49 questionnaires were completed online and there was no interest from stakeholders, patients and the public to attend any of the five stakeholder events arranged. As a result, the events were cancelled, and the engagement team looked at other routes to encourage engagement with patients directly. A possible reason for the general lack of interest and feedback from stakeholders, patients and the public is most likely because this clinical treatments policy either widening the scope of the current service provision, providing policies to protect the current service provision or the intervention is for somewhat rare conditions.

Also, in phase 3 of the harmonisation of policies programme clinicians had been integral to the development of the policies from the beginning of the process. It could therefore be argued the proposed policy shared for public engagement was to some extent already informed from a local patient experience and outcomes perspective.

The potential impact on patients was thought to be minimal as there is no policy in place for the use of biological mesh in hernia repair. Out of the four people who had accessed this service, only one respondent felt this would have a negative impact and the decision to offer this treatment should be left with the patient and GP. There was a consensus that as other meshes are available and used, therefore not using biological mesh should not have a great impact on patients. However, some feedback also suggested that more evidence around the use and impact of synthetic mesh was required.

8. Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work:

The restriction of this policy will have limited impact on those who would wish to receive the treatments as there is no clear evidence to support the use of biological mesh over standard mesh in standard hernia repair. For those whose initial surgery has failed or use of synthetic mesh is inappropriate, the patient will be reviewed by a specialist complex abdominal wall MDT.

This must be balanced against the need to adhere to the clinical effectiveness evidence. The opportunity for any exceptional cases to be considered via IFR remains.

9. Mitigations and Changes :

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.

None identified

10. Contract Monitoring and Key Performance Indicators

Detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract (refer to NHS Standard Contract SC12 and 13):

This policy is not linked to a contract however, prospective providers remain bound by their contracts with the CCG.

11. Procurement

Detail the key equality, health inequalities, human rights, and social value criteria that will be included as part of the procurement activity (to evaluate the providers ability to deliver the service in line with these areas):

N/A

12. Publication

How will you share the findings of the Equality Analysis?

This can include: reports into committee or Governing Body, feedback to stakeholders including patients and the public, publication on the web pages. All Equality Analysis should be recommended for publication unless they are deemed to contain sensitive information.

Publication on the CCG's website.
Following approval all finalised Equality Analysis should be sent to the Communications and Engagement team for publication: bsol.comms@nhs.net

13. Sign Off

The Equality Analysis will need to go through a process of **quality assurance** by the Senior Manager for Equality and Diversity, Senior Manager for Assurance and Compliance or Equality and Human Rights Manager **and** signed-off by a delegated committee

	Name	Date
Quality Assured By:		
Which Committee will be considering the findings and signing off the EA?		
Minute number (to be inserted following presentation to committee)		

Please send to Balvinder Everitt or Michelle Dunne, Equality, Diversity and Inclusion for Quality Assurance.

Once you have committee sign off, please send to Caroline Higgs, Communications & Engagement Team for publication: bsol.comms@nhs.net

Equality Analysis

(Health Inequalities, Human Rights, Social Value)

Policy for use of Domiciliary Continuous Positive Airway Pressure Devices in Obstructive Sleep Apnoea Hypnoea Syndrome

Before completing this equality analysis it is recommended that you:

- ✓ Contact your equality and diversity lead for advice and support
- ✓ Take time to read the accompanying policy and guidance document on how to complete an equality analysis

1. Background

EA Title	Policy for use of domiciliary Non-Invasive Ventilation		
EA Author	David King	**Team**	Equality and Diversity Team
Date Started		**Date Completed**	4/12/2019
EA Version	4	**Reviewed by E&D**	

What are the intended outcomes of this work? Include outline of objectives and function aims

Obstructive Sleep Apnoea Hypopnea Syndrome (OSAHS)

Apnoea is defined as a temporary absence or cessation of breathing. Obstructive Sleep Apnoea hypopnea syndrome (OSAHS) is a condition, in which, a person experiences repeated episodes of apnoea because of a narrowing or closure of the pharyngeal airway during sleep. This is caused by a decrease in the tone of the muscles supporting the airway during sleep. Complete closure (obstruction) stops airflow (apnoea) whereas partial obstruction decreases airflow (hypopnoea). OSAHS results in episodes of brief awakening from sleep to restore normal breathing.

Moderate to severe OSAHS can be diagnosed from patient history and a sleep study using oximetry or other monitoring devices carried out in the person's home. In some cases, further studies that monitor additional physiological variables in a sleep laboratory or at home may be required, especially when alternative diagnoses are being considered. The severity of OSAHS is usually assessed on the basis of both severity of symptoms (particularly the degree of sleepiness) and the sleep study, by using either the apnoea/hypopnoea index (AHI) or the oxygen desaturation index. OSAHS is considered mild when the AHI is 5–14 in a sleep study, moderate when the AHI is 15–30, and severe when the AHI is over 30. In addition to the AHI, the severity of symptoms is also important.

The symptoms of OSAHS include impaired alertness, cognitive impairment, excessive daytime sleepiness, snoring, nocturia, morning headaches and sexual dysfunction. The sleep quality of partners may also be affected. Excessive daytime sleepiness can adversely affect cognitive function, mood and quality of life. OSAHS is associated with high blood pressure, which increases the risk of cardiovascular disease and stroke. OSAHS has also been associated with an increased risk of road traffic accidents.

Major risk factors for developing OSAHS are increasing age, obesity and being male. OSAHS is also associated with certain specific craniofacial characteristics (such as retrognathia), enlarged tonsils and enlarged tongue. Use of alcohol or sedatives can also increase the risk or severity of the condition. OSAHS has been reported to affect up to 4% of middle-aged men and 2% of middle-aged women in the UK. It is estimated that 1% of men in the UK may have severe OSAHS.

The use of Continuous Positive Airway Pressure in OSAHS.

Treatment for OSAHS aims to reduce daytime sleepiness by reducing the number of episodes of apnoea/hypopnoea experienced during sleep. In the clinical management of sleep apnoea, continuous positive airway pressure (CPAP) is the most commonly use intervention for patients with moderate or severe diagnosis of OSAHS.

The potential alternative treatment to CPAP are:

- lifestyle management,
- dental devices
- surgery.

Lifestyle management involves helping people to lose weight, stop smoking and/or decrease alcohol consumption.

Dental devices are designed to keep the upper airway open during sleep. The efficacy of dental devices has been established in clinical trials, but these devices are traditionally viewed as a treatment option only for mild and moderate OSAHS.

Surgery involves resection of the uvula and redundant retrolingual soft tissue. However, there is a lack of evidence of clinical effectiveness, and surgery is not routinely used in clinical practice.

A CPAP device consists of a unit that generates airflow, which is directed to the airway via a mask. Positive pressure is generated by the airflow, which prevents upper airway collapse. For CPAP treatment to be effective the patient must always wear their device when they go to sleep.

Reasons for not adhering to CPAP treatment include poor mask fit, pressure intolerance and, more commonly, upper airway symptoms such as nasal dryness, nasal bleeding and throat irritation. Humidification devices are now commonly used in conjunction with CPAP devices in order to reduce these side effects. Masks should be replaced at least annually, and long-term follow-up of patients is critical to ensure adherence.

There are two types of CPAP devices. Fixed CPAP devices deliver air at constant pressure throughout the night, and the person will continue to receive this pressure until a further titration study is performed to determine whether the set pressure is still appropriate. Auto-titrating CPAP devices continually adjust the pressure delivered throughout the night, with the aim of improving comfort and thus adherence.

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

Eligibility Criteria: Restricted

1. Continuous positive airway pressure (CPAP) is commissioned as a treatment option for adults with moderate or severe symptomatic obstructive sleep apnoea/hypopnoea syndrome (OSAHS).

OR

2. CPAP is only recommended as a treatment option for adults with mild OSAHS if:

    a. The OSAHS is causing severe functional impairment, which is impacting on the patient's ability to carry out activities of daily living

AND

    b. lifestyle advice and any other relevant treatment options have been unsuccessful or are considered inappropriate

The diagnosis and treatment of OSAHS, and the monitoring of the response, should always be carried out by a specialist service with appropriately trained medical and support staff.

N.B. The definition of OSAHS following a sleep study is as follows:
Mild OSAHS= Apnoea–Hypopnoea Index (AHI) 5–14.
Moderate OSAHS = AHI is 15–30.
Severe OSAHS = AHI is over 30.

Functional impairment is defined as preventing activities of daily living to be undertaken independently, i.e. sleeping; eating; walking, driving.

Exclusion criteria:

- Inability to remove mask independently (with no waking night carer)
- Cognitive / behavioural limitation affecting ability to comply safely with NIV
- Intolerance of acute NIV
- Multiple co-morbidities limiting utility of NIV

Funding will be provided for the following if the patient meets the above clinical criteria:

- One CPAP machine
- 1-2 lengths of tubing per year
- 1-2 masks per year

In a small proportion of OSA patients, CPAP proves insufficient to control apnoea and it becomes necessary to use bi-level NIV. If a patient has failed treatment with CPAP, but continues to meet the eligibility criteria outlined above, a further funding application will be considered for:

- One Bi-level NIV machine
- 1-2 lengths of tubing per year
- 1-2 masks per year

Number of procedures undertaken overall and by CCG

	BSOL	Sandwell
	Data is not available for this procedure	

The providers have not collected this data and it is not possible to collate this retrospectively.

The Joint Strategic Needs Assessments for Birmingham, Solihull and Sandwell are available via the links below.

Sandwell

Birmingham

Solihull

2. Research

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

Research/Publications	Working Groups	Clinical Experts
Guidance: CPAP 1. Corrado A, Gorini M, Melej R, et al. Iron lung versus mask ventilat exacerbation of COPD: a randomised crossover study. *Intensive* (2009 Apr. 35(4):648-55. 2. Parke RL, McGuinness SP. Pressures delivered by nasal high flo during all phases of the respiratory cycle. *Respir Care*. 2013 Oct. 4. 3. Spoletini G, Alotaibi M, Blasi F, Hill NS. Heated Humidified High-F Oxygen in Adults: Mechanisms of Action and Clinical Implications Jul. 148 (1):253-61. 4. Ozsancak A, Sidhom S, Liesching TN, Howard W, Hill NS. EVALU THE TOTAL FACE MASKTM FOR NONINVASIVE VENTILATION ACUTE RESPIRATORY FAILURE. *Chest*. 2011 Feb 17. 5. Wysocki M, Richard JC, Meshaka P. Noninvasive proportional ass compared with noninvasive pressure support ventilation in hyperc respiratory failure. *Crit Care Med*. 2002 Feb. 30 (2):323-9. 6. Fernández-Vivas M, Caturla-Such J, González de la Rosa J, Acos J, Alvarez-Sánchez B, Cánovas-Robles J. Noninvasive pressure s proportional assist ventilation in acute respiratory failure. *Intensive* 2003 Jul. 29 (7):1126-33. 7. Hoo, G. 2018. Noninvasive Ventilation. Medscape. https://emedicine.medscape.com/article/304235-overview#a5 8. British Thoracic Society/Intensive Care Society Acute Hypercapni Failure Guideline Development Group. 2016. BTS/ICS Guidelines Ventilatory Management of Acute Hypercapnic Respiratory Failur Journal of the British Thoracic Society. http://thorax.bmj.com/site/about/guidelines.xhtml#open **9.** 18. National Institute for Health and Clinical Excellence (NICE). M disease: assessment and management**.** NICE guideline [NG42] P February 2016 Last updated: July 2019 10. 19. National Institute for Health and Clinical Excellence (NICE). *C Obstructive Pulmonary Disease in Over 16s: Diagnosis and Mana [CG101]*. London, England: NICE; 2010. https://www.nice.org.uk/		
Guidance - OSA		

1. NICE. 2008. Continuous positive airway pressure for the treatmer obstructive sleep apnoea/hypopnoea syndrome. Technology app guidance. Published: 26 March 2008. Updated Feb 2014. nice.org.uk/guidance/ta139

2. Hypoglossal nerve stimulation for moderate to severe obstructive apnoea (2017) - https://www.nice.org.uk/guidance/ipg598

3. Soft-palate implants for obstructive sleep apnoea (2007) - https://www.nice.org.uk/guidance/ipg241

4. A meta-analysis of continuous positive airway pressure therapy in cardiovascular events in patients with obstructive sleep apnoea (2 https://academic.oup.com/eurheartj/article-abstract/39/24/2291/4563763?redirectedFrom=fulltext

5. Sleep-disordered Breathing in Heart Failure (2015) - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6159414/

6. The official website of The Epworth Sleepiness Scale (ESS) - http://epworthsleepinessscale.com/about-the-ess/

7. The Epworth Sleepiness Scale: Minimum Clinically Important Diff Obstructive Sleep Apnea (2018) - https://www.atsjournals.org/doi/abs/10.1164/rccm.201704-0672LE

8. Minimum important difference of the Epworth Sleepiness Scale in sleep apnoea: estimation from three randomised controlled trials (https://thorax.bmj.com/content/early/2018/08/11/thoraxjnl-2018-21

9. Cardiorespiratory interaction with continuous positive airway pres http://jtd.amegroups.com/article/view/18553/14525

10. Continuous positive airway pressure for the treatment of obstructi apnoea/hypopnoea syndrome (2008, reviewed 2012) - https://www.nice.org.uk/guidance/ta139

3. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

Age: Describe age related impact and evidence. This can include safeguarding, consent and welfare issues:

Obstructive Sleep Apnoea Hypopnea Syndrome (OSAHS)

It has been recognised that there is a link to developing OSAHS due to increasing age and alongside other conditions such as obesity. It is also noted that certain specific craniofacial characteristics (such as retrognathia), enlarged tonsils and enlarged tongue are associated with the condition and therefore may be prevalent from birth.

Disability: Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments:

A link can be made with degenerative conditions where the person experiencing is likely to have a disability. Restricting this procedure may have an impact on this group as a result.

The patient must be able to remove the NIV mask either independently or the patient must have a waking night carer whom can remove the mask for them as required. This is a clinical safety issue, as if for example the patient coughs up secretions then if the mask cannot be removed to clear the secretions, then the secretions will be pushed back into the patient's airway which may cause the airway to occlude. Therefore this is a safety requirement to prevent harm to the patient when using the device.

However, an individual can discuss the impact with their GP and has the option for an individual funding request (IFR) request to be made.

Gender reassignment (including transgender): Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment:

No Impact identified

Marriage and civil partnership: Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities:

3. Impact and Evidence:
No impact identified
Pregnancy and maternity: Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities: If any of those conditions are present, then the pregnancy must be managed as the condition may worsen throughout pregnancy.
Race: Describe race related impact and evidence**.** This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers: No impact identified
Religion or belief: Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues: No impact identified
Sex: Describe any impact and evidence on men and women. This could include access to services and employment: Depending on the diagnosis of the patient some conditions are more commonly seen in one gender over the other. Obstructive sleep apnoea hypopnea syndrome (OSAHS) is slightly more evident in males who are obese than females due to how fat is stored in the body. Where the condition has arisen from long term lifestyle choices this could affect either gender.
Sexual orientation: Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers: No impact identified
Carers: Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities: No impact identified

3. Impact and Evidence:

Other disadvantaged groups: Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive)

Health inequalities are present in an area of deprivation – which combines factors such as income, employment, health and education which has the greatest impact on someone's likelihood of smoking.

4. Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals?	No	This condition could be linked to a health inequality due to the prevalence of smoking. As the procedures remains available it is not anticipated that a health inequality will be made worse.
Is there any impact for groups or communities living in particular geographical areas?	Yes	A possible link between smoking and areas of high deprivation has been made.
Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	Yes	A possible link between the likelihood of someone smoking and unemployment, low income and education has been made. Due regard to this will need to be given in supporting such patients.

How will you ensure the proposals reduce health inequalities?

The intention of the policy is to support patients with ventilatory support without using an invasive artificial airway method. For those patients where the condition has been a result of a long-term lifestyle choice, as in obesity, support should be provided to those patients through a number of interventions to help the patient loose weight.

5. FREDA Principles/ Human Rights	Question	Response
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	Yes, this decision has been made in line with clinical recommendation and NICE guidance.
Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	No evidence of impact from this policy
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	No discrimination identified
	How will this affect a person's right to freedom of thought, conscience and religion?	N/A
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	Policy will be applied with due regard to this consideration.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	An individual can discuss the impact with their GP and has the option for an IFR request to be made
Right to **Life**	Will or could it affect someone's right to life? How?	No evidence of impact from this policy
Right to **Liberty**	Will or could someone be deprived of their liberty? How?	No evidence of impact from this policy

6. Social Value

Consider how you might use the opportunity to improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.

Marmot Policy Objective	What actions are you able to build into the procurement activity and/or contract to achieve wider public benefits?
Enable all people to have control over their lives and maximise their capabilities	
Create fair employment and good work for all	
Create and develop health and sustainable places and communities	
Strengthen the role and impact of ill-health prevention	

7. Engagement, Involvement and Consultation

If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:

Engagement Activity	Protected Characteristic/ Group/ Community	Date

For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us …. So we will …..):

As part of the process further targeted engagement is planned with representative groups from among Sandwell, Birmingham and Solihull Patients. In addition, it has been identified that patient and clinician information is key in ensuring that the harmonised treatment policies review delivers effective outcomes. To this end an information leaflet on each procedure will be developed to give more information on the procedure, eligibility criteria and signposting to further information sources, such as NHS Choices. These information leaflets

are also designed to help facilitate discussions between GPs and patients. Information briefing sheets have already been tested and uploaded onto the GP systems for the first 45 harmonised treatment policies for Birmingham and Solihull. Due regard will be given to both the accessible information standard and the potential need to translate such leaflets into relevant local languages.

The engagement team used every possible route throughout the engagement period to encourage people to feedback on the proposed policy. Unfortunately, despite the wide communication undertaken through all communication and engagement channels available, 49 questionnaires were completed online and there was no interest from stakeholders, patients and the public to attend any of the five stakeholder events arranged. As a result, the events were cancelled, and the engagement team looked at other routes to encourage engagement with patients directly. A possible reason for the general lack of interest and feedback from stakeholders, patients and the public is most likely because this clinical treatments policy either widening the scope of the

current service provision, providing policies to protect the current service provision or the intervention is for somewhat rare conditions.

Also, in phase 3 of the harmonisation of policies programme clinicians had been integral to the development of the policies from the beginning of the process. It could therefore be argued the proposed policy shared for public engagement was to some extent already informed from a local patient experience and outcomes perspective.

On behalf of Birmingham and Solihull CCG and Sandwell and West Birmingham CCG, a letter was sent by a specialist respiratory ventilation physiotherapist based at one of the acute NHS providers, inviting 20 patients using domiciliary NIV / CPAP to attend a meeting at the hospital to feedback on the non-invasive ventilation policies. Patients who were unable to attend due to travel difficulties were invited to inform the CCG so that transport could be provided for them. Two people followed up the invitation by telephone to find out more about the meeting, however they decided they would prefer not to attend. One person was calling on behalf of her father and explained that although he would not be able to attend, she would go through the information with him available online. A further telephone meeting was offered, should her father wish to feedback verbally. The other person calling, completed the questionnaire over the telephone with the engagement officer.

The actual meeting on Friday 4 October was attended by a patient with muscular dystrophy and her daughter (also the patient's full-time carer). The patient used non-invasive ventilation to help with her condition during the day and night.

The patient and carer told the interviewer that they strongly agreed with the policy for non-invasive ventilation for neuromuscular patients. This was because they felt the implementation of the policy would help GPs to refer patients for the correct treatment promptly. The patient and carer felt the policy would raise awareness of the respiratory conditions associated with muscular dystrophy and provide guidance on when to refer patients into a specialist respiratory service.

There is currently no policy available and so the potential impact on patients is therefore minimal as the treatment will offered based on criteria. Of the 27 of the 49 people who provided responses to this policy, only 6 had actually received this treatment and their responses were mixed. There was a general agreement that people with respiratory issues should receive this treatment to improve their quality of life.

8. Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work:

The restriction of this policy will have an impact on those who would wish to receive the treatments, this must be balanced against the need to adhere to NICE guidelines and the clinical effectiveness evidence. The opportunity for any exceptional cases to be

considered via IFR remains and will ensure treatment is available in an exceptional case, which is supported by the CCG.

9. Mitigations and Changes :

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.

Consideration will need to be given to what additional support patients from a low socio economic background will require and how due regard can be given to reasonable adjustments in approach for disabled persons.

10. Contract Monitoring and Key Performance Indicators

Detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract (refer to NHS Standard Contract SC12 and 13):

This policy is not linked to a contract however, prospective providers remain bound by their contracts with the CCG.

11. Procurement

Detail the key equality, health inequalities, human rights, and social value criteria that will be included as part of the procurement activity (to evaluate the providers ability to deliver the service in line with these areas):

N/A

12. Publication

How will you share the findings of the Equality Analysis?

This can include: reports into committee or Governing Body, feedback to stakeholders including patients and the public, publication on the web pages. All Equality Analysis should be recommended for publication unless they are deemed to contain sensitive information.
Published on CCG website
Following approval all finalised Equality Analysis should be sent to the Communications and Engagement team for publication: bsol.comms@nhs.net

13. Sign Off

The Equality Analysis will need to go through a process of **quality assurance** by the Senior Manager for Equality Diversity and Inclusion or the Manager for Equality Diversity and Inclusion prior to approval from the delegated committee

	Name	Date
Quality Assured By:		
Which Committee will be considering the findings and signing off the EA?		
Minute number (to be inserted following presentation to committee)		

Please send to Balvinder Everitt or Michelle Dunne, Equality, Diversity and Inclusion for Quality Assurance.

Once you have committee sign off, please send to Caroline Higgs, Communications & Engagement Team for publication: bsol.comms@nhs.net

Equality Analysis

(Health Inequalities, Human Rights, Social Value)

Policy for Hysteroscopy

Before completing this equality analysis it is recommended that you:

- ✓ Contact your equality and diversity lead for advice and support
- ✓ Take time to read the accompanying policy and guidance document on how to complete an equality analysis

NHS Birmingham and Solihull Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group

1. Background

EA Title	Policy for Hysteroscopy		
EA Author	David King	**Team**	Equality and Diversity
Date Started		**Date Completed**	4/12/2019
EA Version	3	**Reviewed by E&D**	

What are the intended outcomes of this work? Include outline of objectives and function aims

Heavy Menstrual Bleeding (HMB/ Heavy Periods)

Heavy Menstrual Bleeding (HMB) is common but can have a big effect on a woman's everyday life. HMB does not always have an underlying cause but can result from problems such as fibroids or endometriosis.

It's difficult to define exactly what a heavy period is because it varies from woman to woman. Heavy for one woman may be normal for another. Most women will lose less than 16 teaspoons of blood (80ml) during their period, with the average being around 6 to 8 teaspoons.

Heavy menstrual bleeding is defined as losing 80ml or more in each period, having periods that last longer than 7 days, or both.

However, it's not usually necessary to measure blood loss. Most women have a good idea of how much bleeding is normal for them during their period and can tell when this changes.

A good indication that your periods are heavy is if you:

- are having to change your sanitary products every hour or two
- are passing blood clots larger than 2.5cm (about the size of a 10p coin)
- are bleeding through to your clothes or bedding
- need to use two types of sanitary product together for example, tampons and pads

In about half of women with heavy menstrual bleeding, no underlying reason is found. But there are several conditions and some treatments that can cause heavy menstrual bleeding.

Some conditions of the womb and ovaries can cause heavy bleeding, including:

- fibroids – non-cancerous growths that develop in or around the womb and can cause heavy or painful periods
- endometriosis – where the tissue that lines the womb (endometrium) is found outside the womb, such as in the ovaries and fallopian tubes (although this is more likely to cause painful periods)

- adenomyosis – when tissue from the womb lining becomes embedded in the wall of the womb; this can also cause painful periods
- pelvic inflammatory disease (PID) – an infection in the upper genital tract (the womb, fallopian tubes or ovaries) that can cause symptoms like pelvic or abdominal pain, bleeding after sex or between periods, vaginal discharge and fever
- endometrial polyps – non-cancerous growths in the lining of the womb or cervix (neck of the womb)
- cancer of the womb – the most common symptom is abnormal bleeding, especially after the menopause
- polycystic ovary syndrome (PCOS) – a common condition that affects how the ovaries work; it causes irregular periods, and periods can be heavy when they start again

Other conditions that can cause heavy periods include:

- blood clotting disorders, such as Von Willebrand disease
- an underactive thyroid gland (hypothyroidism) – where the thyroid gland does not produce enough hormones, causing tiredness, weight gain and feelings of depression
- diabetes

Medical treatments that can sometimes cause heavy periods include:

- an IUD (intrauterine contraceptive device, or "the coil") – this can make your periods heavier for the first 3 to 6 months after insertion
- anticoagulant medication – taken to prevent blood clots
- some medicines used for chemotherapy
- some herbal supplements, which can affect your hormones and may affect your periods – such as ginseng, ginkgo and soya

Hysteroscopy

A hysteroscopy is a procedure used to examine the inside of the womb (uterus).
It is carried out using a hysteroscope, which is a narrow telescope with a light and camera at the end. Images are sent to a monitor so your doctor or specialist nurse can see inside your womb.

The hysteroscope is passed into your womb through your vagina and cervix (entrance to the womb), which means no cuts need to be made in your skin.
In deciding whether to offer the woman a hysteroscopy or ultrasound scan NICE Guidance 88 should be taken into consideration:

Women with suspected submucosal fibroids, polyps or endometrial pathology

Offer outpatient hysteroscopy to women with HMB if their history suggests submucosal fibroids, polyps or endometrial pathology because:

- they have symptoms such as persistent intermenstrual bleeding or
- they have risk factors for endometrial pathology

Women with possible larger fibroids.

Offer pelvic ultrasound to women with HMB if any of the following apply:

- their uterus is palpable abdominally
- history or examination suggests a pelvic mass
- examination is inconclusive or difficult, for example in women who are obese.

Women with suspected adenomyosis

Offer transvaginal ultrasound (in preference to transabdominal ultrasound or MRI) to women with HMB who have:

- significant dysmenorrhoea (period pain) or
- a bulky, tender uterus on examination that suggests adenomyosis.

If a woman declines transvaginal ultrasound or it is not suitable for her, consider transabdominal ultrasound or MRI, explaining the limitations of these techniques. Be aware that pain associated with HMB may be caused by endometriosis rather than adenomyosis (see NICE's guideline on endometriosis).

Other diagnostic tools

Do not use saline infusion sonography as a first-line diagnostic tool for HMB.
Do not use MRI as a first-line diagnostic tool for HMB.
Do not use dilatation and curettage alone as a diagnostic tool for HMB

Evidence Review

In reviewing the evidence NICE 2018 considered the following requirements:

- that the correct identification of the cause of HMB is important as this can impact the treatment options offered to women.
- If a test is sensitive, it may help the clinicians to choose the right initial treatment to be offered to women.
- It is important to avoid false positives because unnecessary treatment, especially surgical treatment, can cause harm.

- The evidence on diagnostic accuracy was assessed using adapted GRADE methodology. GRADE is a systematic approach to rating the certainty of evidence in systematic reviews and other evidence syntheses.
- The evidence on patient satisfaction or acceptability was assessed using Cochrane Collaboration's tool for assessing risk of bias.

NICE in their evidence review accepted that the quality of evidence in these reviews ranged from very low to moderate with most evidence being of very low quality. The NICE committee recognised that the evidence was fragmented and with several limitations. The NICE committee agreed that the quality of evidence was most often downgraded because of unclear sampling, unclear inclusion and exclusion criteria, unclear diagnostic criteria, and at times, considerable number of drop-outs.

However, national clinical consensus under NG 88 has recommended the use of hysteroscopy as a first line intervention in a limited number of clinical circumstances:

The patient must have suspected submucosal fibroids OR polyps OR endometrial pathology **AND** The patient has one of the following symptoms:

- persistent intermenstrual bleeding OR
- risk factors for endometrial pathology

Due to this national clinical expertise, the use of hysteroscopy will be commissioned in specified clinical circumstances in line with the clinical consensus achieved through NICE NG 88.

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

Eligibility Criteria: Restricted

Hysteroscopy for Heavy Menstrual Bleeding is commissioned as a first line investigation in the following clinical circumstances:

The patient must have suspected submucosal fibroids OR polyps OR endometrial pathology **AND**
The patient has one of the following symptoms:

- persistent intermenstrual bleeding OR
- risk factors for endometrial pathology

Risk factors for endometrial pathology are defined as:

- the patient has persistent intermenstrual or persistent irregular bleeding, and the patient has infrequent heavy bleeding and is obese or has polycystic ovary syndrome
- the patient taking tamoxifen

- the patient for whom treatment for HMB has been unsuccessful.

In other clinical circumstances diagnostic hysteroscopy is commissioned in the following clinical circumstances:

- First -line investigation using ultrasound scan has provided inconclusive results. For example, hysteroscopy is clinically required to determine the exact location of a fibroid or the exact nature of the abnormality.

N.B. investigation for suspected or proven malignancy is outside the scope of this policy and should in investigated in line with the relevant cancer pathway.

This means the CCG will only fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Activity data 2018/19

Number of Procedures	BSOL	Sandwell
	746	176

Due to limited data collection by the providers service activity data is available by headcount only not protected characteristic.
The Joint Strategic Needs Assessments for Birmingham, Solihull and Sandwell are available via the links below.

Sandwell

Birmingham

Solihull

2. Research

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

Research/Publications	Working Groups	Clinical Experts
Abd Elkhalek 2016 Abd Elkhalek, Y. I., Kamel, O. F., El-Sabaa, H., Comparison of 3 dimensional sonohysterography and hysteroscopy in		

Premenopausal women with abnormal uterine bleeding, Egyptian Journal of Radiology and Nuclear Medicine, 47, 1117-22, 2016

Abdel Hak 2010
Abdel Hak, A. M., Accuracy of sonographic criteria for diagnosis of adenomyosis in perimenopausal women with menorrhagia, Middle East Fertility Society Journal, 15, 35-8, 2010

Abe 2008
Abe, M., Ogawa, H., Ayhan, A., The use of non-three-layer ultrasound in biopsy recommendation for premenopausal women, Acta Obstetricia et Gynecologica Scandinavica, 87, 2008

Alborzi 2007
Alborzi, S., Parsanezhad, M. E., Mahmoodian, N., Alborzi, S., Alborzi, M., Sonohysterography versus transvaginal sonography for screening of patients with abnormal uterine bleeding, International Journal of Gynaecology & Obstetrics, 96, 20-3, 2007

Bazot 2002
Bazot, M., Darai, E., Rouger, J., Detchev, R., Cortez, A., Uzan, S., Limitations of transvaginal sonography for the diagnosis of adenomyosis, with histopathological correlation, Ultrasound in Obstetrics and Gynecology, 20, 605-11, 2002

Botsis 1998
Botsis, D., Kassanos, D., Antoniou, G., Pyrgiotis, E., Karakitsos, P., Kalogirou, D., Adenomyoma and leiomyoma: differential diagnosis with transvaginal sonography, Journal of Clinical Ultrasound, 26, 21-5, 1998

Champaneria 2010
Champaneria, R., Abedin, P., Daniels, J., Balogun, M., Khan, K.S., Ultrasound scan and magnetic resonance imaging for the diagnosis of adenomyosis: systematic review comparing test accuracy, Acta Obstetricia et Gynecologica, 89, 1374–84, 2010

Cicinelli 1995
Cicinelli, E., Romano, F., Anastasio, P. S., Blasi, N., Parisi, C., Galantino, P., Transabdominal sonohysterography, transvaginal sonography, and hysteroscopy in the evaluation of submucous myomas, Obstet GynecolObstetrics and gynecology, 85, 42-7, 1995

Cooper 2014 Cooper, N. A., Barton, P. M., Breijer, M., Caffrey, O., Opmeer, B. C., Timmermans, A., Mol, B. W., Khan, K. S., Clark, T. J., Cost-effectiveness of diagnostic strategies for the management of abnormal uterine bleeding (heavy menstrual

bleeding and post-menopausal bleeding): a decision analysis, Health Technology Assessment, 18, 1-201, 2014 **Critchley 2004** Critchley, H. O. D., Warner, P., Lee, A. J., Brechin, S., Guise, J., Graham, B., Evaluation of abnormal uterine bleeding: Comparison of three outpatient procedures within cohorts defined by age and menopausal status, Health Technology Assessment, 8, iii-77, 2004 **Dakhly 2016** Dakhly, D. M. R., Abdel Moety, G. A. F., Saber, W., Gad Allah, S. H., Hashem, A. T., Abdel Salam, L. O. E., Accuracy of Hysteroscopic Endomyometrial Biopsy in Diagnosis of Adenomyosis, Journal of Minimally Invasive Gynecology, 23, 364-71, 2016 **Dasgupta 2011a** Dasgupta, S., Chakraborty, B., Karim, R., Aich, R. K., Mitra, P. K., Ghosh, T. K., Abnormal uterine bleeding in peri-menopausal age: Diagnostic options and accuracy, Journal of Obstetrics and Gynecology of India, 61, 189-94, 2011a **Dasgupta 2011b** Dasgupta, S., Sharma, P. P., Mukherjee, A., Ghosh, T. K., Ultrasound assessment of endometrial cavity in perimenopausal women on oral progesterone for abnormal uterine bleeding: comparison of diagnostic accuracy of imaging with hysteroscopy-guided biopsy, The journal of obstetrics and gynaecology research, 37, 2011b **Dueholm 2001a** Dueholm, M., Forman, A., Jensen, M. L., Laursen, H., Kracht, P., Transvaginal sonography combined with saline contrast sonohysterography in evaluating the uterine cavity in premenopausal patients with abnormal uterine bleeding, Ultrasound in Obstetrics and Gynecology, 18, 54-61, 2001a **Dueholm 2001b** Dueholm, M., Lundorf, E., Hansen, E. S., Sorensen, J. S., Ledertoug, S., Olesen, F., Magnetic resonance imaging and transvaginal ultrasonography for the diagnosis of adenomyosis, Fertility and Sterility, 76, 588-94, 2001b **Erdem 2007** Erdem, M., Bilgin, U., Bozkurt, N., Erdem, A., Comparison of transvaginal ultrasonography and saline infusion sonohysterography in evaluating the endometrial cavity in pre-		

and postmenopausal women with abnormal uterine bleeding, Menopause, 14, 2007

Exacoustos 2011
Exacoustos, C., Brienza, L., Di Giovanni, A., Szabolcs, B., Romanini, M. E., Zupi, E., Arduini, D., Adenomyosis: three-dimensional sonographic findings of the junctional zone and correlation with histology, Ultrasound in obstetrics & gynecology : the official journal of the International Society of Ultrasound in Obstetrics and Gynecology, 37, 471-9, 2011

Fakhar and Mahmud 2010
Fakhar, S., Mahmud, G., Validity of hysteroscopy and histopathology in patients with menstrual irregularity, Journal of Ayub Medical College, Abbottabad: JAMC, 22, 129-32, 2010

Gkrozou 2015
Gkrozou, F., Dimakopoulos, G., Vrekoussis, T., Lavasidis, L., Koutlas, A., Navrozoglou, I., Stefos, T., Paschopoulos, M., Hysteroscopy in women with abnormal uterine bleeding: a meta-analysis on four major endometrial pathologies, Arch Gynecol Obstet, 291, 1347-54, 2015

Krampl 2001
Krampl, E., Bourne, T., Hurlen-Solbakken, H., Istre, O., Transvaginal ultrasonography sonohysterography and operative hysteroscopy for the evaluation of abnormal uterine bleeding, Acta Obstetricia et Gynecologica Scandinavica, 80, 616-622, 2001

Meredith 2009
Meredith, S. M., Sanchez-Ramos, L., Kaunitz, A. M., Diagnostic accuracy of transvaginal sonography for the diagnosis of adenomyosis: systematic review and metaanalysis. American Journal of Obstetrics and Gynecology, 201:107, e1-6, 2009

Mukhopadhayay 2007
Mukhopadhayay, S., Bhattacharyya, S. K., Ganguly, R. P., Patra, K. K., Bhattacharya, N., Barman, S. C., Comparative evaluation of perimenopausal abnormal uterine bleeding by transvaginal sonography, hysteroscopy and endometrial biopsy, Journal of the Indian Medical Association, 105, 2007

Najeeb 2010
Najeeb, R., Awan, A. S., Bakhtiar, U., Akhter, S., Role of transvaginal sonography in assessment of abnormal uterine bleeding in perimenopausal age group, Journal of Ayub Medical College, Abbottabad : JAMC, 22, 2010

Nanda 2002
Nanda, S., Chadha, N., Sen, J., Sangwan, K., Transvaginal sonography and saline infusion sonohysterography in the evaluation of abnormal uterine bleeding, Australian and New Zealand Journal of Obstetrics and Gynaecology, 42, 530-4, 2002

NHS 2018
NHS. 2018 Hysteroscopy. Last reviewed 05.12.2018. https://www.nhs.uk/conditions/hysteroscopy/

NHS 2018
NHS. 2018. Heavy Menstrual Bleeding. Last updated 07.06.2018. https://www.nhs.uk/conditions/heavy-periods/

NICE 2018
NICE 2018 NICE Guidelines: Heavy menstrual bleeding: Assessment and Management.
Published: 14 March 2018 nice.org.uk/guidance/ng88

NICE 2018
NICE 2018 NICE Guideline 88: Evidence Reviews.
March 2018. https://www.nice.org.uk/guidance/ng88/evidence/a-diagnostic-test-accuracy-pdf-4782293101

Pennant 2017
Pennant, M. E., Mehta, R., Moody, P., Hackett, G., Prentice, A., Sharp, S. J., Lakshman, R., Premenopausal abnormal uterine bleeding and risk of endometrial cancer, BJOG, 124, 404-11, 2017

RCOG and BSGE 2016
Royal Coll Royal College of Obstetricians and Gynaecologists, British Society for Gynaecological Endoscopy, Management of Endometrial Hyperplasia, Green-top Guideline No. 67, London: RCOG, 2016

RCOG and BSGE 2011
Royal College of Obstetricians and Gynaecologists, British Society for Gynaecological Endoscopy, Best Practice in Outpatient Hysteroscopu, Green-top Guideline No. 59, London: RCOG, 2011

Soguktas 2012
Soguktas, S., Cogendez, E., Kayatas, S. E., Asoglu, M. R., Selcuk, S., Ertekin, A., Comparison of saline infusion sonohysterography and hysteroscopy in diagnosis of premenopausal women with abnormal uterine bleeding, European Journal of Obstetrics, Gynecology, & Reproductive BiologyEur J Obstet Gynecol Reprod Biol, 161, 2012

Taylor 2001 Taylor, S., Jones, S., Dixon, A. M., O'Donovan, P., Evaluation of ultrasound in an outpatient hysteroscopy clinic: Does it alter management in premenopausal women?, Gynaecological Endoscopy, 10, 173-8, 2001 **Vercellini 1998** Vercellini, P., Cortesi, I., De Giorgi, O., Merlo, D., Carinelli, S. G., Crosignani, P. G., Transvaginal ultrasonography versus uterine needle biopsy in the diagnosis of diffuse adenomyosis, Human Reproduction, 13, 1998 **Vercellini 1997** Vercellini, P., Cortesi, I., Oldani, S., Moschetta, M., De Giorgi, O., Crosignani, P. G., The role of transvaginal ultrasonography and outpatient diagnostic hysteroscopy in the evaluation of patients with menorrhagia, Human Reproduction, 12, 1768-71, 1997 **Williams and Marshburn 1998** Williams, C. D., Marshburn, P. B., A prospective study of transvaginal hydrosonography in the evaluation of abnormal uterine bleeding, Am J Obstet GynecolAmerican journal of obstetrics and gynecology, 179, 292-8, 1998 **Yildiz 2009** Yildiz, A., Koksal, A., Ates, P. F., Ivit, H., Keklik, A., Cukurova, K., Hysteroscopy in the evaluation of intrauterine cavity. Is it more valuable than dilatation and curettage?, Turkiye Klinikleri Journal of Medical Sciences, 29, 2009		

3. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

Age: Describe age related impact and evidence. This can include safeguarding, consent and welfare issues:

Although, if clinically required Hysteroscopy can be performed once a person is menstruating the most common reasons to perform the investigative procedure is due to fibroids which usually appear in women between 30 and 50 years old, however, they can be present at any age.

3. Impact and Evidence:
Disability: Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments: No impact identified
Gender reassignment (including transgender): Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment: No impact identified
Marriage and civil partnership: Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities: No impact identified
Pregnancy and maternity: Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities: Hysteroscopy cannot be performed during pregnancy.
Race: Describe race related impact and evidence**.** This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers: No impact identified
Religion or belief: Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues: No impact identified
Sex: Describe any impact and evidence on men and women. This could include access to services and employment: Due to the nature of the condition this procedure is only available to those who require uterus investigative work.

3. Impact and Evidence:
Sexual orientation: Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers: No impact identified
Carers: Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities: No impact identified
Other disadvantaged groups: Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive) No impact identified

4. Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals?	No	This condition is not linked to a health inequality.
Is there any impact for groups or communities living in particular geographical areas?	No	No impact identified
Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	No	No impact identified
How will you ensure the proposals reduce health inequalities?		

5. FREDA Principles/ Human Rights	Question	Response
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	Yes, this decision has been made in line with clinical recommendation and NICE guidance.

Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	No evidence of impact from this policy
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	No discrimination identified
	How will this affect a person's right to freedom of thought, conscience and religion?	N/A
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	Policy will be applied with due regard to this consideration.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	An individual can discuss the impact with their GP and has the option for an IFR request to be made
Right to **Life**	Will or could it affect someone's right to life? How?	No evidence of impact from this policy
Right to **Liberty**	Will or could someone be deprived of their liberty? How?	No evidence of impact from this policy

6. Social Value

Consider how you might use the opportunity to improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.

Marmot Policy Objective	**What actions are you able to build into the procurement activity and/or contract to achieve wider public benefits?**
Enable all people to have control over their lives and maximise their capabilities	None
Create fair employment and good work for all	None
Create and develop health and sustainable places and communities	None
Strengthen the role and impact of ill-health prevention	None

7. Engagement, Involvement and Consultation

If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:

Engagement Activity	Protected Characteristic/ Group/ Community	Date

For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us …. So we will …..):

As part of the process further targeted engagement is planned with representative groups from among Sandwell, Birmingham and Solihull Patients. In addition, it has been identified that patient and clinician information is key in ensuring that the harmonised treatment policies review delivers effective outcomes. To this end an information briefing sheets on each procedure will be developed to give more information on the procedure, eligibility criteria and signposting to further information sources, such as NHS Choices. These information sheets are also designed to help facilitate discussions between GPs and patients. Information briefing sheets have already been tested and uploaded onto the GP systems for the first 45 harmonised treatment policies for Birmingham and Solihull. Due regard will be given to both the accessible information standard and the potential need to translate such leaflets into relevant local languages.

The engagement team used every possible route throughout the engagement period to encourage people to feedback on the proposed policy. Unfortunately, despite the wide communication undertaken through all communication and engagement channels available, 49 questionnaires were completed online and there was no interest from stakeholders, patients and the public to attend any of the five stakeholder events arranged. As a result, the events were cancelled, and the engagement team looked at other routes to encourage engagement with patients directly. A possible reason for the general lack of interest and feedback from stakeholders, patients and the public is most likely because this clinical treatments policy either widening the scope of the current service provision, providing policies to protect the current service provision or the intervention is for somewhat rare conditions.

Also, in phase 3 of the harmonisation of policies programme clinicians had been integral to the development of the policies from the beginning of the process. It could therefore be argued the proposed policy shared for public engagement was to some extent already informed from a local patient experience and outcomes perspective.

Feedback suggested that there was no or limited impact for patients. Over half of the respondents agreed with the proposed policy and there was a general consensus that the possibility of having a hysteroscopy as a first line of treatment in certain clinical circumstances was a welcomed as it would provide a quicker diagnosis.

8. Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work:

The restriction of this policy will have limited impact on those who would wish to receive the treatments as the procedure is commissioned as a first line investigation if

they meet the eligibility criteria. The opportunity for any exceptional cases to be considered via IFR remains and will ensure treatment is available.

9. Mitigations and Changes :

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.

None identified

10. Contract Monitoring and Key Performance Indicators

Detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract (refer to NHS Standard Contract SC12 and 13):

This policy is not linked to a contract however, prospective providers remain bound by their contracts with the CCG.

11. Procurement

Detail the key equality, health inequalities, human rights, and social value criteria that will be included as part of the procurement activity (to evaluate the providers ability to deliver the service in line with these areas):

N/A

12. Publication

How will you share the findings of the Equality Analysis?

This can include: reports into committee or Governing Body, feedback to stakeholders including patients and the public, publication on the web pages. All Equality Analysis should be recommended for publication unless they are deemed to contain sensitive information.

Publication on the CCG's website.

Following approval all finalised Equality Analysis should be sent to the Communications and Engagement team for publication: bsol.comms@nhs.net

13. Sign Off

The Equality Analysis will need to go through a process of **quality assurance** by the Senior Manager for Equality and Diversity, Senior Manager for Assurance and Compliance or Equality and Human Rights Manager **and** signed-off by a delegated committee

	Name	Date
Quality Assured By:		
Which Committee will be considering the findings and signing off the EA?		
Minute number (to be inserted following presentation to committee)		

Please send to Balvinder Everitt or Michelle Dunne, Equality, Diversity and Inclusion for Quality Assurance.

Once you have committee sign off, please send to Caroline Higgs, Communications & Engagement Team for publication: bsol.comms@nhs.net

Equality Analysis

(Health Inequalities, Human Rights, Social Value)

Policy Knee Arthroscopy for Acute Knee Injury

Before completing this equality analysis it is recommended that you:

- ✓ Contact your equality and diversity lead for advice and support
- ✓ Take time to read the accompanying policy and guidance document on how to complete an equality analysis

NHS Birmingham and Solihull Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group

1. Background			
EA Title	Policy Knee Arthroscopy for Acute Knee Injury		
EA Author	David King	**Team**	Equality and Diversity
Date Started	September 2019	**Date Completed**	4/12/2019
EA Version	4	**Reviewed by E&D**	

What are the intended outcomes of this work? Include outline of objectives and function aims

The Knee

The 3 bones that meet in the knee are the:

- thigh bone (femur)
- shin bone (tibia)
- kneecap (patella)

These bones are connected by 4 ligaments – 2 collateral ligaments on the sides of the knee and 2 cruciate ligaments inside the knee.
Ligaments are tough bands of connective tissue. The ligaments in the knee hold the bones together and help keep the knee stable.
The menisci are thick pads of cartilage tissue within the knee which act as shock absorbers to absorb body weight and help improve smooth movement and stability of the knee.

The two main areas within the knee which may be damaged by an acute injury include:

1. Menisci (cartilage)
2. Ligaments

1. **Menisci.**

What is the knee meniscus?

The menisci are thick pads of cartilage tissue within the knee which act as shock absorbers to absorb body weight and help improve smooth movement and stability of the knee. Each knee joint contains a medial and lateral meniscus (inner and outer meniscus).

1. Background

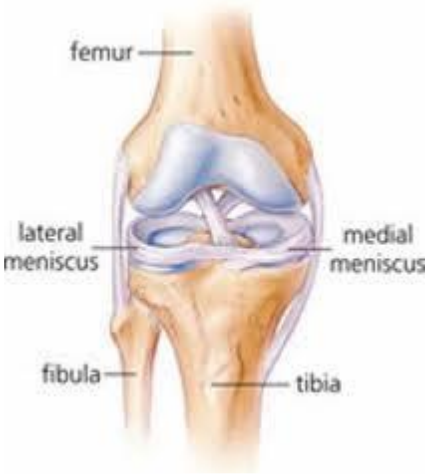


Figure 1. The Knee Joint

What is a meniscal injury?

There are varying degrees of damage a patient can do to the menisci. These range from bruising the menisci through to having large tears of the menisci. Meniscal tears can occur during sporting activities through twisting the knee whilst the foot is still in contact with the ground. In severe injuries, other parts of the knee may also be damaged in addition to a meniscal tear. For example, a patient may also sprain or tear a ligament. Meniscal cartilage does not always heal very well once it is torn. This is mainly because the central area of the meniscus does not have a good blood supply. The outer edge of each meniscus has some blood vessels, but the area in the centre has no direct blood supply.

Conservative Treatment

The PRICE protocol is effective for most sports-related injuries.

PRICE stands for Protection, Rest, Ice, Compression, and Elevation.

- Protection – protect the affected area from further injury – for example, by using a support.
- Rest – avoid exercise and reduce your daily physical activity. Using crutches or a walking stick may help if you can't put weight on your ankle or knee. A sling may help if you've injured your shoulder.
- Ice – apply an ice pack to the affected area for 15-20 minutes every two to three hours. A bag of frozen peas, or similar, will work well. Wrap the ice pack in a towel so that it doesn't directly touch your skin and cause an ice burn.
- Compression – use elastic compression bandages during the day to limit swelling.

1. Background

- Elevation – keep the injured body part raised above the level of your heart whenever possible. This may also help reduce swelling.

Non-steroidal anti-inflammatory medicines. Drugs like aspirin and ibuprofen reduce pain and swelling.

Physiotherapy for those whose symptoms do not resolve.

Surgical Treatment

Procedure. Knee arthroscopy is one of the most commonly performed surgical procedures. In it, a miniature camera is inserted through a small incision (portal). This provides a clear view of the inside of the knee. The orthopaedic surgeon, then inserts miniature surgical instruments through other portals to trim or repair the tear.

- Partial meniscectomy. In this procedure, the damaged meniscus tissue is trimmed away.
- Meniscus repair. Some meniscus tears can be repaired by suturing (stitching) the torn pieces together. Whether a tear can be successfully treated with repair depends upon the type of tear, as well as the overall condition of the injured meniscus. Because the meniscus must heal back together, recovery time for a repair is much longer than from a meniscectomy.

.

Risks of meniscal surgery

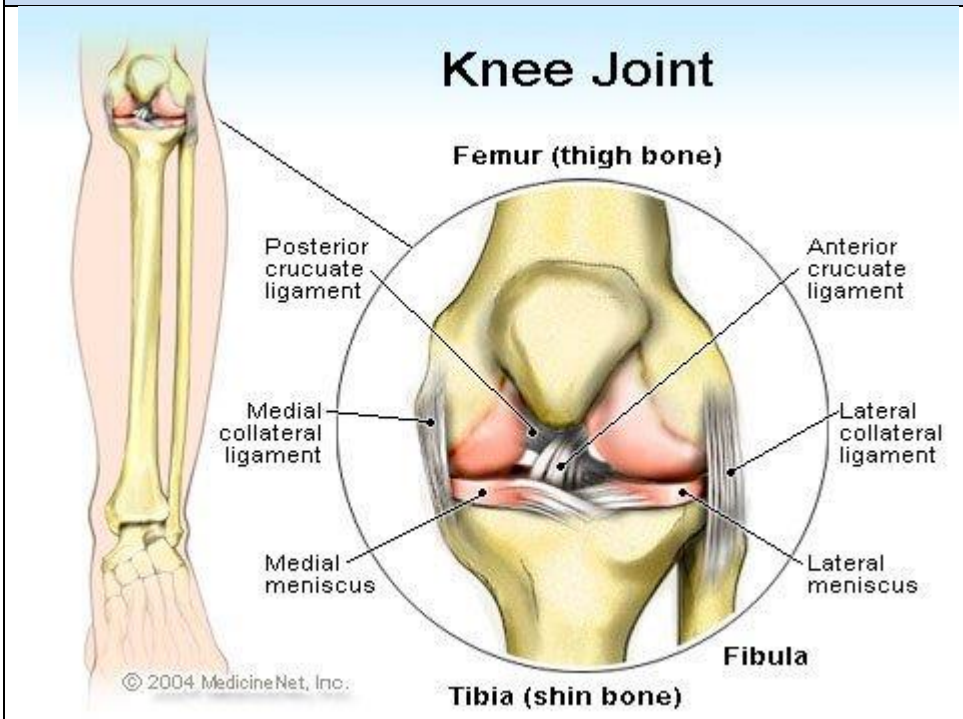
The knee may not be exactly like it was before the injury, and the patient may still have some pain and swelling.
This may be because of other injuries to the knee, such as tears or injuries to ligaments, which happened at the same time as or after the injury.
As with all types of surgery, there are some small risks associated with knee surgery, including infection, a blood clot, knee pain, and knee weakness and stiffness.

2. Ligaments (Anterior Cruciate Ligament (ACL); Posterior Cruciate Ligament (PCL); Collateral Ligaments R/LCL)

What are the Knee Ligaments?

The Ligaments found within the knee are tough bands of tissue joining the thigh bone to the shin bone at the knee joint.
The ligaments run diagonally through the inside of the knee and around each side which give the knee joint stability. It also helps to control the back-and-forth movement of the lower leg.

1. Background



Ligament injuries

Knee injuries can occur during sports such as skiing, tennis, squash, football and rugby. Ligament injuries, in particular Anterior Cruciate Ligament (ACL) injuries are one of the most common types of knee injuries, accounting for around 40% of all sports injuries.

A patient may tear the knee ligaments if the lower leg extends forwards too much. It can also be torn if the knee and lower leg are twisted.

Common causes of a ligament injury include:

- landing incorrectly from a jump
- stopping suddenly
- changing direction suddenly
- having a collision, such as during a football tackle

Conservative management

The PRICE protocol is effective for most sports-related injuries. PRICE stands for Protection, Rest, Ice, Compression, and Elevation.

- Protection – protect the affected area from further injury – for example, by using a support.
- Rest – avoid exercise and reduce your daily physical activity. Using crutches or a walking stick may help if you can't put weight on your ankle or knee. A sling may help if you've injured your shoulder.

1. Background

- Ice – apply an ice pack to the affected area for 15-20 minutes every two to three hours. A bag of frozen peas, or similar, will work well. Wrap the ice pack in a towel so that it doesn't directly touch your skin and cause an ice burn.
- Compression – use elastic compression bandages during the day to limit swelling.
- Elevation – keep the injured body part raised above the level of your heart whenever possible. This may also help reduce swelling.

Non-steroidal anti-inflammatory medicines. Drugs like aspirin and ibuprofen reduce pain and swelling.

Physiotherapy for those whose symptoms do not resolve.

Reconstructive Ligament surgery

A torn ligament cannot be repaired by stitching it back together, but it can be reconstructed by attaching (grafting) new tissue on to it.

The ligament, for example the ACL, may be reconstructed by removing what remains of the torn ligament and replacing it with a tendon from another area of the leg, such as the hamstring or patellar tendon.

The patellar tendon attaches the bottom of the kneecap (patella) to the top of the shinbone (tibia).

Risks of ligament surgery

The knee may not be exactly like it was before the injury, and you may still have some pain and swelling. This may be because of other injuries to the knee, such as tears or injuries to the cartilage, which happened at the same time as or after the ligament injury.

As with all types of surgery, there are some small risks associated with knee surgery, including infection, a blood clot, knee pain, and knee weakness and stiffness.

Evidence Review

There was **no NICE Guidance identified** which reviewed this surgical intervention, and no systematic reviews were identified.

Utsaerts et al. (2016) produced a follow-up paper to their RCT, which is considered high quality with long follow-up.

In this high quality randomised controlled trial, with minimal loss to follow-up, a strategy of rehabilitation plus early ACL reconstruction did not provide better results at five years than a strategy of initial rehabilitation with the option of having a later ACL

1. Background

reconstruction. Results did not differ between knees surgically reconstructed early or late and those treated with rehabilitation alone. These results should encourage clinicians and young active adult patients to consider rehabilitation as a primary treatment option after an acute ACL tear.

Frobell et al (2013) found there was no increased risk of osteoarthritis or meniscal surgery if the ACL injury was treated with physiotherapy alone compared with if it was treated with surgery. Neither was there any difference in patients' experiences of function, activity level, quality of life, pain, symptoms or general health.

Measures included Knee injury and osteoarthritis outcome score (KOOS), the Medical Outcomes Study 36-item short-form health survey (SF-36), short-form health survey (SF-36), and the Tegner activity scale. In the full analysis set, the mean change in KOOS4 score from baseline to five years was 42.9 points for patients assigned to rehabilitation plus early anterior cruciate ligament reconstruction and 44.9 points for those assigned to rehabilitation plus optional delayed reconstruction (between group difference 2.0 points, 95% confidence interval −8.5 to 4.5; P=0.54 after adjustment for the baseline score). No statistically significant differences in KOOS4, any of the five individual subscales of KOOS, SF-36, or Tegner activity scale between the two treatment strategies were identified at five years or in the change between two and five years.

In conclusion, the evidence does not support the use of surgical repair as a primary treatment immediately following injury. However, in cases where conservative treatment over 3 months has failed: physiotherapy; analgesia and PRICE, then the current evidence demonstrates that knee arthroscopy with ligament / menisci repair may be clinically appropriate.

Activity data 2018/19

Number of Procedures	BSOL	Sandwell
	35	10

Due to limited data collection by the providers service activity data is available by headcount only not protected characteristic.
The Joint Strategic Needs Assessments for Birmingham, Solihull and Sandwell are available via the links below.

- Sandwell
- Birmingham
- Solihull

1. Background

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

Knee Arthroscopy for Acute Knee injury is only commissioned in the following clinical circumstances:

- The patient **does not** have degenerative knee disease AND
- The patient has experienced an acute knee injury AND
- Following the acute knee injury, the patient has undergone clinician verified conservative treatment with physiotherapy; analgesia and PRICE which has failed AND
- The patient continues to have mechanical symptoms which are causing functional impairment.

The term degenerative knee disease is used to explicitly include patients with knee pain, particularly if they are >35 years old, with or without:

- Imaging evidence of osteoarthritis
- Meniscus tears
- Locking, clicking, or other mechanical symptoms except persistent objective locked knee **OR**
- Acute or subacute onset of symptoms

N.B. Functional impairment is defined as interfering with activities of daily living, i.e. walking; sleeping; eating.

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

2. Research

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

2. Research		
Research/Publications	**Working Groups**	**Clinical Experts**
[1] Treatment for acute anterior cruciate ligament tear: five-year outcome of randomised trial. BMJ 2013; 346 doi: https://doi.org/10.1136/bmj.f232 [2] Mutsaerts ELAR, van Eck CF, van de Graaf VA, Doornberg JN, van den Bekerom MPJ. Surgical interventions for meniscal tears: a closer look at the evidence. Arch Orthop Trauma Surg 2016;136:361-37 [3] Smith TO, Davies L, Hing CB (2010) Early versus delayed surgery for anterior cruciate ligament reconstruction: a systematic review and meta-analysis. Knee Surg Sports Traumatol Arthrosc 18:304–311 [4] Webb,R., Brammah,T., Lunt,M., et al. (2004) Opportunities for prevention of 'clinically significant' knee pain: results from a population-based cross sectional survey. Journal of Public Health (Oxford). 26(3), 277-284 [5] Brophy RH, Zeltser D, Wright RW, et al. Anterior cruciate ligament reconstruction and concomitant articular cartilage injury: incidence and treatment. Arthroscopy. 2010;26:112-120. http://www.ncbi.nlm.nih.gov/pubmed/20117635?tool=bestpractice.com [6] Bowers AL, Spindler KP, McCarty EC, et al. Height, weight, and BMI predict intra-articular injuries observed during ACL reconstruction: evaluation of 456 cases from a prospective ACL database. Clin J Sport Med. 2005;15:9-13. http://www.ncbi.nlm.nih.gov/pubmed/15654185?tool=bestpractice.com [7] Mandalia V, Fogg AJ, Chari R, et al. Bone bruising of the knee. Clin Radiol. 2005;60:627-636. https://bestpractice.bmj.com/topics/en-gb/589/complications#referencePop109 [8] Rodkey WG, Steadman JR, Li ST. A clinical study of collagen meniscus implants to restore the injured meniscus. Clin Orthop Relat Res. 1999:S281-92. http://www.ncbi.nlm.nih.gov/pubmed/10546653?tool=bestpractice.com [9] NHS website: https://www.nhs.uk/conditions/arthroscopy/		

2. Research

[10] Kruseman N, Geesink RGT, van der Linden AJ *et al*. Acute knee injuries: diagnostic & treatment management proposals. http://arnos.unimasas.nl/show.cgi?fig1?46875 [11] Steve Bollen: Injuries of the sporting knee - Epidemiology of knee injuries: diagnosis and triage https://bjsm.bmj.com/content/34/3/227.2		

3. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

Age: Describe age related impact and evidence. This can include safeguarding, consent and welfare issues:

There is a link to those who participate in high impact sports and are subject to repetitive stress injury such as skiing, tennis, squash, football and rugby and therefore may be at a higher risk of getting injured. Also, those who with certain occupations that put constant repetitive pressure and stress on the joints such as kneeling, squatting may also be at an increased risk.

The chance of developing degenerative knee disease such as osteoarthritis increases with age as the ability of cartilage to heal decreases as you age. However, this must be balanced against the need to adhere to the clinical effectiveness evidence with those who suffer from this condition. The opportunity for any exceptional cases to be considered via IFR remains.

Disability: Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments:

A link can be made with degenerative conditions such as arthritis where the person experiencing is likely to have a disability. Limiting this procedure may have an impact upon this group however the procedure is not be clinically evidence based to treat the arthritis and other treatments to relieve symptoms are available with good supporting clinical evidence of effectiveness. The decision must be balanced against the need to

3. Impact and Evidence:
adhere to the clinical effectiveness evidence, the potential risks and the overall benefit for the patient after surgery.
Gender reassignment (including transgender): Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment: No impact identified
Marriage and civil partnership: Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities: No impact identified
Pregnancy and maternity: Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities: No impact identified
Race: Describe race related impact and evidence**.** This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers: No impact identified
Religion or belief: Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues: No impact identified
Sex: Describe any impact and evidence on men and women. This could include access to services and employment: No impact identified.

3. Impact and Evidence:
Sexual orientation: Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers: No impact identified
Carers: Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities: No impact identified
Other disadvantaged groups: Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive) No impact identified on the basis of the information available. Some interventions may not be suitable where the patient is homeless / of no fixed abode.

4. Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals?	No	This condition is not linked to a health inequality.
Is there any impact for groups or communities living in particular geographical areas?	No	No impact identified
Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	No	No impact identified
How will you ensure the proposals reduce health inequalities? .		

5. FREDA Principles/ Human Rights	Question	Response

Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	This decision has been made in line with clinical recommendation.
Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	No evidence of impact for this policy
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	No discrimination identified
	How will this affect a person's right to freedom of thought, conscience and religion?	N/A
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	Policy will be applied with due regard to this consideration.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	An individual can discuss the impact with their GP and has the option for an IFR request to be made
Right to **Life**	Will or could it affect someone's right to life? How?	No evidence of impact for this policy
Right to **Liberty**	Will or could someone be deprived of their liberty? How?	No evidence of impact for this policy

6. Social Value

Consider how you might use the opportunity to improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.

Marmot Policy Objective	**What actions are you able to build into the procurement activity and/or contract to achieve wider public benefits?**
Enable all people to have control over their lives and maximise their capabilities	none
Create fair employment and good work for all	none
Create and develop health and sustainable places and communities	none
Strengthen the role and impact of ill-health prevention	none

7. Engagement, Involvement and Consultation

If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:

Engagement Activity	Protected Characteristic/ Group/ Community	Date

For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us …. So we will …..):

As part of the process targeted engagement has been undertaken with representative groups from among Sandwell, Birmingham and Solihull Patients. In addition, it has been identified that patient and clinician information is key in ensuring that the harmonised treatment policies review delivers effective outcomes. To this end information briefing sheets on each procedure will be developed to give more information on the procedure, eligibility criteria and signposting to further information sources, such as NHS Choices. These information sheets are also designed to help facilitate discussions between GPs and patients. Information briefing sheets have already been tested for the Phase 1 and Phase 2 Harmonised Clinical Treatment Policies for Birmingham and Solihull CCG and Sandwell and West Birmingham CCG. Due regard will be given to both the accessible information standard and the potential need to translate such leaflets into relevant local languages.

The engagement team used every possible route throughout the engagement period to encourage people to feedback on the proposed policy. Unfortunately, despite the wide communication undertaken through all communication and engagement channels available, 49 questionnaires were completed online and there was little interest from stakeholders, patients and the public to attend any of the five stakeholder events arranged. As a result, the events were cancelled, and the engagement team looked at other routes to encourage engagement with patients directly. A possible reason for the general lack of interest and feedback from stakeholders, patients and the public is most likely because this proposed clinical treatment policy providing a policy to protect the current service provision and has clinical support.

Also, in Phase 3 of the Harmonisation of Clinical Treatment Policies programme clinicians had been integral to the development of the policies from the beginning of the process. It could therefore be argued the proposed policy shared for public engagement was to some extent already informed from a local patient experience and outcomes perspective.

The potential impact on patients was therefore minimal as the policy has been widened and treatment is offered based on specific criteria. Feedback from over 50% of respondents suggested they either agreed or strongly agreed to the proposed policy change. It is noted that within the additional comments the proposed change has been received positively to include acute knee injury, however concerns were raised over degenerative knee injury and subsequent management of this condition, which are outside the remit of this current policy.

7. Engagement, Involvement and Consultation

8. Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work:

Clinical evidence does not support the use of surgical repair as a primary treatment immediately following injury only in cases where conservative treatment over three months has failed: physiotherapy; analgesia and PRICE, then the current evidence demonstrates that knee arthroscopy with ligament / menisci repair may be clinically appropriate.

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

The opportunity for any exceptional cases to be considered via IFR remains.

9. Mitigations and Changes:

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.

None identified

10. Contract Monitoring and Key Performance Indicators

Detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract (refer to NHS Standard Contract SC12 and 13):

This policy is not linked to a contract however, prospective providers remain bound by their contracts with the CCG.

11. Procurement

Detail the key equality, health inequalities, human rights, and social value criteria that will be included as part of the procurement activity (to evaluate the providers ability to deliver the service in line with these areas):

N/A

12. Publication

How will you share the findings of the Equality Analysis? This can include: reports into committee or Governing Body, feedback to stakeholders including patients and the public, publication on the web pages. All Equality Analysis should be recommended for publication unless they are deemed to contain sensitive information.
Publication on the CCG's website.
Following approval all finalised Equality Analysis should be sent to the Communications and Engagement team for publication: bsol.comms@nhs.net

13. Sign Off

The Equality Analysis will need to go through a process of **quality assurance** by the Senior Manager for Equality Diversity and Inclusion or the Manager for Equality Diversity and Inclusion prior to approval from the delegated committee

	Name	Date
Quality Assured By:		
Which Committee will be considering the findings and signing off the EA?		
Minute number (to be inserted following presentation to committee)		

Please send to Balvinder Everitt or Michelle Dunne, Equality, Diversity and Inclusion for Quality Assurance.

Once you have committee sign off, please send to Caroline Higgs, Communications & Engagement Team for publication: bsol.comms@nhs.net

Equality Analysis

(Health Inequalities, Human Rights, Social Value)

Policy for the use of Liposuction in Lipoedema

Before completing this equality analysis it is recommended that you:

- ✓ Contact your equality and diversity lead for advice and support
- ✓ Take time to read the accompanying policy and guidance document on how to complete an equality analysis

NHS Birmingham and Solihull Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group

1. Background

EA Title	**Policy for the use of Liposuction in Lipoedema**		
EA Author	David King	**Team**	Equality and Diversity Team
Date Started	September 2019	**Date Completed**	4/12/2019
EA Version	4	**Reviewed by E&D**	

What are the intended outcomes of this work? Include outline of objectives and function aims

Liposuction

Liposuction is normally deemed to be a cosmetic procedure used to remove unwanted body fat.

It involves sucking out small areas of fat that are hard to lose through exercise and a healthy diet. It is usually carried out on areas of the body where deposits of fat tend to collect, such as the buttocks, hips, thighs and tummy.

The aim is to alter body shape, and the results are generally long-lasting, providing a healthy weight is maintained.

It works best in people who are a normal weight and in areas where the skin is tight.

Liposuction carried out for cosmetic reasons is not normally available on the NHS. However, liposuction can sometimes be used by the NHS to treat certain health conditions.

Liposuction is usually carried out under general anaesthetic, although an epidural anaesthetic may be used to enable treatment on lower parts of the body.

The surgeon would mark on your body the area where fat is to be removed. He or she would then:

- **inject this area** with a solution containing anaesthetic and medication, to reduce blood loss, bruising and swelling
- **break up the fat cells** using high-frequency vibrations, a weak laser pulse or a high-pressure water jet
- **make a small incision (cut) and insert a suction tube attached to a vacuum machine** (several cuts may need to be made if the area is large)
- **move the suction tube back and forth** to loosen the fat and suck it out
- **drain** any excess fluid and blood
- **stitch up and bandage** the treated area

It usually takes one to three hours. Most people need to stay in hospital overnight.

Liposuction in Lipoedema: Category: Not Routinely Commissioned

Lipoedema is a long-term (chronic) condition where there is an abnormal build-up of fat cells in the legs, thighs and buttocks, and sometimes in the arms.

The condition usually only affects women, although in rare cases it can also affect men.

In lipoedema, the thighs, buttocks, lower legs, and sometimes the arms, become enlarged due to a build-up of abnormal fat cells. Both legs and/or the arms are usually enlarged at the same time and to the same extent.

The feet and hands are not affected, which creates a "bracelet" effect or "band-like" appearance just above the ankles and wrists.

Leg and arm size can vary between individuals with lipoedema, and the condition can gradually get worse over time.

As well as becoming enlarged, affected areas of the body may:

- feel soft, "doughy" and cold
- bruise easily
- ache or feel painful or tender
- have small broken veins under the skin

Someone with lipoedema may eventually get fluid retention (lymphoedema) in their legs. This type of swelling can worsen by the end of the day and may improve overnight, whereas the fatty swelling of lipoedema is constant.

Treatments for lipoedema

There has been little research into lipoedema, so there is some uncertainty about the best way to treat the condition.

If you have lipoedema it is important to avoid significant weight gain and obesity because putting on weight will make the fatty swelling worse.

Compression tights are helpful for some people because they support the fatty swelling and may reduce the pain.

Liposcution is the surgical option for the removal of fat.

Tumescent liposuction

Tumescent liposuction involves sucking out the unwanted fat through a tube. A liquid solution is first injected into the legs to help numb the area and reduce blood loss.

Fatty swelling of the legs may return after having the procedure if you subsequently gain weight.

Non-surgical treatments may also be needed for a long period after having tumescent liposuction. For example, you'll need to wear compression garments after surgery to prevent complications such as lymphoedema.

Treatments to prevent lipoedema progression

Non-surgical treatments can sometimes help improve pain and tenderness, prevent or reduce lipoedema, and improve the shape of affected limbs – although they often have little effect on the fatty tissue.

Several different treatments are designed to improve the management of the lipoedema, such as:

- compression therapy – wearing bandages or garments that squeeze the affected limbs
- exercise – usually low-impact exercises, such as swimming and cycling
- massage – techniques that help relieve the aching and heaviness often felt by patients

Treatments that do not work

Treatments used for some types of tissue swelling are generally unhelpful for lipoedema.

Lipoedema doesn't respond to:

- raising the legs
- diuretics (tablets to get rid of excess fluid)
- dieting – this tends to result in a loss of fat from areas not affected by lipoedema, with little effect on the affected areas

Causes of lipoedema

The cause of lipoedema is not known, but in some cases, there is a family history of the condition. It seems likely that the genes you inherit from your parents play a role.

Lipoedema tends to start at puberty or at other times of hormonal change, such during pregnancy or the menopause, which suggests hormones may also have an influence.

Although the accumulation of fat cells is often worse in obese people, lipoedema is not caused by obesity and can affect people who are a healthy weight. It should not be mistaken for obesity and dieting often makes little difference to the condition.

Evidence Review

There is no evidence available which directly compares liposuction with conservative management – where evidence testing the intervention is found, it is applied to patient cohorts that have already received conservative management.

The evidence identified during the evidence review consisted of three trials (totalling 274 patients), along with the NHS website (https://www.nhs.uk/conditions/lipoedema/) which states that this is a relatively new and under researched condition.

The largest study consisting of 164 patients, clearly stated that they had "undergone conservative therapy over a period of years" and as such the benefits stated can be viewed as over and above those offered by conservative treatment.

The results from all of the identified studies, suggests that there are both short and long-term sustained improvements in almost all dimensions around pain and Quality of Life measurements, and one study substantiates this as over and above conservative treatment. However, the number of patients across the research areas are very low and no randomised control trials were identified.

Whilst the three studies seem consistent in their findings, the evidence identified within the review reflects the lack of RCTs (or direct comparison to no treatment on two of the studies) and the need for further research in this area.

Therefore, in light of the paucity of evidence to support this intervention, liposuction for this clinical indication cannot be supported at the present time.

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

<u>Liposuction in Lipoedema: Category: Not Routinely Commissioned</u>

For patients with Lipoedema, Liposuction is Not Routinely Commissioned in these clinical circumstances due to a lack of evidence to support this intervention.

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

This means the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Number of procedures undertaken overall and by CCG

	BSOL	Sandwell
	0	0
	Total is zero as procedure is currently not routinely commissioned	

Due to limited data collection by the providers service activity data is available by headcount only not protected characteristic.
The Joint Strategic Needs Assessments for Birmingham, Solihull and Sandwell are available via the links below.

Sandwell

Birmingham

Solihull

2. Research

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

Research/Publications	Working Groups	Clinical Experts
Liposuction in Lipoedema		
Lipoedema (2017) - https://www.nhs.uk/conditions/lipoedema/		
Liposuction in the Treatment of Lipoedema: A Longitudinal Study (2017) - https://www.ncbi.nlm.nih.gov/pubmed/28728329		
Tumescent liposuction in lipoedema yields good long-term results (2017) - https://www.ncbi.nlm.nih.gov/pubmed/21824127		
Long-term benefit of liposuction in patients with lipoedema: a follow-up study after an average of 4 and 8 years (2015) - https://www.ncbi.nlm.nih.gov/pubmed/26574236		

3. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

Age: Describe age related impact and evidence. This can include safeguarding, consent and welfare issues:

Lipoedema

No data available on patient ages having the procedure, however there may be a link to the condition resulting to hormone change which occurs at the start of puberty, during pregnancy or those reaching the menopause.

Disability: Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments:

Lipoedema

There is no available data to suggest disability has an impact on this condition.

Gender reassignment (including transgender): Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment:

Lipoedema
No impact identified

Marriage and civil partnership: Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities:
No impact identified

3. Impact and Evidence:

Lipoedema
No impact identified

Pregnancy and maternity: Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities:

Lipoedema

No available data to determine impact. However, there may be a correlation to those at the start of pregnancy when hormone levels are changing acquiring the condition, if they may already be genetically susceptible and if the condition is already prevalent within their family history.

Race: Describe race related impact and evidence**.** This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers:

Lipoedema
No impact identified

Religion or belief: Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues:

Lipoedema
No impact identified

Sex: Describe any impact and evidence on men and women. This could include access to services and employment:

Lipoedema

Occurs almost exclusively in females and there is evidence that it is a genetic and inherited condition.

3. Impact and Evidence:

Sexual orientation: Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers:

Lipoedema
No impact identified

Carers: Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities:

Lipoedema
No impact identified

Other disadvantaged groups: Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive)

Lipoedema
No impact identified

4. Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals?	No	This condition is not linked to a health inequality.
Is there any impact for groups or communities living in particular geographical areas?	No	No impact identified
Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	No	No impact identified

How will you ensure the proposals reduce health inequalities?

5. FREDA Principles/ Human Rights	Question	Response
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	Yes, this decision has been made in line with clinical recommendation.
Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	No evidence of impact from this policy
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	No discrimination identified
	How will this affect a person's right to freedom of thought, conscience and religion?	N/A
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	Policy will be applied with due regard to this consideration.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	An individual can discuss the impact with their GP and has the option for an IFR request to be made
Right to **Life**	Will or could it affect someone's right to life? How?	No evidence of impact from this policy
Right to **Liberty**	Will or could someone be deprived of their liberty? How?	No evidence of impact from this policy

6. Social Value	
Consider how you might use the opportunity to improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.	
Marmot Policy Objective	**What actions are you able to build into the procurement activity and/or contract to achieve wider public benefits?**
Enable all people to have control over their lives and maximise their capabilities	None
Create fair employment and good work for all	None
Create and develop health and sustainable places and communities	None

Strengthen the role and impact of ill-health prevention	None

7. Engagement, Involvement and Consultation

If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:

Engagement Activity	Protected Characteristic/ Group/ Community	Date

For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us …. So we will …..):

As part of the process further targeted engagement is planned with representative groups from among Sandwell, Birmingham and Solihull Patients. In addition, it has been identified that patient and clinician information is key in ensuring that the harmonised treatment policies review delivers effective outcomes. To this end an information briefing sheets on each procedure will be developed to give more information on the procedure, eligibility criteria and signposting to further information sources, such as NHS Choices. These information sheets are also designed to help facilitate discussions between GPs and patients. Information briefing sheets have already been tested and uploaded onto the GP systems for the first 45 harmonised treatment policies for Birmingham and Solihull. Due regard will be given to both the accessible information standard and the potential need to translate such leaflets into relevant local languages.

If any further available evidence has been submitted which has not been taken into consideration during this review will be looked at during the engagement period: 2nd September 2019 – 11th October 2019.

The engagement team used every possible route throughout the engagement period to encourage people to feedback on the proposed policy. Unfortunately, despite the wide communication undertaken through all communication and engagement channels available, 49 questionnaires were completed online and there was no interest from stakeholders, patients and the public to attend any of the five stakeholder events arranged. As a result, the events were cancelled, and the engagement team looked at other routes to encourage engagement with patients directly. A possible reason for the general lack of interest and feedback from stakeholders, patients and the public is most likely because this clinical treatments policy either widening the scope of the current service provision, providing policies to protect the current service provision or the intervention is for somewhat rare conditions.

Also, in phase 3 of the harmonisation of policies programme clinicians had been integral to the development of the policies from the beginning of the process. It could therefore be argued the proposed policy shared for public engagement was to some extent already informed from a local patient experience and outcomes perspective.

As there is currently no policy in place, half of the responses from Healthcare professional and patient feedback has welcomed the need to address support for those

who suffer with these conditions and, there is a consensus that further evidence is needed for liposuction for Lipoedema before the treatment is categorised as not routinely commissioned. However, it is recognised that in some conditions for Lymphoedema, conservative management is pointless where the condition is very advanced and those patients who have had liposuction have greatly benefited for the procedure.

8. Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work:

Lipoedema

The restriction of this policy will have limited impact on those who would wish to receive the treatments as a result of the limited clinical evidence to support this intervention as a clinically effective procedure. There is no evidence available which directly compares liposuction with conservative management.

However, it is hoped that a commissioning review will take place once further evidence has been published regarding the use of liposuction in lipoedema. If there is available evidence which has not been considered during this review, please do not hesitate to submit this evidence during the engagement period: 2nd September 2019 – 11th October 2019.

The opportunity for any exceptional cases to be considered via IFR remains and will ensure treatment is available.

It is noted that investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

9. Mitigations and Changes :

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.

None identified

10. Contract Monitoring and Key Performance Indicators

Detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract (refer to NHS Standard Contract SC12 and 13):
This policy is not linked to a contract however, prospective providers remain bound by their contracts with the CCG.

11. Procurement

Detail the key equality, health inequalities, human rights, and social value criteria that will be included as part of the procurement activity (to evaluate the providers ability to deliver the service in line with these areas):
N/A

12. Publication

How will you share the findings of the Equality Analysis? This can include: reports into committee or Governing Body, feedback to stakeholders including patients and the public, publication on the web pages. All Equality Analysis should be recommended for publication unless they are deemed to contain sensitive information.
Publication on the CCG's website.
Following approval all finalised Equality Analysis should be sent to the Communications and Engagement team for publication: bsol.comms@nhs.net

13. Sign Off

The Equality Analysis will need to go through a process of **quality assurance** by the Senior Manager for Equality Diversity and Inclusion or the Manager for Equality Diversity and Inclusion prior to approval from the delegated committee

	Name	Date

Quality Assured By:		
Which Committee will be considering the findings and signing off the EA?		
Minute number (to be inserted following presentation to committee)		

Please send to Balvinder Everitt or Michelle Dunne, Equality, Diversity and Inclusion for Quality Assurance.

Once you have committee sign off, please send to Caroline Higgs, Communications & Engagement Team for publication: bsol.comms@nhs.net

Equality Analysis

(Health Inequalities, Human Rights, Social Value)

Policy for the use of Liposuction in Lymphoedema

Before completing this equality analysis it is recommended that you:

- ✓ Contact your equality and diversity lead for advice and support
- ✓ Take time to read the accompanying policy and guidance document on how to complete an equality analysis

NHS Birmingham and Solihull Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group

1. Background

EA Title	**Policy for the use of Liposuction in** **A. Lymphoedema**		
EA Author	David King	**Team**	Equality and Diversity Team
Date Started	September 2019	**Date Completed**	4/12/2019
EA Version	4	**Reviewed by E&D**	

What are the intended outcomes of this work? Include outline of objectives and function aims

Liposuction

Liposuction is normally deemed to be a cosmetic procedure used to remove unwanted body fat.

It involves sucking out small areas of fat that are hard to lose through exercise and a healthy diet. It's carried out on areas of the body where deposits of fat tend to collect, such as the buttocks, hips, thighs and tummy.

The aim is to alter body shape, and the results are generally long-lasting, providing you maintain a healthy weight.

It works best in people who are a normal weight and in areas where the skin is tight.

Liposuction carried out for cosmetic reasons is not normally available on the NHS. However, liposuction can sometimes be used by the NHS to treat certain health conditions.

Liposuction is usually carried out under general anaesthetic, although an epidural anaesthetic may be used to enable treatment on lower parts of the body.

The surgeon would mark on your body the area where fat is to be removed. He or she would then:

- **inject this area** with a solution containing anaesthetic and medication, to reduce blood loss, bruising and swelling
- **break up the fat cells** using high-frequency vibrations, a weak laser pulse or a high-pressure water jet
- **make a small incision (cut) and insert a suction tube attached to a vacuum machine** (several cuts may need to be made if the area is large)
- **move the suction tube back and forth** to loosen the fat and suck it out
- **drain** any excess fluid and blood
- **stitch up and bandage** the treated area

It usually takes one to three hours. Most people need to stay in hospital overnight.

After the procedure, you would be fitted with a compression garment. This helps to reduce swelling and bruising and should be worn constantly for several weeks after the operation.

You may need to take antibiotics straight after the procedure to reduce the risk of infection. Most people also take mild painkillers to ease any pain and swelling.

Recovery

It may take up to 12 weeks to make a full recovery.

If you had a general anaesthetic, someone would need to drive you home and stay with you for the first 24 hours. You would not be able to drive for a few days.

The compression garment may be taken off while you shower.

You would need to avoid strenuous activity for up to four weeks (but walking and general movement should be fine).

The results of the procedure are not always noticeable until the swelling has gone down or depending on the care plan for the individual patient, it may take more than one surgical episode before results are visible. It can take up to six months for the area to settle completely.

After about a week: Stitches would be removed (unless you had dissolvable stitches).

At four to six weeks: You should be able to resume any contact sports or strenuous activities you would normally do.

Side effects to expect

It is common after liposuction to have:

- **bruising and swelling**, which may last up to a couple of months
- **numbness**, which should go away in six months
- **scars**
- **inflammation** of the treated area, or the veins underneath
- **fluid** coming from the cuts
- **swollen ankles** (if the legs or ankles are treated)and it may require long-term compression garments to be worn.
- Pain which may last for up to a month
- Skin laxity

Liposuction can occasionally result in:

- **lumpy and uneven results, which is often due to skin laxity and cannot be resolved by further episodes of liposuction.**
- Seroma which is a collection of fluid under the skin
- **bleeding under the skin** (haematoma)
- **persistent numbness** that lasts for months
- **changes in skin colour** in the treated area
- **a build-up of fluid in the lungs** (pulmonary oedema) from the fluid injected into the body
- **a blood clot in the lungs** (pulmonary embolism)
- **damage to internal organs** during the procedure

Any type of operation also carries a small risk of:

- **excessive bleeding**
- **developing a blood clot** in a vein
- **infection**
- **an allergic reaction** to the anaesthetic

The surgeon should explain how likely these risks and complications are, and how they would be treated if they occurred.

Liposuction in Lymphoedema: Category: Restricted

Lymphoedema

Lymphoedema is a long-term (chronic) condition that causes swelling in the body's tissues. It can affect any part of the body, but usually develops in the arms or legs.

It develops when the lymphatic system does not work properly. The lymphatic system is a network of channels and glands throughout the body that helps fight infection and remove excess fluid.

There are two main types of lymphoedema:

- **primary lymphoedema** – caused by faulty genes that affect the development of the lymphatic system; it can develop at any age, but usually starts during infancy, adolescence, or early adulthood
- **secondary lymphoedema** – caused by damage to the lymphatic system or problems with the movement and drainage of fluid in the lymphatic system; it can be the result of an infection, injury, cancer treatment, inflammation of the limb, or a lack of limb movement

Lymphoedema is thought to affect more than 200,000 people in the UK. Primary lymphoedema is rare and is thought to affect around 1 in every 6,000 people. Secondary lymphoedema is much more common.

Secondary lymphoedema affects around 2 in 10 women with breast cancer, and 5 in 10 women with vulval cancer. About 3 in every 10 men with penile cancer get lymphoedema.

People who have treatment for melanoma in the lymph nodes in the groin can also get lymphoedema. Research has shown around 20-50% of people are affected.

Treating lymphoedema

There is no cure for lymphoedema, but it's usually possible to control the main symptoms using techniques to minimise fluid build-up and stimulate the flow of fluid through the lymphatic system.

These include wearing compression garments, taking good care of your skin, moving and exercising regularly, and having a healthy diet and lifestyle.

The recommended treatment for lymphoedema is decongestive lymphatic therapy (DLT).

DLT isn't a cure for lymphoedema, but it can help control the symptoms. Although it takes time and effort, the treatment can be used to bring lymphoedema under control.

Decongestive lymphatic therapy (DLT)

There are four components to DLT:

- **compression garments** – to complement exercise by moving fluid out of the affected limb and minimise further build-up
- **skin care** – to keep the skin in good condition and reduce the chances of infection
- **exercises** – to use muscles in the affected limb to improve lymph drainage
- **specialized massage techniques** – known as manual lymphatic drainage (MLD); this stimulates the flow of fluid in the lymphatic system and reduces swelling however, this technique is only appropriate for patients with cancer-related or primary lymphoedema.

DLT is an intensive phase of therapy, during which you may receive treatment up to 3 times per week for several weeks to help reduce the volume of the affected body part.

This is followed by a second phase called the maintenance phase. You will be encouraged to take over your care using simple self-massage techniques, wearing compression garments, and continuing to exercise.

This treatment phase aims to maintain the reduced size of the affected body part.

Surgery

In a small number of cases, surgery may be used to treat lymphoedema. There are three main types of surgery that may be useful for the condition:

- removal of sections of excess skin and underlying tissue (debulking)
- removal of fat from the affected limb (liposuction)
- restoration of the flow of fluid around the affected section of the lymphatic system – for example, by connecting the lymphatic system to nearby blood vessels (lymphaticovenular anastomosis)
- Lymph node transfer

These treatments may help reduce the size of areas of the body affected by lymphoedema, but some are still being evaluated – particularly lymphaticovenular anastomosis – and aren't in widespread use.

This policy ONLY covers the use of Liposuction for Lymphoedema.

Liposuction

Liposuction is where a thin tube is inserted through small cuts (incisions) in the skin to suck fat out of tissue. It can be used to remove excess fat from an affected limb to help reduce its size.

After surgery, you'll have to wear a compression garment on the affected limb day and night for at least a year to help keep the swelling down.

Evidence Review

Searches in the Cochrane Database and the identification of a number of systematic reviews show, good quality of evidence, which support the use of liposuction in patient diagnosed with lymphoedema in certain clinical circumstances.

The evidence demonstrated clear prevention of future illness, due to the nature of lymphoedema and the reduction in the likelihood of serious infections.

Moderate to large health improvement using this procedure was supported within the evidence review by long term follow up which demonstrated on-going clinical benefit to patients.

Current evidence on the safety and efficacy of liposuction for chronic lymphoedema is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.

However, patient selection should only be done by a specialist lymphoedema multidisciplinary team as part of a lymphoedema service pathway.

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

Liposuction in Lymphoedema: Category: Restricted

For patients with Lymphoedema who have failed conservative management in line with the current patient pathway for the treatment of lymphoedema, patients will be eligible for treatment of their lymphoedema with liposuction.

Patient selection should only be done by a specialist lymphoedema multidisciplinary team as part of a lymphoedema service pathway.

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

Conservative management of lymphoedema is defined as:

Current conservative treatments for lymphoedema include manual lymph drainage (MLD), which stimulates the movement of lymph away from the affected limb, and decongestive lymphatic therapy (DLT). DLT combines MLD massage techniques with compressive bandaging, skin care and decongestive exercises. Once DLT sessions are stopped the patient is fitted with a custom-made compression garment, which is worn every day.

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Number of procedures undertaken overall and by CCG

	BSOL	Sandwell
	1	0

Due to limited data collection by the providers service activity data is available by headcount only not protected characteristic.
The Joint Strategic Needs Assessments for Birmingham, Solihull and Sandwell are available via the links below.

Sandwell

Birmingham

Solihull

2. Research

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

Research/Publications	Working Groups	Clinical Experts
Liposuction in Lymphoedema		
Stuiver Martijn M, ten Tusscher Marieke R, McNeely Margaret L. Which are the best conservative interventions for lymphoedema after breast cancer surgery? BMJ 2017; 357 :j233		
Carl, H. M., Walia, G., Bello, R., Clarke-Pearson, E., Hassanein, A. H., Cho, B.Sacks, J. M. (Accepted/In press). Systematic Review of the Surgical Treatment of Extremity Lymphedema (. Journal of Reconstructive Microsurgery. https://doi.org/10.1055/s-0037- 1599100		
Schaverien MV, Munnoch DA, Brorson H. Liposuction Treatment of Lymphedema. Semin Plast Surg. 2018;32(1):42–47. doi:10.1055/s- 0038-1635116		
Greene AK and Maclellan Reid A (2016) Operative treatment of lymphedema using suction-assisted lipectomy. Annals of Plastic Surgery 77: 337-340.		
Lamprou DAA, Voesten HG, Damstra RJ et al. (2017) Circumferential suction-assisted lipectomy in the treatment of primary and secondary end-stage lymphoedema of the leg. The British journal of surgery 104, 84-89.		
Hoffner M, Bagheri S, Hansson E et al. (2017) SF-36 Shows Increased Quality of Life Following Complete Reduction of Postmastectomy Lymphedema with Liposuction. Lymphatic Research and Biology 15, 87-9		
https://www.nhs.uk/conditions/Lymphoedema/		
https://www.mayoclinic.org/diseases-conditions/lymphedema/symptoms-causes/syc-20374682		

3. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

Age: Describe age related impact and evidence. This can include safeguarding, consent and welfare issues:

Lymphoedema

Primary: For those with the condition of primary lymphoedema this is more commonly witnessed in infancy, adolescence or early adulthood however it can start at any age.

Secondary: No impact

Disability: Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments:

Lymphoedema

Primary: There is no data available to suggest a link to disability as this is a genetic and, in most cases, an inherited condition. Those who have the condition of primary Lymphoedema can be anything from mild to a severe disability.

Secondary: Whilst there is no data available on whether the patients who have undergone this procedure have a disability, there may be a link to those who suffer from a disability connected to lack of limb movement such as a degenerative condition which results in problems arising in the lymphatic system and the drainage of fluid.

.

Gender reassignment (including transgender): Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment:

Lymphoedema
Primary/Secondary: No impact identified

3. Impact and Evidence:

Marriage and civil partnership: Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities:
No impact identified

Lymphoedema
Primary/Secondary: No impact identified

Pregnancy and maternity: Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities:

Lymphoedema

Primary: Depending on the type of primary Lymphoedema diagnosed there may be a link to conditions worsening at the time of hormone changings such as pregnancy.

Secondary: No available data to suggest an impact however with primary Lymphoedema the changing to hormone levels may have an effect on this condition.

Race: Describe race related impact and evidence**.** This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers:

Lymphoedema
Primary/Secondary: No impact identified

Religion or belief: Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues:

Lymphoedema
Primary/Secondary: No impact identified

Sex: Describe any impact and evidence on men and women. This could include access to services and employment:

3. Impact and Evidence:
Lymphoedema Primary: No impact identified based on available data however females may be at more risk of having this genetic disorder. Secondary: No data available as the condition is a result of damage or problems to the lymphatic system rather than genetics. However, there is a relationship to those who have already undergone cancer treatment for cancers which are gender specific then acquiring the condition. Approximately, around 2 in 10 women with breast cancer, and 5 in 10 women with vulval cancer. About 3 in every 10 men with penile cancer get lymphoedema.
Sexual orientation: Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers: **Lymphoedema** Primary/Secondary: No impact identified
Carers: Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities: **Lymphoedema** Primary/Secondary: No impact identified
Other disadvantaged groups: Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive) **Lymphoedema** Primary/Secondary: No impact identified

4. Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals?	No	This condition is not linked to a

		health inequality.
Is there any impact for groups or communities living in particular geographical areas?	No	No impact identified
Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	No	No impact identified
How will you ensure the proposals reduce health inequalities?		

5. FREDA Principles/ Human Rights	Question	Response
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	Yes, this decision has been made in line with clinical recommendation.
Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	No evidence of impact from this policy
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	No discrimination identified
	How will this affect a person's right to freedom of thought, conscience and religion?	N/A
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	Policy will be applied with due regard to this consideration.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	An individual can discuss the impact with their GP and has the option for an IFR request to be made
Right to **Life**	Will or could it affect someone's right to life? How?	No evidence of impact from this policy
Right to **Liberty**	Will or could someone be deprived of their liberty? How?	No evidence of impact from this policy

6. Social Value

Consider how you might use the opportunity to improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.	
Marmot Policy Objective	**What actions are you able to build into the procurement activity and/or contract to achieve wider public benefits?**
Enable all people to have control over their lives and maximise their capabilities	None
Create fair employment and good work for all	None
Create and develop health and sustainable places and communities	None
Strengthen the role and impact of ill-health prevention	None

7. Engagement, Involvement and Consultation

If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:

Engagement Activity	Protected Characteristic/ Group/ Community	Date

For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us …. So we will …..):

As part of the process further targeted engagement is planned with representative groups from among Sandwell, Birmingham and Solihull Patients. In addition, it has been identified that patient and clinician information is key in ensuring that the harmonised treatment policies review delivers effective outcomes. To this end an information briefing sheets on each procedure will be developed to give more information on the procedure, eligibility criteria and signposting to further information sources, such as NHS Choices. These information sheets are also designed to help facilitate discussions between GPs and patients. Information briefing sheets have already been tested and uploaded onto the GP systems for the first 45 harmonised treatment policies for Birmingham and Solihull. Due regard will be given to both the accessible information standard and the potential need to translate such leaflets into relevant local languages.

If any further available evidence has been submitted which has not been taken into consideration during this review will be looked at during the engagement period: 2nd September 2019 – 11th October 2019.

The engagement team used every possible route throughout the engagement period to encourage people to feedback on the proposed policy. Unfortunately, despite the wide communication undertaken through all communication and engagement channels available, 49 questionnaires were completed online and there was no interest from stakeholders, patients and the public to attend any of the five stakeholder events arranged. As a result, the events were cancelled, and the engagement team looked at other routes to encourage engagement with patients directly. A possible reason for the

general lack of interest and feedback from stakeholders, patients and the public is most likely because this clinical treatments policy either widening the scope of the current service provision, providing policies to protect the current service provision or the intervention is for somewhat rare conditions.

Also, in phase 3 of the harmonisation of policies programme clinicians had been integral to the development of the policies from the beginning of the process. It could therefore be argued the proposed policy shared for public engagement was to some extent already informed from a local patient experience and outcomes perspective.

As there is currently no policy in place, half of the responses from Healthcare professional and patient feedback has welcomed the need to address support for those who suffer with Lymphoedema and that some patients where conservative treatment has failed have greatly benefited for the procedure.

8. Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work:

Lymphoedema

Primary/Secondary: The restriction of this policy will have limited impact on those who would wish to receive the treatments as the procedure is available where conservative management in line with the current patient pathway has not worked. Moderate to large health improvement using this procedure was supported within the evidence review by long term follow up which demonstrated on-going clinical benefit to patients. This must be balanced against the need to adhere to the clinical effectiveness evidence and services being commissioned continue to be safe and clinically effective to patients. The opportunity for any exceptional cases to be considered via IFR remains and will ensure treatment is available.

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

9. Mitigations and Changes :

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.

None identified

10. Contract Monitoring and Key Performance Indicators

Detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract (refer to NHS Standard Contract SC12 and 13):
This policy is not linked to a contract however, prospective providers remain bound by their contracts with the CCG.

11. Procurement

Detail the key equality, health inequalities, human rights, and social value criteria that will be included as part of the procurement activity (to evaluate the providers ability to deliver the service in line with these areas):
N/A

12. Publication

How will you share the findings of the Equality Analysis? This can include: reports into committee or Governing Body, feedback to stakeholders including patients and the public, publication on the web pages. All Equality Analysis should be recommended for publication unless they are deemed to contain sensitive information.
Publication on the CCG's website.
Following approval all finalised Equality Analysis should be sent to the Communications and Engagement team for publication: bsol.comms@nhs.net

13. Sign Off		
The Equality Analysis will need to go through a process of **quality assurance** by the Senior Manager for Equality Diversity and Inclusion or the Manager for Equality Diversity and Inclusion prior to approval from the delegated committee		
	Name	**Date**
Quality Assured By:		
Which Committee will be considering the findings and signing off the EA?		
Minute number (to be inserted following presentation to committee)		

Please send to Balvinder Everitt or Michelle Dunne, Equality, Diversity and Inclusion for Quality Assurance.

Once you have committee sign off, please send to Caroline Higgs, Communications & Engagement Team for publication: bsol.comms@nhs.net

Equality Analysis

(Health Inequalities, Human Rights, Social Value)

Policy for use of Domiciliary Non-Invasive Ventilation in COPD & NMD

Before completing this equality analysis it is recommended that you:

- ✓ Contact your equality and diversity lead for advice and support
- ✓ Take time to read the accompanying policy and guidance document on how to complete an equality analysis

NHS Birmingham and Solihull Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group

1. Background

EA Title	Policy for use of domiciliary Non-Invasive Ventilation		
EA Author	David King	**Team**	Equality and Diversity Team
Date Started		**Date Completed**	4/12/2019
EA Version	4	**Reviewed by E&D**	

What are the intended outcomes of this work? Include outline of objectives and function aims

Why is Non-Invasive Ventilation (NIV) used and what is it?

When we breathe in, we take oxygen out of the air to keep us alive - this oxygen is transferred to our blood in our lungs. The body then uses the oxygen and produces a waste gas called carbon dioxide, which we breathe out. The process of this exchange is ventilation.

Some people with severe lung disease, have problems getting enough oxygen into the body, which results in hypoxaemia. If their oxygen level drops below a certain level, it is relatively easy to give extra oxygen for them to breathe, which is called oxygenation. However, in some severe cases of obstructive lung conditions, muscle weakness or neurological impairment, the extra effort of trying to keep the oxygen at a satisfactory level in the blood and to expel carbon dioxide results in the person tiring and leading to hypoventilation and hypercapnia causing respiratory failure.

Respiratory failure is more difficult to deal with. It is a particular problem with diseases that cause obstruction to our airways, such as chronic obstructive pulmonary disease (COPD). In COPD, the airways are narrowed, making it harder to get oxygen into the lungs and carbon dioxide out. Patients who have weak or denervated respiratory muscles in neuromuscular/neurological conditions are also unable to take in a sufficient volume of air to expel carbon dioxide. In all these conditions, a person can develop type 2 respiratory failure which cannot be corrected with oxygenation as the person needs help to ventilate to expel carbon dioxide. Type 2 respiratory failure can lead to high heart rate and cardiac complications.

The aim of using Non-Invasive ventilation (NIV) is not only to obtain satisfactory oxygen levels, but also to expire carbon dioxide. It is often first used at night when the patient is asleep and carbon dioxide levels increase, but as the patient's condition progresses, NIV may be required in the day when the patient has diurnal respiratory failure. It is also important to ease the work of breathing associated with respiratory failure as when a patient with respiratory failure becomes overly tired, this can lead to fatigue, further respiratory compromise and potential respiratory arrest. NIV also aims to take some of the effort out of breathing because the patient's chest muscles don't have to work as hard, so it helps to ease the feelings of breathlessness.

People receiving NIV need to wear a cushioned mask or use a mouthpiece, which is connected to an air pump machine. This mask fits either over the nose alone, or over

both the nose and mouth; a strap holds the mask firmly in place, but it can be easily removed, to enable, for example, the patient to eat and drink.

Types of Non-Invasive Ventilation

Noninvasive ventilation (NIV) refers to the administration of ventilatory support without using an invasive artificial airway (endotracheal tube or tracheostomy tube). The use of noninvasive ventilation has markedly increased over the past three decades, and noninvasive ventilation has now become an integral tool in the management of both acute and chronic respiratory failure, in both the home setting and in critical care.

In its simplest terms, noninvasive ventilation differs from invasive ventilation by the interface between the patient and the ventilator. Invasive ventilatory support is provided via either an endotracheal tube or tracheostomy tube. Noninvasive ventilatory support uses a variety of interfaces, and these have continued to evolve with modifications based on patient comfort and efficacy. Many of the interfaces or masks were initially used in patients with obstructive sleep apnoea before they were adapted for use in patients to provide noninvasive ventilatory support.

Nasal masks and orofacial masks were the earliest interfaces, with subsequent development and use of full-face masks, mouthpieces, nasal pillows, and helmets. Hybrid masks and orofacial masks are still the most commonly used interfaces. Orofacial masks are used almost twice as frequently as nasal masks. Both have advantages and disadvantages in the application of noninvasive ventilation.

Noninvasive positive-pressure ventilation

Positive-pressure ventilation delivered through a mask, has become the predominant method of providing noninvasive ventilatory support. Early bedside physiological studies in healthy patients and in patients with respiratory conditions document successful ventilatory support (i.e., reduction in respiratory rate, increase in tidal volume, decrease in dyspnoea) with reduction in diaphragmatic electromyography (EMG), transdiaphragmatic pressures, work of breathing and improvement in oxygenation with a reduction in hypercapnia.

Ventilatory support can be achieved through a variety of interfaces (mouth piece or nasal, face, or helmet mask), using a variety of ventilatory modes (e.g., volume ventilation, pressure support, bilevel positive airway pressure [BiPAP], proportional-assist ventilation [PAV]) with either ventilators dedicated to noninvasive ventilation (NIV) or those capable of providing support through an endotracheal tube or mask. Older models of noninvasive ventilators required oxygen to be bled into the system, but current models incorporate oxygen blenders for precise delivery of the fraction of inspired oxygen (FIO_2).

Current use of Non-invasive Ventilation devices.

Bilevel positive airway pressure (BiPAP) is probably the most common mode of noninvasive positive pressure ventilation and provides for inspiratory positive airway pressure (IPAP) and expiratory positive airway pressure (EPAP). The difference

between IPAP and EPAP reflects the amount of pressure support ventilation provided to the patient, and EPAP is synonymous with positive end-expiratory pressure (PEEP). Some noninvasive ventilation is provided using proportional-assist ventilation (PAV), which provides flow and volume assistance with each breath. Clinical trials have not demonstrated a significant difference between PAV and pressure-support ventilation with BiPAP. [5, 6] However, BiPAP is the most commonly available and more frequently used modality for noninvasive ventilation. PAV remains available on many ventilator models, but use is much less common than BiPAP.

National context

National Guidance for the provision of aspects of specialist non-ventilation services to patients exists for some individual patient groups e.g. Motor Neurone Disease (MND), Duchene's Muscular Dystrophy (DMD); and for broader categories of patients e.g. weaning guidance; and around specific technologies e.g. diaphragmatic pacing and tracheostomies. There are some national standards (NICE, 2010; 2016) available and some specialist society guidance (BTS/ICS 2016).

Provision of complex home ventilation services also falls within the NHS Outcomes Framework:

Domain 1 - preventing people from dying prematurely where Improvement Area 1a specifically identifies reducing mortality from respiratory disease,

Domain 2 – enhancing quality of life for patients with long term conditions

Domain 3 – helping patients to recover after an episode of acute illness, where post-acute admission, non-invasive ventilation has been shown to help people recover better in the community and reduce readmission rates.

Guidance supports delivery of care by respiratory specialists working within MDTs. For example, the National Institute for Health and Clinical Excellence (NICE) clinical guideline around the use of NIV in MND states that "multidisciplinary teams (MDT) should coordinate and provide on-going management and treatment for patients with MND, including regular respiratory assessment and provision of non-invasive ventilation. The team should include a neurologist, a respiratory physician, a MND specialist nurse, a respiratory specialist nurse, a specialist respiratory physiotherapist, a respiratory physiologist, a specialist in palliative care and a speech and language therapist". The guidance also outlines the support and training which need to be provided to the patient and their family and carers: "support and assistance to manage non-invasive ventilation which should include training on using non-invasive ventilation and ventilator interfaces, for example emergency procedures, night-time assistance if the patient is unable to use the equipment independently (for example, emergency removal or replacement of interfaces), how to use the equipment with a wheelchair or other mobility aids, if required, what to do if the equipment fails, assistance with secretion management, information on general palliative strategies, an offer of on-going emotional and psychological support for the patient and their family and carers".

Ensuring NIV is delivered by competent respiratory professionals is emphasised in NICE MND guidance and also in the National Patient Safety Agency (NPSA) alert which identified cases where problems with administering NIV were stated as causing at least moderate harm: key issues included shortage of staff skills or staff time to set up and monitor NIV.

Local context

The CCG, based on strong supporting evidence for the clinical effectiveness of the intervention, will commission the use of domiciliary non-invasive ventilation in the following clinical conditions where the patient's individual clinical circumstances meet the relevant clinical eligibility criteria outlined in Sections A & B respectively:

- Chronic Obstructive Pulmonary Disease (Section A)
- Neuro-muscular and Neurological Weakness Patients (Section B)

Please note the provision of treatment for patients with Cystic Fibrosis and patients with Spinal Muscular Atrophy are specialised services commissioned by NHSE.

NIV – Section A – Chronic Obstructive Pulmonary Disease (COPD)

Chronic obstructive pulmonary disease (COPD) is the collective name for a group of lung conditions that may cause breathing difficulties.

It includes:

- **emphysema** – damage to the air sacs in the lungs
- **chronic bronchitis** – long-term inflammation of the airways

COPD is a common condition that mainly affects middle-aged or older adults who have a smoking history. The breathing problems tend to get gradually worse over time and can limit the patient's normal activities, although treatment can help keep the condition under control.

Symptoms of COPD
The main symptoms of COPD are:

- increasing breathlessness, particularly when the patient is active
- a persistent chesty cough with phlegm
- frequent chest infections
- persistent wheezing

Without treatment, the symptoms usually get slowly worse. There may also be periods when they get suddenly worse, known as a flare-up or exacerbation.

Causes of COPD
COPD occurs when the lungs become inflamed, damaged and narrowed. The main cause is smoking, although the condition can sometimes affect people who have never smoked.

The likelihood of developing COPD increases the more a patient smokes and the longer the patient has smoked. Some cases of COPD are caused by long-term exposure to harmful fumes, or dust or occur as a result of a rare genetic problem that means the lungs are more vulnerable to damage.

The damage to the lungs caused by COPD is permanent, but treatment can help slow down the progression of the condition.

Treatments include:

- smoking cessation – if a patient is diagnosed with COPD still smokes, stopping smoking is the most important thing a patient can do
- **inhalers and medications**
- **pulmonary rehabilitation** – a specialised programme of exercise and education
- **surgery or a** lung transplant –an option for a very small number of people

Chronic obstructive pulmonary disease (COPD) is characterized by recurrent exacerbations that can cause intermittent periods of severe clinical deterioration requiring hospitalisation and ventilator support. Although treating patients with COPD and acute respiratory failure with non-invasive ventilation improves outcomes, persistent hypercapnia after an exacerbation is associated with excess mortality and early rehospitalization. In 2013, the 28-day COPD readmission rate was around 20%, (Suh et al. 2015).

NIV – Section B –Patients with Neuro-muscular and Neurological weakness

A number of chronic neuromuscular disorders, for example muscular dystrophy and motor neurone disease lead to progressive respiratory muscle dysfunction, which in turn can lead to respiratory failure and death. Nocturnal and daytime Non-Invasive Ventilation (NIV) is the preferred method of treatment for these disorders[1].

Non-invasive ventilation as a treatment for neuromuscular disease has several benefits. It has been shown to:

- Improves lung mechanics and gas exchange
- Decrease work of breathing
- Improve symptoms of fatigue
- Reduce daytime sleepiness
- Improve survival in Duchenne Muscular Dystrophy (DMD) and Motor Neurone Disease (MND) patients.

Patients with one of the following conditions will be considered for funding when the patient also meets the eligibility criteria outlined below.

- Motor Neurone Disease
- Muscular Dystrophies including Duchenne Muscular Dystrophy
- Spinal cord injury
- Multiple Sclerosis
- Guillain-Barre Syndrome
- Post polio syndrome with respiratory impairment

- Syringomyelia
- Tuberculosis infection with residual respiratory insufficiency
- Other neuromuscular impairment which is known to cause respiratory muscle weakness or upper airway functional impairment which are the commissioning responsibility of the CCG.

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

NIV – Section A – Chronic Obstructive Pulmonary Disease (COPD)

Eligibility Criteria: Restricted

For patients with COPD the CCG will commission the use of domiciliary non-invasive ventilation in the following clinical circumstances:

The patient has a diagnosis of COPD, identified by post bronchodilator Forced Expiratory Volume (FEV)1 / Forced Vital Capacity (FVC) <0.70

AND

4 weeks post-acute admission the patient has a paCO2 over 7 kPa.

AND

the patient must have ONE of the following:

- A reduction in Quality of life identified by symptoms consistent with Sleep Disordered Breathing Problems (see pg12 for definition)
    - If the patient has reduced quality of life, then overnight oximetry should be undertaken to demonstrate that the patient meets ONE of the following criteria:
        - An apnoea/hypopnoea index >10/hour on respiratory polysomnography or multi-channel respiratory sleep study
        - Four or more episodes of SpO2 <92%
        - Drops in SpO2 of at least 4% per hour of sleep

OR

- A co-morbidity secondary to hypoxemia
    - Pulmonary Hypertension
    - Heart Failure

If the patient has co-morbidities secondary to hypoxemia then the patient should also meet the following criteria:

- Recurrent NIV admissions (2 or more in a 12month period OR difficulty weaning / unable to tolerate weaning)
  AND
- Acute use of NIV has been well tolerated

N.B. Symptoms consistent with Sleep Disordered Breathing Problems are defined as:

- Excessive daytime somnolence (a state of strong desire for sleep, or sleeping for unusually long periods as per the Epworth Sleepiness Score)
- Headache
- Confusion
- Increased shortness of breath
- Resting tremor

Exclusion criteria:

- Inability to remove mask independently (with no waking night carer)
- Cognitive / behavioural limitation affecting ability to comply safely with NIV
- Intolerance of acute NIV
- Multiple co-morbidities limiting utility of NIV

Funding will be provided for the following if the patient with COPD meets the above clinical criteria:

- One NIV machine
- +/- Humidifier as required
- 1-2 lengths of tubing per year
- 1-2 masks per year

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

NIV – Section B –Patients with Neuro-muscular and Neurological weakness
Patients with one of the following conditions will be considered for funding when the patient also meets the eligibility criteria outlined below.

- Motor Neurone Disease
- Muscular Dystrophies including Duchenne Muscular Dystrophy
- Spinal cord injury
- Multiple Sclerosis
- Guillain-Barre Syndrome
- Post polio syndrome with respiratory impairment
- Syringomyelia
- Tuberculosis infection with residual respiratory insufficiency
- Other neuromuscular impairment which is known to cause respiratory muscle weakness or upper airway functional impairment which are the commissioning responsibility of the CCG.

Eligibility Criteria: Restricted

For patients diagnosed with a neuromuscular condition as outlined above, the patient must meet the following criteria for funding f non-invasive ventilation to be approved:

Nocturnal Ventilation

The patient must meet ONE of the following criteria:

- Signs (<50% predicted/<1l) or symptoms of hypoventilation
- MIP< 60cmH_2O
- A baseline SpO_2 <95%
- Blood or end tidal pCO2 >45mmHg whilst awake
- Four or more episodes of SpO2 <92%
- Drops in SpO2 of at least 4% per hour of sleep

Daytime Ventilation (in addition to meeting the above criteria the patient must also meet ONE of the following criteria):

- Abnormal deglutition due to dyspnoea, which is relieved by ventilatory assistance
- Inability to speak in full sentences without breathlessness
- Symptoms of hypoventilation with baseline SpO2 <95%
- Blood or end tidal pCO2 >45mmHG whilst awake
- Symptoms of awake dyspnoea are present

Exclusion criteria:

- Inability to remove mask independently (with no waking night carer)
- Cognitive / behavioural limitation affecting ability to comply safely with NIV
- Intolerance of acute NIV
- Multiple co-morbidities limiting utility of NIV

Funding will be provided for the following if the patient meets the above clinical criteria:

Below 14 hours of ventilation required.

- One NIV machine
- +/- Humidifier as required
- 1-2 lengths of tubing per year
- 1-2 masks per year

Above 14 hours / 24-hour period of ventilation required.

- Two NIV machines
- +/- ONE Humidifier as required
- 2-4 lengths of tubing per year
- 2-4 masks per year

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Number of procedures undertaken overall and by CCG

	BSOL	Sandwell
	Data is not available for this procedure	

The providers have not collected this data and it is not possible to collate this retrospectively.

The Joint Strategic Needs Assessments for Birmingham, Solihull and Sandwell are available via the links below.

Sandwell

Birmingham

Solihull

2. Research		
What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.		
Research/Publications	**Working Groups**	**Clinical Experts**
Guidance: Non-Invasive Ventilation		

1. Corrado A, Gorini M, Melej R, et al. Iron lung versus mask ventilation in acute exacerbation of COPD: a randomised crossover study. *Intensive Care Med*. 2009 Apr. 35(4):648-55.
2. Parke RL, McGuinness SP. Pressures delivered by nasal high flow oxygen during all phases of the respiratory cycle. *Respir Care*. 2013 Oct. 58 (10):1621-4.
3. Spoletini G, Alotaibi M, Blasi F, Hill NS. Heated Humidified High-Flow Nasal Oxygen in Adults: Mechanisms of Action and Clinical Implications. *Chest*. 2015 Jul. 148 (1):253-61.
4. Ozsancak A, Sidhom S, Liesching TN, Howard W, Hill NS. EVALUATION OF THE TOTAL FACE MASKTM FOR NONINVASIVE VENTILATION TO TREAT ACUTE RESPIRATORY FAILURE. *Chest*. 2011 Feb 17.
5. Wysocki M, Richard JC, Meshaka P. Noninvasive proportional assist ventilation compared with noninvasive pressure support ventilation in hypercapnic acute respiratory failure. *Crit Care Med*. 2002 Feb. 30 (2):323-9.
6. Fernández-Vivas M, Caturla-Such J, González de la Rosa J, Acosta-Escribano J, Alvarez-Sánchez B, Cánovas-Robles J. Noninvasive pressure support versus proportional assist ventilation in acute respiratory failure. *Intensive Care Med*. 2003 Jul. 29 (7):1126-33.
7. Hoo, G. 2018. Noninvasive Ventilation. Medscape. https://emedicine.medscape.com/article/304235-overview#a5
8. British Thoracic Society/Intensive Care Society Acute Hypercapnic Respiratory Failure Guideline Development Group. 2016. BTS/ICS Guidelines for the Ventilatory Management of Acute Hypercapnic Respiratory Failure in Adults. Journal of the British Thoracic Society. http://thorax.bmj.com/site/about/guidelines.xhtml#open
9. 18. National Institute for Health and Clinical Excellence (NICE). Motor neurone disease: assessment and management**.** NICE guideline [NG42] Published date: February 2016 Last updated: July 2019
10. 19. National Institute for Health and Clinical Excellence (NICE). *Chronic Obstructive Pulmonary Disease in Over 16s: Diagnosis and Management [CG101]*. London, England: NICE; 2010. https://www.nice.org.uk/guidance/ng42

Guidance – Section A: COPD

1. Brochard L, Mancebo J,Wysocki M, et al. Noninvasive ventilation for acute exacerbations of chronic obstructive pulmonary disease. *N Engl J Med*. 1995;333(13):817-822.
2. Bott J, Carroll MP, Conway JH, et al. Randomised controlled trial of nasal ventilation in acute ventilatory failure due to chronic obstructive airways disease. *Lancet*. 1993;341(8860):1555-1557.

3. Connors AF Jr, Dawson NV, Thomas C, et al; SUPPORT Investigators (Study to Understand
Prognoses and Preferences for Outcomes and Risks of Treatments). Outcomes following acute exacerbation of severe chronic obstructive lung disease. *Am J Respir Crit Care Med*. 1996;154(4 pt 1): 959-967.
4. Murray I, Paterson E, Thain G, Currie GP. Outcomes following non-invasive ventilation for
hypercapnic exacerbations of chronic obstructive pulmonary disease. *Thorax*. 2011;66(9):825-826.
5. Chu CM, Chan VL, Lin AW,Wong IW, LeungWS, Lai CK. Readmission rates and life threatening events in COPD survivors treated with non-invasive ventilation for acute hypercapnic respiratory failure. *Thorax*. 2004;59(12):1020-1025.
6. Suh ES, Mandal S, Harding R, et al. Neural respiratory drive predicts clinical deterioration and safe discharge in exacerbations of COPD. *Thorax*. 2015;70(12):1123-1130.
7. Nickol AH, Hart N, Hopkinson NS, et al. Mechanisms of improvement of respiratory failure
in patients with COPD treated with NIV. *Int J Chron Obstruct Pulmon Dis*. 2008;3(3):453-462.
8. Meecham Jones DJ, Paul EA, Jones PW, Wedzicha JA. Nasal pressure support ventilation
plus oxygen compared with oxygen therapy alone in hypercapnic COPD. *Am J Respir Crit Care Med*. 1995;152(2):538-544.
9. ElliottMW, Mulvey DA,Moxham J, Green M, Branthwaite MA. Domiciliary nocturnal nasal
intermittent positive pressure ventilation in COPD: mechanisms underlying changes in arterial blood gas tensions. *Eur Respir J*. 1991;4(9):1044-1052.
10. Lloyd-Owen SJ, Donaldson GC, Ambrosino N, et al. Patterns of home mechanical ventilation use in Europe: results from the Eurovent survey. *Eur Respir J*. 2005;25(6):1025-1031.
11. Clini E, Sturani C, Rossi A, et al; Rehabilitation and Chronic Care Study Group, Italian Association of Hospital Pulmonologists (AIPO). The Italian multicentre study on noninvasive ventilation in chronic obstructive pulmonary disease patients. *Eur Respir J*. 2002;20(3):529-538.
12. McEvoy RD, Pierce RJ, Hillman D, et al; Australian trial of non-invasive Ventilation in
Chronic Airflow Limitation (AVCAL) Study Group. Nocturnal non-invasive nasal ventilation in stable hypercapnic COPD: a randomised controlled trial. *Thorax*. 2009;64(7):561-566.
13. WindischW. Noninvasive positive pressure ventilation in COPD. *Breathe*. 2011;8(2):114-123.
14. Köhnlein T, WindischW, Köhler D, et al. Non-invasive positive pressure ventilation for the
treatment of severe stable chronic obstructive pulmonary disease: a prospective, multicentre, randomised, controlled clinical trial. *Lancet Respir Med*. 2014;2(9):698-705.

15. Struik FM, Sprooten RT, Kerstjens HA, et al. Nocturnal non-invasive ventilation in COPD
patients with prolonged hypercapnia after ventilatory support for acute respiratory failure:
a randomised, controlled, parallel-group study. *Thorax*. 2014;69(9):826-834.
16. Altman DG, Bland JM. Treatment allocation by minimisation. *BMJ*. 2005;330(7495):843.
17. Murphy PB, Brignall K, Moxham J, Polkey MI, Davidson AC, Hart N. High pressure versus high intensity noninvasive ventilation in stable hypercapnic chronic obstructive pulmonary
disease: a randomized crossover trial. *Int J Chron Obstruct Pulmon Dis*. 2012;7:811-818.
18. National Institute for Health and Clinical Excellence (NICE). Motor neurone disease: assessment and management**.** NICE guideline [NG42] Published date: February 2016 Last updated: July 2019
19. National Institute for Health and Clinical Excellence (NICE). *Chronic Obstructive Pulmonary Disease in Over 16s: Diagnosis and Management [CG101]*. London, England: NICE; 2010. https://www.nice.org.uk/guidance/ng42
20. Bestall JC, Paul EA, Garrod R, Garnham R, Jones PW,Wedzicha JA. Usefulness of the Medical Research Council (MRC) dyspnoea scale as a measure of disability in patients with chronic obstructive pulmonary disease. *Thorax*. 1999;54(7): 581-586.

20. Ghosh D, Rzehak P, ElliottMW, WindischW. Validation of the English Severe Respiratory
Insufficiency Questionnaire. *Eur Respir J*. 2012;40 (2):408-415.
21. Jones PW, Quirk FH, Baveystock CM. The St George's Respiratory Questionnaire. *Respir
Med*. 1991;85(suppl B):25-31.
22. Jones PW. St George's Respiratory Questionnaire: MCID. *COPD*. 2005;2(1):75-79.
23. Kahan BC, Morris TP. Improper analysis of trials randomised using stratified blocks or minimisation. *Stat Med*. 2012;31(4):328-340.
24. Costello R, Deegan P, Fitzpatrick M, McNicholasWT. Reversible hypercapnia in
chronic obstructive pulmonary disease: a distinct pattern of respiratory failure with a favourable prognosis. *Am J Med*. 1997;102(3):239-244.
25. Seemungal TA, Donaldson GC, Paul EA, Bestall JC, Jeffries DJ,Wedzicha JA. Effect of exacerbation on quality of life in patients with chronic obstructive
pulmonary disease. *Am J Respir Crit Care Med*. 1998;157(5 pt 1):1418-1422.
26. De Backer L, VosW, Dieriks B, et al. The effects of long-term noninvasive ventilation in hypercapnic COPD patients: a randomized controlled pilot study. *Int J Chron Obstruct Pulmon Dis*. 2011;6:615-624.

27. Gates KL, Howell HA, Nair A, et al. Hypercapnia impairs lung neutrophil function and increases mortality in murine pseudomonas pneumonia. *Am J Respir Cell Mol Biol*. 2013;49(5):821-828.
28. Pepperell JC, Ramdassingh-Dow S, Crosthwaite N, et al. Ambulatory blood pressure
after therapeutic and subtherapeutic nasal continuous positive airway pressure for obstructive sleep apnoea: a randomised parallel trial. *Lancet*. 2002;359(9302):204-210.
29. Saatci E, Miller DM, Stell IM, Lee KC, Moxham J. Dynamic dead space in face masks used with noninvasive ventilators: a lung model study. *Eur Respir J*. 2004;23(1):129-135.
30. Rodway GW,Weaver TE, Mancini C, et al. Evaluation of sham-CPAP as a placebo in CPAP
intervention studies. *Sleep*. 2010;33(2):260-266.
31. Djavadkhani Y, Marshall NS, D'Rozario AL, et al. Ethics, consent and blinding: lessons from a placebo/sham controlled CPAP crossover trial. *Thorax*. 2015;70(3):265-269.
32. Schwartz SW, Cimino CR, Anderson WM. CPAP or placebo-effect? *Sleep*. 2012;35(12):1585- 1586.
33. Murphy, P. Rehal, S. et al. 2017. Effect of Home Noninvasive Ventilation With Oxygen Therapy vs Oxygen Therapy Alone on Hospital Readmission or Death After an Acute COPD Exacerbation: A Randomized Clinical Trial. *JAMA.* 2017;317(21):2177-2186. doi:10.1001/jama.2017.4451.
https://jamanetwork.com/journals/jama/issue/317/21
34. Murphy P, Arbane G, Phillips R, Hart N. S37 Home mechanical ventilation (HMV) and home oxygen therapy (HOT) following an acute exacerbation of COPD in patients with persistent hypercapnia: results of the per protocol analysis from the HOT-HMV UK trial. *Thorax* 2017; 72: A25– A6. https://onlinelibrary.wiley.com/doi/full/10.1111/resp.13484

Section B: Guidance for NMD

1. Joshua O. Benditt1 and Louis J. Boitano. Pulmonary Issues in Patients with Chronic Neuromuscular Disease. Am J Respir Crit Care Med Vol 187, Iss. 10, pp 1046–1055, May 15, 2013

2. Miller RG, Jackson CE, Kasarskis EJ, England JD, Forshew D, Johnston W, Kalra S, Katz JS, Mitsumoto H, Rosenfeld J, et al.; Quality Standards Subcommittee of the American Academy of Neurology. Practice parameter update: the care of the patient with amyotrophic lateral sclerosis: drug, nutritional, and respiratory therapies (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology 2009;73: 1218–1226.

3. Bourke SC, Gibson GJ. Sleep and breathing in neuromuscular disease. Eur Respir J 2002;19:1194–1201.

4. Birnkrant DJ, Panitch HB, Benditt JO, Boitano LJ, Carter ER, Cwik VA, Finder JD, Iannaccone ST, Jacobson LE, Kohn GL, et al. American College of Chest Physicians consensus statement on the respiratory and related management of patients with Duchenne muscular dystrophy undergoing anesthesia or sedation. Chest 2007; 132:1977–1986.

5. Mehta S, Hill NS. Noninvasive ventilation. Am J Respir Crit Care Med 2001;163:540–577.

6. Eagle M, Baudouin SV, Chandler C, Giddings DR, Bullock R, Bushby K. Survival in Duchenne muscular dystrophy: improvements in life expectancy since 1967 and the impact of home nocturnal ventilation. Neuromuscul Disord 2002;12:926–929.

7. Toussaint M, Steens M, Wasteels G, Soudon P. Diurnal ventilation via mouthpiece: survival in end-stage Duchenne patients. Eur Respir J 2006; 28:549–555

8. Radunovic A, Annane D, Jewitt K, Mustfa N. Mechanical ventilation for amyotrophic lateral sclerosis/motor neuron disease. Cochrane Database Syst Rev 2009;4:CD004427. Update in: Cochrane Database Syst Rev 2013;3:CD004427.

9. Motor neurone disease: assessment and management (2016) - https://www.nice.org.uk/guidance/ng42/chapter/Recommendations#non-invasive-ventilation

10. Outcome of non-invasive positive pressure ventilation in paediatric neuromuscular disease (2004) - https://www.ncbi.nlm.nih.gov/pubmed/14736624

11. Effects of non-invasive ventilation on survival and quality of life in patients with amyotrophic lateral sclerosis: a randomised controlled trial (2006) - https://www.ncbi.nlm.nih.gov/pubmed/16426990

12. Non-invasive ventilation in amyotrophic lateral sclerosis: a 10 year population based study (2012) - https://www.ncbi.nlm.nih.gov/pubmed/22013242

13. Mechanical ventilation for amyotrophic lateral sclerosis/motor neuron disease (2017) - https://www.ncbi.nlm.nih.gov/pubmed/28982219

14. Outcome of non-invasive positive pressure ventilation in paediatric neuromuscular disease (2004) - https://www.ncbi.nlm.nih.gov/pubmed/14736624

15. Polysomnographic evaluation of non-invasive ventilation in children with neuromuscular disease (2014) - https://www.ncbi.nlm.nih.gov/pubmed/24033486

16. Mechanical ventilation for amyotrophic lateral sclerosis/motor neuron disease (2017) - https://www.ncbi.nlm.nih.gov/pubmed/28982219

17. Sleep disordered breathing in motor neurone disease (2018) - http://jtd.amegroups.com/article/view/18178/14526

18. The use of non-invasive ventilation at end of life in patients with motor neurone disease: a qualitative exploration of family carer and health professional experiences (2013) - https://www.ncbi.nlm.nih.gov/pubmed/23462702

19. Sheehan, D. Birnkrant, J. et al. 2018. Respiratory Management of the Patient With Duchenne Muscular Dystrophy Paediatrics, October 2018, vol 142 https://pediatrics.aappublications.org/content/142/Supplement_2/S62

20. Hamada et al. 2011. Indicators for ventilator use in Duchenne muscular dystrophy. Respiratory Medicine. Volume 105, Issue 4, April 2011, Pages 625-629. https://www.sciencedirect.com/science/article/pii/S0954611110005317#tbl1

21. Birnkrant et al 2010. The Respiratory Management of Patients With Duchenne Muscular Dystrophy: A DMD Care Considerations Working Group Specialty Article. Pediatric Pulmonology. DOI 10.1002/ppul.21254. http://muscle.ca/wp-content/uploads/2012/11/Respirarory_Management_DMD_Publication_2010.pdf

3. Impact and Evidence:
In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.
Age: Describe age related impact and evidence. This can include safeguarding, consent and welfare issues: **NIV – Section A – Chronic Obstructive Pulmonary Disease (COPD)** Long term lifestyle choices (smoking) in most cases is the most common reason for diagnoses, as such COPD is a common condition that mainly affects middle aged or older people who smoke. It is recognised that genetic conditions can predispose younger people to developing such conditions as COPD. **NIV – Section B – Neuro-Muscular Patients** Depending upon the diagnosed condition of the patient if it's an inherited genetic condition this will be present at birth which may or may not show symptoms until later in life. However, the condition may link to age in cases of motor neurones disease where cells in the brain and nerves stop working over-time, and mainly affects people in their 60's and 70s, but it can affect adults of all ages.
Disability: Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments: A link can be made with degenerative conditions where the person experiencing is likely to have a disability. Restricting this procedure may have an impact on this group as a result. The patient must be able to remove the NIV mask either independently or the patient must have a waking night carer whom can remove the mask for them as required. This is a clinical safety issue, as if for example the patient coughs up secretions then if the mask cannot be removed to clear the secretions, then the secretions will be pushed back into the patient's airway which may cause the airway to occlude. Therefore this is a safety requirement to prevent harm to the patient when using the device. However, an individual can discuss the impact with their GP and has the option for an individual funding request (IFR) request to be made.

3. Impact and Evidence:
Gender reassignment (including transgender): Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment: No Impact identified
Marriage and civil partnership: Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities: No impact identified
Pregnancy and maternity: Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities: If any of those conditions are present, then the pregnancy must be managed as the condition may worsen throughout pregnancy.
Race: Describe race related impact and evidence**.** This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers: No impact identified
Religion or belief: Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues: No impact identified
Sex: Describe any impact and evidence on men and women. This could include access to services and employment: Depending on the diagnosis of the patient some conditions are more commonly seen in one gender over the other. For example, motor neurone disease although a rare condition is more likely to effect males than females.. Where the condition has arisen from long term lifestyle choices e.g. smoking and COPD, this could affect either gender.

3. Impact and Evidence:
Sexual orientation: Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers: No impact identified
Carers: Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities: No impact identified
Other disadvantaged groups: Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive) Health inequalities are present in an area of deprivation – which combines factors such as income, employment, health and education which has the greatest impact on someone's likelihood of smoking.

4. Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals?	No	This condition could be linked to a health inequality due to the prevalence of smoking. As the procedures remains available it is not anticipated that a health inequality will be made worse.
Is there any impact for groups or communities living in particular geographical areas?	Yes	A possible link between smoking and areas of high

		deprivation has been made.
Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	Yes	A possible link between the likelihood of someone smoking and unemployment, low income and education has been made. Due regard to this will need to be given in supporting such patients.
How will you ensure the proposals reduce health inequalities? The intention of the policy is to support patients with ventilatory support without using an invasive artificial airway method. For those patients where the condition has been a result of a long-term lifestyle choice, as in smoking, support should be provided to those patients through a number of interventions to help the patient stop smoking.		

5. FREDA Principles/ Human Rights	**Question**	**Response**
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	Yes, this decision has been made in line with clinical recommendation and NICE guidance.
Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	No evidence of impact from this policy
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	No discrimination identified
	How will this affect a person's right to freedom	N/A

	of thought, conscience and religion?	
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	Policy will be applied with due regard to this consideration.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	An individual can discuss the impact with their GP and has the option for an IFR request to be made
Right to **Life**	Will or could it affect someone's right to life? How?	No evidence of impact from this policy
Right to **Liberty**	Will or could someone be deprived of their liberty? How?	No evidence of impact from this policy

6. Social Value	
Consider how you might use the opportunity to improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.	
Marmot Policy Objective	**What actions are you able to build into the procurement activity and/or contract to achieve wider public benefits?**
Enable all people to have control over their lives and maximise their capabilities	
Create fair employment and good work for all	
Create and develop health and sustainable places and communities	
Strengthen the role and impact of ill-health prevention	

7. Engagement, Involvement and Consultation		
If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:		
Engagement Activity	**Protected Characteristic/ Group/ Community**	**Date**
For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us …. So we will …..):		

As part of the process further targeted engagement is planned with representative groups from among Sandwell, Birmingham and Solihull Patients. In addition, it has been identified that patient and clinician information is key in ensuring that the harmonised treatment policies review delivers effective outcomes. To this end an information briefing sheets on each procedure will be developed to give more information on the procedure, eligibility criteria and signposting to further information sources, such as NHS Choices. These information sheets are also designed to help facilitate discussions between GPs and patients. Information briefing sheets have already been tested and uploaded onto the GP systems for the first 45 harmonised treatment policies for Birmingham and Solihull. Due regard will be given to both the accessible information standard and the potential need to translate such leaflets into relevant local languages.

The engagement team used every possible route throughout the engagement period to encourage people to feedback on the proposed policy. Unfortunately, despite the wide communication undertaken through all communication and engagement channels available, 49 questionnaires were completed online and there was no interest from stakeholders, patients and the public to attend any of the five stakeholder events arranged. As a result, the events were cancelled, and the engagement team looked at other routes to encourage engagement with patients directly. A possible reason for the general lack of interest and feedback from stakeholders, patients and the public is most likely because this clinical treatments policy either widening the scope of the current service provision, providing policies to protect the current service provision or the intervention is for somewhat rare conditions.

Also, in phase 3 of the harmonisation of policies programme clinicians had been integral to the development of the policies from the beginning of the process. It could therefore be argued the proposed policy shared for public engagement was to some extent already informed from a local patient experience and outcomes perspective.

On behalf of Birmingham and Solihull CCG and Sandwell and West Birmingham CCG, a letter was sent by a specialist respiratory ventilation physiotherapist based at one of the acute NHS providers, inviting 20 patients using domiciliary NIV / CPAP to attend a meeting at the hospital to feedback on the non-invasive ventilation policies. Patients who were unable to attend due to travel difficulties were invited to inform the CCG so that transport could be provided for them. Two people followed up the invitation by telephone to find out more about the meeting, however they decided they would prefer not to attend. One person was calling on behalf of her father and explained that although he would not be able to attend, she would go through the information with him available online. A further telephone meeting was offered, should her father wish to feedback verbally. The other person calling, completed the questionnaire over the telephone with the engagement officer.

The actual meeting on Friday 4 October was attended by a patient with muscular dystrophy and her daughter (also the patient's full-time carer). The patient used non-invasive ventilation to help with her condition during the day and night.

The patient and carer told the interviewer that they strongly agreed with the policy for non-invasive ventilation for neuromuscular patients. This was because they felt the implementation of the policy would help GPs to refer patients for the correct treatment

promptly. The patient and carer felt the policy would raise awareness of the respiratory conditions associated with muscular dystrophy and provide guidance on when to refer patients into a specialist respiratory service.

As there is currently no policy available, the potential impact on patients is therefore minimal as the treatment will offered based on criteria. Of the 27 of the 49 people who provided responses to this policy, only 6 had actually received this treatment and their responses were mixed. There was a general agreement that people with respiratory issues should receive this treatment to improve their quality of life.

8. Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work:

The restriction of this policy will have an impact on those who would wish to receive the treatments, this must be balanced against the need to adhere to NICE guidelines and the clinical effectiveness evidence. The opportunity for any exceptional cases to be considered via IFR remains and will ensure treatment is available in an exceptional case where the CCG support the IFR.

9. Mitigations and Changes :

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.

Consideration will need to be given to what additional support patients from a low socio economic background will require and how due regard can be given to reasonable adjustments in approach for disabled persons.

10. Contract Monitoring and Key Performance Indicators

Detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract (refer to NHS Standard Contract SC12 and 13):

This policy is not linked to a contract however, prospective providers remain bound by their contracts with the CCG.

11. Procurement
Detail the key equality, health inequalities, human rights, and social value criteria that will be included as part of the procurement activity (to evaluate the providers ability to deliver the service in line with these areas):
N/A

12. Publication
How will you share the findings of the Equality Analysis? This can include: reports into committee or Governing Body, feedback to stakeholders including patients and the public, publication on the web pages. All Equality Analysis should be recommended for publication unless they are deemed to contain sensitive information.
Published on CCG website
Following approval all finalised Equality Analysis should be sent to the Communications and Engagement team for publication: bsol.comms@nhs.net

13. Sign Off		
The Equality Analysis will need to go through a process of **quality assurance** by the Senior Manager for Equality Diversity and Inclusion or the Manager for Equality Diversity and Inclusion prior to approval from the delegated committee		
	Name	**Date**
Quality Assured By:		
Which Committee will be considering the findings and signing off the EA?		
Minute number (to be inserted following presentation to committee)		

Please send to Balvinder Everitt or Michelle Dunne, Equality, Diversity and Inclusion for Quality Assurance.

Once you have committee sign off, please send to Caroline Higgs, Communications & Engagement Team for publication: bsol.comms@nhs.net

Equality Analysis

(Health Inequalities, Human Rights, Social Value)

Policy for Subacromial Pain in Adults.

Before completing this equality analysis it is recommended that you:

- ✓ Contact your equality and diversity lead for advice and support
- ✓ Take time to read the accompanying policy and guidance document on how to complete an equality analysis

1. Background			
EA Title	Policy for Subacromial Pain in Adults.		
EA Author	David King	**Team**	Equality and Diversity Team
Date Started	13/08/2019	**Date Completed**	4/12/2019
EA Version	4	**Reviewed by E&D**	
What are the intended outcomes of this work? Include outline of objectives and function aims			

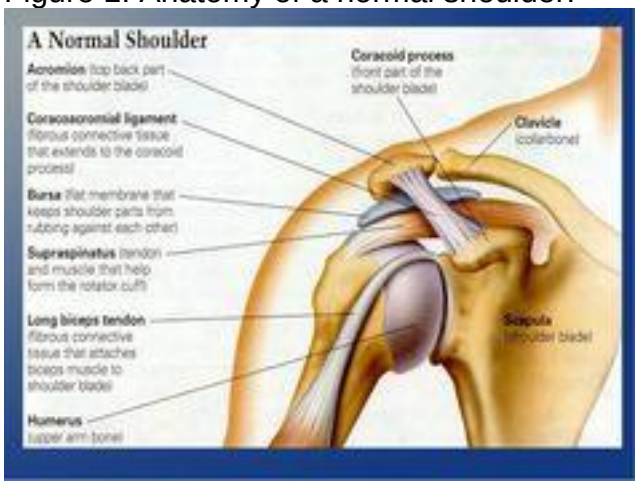
Sub-acromial Pain in Adults

Rotator cuff disease (wear and tear of the rotator cuff tendons) is thought to be a continuum ranging from shoulder impingement syndrome (SIS) through to partial and then full thickness rotator cuff tears [1]. It is one of the most common causes of non-traumatic shoulder pain which presents in primary care and is a normal part of aging [2].

The rotator cuff tendons hold the shoulder joint in place and allow people to lift the arm and reach overhead. When the arm is lifted, the rotator cuff tendon passes through a narrow space at the top of the shoulder, known as the sub-acromial space. The illustration of a healthy shoulder joint below (Figure 1) shows the relationship of tendons, ligaments, soft tissue and bony anatomy of the sub-acromial space.

Arthroscopic sub-acromial decompression is a surgical procedure that involves decompressing the sub-acromial space by removing bone spurs and soft tissue arthroscopically.

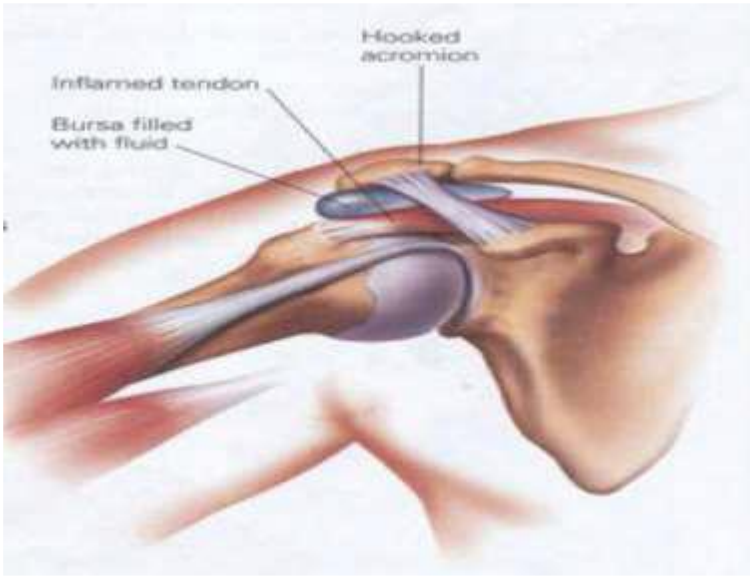
Figure 1: Anatomy of a normal shoulder.



Source: Orthopaedic Surgeons of Long Island Association.
Retrieved from http://www.orthomd.com/procedures/impingement_syndrome.html

Previously it was thought that sub acromial pain occurs when the top of the tendon rubs or catches on the acromion and the sub-acromial bursa, however more recent studies have shown that between 76-91% of rotator cuff tears occur within the tendon or on the 'under-side' of the tendon. There has been shown to be poor correlation between acromial shape and pain. Furthermore, rotator cuff tears can continue to develop post sub-acromial decompression. To this end subacromial decompression surgery is no longer recommended routinely in any clinical circumstances.

Figure 2: Anatomy of a shoulder affected by shoulder impingement syndrome



The main problem in shoulder impingement syndrome is of pain in the top and outer side of the shoulder, which is worse when the arm is raised overhead [1]. Pain is associated with dysfunction, affecting usual activities of daily living, sporting activities and ability to work full time. Patients often report a significant reduction in terms of health-related quality of life [3].

Shoulder impingement will often improve in a few weeks or months, especially with prescribed shoulder exercises.

Arthroscopic Sub-acromial Decompression.

The term 'arthroscopic' describes any surgical procedure which is performed using surgical instruments inserted through a small 'keyhole' incision and an endoscope inserted via a separate incision to visualise the area.

Arthroscopic shoulder surgery is not one single surgical procedure; rather it refers to a wide range of procedures to different parts of the shoulder anatomy. These may repair damaged cartilage or torn tendons, remove loose fragments of bone or cartilage, drain excess fluid, or release adhesions.

Arthroscopic sub-acromial decompression (ASD) is the most common surgical procedure in patients with shoulder impingement syndrome (SIS) [3]. The standard procedure is antero-inferior acromioplasty, i.e. the resection of bone spurs under the

lateral third of the acromion, as well as the excision of the coracoacromial ligament and the sub-acromial bursa. If a partial or small full-thickness tear of the rotator cuff is present, it may be mildly debrided or left alone [3].

Evidence Review

Shoulder Impingement Syndrome

Three randomised controlled trials were identified and reviewed, which compared ASD to conservative treatment for patients with SIS (at 24 months in two of the trials and 12 months only in the CSAW RCT). Patients with partial thickness rotator cuff tears were not excluded from these RCTs. The key differences between the study design were that Ketola et al [7] compared ASD plus physiotherapy to physiotherapy alone [7], whereas in the FIMPACT [6] and CSAW [4] RCTs, there were three treatment arms. Both FIMPACT and CSAW included ASD plus physiotherapy and diagnostic arthroscopy plus physiotherapy as two of the three arms. However, in the UK based multicentre RCT known as CSAW, the third arm was no treatment at all, whereas in the FIMPACT RCT, the non-operative third arm was a home exercise regime as well as 15 hysiotherapy visits.

ASD plus physiotherapy versus diagnostic arthroscopy plus physiotherapy. There was no clinically significant difference between ASD plus physiotherapy treatment compared to diagnostic (sham) arthroscopy plus physiotherapy at either 12-month follow-up in the CSAW RCT [4] or at 24 months (FIMPACT RCT) [6]. This was consistent for all of the outcomes measured: OSS, Constant score, pain, depression and anxiety, quality of life, simple shoulder test,15D and patient satisfaction.

ASD plus physiotherapy versus no treatment: Although small statistical differences were seen in favour of ASD followed by up to four sessions of physiotherapy, there were no clinically important differences for any outcomes measured at 12 months compared to no treatment at all [4].

ASD plus physiotherapy versus physiotherapy therapy only: There were no clinically important differences reported between these two treatment groups at 24-month follow-up [6,7] even though the physiotherapy protocol for the FIMPACT RCT was for 15 sessions (compared to just one post-operative session for those being treated with ASD). Both the ASD plus PT and PT only groups in the RCT by Ketola et al [7] had a similar number of physiotherapy sessions (6 and 7 sessions respectively). Within each treatment group, all three trials showed clinically significant improvements at 12 or 24 months, when compared to baseline for the OSS, the Constant score and for pain [4,6,7].

These RCTs showed that ASD for SIS was no more effective than physiotherapy alone or no treatment at achieving clinically important differences at 12 months and 24 months (OSS, Constant Score and pain). In addition, all three treatment groups

achieved clinically important improvements over time compared to baseline. This suggests that the natural history of non-traumatic shoulder impingement syndrome, which has previously failed conservative treatment, is for the painful and disabling symptoms to resolve without intervention.

Supraspinatus Tear

There was one single RCT where 180 patients with a supraspinatus tear were treated with arthroscopic acromioplasty and physiotherapy, or tendon repair, acromioplasty and physiotherapy and the outcomes were compared to patients who had 10 sessions of physiotherapy alone. All the patients followed the same physiotherapy plan. There were no between group differences in the Constant score at 12 months. Although the ASD was performed concomitantly with repair of the supraspinatus tendon, the results are consistent with the results of the RCTs which assessed the effectiveness of ASD for the management of shoulder impingement syndrome.

Cost Effectiveness

No studies generalisable to the NHS were found which measured the cost effectiveness of ASD compared to conservative treatment in patients with subacromial shoulder pain.

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

Patients who would wish to access this approach**.**

Eligibility Criteria

Due to the lack of evidence for the clinical effectiveness of arthroscopic shoulder decompression (ASD) compared to conservative treatment, ASD patients with sub-acromial pain is not routinely commissioned.

N.B. **Acute Severe Shoulder Pain**

- Any shoulder ‘red flags’ identified during primary care assessment need urgent secondary care referral. A suspected infected joint needs same day emergency referral.
- An unreduced dislocation needs same day emergency referral.
- Suspected tumour and malignancy will need urgent referral following the local 2-week cancer referral pathway.
- An acute cuff tear as a result of a traumatic event needs urgent referral and ideally should be seen in the next available outpatient clinic.

- Acute calcific tendinopathy is not a red flag, it is severely painful, often mimicking malignant pain and usually necessitates an early secondary care referral for more interventional treatment.
- It should also be noted that patients with subacromial shoulder pain in which the symptoms and signs suggest a more systemic inflammatory joint disease, should be considered as a 'rheumatological red flag'.
- Any new inflammatory oligo or polyarthritis, with symptoms of inflammation in several joints, should be referred urgently (following local rheumatology referral pathways) because time is of the essence with these diseases and a prompt diagnosis with early commencement of disease modifying drugs where appropriate is essential.

This means the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Activity data:

Number of procedures	BSOL	Sandwell
	217	90

Number of procedures undertaken overall and by CCG

Due to limited data collection by the providers service activity data is available by headcount only not protected characteristic.
The Joint Strategic Needs Assessments for Birmingham, Solihull and Sandwell are available via the links below.

Sandwell

Birmingham

Solihull

2. Research

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

Research/Publications	**Working Groups**	**Clinical Experts**

Guidance

1. NHS choices. Shoulder Pain. https://www.nhs.uk/conditions/shoulder-pain/
2. Artus M, Holt T and Rees J. The painful shoulder: an update on assessment, treatment, and referral. British Journal of General Practice. 2014;64(626), e593-e595.
3. Chipchase LS, O'Connor DA, Costi JJ, Krishnan J (2000) Shoulder impingement syndrome: preoperative health status. J Shoulder Elbow Surg 9:12–15
4. Beard DJ, Rees JL, Cook JA CSAW Study Group et al. Arthroscopic subacromial decompression for subacromial shoulder pain (CSAW): a multicentre, pragmatic, parallel group, placebo-controlled, three-group, randomised surgical trial. Lancet 2018;391:329-38.
5. Linsell L, Dawson J, Zondervan K, Rose P, Randall T, Fitzpatrick R, Carr A. Prevalence and incidence of adults consulting for shoulder conditions in UK primary care; patterns of diagnosis and referral. Rheumatology (Oxford). 2006;45(2):215-21.
6. Paavola M, Malmivaara A, Taimela S et al. Subacromial decompression versus diagnostic arthroscopy for shoulder impingement: randomised, placebo surgery controlled clinical trial. BMJ 2018;362:k2860
7. Ketola S, Lehtinen J, Arnala I, et al. Does arthroscopic acromioplasty provide any additional value in the treatment of shoulder impingement syndrome? a two-year randomised controlled trial. J Bone Joint Surg Br 2009;91:1326-34
8. Ketola S, Lehtinen J, Rousi T et al. Which patients do not recover from shoulder impingement syndrome, either with operative treatment or with non-operative treatment? Subgroup analysis involving 140 patients at 2 and 5 years in a randomised study. Acta Orthop 2015;86:641-46
9. Ketola S, Lehtinen J, Elo P et al. No difference in long-term development of rotator cuff rupture and muscle volumes in impingement patients with or without decompression. Acta Orthop 2016;87(4):351-55
10. Ketola S, Lehtinen J, Arnala I. Arthroscopic decompression not recommended in the treatment of rotator cuff tendinpathy. Bone Joint J 2017;99-B:799-805
11. Kukkonen J, Joukainen A, Lehtinen J et al. Treatment of non-traumatic rotator cuff tears. Bone Joint J 2014;96-B:75-81
12. Longo UG, Vasta S, Maffulli N, Denaro V. Scoring systems for the functional assessment of patients with rotator cuff pathology Sports Med Arthrosc Rev. 2011;19(3):310-20.doi: 10.1097/JSA.0b013e31820af9b6.
13. Christiansen DH1, Frost P, Falla D, Haahr JP, Frich LH, Svendsen SW. Responsiveness and Minimal Clinically Important Change: A Comparison Between Shoulder Outcome Measures. J Orthop Sports Phys Ther. 2015 Aug;45(8):620-5.
14. Constant CR, Murley AH. A clinical method of functional assessment of the shoulder. Clin Orthop Relat Res 1987;214:160–164

15. Mathieson S, LinC. PainDETECT Questionnaire Clinimetrics. Journal of Physiotherapy 2013 Vol. 59
16. Stern AF. Questionnaire Review: The Hospitals Anxiety and Depression Score. Occupational Medicine 2014;64:393–394
17. EuroQol Research Foundation 2018. EQ-5D Instruments. https://euroqol.org/eq-5d-instruments/. Accessed 19.11.2018
18. National Clinical Coding Standards OPCS-4 (2017) - NHS Digitalhttps://hscic.kahootz.com/gf2.ti/f/762498/27837541.1/.../-/NCCSOPCS42017.pdf
19. McCormack HM, Horne DJ, Sheather S. Clinical applications of visual analogue scales: a critical review. Psychol Med 1988;18:1007–1019
20. Beard D, Rees J, Rombach I et al. The CSAW Study (Can Shoulder Arthroscopy Work?)—a placebo-controlled surgical intervention trial assessing the clinical and cost effectiveness of arthroscopic subacromial decompression for shoulder pain: study protocol for a randomised controlled trial.Trials. 2015; 16: 210
21. Kukkonen J, Kauko T, Vahlberg T et al Investigating minimal clinically important difference for Constant score in patients undergoing rotator cuff surgery. J Shoulder Elbow Surg 2013;22:1650–1655
22. Salaffi F, Stancati A, Silvestri CA et al. Minimal clinically important changes in chronic musculoskeletal pain intensity measured on a numerical rating scale. Eur JPain 2004;8:283-91
23. Beard DJ, Carr AJ, Cook JA et al. Can Shoulder Arthroscopy Work? (CSAW) trial –Authors' reply. Lancet. July 28, 2018.
24. Kulkarnhi, R. et al. 2015) Sub-acromial Shoulder pain: BESS/BOA Patient Care Pathways.http://www.bess.org.uk/media/Research%20Committee/National%20Guidelines/Subacromial%20Shoulder%20Pain.pdf
25. NHS. Shoulder impingement. https://www.nhs.uk/conditions/shoulder-impingement-syndrome/

3. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

Age: Describe age related impact and evidence. This can include safeguarding, consent and welfare issues:

Age range data is not available for the profile of patients requesting the procedure. Some link may be identified between older patients and increased instances of joint pain, particularly in relation to Osteoarthritis.

As the treatment has been not routinely commissioned, those who meet the criteria will be able to access treatment, who are the group who are deemed to benefit most. It is expected that patients not eligible would receive more suitable alternative treatment.

3. Impact and Evidence:
Disability: Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments:
As with age pain is itself a life limiting condition and is commonly found as a co morbidity with other conditions. It has not been shown that restricting this treatment will impact on this group negatively since the treatment has not been shown to offer significant benefit. The CCG recognises its obligations to meet the needs of disabled people. The overall intention for this policy since it is NRC is for conservative management to be offered to all patients, but due regard will be given to the CCG's obligations to disabled people.
Gender reassignment (including transgender): Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment:
No impact identified
Marriage and civil partnership: Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities:
No impact identified
Pregnancy and maternity: Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities:
No impact identified on the basis of available data.
Race: Describe race related impact and evidence**.** This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers:
No impact identified
Religion or belief: Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues:
No impact identified
Sex: Describe any impact and evidence on men and women. This could include access to services and employment:
No impact identified
Sexual orientation: Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers:
No impact identified
Carers: Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities:

3. Impact and Evidence:
No impact identified
Other disadvantaged groups: Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive)
No impact identified

4. Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals?	No	This condition is not linked to any identified health inequality
Is there any impact for groups or communities living in particular geographical areas?	No	No impact identified
Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	No	No impact identified
How will you ensure the proposals reduce health inequalities?		
This condition is not linked to any identified health inequality		

5. FREDA Principles/ Human Rights	Question	Response
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	Yes, this decision has been made in line with clinical recommendation
Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	No evidence of impact for this policy
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	No discrimination identified
	How will this affect a person's right to freedom of thought, conscience and religion?	N/A
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being	Policy will be applied with due regard to this consideration.

	treated in an inhuman or degrading way?	
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	An individual can discuss the impact with their GP and has the option for an IFR request to be made
Right to **Life**	Will or could it affect someone's right to life? How?	No evidence of impact for this policy
Right to **Liberty**	Will or could someone be deprived of their liberty? How?	No evidence of impact for this policy

6. Social Value

Consider how you might use the opportunity to improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.

Marmot Policy Objective	**What actions are you able to build into the procurement activity and/or contract to achieve wider public benefits?**
Enable all people to have control over their lives and maximise their capabilities	None
Create fair employment and good work for all	None
Create and develop health and sustainable places and communities	None
Strengthen the role and impact of ill-health prevention	None

7. Engagement, Involvement and Consultation

If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:

Engagement Activity	**Protected Characteristic/ Group/ Community**	**Date**

For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us …. So we will …):

As part of the process further targeted engagement is planned with representative groups from among Birmingham and Solihull Patients. In addition, it has been identified that patient and clinician information is key in ensuring that the harmonised treatment policies review delivers effective outcomes. To this end an information briefing sheets on each procedure will be developed to give more information on the procedure, eligibility criteria and signposting to further information sources, such as NHS Choices. These information sheets are also designed to help facilitate discussions between GPs and patients. Information briefing sheets have already been tested and uploaded onto the GP systems for the first 45 harmonised treatment policies for Birmingham and Solihull. Due regard will

be given to both the accessible information standard and the potential need to translate such leaflets into relevant local languages.

The engagement team used every possible route throughout the engagement period to encourage people to feedback on the proposed policy. Unfortunately, despite the wide communication undertaken through all communication and engagement channels available, 49 questionnaires were completed online and there was no interest from stakeholders, patients and the public to attend any of the five stakeholder events arranged. As a result, the events were cancelled, and the engagement team looked at other routes to encourage engagement with patients directly. A possible reason for the general lack of interest and feedback from stakeholders, patients and the public is most likely because this clinical treatments policy either widening the scope of the current service provision, providing policies to protect the current service provision or the intervention is for somewhat rare conditions.

Also, in phase 3 of the harmonisation of policies programme clinicians had been integral to the development of the policies from the beginning of the process. It could therefore be argued the proposed policy shared for public engagement was to some extent already informed from a local patient experience and outcomes perspective.

The potential impact on patients was therefore minimal as the treatment is offered based on specific criteria. Feedback suggested that the decision should to offer this treatment is between the doctor and patient, based on individual circumstances and needs.

8. Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work:

The restriction of surgery or conservative management will have limited impact on those who would wish to receive the treatments, this must be balanced against the need to adhere to clinical effectiveness evidence. The opportunity for any exceptional cases to be considered via IFR remains and will ensure treatment is available in an exceptional case.

9. Mitigations and Changes

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.

The CCG will need to review the impact on disabled patients of the operation of this policy and whether further exploration of suitable treatments is required.

10. Contract Monitoring and Key Performance Indicators

Detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract (refer to NHS Standard Contract SC12 and 13):

This policy is not linked to a contract however, prospective providers remain bound by their contracts with the CCG.

11. Procurement

Detail the key equality, health inequalities, human rights, and social value criteria that will be included as part of the procurement activity (to evaluate the providers ability to deliver the service in line with these areas):
N/A

12. Publication

How will you share the findings of the Equality Analysis? This can include: reports into committee or Governing Body, feedback to stakeholders including patients and the public, publication on the web pages. All Equality Analysis should be recommended for publication unless they are deemed to contain sensitive information.
Publication on the CCG's website.
Following approval all finalised Equality Analysis should be sent to the Communications and Engagement team for publication: bsol.comms@nhs.net

13. Sign Off

The Equality Analysis will need to go through a process of **quality assurance** by the Senior Manager for Equality and Diversity, Senior Manager for Assurance and Compliance or Equality and Human Rights Manager **and** signed-off by a delegated committee

	Name	Date
Quality Assured By:		
Which Committee will be considering the findings and signing off the EA?		
Minute number (to be inserted following presentation to committee)		

Please send to Balvinder Everitt or Michelle Dunne, Equality, Diversity and Inclusion for Quality Assurance.

Once you have committee sign off, please send to Caroline Higgs, Communications & Engagement Team for publication: bsol.comms@nhs.net

Equality Analysis

(Health Inequalities, Human Rights, Social Value)

Image Guided High Volume Intra-Articular Injections

Before completing this equality analysis it is recommended that you:

- ✓ Contact your equality and diversity lead for advice and support
- ✓ Take time to read the accompanying policy and guidance document on how to complete an equality analysis

NHS Birmingham and Solihull Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group

1. Background			
EA Title	Image Guided High Volume Intra-Articular Injections		
EA Author	David King	**Team**	Equality and Diversity
Date Started	13/08/2019	**Date Completed**	4/12/2019
EA Version	4	**Reviewed by E&D**	

What are the intended outcomes of this work? Include outline of objectives and function aims

Joint Pain
Pain in the joints affects millions of people worldwide. The causes of joint pain are numerous. Joint pain can be related to osteoarthritis or inflammatory joint disorders such as rheumatoid arthritis and psoriatic arthritis. Joint pain can also be as a result of traumatic injury, joint surgery or crystal deposition in the joints such as gout or chondrocalcinosis. Other causes of joint pain include sports injuries, general sprains and strains, frozen or unstable shoulder, and bleeding into joint spaces caused by torn ligaments.

Depending on the individual, pain might be felt in the joint or in the muscles around the joint. Depending on the cause the pain may be diffuse and constant, occurring at rest or while moving. Despite the wide range of underlying conditions and symptoms, joint pain of different aetiology may share similar mechanisms, manifestations, and potential treatments.

Image Guided High Volume Intra-Articular Injections
Treatment of joint pain consists of both pharmacologic and non-pharmacologic modalities. First-line therapy generally includes analgesia and physiotherapy. If these fail, intraarticular steroid injection may be considered.

Hydrodilatation (HD) also known as arthrographic capsular distension or distension arthrography is a procedure where a high volume injection of saline solution and/or steroids or air is given into the joint usually into the glenohumeral (shoulder) joint. HD is generally carried out with a mixture of contrast medium, long acting anaesthetics, steroids, saline or air. However, because of the inherent compressibility of air, the procedure is more difficult than when saline is used. Dependent upon the contracted state of the joint capsule, HD usually occurs with an injection of between 10ml and 55ml of normal saline.

The procedure is performed under imaging guidance, using fluoroscopy, ultrasound or Computed Tomography (CT). HD is felt to provide benefit via two mechanisms: manual stretching of the capsule and thus disruption of adhesions that might be limiting the movements of the glenohumeral joint and causing pain and disability which are characteristic of adhesive capsulitis; and the introduction of cortisone, which provides a potent anti-inflammatory effect and thus prevents further recurrence of adhesion. The risk of complications is thought to be low.

1. Background

Clinical Evidence Review

From the evidence reviewed, there is no clear benefit of treatment for joint pain with an image-guided high volume intra-articular injection.

Evidence from two systematic reviews of Randomised Controlled Trials (RCTS) comparing hydrodilatation with corticosteroids, and corticosteroid injection only, is conflicting. The systematic review (with meta-analysis) by Saltychev et al (2018) reported that hydrodilatation with corticosteroids has only a small, clinically insignificant effect for pain and Range Of Movement (ROM) (seven RCTs) when treating adhesive capsulitis. Conversely, Catapano et al (2018) reported that the intervention is likely to be effective. However, this conclusion was based on the results from two of five RCTs and three of five RCTs which reported improvements in pain scores and range of movement respectively. The evidence is therefore at best inconsistent. No long term results were reported. Both authors report that the included RCTs were of moderate quality.

Evidence from one small RCT suggests that arthrographic capsular release is associated with a higher Oxford Shoulder Score (OSS) than hydrodilatation at six months follow-up. It is not known for how long this effect is likely to be sustained (Gallacher 2018). In addition, the study may not have been sufficiently powered to show any meaningful differences. The pain scores were reported by the patients who were not blinded to their treatment, this could have introduced bias. It is also unclear whether the ROM assessors were blinded to the treatments.

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

Eligibility Criteria:

Due to the limited quality of evidence of clinical and cost effectiveness for image-guided high volume intra-articular injections compared to alternative treatment options, this intervention is Not Routinely Commissioned.

This means the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Number of procedures undertaken overall and by CCG – data not available.

	BSOL	Sandwell
	Activity data on this procedure is not available from the providers	

1. Background

Due to limited data collection by the providers information on the protected characteristics of patients who have received the procedure is not available and is thus shown as patient headcount only.

Population data for the Birmingham Solihull and Sandwell and West Birmingham areas can be found via the following links.

2. Research

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

Research/Publications	Working Groups	Clinical Experts
Guidance 1. International Association for the Study of Pain (IASP). Treating people with joint pain. Global year against pain in the joint 2016; Fact sheet no 1. https://s3.amazonaws.com/rdcmsiasp/ files/production/public/Content/ContentFolders/GlobalYearAgainstPain2/2016/FactSheets/English/1.%20Patients%20and%20Joint%20Pain.pdf Last accessed 15 October 2018 2. NHS Choices [online] https://www.nhs.uk/conditions/joint-pain/ Last accessed 15 October 2018 3. Gallacher S, Beazley JC et al. A randomized controlled trial of arthroscopic capsular release versus hydrodilatation in the treatment of primary frozen shoulder. Journal of Shoulder & Elbow Surgery. 2018 Aug; 27(8):1401-6. 4. Neogi T. Joint pain epidemiology. Global year against pain in the joint 2016; Fact sheet no 11. https://s3.amazonaws.com/rdcmsiasp/files/production/public/Content/ContentFolders/GlobalYearAgainstPain2/2016/FactSheets/English/11.%20Joint%20Pain%20Epidemiology.pdf Last accessed 15 October 2018 5. Duncan R, Francis RM et al. Prevalence of arthritis and joint pain in the oldest old: findings from the Newcastle 85+ Study. Age and Aging 2011; 40(6):752-5. 6. Georgiannos D, Markopoulos G et al. Adhesive Capsulitis of the Shoulder. Is there Consensus Regarding the Treatment? A		

2. Research

Comprehensive Review. The open orthopaedics journal. [Review]. 2017; 11:65-76.

7. Buchbinder R, Green S et al. Arthrographic distension for adhesive capsulitis (frozen shoulder). Cochrane Database of Systematic Reviews 2008, Issue 1. Art. No.:

CD007005.

8. Saltychev M, Laimi K et al. Effectiveness of Hydrodilatation in Adhesive Capsulitis of Shoulder: A Systematic Review and Meta-Analysis. Scandinavian Journal of Surgery: SJS. 2018:1457496918772367.

9. Catapano M, Mittal N et al. Hydrodilatation with Corticosteroid for the Treatment of Adhesive Capsulitis: A Systematic Review. Pm & R. [Review]. 2018; 10(6):623-35.

10. Maund E, Craig D et al. Management of frozen shoulder: a systematic review and cost-effectiveness analysis. Health Technology Assessment (Winchester, England).

[Research Support, Non-U.S. Gov't Review]. 2012; 16(11):1-264.

3. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

Age: Describe age related impact and evidence. This can include safeguarding, consent and welfare issues:

Age range data is not available for the profile of patients requesting the procedure. Some link may be identified between older patients and increased instances of joint pain, particularly in relation to arthritis.

As the treatment has not been shown to demonstrate significant benefits the impact on this group will be more around a perception of not being able to access a treatment. It is expected that patients would receive more suitable alternative treatment.

Disability: Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments:

3. Impact and Evidence:

As with age pain is itself a life limiting condition and is commonly found as a co morbidity with other conditions. It has not been shown the restricting this condition will impact on this group negatively.

Gender reassignment (including transgender): Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment:

No impact identified

Marriage and civil partnership: Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities:

No impact identified

Pregnancy and maternity: Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities:

No impact identified on the basis of available data.

Race: Describe race related impact and evidence**.** This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers:

No impact identified

Religion or belief: Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues:

No impact identified

Sex: Describe any impact and evidence on men and women. This could include access to services and employment:

No impact identified

Sexual orientation: Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers:

No impact identified

Carers: Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities:

No impact identified

Other disadvantaged groups: Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive)

3. Impact and Evidence:
No impact identified

4. Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals?	No	This condition is not linked to any identified health inequality
Is there any impact for groups or communities living in particular geographical areas?	No	No impact identified
Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	No	No impact identified
How will you ensure the proposals reduce health inequalities? This condition is not linked to any identified health inequality.		

5. FREDA Principles/ Human Rights	Question	Response
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	Yes, this decision has been made in line with clinical recommendation
Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	No evidence of impact for this policy
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	No discrimination identified
	How will this affect a person's right to freedom of thought, conscience and religion?	N/A
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	Policy will be applied with due regard to this consideration.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	An individual can discuss the impact with their GP and has the option for an IFR request to be made

5. FREDA Principles/ Human Rights	Question	Response
Right to **Life**	Will or could it affect someone's right to life? How?	No evidence of impact for this policy
Right to **Liberty**	Will or could someone be deprived of their liberty? How?	No evidence of impact for this policy

6. Social Value

Consider how you might use the opportunity to improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.

Marmot Policy Objective	What actions are you able to build into the procurement activity and/or contract to achieve wider public benefits?
Enable all people to have control over their lives and maximise their capabilities	None
Create fair employment and good work for all	None
Create and develop health and sustainable places and communities	None
Strengthen the role and impact of ill-health prevention	None

7. Engagement, Involvement and Consultation

If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:

Engagement Activity	Protected Characteristic/ Group/ Community	Date

For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us …. So we will …..):

As part of the process further targeted engagement is planned with representative groups from among Birmingham and Solihull Patients and Sandwell and West Birmingham CCG. In addition, it has been identified that patient and clinician information is key in ensuring that the harmonised treatment policies review delivers effective outcomes. To this end an information briefing sheets on each procedure will be developed to give more information on the procedure, eligibility criteria and signposting to further information sources, such as NHS Choices. These information sheets are also designed to help facilitate discussions between GPs and patients. Information briefing sheets have already been tested and uploaded for the Phase 1 and Phase 2 harmonised treatment policies for Birmingham and Solihull CCG and Sandwell and West Birmingham CCG. Due regard will be given to both the accessible information standard and the potential need to translate such leaflets into relevant local languages.

7. Engagement, Involvement and Consultation

The engagement team used every possible route throughout the engagement period to encourage people to feedback on the proposed policy. Unfortunately, despite the wide communication undertaken through all communication and engagement channels available, 49 questionnaires were completed online and there was no interest from stakeholders, patients and the public to attend any of the proposed stakeholder events arranged across the footprint of Birmingham, Solihull, Sandwell and West Birmingham. As a result, the events were cancelled, and the engagement team looked at other routes to encourage engagement with patients directly. A possible reason for the general lack of interest and feedback from stakeholders, patients and the public is most likely because this clinical treatments policy either widening the scope of the current service provision, providing policies to protect the current service provision or the intervention is for somewhat rare conditions.

Also, in phase 3 of the harmonisation of policies programme clinicians had been integral to the development of the policies from the beginning of the process. It Therefore the proposed policy shared for public engagement was to some extent already informed from a local patient experience and outcomes perspective.

Feedback received form patients who have accessed this service commented that the treatment was 'highly effective'. However over 30% of the comments received refer to not enough clinical evidence in ascertaining whether they agree or disagree with the proposed change due to ongoing clinical study. It was felt until this was available, the decision to offer the treatment should be between the GP and the patient.

8. Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work:

The restriction of this policy will have limited impact on those who would wish to receive the treatments, this must be balanced against the need to adhere to the clinical effectiveness evidence. The opportunity for any exceptional cases to be considered via IFR remains and will ensure treatment is available in an exceptional case.

9. Mitigations and Changes :

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.

None required

10. Contract Monitoring and Key Performance Indicators

Detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract (refer to NHS Standard Contract SC12 and 13):
This policy is not linked to a contract however, prospective providers remain bound by their contracts with the CCG.

11. Procurement

Detail the key equality, health inequalities, human rights, and social value criteria that will be included as part of the procurement activity (to evaluate the providers ability to deliver the service in line with these areas):
N/A

12. Publication

How will you share the findings of the Equality Analysis? This can include: reports into committee or Governing Body, feedback to stakeholders including patients and the public, publication on the web pages. All Equality Analysis should be recommended for publication unless they are deemed to contain sensitive information.
Publication on the CCG's website.
Following approval all finalised Equality Analysis should be sent to the Communications and Engagement team for publication: bsol.comms@nhs.net

13. Sign Off

The Equality Analysis will need to go through a process of **quality assurance** by the Senior Manager for Equality and Diversity, Senior Manager for Assurance and Compliance or Equality and Human Rights Manager **and** signed-off by a delegated committee

	Name	**Date**
Quality Assured By:		
Which Committee will be considering the findings and signing off the EA?		

Minute number (to be inserted following presentation to committee)		

Please send to Balvinder Everitt or Michelle Dunne, Equality, Diversity and Inclusion for Quality Assurance.

Once you have committee sign off, please send to Caroline Higgs, Communications & Engagement Team for publication: bsol.comms@nhs.net

Equality Analysis

(Health Inequalities, Human Rights, Social Value)

Policy for the use of Non-Cosmetic Body Contouring Surgery

Before completing this equality analysis it is recommended that you:

- ✓ Contact your equality and diversity lead for advice and support
- ✓ Take time to read the accompanying policy and guidance document on how to complete an equality analysis

NHS Birmingham and Solihull Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group

1. Background			
EA Title	Policy for the use of Non-Cosmetic Body Contouring Surgery		
EA Author	David King	**Team**	Equality and Diversity
Date Started	September 2019	**Date Completed**	4/12/2019
EA Version	4	**Reviewed by E&D**	

What are the intended outcomes of this work? Include outline of objectives and function aims

Body Contouring Surgery

The Surgical Procedures included in Body Contouring

- Full abdominoplasty

For patients who have significant skin laxity, excess fat and separation of the muscles, a classic tummy tuck is the most common procedure. Performed under general anaesthetic, this operation can require patients to be in hospital for two or three days.

During the operation, an incision is made from hip to hip and around the umbilicus. The excess skin and fat is excised from the umbilicus to just above the pubic hair. The muscles above and below the umbilicus are tightened. The skin is then sewn up to give a circular scar around the umbilicus and a long scar across the lower abdomen. Although this operation leaves a large scar, it does provide the greatest improvement in abdominal shape.

Patients who are thinking about becoming pregnant should not undergo this procedure and should wait until they are sure they are not having any more children. All the skin and fat below the umbilicus can be removed in a standard abdominoplasty. This results in a scar across the lower abdomen and a scar around the umbilicus.

- Mini abdominoplasty

For patients with only a small amount of excess skin a lesser abdominoplasty might be appropriate. A general anaesthetic is still needed.

During the operating, a wedge of skin and fat is excised from the lower tummy leaving a horizontal scar above the pubic hair. Sometimes the muscles will also be tightened. No scar is left around the umbilicus, which may be stretched slightly to become a different shape.
A mini abdominoplasty will give a smaller effect than a full abdominoplasty.

- Extended abdominoplasty

Surplus skin and fat of the loins and back are removed at the same time as the abdomen.

1. Background

- Endoscopic abdominoplasty

Tightens the muscles of the abdominal wall. Skin is not removed but liposuction can be carried out at the same time.

- Apronectomy (Panniculectomy)

An Apronectomy is a modified mini-abdominoplasty, mainly for patients who have a large excess of skin and fat hanging down over the pubic area and only the surplus skin and fat is removed. A modification to an abdominoplasty might also be necessary when the patient has problems with scars from previous operations.

A panniculus is excess adipose tissue hanging downward from the abdomen and resembles an "apron of skin" overlying the front of the pelvic girdle. A large panniculus can interfere with normal activities such as walking, and lead to serious medical problems. The heavy overhanging tissue can cause chronic skin inflammation under the flap, and subsequently, skin breakdown and infection.

The panniculus hanging below the symphysis pubis when the individual is standing normally can cause significant functional impairment and other complications such as intertrigo.

- Arm reduction and lift (Brachioplasty)

Brachioplasty, or upper arm reduction or arm lift is a surgical procedure which removes and tightens loose skin and excess fat in the upper arm. It is usually performed under a general anaesthetic. The surgeon makes a long incision between the elbow and axilla. Segments of skin and fat are removed and the remaining skin and tissue lifted resulting in a tight, smooth look.

- Buttock and/or Thigh lift (Thighplasty)

Thighplasty is aesthetic reshaping surgery with the removal of excess skin and fat. Buttock or thigh lift surgery is performed to lift the excess skin to firm and tighten the skin around the buttocks and/or thighs. Liposuction may also be performed during this procedure. Sometimes a buttock lift is combined with this procedure.

- Liposuction / Liposculpture / Suction Assisted Lipectomy

Liposuction is also known as liposculpture or suction assisted lipectomy. It is a technique most commonly performed to remove unwanted fat deposits. Liposuction can be performed on other areas of the body, including the neck, arms, tummy, loins, thighs, inner side of the knees and the ankles.

1. Background

Evidence Review

The results from the search strategy found 3 systematic reviews, 1 economic systematic review and 4 clinical trials & guidance which directly informed 'Body Contouring' in reference to the effectiveness measurable by physical, physiological, and/or qualitative patient reported outcomes.

The BAPRAS UK Commissioning Guide 2017 highlights an expert interpretation of various papers to inform NICE and clinical commissioners in the UK health care sector. All results highlighted in the evidence review are also utilised within the commissioning guide.

The 'BODY-Q' systematic review is strong evidence to support the method in measuring the effectiveness of body contouring from patient-reported outcomes (PRO. 'BODY-Q' method is the framework of the BODY-Q scales, presented below, is comprised of three overarching themes as follows: 1) Appearance; 2) Health-Related Quality of Life; and 3) Patient Experience. Under these domains, there are 18 independently functioning scales that measure important COI. In addition to the 18 scales, there is 1 obesity-specific symptom checklist.

Due to the statistically significant health improvement benefits both in relation to QoL and clinical outcomes of more than 30%, and that the evidence has demonstrated the potential of removal of excess skin to prevent both 1st and 2nd prevention of future illness such as mobility, QoL concerns, infection, lymphoedema and other illnesses, it was deemed within certain clinical circumstances that excess skin removal could be an effective surgical intervention.

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

Eligibility Criteria: Restricted

Removal of excess skin is commissioned in the following clinical circumstances:
The patient is 18 or over at the time of application.

AND

The patient has lost at least 50% of their original excess weight and maintained their weight for at least two years, both of which have been recorded and documented by a clinician in the patient's medical notes.

AND the patient has one of the following:

- Skin folds are causing severe functional impairment which is impacting on the patient's ability to carry out activities of daily living.

1. Background

OR

- Recurrent skin infections in the skin folds which fail to resolve, despite appropriate medical treatment for at least 6 months.

Definition

Body mass index (BMI) A measure for human body shape based on an individual's weight and height. BMI = body weight in kilograms / height in meters squared

Excess body weight Calculation of change of BMI relative to a maximum normal BMI of 25kg/m2

Massive weight loss Loss of 50% or more excess body weight

BODY-Q The Patient-Reported Outcome Instrument for Weight Loss and Body Contouring Treatments

N.B. Functional impairment is defined as preventing activities of daily living to be undertaken independently, i.e. sleeping; eating; walking.

Funding is for procedures to remove excess skin from an area of the body, which is causing functional impairment / recurrent skin infections. Procedures to aid weight loss or muscle tightening e.g. full abdominoplasty are not commissioned under this policy.

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

Other procedures **which are not included** within the Body Contouring Surgery policy are:

- Breast Surgery
- Liposuction
- Cosmetic Surgery

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG

Number of procedures undertaken overall and by CCG

	BSOL	Sandwell
	1	0

1. Background

Due to limited data collection by the providers service activity data is available by headcount only not protected characteristic.
The Joint Strategic Needs Assessments for Birmingham, Solihull and Sandwell are available via the links below.

- Sandwell
- Birmingham
- Solihull

2. Research

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

Research/Publications	Working Groups	Clinical Experts
Guidance [1] British Association of Plastic Reconstructive and Aesthetic Surgeons (BAPRAS), Royal College of Surgeons: UK Commissioning Guide: Massive Weight Loss Body Contouring, 2017. http://www.bapras.org.uk/docs/default-source/commissioning-and-policy/2017--draft-for-consultation--body-contouring-surgery-commissioning.pdf?sfvrsn=0 [2] Measuring Quality of Life and Patient Satisfaction After Body Contouring: A Systematic Review of Patient-Reported Outcome Measures, Patrick L. Reavey et al, Aesthetic Surgery Journal September 2011 vol. 31 no. 7 807-813 https://academic.oup.com/asj/article/31/7/807/176334 [3] Recommendations on the most suitable quality-of-life measurement instruments for bariatric and body contouring surgery: a systematic review. C.E.E. de Vries, et al. – https://www.ncbi.nlm.nih.gov/pubmed/29883059 [4] Quality of life among adults following bariatric and body contouring surgery: a systematic review. J. Gilmartin, et al. JBI Database of Systematic Reviews and Implementation Reports November 2016 vol.14 no.11 240-270 https://journals.lww.com/jbisrir/Abstract/2016/11000/Quality_of_life_among_adults_following_bariatric.16.aspx		

2. Research

[5] Diverse approaches to the health economic evaluation of bariatric surgery: a comprehensive systematic review. J.A. Campbel, et al. https://www.ncbi.nlm.nih.gov/pubmed/27383557

[6] Body image and quality of life in patients with and without body contouring surgery following bariatric surgery: a comparison of pre- and post-surgery groups. M. de Zwaan, et al - https://www.frontiersin.org/articles/10.3389/fpsyg.2014.01310/full

[7] The impact of reconstructive procedures following bariatric surgery onpatient well-being and quality of life. Van der Beek ES, et al. - https://www.ncbi.nlm.nih.gov/pubmed/19688408

[8] The BODY-Q: A Patient-Reported Outcome Instrument for Weight Loss and Body Contouring Treatments. A.F. Klassen, et al. - https://www.ncbi.nlm.nih.gov/pubmed/27200241

[9] Body-Q User Manual, Royal College of Surgeons - https://tinyurl.com/y53b9xmn

[10] Body Image and Quality of Life in Post Massive Weight Loss Body Contouring Patients. AY. Song, et al. - https://www.ncbi.nlm.nih.gov/pubmed/17030974

[11] Mukherjee,S.,Kamat,S.,Adegbola,S.,andAgrawal,S.(2014). Funding for post-bariatric body contouring (bariplastic) surgery in England: a post code lottery. Plast.Surg.Int. 2014:153194. doi:10.1155/2014/153194 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3980931/

[12] NHS Digital: Statistics on Obesity, Physical Activity and Diet - England, 2018 [PAS] https://digital.nhs.uk/data-and-information/publications/statistical/statistics-on-obesity-physical-activity-and-diet/statistics-on-obesity-physical-activity-and-diet-england-2018

3. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

Age: Describe age related impact and evidence. This can include safeguarding, consent and welfare issues:

Age range data is not available for the profile of patients requesting the procedure. Some link may be identified between obesity, reduced mobility and the occurrence of the condition if it's a genetic disorder.

Disability: Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments:

As with age obesity is itself a life limiting condition and is commonly found as a co morbidity with other conditions. It has not been shown that restricting this treatment will impact on this group negatively since those who would benefit and are eligible can access surgery.

It is noted that exercise may be more difficult / impossible for patients with some conditions which reduce mobility. In such case the approach would give due regard to reasonable adjustments.

There may be an impact on patients experiencing significant mental health difficulties resulting in a functional impairment related to body image. However, the CCGs have a number of policies (Cosmetic Policy 2017) for body contouring related to body image - to improve the patient's physical appearance, which would include the cohort of patients described above. The currently revised policy was developed following a number of IFRs from clinicians, where the patient was so physically disabled by the size and weight of their excess skin folds or were having numerous hospital admissions due to the recurrent skin infections, that surgery would be the most beneficial outcome for these patients. This cohort of patient was not included in the 2017 policies. Therefore, the evidence review reviewed the physical impact of the removal of the excess skin on improving activities of daily living, not the impact on the patient's mental health as this was already covered by existing CCG policies. Whilst there is undoubtedly a cohort of patients who experience a mental health impact from their body image, this cohort of patients would fall under the already commissioned cosmetic surgery policy 2017.

Gender reassignment (including transgender): Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment:

3. Impact and Evidence:

No impact identified

Marriage and civil partnership: Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities:

No impact identified

Pregnancy and maternity: Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities:

No impact identified

Due to the surgical procedures involved within some of the body contouring techniques across the stomach area such as the full abdominoplasty, it is not advisable to have surgery for patients who are thinking about becoming pregnant.

Also, if condition has arisen from a genetic disorder such as lymphoedema, there may be a link to conditions worsening at the time of hormone changings such as pregnancy.

Race: Describe race related impact and evidence**.** This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers:

No impact identified

Religion or belief: Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues:

No impact identified

Sex: Describe any impact and evidence on men and women. This could include access to services and employment:

No impact identified

Sexual orientation: Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers:

3. Impact and Evidence:
No impact identified
Carers: Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities: No impact identified
Other disadvantaged groups: Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive) No impact identified

4. Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals?	No	This condition could be linked to a health inequality due to the prevalence of obesity. As the surgical procedures remain available it is not anticipated that a health inequality will be made worse.
Is there any impact for groups or communities living in particular geographical areas?	Yes	A limited link between obesity and areas of high deprivation has been made.
Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	Yes	The ability to access better diet and exercise may be reduced for those in low socio economic

4. Health Inequalities	Yes/No	Evidence
		groups. Due regard to this will need to be given in supporting such patients.

How will you ensure the proposals reduce health inequalities?

The intention of the policy is to support patients who have managed to maintain their weight for at least two years and where they have lost at least 50% of their original excess weight. Through the procedure the quality of life for all patients can be improved.

5. FREDA Principles/ Human Rights	Question	Response
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	Yes, this decision has been made in line with clinical recommendation and NICE
Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	No evidence of impact for this policy
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	No discrimination identified
	How will this affect a person's right to freedom of thought, conscience and religion?	N/A
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	Policy will be applied with due Regard to this consideration.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	An individual can discuss the impact with their GP and has the option for an IFR request to be made
Right to **Life**	Will or could it affect someone's right to life? How?	No evidence of impact for this policy
Right to **Liberty**	Will or could someone be deprived of their liberty? How?	No evidence of impact for this policy

6. Social Value

Consider how you might use the opportunity to improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.

Marmot Policy Objective	What actions are you able to build into the procurement activity and/or contract to achieve wider public benefits?
Enable all people to have control over their lives and maximise their capabilities	None
Create fair employment and good work for all	None
Create and develop health and sustainable places and communities	None
Strengthen the role and impact of ill-health prevention	None

7. Engagement, Involvement and Consultation

If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:

Engagement Activity	Protected Characteristic/ Group/ Community	Date

For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us …. So we will …..):

As part of the process further targeted engagement was planned with representative groups from among Sandwell, Birmingham and Solihull Patients. In addition, it has been identified that patient and clinician information is key in ensuring that the harmonised treatment policies review delivers effective outcomes. To this end an information briefing leaflet on each procedure has been developed to give more information on the procedure, eligibility criteria and signposting to further information sources, such as NHS Choices. These information leaflets are also designed to help facilitate discussions between GPs and patients. Information briefing leaflets have already been tested for the Pjase 1 and Phase 2 Harmonised Clinical Treatment Policy Projects for Birmingham and Solihull CCG and Sandwell and West Birmingham CCGs. Due regard will be given to both the accessible information standard and the potential need to translate such leaflets into relevant local languages.

The engagement team used every possible route throughout the engagement period to encourage people to feedback on the proposed policy. Unfortunately, despite the wide communication undertaken through all communication and engagement channels available, 49 questionnaires were completed online and there was no interest from stakeholders, patients and the public to attend any of the five stakeholder events arranged. As a result, the events were cancelled, and the engagement team looked at other routes to encourage engagement with patients directly. A possible reason for the lack feedback from stakeholders, patients and the public is most likely because this clinical treatments policy is widening the scope of the current service provision.

7. Engagement, Involvement and Consultation

Also, in phase 3 of the harmonisation of policies programme clinicians had been integral to the development of the policies from the beginning of the process. It could therefore be argued the proposed policy shared for public engagement was to some extent already informed from a local patient experience and outcomes perspective.

The potential impact on patients is minimal and feedback from approximately 59% of responders either strongly agree or agree to the proposed eligibility criteria for this draft policy. Additional comments are also in favour of this policy and also relate to supporting patients at the early stages of obesity to prevent them reaching advance stages. There was wide ranging clinical support for this policy.

8. Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work:

The restriction of this policy will have limited impact on those who would wish to receive the treatments, this must be balanced against the need to adhere to the clinical effectiveness evidence, overall health improvements in relation to quality of life for the patient and clinical outcomes.

The opportunity for any exceptional cases to be considered via IFR remains and will ensure treatment is available in a clinically exceptional case.

9. Mitigations and Changes :

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.

Consideration will need to be given to what additional support patients from a low socio economic background will require and how due regard can be given to reasonable adjustments in approach for disabled persons.

10. Contract Monitoring and Key Performance Indicators

Detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract (refer to NHS Standard Contract SC12 and 13):

This policy is not linked to a contract however, prospective providers remain bound by their contracts with the CCG.

11. Procurement

Detail the key equality, health inequalities, human rights, and social value criteria that will be included as part of the procurement activity (to evaluate the providers ability to deliver the service in line with these areas):
N/A

12. Publication

How will you share the findings of the Equality Analysis? This can include: reports into committee or Governing Body, feedback to stakeholders including patients and the public, publication on the web pages. All Equality Analysis should be recommended for publication unless they are deemed to contain sensitive information.
Publication on the CCG's website.
Following approval all finalised Equality Analysis should be sent to the Communications and Engagement team for publication: bsol.comms@nhs.net

13. Sign Off

The Equality Analysis will need to go through a process of **quality assurance** by the Senior Manager for Equality Diversity and Inclusion or the Manager for Equality Diversity and Inclusion prior to approval from the delegated committee

	Name	Date
Quality Assured By:		

Which Committee will be considering the findings and signing off the EA?		
Minute number (to be inserted following presentation to committee)		

Please send to Balvinder Everitt or Michelle Dunne, Equality, Diversity and Inclusion for Quality Assurance.

Once you have committee sign off, please send to Caroline Higgs, Communications & Engagement Team for publication: bsol.comms@nhs.net

NHS
Sandwell and West Birmingham
Clinical Commissioning Group

Policy for Adenoidectomy

Adenoids

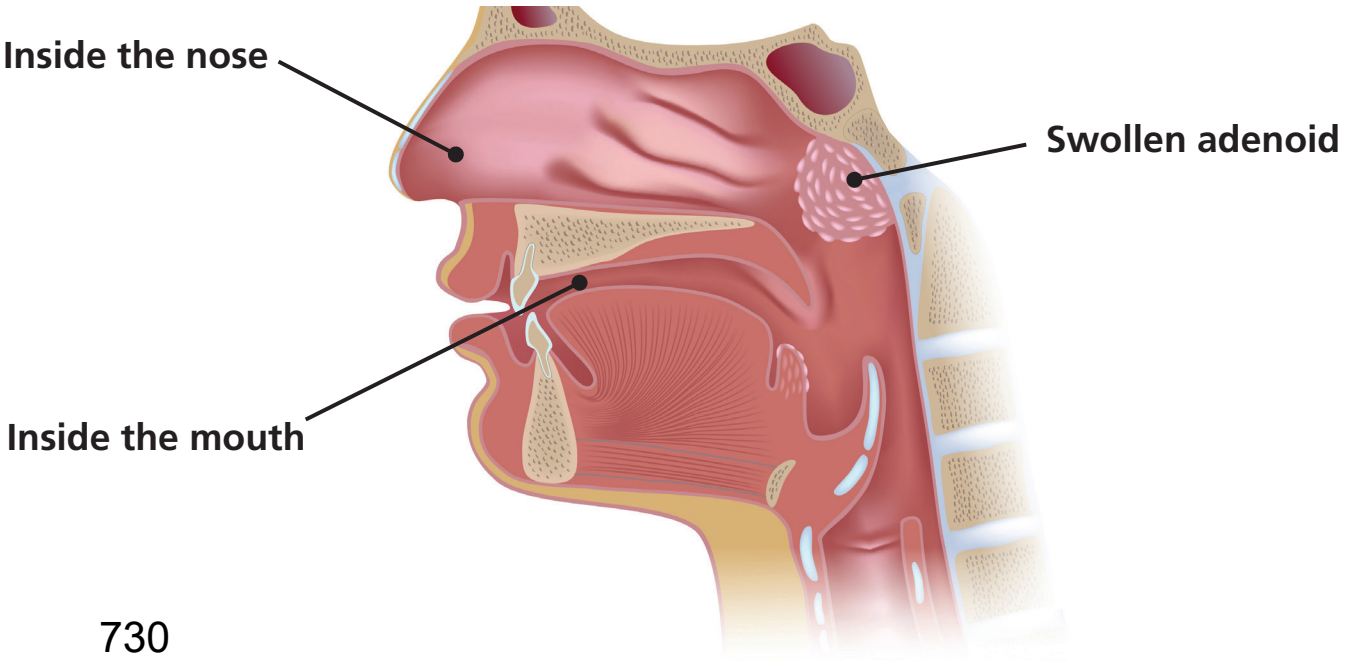
Adenoids are small lumps of tissue at the back of the nose, above the roof of the mouth. They are part of the immune system and produce white blood cells to help fight infections and viruses that get trapped when breathed in or swallowed.

Babies and children have adenoids. The adenoids start to shrink from around age five years and almost disappear by the late teens. In rare circumstances adults may have enlarged adenoids.

Adenoids can become swollen for a while when fighting a bacterial or viral infection and block the nasal passage. This swelling does get better, however sometimes the adenoids can become enlarged and cause:

- a constant runny nose
- difficulty breathing through the nose
- difficulty sleeping
- constant ear infections.

Conservative treatment with nasal sprays may help with these medical problems, but in certain cases, the adenoids may need to be removed.



Adenoidectomy

Adenoidectomy is a short operation carried out under general anaesthetic to remove the adenoids. The surgeon will remove the adenoids by scraping them away or by applying heat using a diathermy instrument. A diathermy instrument produces high-frequency electrical currents that burn the adenoids.

Risks

After an adenoidectomy, some patients may experience temporary minor health problems which rarely requires further treatment. They can include: sore throat, earache, stiff joy, blocked nose, bad breath and change in voice (may sound like they are speaking through their nose).

Eligibility Criteria

Adenoidectomy is a restricted procedure. It will only be funded if other treatments have not worked and the patient meets the following criteria:

- difficulty sleeping, may start to snore or develop irregular breathing during sleep and excessive sleepiness during the day
- recurrent or constant problems with ear infections
- recurrent or constant sinusitis including symptoms such as a frequent runny nose, facial pain and nasal-sounding speech.

This means the patient's NHS commissioning organisation (CCG), who is responsible for buying healthcare services on behalf of patients, will only fund the treatment if the patient meets the above eligibility criteria or if an Individual Funding Request (IFR) application has shown exceptional clinical need and the CCG supports this.

Advice and further guidance:

For more information and advice, search 'adenoids' at www.nhs.uk

NHS
Sandwell and West Birmingham
Clinical Commissioning Group

Policy for Bariatric Surgery in Adults

What is Bariatric Surgery?

Bariatric surgery is a group of surgical procedures used to promote weight loss for people who are considered obese (a Body Mass Index (BMI) of 30kg/m2 or more) with certain health needs. The procedures are performed by keyhole surgery (laparoscopically), which means patients spend a shorter time in hospital and the recovery time is quicker.

These surgical procedures include:

Restrictive procedures which help to limit the amount of food the stomach can hold.

Malabsorptive procedures which shorten or bypass a section of the intestine to reduce the amount of food intake.

Combined procedures which use elements of restriction and malabsorptive techniques to help weight loss.

Eligibility Criteria

Bariatric surgery is a restricted funded procedure and will only be funded the if a patient meets one of the following criteria:

- A BMI of more than 35kg/m2 and has Type 2 diabetes mellitus which has been diagnosed within the last 10 years

OR

- A BMI of more than 50kg/m2

This means the patient's NHS commissioning organisation (CCG), who is responsible for buying healthcare services on behalf of patients, will only fund the treatment if an Individual Funding Request (IFR) application has shown exceptional clinical need and the CCG supports this.

Advice and further guidance:

For more information and advice, search 'weight loss surgery' at www.nhs.uk

Policy for the use of Biological Mesh

Surgical mesh

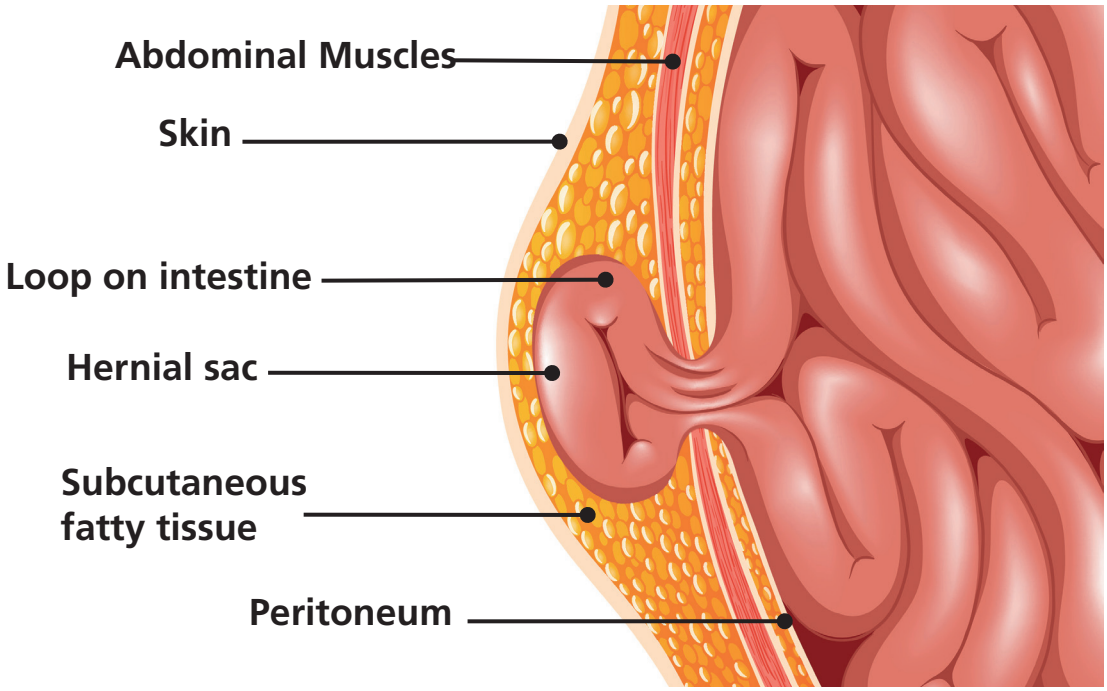
Mesh is a screen like material used during an operation to provide extra support to weak or damaged tissue or bone. There are three types of surgical mesh:

1. Standard Surgical Synthetic Mesh made from synthetic or manmade materials which will or will not absorb in the body.
2. Biological Mesh made from animal or human tissues.
3. Biosynthetic Mesh made from a combination of animal, human or synthetic tissues.

Surgical mesh is most commonly used to repair different types of hernias.

Hernia

A hernia occurs when an internal part of the body pushes through a part of a weakened muscle or the surrounding tissue wall. This results in a lump or swelling which may or may not be painful. They mainly occur in the groin or abdominal wall which holds the large and small intestines.



Treatment

Hernias which cause the patient to have symptoms, which affect their daily life, often need an operation. Hernia repair surgery is carried out using surgery to put the hernia back in its place. During this operation a mesh may be fixed to the muscle or tissue to strengthen it and repair the hernia.

Eligibility Criteria

Due to the limited quality of evidence of clinical effectiveness, the use of biological or biosynthetic mesh in standard hernia repair is Not Routinely Commissioned.

Biological or biosynthetic mesh in hernia repair may only be used in the following clinical circumstances following a review by a specialist complex abdominal wall repair multidisciplinary team:

- The first hernia repair surgery with synthetic surgical mesh did not work and the wound has not healed

OR

- The use of synthetic mesh would not be clinically appropriate for that individual patient, e.g. the mesh would need to be placed directly against the patient's bowel.

This means, for patients who **DO NOT** meet the above criteria, the patient's NHS commissioning organisation (CCG), who is responsible for buying healthcare services on behalf of patients, will only fund the treatment if an Individual Funding Request (IFR) application has shown exceptional clinical need and the CCG supports this.

NHS
Sandwell and West Birmingham
Clinical Commissioning Group

Policy for the use of continuous positive airway pressure for obstructive sleep apnoea hypopnea syndrome at home

Continuous positive airway pressure (CPAP)

CPAP is a small machine that pumps a non-stop supply of compressed air through a mask which keeps the walls of the throat open. The mask may either cover the nose or the nose and mouth. The compressed air helps to stop the throat from closing. It is considered the most effective therapy for treating severe cases of obstructed sleep apnoea/hypopnea syndrome and must always be worn when sleeping.

Why is it used?

Everyone breathes in oxygen from the air to stay alive. The oxygen goes into the blood through the lungs. When the body has used the oxygen, it produces carbon dioxide which is breathed out. This is called ventilation.

Some people with severe lung problems are unable to breathe in enough oxygen and breathe out carbon dioxide which can lead to the lungs not working properly.

Obstructive Sleep Apnoea Hypopnea Syndrome (OSAHS)

Obstructive Sleep Apnoea Hypopnea Syndrome (OSAHS) is a condition where the muscles supporting the walls of the throat relax and narrow during sleep. This affects normal breathing and causes the airflow to be blocked for a few seconds or more. At times, the airflow can stop completely. It may also wake you up from sleep several times so breathing can return to normal.

Apnoea

Apnoea is where the walls of the throat relax and narrow, usually during sleep, which affects normal breathing. It causes the airflow to be blocked for 10 or more seconds.

Hypopnea

This is a partial blockage of the airway that results in an airflow reduction of greater than 50% for 10 seconds or more.

In some patients, OSAHS can cause extreme daytime sleepiness, and affect daily life including not being able to sleep, eat, walk or drive on their own. The condition is also associated with ageing, obesity and high blood pressure, which increases the risk of heart disease and stroke.

Treatment

Treatment for OSAHS aims to reduce daytime sleepiness by reducing the number of episodes of apnoea/hypopnoea experienced during sleep. CPAP is most commonly used to help manage moderate or severe sleep OSAHS.

Other treatments include lifestyle management such as losing weight, eating healthier, stopping smoking, decrease the amount of alcohol consumed and not taking sleep medicines.

Eligibility Criteria

The use of CPAP at home for OSAHS is restricted. Patients with moderate or severe symptoms of obstructive sleep apnoea hypopnoea syndrome must meet the following criteria to be approved:

- severe inability to function properly during the day which is impacting on the patient's ability to carry out activities of daily living
- lifestyle changes have not helped
- other relevant treatment options have not worked or are considered unsuitable
- have an Apnoea–Hypopnoea Index level between 15 to 30 or over.

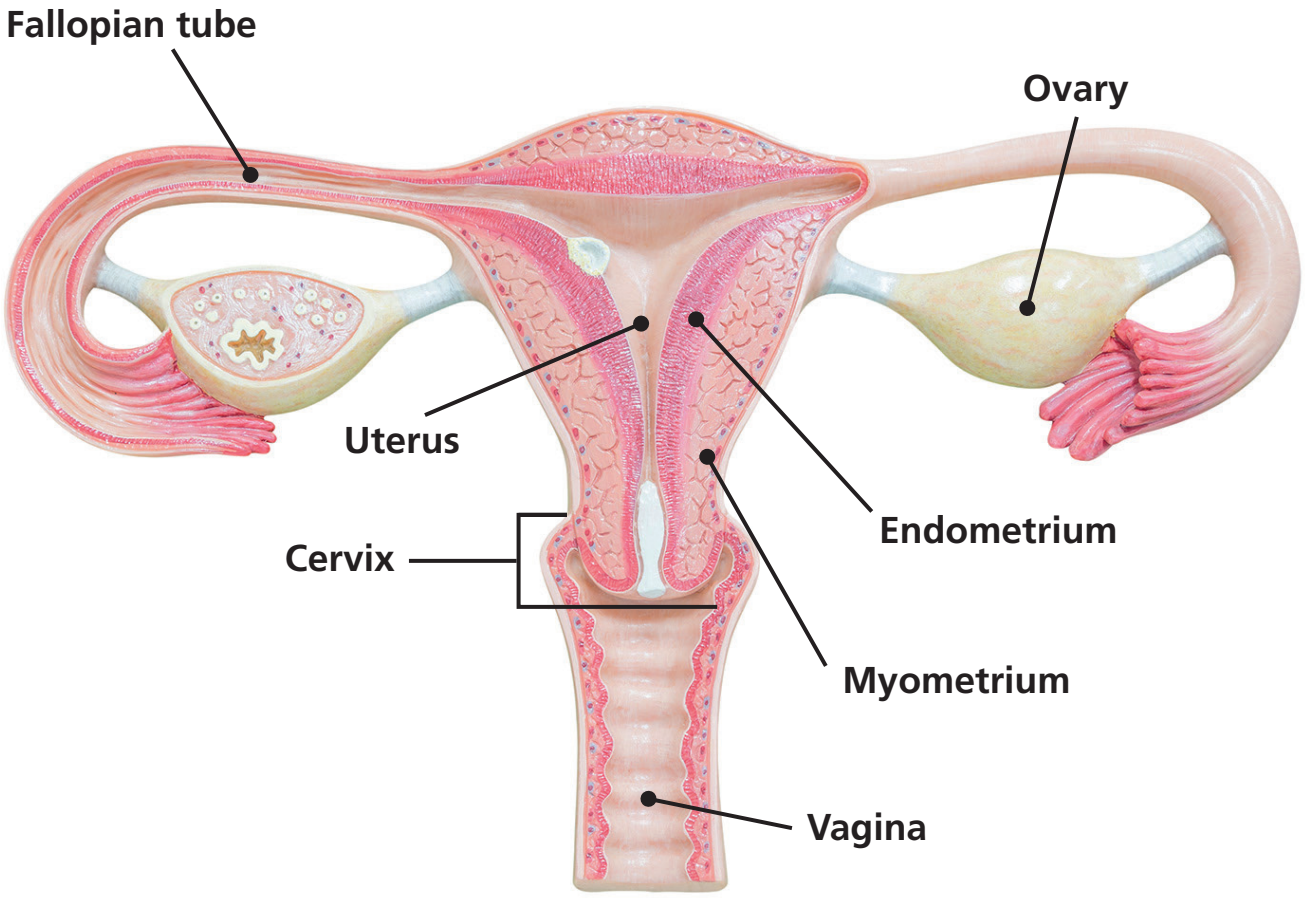
This means **(for patients who DO NOT meet the above criteria)** the Clinical Commissioning Group (CCG) will only fund the treatment if an Individual Funding Request (IFR) application proves clinical need and the CCG supports this.

NHS
Sandwell and West Birmingham
Clinical Commissioning Group

Policy for hysteroscopy for heavy menstrual bleeding

Hysteroscopy

A hysteroscopy is a procedure used to examine the inside of the womb (uterus). It is carried out using a hysteroscope, which is a narrow telescope with a light and camera at the end. It is passed into the womb through the vagina and cervix (entrance to the womb). This procedure helps to see what the problem is, make a diagnosis or even treat the problem.



Heavy Menstrual Bleeding (HMB/heavy periods)

Heavy bleeding during a woman's menstrual cycle (period) is common and can affect everyday life. In some women heavy bleeding can happen if they have problems such as fibroids or endometriosis.

Most women know how much bleeding is normal for them during their period and can tell when this changes. A good indication that your periods are heavy is if they last longer than seven days and you are:

- having to change your sanitary products every hour or two hours
- passing blood clots larger than 2.5cm (about the size of a 10p coin)
- bleeding through to your clothes or bedding
- using two types of sanitary product together – for example, tampons and pads

Usually there is no reason for heavy bleeding during a period. However, there are some conditions which can cause heavy bleeding:

Endometrial conditions

- **Endometriosis** is a condition that occurs when the lining (endometrium) of the womb (uterus) grows outside of the womb such as the fallopian tubes, ovaries or along the pelvis. Some women with this condition may experience extremely heavy periods with or without clots in their period blood. It can also cause painful periods.
- **Endometrial polyps** are non-cancerous growths in the lining of the womb or cervix.

Polycystic ovary syndrome (PCOS)

Polycystic ovary syndrome affects how the ovaries work. The ovaries may become enlarged and contain many fluid-filled sacs (follicles) that surround the eggs. These follicles are underdeveloped sacs and are often unable to release an egg (ovulation). This can cause irregular periods and periods can be heavy when they start again.

Fibroids

Fibroids are non-cancerous growths made up of muscle and tough tissue that develop in or around the womb and can vary in size.

Other reasons for heavy periods may include:

- an infection in the womb, fallopian tubes or ovaries
- womb cancer – the most common symptom is abnormal bleeding, especially after menopause
- blood clotting disorders
- diabetes

- the coil, a contraceptive device which can make periods heavier for the first three to six month
- medication to prevent blood clots
- some chemotherapy medicines
- herbal supplements such as ginseng, ginkgo and soya which can affect hormones and periods.

Eligibility Criteria

Hysteroscopy for heavy menstrual bleeding is a restricted procedure. It will only be funded if the patient meets one or more of the following conditions:

- suspected fibroids, polyps or endometrial symptoms inside the womb and continual bleeding between periods or irregular bleeding **OR**
- irregular heavy bleeding and is obese or has polycystic ovary syndrome **OR**
- women taking tamoxifen (type of hormone (endocrine) therapy used to treat breast cancer) **OR**
- heavy menstrual bleeding after having treatment and it has not worked **OR**
- has an ultrasound which did not show clear results.

This means the patient's NHS commissioning organisation (CCG), who is responsible for buying healthcare services on behalf of patients, will only fund the treatment if the patient meets the above eligibility criteria or an Individual Funding Request (IFR) application has shown exceptional clinical need and the CCG supports this.

Advice and further guidance:

For more information and advice, search 'heavy menstrual bleeding' at www.nhs.uk

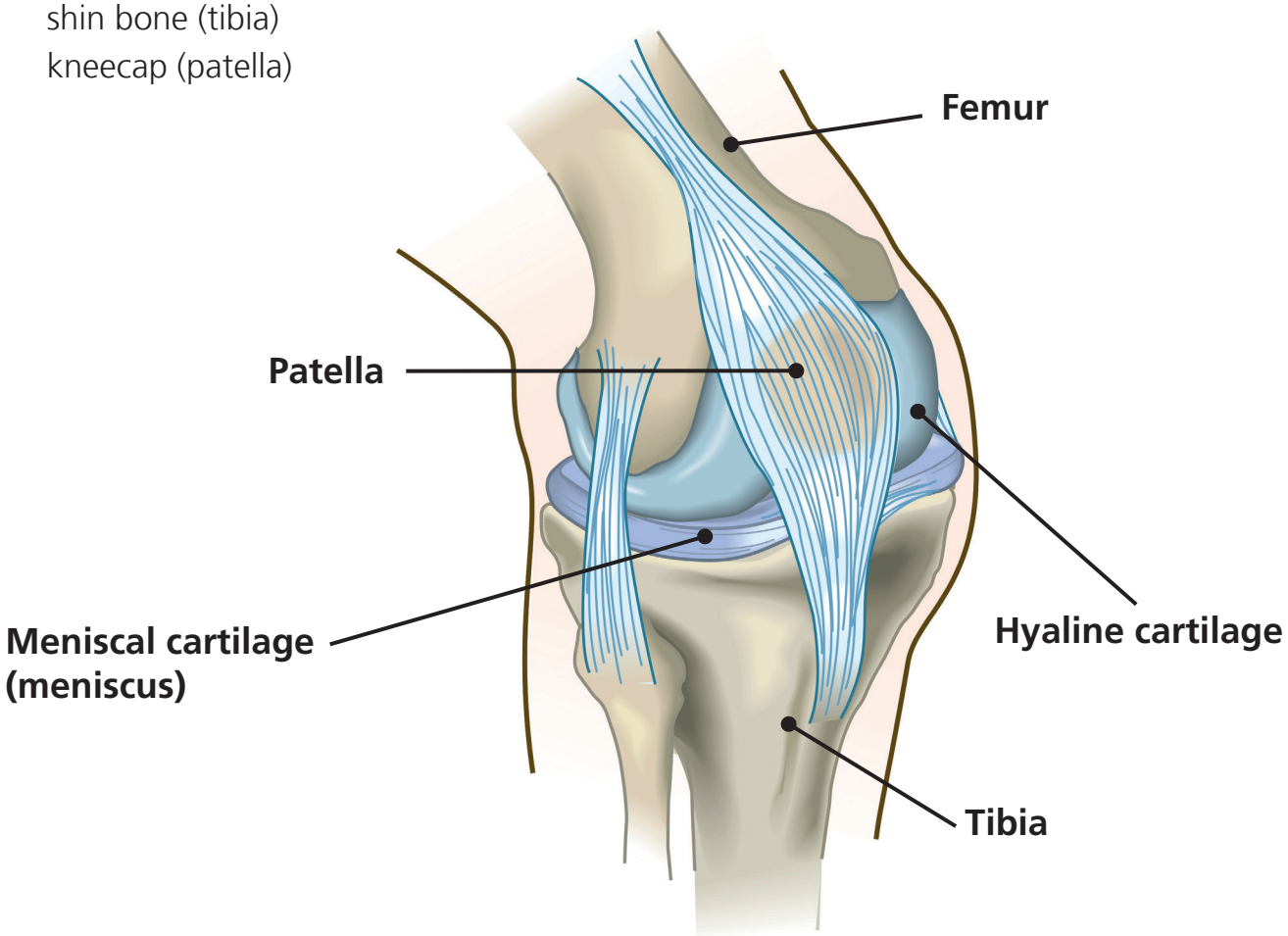
NHS
Sandwell and West Birmingham
Clinical Commissioning Group

Policy for Knee Arthroscopy for Acute Knee Injury

The knee

The knee joint acts like a hinge to let you bend, straighten and move the leg. It is made up of three bones:

- thigh bone (femur)
- shin bone (tibia)
- kneecap (patella)



Ligaments

Ligaments are tough bands of connective tissue in the knee which join the thigh bone to the shin bone at the knee joint. They help keep the knee steady and balanced.

Menisci

The meniscus is a piece of cartilage - firm rubbery material. It covers the ends of the bones in the knee and helps to provide a cushion between your thighbone and shinbone. There are two menisci in each knee joint which help to:

- absorb impact from body weight
- improve movement
- support the stability of the knee.

Acute knee injury

An acute knee injury is usually the result of a sudden twist, sprain, fall, force or direct bang to the knee. Common sports injuries can tear, damage or bruise the knee cartilage or ligaments. When they become damaged this can limit the knee's normal movement and cause pain.

Treatment

Treatment for acute knee injuries is generally conservative management, such as the PRICE protocol, medicines and physiotherapy.

PRICE stands for Protection, Rest, Ice, Compression and Elevation which is effective pain and symptom management for most sports-related injuries.

- **Protection** – protect the affected area from further injury, for example, by using a support.
- **Rest** – avoid exercise and reduce your daily physical activity. Using crutches or a walking stick may help if you can't put weight on your knee.
- **Ice** – apply an ice pack to the affected area for 15-20 minutes every two to three hours. A bag of frozen peas, or similar, will work well. Wrap the ice pack in a towel so that it doesn't directly touch your skin and cause an ice burn.
- **Compression** – use elastic compression bandages during the day to limit swelling.
- **Elevation** – keep the injured body part raised above the level of your heart whenever possible. This may also help reduce swelling.

Non-steroidal anti-inflammatory medicines like aspirin and ibuprofen can also be taken to reduce pain and swelling.

Physiotherapy is offered to patients whose symptoms have not resolved after PRICE and taking medicines.

Knee arthroscopy

A knee arthroscopy is a type of keyhole surgery which may be used to treat problems in the knee. A very small cut is made on the knee joint to insert a tiny camera (an arthroscope) so the inside of your knee can be seen on a monitor screen. This allows the surgeon to repair or remove any damage using small surgical tools.

Meniscectomy

This procedure involves removing some or all of the damaged or torn tissue.

Reconstructive ligament surgery

A torn ligament cannot be repaired by stitching it back together. However, it can be rebuilt by attaching new tissue from other areas of the leg.

Risks

There is a small risk of infection, worse pain, stiffness and damage to the nerves and blood vessels around the shoulder. In some cases, the surgery may need to be done again.

Eligibility Criteria

A knee arthroscopy for acute knee injury is a restricted surgical procedure. It is considered when other forms of treatment such as PRICE (Protection, Rest, Ice, Compression and Elevation), physiotherapy and painkillers after three months have not enabled knee function to be restored.

The treatment will only be funded if a patient is under 35 years old and:

- does not already have a degenerative knee disorder such as osteoarthritis

  AND
- continues to experience locking, clicking, popping or giving way of the knee

  AND
- has difficulties carrying out daily activities such as walking, sleeping or eating.

This means the patient's NHS commissioning organisation (CCG), who is responsible for buying healthcare services on behalf of patients, will only fund the treatment if the patient meets the eligibility criteria above or an Individual Funding Request (IFR) application has shown exceptional clinical need and the CCG supports this.

Advice and further guidance:

For more information and advice, search 'knee pain' at www.nhs.uk

NHS
Sandwell and West Birmingham
Clinical Commissioning Group

Policy for the use of Liposuction for Lipoedema

Liposuction

Liposuction is an operation which involves a suction technique to remove fat from certain areas of the body. As liposuction is normally seen as a cosmetic procedure, it is not normally available through the NHS. However, liposuction can sometimes be used to treat certain health conditions.

Lipoedema

Lipoedema is a long-term condition where an unusual build-up of fat in the legs, thighs, buttocks, and sometimes in the arms occurs which makes them increase in size. The condition usually affects women, although in rare cases it can also affect men.

Causes of lipoedema

The cause of lipoedema is not known, however in some cases there's a family history of the condition and the genes inherited from your parents play a role.

Lipoedema tends to start at puberty or at other times of hormonal change, such as during pregnancy or menopause. This suggests that hormones may also have an influence, however the build-up of fat cells is often worse in obese people. Lipoedema is not caused by obesity and can affect people who are a healthy weight.

Treatments

There's been little research into lipoedema, so there's some uncertainty about the best way to treat the condition. If you have lipoedema, it's important to avoid significant weight gain and obesity because putting on weight will make the fatty swelling worse. Compression tights are helpful for some people because they support the fatty swelling and may reduce the pain. Liposuction can be a surgical option for the removal of fat.

Non-surgical treatments

Non-surgical treatments can sometimes help to improve pain, tenderness and prevent or reduce lipoedema by improving the shape of affected limbs – although they often have little effect on the fatty tissue.

Several different treatments are designed to improve the flow and drainage of fluid in body tissues, such as:

- **compression therapy** – wearing bandages or garments that squeeze the affected limbs
- **exercise** – usually low-impact exercises, such as swimming and cycling
- **massage** – techniques that help encourage the flow of fluid through your body

Treatments which won't help

Some treatments used for some types of tissue swelling are generally unhelpful for lipoedema. Lipoedema doesn't respond to:

- raising the legs
- diuretics (tablets to get rid of excess fluid)
- dieting – this usually tends to result in a loss of fat from areas which are not affected by lipoedema.

Eligibility Criteria

Due to a lack of evidence, liposuction for patients with lipoedema is Not Routinely Commissioned.

This means the patient's NHS commissioning organisation (CCG), who are responsible for purchasing healthcare services on behalf of the population, will only fund the treatment if an Individual Funding Request (IFR) application has exceptional clinical need and the CCG supports this.

NHS
Sandwell and West Birmingham
Clinical Commissioning Group

Policy for the use of Liposuction for Lymphoedema

Liposuction

Liposuction is an operation which involves a suction technique to remove fat from certain areas of the body. This is done by inserting a thin tube through small cuts in the skin to draw fat out from the affected limbs, which helps to reduce the size of the limb. As liposuction is normally seen as a cosmetic procedure, it is not normally available through the NHS. However, liposuction can sometimes be used to treat certain health conditions.

Lymphoedema

Lymphoedema is a long-term (chronic) condition which causes swelling in the body's tissues. It can affect any part of the body; however, it usually develops in the arms or legs when the lymphatic system doesn't work properly.

The lymphatic system

The lymphatic system is part of the immune system. It is made up of a network of tissues, organs and glands throughout the body which help to transport 'lymph', an infection fighting fluid around the body. It also helps to remove excess fluid and fats from our bodies. When it doesn't work properly, it can cause swelling and encourage body fat to grow.

Treatment

Conservative treatment for lymphoedema is the first choice and the patient should be referred to a specialist lymphoedema service for assessment. Current conservative treatments for lymphoedema includes:

- **Decongestive Lymphatic Therapy (DLT)** which combines MLD massage with tight bandaging, good skin care, decongestive and exercise. Once DLT sessions are stopped, the patient is fitted with a custom-made compression garment, which is worn every day.

Eligibility Criteria

Patients with lymphoedema will be considered for funding for liposuction if they have not responded to conservative treatments of lymphoedema. If conservative treatment fails, the patient's specialist lymphoedema multidisciplinary team may consider recommending the patient for liposuction surgery to treat lymphoedema.

This means the patient's NHS commissioning organisation (CCG), who is responsible for buying healthcare services on behalf of patients, will only fund the treatment if the patient meets the above eligibility criteria or if an Individual Funding Request (IFR) application has shown exceptional clinical need and the CCG supports this.

Advice and further guidance:

For more information and advice, search 'lymphoedema' at www.nhs.uk

Policy for use of non-invasive ventilation for Chronic Obstructive Pulmonary Disease at home

What is Non-invasive ventilation?

Non-invasive ventilation (NIV) is an external treatment used to help people with severe problems with breathing. It involves wearing a mask connected to a machine (ventilator) which makes breathing in and out easier. It supports the muscles in the lungs to work properly, especially during the night.

Why is it used?

Everyone breathes in oxygen from the air to stay alive. The oxygen goes into the blood through the lungs. When the body has used the oxygen, it produces carbon dioxide which is breathed out. This is called ventilation. Some people with severe lung problems are unable to breathe in enough oxygen and breathe out carbon dioxide which can lead to the lungs not working properly.

Chronic Obstructive Pulmonary Disease

Chronic Obstructive Pulmonary Disease (COPD) is the name for a group of lung conditions that cause breathing difficulties. It includes: emphysema (damage to the air sacs in the lungs) and chronic bronchitis (long-term inflammation of the airways). Symptoms may include constant breathlessness, constant chesty cough with phlegm, frequent chest infections and constant wheeze. The breathing problems tend to get gradually worse over time and can limit the patient's normal activities.

Causes of COPD

COPD happens when the lungs become inflamed, damaged and narrowed. The main cause of COPD is smoking. However, it can sometimes affect people who have never smoke, however have had long term exposure to harmful fumes or dust. Damage to the lungs caused by COPD is permanent; however, treatment may help to slow down the condition.

Treatments

Treatments for COPD include:

- smoking cessation to help patient with COPD to stop smoking
- inhalers and medications
- programme of exercise and education
- surgery or a lung transplant

COPD can result in patients being admitted to hospital and needing support to breathe through non-invasive ventilation.

Eligibility Criteria

Non-invasive ventilation for Chronic Obstructive Pulmonary Disease at home is restricted. To be considered the patient must have been reviewed by their specialist respiratory/ventilation team to confirm they meet the following criteria:

- The patient has a lowered lung capacity which has been measured by the specialist respiratory team

AND

- Blood tests show the patient is not breathing out enough carbon dioxide

The patient must also have **ONE** of the following:

- A reduced quality of life identified by symptoms consistent with sleep disordered breathing problems e.g. extreme daytime sleepiness, headache, confusion, increased shortness of breath, resting tremor

OR

- More than one condition affecting the level of oxygen in the blood which could lead to high blood pressure in the lungs or heart failure

OR

- Two or more hospital admissions over the past 12 months needing non-invasive ventilation treatment during the admissions to which the patient has responded well.

This means the patient's NHS commissioning organisation (CCG), who is responsible for buying healthcare services on behalf of patients, will fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and the CCG supports this.

NHS
Sandwell and West Birmingham
Clinical Commissioning Group

Policy for the use of non-invasive ventilation for neuro muscular patients at home

What is Non-invasive ventilation?

Non-invasive ventilation (NIV) is an external treatment used to help people with severe problems with breathing. It involves wearing a mask connected to a machine (ventilator) which makes breathing in and out easier.

Why is it used?

Everyone breathes in oxygen from the air to stay alive. The oxygen goes into the blood through the lungs. When the body has used the oxygen, it produces carbon dioxide which is breathed out. This is called ventilation. Some people with severe lung problems are unable to breathe in enough oxygen and breathe out carbon dioxide which can lead to the lungs not working properly.

Neuro-muscular disorders

Neuro-muscular disorders cause weakness of muscles which can lead to not being able to breathe properly. Patients with some of these conditions may need to use NIV during the day and night to breathe more easily.

Patients with one of the following conditions who also meet the eligibility criteria below will be considered for non-invasive ventilation treatment at home:

Motor Neurone Disease

Motor neurone disease (MND) is a rare condition that affects the brain and nerves. It causes muscles and nerves to become weak which worsens over time.

Muscular Dystrophy

Muscular Dystrophy, including Duchenne Muscular Dystrophy gradually causes the muscles to weaken, leading to an increasing level of disability.

Multiple Sclerosis

Multiple sclerosis (MS) is a condition that can affect the brain and spinal cord, causing a wide range of potential symptoms including problems with vision, arm or leg movement, sensation or balance.

Post-polio syndrome

Polio is a viral infection which most people would have fought off without even knowing they had it. Post-polio syndrome is rarely life-threatening, however some people may develop breathing and swallowing difficulties.

Guillain-Barré syndrome

Guillain-Barré (pronounced ghee-yan bar-ray) syndrome is a very rare and serious condition that affects the nerves. It mainly affects the feet, hands and limbs, causing problems such as numbness, weakness and pain.

Syringomyelia

Syringomyelia is where a fluid-filled cavity called a 'syrinx' develops in the spinal cord. This can damage the spinal cord and cause muscular problems.

Tuberculosis (with respiratory impairment)

Tuberculosis (TB) is a bacterial infection which generally affects the lungs. If not treated it can cause the lungs to stop working properly.

Spinal Cord Injury

A spinal cord injury is where damage has been done to any part of the spinal cord or nerves at the end of the spine. It can cause the muscles that help you to breathe to stop working properly.

Other neuro muscular diseases which are known to cause muscle weakness and also affect breathing may be considered.

Eligibility Criteria

NIV for neuro muscular diseases at home is restricted. Patients with one of the neuromuscular conditions listed above must also meet the following criteria:

Ventilation at night

The patient must meet ONE of the following criteria:

- Signs or symptoms of hypoventilation
- Blood tests show the patient is not breathing in enough oxygen
- Blood tests show the patient is not breathing out enough carbon dioxide

Daytime Ventilation (in addition to meeting the above criteria the patient must also meet ONE of the following criteria):

- Not being able to swallow properly due to shortness of breath, which is relieved by using a ventilator
- Unable to speak in full sentences due to breathlessness
- Blood tests show the patient is not breathing in enough oxygen
- Blood tests show the patient is not breathing out enough carbon dioxide
- Symptoms of breathing difficulties whilst awake

This means **(for patients who DO NOT meet the above criteria)** patient's NHS commissioning organisation (CCG), who is responsible for buying healthcare services on behalf of patients, will only fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and the CCG supports this.

NHS
Sandwell and West Birmingham
Clinical Commissioning Group

Policy for the use of Non-Cosmetic Body Contouring Surgery

Non-cosmetic body contouring surgery

Non-cosmetic body contouring surgery is an operation to remove loose and saggy skin folds after weight loss from certain areas of the body which are causing medical problems. This type of operation helps patients to prevent further or future illnesses.

There are a number of surgical interventions which can be described as body contouring procedures:

Full abdominoplasty

Also known as a 'tummy tuck', a full abdominoplasty involves making openings from hip to hip and around the belly button to remove extra skin and fat. Some tissues and muscles are also tightened before the skin is repositioned and sewn up. This procedure will leave a circular scar around the belly button and a long scar along the bikini line.

Mini abdominoplasty

A mini tummy tuck involves making a horizontal cut along the bikini line to remove a block of skin and fat from the lower tummy. Sometimes the muscles will also be tightened. This procedure will leave a smaller scar along the bikini line.

Extended abdominoplasty

An extended abdominoplasty involves a full 'tummy tuck', with the additional removal of extra skin and fat from the thighs and back at the same time.

Endoscopic abdominoplasty

Endoscopic abdominoplasty is a procedure carried out if only the muscles of the abdominal wall need to be tightened. A small cut near the bikini line, or around the belly button is made to insert special surgical tools to tighten the muscles. As skin is not removed during this procedure, liposuction can also be carried out at the same time.

Apronectomy (Panniculectomy)

An Apronectomy removes the large excess of skin and fat hanging down over the pubic area which looks like an 'apron of skin'. This extra skin can affect normal activities such as walking and may lead to serious medical problems such as skin inflammation or infection under the flap.

Brachioplasty

Brachioplasty, also known as an arm lift, removes and tightens loose skin and excess fat in the upper arm. A long cut is made between the elbow and armpit to remove sections of the skin and fat. The remaining skin and tissue are lifted and sewn up.

Thighplasty

Thighplasty, also known as a bum and/or thigh lift, involves removing the 'extra' loose and saggy skin around the bottom and thighs. Liposuction may also be performed during this procedure to tighten the bottom and thighs.

Liposuction

Liposuction is an operation using a suction technique to remove fat from certain areas of the body which haven't responded to exercise and diet.

Evidence Review

The clinical evidence reviewed showed the benefit to patients in certain clinical circumstances where excess skin is causing problems with daily life activities or ongoing skin infections which have not improved after six months of treatment.

Eligibility Criteria

Non-cosmetic body contouring is a restricted procedure and the removal of excess skin will only be funded if the patient:

- Is 18 years old or over at the time of application and has lost at least 50% of their original excess weight and maintained their weight for at least two years

AND

- The patient has skin folds which are affecting their ability to carry out activities of everyday life such as sleeping, eating, walking

OR

- The patient has recurrent skin infections in the skin folds which have not improved after six months of treatment.

This means the patient's NHS commissioning organisation (CCG), who is responsible for buying healthcare services on behalf of patients, will only fund the treatment if the patient meets the eligibility criteria above, or if an Individual Funding Request (IFR) application has shown exceptional clinical need and the CCG supports this.

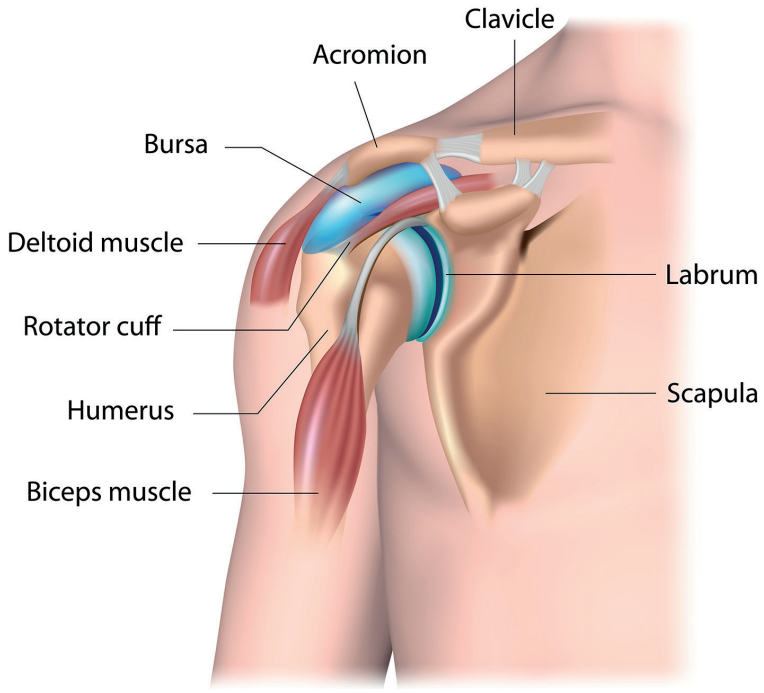
NHS
Sandwell and West Birmingham
Clinical Commissioning Group

Policy for Subacromial Pain Syndrome in Adults

What is subacromial pain in adults?

Subacromial pain in adults is one of the most common causes of non-traumatic shoulder pain and is a normal part of ageing. It can also be known as 'rotator cuff disease', which is thought to be the wear and tear of the rotator cuff tendons.

The rotator cuff tendons hold the shoulder joint in place and allow people to lift the arm and reach overhead. When the arm is lifted, the rotator cuff tendon passes through a narrow space at the top of the shoulder, known as the sub-acromial space. Most rotator cuff tears occur within the tendon or on the 'under-side' of the tendon.



Shoulder impingement (pain in the top and outer side of the shoulder) will often improve in a few weeks or months, especially with prescribed shoulder exercises.

Treatment

Arthroscopic sub-acromial decompression is a series of surgical 'keyhole' procedures to different parts of the shoulder. It involves decompressing the subacromial space by removing bone spurs and soft tissue arthroscopically.

Risks

There is a small risk of infection, worse pain, stiffness and damage to the nerves and blood vessels around the shoulder. In some cases, the surgery may need to be done again.

Eligibility Criteria

Due to the limited quality of evidence of clinical effectiveness, surgery for subacromial pain syndrome is not routinely commissioned.

This means the patient's NHS commissioning organisation (CCG), who is responsible for buying healthcare services on behalf of patients, will only fund the treatment if an Individual Funding Request (IFR) application has shown exceptional clinical need and the CCG supports this.

Advice and further guidance:

For more information, search 'shoulder pain' at www.nhs.uk

NHS Birmingham and Solihull CCG
NHS Sandwell and West Birmingham CCG

DRAFT
Policy Knee Arthroscopy for Acute Knee Injury

Document Details:

Version:	DRAFT v1.
Ratified by (name and date of Committee):	Treatment Policy Clinical Development Group
Date issued for Public Consultation:	02.09.2019
Equality & Diversity Impact Assessment	

The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decisions are considered within the wider constraints of the CCG's legally responsibility to remain fiscally responsible.

Category: Restricted

The Knee

The 3 bones that meet in the knee are the:

- thigh bone (femur)
- shin bone (tibia)
- kneecap (patella)

These bones are connected by 4 ligaments – 2 collateral ligaments on the sides of the knee and 2 cruciate ligaments inside the knee.

Ligaments are tough bands of connective tissue. The ligaments in the knee hold the bones together and help keep the knee stable.

The menisci are thick pads of cartilage tissue within the knee which act as shock absorbers to absorb body weight and help improve smooth movement and stability of the knee.

The two main areas within the knee which may be damaged by an acute injury include:

1. Menisci (cartilage)
2. Ligaments

1. **Menisci.**

What is the knee meniscus?

The menisci are thick pads of cartilage tissue within the knee which act as shock absorbers to absorb body weight and help improve smooth movement and stability of the knee. Each knee joint contains a medial and lateral meniscus (inner and outer meniscus).

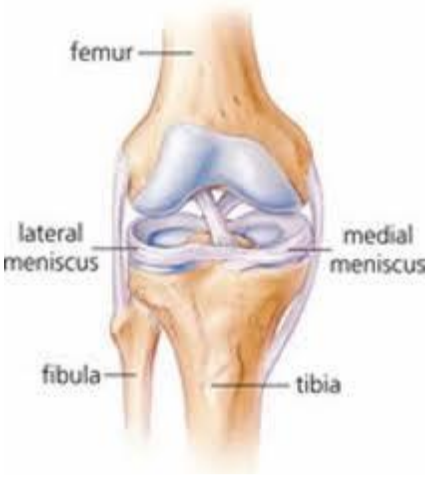


Figure 1. The Knee Joint

What is a meniscal injury?

There are varying degrees of damage a patient can do to the menisci. These range from bruising the menisci through to having large tears of the menisci. Meniscal tears can occur during sporting activities through twisting the knee whilst the foot is still in contact with the ground. In severe injuries, other parts of the knee may also be damaged in addition to a meniscal tear. For example, a patient may also sprain or tear a ligament. Meniscal cartilage does not always heal very well once it is torn. This is mainly because the central area of the meniscus does not have a good blood supply. The outer edge of each meniscus has some blood vessels, but the area in the centre has no direct blood supply.

Conservative Treatment

The PRICE protocol is effective for most sports-related injuries. PRICE stands for Protection, Rest, Ice, Compression, and Elevation.

- **Protection** – protect the affected area from further injury – for example, by using a support.
- **Rest** – avoid exercise and reduce your daily physical activity. Using crutches or a walking stick may help if you can't put weight on your ankle or knee. **Ice** – apply an ice pack to the affected area for 15-20 minutes every two to three hours. A bag of frozen peas, or similar, will work well. Wrap the ice pack in a towel so that it doesn't directly touch your skin and cause an ice burn.
- **Compression** – use elastic compression bandages during the day to limit swelling.
- **Elevation** – keep the injured body part raised above the level of your heart whenever possible. This may also help reduce swelling.

Non-steroidal anti-inflammatory medicines. Drugs like aspirin and ibuprofen reduce pain and swelling.

Physiotherapy for those whose symptoms do not resolve.

Surgical Treatment

Procedure. Knee arthroscopy is one of the most commonly performed surgical procedures. During a knee arthroscopy,, a miniature camera is inserted through a small incision (portal). This provides a clear view of the inside of the knee. The orthopaedic surgeon, then inserts miniature surgical instruments through other portals to trim or repair the tear.

- Partial meniscectomy. In this procedure, the damaged meniscus tissue is trimmed away.

- Meniscus repair. Some meniscus tears can be repaired by suturing (stitching) the torn pieces together. Whether a tear can be successfully treated with repair depends upon the type of tear, as well as the overall condition of the injured meniscus. Because the meniscus must heal back together, recovery time for a repair is much longer than from a meniscectomy.

.

Risks of meniscal surgery

The knee may not be exactly like it was before the injury, and the patient may still have some pain and swelling.

This may be because of other injuries to the knee, such as tears or injuries to ligaments, which happened at the same time as or after the injury.

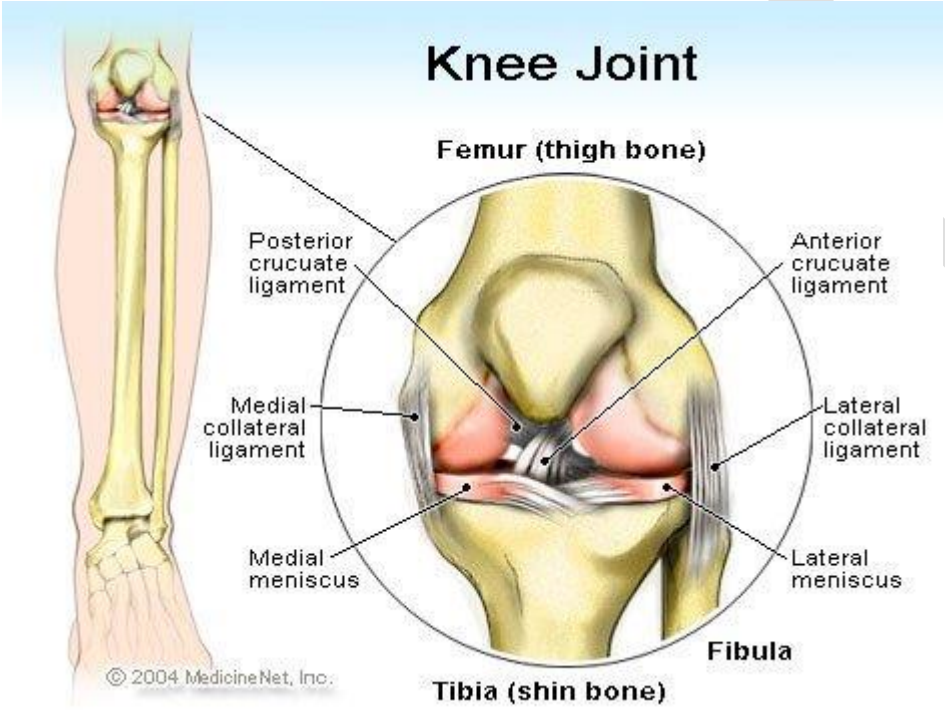
As with all types of surgery, there are some small risks associated with knee surgery, including infection, a blood clot, knee pain, and knee weakness and stiffness.

2. **Ligaments (Anterior Cruciate Ligament (ACL); Posterior Cruciate Ligament (PCL); Collateral Ligaments R/LCL)**

What are the Knee Ligaments?

The Ligaments found within the knee are tough bands of tissue joining the thigh bone to the shin bone at the knee joint.

The ligaments run diagonally through the inside of the knee and around each side which give the knee joint stability. It also helps to control the back-and-forth movement of the lower leg.



Ligament injuries

Knee injuries can occur during sports such as skiing, tennis, squash, football and rugby. Ligament injuries, in particular Anterior Cruciate Ligament (ACL) injuries are one of the most common types of knee injuries, accounting for around 40% of all sports injuries.

A patient may tear the knee ligaments if the lower leg extends forwards too much. It can also be torn if the knee and lower leg are twisted.

Common causes of a ligament injury include:

- landing incorrectly from a jump
- stopping suddenly
- changing direction suddenly
- having a collision, such as during a football tackle

Conservative management

The PRICE protocol is effective for most sports-related injuries. PRICE stands for Protection, Rest, Ice, Compression, and Elevation.

- **Protection** – protect the affected area from further injury – for example, by using a support.
- **Rest** – avoid exercise and reduce your daily physical activity. Using crutches or a walking stick may help if you can't put weight on your ankle or knee. A sling may help if you've injured your shoulder.
- **Ice** – apply an ice pack to the affected area for 15-20 minutes every two to three hours. A bag of frozen peas, or similar, will work well. Wrap the ice pack in a towel so that it doesn't directly touch your skin and cause an ice burn.
- **Compression** – use elastic compression bandages during the day to limit swelling.
- **Elevation** – keep the injured body part raised above the level of your heart whenever possible. This may also help reduce swelling.

Non-steroidal anti-inflammatory medicines. Drugs like aspirin and ibuprofen reduce pain and swelling.

Physiotherapy for those whose symptoms do not resolve.

Reconstructive Ligament surgery

A torn ligament cannot be repaired by stitching it back together, but it can be reconstructed by attaching (grafting) new tissue on to it.

The ligament, for example the ACL, may be reconstructed by removing what remains of the torn ligament and replacing it with a tendon from another area of the leg, such as the hamstring or patellar tendon.

The patellar tendon attaches the bottom of the kneecap (patella) to the top of the shinbone (tibia).

Risks of ligament surgery

The knee may not be exactly like it was before the injury, and you may still have some pain and swelling.

This may be because of other injuries to the knee, such as tears or injuries to the cartilage, which happened at the same time as or after the ligament injury.

As with all types of surgery, there are some small risks associated with knee surgery, including infection, a blood clot, knee pain, and knee weakness and stiffness.

Evidence Review

There was no NICE Guidance identified which reviewed this surgical intervention, and no systematic reviews were identified.

Utsaerts et al. (2016) produced a follow-up paper to their RCT, which is considered high quality with long follow-up. In this high quality randomised controlled trial, with minimal loss to follow-up, a strategy of rehabilitation plus early ACL reconstruction did not provide better results at five years than a strategy of initial rehabilitation with the option of having a later ACL reconstruction. Results did not differ between knees surgically reconstructed early or late and those treated with rehabilitation alone. These results should encourage clinicians and young active adult patients to consider rehabilitation as a primary treatment option after an acute ACL tear.

Frobell et al (2013) found there was no increased risk of osteoarthritis or meniscal surgery if the ACL injury was treated with physiotherapy alone compared with if it was treated with surgery. Neither was there any difference in patients' experiences of function, activity level, quality of life, pain, symptoms or general health.

Measures included Knee injury and osteoarthritis outcome score (KOOS), the Medical Outcomes Study 36-item short-form health survey (SF-36), short-form health survey (SF-36), and the Tegner activity scale. In the full analysis set, the mean change in KOOS4 score from baseline to five years was 42.9 points for patients assigned to rehabilitation plus early anterior cruciate ligament reconstruction and 44.9 points for those assigned to rehabilitation plus optional delayed reconstruction (between group difference 2.0 points, 95% confidence interval −8.5 to 4.5; P=0.54 after adjustment for the baseline score). No statistically significant differences in KOOS4, any of the five individual subscales of KOOS, SF-36, or Tegner activity scale between the two treatment strategies were identified at five years or in the change between two and five years.

In conclusion, the evidence does not support the use of surgical repair as a primary treatment immediately following injury. However, in cases where conservative treatment over 3 months has failed: physiotherapy; analgesia and PRICE, then the current evidence demonstrates that knee arthroscopy with ligament / menisci repair may be clinically appropriate.

Eligibility Criteria: Restricted

Knee Arthroscopy for Acute Knee injury is only commissioned in the following clinical circumstances:

- The patient does not have degenerative knee disease AND
- The patient has experienced an acute knee injury AND
- Following the acute knee injury, the patient has undergone clinician verified conservative treatment for at least 3 months with physiotherapy; analgesia and PRICE, which have all failed AND
- The patient continues to have mechanical symptoms which are causing functional impairment.

Degenerative knee disease is an inclusive term, which many consider synonymous with osteoarthritis. The term degenerative knee disease is used to explicitly include patients with knee pain, particularly if they are >35 years old, with or without:

– Imaging evidence of osteoarthritis

– Meniscus tears

– Locking, clicking, or other mechanical symptoms except persistent objective locked knee OR

– Acute or subacute onset of symptoms

N.B. Functional impairment is defined as interfering with activities of daily living, i.e. walking; sleeping; eating.

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Guidance

[1] Treatment for acute anterior cruciate ligament tear: five-year outcome of randomised trial. BMJ 2013; 346 doi: https://doi.org/10.1136/bmj.f232

[2] Mutsaerts ELAR, van Eck CF, van de Graaf VA, Doornberg JN, van den Bekerom MPJ. Surgical interventions for meniscal tears: a closer look at the evidence. Arch Orthop Trauma Surg 2016;136:361-37

[3] Smith TO, Davies L, Hing CB (2010) Early versus delayed surgery for anterior cruciate ligament reconstruction: a systematic review and meta-analysis. Knee Surg Sports Traumatol Arthrosc 18:304–311

[4] Webb,R., Brammah,T., Lunt,M., et al. (2004) Opportunities for prevention of 'clinically significant' knee pain: results from a population-based cross sectional survey. Journal of Public Health (Oxford). 26(3), 277-284

[5] Brophy RH, Zeltser D, Wright RW, et al. Anterior cruciate ligament reconstruction and concomitant articular cartilage injury: incidence and treatment. Arthroscopy. 2010;26:112-120. http://www.ncbi.nlm.nih.gov/pubmed/20117635?tool=bestpractice.com

[6] Bowers AL, Spindler KP, McCarty EC, et al. Height, weight, and BMI predict intra-articular injuries observed during ACL reconstruction: evaluation of 456 cases from a prospective ACL database. Clin J Sport Med. 2005;15:9-13. http://www.ncbi.nlm.nih.gov/pubmed/15654185?tool=bestpractice.com

[7] Mandalia V, Fogg AJ, Chari R, et al. Bone bruising of the knee. Clin Radiol. 2005;60:627-636. https://bestpractice.bmj.com/topics/en-gb/589/complications#referencePop109

[8] Rodkey WG, Steadman JR, Li ST. A clinical study of collagen meniscus implants to restore the injured meniscus. Clin Orthop Relat Res. 1999:S281-92. http://www.ncbi.nlm.nih.gov/pubmed/10546653?tool=bestpractice.com

[9] NHS website: https://www.nhs.uk/conditions/arthroscopy/

[10] Kruseman N, Geesink RGT, van der Linden AJ *et al*. Acute knee injuries: diagnostic & treatment management proposals. http://arnos.unimasas.nl/show.cgi?fig1?46875

[11] Steve Bollen: Injuries of the sporting knee - Epidemiology of knee injuries: diagnosis and triage https://bjsm.bmj.com/content/34/3/227.2

NHS Birmingham and Solihull CCG
NHS Sandwell and West Birmingham CCG

DRAFT
Policy Adenoidectomy

Document Details:

Version:	DRAFT v1.
Ratified by (name and date of Committee):	Treatment Policy Clinical Development Group
Date issued for Public Consultation:	02.09.2019
Equality & Diversity Impact Assessment	

The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decisions are considered within the wider constraints of the CCG's legally responsibility to remain fiscally responsible.

Category: Restricted

Adenoids

Adenoids are small lumps of tissue at the back of the nose, above the roof of the mouth. You can't see a person's adenoids by looking in their mouth.

Adenoids are part of the immune system, which helps fight infection and protects the body from bacteria and viruses.

In most cases only children have adenoids. They start to grow from birth and are at their largest when a child is around three to five years of age.

By age seven to eight, the adenoids start to shrink and by the late teens, they're barely visible. By adulthood, in most people they will have disappeared completely.

Adenoids can be helpful in young children, but they're not an essential part of an adult's immune system.

Adenoids can sometimes become swollen or enlarged. This can happen after a bacterial or viral infection, or after a substance triggers an allergic reaction.

In most cases, swollen adenoids only cause mild discomfort and treatment isn't needed. However, for some, it can cause severe discomfort and interfere with their daily life.

Adenoidectomy

The adenoids can be removed during an adenoidectomy.

The operation is usually carried out by an ear, nose and throat (ENT) surgeon and takes around 30 minutes. Afterwards, the patient will need to stay in the recovery ward until the anaesthetic has worn off.

Adenoidectomies are sometimes day cases if carried out in the morning, in which case you / your child may be able to go home on the same day. However, if the procedure is carried out in the afternoon, you / your child may need to stay in hospital overnight.

Eligibility Criteria

Adenoids may be removed in the following clinical circumstances:

- Documented medical problems caused by obstruction of the airway by enlarged adenoids **AND** all conservative treatments have been exhausted.

For the purposes of this eligibility criteria, a medical problem is defined as a medical problem that continually impairs sleep and/or breathing, e.g.

- difficulty sleeping – the patient has problems sleeping and may start to snore; in severe cases, some patients may develop sleep apnoea (irregular breathing during sleep and excessive sleepiness during the day) due to enlarged adenoids
- recurrent or persistent problems with the ears – such as middle ear infections (otitis media) or glue ear (where the middle ear becomes filled with fluid)
- recurrent or persistent sinusitis – leading to symptoms such as a constantly runny nose, facial pain and nasal-sounding speech.

All clinical circumstances which meet the above eligibility criteria, must have failed conservative medical treatment, before being eligible for surgical intervention.

Conservative medical treatments include:

Topical nasal steroids.

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG

Guidance

1. NHS. Adenoids & Adenoidectomy 29.12.2016. https://www.nhs.uk/conditions/adenoids-and-adenoidectomy/

2. Kamel RH[1], Ishak EA. 1990 Enlarged adenoid and adenoidectomy in adults: endoscopic approach and histopathological study. J Laryngol Otol. 1990 Dec;104(12):965-7.

3. Torretta S[1,2], Guastella C[3], Ibba T[4], Gaffuri M[5], Pignataro L[6] Prevalence of adenoid hypertrophy: A systematic review and meta-analysis. Clin Med. 2019 May 15;8(5). pii: E684. doi: 10.3390/jcm8050684.

4. Torretta S[1,2], Guastella C[3], Ibba T[4], Gaffuri M[5], Pignataro L[6] Surgical Treatment of Paediatric Chronic Rhinosinusitis. https://www.ncbi.nlm.nih.gov/pubmed/31096610

5. Vanneste P[1], Page C[1]. Otitis media with effusion in children: Pathophysiology, diagnosis, and treatment. A review. J Otol. 2019 Jun;14(2):33-39. doi: 10.1016/j.joto.2019.01.005. Epub 2019 Jan 31. https://www.ncbi.nlm.nih.gov/pubmed/31223299

6. Kugelman N[1,2], Ronen O[1,2], Stein N[3,2], Huberfeld O[1,2], Cohen-Kerem R[1,4,2]. Adenoid Obstruction Assessment in Children: Clinical Evaluation Versus Endoscopy and Radiography. Isr Med Assoc J. 2019 Jun;21(6):376-380. https://www.ncbi.nlm.nih.gov/pubmed/31280504

7. Durgut O[1], Dikici O[2]. The effect of adenoid hypertrophy on hearing thresholds in children with otitis media with effusion. Int J Pediatr Otorhinolaryngol. 2019 Jun 1;124:116-119. doi: 10.1016/j.ijporl.2019.05.046. https://www.ncbi.nlm.nih.gov/pubmed/31176025

8. Pereira L[1], Monyror J[2], Almeida FT[3], Almeida FR[4], Guerra E[5], Flores-Mir C[6], Pachêco-Pereira CPrevalence of adenoid hypertrophy: A systematic review and meta-analysis. Sleep Med Rev. 2018 Apr;38:101-112. doi: 10.1016/j.smrv.2017.06.001. Epub 2017 Jun 14. https://www.ncbi.nlm.nih.gov/pubmed/29153763

9. Zhang L, Mendoza-Sassi RA, César JA, Chadha NK. 2008. Topical steroids for nasal airway obstruction in children with moderately to severely enlarged adenoids. Cochrane Review. https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD006286.pub2/full

NHS Birmingham and Solihull CCG
NHS Sandwell and West Birmingham CCG

DRAFT
Policy for the use of Biological Mesh.

Document Details:

Version:	DRAFT v1.
Ratified by (name and date of Committee):	Treatment Policy Clinical Development Group
Date issued for Public Consultation:	02.09.2019
Equality & Diversity Impact Assessment	21.11.2019

The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decisions are considered within the wider constraints of the CCG's legally responsibility to remain fiscally responsible.

Category: Restricted

Surgical Mesh

Surgical mesh is a screen-like material that is used as a reinforcement for tissue or bone. It can be made of synthetic polymers or biopolymers.

Materials used for surgical mesh include:

- Non-absorbable synthetic polymers (polypropylene)
- Absorbable synthetic polymers (polyglycolic acid or polycaprolactone)
- Biologic (acellular collagen sourced from cows or pigs)
- Composite (a combination of any of the three previous materials e.g. Biosynthetic)

Mesh implants may be used in a number of surgical procedures to provide additional support when repairing weakened or damaged tissue.

Over recent years attention has increased on complications that can occur with the use of this mesh in urogynaecological procedures to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI). These complications may include persistent pain, sexual problems, mesh exposure through vaginal tissues and occasionally injury to nearby organs, such as the bladder or bowel. There has been an acknowledgement from the NHS England Mesh Working Group that there is a lack of comprehensive data on these complications. Work is ongoing to ensure that patients are encouraged to report complications and clinicians report adverse events.

Currently, the use of mesh in urogynaecological procedures to treat pelvic organ prolapse and stress urinary incontinence is not supported across the NHS and a wider NHS England review of the use of mesh in these clinical circumstances, means that at the current time in line with NHSE recommendation, the CCG does not support the use of mesh implants in these urogynaecological procedures.

However, surgical mesh implants (non-biological mesh) are routinely used across the NHS to address the clinical problem of hernia. A hernia may be inguinal, femoral; umbilical; para-umbilical or incisional. These implants typically restore structural domain to the abdominal/pelvic wall and prevent extrusion of visceral contents. Surgery takes place either as an open or laprascopic procedure.

Open surgery

The surgeon makes a single cut (incision) over the hernia. This incision is usually about 6 to 8cm long. The surgeon then places the lump of fatty tissue or loop of bowel back into your abdomen (tummy). A mesh is placed in the abdominal wall, at the weak spot where the hernia came through, to strengthen it. When the repair is complete, your skin will be sealed with stitches. These stitches usually dissolve on their own over the course of a few days after the operation.

If the hernia has become strangulated and part of the bowel is damaged, the affected segment may need to be removed and the 2 ends of healthy bowel rejoined. This is a bigger operation and you may need to stay in hospital for 4 to 5 days.

Laparoscopic (keyhole) surgery

During keyhole surgery, the surgeon usually makes 3 small incisions in your abdomen instead of a single larger incision. A thin tube containing a light source and a camera (laparoscope) is inserted through one of these incisions so the surgeon can see inside your abdomen. Special surgical instruments are inserted through the other incisions so the surgeon can pull the hernia back into place.

There are 2 types of keyhole surgery.

1. Transabdominal preperitoneal (TAPP)

Instruments are inserted through the muscle wall of your abdomen and through the lining covering your organs (the peritoneum).

A flap of the peritoneum is then peeled back over the hernia and a piece of mesh is stapled or glued to the weakened area in your abdomen wall to strengthen it.

2. Totally extraperitoneal (TEP)

This is the newest keyhole technique and involves repairing the hernia without entering the peritoneal cavity.

Once the repair is complete, the incisions in your skin are sealed with stitches or surgical glue.

Evidence Review

A review of the clinical evidence found mixed clinical review, with no strong basis for the use of biological mesh over standard mesh in standard or first line hernia repair operations (inguinal; umbilical; paraumbilical or incisional). The standard of the evidence reviewed comprised mainly of retrospective studies of low to moderate quality, but with hernia reoccurrence being slightly higher following the use of biological mesh, but no significant difference was determined in the occurrence of wound and mesh infection. It is possible due to the nature of the studies that the high rates of reoccurrence could be accounted for due to the more complex nature of the hernia repairs where biological mesh was utilised. Therefore, in light of the currently available low quality evidence, to support the use of biological mesh over standard mesh, in first line or standard hernia repair procedures, the use of biological or bio-synthetic mesh is not routinely commissioned.

However, the use of biological or biosynthetic mesh in hernia repair may be undertaken when first line hernia repair surgery with permanent synthetic mesh or conservative treatment has failed or is inappropriate to use synthetic mesh and the use of biological / biosynthetic mesh has been deemed the most clinically appropriate surgical intervention by a complex abdominal wall repair multidisciplinary team.

Eligibility Criteria: Restricted

The use of biological or biosynthetic mesh in standard hernia (inguinal; femoral; umbilical, para-umbilical and incisional) repair is Not Routinely Commissioned.

The use of biological or biosynthetic mesh in hernia repair is only to be undertaken when:

- first line hernia repair surgery with permanent synthetic mesh followed by conservative wound care management has failed

OR

- first line hernia repair surgery with permanent synthetic mesh followed by conservative wound care management is deemed inappropriate

In ALL surgical cases, where the use of biological / biosynthetic mesh is to be considered for use in hernia repair, the patient must be reviewed by a specialist complex abdominal wall repair MDT and the use of biological / biosynthetic mesh must be deemed the most clinically appropriate surgical intervention by a complex abdominal wall repair MDT.

Conservative wound care management is defined as follows:

- Wound care management plan developed for the individual patient by the specialist wound care management team has failed.

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Guidance

1. Barber, S. 2018. BRIEFING PAPER: Surgical mesh implants. Number CBP 8108, 15 January 2018. House of Commons Library. https://www.baus.org.uk/_userfiles/pages/files/Patients/CBP-8108.pdf

2. RCOG. (2019) https://www.rcog.org.uk/globalassets/documents/guidelines/safety-alerts/nhs-mesh-letter-extension-of-pause-on-the-use-of-vaginal-mesh-29-march-2019.pdf

3. F. Köckerling, N. N. Alam, S. A. Antoniou, I. R. Daniels, F. Famiglietti, R. H. Fortelny, M. M. Heiss, F. Kallinowski, I. Kyle-Leinhase, F. Mayer, M. Miserez, A. Montgomery, S. Morales-Conde, F. Muysoms, S. K. Narang, A. Petter-Puchner, W. Reinpold, H. Scheuerlein, M. Smietanski, B. Stechemesser, C. Strey, G. Woeste, N. J. Smart. What is the evidence for the use of biologic or biosynthetic meshes in abdominal wall reconstruction? Hernia. 2018; 22(2): 249–269. Published online 2018 Jan 31. doi: 10.1007/s10029-018-1735-y https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5978919/

4. James F. FitzGerald, Anjali S. Kumar. 2014. Biologic versus Synthetic Mesh Reinforcement: What are the Pros and Cons? Clin Colon Rectal Surg. 2014 Dec; 27(4): 140–148. doi: 10.1055/s-0034-1394155 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4477030/

5. Majumder A[1], Winder JS[2], Wen Y[1], Pauli EM[2], Belyansky I[3], Novitsky YW[4]. 2016. Comparative analysis of biologic versus synthetic mesh outcomes in contaminated hernia repairs. Surgery. 2016 Oct;160(4):828-838. doi: 10.1016/j.surg.2016.04.041. Epub 2016 Jul 21. https://www.ncbi.nlm.nih.gov/pubmed/27452954

6. Carver DA, Kirkpatrick AW, Eberle TL, *et al.* 2018. Performance of biological mesh materials in abdominal wall reconstruction: study protocol for a randomised controlled trial. BMJ Open 2019;9:e024091. doi: 10.1136/bmjopen-2018-024091 . https://bmjopen.bmj.com/content/9/2/e024091

7. C. S. Seefeldt, J. S. Meyer; J. Knievel, A. Rieger, R. Geißen,R. Lefering, M. M. Heiss (2019) BIOLAP: biological versus synthetic mesh in laparo-endoscopic inguinal hernia repair: study protocol for a randomized, multicenter, self-controlled clinical trial. *Trials*2019**20**:55. https://doi.org/10.1186/s13063-018-3122-5https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-018-3122-5

8. Loes Knaapen, Otmar Buyne, Harry van Goor, Nicholas J (2016) Synthetic vs biologic mesh for the repair and prevention of parastomal hernia. *World J Meta-Anal* 2017 December 26; 5(6): 150-166. DOI: 10.13105/wjma.v5.i6.150. https://f6publishing.blob.core.windows.net/66e60003-20b2-4ada-9595-26b5152dc122/WJMA-5-150.pdf

9. David A Carver, Andrew W Kirkpatrick, Tammy L Eberle, Chad G Ball (2019)Performance of biological mesh materials in abdominal wall reconstruction: study protocol for a randomised controlled trial BMJ Open. 2019; 9(2): e024091. Published online 2019 Feb 15. doi: 10.1136/bmjopen-2018-024091

10. Hubert Scheuerlein, Andreas Thiessen, Christine Schug-Pass, Ferdinand Köckerling. (2018)What Do We Know About Component Separation Techniques for Abdominal Wall Hernia Repair? Front Surg. 2018; 5: 24. Published online 2018 Mar 27. doi: 10.3389/fsurg.2018.00024

NHS Birmingham and Solihull CCG
NHS Sandwell and West Birmingham CCG

DRAFT
Policy for use of domiciliary Continuous Positive Airway Pressure (CPAP) Devices.

Document Details:

Version:	DRAFT v2.
Ratified by (name and date of Committee):	Treatment Policy Clinical Development Group
Date issued for Public Engagement:	02.09.2019
Equality & Diversity Impact Assessment:	

The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decisions are considered within the wider constraints of the CCG's legally responsibility to remain fiscally responsible.

Obstructive Sleep Apnoea Hypopnea Syndrome (OSAHS)

Apnoea is defined as a temporary absence or cessation of breathing. Obstructive Sleep Apnoea hypopnea syndrome (OSAHS) is a condition in which a person experiences repeated episodes of apnoea because of a narrowing or closure of the pharyngeal airway during sleep. This is caused by a decrease in the tone of the muscles supporting the airway during sleep. Complete closure (obstruction) stops airflow (apnoea) whereas partial obstruction decreases airflow (hypopnoea). OSAHS results in episodes of brief awakening from sleep to restore normal breathing.

Moderate to severe OSAHS can be diagnosed from patient history and a sleep study using oximetry or other monitoring devices carried out in the person's home. In some cases, further studies that monitor additional physiological variables in a sleep laboratory or at home may be required, especially when alternative diagnoses are being considered. The severity of OSAHS is usually assessed on the basis of both severity of symptoms (particularly the degree of sleepiness) and the sleep study, by using either the apnoea/hypopnoea index (AHI) or the oxygen desaturation index. OSAHS is considered mild when the AHI is 5–14 in a sleep study, moderate when the AHI is 15–30, and severe when the AHI is over 30. In addition to the AHI, the severity of symptoms is also important.

The symptoms of OSAHS include impaired alertness, cognitive impairment, excessive daytime sleepiness, snoring, nocturia, morning headaches and sexual dysfunction. The sleep quality of partners may also be affected. Excessive daytime sleepiness can adversely affect cognitive function, mood and quality of life. OSAHS is associated with high blood pressure, which increases the risk of cardiovascular disease and stroke. OSAHS has also been associated with an increased risk of road traffic accidents.

Major risk factors for developing OSAHS are increasing age, obesity and being male. OSAHS is also associated with certain specific craniofacial characteristics (such as retrognathia), enlarged tonsils and enlarged tongue. Use of alcohol or sedatives can also increase the risk or severity of the condition. OSAHS has been reported to affect up to 4% of middle-aged men and 2% of middle-aged women in the UK. It is estimated that 1% of men in the UK may have severe OSAHS.

The use of Continuous Positive Airway Pressure in OSAHS.

Treatment for OSAHS aims to reduce daytime sleepiness by reducing the number of episodes of apnoea/hypopnoea experienced during sleep. In the clinical management of sleep apnoea, continuous positive airway pressure (CPAP) is the most commonly use intervention for patients with moderate or severe diagnosis of OSAHS.

The potential alternative treatment to CPAP are:

- lifestyle management,
- dental devices
- surgery.

Lifestyle management involves helping people to lose weight, stop smoking and/or decrease alcohol consumption.

Dental devices are designed to keep the upper airway open during sleep. The efficacy of dental devices has been established in clinical trials, but these devices are traditionally viewed as a treatment option only for mild and moderate OSAHS.

Surgery involves resection of the uvula and redundant retrolingual soft tissue. However, there is a lack of evidence of clinical effectiveness, and surgery is not routinely used in clinical practice.

A CPAP device consists of a unit that generates airflow, which is directed to the airway via a mask. Positive pressure is generated by the airflow, which prevents upper airway collapse. For CPAP treatment to be effective the patient must always wear their device when they go to sleep.

Reasons for not adhering to CPAP treatment include poor mask fit, pressure intolerance and, more commonly, upper airway symptoms such as nasal dryness, nasal bleeding and throat irritation. Humidification devices are now commonly used in conjunction with CPAP devices in order to reduce these side effects. Masks should be replaced at least annually, and long-term follow-up of patients is critical to ensure adherence.

There are two types of CPAP devices. Fixed CPAP devices deliver air at constant pressure throughout the night, and the person will continue to receive this pressure until a further titration study is performed to determine whether the set pressure is still appropriate. Auto-titrating CPAP devices continually adjust the pressure delivered throughout the night, with the aim of improving comfort and thus adherence.

Eligibility Criteria: Restricted

1. Continuous positive airway pressure (CPAP) is commissioned as a treatment option for adults with moderate or severe symptomatic obstructive sleep apnoea/hypopnoea syndrome (OSAHS).

   OR

2. CPAP is only recommended as a treatment option for adults with mild OSAHS if:

   a. The OSAHS is causing severe functional impairment, which is impacting on the patient's ability to carry out activities of daily living

AND

   b. lifestyle advice and any other relevant treatment options have been unsuccessful or are considered inappropriate

The diagnosis and treatment of OSAHS, and the monitoring of the response, should always be carried out by a specialist service with appropriately trained medical and support staff.

N.B. The definition of OSAHS following a sleep study is as follows:
Mild OSAHS= Apnoea–Hypopnoea Index (AHI) 5–14.
Moderate OSAHS = AHI is 15–30.
Severe OSAHS = AHI is over 30.

Functional impairment is defined as preventing activities of daily living to be undertaken independently, i.e. sleeping; eating; walking, driving.

Exclusion criteria:

- Inability to remove mask independently (with no waking night carer)
- Cognitive / behavioural limitation affecting ability to comply safely with NIV
- Intolerance of acute NIV
- Multiple co-morbidities limiting utility of NIV

Funding will be provided for the following if the patient meets the above clinical criteria:

- One CPAP machine
- 1-2 lengths of tubing per year
- 1-2 masks per year

In a small proportion of OSA patients, CPAP proves insufficient to control apnoea and it becomes necessary to use bi-level NIV. If a patient has failed treatment with CPAP, but continues to meet the eligibility criteria outlined above, a further funding application will be considered for:

- One Bi-level NIV machine
- 1-2 lengths of tubing per year

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Guidance - OSA

1. NICE. 2008. Continuous positive airway pressure for the treatment of obstructive sleep apnoea/hypopnoea syndrome. Technology appraisal guidance. Published: 26 March 2008. Updated Feb 2014. nice.org.uk/guidance/ta139

2. Hypoglossal nerve stimulation for moderate to severe obstructive sleep apnoea (2017) - https://www.nice.org.uk/guidance/ipg598

3. Soft-palate implants for obstructive sleep apnoea (2007) - https://www.nice.org.uk/guidance/ipg241

4. A meta-analysis of continuous positive airway pressure therapy in prevention of cardiovascular events in patients with obstructive sleep apnoea (2017) - https://academic.oup.com/eurheartj/article-abstract/39/24/2291/4563763?redirectedFrom=fulltext

5. Sleep-disordered Breathing in Heart Failure (2015) - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6159414/

6. The official website of The Epworth Sleepiness Scale (ESS) - http://epworthsleepinessscale.com/about-the-ess/

7. The Epworth Sleepiness Scale: Minimum Clinically Important Difference in Obstructive Sleep Apnea (2018) - https://www.atsjournals.org/doi/abs/10.1164/rccm.201704-0672LE

8. Minimum important difference of the Epworth Sleepiness Scale in obstructive sleep apnoea: estimation from three randomised controlled trials (2018) - https://thorax.bmj.com/content/early/2018/08/11/thoraxjnl-2018-211959

9. Cardiorespiratory interaction with continuous positive airway pressure (2018) - http://jtd.amegroups.com/article/view/18553/14525

10. Continuous positive airway pressure for the treatment of obstructive sleep apnoea/hypopnoea syndrome (2008, reviewed 2012) - https://www.nice.org.uk/guidance/ta139

NHS Birmingham and Solihull CCG
NHS Sandwell and West Birmingham CCG

DRAFT
Policy for use of domiciliary Non-Invasive Ventilation.

Document Details:

Version:	DRAFT v2.
Ratified by (name and date of Committee):	Treatment Policy Clinical Development Group
Date issued for Public Engagement:	02.09.2019
Equality & Diversity Impact Assessment:	

The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decisions are considered within the wider constraints of the CCG's legally responsibility to remain fiscally responsible.

Why is Non-Invasive Ventilation (NIV) used and what is it?

When we breathe in, we take oxygen out of the air to keep us alive - this oxygen is transferred to our blood in our lungs. The body then uses the oxygen and produces a waste gas called carbon dioxide, which we breathe out. The process of this exchange is ventilation.

Some people with severe lung disease, have problems getting enough oxygen into the body, which results in hypoxaemia. If their oxygen level drops below a certain level, it is relatively easy to give extra oxygen for them to breathe, which is called oxygenation. However, in some severe cases of obstructive lung conditions, muscle weakness or neurological impairment, the extra effort of trying to keep the oxygen at a satisfactory level in the blood and to expel carbon dioxide results in the person tiring and leading to hypoventilation and hypercapnia causing respiratory failure.

Respiratory failure is more difficult to deal with. It is a particular problem with diseases that cause obstruction to our airways, such as chronic obstructive pulmonary disease (COPD). In COPD, the airways are narrowed, making it harder to get oxygen into the lungs and carbon dioxide out. Patients who have weak or denervated respiratory muscles in neuromuscular/neurological conditions are also unable to take in a sufficient volume of air to expel carbon dioxide. In all these conditions, a person can develop type 2 respiratory failure which cannot be corrected with oxygenation as the person needs help to ventilate to expel carbon dioxide. Type 2 respiratory failure can lead to high heart rate and cardiac complications.

The aim of using Non-Invasive ventilation (NIV) is not only to obtain satisfactory oxygen levels, but also to expire carbon dioxide. It is often first used at night when the patient is asleep and carbon dioxide levels increase, but as the patient's condition progresses, NIV may be required in the day when the patient has diurnal respiratory failure. It is also important to ease the work of breathing associated with respiratory failure as when a patient with respiratory failure becomes overly tired, this can lead to fatigue, further respiratory compromise and potential respiratory arrest. NIV also aims to take some of the effort out of breathing because the patient's chest muscles don't have to work as hard, so it helps to ease the feelings of breathlessness.

People receiving NIV need to wear a cushioned mask or use a mouthpiece, which is connected to an air pump machine. This mask fits either over the nose alone, or over both the nose and mouth; a strap holds the mask firmly in place, but it can be easily removed, to enable, for example, the patient to eat and drink.

Types of Non-Invasive Ventilation

Noninvasive ventilation (NIV) refers to the administration of ventilatory support without using an invasive artificial airway (endotracheal tube or tracheostomy tube). The use of noninvasive ventilation has markedly increased over the past three decades, and noninvasive ventilation has now become an integral tool in the management of both acute and chronic respiratory failure, in both the home setting and in critical care.

In its simplest terms, noninvasive ventilation differs from invasive ventilation by the interface between the patient and the ventilator. Invasive ventilatory support is provided via either an endotracheal tube or tracheostomy tube. Noninvasive ventilatory support uses a variety of interfaces, and these have continued to evolve with modifications based on patient comfort and efficacy. Many of the interfaces or masks were initially used in patients with obstructive sleep apnoea before they were adapted for use in patients to provide noninvasive ventilatory support.

Nasal masks and orofacial masks were the earliest interfaces, with subsequent development and use of full-face masks, mouthpieces, nasal pillows, and helmets. Hybrid masks and orofacial masks are still the most commonly used interfaces. Orofacial masks are used almost twice as frequently as nasal masks. Both have advantages and disadvantages in the application of noninvasive ventilation.

Noninvasive positive-pressure ventilation

Positive-pressure ventilation delivered through a mask, has become the predominant method of providing noninvasive ventilatory support. Early bedside physiological studies in healthy patients and in patients with respiratory conditions document successful ventilatory support (i.e., reduction in respiratory rate, increase in tidal volume, decrease in dyspnoea) with reduction in diaphragmatic electromyography (EMG), transdiaphragmatic pressures, work of breathing and improvement in oxygenation with a reduction in hypercapnia.

Ventilatory support can be achieved through a variety of interfaces (mouth piece or nasal, face, or helmet mask), using a variety of ventilatory modes (e.g., volume ventilation, pressure support, bilevel positive airway pressure [BiPAP], proportional-assist ventilation [PAV]) with either ventilators dedicated to noninvasive ventilation (NIV) or those capable of providing support through an endotracheal tube or mask. Older models of noninvasive ventilators required oxygen to be bled into the system, but current models incorporate oxygen blenders for precise delivery of the fraction of inspired oxygen (FIO_2).

Current use of Non-invasive Ventilation devices.

Bilevel positive airway pressure (BiPAP) is probably the most common mode of noninvasive positive pressure ventilation and provides for inspiratory positive airway pressure (IPAP) and expiratory positive airway pressure (EPAP). The difference between IPAP and EPAP reflects the amount of pressure support ventilation provided to the patient, and EPAP is synonymous with positive end-expiratory pressure (PEEP). Some noninvasive ventilation is provided using proportional-assist ventilation (PAV), which provides flow and volume assistance with each breath. Clinical trials have not demonstrated a significant difference between PAV and pressure-support ventilation with BiPAP. [5, 6] However, BiPAP is the most commonly available and more frequently used modality for noninvasive ventilation. PAV remains available on many ventilator models, but use is much less common than BiPAP.

National context

National Guidance for the provision of aspects of specialist non-ventilation services to patients exists for some individual patient groups e.g. Motor Neurone Disease (MND), Duchene's Muscular Dystrophy (DMD); and for broader categories of patients e.g. weaning guidance; and around specific technologies e.g. diaphragmatic pacing and tracheostomies. There are some national standards (NICE, 2010; 2016) available and some specialist society guidance (BTS/ICS 2016).

Provision of complex home ventilation services also falls within the NHS Outcomes Framework:
Domain 1 - preventing people from dying prematurely where Improvement Area 1a specifically identifies reducing mortality from respiratory disease,
Domain 2 – enhancing quality of life for patients with long term conditions
Domain 3 – helping patients to recover after an episode of acute illness, where post-acute admission, non-invasive ventilation has been shown to help people recover better in the community and reduce readmission rates.

Guidance supports delivery of care by respiratory specialists working within MDTs. For example, the National Institute for Health and Clinical Excellence (NICE) clinical guideline around the use of NIV in MND states that "multidisciplinary teams (MDT) should coordinate and provide on-going management and treatment for patients with MND, including regular respiratory assessment and provision of non-invasive ventilation. The team should include a neurologist, a respiratory physician, a MND specialist nurse, a respiratory specialist nurse, a specialist respiratory physiotherapist, a respiratory physiologist, a specialist in palliative care and a speech and language therapist". The guidance also outlines the support and training which need to be provided to the patient and their family and carers: "support and assistance to manage non-invasive ventilation which should include training on using non-invasive ventilation and ventilator interfaces, for example emergency procedures, night-time assistance if the patient is unable to use the equipment independently (for example, emergency removal or replacement of interfaces), how to use the equipment with a wheelchair or other mobility aids, if required, what to do if the equipment fails, assistance with secretion management, information on general palliative strategies, an offer of on-going emotional and psychological support for the patient and their family and carers".

Ensuring NIV is delivered by competent respiratory professionals is emphasised in NICE MND guidance and also in the National Patient Safety Agency (NPSA) alert which identified cases where problems with administering NIV were stated as causing at least moderate harm: key issues included shortage of staff skills or staff time to set up and monitor NIV.

Local context

The CCG, based on strong supporting evidence for the clinical effectiveness of the intervention, will commission the use of domiciliary non-invasive ventilation in the following clinical conditions where the patient's individual clinical circumstances meet the relevant clinical eligibility criteria outlined in Sections A & B respectively:

- Chronic Obstructive Pulmonary Disease (Section A)
- Neuro-muscular and Neurological Weakness Patients (Section B)

Please note the provision of treatment for patients with Cystic Fibrosis and patients with Spinal Muscular Atrophy are specialised services commissioned by NHSE.

Guidance

1. Corrado A, Gorini M, Melej R, et al. Iron lung versus mask ventilation in acute exacerbation of COPD: a randomised crossover study. *Intensive Care Med*. 2009 Apr. 35(4):648-55.
2. Parke RL, McGuinness SP. Pressures delivered by nasal high flow oxygen during all phases of the respiratory cycle. *Respir Care*. 2013 Oct. 58 (10):1621-4.
3. Spoletini G, Alotaibi M, Blasi F, Hill NS. Heated Humidified High-Flow Nasal Oxygen in Adults: Mechanisms of Action and Clinical Implications. *Chest*. 2015 Jul. 148 (1):253-61.
4. Ozsancak A, Sidhom S, Liesching TN, Howard W, Hill NS. EVALUATION OF THE TOTAL FACE MASKTM FOR NONINVASIVE VENTILATION TO TREAT ACUTE RESPIRATORY FAILURE. *Chest*. 2011 Feb 17.
5. Wysocki M, Richard JC, Meshaka P. Noninvasive proportional assist ventilation compared with noninvasive pressure support ventilation in hypercapnic acute respiratory failure. *Crit Care Med*. 2002 Feb. 30 (2):323-9.
6. Fernández-Vivas M, Caturla-Such J, González de la Rosa J, Acosta-Escribano J, Alvarez-Sánchez B, Cánovas-Robles J. Noninvasive pressure support versus proportional assist ventilation in acute respiratory failure. *Intensive Care Med*. 2003 Jul. 29 (7):1126-33.
7. Hoo, G. 2018. Noninvasive Ventilation. Medscape. https://emedicine.medscape.com/article/304235-overview#a5
8. British Thoracic Society/Intensive Care Society Acute Hypercapnic Respiratory Failure Guideline Development Group. 2016. BTS/ICS Guidelines for the Ventilatory Management of Acute Hypercapnic Respiratory Failure in Adults. Journal of the British Thoracic Society. http://thorax.bmj.com/site/about/guidelines.xhtml#open
9. National Institute for Health and Clinical Excellence (NICE). Motor neurone disease: assessment and management**.** NICE guideline [NG42] Published date: February 2016 Last updated: July 2019
10. National Institute for Health and Clinical Excellence (NICE). *Chronic Obstructive Pulmonary Disease in Over 16s: Diagnosis and Management [CG101]*. London, England: NICE; 2010. https://www.nice.org.uk/guidance/ng42
11. Murphy, P. Rehal, S. et al. 2017. Effect of Home Noninvasive Ventilation With Oxygen Therapy vs Oxygen Therapy Alone on Hospital Readmission or Death After an Acute COPD Exacerbation: A Randomized Clinical Trial. *JAMA.* 2017;317(21):2177-2186. doi:10.1001/jama.2017.4451. https://jamanetwork.com/journals/jama/issue/317/21

NIV – Section A – Chronic Obstructive Pulmonary Disease (COPD)

Chronic obstructive pulmonary disease (COPD) is the collective name for a group of lung conditions that may cause breathing difficulties.

It includes:

- **emphysema** – damage to the air sacs in the lungs
- **chronic bronchitis** – long-term inflammation of the airways

COPD is a common condition that mainly affects middle-aged or older adults who have a smoking history. The breathing problems tend to get gradually worse over time and can limit the patient's normal activities, although treatment can help keep the condition under control.

Symptoms of COPD

The main symptoms of COPD are:

- increasing breathlessness, particularly when the patient is active
- a persistent chesty cough with phlegm
- frequent chest infections
- persistent wheezing

Without treatment, the symptoms usually get slowly worse. There may also be periods when they get suddenly worse, known as a flare-up or exacerbation.

Causes of COPD

COPD occurs when the lungs become inflamed, damaged and narrowed. The main cause is smoking, although the condition can sometimes affect people who have never smoked.

The likelihood of developing COPD increases the more a patient smokes and the longer the patient has smoked. Some cases of COPD are caused by long-term exposure to harmful fumes, or dust or occur as a result of a rare genetic problem that means the lungs are more vulnerable to damage.

The damage to the lungs caused by COPD is permanent, but treatment can help slow down the progression of the condition.

Treatments include:

- smoking cessation – if a patient is diagnosed with COPD still smokes, stopping smoking is the most important thing a patient can do
- inhalers and medications
- pulmonary rehabilitation – a specialised programme of exercise and education
- surgery or a lung transplant –an option for a very small number of people

Chronic obstructive pulmonary disease (COPD) is characterized by recurrent exacerbations that can cause intermittent periods of severe clinical deterioration requiring hospitalisation and ventilator support. Although treating patients with COPD and acute respiratory failure with non-invasive ventilation improves outcomes, persistent hypercapnia after an exacerbation is associated with excess mortality and early rehospitalization. In 2013, the 28-day COPD readmission rate was around 20%, (Suh et al. 2015).

Eligibility Criteria: Restricted

For patients with COPD the CCG will commission the use of domiciliary non-invasive ventilation in the following clinical circumstances:

The patient has a diagnosis of COPD, identified by post bronchodilator Forced Expiratory Volume (FEV)1 / Forced Vital Capacity (FVC) <0.70

AND

4 weeks post-acute admission the patient has a paCO2 over 7 kPa.

AND

the patient must have ONE of the following:

- A reduction in Quality of life identified by symptoms consistent with Sleep Disordered Breathing Problems (see pg12 for definition)
    - If the patient has reduced quality of life, then overnight oximetry should be undertaken to demonstrate that the patient meets ONE of the following criteria:
        - An apnoea/hypopnoea index >10/hour on respiratory polysomnography or multi-channel respiratory sleep study
        - Four or more episodes of SpO2 <92%
        - Drops in SpO2 of at least 4% per hour of sleep

OR

- A co-morbidity secondary to hypoxemia
    - Pulmonary Hypertension
    - Heart Failure

If the patient has co-morbidities secondary to hypoxemia then the patient should also meet the following criteria:

- Recurrent NIV admissions (2 or more in a 12month period OR difficulty weaning / unable to tolerate weaning)
  AND
- Acute use of NIV has been well tolerated

N.B. Symptoms consistent with Sleep Disordered Breathing Problems are defined as:

- Excessive daytime somnolence (a state of strong desire for sleep, or sleeping for unusually long periods as per the Epworth Sleepiness Score)
- Headache
- Confusion
- Increased shortness of breath
- Resting tremor

Exclusion criteria:

- Inability to remove mask independently (with no waking night carer)
- Cognitive / behavioural limitation affecting ability to comply safely with NIV
- Intolerance of acute NIV
- Multiple co-morbidities limiting utility of NIV

Funding will be provided for the following if the patient with COPD meets the above clinical criteria:

- One NIV machine
- +/- Humidifier as required
- 1-2 lengths of tubing per year
- 1-2 masks per year

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Guidance – Section A: COPD

1. Brochard L, Mancebo J,Wysocki M, et al. Noninvasive ventilation for acute exacerbations of chronic obstructive pulmonary disease. *N Engl J Med*. 1995;333(13):817-822.
2. Bott J, Carroll MP, Conway JH, et al. Randomised controlled trial of nasal ventilation in acute ventilatory failure due to chronic obstructive airways disease. *Lancet*. 1993;341(8860):1555-1557.
3. Connors AF Jr, Dawson NV, Thomas C, et al; SUPPORT Investigators (Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments). Outcomes following acute exacerbation of severe chronic obstructive lung disease. *Am J Respir Crit Care Med*. 1996;154(4 pt 1): 959-967.
4. Murray I, Paterson E, Thain G, Currie GP. Outcomes following non-invasive ventilation for hypercapnic exacerbations of chronic obstructive pulmonary disease. *Thorax*. 2011;66(9):825-826.
5. Chu CM, Chan VL, Lin AW,Wong IW, LeungWS, Lai CK. Readmission rates and life threatening events in COPD survivors treated with non-invasive ventilation for acute hypercapnic respiratory failure. *Thorax*. 2004;59(12):1020-1025.
6. Suh ES, Mandal S, Harding R, et al. Neural respiratory drive predicts clinical deterioration and safe discharge in exacerbations of COPD. *Thorax*. 2015;70(12):1123-1130.
7. Nickol AH, Hart N, Hopkinson NS, et al. Mechanisms of improvement of respiratory failure in patients with COPD treated with NIV. *Int J Chron Obstruct Pulmon Dis*. 2008;3(3):453-462.
8. Meecham Jones DJ, Paul EA, Jones PW, Wedzicha JA. Nasal pressure support ventilation plus oxygen compared with oxygen therapy alone in hypercapnic COPD. *Am J Respir Crit Care Med*. 1995;152(2):538-544.
9. Elliott MW, Mulvey DA,Moxham J, Green M, Branthwaite MA. Domiciliary nocturnal nasal intermittent positive pressure ventilation in COPD: mechanisms underlying changes in arterial blood gas tensions. *Eur Respir J*. 1991;4(9):1044-1052.
10. Lloyd-Owen SJ, Donaldson GC, Ambrosino N, et al. Patterns of home mechanical ventilation use in Europe: results from the Eurovent survey. *Eur Respir J*. 2005;25(6):1025-1031.
11. Clini E, Sturani C, Rossi A, et al; Rehabilitation and Chronic Care Study Group, Italian Association of Hospital Pulmonologists (AIPO). The Italian multicentre study on noninvasive ventilation in chronic obstructive pulmonary disease patients. *Eur Respir J*. 2002;20(3):529-538.
12. McEvoy RD, Pierce RJ, Hillman D, et al; Australian trial of non-invasive Ventilation in Chronic Airflow Limitation (AVCAL) Study Group. Nocturnal non-invasive nasal ventilation in stable hypercapnic COPD: a randomised controlled trial. *Thorax*. 2009;64(7):561-566.
13. WindischW. Noninvasive positive pressure ventilation in COPD. *Breathe*. 2011;8(2):114-123.
14. Köhnlein T, WindischW, Köhler D, et al. Non-invasive positive pressure ventilation for the treatment of severe stable chronic obstructive pulmonary disease: a prospective,

multicentre, randomised, controlled clinical trial. *Lancet Respir Med*. 2014;2(9):698-705.
15. Struik FM, Sprooten RT, Kerstjens HA, et al. Nocturnal non-invasive ventilation in COPD patients with prolonged hypercapnia after ventilatory support for acute respiratory failure: a randomised, controlled, parallel-group study. *Thorax*. 2014;69(9):826-834.
16. Altman DG, Bland JM. Treatment allocation by minimisation. *BMJ*. 2005;330(7495):843.
17. Murphy PB, Brignall K, Moxham J, Polkey MI, Davidson AC, Hart N. High pressure versus high intensity noninvasive ventilation in stable hypercapnic chronic obstructive pulmonary disease: a randomized crossover trial. *Int J Chron Obstruct Pulmon Dis*. 2012;7:811-818.
18. 18. National Institute for Health and Clinical Excellence (NICE). Motor neurone disease: assessment and management**.** NICE guideline [NG42] Published date: February 2016 Last updated: July 2019
19. National Institute for Health and Clinical Excellence (NICE). *Chronic Obstructive Pulmonary Disease in Over 16s: Diagnosis and Management [CG101]*. London, England: NICE; 2010. https://www.nice.org.uk/guidance/ng42
20. Bestall JC, Paul EA, Garrod R, Garnham R, Jones PW,Wedzicha JA. Usefulness of the Medical Research Council (MRC) dyspnoea scale as a measure of disability in patients with chronic obstructive pulmonary disease. *Thorax*. 1999;54(7): 581-586.20. Ghosh D, Rzehak P, ElliottMW, WindischW. Validation of the English Severe Respiratory Insufficiency Questionnaire. *Eur Respir J*. 2012;40 (2):408-415.
21. Jones PW, Quirk FH, Baveystock CM. The St George's Respiratory Questionnaire. *Respir Med*. 1991;85(suppl B):25-31.
22. Jones PW. St George's Respiratory Questionnaire: MCID. *COPD*. 2005;2(1):75-79
23. Kahan BC, Morris TP. Improper analysis of trials randomised using stratified blocks or minimisation. *Stat Med*. 2012;31(4):328-340.
24. Costello R, Deegan P, Fitzpatrick M, McNicholasWT. Reversible hypercapnia in chronic obstructive pulmonary disease: a distinct pattern of respiratory failure with a favourable prognosis. *Am J Med*. 1997;102(3):239-244.
25. Seemungal TA, Donaldson GC, Paul EA, Bestall JC, Jeffries DJ,Wedzicha JA. Effect of exacerbation on quality of life in patients with chronic obstructive pulmonary disease. *Am J Respir Crit Care Med*. 1998;157(5 pt 1):1418-1422.
26. De Backer L, VosW, Dieriks B, et al. The effects of long-term non-invasive ventilation in hypercapnic COPD patients: a randomized controlled pilot study. *Int J Chron Obstruct Pulmon Dis*. 2011;6:615-624.
27. Gates KL, Howell HA, Nair A, et al. Hypercapnia impairs lung neutrophil function and increases mortality in murine pseudomonas pneumonia. *Am J Respir Cell Mol Biol*. 2013;49(5):821-828.
28. Pepperell JC, Ramdassingh-Dow S, Crosthwaite N, et al. Ambulatory blood pressure after therapeutic and subtherapeutic nasal continuous positive airway pressure for obstructive sleep apnoea: a randomised parallel trial. *Lancet*. 2002;359(9302):204-210.
29. Saatci E, Miller DM, Stell IM, Lee KC, Moxham J. Dynamic dead space in face masks used with non-invasive ventilators: a lung model study. *Eur Respir J*. 2004;23(1):129-135.

800

30. Rodway GW,Weaver TE, Mancini C, et al. Evaluation of sham-CPAP as a placebo in CPAP intervention studies. *Sleep*. 2010;33(2):260-266.
31. Djavadkhani Y, Marshall NS, D'Rozario AL, et al. Ethics, consent and blinding: lessons from a placebo/sham controlled CPAP crossover trial. *Thorax*. 2015;70(3):265-269.
32. Schwartz SW, Cimino CR, Anderson WM. CPAP or placebo-effect? *Sleep*. 2012;35(12):1585- 1586.
33. Murphy, P. Rehal, S. et al. 2017. Effect of Home Noninvasive Ventilation With Oxygen Therapy vs Oxygen Therapy Alone on Hospital Readmission or Death After an Acute COPD Exacerbation: A Randomized Clinical Trial. *JAMA.* 2017;317(21):2177-2186. doi:10.1001/jama.2017.4451. https://jamanetwork.com/journals/jama/issue/317/21
34. Murphy PB, Arbane G, Bourke S, Calverley P, Crooks A, Dowson L, Duffy N, Gibson GJ, Hughes SP, Hurst JR, Lewis KR**, Mukherjee R**, Nickol A, Oscroft N, Pepperell J, Rehal S, Smith I, Stradling J, Wedizcha W, Polkey MI, Elliott M, Hart N. Effect of home noninvasive ventilation with oxygen therapy vs. oxygen therapy alone on hospital readmission or death after an acute COPD exacerbation: a randomized clinical trial. *JAMA* 2017; 317(21):2177-2186. **doi:** 10.1001/jama.2017.4451 [PubMed ID: 28528348]
35. 35. Dretzke J, et al. The cost-effectiveness of domiciliary non-invasive ventilation in patients with end-stage chronic obstructive pulmonary disease: a systematic review and economic evaluation. *Health technology assessment.* 10/2015; **19**(81):1-246. **doi**: 10.3310/hta19810. [PubMed ID: 26470875 PMCID: PMC4781210]

NIV – Section B –Patients with Neuro-muscular and Neurological weakness

A number of chronic neuromuscular disorders, for example muscular dystrophy and motor neurone disease lead to progressive respiratory muscle dysfunction, which in turn can lead to respiratory failure and death. Nocturnal and daytime Non-Invasive Ventilation (NIV) is the preferred method of treatment for these disorders[1].

Non-invasive ventilation as a treatment for neuromuscular disease has several benefits. It has been shown to:

- Improves lung mechanics and gas exchange
- Decrease work of breathing
- Improve symptoms of fatigue
- Reduce daytime sleepiness
- Improve survival in Duchenne Muscular Dystrophy (DMD) and Motor Neurone Disease (MND) patients.

Patients with one of the following conditions will be considered for funding when the patient also meets the eligibility criteria outlined below.

- Motor Neurone Disease
- Muscular Dystrophies including Duchenne Muscular Dystrophy
- Spinal cord injury
- Multiple Sclerosis
- Guillain-Barre Syndrome
- Post polio syndrome with respiratory impairment
- Syringomyelia
- Tuberculosis infection with residual respiratory insufficiency
- Other neuromuscular impairment which is known to cause respiratory muscle weakness or upper airway functional impairment which are the commissioning responsibility of the CCG.

Eligibility Criteria: Restricted

For patients diagnosed with a neuromuscular condition as outlined above, the patient must meet the following criteria for funding f non-invasive ventilation to be approved:

Nocturnal Ventilation

The patient must meet ONE of the following criteria:

- Signs (<50% predicted/<1l) or symptoms of hypoventilation
- MIP< 60cmH_2O
- A baseline SpO_2 <95%
- Blood or end tidal pCO2 >45mmHg whilst awake
- Four or more episodes of SpO2 <92%
- Drops in SpO2 of at least 4% per hour of sleep

Daytime Ventilation (in addition to meeting the above criteria the patient must also meet ONE of the following criteria):

- Abnormal deglutition due to dyspnoea, which is relieved by ventilatory assistance
- Inability to speak in full sentences without breathlessness
- Symptoms of hypoventilation with baseline SpO2 <95%
- Blood or end tidal pCO2 >45mmHG whilst awake
- Symptoms of awake dyspnoea are present

Exclusion criteria:

- Inability to remove mask independently (with no waking night carer)
- Cognitive / behavioural limitation affecting ability to comply safely with NIV
- Intolerance of acute NIV
- Multiple co-morbidities limiting utility of NIV

Funding will be provided for the following if the patient meets the above clinical criteria:

Below 14 hours of ventilation required.

- One NIV machine
- +/- Humidifier as required
- 1-2 lengths of tubing per year
- 1-2 masks per year

Above 14 hours / 24-hour period of ventilation required.

- Two NIV machines
- +/- ONE Humidifier as required
- 2-4 lengths of tubing per year
- 2-4 masks per year

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Guidance for NMD

1. Joshua O. Benditt1 and Louis J. Boitano. Pulmonary Issues in Patients with Chronic Neuromuscular Disease. Am J Respir Crit Care Med Vol 187, Iss. 10, pp 1046–1055, May 15, 2013
2. Miller RG, Jackson CE, Kasarskis EJ, England JD, Forshew D, Johnston W, Kalra S, Katz JS, Mitsumoto H, Rosenfeld J, et al.; Quality Standards Subcommittee of the American Academy of Neurology. Practice parameter update: the care of the patient with amyotrophic lateral sclerosis: drug, nutritional, and respiratory therapies (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology 2009;73: 1218–1226.
3. Bourke SC, Gibson GJ. Sleep and breathing in neuromuscular disease. Eur Respir J 2002;19:1194–1201.
4. Birnkrant DJ, Panitch HB, Benditt JO, Boitano LJ, Carter ER, Cwik VA, Finder JD, Iannaccone ST, Jacobson LE, Kohn GL, et al. American College of Chest Physicians consensus statement on the respiratory and related management of patients with Duchenne muscular dystrophy undergoing anesthesia or sedation. Chest 2007; 132:1977–1986.
5. Mehta S, Hill NS. Noninvasive ventilation. Am J Respir Crit Care Med 2001;163:540–577.
6. Eagle M, Baudouin SV, Chandler C, Giddings DR, Bullock R, Bushby K. Survival in Duchenne muscular dystrophy: improvements in life expectancy since 1967 and the impact of home nocturnal ventilation. Neuromuscul Disord 2002;12:926–929.
7. Toussaint M, Steens M, Wasteels G, Soudon P. Diurnal ventilation via mouthpiece: survival in end-stage Duchenne patients. Eur Respir J 2006; 28:549–555
8. Radunovic A, Annane D, Jewitt K, Mustfa N. Mechanical ventilation for amyotrophic lateral sclerosis/motor neuron disease. Cochrane Database Syst Rev 2009;4:CD004427. Update in: Cochrane Database Syst Rev 2013;3:CD004427.
9. Motor neurone disease: assessment and management (2016) - https://www.nice.org.uk/guidance/ng42/chapter/Recommendations#non-invasive-ventilation
10. Outcome of non-invasive positive pressure ventilation in paediatric neuromuscular disease (2004) - https://www.ncbi.nlm.nih.gov/pubmed/14736624
11. Effects of non-invasive ventilation on survival and quality of life in patients with amyotrophic lateral sclerosis: a randomised controlled trial (2006) - https://www.ncbi.nlm.nih.gov/pubmed/16426990

12. Non-invasive ventilation in amyotrophic lateral sclerosis: a 10 year population based study (2012) - https://www.ncbi.nlm.nih.gov/pubmed/22013242
13. Mechanical ventilation for amyotrophic lateral sclerosis/motor neuron disease (2017) - https://www.ncbi.nlm.nih.gov/pubmed/28982219
14. Outcome of non-invasive positive pressure ventilation in paediatric neuromuscular disease (2004) - https://www.ncbi.nlm.nih.gov/pubmed/14736624
15. Polysomnographic evaluation of non-invasive ventilation in children with neuromuscular disease (2014) - https://www.ncbi.nlm.nih.gov/pubmed/24033486
16. Mechanical ventilation for amyotrophic lateral sclerosis/motor neuron disease (2017) - https://www.ncbi.nlm.nih.gov/pubmed/28982219
17. Sleep disordered breathing in motor neurone disease (2018) - http://jtd.amegroups.com/article/view/18178/14526
18. The use of non-invasive ventilation at end of life in patients with motor neurone disease: a qualitative exploration of family carer and health professional experiences (2013) - https://www.ncbi.nlm.nih.gov/pubmed/23462702
19. Sheehan, D. Birnkrant, J. et al. 2018. Respiratory Management of the Patient With Duchenne Muscular Dystrophy Paediatrics, October 2018, vol 142 https://pediatrics.aappublications.org/content/142/Supplement_2/S62
20. Hamada et al. 2011. Indicators for ventilator use in Duchenne muscular dystrophy. Respiratory Medicine. Volume 105, Issue 4, April 2011, Pages 625-629. https://www.sciencedirect.com/science/article/pii/S0954611110005317#tbl1
21. Birnkrant et al 2010. The Respiratory Management of Patients With Duchenne Muscular Dystrophy: A DMD Care Considerations Working Group Specialty Article. Pediatric Pulmonology. DOI 10.1002/ppul.21254. http://muscle.ca/wp-content/uploads/2012/11/Respirarory_Management_DMD_Publication_2010.pdf

Evidence Review

Knee Arthroscopy in Under 35 year olds in comparison to Conservative Management.

Questions to be addressed:

What is the evidence of clinical and cost effectiveness of Knee arthroscopy in under 35 year olds with Acute knee injury compared to conservative treatment?

Reason for review:

NHS Birmingham and Solihull CCG and Sandwell and West Birmingham CCG, requested a rapid evidence review of the clinical and cost effectiveness of knee arthroscopy in patients who are under 35 years and have had an acute meniscal or anterior cruciate ligament (ACL) tear. The review was requested because of the influx of prior approval requests for this cohort of patients following injury for instance while playing sports. This cohort of patients is not currently considered in the national policy for Knee Arthroscopy which covers the cohort of over 35 year olds with degenerative diseases of the knee.

Options for commissioners:

1. Due to insufficient quality of evidence demonstrating that Knee arthroscopy in cases of acute knee injury in under 35 year olds is no more effective than conservative treatment, develop a commissioning policy that clearly stipulates that the intervention is not routinely commissioned, until more evidence is available.
2. Due to the lack of evidence for the clinical effectiveness for Knee arthroscopy in acute knee injury compared to conservative treatment, develop a commissioning policy that considers that the cohort of patients with acute ACL tears should undergo a minimum of 12 weeks of conservative treatment following which, where symptoms persist should be considered for knee arthroscopy in line with restricted criteria.

Summary

The conditions relevant to this scope for acute meniscal tear and acute anterior cruciate ligament (ACL) tear.

Background

The 3 bones that meet in the knee are the:

- thigh bone (femur)
- shin bone (tibia)
- kneecap (patella)

(See Figure 1)

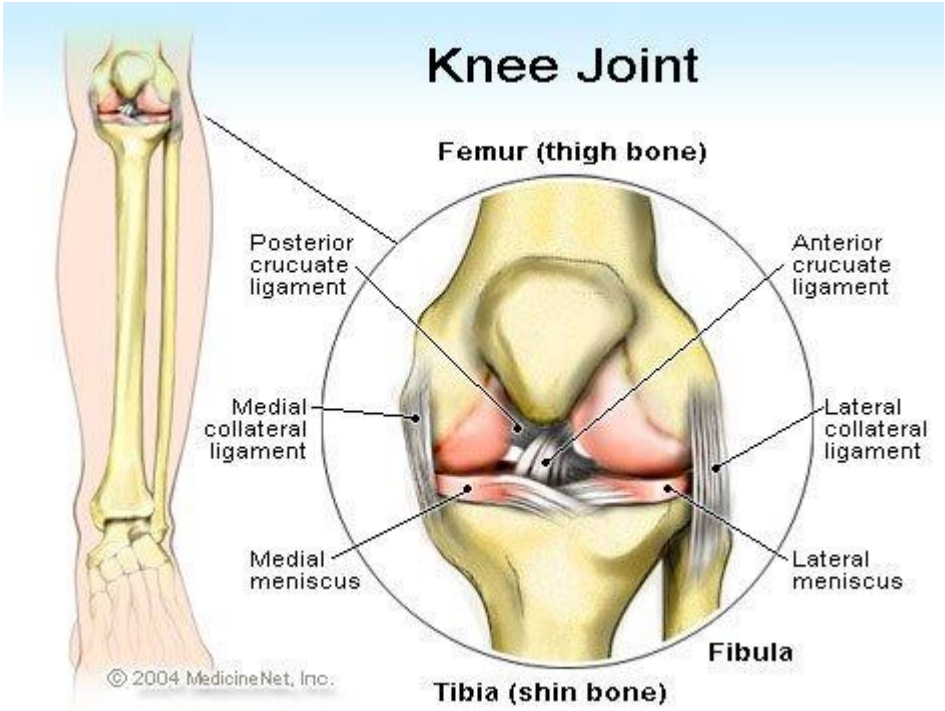


Fig 1: The Knee Joint (Source: https://www.emedicinehealth.com/torn_acl/article_em.htm#what_is_the_anatomy_of_the_knee)

These bones are connected by 4 ligaments – **2 collateral ligaments on the sides of the knee and 2 cruciate ligaments inside the knee.** Ligaments are tough bands of connective tissue. The ligaments in the knee hold the bones together and help keep the knee stable.

The menisci are thick pads of cartilage tissue within the knee which act as shock absorbers to absorb body weight and help improve smooth movement and stability of the knee.

The two main areas within the knee which may be damaged by an acute injury include:

1. Menisci (cartilage)
2. Ligaments

- **Menisci.**

What is the knee meniscus?

The menisci are thick pads of cartilage tissue within the knee which act as shock absorbers to absorb body weight and help improve smooth movement and stability of the knee. Each knee joint contains a medial and lateral meniscus (inner and outer meniscus).

What is a meniscal injury?

There are varying degrees of damage you can do to your menisci. These range from bruising them through to having large tears. Meniscal tears can occur with sport through twisting the knee whilst the foot is still in contact with the ground. In severe injuries, other parts of the knee may also be damaged in addition to a meniscal tear. For example, you may also sprain

or tear a ligament. Meniscal cartilage does not always heal very well once it is torn. This is mainly because the central area of the meniscus does not have a good blood supply. The outer edge of each meniscus has some blood vessels, but the area in the centre has no direct blood supply.

- **Ligaments - Anterior Cruciate Ligament (ACL); Posterior Cruciate Ligament (PCL); Medial Collateral Ligaments (MCL)**

What are the Knee Ligaments?

The Ligaments found within the knee are tough bands of tissue joining the thigh bone to the shin bone at the knee joint. The ligaments run diagonally through the inside of the knee and around each side to give the knee joint stability. They also help to control the back-and-forth movement of the lower leg.

What is an injury of the ligament?

Knee injuries can occur during sports such as skiing, tennis, squash, football and rugby. Ligament injuries, in particular Anterior Cruciate Ligament (ACL) injuries are one of the most common types of knee injuries, accounting for around 40% of all sports injuries.

You can tear your ligaments if your lower leg extends forwards too much. It can also be torn if your knee and lower leg are twisted.

Common causes of a ligament injury include:

• landing incorrectly from a jump

• stopping suddenly

• changing direction suddenly

• having a collision, such as during a football tackle

The intervention

Knee arthroscopy is one of the most commonly performed surgical procedures. In it, a miniature camera is inserted through a small incision (portal). This provides a clear view of the inside of the knee. Your orthopaedic surgeon inserts miniature surgical instruments through other portals to trim or repair the tear.

• Partial meniscectomy: In this procedure, the damaged meniscus tissue is trimmed away.

• Meniscus repair: Some meniscus tears can be repaired by suturing (stitching) the torn pieces together. Whether a tear can be successfully treated with repair depends upon the type of tear, as well as the overall condition of the injured meniscus. Because the meniscus must heal back together, recovery time for a repair is much longer than from a meniscectomy.

• Reconstructive Ligament surgery: A torn ligament cannot be repaired by stitching it back together, but it can be reconstructed by attaching (grafting) new tissue on to it. The ligament, for example the ACL can be reconstructed by removing what remains of the torn ligament and replacing it with a tendon from another area of the leg, such as the hamstring or patellar tendon. The patellar tendon attaches the bottom of the kneecap (patella) to the top of the shinbone (tibia).

Conservative Management

The RICE protocol is effective for most sports-related injuries. RICE stands for:

- **Rest:** Take a break from the activity that caused the injury. Your doctor may recommend that you use crutches to avoid putting weight on your leg.
- **Ice:** Use cold packs for 20 minutes at a time, several times a day. Do not apply ice directly to the skin.
- **Compression:** To prevent additional swelling and blood loss, wear an elastic compression bandage.
- **Elevation:** To reduce swelling, recline when you rest, and put your leg up higher than your heart.

Other conservative management includes Non-steroidal anti-inflammatory medicines which are drugs like aspirin and ibuprofen which assist by reducing pain and swelling.

1 Context

1.1 Introduction

A knee arthroscopy is a type of keyhole surgery used to diagnose and treat problems of the knee joint. Knee arthroscopy is usually done under a general anaesthetic, but a patient may be able to have it under local anaesthetic, depending on the anaesthetist or surgeon's advice.

With this procedure, the surgeon through a small incision that measures only few millimetres, introduces optics in the joints. It is a system of lenses, which usually measure 3-5mm in diameter, and are located in a metal tube in the dimension of a pencil, and allows concentrated artificial light to flow into the joint through this system.

There is a special camera attached to the optics that can monitor the interior part of the joint and transfers the image onto a high resolution monitor. In this way arthroscopy gives the surgeon a view of all joint structures, also of ones that cannot easily be seen in classical surgeries or are even inaccessible to examine. In addition to the incision, which is necessary for introducing the optics, there is normally also needed one or more extra, also only few millimeters small incisions, through which we can insert different operative instruments into the joint. These different sensors, tongs, clips, miniature motorized, and electric instruments are used for the surgical procedure performed in the interior part of the joint.

The procedure can take up to 2 hours depending on the clinical presentation and patients may be able to leave hospital within a few hours. Physiotherapy and pain management will be recommended as required by the surgeon.

1.2 Existing national policies and guidance

- No NICE Guidelines

2 Epidemiology

The knee is injured more frequently than any other joint in the body because it is part of a weight-bearing limb, and second, it does not have the stability procured by the joint congruity of the hip and ankle [10].

Meniscal tears are responsible for 750,000 arthroscopies per year in the US and are the most common soft tissue injury to the knee joint [8]. Traumatic meniscal tears most commonly occur in young, active people during twisting sports such as football and basketball.

3 Findings

3.1 Evidence of effectiveness

3.1.1 A high quality RCT [1] enrolled active adults, 18 to 35 years of age, with an acute anterior cruciate ligament tear occurring not more than four weeks. These were the highlights from the RCT:

- In this high quality randomised controlled trial with minimal loss to follow-up, a strategy of rehabilitation plus early ACL reconstruction did not provide better results at five years than a strategy of initial rehabilitation with the option of having a later ACL reconstruction.
- Results did not differ between knees surgically reconstructed early or late and those treated with rehabilitation alone. These results should encourage clinicians and young active adult patients to consider rehabilitation as a primary treatment option after an acute ACL tear [1].
- This RCT is considered high quality with long follow-up – moderate confidence that evidence reflect true effect in absence of other directly comparable evidence.
- After five years in this randomised controlled trial, it was found that there was no statistically significant differences in pain, symptoms, function in activities of daily living, function in sports and recreation, knee related quality of life, general physical or mental health status, current physical activity level, return to pre-injury activity level, radiographic osteoarthritis, or meniscus surgery between patients assigned to rehabilitation plus early anterior cruciate ligament reconstruction and those assigned to initial rehabilitation with the

option of having a later reconstruction if needed [1]. The results also showed no difference between early or late surgical reconstruction and rehabilitation alone.

- No evidence that arthroscopy improves quality of life compared to conservative treatment at five years. However, the intervention is normally performed on an otherwise young and healthy cohort of patients. Due to short duration nature of the injury, high health utility and low or moderate capacity of intervention to improve the health state the capacity of the intervention to improve quality of life is low. [1]

3.1.2 A systematic review of meniscal tear surgery types was considered including arthroscopic versus open surgery but not surgery versus conservative treatment. [2]

3.1.3 A further systematic review with patients where the mean age was 26.2 was considered. Though the review isn't specifically on patients under 35, the findings of this study suggested that there was no statistically significant difference in outcomes between those patients who underwent earlier compared to delayed ACL reconstruction [3].

3.2 Clinical effectiveness

1 randomised controlled trial (RCT) and 2 systematic reviews were highlighted from the search.

The RCT is high quality and clear, but both of the systematic reviews, although they agree with the RCT findings, do not fully reflect the evidence selection criteria (PICO – Population, Intervention, Comparator, Outcome) used. This means that overall there is moderate confidence that the evidence reflects the true effect of the defined intervention.

RANDOMISED CONTROLLED TRIAL

1. **Treatment for acute anterior cruciate ligament tear: five-year outcome of randomised trial [1]:**

ABSTRACT

Objective: To compare, in young active adults with an acute anterior cruciate ligament (ACL) tear, the mid-term (five year) patient reported and radiographic outcomes between those treated with rehabilitation plus early ACL reconstruction and those treated with rehabilitation and optional delayed ACL reconstruction.

Design Extended follow-up of prospective randomised controlled trial.

Setting Orthopaedic departments at two hospitals in Sweden.

Participants 121 young, active adults (mean age 26 years) with acute ACL injury to a previously uninjured knee. One patient was lost to five-year follow-up.

Intervention: All patients received similar structured rehabilitation. In addition to rehabilitation, 62 patients were assigned to early ACL reconstruction and 59 were assigned to the option of having a delayed ACL reconstruction if needed.

Main outcome measure: The main outcome was the change from baseline to five years in the mean value of four of the five subscales of the knee injury and osteoarthritis outcome score (KOOS4). Other outcomes included the absolute KOOS4 score, all five KOOS subscale scores, SF-36, Tegner activity scale, meniscal surgery, and radiographic osteoarthritis at five years.

Results: Thirty (51%) patients assigned to optional delayed ACL reconstruction had delayed ACL reconstruction (seven between two and five years). The mean change in KOOS4 score from baseline to five years was 42.9 points for those assigned to rehabilitation plus early ACL reconstruction and 44.9 for those assigned to rehabilitation plus optional delayed reconstruction (between group difference 2.0 points, 95% confidence interval −8.5 to 4.5; P=0.54 after adjustment for baseline score). At five years, no significant between group differences were seen in KOOS4 (P=0.45), any of the KOOS subscales (P≥0.12), SF-36 (P≥0.34), Tegner activity scale (P=0.74), or incident radiographic osteoarthritis of the index knee (P=0.17). No between group differences were seen in the number of knees having meniscus surgery (P=0.48) or in a time to event analysis of the proportion of meniscuses operated on (P=0.77). The results were similar when analysed by treatment actually received.

Conclusion: In this first high quality randomised controlled trial with minimal loss to follow-up, a strategy of rehabilitation plus early ACL reconstruction did not provide better results at five years than a strategy of initial rehabilitation with the option of having a later ACL reconstruction. Results did not differ between knees surgically reconstructed early or late and those treated with rehabilitation alone. These results should encourage clinicians and young active adult patients to consider rehabilitation as a primary treatment option after an acute ACL tear.

SYSTEMATIC REVIEWS:

1. **Surgical interventions for meniscal tears: a closer look at the evidence [2].**

ABSTRACT:

The aim of the present study was to compare the outcomes of various surgical treatments for meniscal injuries including (1) total and partial meniscectomy; (2) meniscectomy and meniscal repair; (3) meniscectomy and meniscal transplantation; (4) open and arthroscopic meniscectomy and (5) various different repair techniques. The Bone, Joint and Muscle Trauma Group Register, Cochrane Database, MEDLINE, EMBASE and CINAHL were searched for all (quasi) randomized controlled clinical trials comparing various surgical techniques for

meniscal injuries. Primary outcomes of interest included patient-reported outcomes scores, return to pre-injury activity level, level of sports participation and persistence of pain using the visual analogue score. Where possible, data were pooled and a meta-analysis was performed. A total of nine studies were included, involving a combined 904 subjects, 330 patients underwent a meniscal repair, 402 meniscectomy and 160 a collagen meniscal implant. The only surgical treatments that were compared in homogeneous fashion across more than one study were the arrow and inside-out technique, which showed no difference for re-tear or complication rate. Strong evidence-based recommendations regarding the other surgical treatments that were compared could not be made.This meta-analysis illustrates the lack of level I evidence to guide the surgical management of meniscal tears.Level I meta-analysis.

Introduction: The aim of the present study was to compare the outcomes of various surgical treatments for meniscal injuries including (1) total and partial meniscectomy; (2) meniscectomy and meniscal repair; (3) meniscectomy and meniscal transplantation; (4) open and arthroscopic meniscectomy and (5) various different repair techniques.

Materials and methods: The Bone, Joint and Muscle Trauma Group Register, Cochrane Database, MEDLINE, EMBASE and CINAHL were searched for all (quasi) randomized controlled clinical trials comparing various surgical techniques for meniscal injuries. Primary outcomes of interest included patient-reported outcomes scores, return to pre-injury activity level, level of sports participation and persistence of pain using the visual analogue score. Where possible, data were pooled and a meta-analysis was performed.

Results: A total of nine studies were included, involving a combined 904 subjects, 330 patients underwent a meniscal repair, 402 meniscectomy and 160 a collagen meniscal implant. The only surgical treatments that were compared in homogeneous fashion across more than one study were the arrow and inside-out technique, which showed no difference for re-tear or complication rate. Strong evidence-based recommendations regarding the other surgical treatments that were compared could not be made.

Conclusions: This meta-analysis illustrates the lack of level I evidence to guide the surgical management of meniscal tears.

Level of evidence: Level I meta-analysis.

2. **Early versus delayed surgery for anterior cruciate ligament reconstruction: a systematic review and meta-analysis [3].**

ABSTRACT:

There is no consensus in the literature regarding the optimal timing of surgical reconstruction of the ruptured anterior cruciate ligament (ACL). Previous authors have suggested that early reconstruction may facilitate an early return to work or sport but may increase the incidence

of post-operative complications such as arthrofibrosis. This study systematically reviewed the literature to determine whether ACL reconstruction should be performed acutely following rupture. Medline, CINAHL, AMED, EMBASE databases and grey literature were reviewed with a meta-analysis of pooled mean differences where appropriate. Six papers including 370 ACL reconstructions were included. Early ACL reconstructions were considered as those undertaken within a mean of 3 weeks post-injury; delayed ACL reconstructions were those undertaken a minimum of 6 weeks post-injury. We found there was no difference in clinical outcome between patients who underwent early compared to delayed ACL reconstruction. However, this conclusion is based on the current literature which has substantial methodological limitations.

3.3 Cost effectiveness

No studies were found to demonstrate the cost effectiveness of Knee arthroscopy in acute indications in under 35s.

3.4 Magnitude of Health Improvement Benefit

There was no increased risk of osteoarthritis or meniscal surgery if the ACL injury was treated with physiotherapy alone compared with if it was treated with surgery. Neither was there any difference in patients' experiences of function, activity level, quality of life, pain, symptoms or general health.

Measures included Knee injury and osteoarthritis outcome score (KOOS), the Medical Outcomes Study 36-item short-form health survey (SF-36), and the Tegner activity scale. In the full analysis set, the mean change in KOOS4 score from baseline to five years was 42.9 points for patients assigned to rehabilitation plus early anterior cruciate ligament reconstruction and 44.9 points for those assigned to rehabilitation plus optional delayed reconstruction (between group difference 2.0 points, 95% confidence interval −8.5 to 4.5; P=0.54 after adjustment for the baseline score). No statistically significant differences were found in KOOS4, any of the five individual subscales of KOOS, SF-36, or Tegner activity scale between the two treatment strategies at five years or in the change between two and five years. Knee stability at rest at five years was statistically significantly better in knees assigned to early anterior cruciate ligament reconstruction [1].

There is a small indication in favour of surgical intervention for multi-ligament injuries [1].

3.5 Safety

- Mild chondral injury often occurs at the time of ACL tearing, as the femur and tibia bang against each other [5].
- Increasing age, height, weight, and BMI may also increase the risk for meniscal and articular cartilage injury [6]. Over time, recurrent instability episodes may cause further cartilage damage. Although no method yet exists for fully restoring normal

articular cartilage, techniques can be combined with ACL reconstruction to address full-thickness chondral defects.

- Bone bruising may accompany ACL tears and is thought to set in motion a biochemical cascade, which, even in reconstructed knees, may lead to post-traumatic arthrosis [7].
- Risks of the surgery include infection, DVT/venous thrombo-embolism, neurovascular injury, loss of motion, patellofemoral pain, harvest site pain, patellar fracture, tendon rupture, and pain from hardware [8].
- More serious problems are much less common, occurring in less than 1 in 100 cases [9]. They include:
    - •a blood clot that develops in one of the limbs – known as deep vein thrombosis (DVT), it can cause pain and swelling in the affected limb
    - •infection inside the joint – known as septic arthritis, it can cause fever, pain and swelling in the joint
    - •bleeding inside the joint – which often causes severe pain and swelling
    - •accidental damage to the nerves near the joint – which can lead to temporary or permanent numbness and some loss of sensation

3.6 Equity issues

The prevalence of knee pain (lasting for more than 1 week in the past month) was 19% in a community-based survey of people 16 years of age or older registered with one of three general practices near Manchester [4]. Responses were received from 4515 people (78.5%).

The prevalence of knee pain increased with age in both sexes. The age-standardized prevalence of knee pain was equal for men and women, but prevalence was higher in older women than in older men. In people 75 years of age or older, the prevalence in women was 36% and in men was 27%. The prevalence of knee pain with disability was 6%, and the prevalence of moderate or severe knee pain was 12%. It was estimated (from a survey of a subset of initial responders) that 13% of people had consulted their GP for knee pain.

Limited information available particularly under the age of 35. However, no obvious inequalities have been identified in younger age group.

4. Activity and finance

At all levels, injury is a constant threat, and, of all injuries, those of the knee fulfil the athlete's greatest fear of spending a long time out of action. This is confirmed by a study from Sheffield, which showed the knee to have been the most commonly injured joint and soccer and rugby to have the highest risks [11].

Not only may a knee injury require surgery followed by months of rehabilitation, but permanent disability from both sport and work may be the outcome. Indeed, a large study from Scandinavia found that the most common cause of permanent disability following a sports injury was injury to the knee.

There is little work on the pattern of knee injuries in the United Kingdom [11], although a multicenter study is currently in progress. The work that has been carried out abroad, however, has produced some interesting information. It is not widely appreciated that ligament damage to the knee is more common than any other type of knee injury pathology.

Many medical students, general practitioners, and paramedics may be familiar with the story of a weight bearing, twisting injury producing a meniscal tear; however, there is generally a profound ignorance about the history and signs of the more common (and potentially more devastating) ligament injuries. The "miscellaneous injuries" category takes up a quarter of the total, and this is made up of a selection of pathologies such as contusions of the knee and traumatic bursitis. Projecting from American figures, a casualty department covering a population of 400 000 should expect to see about 500 significant knee injuries a year [11].

5.Summary of findings

- Absence of systematic review evidence which fits the specified PICO.
- Conservative management – such as rehabilitation shows as good outcomes if not better than arthroscopy, however there may be an indication in multiligament injuries.
- With reference to specific disease related to the knee, the review found no evidence that arthroscopy prevents further conditions such as osteoarthritis
- Not much evidence was available to form conclusive recommendations for knee arthroscopy following acute meniscal tear.
- No definite length of period for conservative management was evident in the review undertaken.

6.Search Strategy

The following databases are routinely searched: NICE Clinical Guidance and full website search; NHS Evidence and NICE CKS; SIGN; Cochrane; York; and the relevant Royal College and any other relevant bespoke sites. A Medline search was also undertaken and a general google search for key terms carried out.

The search identified publications with relating to acute knee injuries and the abstracts and titles were then sifted to select those that met the criteria in the PICO below. Where there was ambiguity in the PICO criteria, the reviewer also referred to the wording of the research question for this evidence review, which specified that the intervention of interest was knee arthroscopy.

6.1 PICO parameters:

Population: Under 35 years, Acute Meniscal Tear or Anterior Cruciate Ligament Tear
Intervention: Knee arthroscopy with repair of tear
Comparator / Control: Conservative management; physiotherapy, analgesia, steroid injections
Outcome: Improved knee function; pain; mobility

7 References

[1] Treatment for acute anterior cruciate ligament tear: five-year outcome of randomised trial. BMJ 2013; 346 doi: https://doi.org/10.1136/bmj.f232

[2] Mutsaerts ELAR, van Eck CF, van de Graaf VA, Doornberg JN, van den Bekerom MPJ. Surgical interventions for meniscal tears: a closer look at the evidence. Arch Orthop Trauma Surg 2016;136:361-37

[3] Smith TO, Davies L, Hing CB (2010) Early versus delayed surgery for anterior cruciate ligament reconstruction: a systematic review and meta-analysis. Knee Surg Sports Traumatol Arthrosc 18:304–311

[4] Webb,R., Brammah,T., Lunt,M., et al. (2004) Opportunities for prevention of 'clinically significant' knee pain: results from a population-based cross sectional survey. Journal of Public Health (Oxford). 26(3), 277-284

[5] Brophy RH, Zeltser D, Wright RW, et al. Anterior cruciate ligament reconstruction and concomitant articular cartilage injury: incidence and treatment. Arthroscopy. 2010;26:112-120. http://www.ncbi.nlm.nih.gov/pubmed/20117635?tool=bestpractice.com

[6] Bowers AL, Spindler KP, McCarty EC, et al. Height, weight, and BMI predict intra-articular injuries observed during ACL reconstruction: evaluation of 456 cases from a prospective ACL database. Clin J Sport Med. 2005;15:9-13. http://www.ncbi.nlm.nih.gov/pubmed/15654185?tool=bestpractice.com

[7] Mandalia V, Fogg AJ, Chari R, et al. Bone bruising of the knee. Clin Radiol. 2005;60:627-636. https://bestpractice.bmj.com/topics/en-gb/589/complications#referencePop109

[8] Rodkey WG, Steadman JR, Li ST. A clinical study of collagen meniscus implants to restore the injured meniscus. Clin Orthop Relat Res. 1999:S281-92. http://www.ncbi.nlm.nih.gov/pubmed/10546653?tool=bestpractice.com

[9] NHS website: https://www.nhs.uk/conditions/arthroscopy/

[10] Kruseman N, Geesink RGT, van der Linden AJ *et al*. Acute knee injuries: diagnostic & treatment management proposals. http://arnos.unimasas.nl/show.cgi?fig1?46875

[11] Steve Bollen: Injuries of the sporting knee - Epidemiology of knee injuries: diagnosis and triage https://bjsm.bmj.com/content/34/3/227.2

Evidence Review

Non-Cosmetic Body Contouring Surgery following massive sustained weight loss.

Questions to be addressed:

What is the evidence of clinical and cost effectiveness of clinically indicated Body Contouring Surgery (BCS), following massive sustained weight loss in adults with a starting BMI of above 40kg/m2; or above 35kg/m2 with co-morbidities AND current BMI of less than 30.0kg/m2 AND weight stability of 12 months who are experiencing significant functional disturbance, in comparison to no surgical treatment?

Reason for review:

NHS Birmingham and Solihull CCG and Sandwell and West Birmingham CCG, requested a rapid evidence review of the clinical and cost effectiveness of clinically indicated Body contouring surgery. The review was requested to support policy development and to define the procedures to be considered within the policy for body contouring.

Options for commissioners:

1. Due to consistent and strong volume of evidence demonstrating that body contouring surgery (BCS) is clinically effective, develop a commissioning policy that details a restricted criterion and defines the exclusions to the policy.
2. Due to the strong evidence identified in the "Body Q" Systematic review develop a policy with criteria that defines the overarching themes: 1) Appearance; 2) Health related Quality of life; and 3) Patient experience.

Summary

Body contouring is a procedure that alters the shape of the human body. It includes procedures that eliminate or reduce excess skin and fat that remains after losing a significant amount of weight, in a variety of places including the torso, upper arms, chest, and thighs. Body contouring may also be requested by women who have excess abdominal skin following pregnancy or to treat excessive 'stretch marks'.

Massive weight loss is defined as loss of 50% or more of body weight [1].

Background

Individuals are increasingly suffering with excess skin after being encouraged to lose weight either through diet and exercise (often supported by community weight loss programs) or as a result of bariatric surgery undertaken either privately or on the NHS. Rapid, marked weight loss often results in large areas of loose skin. Patients have increasing expectations that

removal of this excess skin will be funded by the NHS especially if the bariatric surgery was NHS funded.

These surgical procedures can involve removing fat and excess loose skin and tightening the abdominal muscles. The aim is to remove excess skin that can't be removed through exercise - It is not a quick fix for losing weight.

The interventions

Body contouring covers a variety of requests to remove redundant skin usually following major weight loss, therefore NHS Birmingham and Solihull CCG and Sandwell and West Birmingham CCG have brought the following body contouring procedures together into one policy:

- **Surgery to improve the appearance of the abdomen where clinically indicated:**

There are a number of procedures available, for example, in abdominoplasty it may involve removing excess skin and fat and tightening the abdominal muscles. Panniculectomy / apronectomy is a limited abdominoplasty procedure and is performed to remove the excess skin only. Documented clinical evidence of severe impairment associated to the excess skin and a definition of how far down the excess skin hangs (panniculus) is required.

- **Full abdominoplasty:**

For patients who have significant skin laxity, excess fat and separation of the muscles, a classic tummy tuck is the most common procedure. Performed under general anaesthetic, this operation can require patients to be in hospital for two or three days.

During the operation, an incision is made from hip to hip and around the umbilicus. The excess skin and fat is excised from the umbilicus to just above the pubic hair. The muscles above and below the umbilicus are tightened. The skin is then sewn up to give a circular scar around the umbilicus and a long scar across the lower abdomen. Although this operation leaves a large scar, it does provide the greatest improvement in abdominal shape.

Patients who are thinking about becoming pregnant should not undergo this procedure, and should wait until they are sure they are not having any more children. All the skin and fat below the umbilicus can be removed in a standard abdominoplasty. This results in a scar across the lower abdomen and a scar around the umbilicus.

- **Mini abdominoplasty**

For patients with only a small amount of excess skin, a lesser abdominoplasty might be appropriate. A general anaesthetic is still needed.

During the operating, a wedge of skin and fat is excised from the lower tummy leaving a horizontal scar above the pubic hair. Sometimes the muscles will also be tightened. No scar is

left around the umbilicus, which may be stretched slightly to become a different shape. A mini abdominoplasty will give a smaller effect than a full abdominoplasty.

- **Extended abdominoplasty**

Surplus skin and fat of the loins and back are removed at the same time as the abdomen.

- **Endoscopic abdominoplasty**

Tightens the muscles of the abdominal wall. Skin is not removed but liposuction can be carried out at the same time.

- **Apronectomy (Panniculectomy)**

An Apronectomy is a modified mini-abdominoplasty, mainly for patients who have a large excess of skin and fat hanging down over the pubic area and only the surplus skin and fat is removed. A modification to an abdominoplasty might also be necessary when the patient has problems with scars from previous operations.

A panniculus is excess adipose tissue hanging downward from the abdomen and resembles an "apron of skin" overlying the front of the pelvic girdle. A large panniculus can interfere with normal activities such as walking, and lead to serious medical problems. The heavy overhanging tissue can cause chronic skin inflammation under the flap, and subsequently, skin breakdown and infection.

The panniculus hanging below the symphysis pubis when the individual is standing normally can cause significant functional impairment and other complications such as intertrigo.

Historically, panniculectomy/apronectomy has been considered primarily a cosmetic procedure; however, for some patients, surgery is the only option if a large panniculus causes debilitating symptoms that do not respond to conventional medical therapy.

- **Arm reduction and lift (Brachioplasty):**

Brachioplasty, or upper arm reduction or arm lift is a surgical procedure which removes and tightens loose skin and excess fat in the upper arm. It is usually performed under a general anaesthetic. The surgeon makes a long incision between the elbow and axilla. Segments of skin and fat are removed and the remaining skin and tissue lifted resulting in a tight, smooth look.

- **Buttock and/or Thigh lift (Thighplasty):**

Thighplasty is aesthetic reshaping surgery with the removal of excess skin and fat. Buttock or thigh lift surgery is performed to lift the excess skin to firm and tighten the skin around the buttocks and/or thighs. Liposuction may also be performed during this procedure. Sometimes a buttock lift is combined with this procedure.

- **Liposuction / Liposculpture / Suction Assisted Lipectomy**

Liposuction is also known as liposculpture or suction assisted lipectomy. It is a technique most commonly performed to remove unwanted fat deposits. Liposuction can be performed on other areas of the body, including the neck, arms, tummy, loins, thighs, inner side of the knees and the ankles.

Funding for procedures to remove excess skin from other areas of the body other than the abdomen has been deemed cosmetic with much greater risks than non-surgical procedures.

Other procedures that are not included within the Body Contouring Surgery policy are:

- Mastopexy/ Breast Lift, surgery for gynaecomastia other breast surgery procedures
- Liposuction for Lipoedema and Lymphoedema

Current Management

Weight loss surgery or bariatric surgery is commissioned nationally across England. In adults with a BMI of more than 40kg/m2 (or more than 35kg/m2 with co-morbidities) in whom surgical intervention is considered appropriate, bariatric surgery is recommended as a treatment option in the National Institute for Health and Clinical Excellence (NICE) guidelines [1].

Where body contouring interventions are required solely to improve the appearance, these are regarded as cosmetic surgery and so not normally available on the NHS. There are however, some clinical circumstances in which there is documented evidence of clinical benefit to be attained by undertaking such a procedure.

1 Context

1.1 Introduction

The resultant redundant skin presents new quality of life concerns in a range of areas such as mobility, decreased activity, body image dissatisfaction and depression. The excess skin causing physical discomfort, psychosocial problems, lost work days/productivity and concern about quality of life in general has led to an increasing uptake of body contouring surgery, to manage the complex problems that span multiple parts of the body after massive weight loss.

Research demonstrates significant improvements in patients' physical function, emotional wellbeing, stability in mood, body image satisfaction, identity shifts and identity transformation, sexual vitality, greater wellbeing and quality of life once they have undergone body contouring surgery following massive weight loss [1].

Body contouring surgery has been shown to have positive benefits, especially in relation to improved wellbeing, function and Quality of Life (QoL). However, adjustment to changing

body image following body contouring is both challenging and empowering and seems to be a transitional process [2].

The commissioning guide provides the overview of the types of health conditions that can be prevented if body contouring procedures are carried out after massive weight loss and/or post-bariatric surgery [1]. The purpose of the evidence review is to draw out the benefits of clinically indicated body contouring.

1.2 Existing national policies and guidance

- NICE have not currently issued guidance on this treatment.
- The Royal College of Surgeons in association with the British Association of Plastic Reconstructive and Aesthetic Surgeons (BAPRAS) have recently produced guidance on body contouring using a NICE accredited process. Those guidelines have been taken into account in the review of the evidence to support policy development.

2 Epidemiology

In 2010, 65.1% of all adults aged 16 years and over were overweight or obese. Morbid obesity rates (body mass index (BMI) ≥40kg/m2) increased from 1.2% in 1995 to 2.7% in 2003, and fluctuated between 2.2% and 2.7% between 2008 and 2010 [1].

3 Findings

3.1 Evidence of effectiveness

- The UK Commissioning Guide [1] highlights an expert interpretation of various papers to inform NICE and clinical commissioners in the UK health care sector. All results highlighted of the search strategy are also utilised within the commissioning guide.
- The commissioning guide [1] is a strong example of evidence of Body Contouring in the UK Health Sector.

3.1.1 Clinical effectiveness

3 systematic reviews, 1 economic systematic review and 4 clinical trials & guidance were highlighted from the search that directly informed 'Body Contouring' in reference to the effectiveness measurable by physical, physiological, and/or qualitative patient reported outcomes:

SYSTEMATIC REVIEWS:

1. **Measuring Quality of Life and Patient Satisfaction After Body Contouring [2]:**

ABSTRACT

Evidence-Based Background: In both cosmetic and post bariatric body contouring populations, the primary determinants of success are patient satisfaction and quality of life

(QOL). These patient-reported outcomes (PRO) are ideally measured with specially-designed, procedure- or condition-specific questionnaires.

Objective: The authors identify and appraise all patient-reported outcome (PRO) measures (questionnaires) developed for patients undergoing body contouring surgery.

Methods: MEDLINE, EMBASE, PsychINFO, Ebase, CINAHL, HAPI, Science Citation Index/Social Sciences Citation Index, Ovid Evidence Based Medicine databases were searched from the inception of each database through August 2010. Articles included in the study described the development and/or psychometric evaluation of a PRO measure developed for body contouring patients. Each measure was then appraised for adherence to internationally-recommended guidelines for item generation, item reduction, and psychometric evaluation.

Results: The following five PRO questionnaires were identified by our search: one liposuction (the Freiburg Questionnaire on Aesthetic Dermatology and Cosmetic Surgery, FQAD), one general plastic surgery (Derriford Appearance Scale, DAS-59/24), and three breast reduction measures (the Breast Reduction Assessed Severity Scale Questionnaire, BRASSQ; Breast Related Symptoms questionnaire, BRS; and the BREAST-Q reduction module. Detailed examination of these measures revealed that the FQAD, DAS-59, and BRS are limited by both their content range and psychometric properties. The BRASSQ and BREAST-Q both have strong psychometric properties, and the BREAST-Q is unique in its inclusion of items covering specific postoperative issues such as scarring.

Conclusions: While instruments are available for measuring outcomes in breast reduction patients, reliable, valid, and responsive PRO measures are lacking for the majority of body contouring procedures. To demonstrate the unique outcomes of body contouring surgery, future research to rigorously develop and validate new PRO measures in this population is necessary.

2. **Recommendations on the most suitable quality-of-life measurement instruments for bariatric and body contouring surgery [3]:**

ABSTRACT

Objective: The objective of this study is to systematically assess the quality of existing patient-reported outcome measures developed and/or validated for Quality of Life measurement in bariatric surgery (BS) and body contouring surgery (BCS).

Methods: We conducted a systematic literature search in PubMed, EMBASE, PsycINFO, CINAHL, Cochrane Database Systematic Reviews and CENTRAL identifying studies on measurement properties of BS and BCS Quality of Life instruments. For all eligible studies, we evaluated the methodological quality of the studies by using the COnsensus-based Standards for the selection of health Measurement INstruments checklist and the quality of the

measurement instruments by applying quality criteria. Four degrees of recommendation were assigned to validated instruments (A-D).

Results: Out of 4,354 articles, a total of 26 articles describing 24 instruments were included. No instrument met all requirements (category A). Seven instruments have the potential to be recommended depending on further validation studies (category B). Of these seven, the BODY-Q has the strongest evidence for content validity in BS and BCS. Two instruments had poor quality in at least one required quality criterion (category C). Fifteen instruments were minimally validated (category D).

Conclusion: The BODY-Q, developed for BS and BCS, possessed the strongest evidence for quality of measurement properties and has the potential to be recommended in future clinical trials.

3. **Quality of life among adults following bariatric and body contouring surgery: a systematic review [4]:**

ABSTRACT

Background: Weight loss following bariatric surgery is associated with significant improvements in obesity-related comorbidities, body satisfaction and psychosocial outcomes, at least in the short term. However, in the context of extreme weight loss, body image and appearance may worsen again because the “excess” or “loose” skin can lead to both functional and profound dissatisfaction with appearance. These concerns have led to an increasing uptake of post-bariatric surgery, “body-contouring” procedures but the implications for quality of life (QoL) have not been thoroughly considered.

Objective/purpose: The objective was to identify the best available evidence regarding the QoL outcomes for adults following bariatric and body contouring surgery.

Inclusion criteria - Types of participants: The review considered studies involving people aged 18 years and beyond who underwent bariatric surgery and body contouring surgery.

Types of interventions: The review considered studies that evaluated bariatric surgery as well as body contouring surgery.

Types of studies: The review considered both experimental and epidemiological study designs.

Outcomes: The primary outcomes were QoL as measured by validated tools at less than two years, two to five years and more than five years following body contouring surgery. The secondary outcomes were adverse events, unsatisfactory aesthetic appearance and weight gain.

Search strategy: Six databases were searched, including Cochrane Central, MEDLINE, Embase, Web of Science, PsycINFO and CINAHL. Studies published from 1954 to 2014 were considered.

Additional searches for unpublished studies were undertaken in BIOSIS citation index, Register of Current Controlled Trials and Global Health Observatory.

Methodological quality: The methodological quality of eligible studies was assessed independently by two reviewers using the Joanna Briggs Institute quality assessment tool.

Data extraction: Data extraction from the included studies was undertaken and summarized independently by two reviewers using the standardized Joanna Briggs Institute data extraction tool.

Data synthesis: Studies were too heterogeneous and could not be pooled in statistical meta-analysis. Therefore, the data results are presented as a narrative summary in relation to the outcomes of interest.

Results: Nine quantitative studies (four comparable cohort studies, including two group design and two four-group designs and five descriptive or case-series studies) were included in the review. The included studies reported significant clinical improvements in appearance, wellbeing and QoL. These included primary outcomes pointing to body image satisfaction, improved self-esteem and confidence, improved physical function/pain and improved social function. The secondary outcomes were related to adverse events in the early postoperative period and reported wound healing problems, including seromas, partial necrosis, dehiscence, hematoma and anaemia because of blood loss. Also, some data sets shed light on appearance-related distress and body dysphoria post-surgery associated with visible scars and contour deformities.

Conclusion: Body contouring surgery has been shown to have positive benefits, especially in relation to improved wellbeing, function and QoL. However, adjustment to changing body image following body contouring is both challenging and empowering and seems to be a transitional process.

ECONOMIC SYSTEMATIC REVIEWS:

1. **Diverse approaches to the health economic evaluation of bariatric surgery: a comprehensive systematic review [5]:**

ABSTRACT

Background: Health economic evaluations inform healthcare resource allocation decisions for treatment options for obesity including bariatric/metabolic surgery. As an important advance on existing systematic reviews, we aimed to capture, summarize and synthesize a diverse range of economic evaluations on bariatric surgery.

Methods: Studies were identified by electronic screening of all major biomedical/economic databases. Studies included if they reported any quantified health economic cost and/or consequence with a measure of effect for any type of bariatric surgery from 1995 to

September 2015. Study screening, data extraction and synthesis followed international guidelines for systematic reviews.

Results: Six thousand one hundred eighty-seven studies were initially identified. After two levels of screening, 77 studies representing 17 countries (56% USA) were included. Despite study heterogeneity, common themes emerged, and important gaps were identified. Most studies adopted the healthcare system/third-party payer perspective; reported costs were generally healthcare resource use (inpatient/shorter-term outpatient). Out-of-pocket costs to individuals, family members (travel time, caregiving) and indirect costs due to lost productivity were largely ignored. Costs due to reoperations/complications were not included in one-third of studies. Body-contouring surgery included in only 14%. One study evaluated long-term waitlisted patients. Surgery was cost-effective/cost-saving for severely obese with type 2 diabetes mellitus. Study quality was inconsistent.

Discussion: There is a need for studies that assume a broader societal perspective (including out-of-pocket costs, costs to family and productivity losses) and longer-term costs (capture reoperations/complications, waiting, body contouring), and consequences (health-related quality-of-life). Full economic evaluation underpinned by reporting standards should inform prioritization of patients (e.g. type 2 diabetes mellitus with body mass index 30 to 34.9 kg/m 2 or long-term waitlisted) for surgery.

GUIDANCE & CLINICAL STUDIES:

1. **Body image and quality of life in patients with and without body contouring surgery following bariatric surgery: a comparison of pre- and post-surgery groups [6].**

ABSTRACT

Background: Massive weight loss (MWL) following bariatric surgery frequently results in an excess of overstretched skin causing physical discomfort and negatively affecting quality of life, self-esteem, body image, and physical functioning.

Methods: In this cross-sectional study 3 groups were compared: (1) patients prior to bariatric surgery (n = 79), (2) patients after bariatric surgery who had not undergone body contouring surgery (BCS) (n = 252), and (3) patients after bariatric surgery who underwent subsequent BCS (n = 62). All participants completed self-report questionnaires assessing body image (Multidimensional Body-Self Relations Questionnaire, MBSRQ), quality of life (IWQOL-Lite), symptoms of depression (PHQ-9), and anxiety (GAD-7).

Results: Overall, 62 patients (19.2%) reported having undergone a total of 90 BCS procedures. The most common were abdominoplasties (88.7%), thigh lifts (24.2%), and breast lifts (16.1%). Post-bariatric surgery patients differed significantly in most variables from pre-bariatric surgery patients. Although there were fewer differences between patients with and without BCS, patients after BCS reported better appearance evaluation (AE), body area

satisfaction (BAS), and physical functioning, even after controlling for excess weight loss and time since surgery. No differences were found for symptoms of depression and anxiety, and most other quality of life and body image domains.

Discussion: Our results support the results of longitudinal studies demonstrating significant improvements in different aspects of body image, quality of life, and general psychopathology after bariatric surgery. Also, we found better AE and physical functioning in patients after BCS following bariatric surgery compared to patients with MWL after bariatric surgery who did not undergo BCS. Overall, there appears to be an effect of BCS on certain aspects of body image and quality of life but not on psychological aspects on the whole.

2. **The impact of reconstructive procedures following bariatric surgery on patient well-being and quality of life [7]:**

ABSTRACT

Background: Massive weight loss following bariatric surgery may lead to an excess of lax, overstretched skin, causing physical discomfort which may affect the patient's quality of life. Whereas the functional and aesthetic deformity is an expected result of massive weight loss, the role of the plastic surgeon in the multidisciplinary approach of the morbidly obese is still unclear. The purpose of the current study is to evaluate the results of reconstructive surgery following weight loss surgery, focusing on the impact on the physical and psycho-social well-being and quality of life of the patients.

Methods: Out of a group of 465 patients, 61 patients underwent reconstructive surgery following weight loss surgery. In 43 respondents, the quality of life after reconstructive surgery was measured by the Obesity Psychological State Questionnaire. Patient satisfaction was evaluated.

Results: Reconstructive surgery resulted in a significant improvement in quality of life in patients at a mean interval of 42 months between weight loss and reconstructive surgery. The most frequent procedures were abdominoplasty and breast reconstruction. The relative high complication rate of 27.9% was of no influence on quality of life and the majority of the patients (67%) were satisfied with reconstructive surgery.

Conclusions: This study shows that reconstructive surgery following weight loss after bariatric surgery results in a significant improvement in overall quality of life. Reconstructive surgery should be incorporated in the multidisciplinary care programme following weight loss surgery in the morbidly obese patient.

3. **The BODY-Q: A Patient-Reported Outcome Instrument for Weight Loss and Body Contouring Treatments [8]:**

ABSTRACT

Background: Body contouring performed for cosmetic purposes, or after weight loss, has the potential to improve body image and health-related quality of life (HRQL). The BODY-Q is a new patient-reported outcome (PRO) instrument designed to measure patient perceptions of weight loss and/or body contouring. In this article, we describe the psychometric properties of the BODY-Q scales after an international field-test.

Methods: Weight loss and body contouring patients from Canada, United States, and United Kingdom were recruited between November 2013 and February 2015. Data were collected using an iPad directly into a web-based application or a questionnaire booklet. Rasch measurement theory analysis was used for item reduction and to examine reliability, validity, and ability to detect change.

Results: The sample included 403 weight loss and 331 body contouring patients. Most BODY-Q items had ordered thresholds (134/138) and good item fit. Scale reliability was acceptable, i.e., Person separation index >0.70 for 16 scales, Cronbach α ≥0.90 for 18 of 18 scales, and Test-retest ≥0.87 for 17 of 18 scales. Appearance and HRQL scores were lower in participants with more obesity-related symptoms, higher body mass index, and more excess skin and in those pre- versus postoperative body contouring. The 134 weight loss patients who completed the BODY-Q twice, either 6 weeks (weight loss/nonsurgical body contouring program) or 6 months (bariatric program) later, improved significantly on 7 appearances and 4 HRQL scales.

Conclusion: The BODY-Q is a clinically meaningful and scientifically sound patient-reported outcome instrument that can be used to measure outcomes in patients who undergo weight loss and/or body contouring.

4. **Body-Q User Manual, Royal College of Surgeons [9]:**

The 'BODY-Q' systematic review is strong evidence to support the method in measuring the effectiveness of body contouring from patient-reported outcomes. 'BODY-Q' method is the framework of the BODY-Q scales, is comprised of three overarching themes as follows:

1) Appearance; 2) Health-Related Quality of Life; and 3) Patient Experience.

Under these domains, there are 18 independently functioning scales that measure important Concepts of Interest (COI). In addition to the 18 scales, there is 1 obesity-specific symptom checklist.

5. **Body Image and Quality of Life in Post Massive Weight Loss Body Contouring Patients [10]:**

ABSTRACT

Objective: Because post-bariatric surgery patients undergo massive weight loss, the resulting skin excess can lead to both functional problems and profound dissatisfaction with

appearance. Correcting skin excess could improve all these corollaries, including body image. Presently, few data are available documenting body image and weight-related quality of life in this population.

Research methods and procedures: Eighteen patients who underwent both bariatric surgery and body contouring completed our study. Both established surveys and new surveys designed specifically for the study were used to assess body perception and ideals, quality of life, and mood. Patients were surveyed at the following time-points: pre-body contouring (after massive weight loss) and both 3 and 6-month post-body contouring. Statistical testing was performed using Student's t test and ANOVA.

Results: The mean age of the patients was 46 +/- 10 years (standard deviation). Quality of life improved after obesity surgery and was significantly enhanced after body contouring. Three months after body contouring, subjects ascribed thinner silhouettes to both current appearance and ideal body image. Body image also improved with body contouring surgery. Mood remained stable over 6 months.

Discussion: Body contouring after surgical weight loss improved both quality-of-life measurements and body image. Initial body dissatisfaction did not correlate with mood. Body contouring improved body image but produced dissatisfaction with other parts of the body, suggesting that as patients become closer to their ideal, these ideals may shift. We further developed several new assessment methods that may prove useful in understanding these post-surgical weight loss patients.

3.1.2 Cost effectiveness

Studies were found in a systematic review that appeared to reference QALYs in relation to body contouring. On further review of the literature referenced these were in relation to gastric bypass surgery and similar. No QALYs relevant to body contouring specifically were found.

3.2 Magnitude of Health Improvement Benefit

- All studies [1], [2] and [7] highlight the psychological and physiological improvement post-body contouring surgery. [2] and [7] explore in various tables the score improvement in physical movement and psychological benefit as high as 74% of study population [7].
- The papers also highlight the importance of support during the process and post-body contouring procedure to deal with the transition which resulted in higher QoL from the study population. It is highly suggested a sound support package is beneficial for maximum health outcomes.
- Clinical Outcomes of Body Contouring have been highlighted as achieving statistically significant improvements in conditions such as Neck, Back and Abdominal pain and conditions such as Lymphedema.

Outcome	Pre Body Contouring Score	Post Body Contouring Score	p Value
Neck Pain	2.52	2.02	≤ 0.05
Back Pain	5.63	2.10	≤ 0.0001
Abdominal Pain	5.96	1.43	≤ 0.0001
Lymphedema	3.35	1.65	≤ 0.0001

Table 7 [2]: Wilcoxon-signed rank demonstrating statistical significant improvement in all clinical outcomes above.

- Complications are recognised as a 'relative high complication rate of 27.9%' however this is substantially outweighed by the high patient satisfaction and QoL improvement post-surgery with or without complications [7].
- Reconstructive surgery resulted in a significant improvement in quality of life in patients at a mean interval of 42 months between weight loss and reconstructive surgery. The most frequent procedures were abdominoplasty and breast reconstruction. The relative high complication rate of 27.9% was of no influence on quality of life and the majority of the patients (67%) were satisfied with reconstructive surgery [7].
- QoL of existing health conditions with large reductions in 'Pain during exercise' by 4.34 (P≤0.0001) and 'Lymphedema' by 1.70 (P≤0.0001) and others [4].

3.3 Supports people with existing health problems

- The commissioning guidelines [1] provide a clear narrative on how body contouring can support the QoL for patients with existing health problems.
- The systematic review [4] explores in greater detail with scoring on the improvement of QoL of existing health conditions with large reductions in 'Pain during exercise' by 4.34 (P≤0.0001) and 'Lymphedema' by 1.70 (P≤0.0001) and others - distant indirect health utility benefit.

3.4 Safety

- Complications recognised included post procedure hematomas, abscesses which required secondary intervention; and few complications such as seromas and focal

skin neuroses. It is also highlighted that complications and infections are higher within smokers than non-smokers who receive procedure [1], [2], [7].

- Body contouring surgery (BCS) creates large wounds. The current evidence favours this surgery when patients have 'fully deflated'. Performing BCS at higher BMI's is associated with higher risk of complications [1].
- The following were defined as exceptions to BCS within the Commissioning Guide [1]:
    - Current smoker
    - Active psychiatric or psychological condition that would benefit from diagnosis and treatment prior to referral for body contouring surgery or that would contraindicate surgery including:
        - patients who have had an episode of self-harm within the last two years;
        - patients with a previous diagnosis of body dysmorphic disorder;
        - patients with a disproportionate view of the problem following consultation with a consultant Plastic Surgeon;
        - patients who currently have on going alcohol or drug misuse problems.

  NB: General health, social and lifestyle issues should also be taken into account before offering body contouring surgery to patients.

3.5 Equity issues

- Patients requiring body contouring surgery after bariatric surgery have been described as a new and unique population that is difficult to manage, with 96% of post-bariatric surgery patients developing multiple redundant skin flaps [5].
- Study [11] shows that there exists a postcode lottery for bariplastic surgery in England. The PCTs act independently of each other while drawing up their guidelines for the purposes of rationing. This leads to variability in funding for procedures in different regions within the NHS. The study showed a variation in guidelines across Trusts in the UK, amounting to a “postcode lottery” and stated that it is also evident from our survey that majority (101/106, 95.3%) of PCTs have their own guidelines and individual cut-off points for referrals leading to a postcode lottery for bariplastic surgery.

4. Activity and finance

There are a number of co-morbidities linked to obesity such as Type 2 diabetes, heart disease, some cancers, arthritis etc. The evidence demonstrates that there are statistically significant health improvement benefits to be realised in the overall health economy from Body Contouring Surgery following massive weight loss.

A Statistical report published in England 2018 [12] details the following facts on obesity, physical activity and diet, drawn together from a variety of sources.:

- In 2016/17, there were 617,000 admissions in NHS hospitals where obesity was a factor. This is an increase of 18% from 2015/16.

- In 2016, 26% of adults were classified as obese. This has increased from 15% in 1993 but has remained at a similar level since 2010.
- In 2016, 26% of adults consumed 5 or more portions of fruit and vegetables a day.

5. Summary of findings

- Consistent evidence and high score relates to high confidence the evidence will not change and any change will not be substantial.
- As stated in the justification the method in which to measure the effectiveness clinically is currently investigating & researching under the BODY-Q Method.
- Statistically significant health improvement benefits both in relation to QoL and clinical outcomes of more than 30% improvement
- Body Contouring based on the evidence has the potential to prevent both primary and secondary prevention of future illness such as mobility, QoL concerns, infection, lymphedema and other illnesses.
- A high capacity to improve health and starting with a high baseline health utility.
- No relevant QALYs found
- There is evidence from the systematic review that there is a vulnerable group (post bariatric surgery) that are more in need of body contouring.
- Diabetes was noted as a local and national priority that is linked to reducing obesity

6. Search Strategy

The following databases were routinely searched: NICE Clinical Guidance and full website search; NHS Evidence and NICE CKS; SIGN; Cochrane; York; and the relevant Royal College and any other relevant bespoke sites. A Medline search was undertaken where indicated and a general google search for key terms also undertaken.

Most of the evidence relating to these procedures was non-specific and included in reviews of obesity management. Systematic reviews of quality of outcome measures found that the papers studied did not use robust measures of outcomes and more work was needed but that overall patients appeared satisfied with the outcomes (based on low grade evidence). Studies looking at complications following these procedures found relatively high rates of complications but these were confounded by high rates of comorbidity.

6.1 Clinical criteria & definition:

Age over 16 years. Starting BMI above 40kg/m2 or above 35kg/m2 with co-morbidities AND current BMI of less than 30.0kg/m2 AND weight stability of 12 months AND significant functional disturbance (both physical and psychological). Weight stability allows for a maximum of 5kg increase or a 5kg decrease in weight [1].

6.2 Exceptions to general criteria:

Starting BMI above 40kg/m2 or above 35kg/m2 with co-morbidities and 75% excess body weight lost– should be eligible for apronectomy only - if they are unable to slim down to a

BMI of less than 30.0g/m2. A BMI of up to 40kg/m2 can be considered here. Weight stability of 12 months and significant functional disturbance applies here too.

6.3 PICO parameters:

Population: Those who clinically need 'Body Contouring' due to massive sustained weight loss.
Intervention: 'Body Contouring' (All procedures that are include under 'Body Contouring')
Comparator / Control: No surgery
Outcome: Clinical Benefit, Wider Health Utility, Mental Health

7. Glossary

Term	Meaning
Bariatric Surgery	Surgery to reduce the size of the stomach in order to promote weight loss.
Intertrigo	A dermatitis occurring between juxtaposed folds of skin. The dermatitis is usually caused by retention of sweat, moisture, and warmth which results in an overgrowth of normal skin microorganisms.
The Symphysis Pubis	The area of junction of the pubic bones and lies at the centre-front of the pelvic girdle.

8. References

[1] British Association of Plastic Reconstructive and Aesthetic Surgeons (BAPRAS), Royal College of Surgeons: UK Commissioning Guide: Massive Weight Loss Body Contouring, 2017. http://www.bapras.org.uk/docs/default-source/commissioning-and-policy/2017--draft-for-consultation--body-contouring-surgery-commissioning.pdf?sfvrsn=0

[2] Measuring Quality of Life and Patient Satisfaction After Body Contouring: A Systematic Review of Patient-Reported Outcome Measures, Patrick L. Reavey et al, Aesthetic Surgery Journal September 2011 vol. 31 no. 7 807-813
https://academic.oup.com/asj/article/31/7/807/176334

[3] Recommendations on the most suitable quality-of-life measurement instruments for bariatric and body contouring surgery: a systematic review. C.E.E. de Vries, et al. – https://www.ncbi.nlm.nih.gov/pubmed/29883059

[4] Quality of life among adults following bariatric and body contouring surgery: a systematic review. J. Gilmartin, et al. JBI Database of Systematic Reviews and Implementation Reports November 2016 vol.14 no.11 240-270
https://journals.lww.com/jbisrir/Abstract/2016/11000/Quality_of_life_among_adults_following_bariatric.16.aspx

[5] Diverse approaches to the health economic evaluation of bariatric surgery: a comprehensive systematic review. J.A. Campbel, et al. https://www.ncbi.nlm.nih.gov/pubmed/27383557

[6] Body image and quality of life in patients with and without body contouring surgery following bariatric surgery: a comparison of pre- and post-surgery groups. M. de Zwaan, et al - https://www.frontiersin.org/articles/10.3389/fpsyg.2014.01310/full

[7] The impact of reconstructive procedures following bariatric surgery onpatient well-being and quality of life. Van der Beek ES, et al. - https://www.ncbi.nlm.nih.gov/pubmed/19688408

[8] The BODY-Q: A Patient-Reported Outcome Instrument for Weight Loss and Body Contouring Treatments. A.F. Klassen, et al. - https://www.ncbi.nlm.nih.gov/pubmed/27200241

[9] Body-Q User Manual, Royal College of Surgeons - https://tinyurl.com/y53b9xmn

[10] Body Image and Quality of Life in Post Massive Weight Loss Body Contouring Patients. AY. Song, et al. - https://www.ncbi.nlm.nih.gov/pubmed/17030974

[11] Mukherjee,S.,Kamat,S.,Adegbola,S.,andAgrawal,S.(2014). Funding for post-bariatric body contouring (bariplastic) surgery in England: a post code lottery. Plast.Surg.Int. 2014:153194. doi:10.1155/2014/153194 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3980931/

[12] NHS Digital: Statistics on Obesity, Physical Activity and Diet - England, 2018 [PAS] https://digital.nhs.uk/data-and-information/publications/statistical/statistics-on-obesity-physical-activity-and-diet/statistics-on-obesity-physical-activity-and-diet-england-2018

Evidence Review

Liposuction for Lymphoedema and Lipoedema

Questions to be addressed:

What is the evidence of clinical and cost effectiveness of liposuction specifically in patients with lymphoedema or lipoedema, in comparison to conservative treatment?

Reason for review:

NHS Birmingham and Solihull CCG and Sandwell and West Birmingham CCG, requested a rapid evidence review of the clinical and cost effectiveness of liposuction in lymphoedema and lipoedema. The review was requested to support policy development.

Options for commissioners:

1. Due to consistent and strong volume of evidence demonstrating that liposuction in lymphoedema is clinically effective, develop a commissioning policy that details restricted criteria.
2. Due to there being a lack of evidence identified to directly compare liposuction in lipoedema with conservative management develop a policy that indicates that this procedure is not routinely commissioned in this indication. Should further evidence be available in future, the policy will be reviewed accordingly.

Summary

Liposuction is normally deemed to be a cosmetic procedure used to remove unwanted body fat. It involves sucking out small areas of fat that are hard to lose through exercise and a healthy diet. It is carried out on areas of the body where deposits of fat tend to collect, such as the buttocks, hips, thighs and tummy.

The aim is to alter body shape, and the results are generally long-lasting, providing you maintain a healthy weight. It works best in people who are a normal weight and in areas where the skin is tight.

Background

Liposuction carried out for cosmetic reasons is not normally available on the NHS. However, liposuction can sometimes be used by the NHS to treat certain health conditions.

The intervention

Liposuction for chronic lymphoedema is usually done under general anaesthesia, but regional nerve blockade is also possible. Small incisions are made in the target area and cannulas, connected to a vacuum pump are inserted and oedematous adipose tissue is removed by vacuum aspiration. Liposuction is done around and all the way along the limb.

Immediately after liposuction, a compression bandage is applied to the limb to control any bleeding and to prevent postoperative oedema. Antibiotics are typically prescribed after the operation. The limb is elevated during hospital stay for 3 to 7 days after the procedure.

From about 2 weeks after the procedure, a custom-made compression garment is worn. This garment is revised 3 or 4 times during the first year until the oedema volume has been reduced as much as possible and a steady state has been reached [9].

Safety:

Side effects to expect - It's common after liposuction to have:

- **bruising and swelling**, which may last up to six months
- **numbness**, which should go away in six to eight weeks
- **scars**
- **inflammation** of the treated area, or the veins underneath
- **fluid** coming from the cuts
- **swollen ankles** (if the legs or ankles are treated)

What could go wrong - Liposuction can occasionally result in:

- **lumpy and uneven results**
- **bleeding under the skin** (haematoma)
- **persistent numbness** that lasts for months
- **changes in skin colour** in the treated area
- **a build-up of fluid in the lungs** (pulmonary oedema) from the fluid injected into the body
- **a blood clot in the lungs** (pulmonary embolism)
- **damage to internal organs** during the procedure

Any type of operation also carries a small risk of:

- **excessive bleeding**
- **developing a blood clot** in a vein
- **infection**
- **an allergic reaction** to the anaesthetic

The surgeon should explain how likely these risks and complications are, and how they would be treated if they occurred.

Occasionally, people find the desired effect wasn't achieved and feel they need another operation.

PART I: LIPOSUCTION IN LYMPHOEDEMA

Current Management

1 Context

Lymphoedema is a long-term (chronic) condition that causes swelling in the body's tissues. It can affect any part of the body, but usually develops in the arms or legs.

It develops when the lymphatic system doesn't work properly. The lymphatic system is a network of channels and glands throughout the body that helps fight infection and remove excess fluid.

There are two main types of lymphoedema:

- **primary lymphoedema** – caused by faulty genes that affect the development of the lymphatic system; it can develop at any age, but usually starts during infancy, adolescence, or early adulthood

- **secondary lymphoedema** – caused by damage to the lymphatic system or problems with the movement and drainage of fluid in the lymphatic system; it can be the result of an infection, injury, cancer treatment, inflammation of the limb, or a lack of limb movement

1.1 Introduction

There's no cure for lymphoedema, but it's usually possible to control the main symptoms using techniques to minimize fluid build-up and stimulate the flow of fluid through the lymphatic system.

These include wearing compression garments, taking good care of your skin, moving and exercising regularly, having a healthy diet and lifestyle, and using specialised massage techniques.

1.1.1 Decongestive lymphatic therapy (DLT)

The recommended treatment for lymphoedema is decongestive lymphatic therapy (DLT).

DLT isn't a cure for lymphoedema, but it can help control the symptoms. Although it takes time and effort, the treatment can be used to bring lymphoedema under control. There are four components to DLT:

- **compression bandages** – to complement exercise by moving fluid out of the affected limb and minimise further build-up
- **skin care** – to keep the skin in good condition and reduce the chances of infection
- **exercises** – to use muscles in the affected limb to improve lymph drainage
- **specialised massage techniques** – known as manual lymphatic drainage (MLD); this stimulates the flow of fluid in the lymphatic system and reduces swelling

DLT is an intensive phase of therapy, during which you may receive daily treatment for several weeks to help reduce the volume of the affected body part.

This is followed by a second phase called the maintenance phase. You'll be encouraged to take over your care using simple self-massage techniques, wearing compression garments, and continuing to exercise.

This treatment phase aims to maintain the reduced size of the affected body part.

1.1.2 Surgery

In a small number of cases, surgery may be used to treat lymphoedema. There are three main types of surgery that may be useful for the condition:

- removal of sections of excess skin and underlying tissue (debulking)
- removal of fat from the affected limb (liposuction)
- restoration of the flow of fluid around the affected section of the lymphatic system – for example, by connecting the lymphatic system to nearby blood vessels (lymphaticovenular anastomosis)

These treatments may help reduce the size of areas of the body affected by lymphoedema, but some are still being evaluated – particularly lymphaticovenular anastomosis – and aren't in widespread use.

1.2 Existing national policies and guidance

- NICE Guideline (IPG588): Liposuction for chronic lymphoedema

2 Epidemiology

Lymphoedema is thought to affect more than 200,000 people in the UK. Primary lymphoedema is rare and is thought to affect around 1 in every 6,000 people. Secondary lymphoedema is much more common.

Secondary lymphoedema affects around 2 in 10 women with breast cancer, and 5 in 10 women with vulval cancer. About 3 in every 10 men with penile cancer get lymphoedema. In the UK, one of the most common types of chronic lymphoedema is secondary lymphoedema of the arm after breast cancer or its treatment [9].

People who have treatment for melanoma in the lymph nodes in the groin can also get lymphoedema. Research has shown around 20-50% of people are affected [1].

3 Findings

3.1 Evidence of effectiveness

Cochrane systematic review in 2015 (six randomised controlled trials, 208 patients) considered the effectiveness of combined manual lymph drainage and other treatments compared with other treatments alone for lymphoedema after breast cancer treatment. [3]

In a second systematic review, studies were scored for methodological quality using the methodological index for nonrandomized studies (MINORS) scoring system. A total of 69 articles met inclusion criteria and were assigned MINORS scores with a maximum score of 16 or 24 for non-comparative or comparative studies, respectively. The average MINORS scores using non-comparative criteria were 12.1 for excision, 13.2 for liposuction. Thirty-nine studies scoring > 12/16 or > 19/24 were considered high quality. [4]

Both of the systematic reviews show good quality evidence and support the same outcome; further studies are unlikely to change confidence in the effect of the intervention. It is however important to note that no direct comparisons with conservative management in published sources.

SYSTEMATIC REVIEWS:

1. **Which are the best conservative interventions for lymphoedema after breast cancer surgery? [3]:**

ABSTRACT

Background: Breast cancer-related lymphoedema can be a debilitating long-term sequela of breast cancer treatment. Several studies have investigated the effectiveness of different treatment strategies to reduce the risk of breast cancer-related lymphoedema.

Objectives: To assess the effects of conservative (non-surgical and non-pharmacological) interventions for preventing clinically-detectable upper-limb lymphoedema after breast cancer treatment.

Search methods: Searched the Cochrane Breast Cancer Group's (CBCG) Specialised Register, CENTRAL, MEDLINE, EMBASE, CINAHL, PEDro, PsycINFO, and the World Health Organization (WHO) International Clinical Trials Registry Platform in May 2013. Reference lists of included trials and other systematic reviews were searched.

Selection criteria: Randomised controlled trials that reported lymphoedema as the primary outcome and compared any conservative intervention to either no intervention or to another conservative intervention.

Data collection and analysis: Three authors independently assessed the risk of bias and extracted data. Outcome measures included lymphoedema, infection, range of motion of the

shoulder, pain, psychosocial morbidity, level of functioning in activities of daily life (ADL), and health-related quality of life (HRQoL). Where possible, meta-analyses were performed. Risk ratio (RRs) or hazard ratio (HRs) were reported for dichotomous outcomes or lymphoedema incidence, and mean differences (MDs) for range of motion and patient-reported outcomes.

Main results: Ten trials involving 1205 participants were included. The duration of patient follow-up ranged from 2 days to 2 years after the intervention. Overall, the quality of the evidence generated by these trials was low, due to risk of bias in the included trials and inconsistency in the results.

Manual lymph drainage: In total, four studies used manual lymph drainage (MLD) in combination with usual care or other interventions. In one study, lymphoedema incidence was lower in patients receiving MLD and usual care (consisting of standard education or exercise, or both) compared to usual care alone. A second study reported no difference in lymphoedema incidence when MLD was combined with physiotherapy and education compared to physiotherapy alone. Two other studies combining MLD with compression and scar massage or exercise observed a reduction in lymphoedema incidence compared to education only, although this was not significant in one of the studies. Two out of the four studies reported on shoulder mobility where MLD combined with exercise gave better shoulder mobility for lateral arm movement (shoulder abduction) and forward flexion in the first weeks after breast cancer surgery, compared to education only (mean difference for abduction 22°; 95% confidence interval (CI) 14 to 30; mean difference for forward flexion 14°; 95% CI 7 to 22). Two of the studies on MLD reported on pain, with inconsistent results. Results on HRQoL in two studies on MLD were also contradictory.

Exercise: early versus delayed start of shoulder mobilising exercises

Three studies examined early versus late start of postoperative shoulder exercises. The pooled relative risk of lymphoedema after an early start of exercises was 1.69 (95% CI 0.94 to 3.01, 3 studies, 378 participants). Shoulder forward flexion was better at one and six months' follow-up for participants who started early with mobilisation exercises compared to a delayed start (two studies), but no meta-analysis could be performed due to statistical heterogeneity. There was no difference in shoulder mobility or self-reported shoulder disability at 12 months' follow-up (one study). One study evaluated HRQoL and reported difference at one-year follow-up (mean difference 1.6 points, 95% CI -2.14 to 5.34, on the Trial Outcome Index of the FACT-B). Two studies collected data on wound drainage volumes and only one study reported higher wound drainage volumes in the early exercise group.

Exercise: resistance training

Two studies compared progressive resistance training to restricted activity. Resistance training after breast cancer treatment did not increase the risk of developing lymphoedema (RR 0.58; 95% CI 0.30 to 1.13, two studies, 358 participants) provided that symptoms are

monitored and treated immediately if they occur. One out of the two studies measured pain where participants in the resistance training group reported pain more often at three months and six months compared to the control group. One study reported HRQoL and found no significant difference between the groups.

Patient education, monitoring and early intervention.

One study investigated the effects of a comprehensive outpatient follow-up programme, consisting of patient education, exercise, monitoring of lymphoedema symptoms and early intervention for lymphoedema, compared to education alone. Lymphoedema incidence was lower in the comprehensive outpatient follow-up programme (at any time point) compared to education alone (65 people). Participants in the outpatient follow-up programme had a significantly faster recovery of shoulder abduction compared to the education alone group.

Authors' conclusions: Based on the current available evidence, we cannot draw firm conclusions about the effectiveness of interventions containing MLD. The evidence does not indicate a higher risk of lymphoedema when starting shoulder-mobilising exercises early after surgery compared to a delayed start (i.e. seven days after surgery). Shoulder mobility (that is, lateral arm movements and forward flexion) is better in the short term when starting shoulder exercises earlier compared to later. The evidence suggests that progressive resistance exercise therapy does not increase the risk of developing lymphoedema, provided that symptoms are closely monitored and adequately treated if they occur. Given the degree of heterogeneity encountered, limited precision, and the risk of bias across the included studies, the results of this review should be interpreted with caution.

2. **Systematic Review of the Surgical Treatment of Extremity Lymphedema [4]**

ABSTRACT

Background: Although conservative management of lymphedema remains the first-line approach, surgery is effective in select patients. The purpose of this study was to review the literature and develop a treatment algorithm based on the highest quality lymphedema research.

Methods: A systematic literature review was performed to examine the surgical treatments for lymphedema. Studies were categorized into five groups describing excision, liposuction, lymphovenous anastomosis (LVA), vascularized lymph node transfer (VLNT), and combined/multiple approaches. Studies were scored for methodological quality using the methodological index for nonrandomized studies (MINORS) scoring system.

Results: A total of 69 articles met inclusion criteria and were assigned MINORS scores with a maximum score of 16 or 24 for noncomparative or comparative studies, respectively. The average MINORS scores using noncomparative criteria were 12.1 for excision, 13.2 for liposuction, 12.6 for LVA, 13.1 for VLNT, and 13.5 for combined/multiple approaches. Loss to follow-up was the most common cause of low scores. Thirty-nine studies scoring > 12/16

or > 19/24 were considered high quality. In studies measuring excess volume reduction, the mean reduction was 96.6% (95% confidence interval [CI]: 86.2–107%) for liposuction, 33.1% (95% CI: 14.4–51.9%) for LVA, and 26.4% (95% CI: − 7.98 to 60.8%) for VLNT. Included excision articles did not report excess volume reduction.

Conclusion: Although the overall quality of lymphedema literature is fair, the MINORS scoring system is an effective method to isolate high-quality studies. These studies were used to develop an evidence-based algorithm to guide clinical practice. Further studies with a particular focus on patient follow-up will improve the validity of lymphedema surgery research.

CASE SERIES:

1. **Operative Treatment of Lymphedema Using Suction-Assisted Lipectomy [7].**

ABSTRACT

Surgical management of lymphedema includes removal of affected tissues (excisional procedures), or operations that create new lymphatic connections (physiologic procedures). The purpose of this study was to determine the efficacy of one type of excisional procedure, suction-assisted lipectomy, for extremity lymphedema. Patients treated in our Lymphedema Program between 2007 and 2015 with liposuction that had postoperative follow-up were reviewed. The diagnosis of lymphedema was made by history/physical examination and confirmed with lymphoscintigraphy. Patient sex, age, type of lymphedema (primary or secondary), location of disease, infection history, volume of lipoaspirate, and reduction of extremity volume were recorded. Fifteen patients were included, mean age was 45 years (range, 17-71). Six patients had secondary upper extremity lymphedema, and 9 patients had lower limb disease. Eight patients had a history of repeated cellulitis involving the lymphedematous extremity. Mean lipoaspirate volume was 1612 mL (range, 1200-2800) for the upper extremity and 2902 mL (range, 2000-4800) for the lower limb. Postoperative follow-up averaged 3.1 years. The mean reduction in excess extremity volume was 73% (range, 48% to 94%), and patients reported improvement in their quality of life. Suction-assisted lipectomy is an effective technique to reduce extremity volume for patients with lymphedema.

Background: Surgical management of lymphedema includes removal of affected tissues (excisional procedures), or operations that create new lymphatic connections (physiologic procedures). The purpose of this study was to determine the efficacy of one type of excisional procedure, suction-assisted lipectomy, for extremity lymphedema.

Methods: Patients treated in our Lymphedema Program between 2007 and 2015 with liposuction that had postoperative follow-up were reviewed. The diagnosis of lymphedema was made by history/physical examination and confirmed with lymphoscintigraphy. Patient

sex, age, type of lymphedema (primary or secondary), location of disease, infection history, volume of lipoaspirate, and reduction of extremity volume were recorded.

Results: Fifteen patients were included, mean age was 45 years (range, 17–71). Six patients had secondary upper extremity lymphedema, and 9 patients had lower limb disease. Eight patients had a history of repeated cellulitis involving the lymphedematous extremity. Mean lipoaspirate volume was 1612 mL (range, 1200–2800) for the upper extremity and 2902 mL (range, 2000–4800) for the lower limb. Postoperative follow-up averaged 3.1 years. The mean reduction in excess extremity volume was 73% (range, 48% to 94%), and patients reported improvement in their quality of life.

Conclusions: Suction-assisted lipectomy is an effective technique to reduce extremity volume for patients with lymphedema.

3.1.1 Cost effectiveness

No information available.

3.2 Magnitude of Health Improvement Benefit

No direct comparison in literature so indirect comparison made. Evidence shows a moderate to large health improvement using this procedure supported by long term follow up.

- In studies measuring excess volume reduction, the mean reduction was 96.6% (95% confidence interval [CI]: 86.2–107%) for liposuction [4]
- Findings support the use of an intensive course of compression bandaging to reduce lymphoedema volume. One year follow-up findings suggest better maintenance of reduction in limb volume in those who used compression hosiery. Manual lymph drainage was found to offer additional benefit when added to compression bandaging (mean difference in reduction of arm volume 7%, 95% confidence interval 1.75-12.47, P=0.009) [3]
- To determine the longer term outcomes of the technique, Schaverien et al published 21-year prospective data in 146 women with arm lymphedema. 11 Preoperative mean excess volume was 1,568 mL (range: 545–4,235), aspirate mean volume was 1,807 mL (range 650–3,850), and postoperative mean reduction was 103% (range 50–194) at 3 months and more than 100% during 21 years' follow-up. The preoperative mean volume ratio between the affected and unaffected arms was 1.5, declining to 1.0 at 3 months, and <1.0 after 1 year. This demonstrates the long-term effectiveness and stability of the technique. [5]

3.3 Supports people with existing health problems

The condition presents as a moderate health utility, and there is moderate capacity for improvement for the intervention (liposuction). Moderate health utility has been used because there is a wide range of severity and considerable variability for Lymphoedema.

- 3 Studies included in a Systematic Review reported improved well-being and decreased depression and anxiety postoperatively at 12- to 38-month follow-up after liposuction. [4]
- A consecutive cohort of 90 patients treated by liposuction for chronic lymphoedema responded to a SF-36 questionnaire before and at different points after the procedure. At 3-month follow-up the physical functioning, bodily pain, mental health and vitality dimensions were statistically significantly improved from baseline assessment, $p<0.05$. At 12-month follow-up the all of the above dimension plus social functioning were statistically significantly improved from baseline assessment, $p<0.05$. [6]

3.4 Prevention of Future illness

There is clear evidence that the intervention prevents future illness; due to the nature of the illness and the reduction in the likelihood of serious infections.

- In the case series of 15 patients (12 women, 3 men) treated by liposuction, all patients reported improved extremity function, reduction in episodes of cellulitis and better quality of life. [7]
- In the case series of 88 patients treated by liposuction, the rate of cellulitis was statistically significantly reduced from 8 (per limb per year) at baseline to 0.2 in the patients with primary lymphoedema and from 6 to 0.3 in the secondary lymphoedema group, at 24-month follow-up. [8]

3.5 Equity issues

There are indirect associations between lymphoedema and socioeconomic and population inequalities; lymphoedema is associated with obesity and cancer and these are both associated with socioeconomic inequalities [1]. A number of causes of secondary Lymphoedema [2] include:

- **Surgery.** Removal of or injury to lymph nodes and lymph vessels may result in lymphedema. For example, lymph nodes may be removed to check for spread of breast cancer, and lymph nodes may be injured in surgery that involves blood vessels in your limbs.
- **Radiation treatment for cancer.** Radiation can cause scarring and inflammation of your lymph nodes or lymph vessels.
- **Cancer.** If cancer cells block lymphatic vessels, lymphedema may result. For instance, a tumour growing near a lymph node or lymph vessel could enlarge enough to block the flow of the lymph fluid.

- **Infection.** An infection of the lymph nodes or parasites can restrict the flow of lymph fluid. Infection-related lymphedema is most common in tropical and subtropical regions and is more likely to occur in developing countries.

4.Activity and finance

The National Lymphoedema Tariff Guide recommended by BLS represents an average treatment schedule. The costing models are based on a 42-week year, staff cost and related service provision costs. The cost for simple/early to complex treatment ranges from £922.50 to £4551 [10].

5.Summary of findings

- Cochrane and Systematic Reviews show good quality of evidence, multiple Systematic Reviews supporting the same outcome therefore further studies unlikely to change confidence in the effect.
- No direct comparison with conservative management noted in literature so indirect comparisons have been made.
- Evidence shows that there is moderate to large health improvement of using this procedure supported by long term follow up.
- There is clear evidence of prevention of future illness, due to the nature of the illness and the reduction in the likelihood of serious infections.
- There is a high prevention benefit.
- Moderate health utility and moderate capacity of intervention to improve the health state
- Indirect socioeconomic associations for some of the main causes including obesity and cancer.

6.Search Strategy

PICO parameters:

Population: Patients with primary and secondary lymphoedema all limbs
Intervention: Liposuction +/- tourniquet +/- adrenaline
Comparator / Control: conservative management
Outcome: Clinical effectiveness including Pain, Function/mobility, Quality of Life score AE,

7 References

[1]NHS website: Overview- Lymphoedema https://www.nhs.uk/conditions/lymphoedema/

[2] Mayo Clinic Website: Lymphoedema https://www.mayoclinic.org/diseases-conditions/lymphedema/symptoms-causes/syc-20374682

[3] Stuiver Martijn M, Tusscher Marieke R, McNeely Margaret L. Which are the best conservative interventions for lymphoedema after breast cancer surgery?

BMJ 2017; 357:j233 https://www.uptodate.com/contents/breast-cancer-associated-lymphedema/abstract/43

[4] Hannah M. Carl, Gurjot Walia, Ricardo Bello, Emily Clarke-Pearson, Aladdin H. Hassanein, Brian Cho, Rachel Pedreira, Justin M. Sacks: Systematic Review of the Surgical Treatment of Extremity Lymphedema
https://www.thieme-connect.de/products/ejournals/abstract/10.1055/s-0037-1599100

[5] Schaverien MV, Munnoch DA, Brorson H. Liposuction Treatment of Lymphedema: Semin Plast Surg. 2018;32(1):42–47. doi:10.1055/s-0038-1635116
https://www.ncbi.nlm.nih.gov/pubmed/29636653

[6] Hoffner M, Bagheri S, Hansson E et al. (2017) SF-36 Shows Increased Quality of Life Following Complete Reduction of Postmastectomy Lymphedema with Liposuction. Lymphatic Research and Biology 15, 87-9 https://www.liebertpub.com/doi/full/10.1089/lrb.2016.0035

[7] Greene AK and Maclellan Reid A (2016) Operative treatment of lymphedema using suction-assisted lipectomy. Annals of Plastic Surgery 77: 337-340.

[8] Lamprou DAA, Voesten HG, Damstra RJ et al. (2017) Circumferential suction-assisted lipectomy in the treatment of primary and secondary end-stage lymphoedema of the leg. The British journal of surgery 104, 84-89.

[9] NICE (2017): Interventional procedure overview of liposuction for chronic lymphoedema https://www.nice.org.uk/guidance/ipg588/evidence/overview-final-pdf-4548738349

[10]British Lymphology Society (2019) - The National Lymphoedema Tariff Guide https://www.thebls.com/public/uploads/documents/document-90631551700163.pdf

PART II: LIPOSUCTION IN LIPOEDEMA

Current Management

1 Context

Lipoedema is a long-term (chronic) condition where there's an abnormal build-up of fat cells and usually only affects women, although in rare cases it can also affect men. This normally occurs in the legs, thighs and buttocks, and sometimes in the arms which are usually enlarged at the same time and to the same extent.

The feet and hands aren't affected, which creates a "bracelet" effect or "band-like" appearance just above the ankles and wrists. Leg and arm size can vary between individuals with lipoedema, and the condition can gradually get worse over time.

As well as becoming enlarged, affected areas of the body may:

- feel soft, "doughy" and cold
- bruise easily
- ache or feel painful or tender
- have small broken veins under the skin

Someone with lipoedema may eventually get fluid retention (lymphoedema) in their legs. This type of swelling can worsen by the end of the day and may improve overnight, whereas the fatty swelling of lipoedema is constant.

1.1 Introduction

There's been little research into lipoedema, so there's some uncertainty about the best way to treat the condition.

If you have lipoedema it's important to avoid significant weight gain and obesity because putting on weight will make the fatty swelling worse.

1.2 Treatments for lipoedema

1.2.1 Non-surgical treatments

These can sometimes help improve pain and tenderness, prevent or reduce lymphoedema, and improve the shape of affected limbs – although they often have little effect on the fatty tissue.

Several different treatments are designed to improve the flow and drainage of fluid in your tissues, such as:

- compression therapy – wearing bandages or garments that squeeze the affected limbs
- exercise – usually low-impact exercises, such as swimming and cycling
- massage – techniques that help encourage the flow of fluid through your body

Compression tights are helpful for some people because they support the fatty swelling and may reduce the pain.

1.2.2 Tumescent liposuction

Liposuction is the surgical option for the removal of fat.

Tumescent liposuction involves sucking out the unwanted fat through a tube. A liquid solution is first injected into the legs to help numb the area and reduce blood loss.

Fatty swelling of the legs may return after having the procedure if weight gain occurs.

Non-surgical treatments may also be needed for a long period after having tumescent liposuction. For example, you'll need to wear compression garments after surgery to prevent complications such as lymphoedema.

1.3 Treatments that don't work

Treatments used for some types of tissue swelling are generally unhelpful for lipoedema.

Lipoedema doesn't respond to:

- raising the legs
- diuretics (tablets to get rid of excess fluid)
- dieting – this tends to result in a loss of fat from areas not affected by lipoedema, with little effect on the affected areas

1.4 Causes of lipoedema

The cause of lipoedema isn't known, but in some cases there's a family history of the condition. It seems likely that the genes you inherit from your parents play a role.

Lipoedema tends to start at puberty or at other times of hormonal change, such as during pregnancy or the menopause, which suggests hormones may also have an influence.

Although the accumulation of fat cells is often worse in obese people, lipoedema isn't caused by obesity and can affect people who are a healthy weight. It shouldn't be mistaken for obesity, and dieting often makes little difference to the condition.

1.5 Existing national policies and guidance

There is currently no national policy or guidance around liposuction in lipoedema.

2 Epidemiology

Relatively little epidemiological research has been carried out on lipoedema and so it is unclear exactly how many people are affected and to what extent. The research so far has

produced widely varying figures. In the UK, the minimum prevalence of lipoedema has been estimated to be 1 in 72,000 which is also noted as likely to be an underestimate [5].

3 Findings

3.1 Evidence of effectiveness

There has been little research into lipoedema, so there's some uncertainty about the best way to treat the condition. If you have lipoedema it's important to avoid significant weight gain and obesity because putting on weight will make the fatty swelling worse. Compression tights are helpful for some people because they support the fatty swelling and may reduce the pain. The only treatment that appears to be effective in reducing the build-up of fatty tissue associated with lipoedema is a procedure called tumescent liposuction [1].

3.1.1 Quality and strength of evidence

No Randomised Controlled trials or systematic reviews were found during the evidence review; however, 3 relevant case series were considered and below is the summary of the evidence review. No studies directly compared liposuction to conservative treatment, but patients undergoing the intervention had previously received conservative management so any benefits stated for interventions were in addition to any benefits achieved by conservative management:

- Twenty-five patients [2] who received 72 liposuction procedures for the treatment of lipoedema completed a standardized questionnaire. Lipoedema-associated complaints and the need for combined decongestive therapy (CDT) were assessed for the preoperative period and during 2 separate postoperative follow-ups using a visual analogue scale and a composite CDT score. The mean follow-up times for the first postoperative follow-up and the second postoperative follow-up were 16 months and 37 months, respectively.
- Whereas conservative methods with combined decongestive therapy (manual lymphatic drainage, compression garments) have been well established over the past 50 years, surgical therapy with tumescent liposuction has only been used for about 10 years and long-term results are unknown. A total of 164 patients who had undergone conservative therapy over a period of years, were treated by liposuction under tumescent local anaesthesia with vibrating microcannulas. In a monocentric study, 112 could be re-evaluated with a standardized questionnaire after a mean of 3years and 8months (range 1year and 1month to 7years and 4months) following the initial surgery and a mean of 2years and 11months (8months to 6years and 10months) following the last surgery. [3]
- In a single-centre study, 85 patients with lipoedema had already been examined after 4 years. A mail questionnaire - often in combination with clinical controls - was

repeated after another 4 years (8 years after liposuction). Compared with the results after 4 years, the improvement in spontaneous pain, sensitivity to pressure, oedema, bruising and restriction of movement persisted. The same held true for patient self-assessment of cosmetic appearance, quality of life and overall impairment. Eight years after surgery, the reduction in the amount of conservative treatment (combined decongestive therapy, compression garments) was similar to that observed 4 years earlier. [4]

3.1.2 Clinical Effectiveness

CASE SERIES

1. **Liposuction in the Treatment of Lipoedema: A Longitudinal Study [2].**

ABSTRACT

Background: Lipoedema is a condition consisting of painful bilateral increases in subcutaneous fat and interstitial fluid in the limbs with secondary lymphedema and fibrosis during later stages. Combined decongestive therapy (CDT) is the standard of care in most countries. Since the introduction of tumescent technique, liposuction has been used as a surgical treatment option. The aim of this study was to determine the outcome of liposuction used as treatment for lipoedema.

Methods: Twenty-five patients who received 72 liposuction procedures for the treatment of lipoedema completed a standardized questionnaire. Lipoedema-associated complaints and the need for CDT were assessed for the preoperative period and during 2 separate postoperative follow-ups using a visual analogue scale and a composite CDT score. The mean follow-up times for the first postoperative follow-up and the second postoperative follow-up were 16 months and 37 months, respectively.

Results: Patients showed significant reductions in spontaneous pain, sensitivity to pressure, feeling of tension, bruising, cosmetic impairment, and general impairment to quality of life from the preoperative period to the first postoperative follow-up, and these results remained consistent until the second postoperative follow-up. A comparison of the preoperative period to the last postoperative follow-up, after 4 patients without full preoperative CDT were excluded from the analysis, indicated that the need for CDT was reduced significantly. An analysis of the different stages of the disease also indicated that better and more sustainable results could be achieved if patients were treated in earlier stages.

Conclusions: Liposuction is effective in the treatment of lipoedema and leads to an improvement in quality of life and a decrease in the need for conservative therapy.

2. **Tumescent liposuction in lipoedema yields good long-term results [3].**

ABSTRACT

Background: Lipoedema is a painful disease in women with circumscribed increased subcutaneous fatty tissue, oedema, pain and bruising. Whereas conservative methods with combined decongestive therapy (manual lymphatic drainage, compression garments) have been well established over the past 50years, surgical therapy with tumescent liposuction has only been used for about 10years and long-term results are unknown.

Objectives: To determine the efficacy of liposuction concerning appearance (body shape) and associated complaints after a long-term period.

Methods: A total of 164 patients who had undergone conservative therapy over a period of years, were treated by liposuction under tumescent local anaesthesia with vibrating microcannulas. In a monocentric study, 112 could be re-evaluated with a standardized questionnaire after a mean of 3years and 8months (range 1year and 1month to 7years and 4months) following the initial surgery and a mean of 2years and 11months (8months to 6years and 10months) following the last surgery.

Results: All patients showed a distinct reduction of subcutaneous fatty tissue (average 9846mL per person) with improvement of shape and normalization of body proportions. Additionally, they reported either a marked improvement or a complete disappearance of spontaneous pain, sensitivity to pressure, oedema, bruising, restriction of movement and cosmetic impairment, resulting in a tremendous increase in quality of life; all these complaints were reduced significantly (P<0·001). Patients with lipoedema stage II and III showed better improvement compared with patients with stage I. Physical decongestive therapy could be either omitted (22·4% of cases) or continued to a much lower degree. No serious complications (wound infection rate 1·4%, bleeding rate 0·3%) were observed following surgery.

Conclusions: Tumescent liposuction is a highly effective treatment for lipoedema with good morphological and functional long-term results.

3. **Long-term benefit of liposuction in patients with lipoedema: a follow-up study after an average of 4 and 8 years [4].**

ABSTRACT

Background: Long-term results following liposuction in patients with lipoedema are available only for an average period of 4 years.

Objective: To find out whether the improvement of complaints persists for a further 4 years.

Methods: In a single-centre study, 85 patients with lipoedema had already been examined after 4 years. A mail questionnaire - often in combination with clinical controls - was repeated after another 4 years (8 years after liposuction).

Results: Compared with the results after 4 years, the improvement in spontaneous pain, sensitivity to pressure, oedema, bruising and restriction of movement persisted. The same held true for patient self-assessment of cosmetic appearance, quality of life and overall impairment. Eight years after surgery, the reduction in the amount of conservative treatment (combined decongestive therapy, compression garments) was similar to that observed 4 years earlier.

Conclusion: These results demonstrate for the first time the long-lasting positive effects of liposuction in patients with lipoedema.

3.1.2 Cost effectiveness

No relevant studies identified.

3.2 Magnitude of Health Improvement Benefit

The health improvement benefits shown within the two trials, and are directly comparable with the benefits requested within the research parameters, are substantial.

The results suggest that there are both short and long-term sustained improvements in almost all dimensions around pain and Quality of Life (QoL), and one study substantiates this as over and above conservative treatment.

- Tumescent liposuction involves sucking out the unwanted fat through a tube. A liquid solution is first injected into the legs to help numb the area and reduce blood loss. The procedure can be effective and have good results, but several operations may be needed to remove the fat from different parts of your body. Fatty swelling of the legs may return after having the procedure if weight is gained. Non-surgical treatments may also be needed for a long period after having tumescent liposuction. For example, compression garments will need to be worn after surgery to prevent complications such as lymphoedema [1].
- Patients showed significant reductions in spontaneous pain, sensitivity to pressure, feeling of tension, bruising, cosmetic impairment, and general impairment to quality of life from the preoperative period to the first postoperative follow-up, and these results remained consistent until the second postoperative follow-up. Patients also reported substantial lipoedema-associated complaints preoperatively. Spontaneous pain was reported with a mean VAS score of 7.2 (standard deviation [SD], 1.46); the equivalent of “severe” to “very severe” spontaneous pain. Sensitivity to pressure and feeling of tension were reported with mean VAS scores of 7.38 (SD, 1.79) and 7.52 (SD, 1.36), respectively, falling within the “very severe” range. The reported cosmetic

impairment ranged from “severe” to “unbearable,” resulting in a mean VAS score of 8.98 (SD, 0.81). General impairment to quality of life was also reported as “very severe,” with a mean VAS score of 8.38 (SD, 1.06). The severity of all analysed complaints was significantly reduced over the course of liposuction treatment by the time of the first postoperative follow-up. All but 1 of the patients reported a reduction in spontaneous pain (the chief complaint in lipoedema), with a mean difference in VAS score of 3.5 (95% confidence interval [CI], 2.83–4.17). Furthermore, all but 1 of the patients reported a reduction in impairment of quality of life, with a mean difference in VAS score of 4.08 (95% CI, 3.12–5.04). The Bonferroni-corrected P-value was <0.001 for all 6 complaints. At the second postoperative follow-up, only the severity of cosmetic impairment significantly increased since the first postoperative follow-up, and there was significant improvement in all symptoms between the preoperative period and the second postoperative follow-up [2].

VAS - Is a visual system form scoring pain levels, 0=no pain, 5 is moderate, 10 is extreme pain/worst pain ever

- The patients reported either a marked improvement or a complete disappearance of spontaneous pain, sensitivity to pressure, oedema, bruising, restriction of movement and cosmetic impairment, resulting in a tremendous increase in quality of life; all these complaints were reduced significantly (P<0·001). Patients with lipoedema stage II and III showed better improvement compared with patients with stage I. Physical decongestive therapy could be either omitted (22·4% of cases) or continued to a much lower degree. No serious complications (wound infection rate 1·4%, bleeding rate 0·3%) were observed following surgery [3].
- The results of the studies suggest that there are both short and long-term sustained improvements in almost all dimensions relating to pain and quality of life.

3.3 Supports people with existing health problems

Baseline health utility living with the condition has been considered as high, with the capacity to benefit also being high (the results show almost universal improvement across patients).

- The combination of symptoms can lead to reduced mobility and psychological issues, such as low self-esteem [1].
- The condition is a major psychosocial burden for most patients, causing pain that often limits their capacity for exercise. In addition, standing for long periods of time and high temperatures are not tolerated well by those with lipoedema, and in severe cases, the condition may cause absence from work or lead to occupational disability [2].

3.4 Prevention of future illness

There are statements that suggest lipoedema may develop into lymphoedemia, which is a serious condition. However, there was no evidence how often this may occur and whether this intervention would mitigate such development, the minimum score has been awarded.

There is potential plausibility in such statements and if the evidence base became more robust there would be potential to modify this score.

- A person with lipoedema may eventually develop lymphoedema as well, if the build-up of fat affects lymphatic drainage. This combination of the two conditions is known as lipo-lymphoedema [1].
- Data published in a longitudinal study suggest that liposuction treatment for stage II lipoedema provides a more sustainable reduction in the impairment of quality to life and a larger decrease in the need for conservative therapy than liposuction treatment for stage III lipoedema. The authors state that due to the development of secondary lymphedema and the irreversible damage to the lymphatic system that occurs in later stages of the disease, liposuction should be implemented as part of the standard therapy for lipoedema at early stages. This will prevent disease progression, improve quality of life, and reduce the need for decongestive therapy [2].

3.5 Equity issues

Very strong direct associated between being female and the presentation of the condition, although no other associations are cited.

- The condition usually only affects women, although in rare cases it can also affect men [1].
- It almost exclusively affects women, and there are very few published case reports of men with lipoedema [2].

4 Activity and finance

Lipoedema is estimated to occur in 11% of the adult female population, meaning that millions of women worldwide are affected [5]. No further activity or finance data available.

5 Summary of findings

- There is no evidence available that directly compares the intervention with conservative management – where evidence testing the intervention is found it is applied to patient cohorts that have already received conservative management so any benefits reported for the intervention are in addition to any benefits already delivered by conservative treatment [1].
- The evidence [2] itself (consisting of three trials totalling 274 patients) along with the NHS website states that this is a relatively new and under researched condition. The study consisting of 164 patients clearly stated that they had “undergone conservative therapy over a period of years” and as such the benefits stated can be viewed as over and above those offered by conservative treatment.

- The studies [2] were consistent on their findings and provided moderate confidence that the research reflects the true effect, however the lack of RCTs (or direct comparison to no treatment on two of the studies) is noted.
- The health improvement benefits shown within the two trials, are directly comparable with the benefits requested within the PICO.
- The results suggest that there are both short and long-term sustained improvements in almost all dimensions around pain and Quality of Life (QoL), and one study substantiates this as over and above conservative treatment.
- There are statements that suggest lipoedema may develop into lymphoedemia, which is a serious condition. However, there was no evidence how often this may occur and whether this intervention would mitigate such development.
- Baseline health utility if living with the condition has been considered as high, with the capacity to benefit also being high (the results show almost universal improvement across patients).
- Very strong direct associated between being female and the presentation of the condition, although no other associations with socioeconomic factors are cited.

6 Search Strategy

The following databases were routinely searched: NICE Clinical Guidance and full website search; Cochrane; York; and the relevant Royal College and any other relevant bespoke sites. A Medline / Open Athens search was undertaken where indicated and a general google search for key terms was also undertaken.

6.1 PICO parameters:

Population: Patients with Lipoedema
Intervention: Liposuction
Comparator / Control: Conservative Treatment
Outcome: Clinical improvement in pain, Quality of Life (QoL)

7 References

[1] Lipoedema (2017) - https://www.nhs.uk/conditions/lipoedema/

[2]Liposuction in the Treatment of Lipedema: A Longitudinal Study (2017) - https://www.ncbi.nlm.nih.gov/pubmed/28728329

[3]Tumescent liposuction in lipoedema yields good long-term results (2017) - https://www.ncbi.nlm.nih.gov/pubmed/21824127

[4] Long-term benefit of liposuction in patients with lipoedema: a follow-up study after an average of 4 and 8 years (2015) - https://www.ncbi.nlm.nih.gov/pubmed/26574236

[5] Best Practice Guidelines (Wounds UK – 2017): The management of lipoedema https://www.lipoedema.co.uk/wp-content/uploads/2017/05/WUK_Lipoedema-BPS_Web.pdf

Evidence Review for Adenoidectomy

Question to be addressed

1. In patients with documented medical problems caused by obstruction of the airway by the adenoids and all conservative treatments have been exhausted is there evidence to support adenoidectomy?

Reason for review

NHS Birmingham and Solihull CCG, Sandwell and West Birmingham CCG, requested a rapid evidence review of the clinical and cost effectiveness of adenoidectomy for adults with a documented medical problem, caused by obstruction of the airway compared to alternative treatment options, to inform their decisions on commissioning policy development.

Options for commissioners:

1. The Committee considers that due to the limited quality of evidence of clinical and cost effectiveness for the use adenoidectomy compared to conservative treatment options, its use should be considered a low priority.
2. The Committee recommends that, due to the limited quality of evidence of its clinical and cost effectiveness, adenoidectomy should be offered ONLY to patients who have failed conservative treatment.
3. The Committee considers that there is sufficient evidence to suggest that the use of adenoidectomy in patients with enlarged adenoids which care causing documented medical probelms is at least as effective as alternative treatment options and the costs are comparable, therefore the decision about which approach to proceed with should be made after an informed discussion between the clinician and the individual person about the risks and benefits of each procedure.

Summary

Background

- Adenoids are small lumps of tissue at the back of the nose, above the roof of the mouth.
- Adenoids are part of the immune system, which helps fight infection and protects the body from bacteria and viruses.
- By age seven to eight, the adenoids start to shrink and by the late teens, they're barely visible. By adulthood, they should have disappeared completely.
- Adenoidectomy is the surgical procedure to remove enlarged adenoids

Clinical effectiveness

- There was a paucity of evidence available to determine the clinical effectiveness of adenoidectomy, however NICE IPG supports this intervention.

Safety

NICE supports the use of adenoidectomy and deems it a safe intervention.

Cost effectiveness

NICE deems adenoidectomy with suction diathermy to be cost effective.

Equity issues

None were identified within the course of this review.

Context

1.1 Introduction

- Adenoids are small lumps of tissue at the back of the nose, above the roof of the mouth. You can't see a person's adenoids by looking in their mouth.
- Adenoids are part of the immune system, which helps fight infection and protects the body from bacteria and viruses.
- In most cases only children have adenoids. They start to grow from birth and are at their largest when a child is around three to five years of age. By age seven to eight, the adenoids start to shrink and by the late teens, they're barely visible. By adulthood, in most people they will have disappeared completely.
- Adenoids can be helpful in young children, but they're not an essential part of an adult's immune system. This is why they shrink and eventually disappear.
- Adenoids can sometimes become swollen or enlarged. This can happen after a bacterial or viral infection, or after a substance triggers an allergic reaction.
- In most cases, swollen adenoids only cause mild discomfort and treatment isn't needed. However, for some, it can cause severe discomfort and interfere with their daily life.

Management

- The adenoids can be removed during an adenoidectomy.
- The operation is usually carried out by an ear, nose and throat (ENT) surgeon and takes around 30 minutes. Afterwards, the patient will need to stay in the recovery ward for up to an hour until the anaesthetic has worn off.
- Adenoidectomies are sometimes day cases if carried out in the morning, in which case you / your child may be able to go home on the same day. However, if the

procedure is carried out in the afternoon, you / your child may need to stay in hospital overnight.

1.2 Existing national policies and guidance

NICE Interventional procedures guidance [IPG328] Suction diathermy adenoidectomy Published date: December 2009

- Guidance was published in 2009 on suction diathermy adenoidectomy which states that this procedure should only be carried out by trained surgeons who perform the procedure regularly.
- The use of adenoidectomy is considered by NICE to be an 'Interventional Procedure', and therefore is not 'approved' as may be the case for a drug or procedure subject to technology appraisal. NICE do not examine interventional procedures which are considered established practice unless there are data demonstrating uncertainty about their efficacy or safety.

- **Epidemiology**

There was a lack of epidemiology data available relating to adenoidectomy in adults.

- **Findings**

.1 Evidence of effectiveness

NICE IPG 328 found clinical effectiveness of the suction diathermy procedure, however no systematic reviews were found of adenoidectomy in adults / adolescents.

.1.1 Clinical effectiveness

Adenoidectomy is an accepted intervention in children with medical problems caused by enlarged adenoids.

However, there is very little available evidence on the use of adenoidectomy in adults with adenoid hypertrophy.

4.1.2 Trials in progress

A search of clinicaltrials.gov found no clinical trials currently recruiting for a review of adenoidectomy vs conservative management in either adults or children.

4.1.3 Cost-effectiveness

NICE deems adenoidectomy with suction diathermy to be cost effective.

.2 Safety

- NICE IPG 328 found clinical effectiveness and safety of the suction diathermy procedure.

.1 Summary of findings

There is a significant paucity of evidence available to review the use of adenoidectomy fully. However, the available evidence along with clinical review, supports the use of adenoidectomy in certain clinical circumstances.

- Equity issues

There is a greater occurrence rates of adenoidectomy in children as most adenoids have resolved by the time a child has reached the age of 8 years old.

- Search Strategy

PubMed:

Publication types, MeSH terms

Publication types

- Meta-Analysis
- Review
- Systematic Review

MeSH terms

- Adenoids/abnormalities*
- Humans
- Hypertrophy/diagnosis
- Hypertrophy/epidemiology*
- Prevalence

8. References

1. Kamel et al. 1990. Enlarged adenoid and adenoidectomy in adults: endoscopic approach and histopathological study. J Laryngol Otol. 1990 Dec;104(12):965-7.

2. Torretta et al. 2019. Surgical Treatment of Paediatric Chronic Rhinosinusitis. Clin Med. 2019 May 15;8(5). pii: E684. doi: 10.3390/jcm8050684. https://www.ncbi.nlm.nih.gov/pubmed/31096610

3. Vanneste et al. 2019. Otitis media with effusion in children: Pathophysiology, diagnosis, and treatment. A review. J Otol. 2019 Jun;14(2):33-39. doi: 10.1016/j.joto.2019.01.005. Epub 2019 Jan 31. https://www.ncbi.nlm.nih.gov/pubmed/31223299

4. Kugelman et al. Adenoid Obstruction Assessment in Children: Clinical Evaluation Versus Endoscopy and Radiography. Isr Med Assoc J. 2019 Jun;21(6):376-380. https://www.ncbi.nlm.nih.gov/pubmed/31280504

5. Durgut et al. 2019. The effect of adenoid hypertrophy on hearing thresholds in children with otitis media with effusion. Int J Pediatr Otorhinolaryngol. 2019 Jun 1;124:116-119. doi: 10.1016/j.ijporl.2019.05.046. https://www.ncbi.nlm.nih.gov/pubmed/31176025

6. Pereira et al. 2018. Prevalence of adenoid hypertrophy: A systematic review and meta-analysis. Sleep Med Rev. 2018 Apr;38:101-112. doi: 10.1016/j.smrv.2017.06.001. Epub 2017 Jun 14. https://www.ncbi.nlm.nih.gov/pubmed/29153763

Evidence Review for the Use of Non-Invasive Ventilation in a Domiciliary Setting

Question to be addressed

1. In adults with respiratory failure in:
    a. Chronic obstructive pulmonary disease
    b. Neuro-muscular disease
    c. Obstructive Sleep Apnoea

is there evidence to support the use of non-invasive domiciliary ventilation and if so, in what clinical circumstances is the use of domiciliary NIV appropriate?

Reason for review

NHS Birmingham and Solihull CCG, Sandwell and West Birmingham CCG, requested a rapid evidence review of the clinical and cost effectiveness of the use of domiciliary non-invasive ventilation in reducing hospital admissions and preventing death to inform their decisions on commissioning policy development.

Options for commissioners:

1. The Committee considers that due to the limited quality of evidence of clinical and cost effectiveness for the use of domiciliary non-invasive ventilation compared to alternative treatment options, its use should be considered a low priority.
2. The Committee recommends that, due to the limited quality of evidence of its clinical and cost effectiveness, the use of domiciliary non-invasive ventilation should be offered ONLY to patients who have certain clinical diagnoses and have a certain degree of respiratory failure.
3. The Committee considers that there is sufficient evidence to suggest that the use of domiciliary NIV is at least as effective as alternative treatment options and the costs are comparable, therefore the decision to commence non-invasive ventilation should be made after an informed discussion between the clinician and the individual person about the risks and benefits.

Summary

Background

- Respiratory Failure can occur in a number of clinical circumstances and can impact on a patient's ability to carry out activities of daily living and can ultimately result in death.
- Non-invasive ventilation can be undertaken using positive or negative pressure, though the most commonly used form of non-invasive ventilation is positive pressure.
- Positive pressure ventilation can be undertaken through continuous positive airway pressure through to bi-level ventilation.

Clinical effectiveness

- Clinical effectiveness of non-invasive ventilation was clearly identified in number of clinical scenarios:

.1 Chronic Obstructive Pulmonary Disease

.2 Neuromuscular Diseases
.3 Obstructive Sleep Apnoea

- NICE clearly supports the use of this intervention in OSA & Motor Neurone Disease.
- There is strong evidence not only for the clinical effectiveness of the use of NIV in certain clinical circumstances but also for the cost-effectiveness of this intervention in preventing deterioration in patient symptoms, readmission to an acute care setting and death.

Safety

NICE & MHRA support the use of Non-invasive ventilation support in certain clinical circumstances.

Cost effectiveness

A. COPD

No QALY identified within the literature.

B. NMD

Cost-effectiveness of the use of Non-invasive ventilation was supported by NICE (NG 42) with certain cohorts of this patient population diagnosed with NMD

C. OSA

Cost-effectiveness of the use of Non-invasive ventilation was supported by NICE (2012 TA139) with certain cohorts of this patient population diagnosed with OSA.

Equity issues

None were identified within the course of this review for OSA or Neuro-

dependent patient, however COPD was associated with deprivation. Major risk factors for developing COPD are smoking, and occupation dust exposure in patients over the age of 40 years old. Ensuring good smoking cessation support in all ages may help to reduce any inequity issues. Due to the links to smoking and exposure to dust and chemicals more likely to be found in manual labour roles, this would indicate indirect links with deprivation.

Context

1.1 Introduction

A. COPD

Chronic obstructive pulmonary disease (COPD) is the collective name for a group of lung conditions that may cause breathing difficulties.

It includes:

- emphysema – damage to the air sacs in the lungs
- chronic bronchitis – long-term inflammation of the airways

COPD is a common condition that mainly affects middle-aged or older adults who have a smoking history. The breathing problems tend to get gradually worse over time and can limit the patient's normal activities, although treatment can help keep the condition under control.

Symptoms of COPD

The main symptoms of COPD are:

- increasing breathlessness, particularly when the patient is active
- a persistent chesty cough with phlegm
- frequent chest infections
- persistent wheezing

Without treatment, the symptoms usually get slowly worse. There may also be periods when they get suddenly worse, known as a flare-up or exacerbation.

Causes of COPD

COPD occurs when the lungs become inflamed, damaged and narrowed. The main cause is smoking, although the condition can sometimes affect people who have never smoked.

The likelihood of developing COPD increases the more a patient smokes and the longer the patient has smoked. Some cases of COPD are caused by long-term exposure to harmful fumes, or dust or occur as a result of a rare genetic problem that means the lungs are more vulnerable to damage.

The damage to the lungs caused by COPD is permanent, but treatment can help slow down the progression of the condition.

B. NMD

Neuromuscular disorder (NMD) is a very broad term encompassing a range of conditions that impair the functioning of the muscles, either directly, being pathologies of the voluntary muscle, or indirectly, being pathologies of the peripheral nervous system or neuromuscular junctions. Other spinal cord or brain diseases are not considered “neuromuscular” diseases.

NMD affect the nerves controlling voluntary muscles. Voluntary muscles are the ones that can be controlled such as those in arms and legs. Nerve cells, also called neurons, send the messages that control these muscles. When the neurons become unhealthy or die, communication between the nervous system and muscles breaks down. As a result, muscles weaken and waste away. The weakness can lead to twitching, cramps, aches and pains, and joint and movement problems. Sometimes it also affects heart function and the ability to breathe.

Examples of NMD include:

- Motor Neurone Disease
- Multiple sclerosis
- Myasthenia gravis
- Spinal muscular atrophy.

Many NMD are genetic, which means they run in families or there is a gene mutation for example in muscle dystrophies. Sometimes, an immune system disorder can cause them as in myasthenia.

C. OSA

Apnoea is defined as a temporary absence or cessation of breathing. Obstructive Sleep Apnoea hypopnea syndrome (OSAHS) is a condition in which a person experiences repeated episodes of apnoea because of a narrowing or closure of the pharyngeal airway during sleep. This is caused by a decrease in the tone of the muscles supporting the airway during sleep. Complete closure (obstruction) stops airflow (apnoea) whereas partial obstruction decreases airflow (hypopnoea). OSAHS results in episodes of brief awakening from sleep to restore normal breathing.

Moderate to severe OSAHS can be diagnosed from patient history and a sleep study using oximetry or other monitoring devices carried out in the person's

home. In some cases, further studies that monitor additional physiological variables in a sleep laboratory or at home may be required, especially when alternative diagnoses are being considered. The severity of OSAHS is usually assessed on the basis of both severity of symptoms (particularly the degree of sleepiness) and the sleep study, by using either the apnoea/hypopnoea index (AHI) or the oxygen desaturation index. OSAHS is considered mild when the AHI is 5–14 in a sleep study, moderate when the AHI is 15–30, and severe when the AHI is over 30. In addition to the AHI, the severity of symptoms is also important.

The symptoms of OSAHS include impaired alertness, cognitive impairment, excessive daytime sleepiness, snoring, nocturia, morning headaches and sexual dysfunction. The sleep quality of partners may also be affected. Excessive daytime sleepiness can adversely affect cognitive function, mood and quality of life. OSAHS is associated with high blood pressure, which increases the risk of cardiovascular disease and stroke. OSAHS has also been associated with an increased risk of road traffic accidents.

Major risk factors for developing OSAHS are increasing age, obesity and being male. OSAHS is also associated with certain specific craniofacial characteristics (such as retrognathia), enlarged tonsils and enlarged tongue. Use of alcohol or sedatives can also increase the risk or severity of the condition. OSAHS has been reported to affect up to 4% of middle-aged men and 2% of middle-aged women in the UK. It is estimated that 1% of men in the UK may have severe OSAHS.

Management

Noninvasive ventilation (NIV) refers to the administration of ventilatory support without using an invasive artificial airway (endotracheal tube or tracheostomy tube). The use of noninvasive ventilation has markedly increased over the past three decades, and noninvasive ventilation has now become an integral tool in the management of both acute and chronic respiratory failure, in both the home setting and in critical care.

In its simplest terms, noninvasive ventilation differs from invasive ventilation by the interface between the patient and the ventilator. Invasive ventilatory support is provided via either an endotracheal tube or tracheostomy tube. Noninvasive ventilatory support uses a variety of interfaces, and these have continued to evolve with modifications based on patient comfort and efficacy. Many of the interfaces or masks were initially used in patients with obstructive sleep apnea before they were adapted for use in patients to provide noninvasive ventilatory support.

Nasal masks and orofacial masks were the earliest interfaces, with subsequent development and use of full-face masks, mouthpieces, nasal pillows, and helmets. Nasal masks and orofacial masks are still the most commonly used interfaces. Orofacial masks are used almost twice as frequently as nasal masks. Both have advantages and disadvantages in the application of noninvasive ventilation.

1.2 Existing national policies and guidance

National Guidance for the provision of aspects of specialist non-ventilation services to patients exists for some individual patient groups e.g. Motor Neurone Disease (MND), Duchene's Muscular Dystrophy; and for broader categories of patients e.g. weaning guidance; and around specific technologies e.g. diaphragmatic pacing and tracheostomies. There are some national standards (NICE, 2010; 2016) available and some specialist society guidance (BTS/ICS 2016).

Provision of complex home ventilation services also falls within the NHS Outcomes Framework Domain 1 - preventing people from dying prematurely where Improvement Area 1a specifically identifies reducing mortality from respiratory disease, and Domain 2 – enhancing quality of life for patients with long term conditions.

Guidance supports delivery of care by respiratory specialists working within MDTs. For example, the National Institute for Health and Clinical Excellence (NICE) clinical guideline (CG) around use of NIV in MND states that "multidisciplinary teams (MDT) should coordinate and provide on-going management and treatment for patients with MND, including regular respiratory assessment and provision of non-invasive ventilation. The team should include a neurologist, a respiratory physician, an MND specialist nurse, a respiratory specialist nurse, a specialist respiratory physiotherapist, a respiratory physiologist, a specialist in palliative care and a speech and language therapist". The guidance also outlines the support and training which need to be provided to the patient and their family and carers: "support and assistance to manage non-invasive ventilation which should include training on using non-invasive ventilation and ventilator interfaces, for example emergency procedures, night-time assistance if the patient is unable to use the equipment independently (for example, emergency removal or replacement of interfaces), how to use the equipment with a wheelchair or other mobility aids if required, what to do if the equipment fails, assistance with secretion management, information on general palliative strategies, an offer of on-going emotional and psychological support for the patient and their family and carers".

Ensuring NIV is delivered by competent respiratory professionals is emphasised in NICE MND guidance and also in the National Patient Safety Agency (NPSA) alert which identified cases where problems with administering NIV were stated as causing at least moderate harm: key issues included shortage of staff skills or staff time to set up and monitor NIV.

2 Epidemiology

A. Chronic Obstructive Pulmonary Disease

An estimated 1.2 million people are living with diagnosed COPD (BLF, 2019) – considerably more than the 835,000 estimated by the Department of Health in 2011. In terms of diagnosed cases, this makes COPD the second most common lung disease in the UK, after asthma. Around 2% of the whole population – 4.5% of all people aged over 40 – live with diagnosed COPD.

The number of people who have ever had a diagnosis of COPD has increased by 27% in the last decade, from under 1,600 to nearly 2,000 per 100,000. This could mean that more undiagnosed cases are being found, or that the disease is becoming more common. Changes in record-keeping could also be a factor.

However, prevalence increased by 9% between 2008 and 2012, while record-keeping practices remained the same. Research has indicated that up to two-thirds of people with COPD remain undiagnosed.

In 2012, 29,776 people died from COPD (5.3 per cent of the total number of UK deaths and 26.1 per cent of deaths from lung disease). Of these, 15,245 were males and 14,531 were females. The total number of deaths was up from 28,344 in 2008.

B. Neuromuscular Disorders

Deenen et al 2015 found incidence rates for ten neuromuscular disorders, ranging from 0.05 to 9 per 100,000/yr. Most NMDs showed prevalence rates between 1 and 10 per 100,000 population, except for multifocal motor neuropathy,

C. Obstructive Sleep Apnoea

OSA is common, affecting an estimated 1.5 million adults in the UK, and yet up to 85% are undiagnosed, therefore untreated. Only an estimated 330,000 adults are currently being treated, out of an OSA population of 1.5 million. (BLF 2015)

3 The interventions

Noninvasive positive-pressure ventilation

Positive-pressure ventilation delivered through a mask, has become the predominant method of providing noninvasive ventilatory support. Early bedside physiologic studies in healthy patients and in patients with respiratory conditions document successful ventilatory support (ie, reduction in respiratory rate, increase in tidal volume, decrease in dyspnea) with reduction in diaphragmatic electromyography (EMG), transdiaphragmatic pressures, work of breathing and improvement in oxygenation with a reduction in hypercapnia.

Ventilatory support can be achieved through a variety of interfaces (mouth piece or nasal, face, or helmet mask), using a variety of ventilatory modes (eg, volume ventilation, pressure support, bilevel positive airway pressure [BiPAP], proportional-assist ventilation [PAV], continuous positive airway pressure [CPAP]) with either ventilators dedicated to noninvasive ventilation (NIV) or those capable of providing support through an endotracheal tube or mask. Older models of noninvasive ventilators required oxygen to be bled into the system, but current models incorporate oxygen blenders for precise delivery of the fraction of inspired oxygen (FIO_2).

Noninvasive negative-pressure ventilation

Negative-pressure ventilators provide ventilatory support using a device that encases the thoracic cage starting from the neck, and devices range from a whole-body tank to a cuirass shell. The general principal is the same with a vacuum device, which lowers the pressure surrounding the thorax, creating sub-atmospheric pressure and thereby passively expanding the chest wall with diaphragmatic descent, all leading to lung inflation. Exhalation occurs with passive recoil of the chest wall.

This was the predominant technology during the polio epidemics, but these devices were bulky and cumbersome to use. Upper airway obstruction was also a problem. These ventilators have been largely supplanted by the more widespread positive-pressure noninvasive ventilators; however, some patients continue to be treated with this modality. While the bulk of the experience lies in patients with chronic respiratory failure, specifically neuromuscular respiratory failure, reports described successful application in patients with acute respiratory failure.

Current use of Non-invasive Ventilation devices.

With respect to the two modes, positive-pressure ventilation has supplanted negative-pressure ventilation as the dominant mode of delivery of noninvasive ventilation. Positive-pressure ventilation is more effective than negative-pressure ventilation in unloading the respiratory muscles, at least under investigational conditions. The primary focus of this policy is domiciliary positive-pressure noninvasive ventilation, and the mention of "noninvasive ventilation" will refer to positive-pressure delivery.

Many patients who are assessed as requiring noninvasive ventilation are provided support with pressure ventilation, i.e. continuous positive airway pressure (CPAP), which is the most basic level of support. CPAP pumps a steady flow of air at constant pressure through the nose to prevent the narrowing or collapse of air passages or to help the lungs to expand. CPAP may be especially useful in patients with congestive heart failure or obstructive sleep apnea.

Bilevel positive airway pressure (BiPAP) is probably the most common mode of noninvasive positive pressure ventilation and requires provisions for inspiratory positive airway pressure (IPAP) and expiratory positive airway pressure (EPAP). The difference between IPAP and EPAP is a reflection of the amount of pressure support ventilation provided to the patient, and EPAP is synonymous with positive end-expiratory pressure (PEEP). Some noninvasive ventilation is provided using proportional-assist ventilation (PAV), which provides flow and volume assistance with each breath. Clinical trials have not demonstrated a significant difference between PAV and pressure-support ventilation with BiPAP. [5, 6] However, BiPAP is the most commonly available and more frequently used modality for noninvasive ventilation. PAV remains available on many ventilator models, but use is much less common than BiPAP.

4 Findings

4.1 Evidence of effectiveness

4.1.1 Clinical effectiveness

A. COPD

Murphy et al (2017), undertook a randomized clinical trial of patients with persistent hypercapnia (PaCO2 >53mmHg), a total of 116 patients (mean [SD] age of 67 [10] years, 53%female, mean BMI of 21.6 [IQR, 18.2-26.1], mean [SD] forced expiratory volume in the first second of expiration of 0.6 L [0.2 L], and mean [SD] PaCO2 while breathing room air of 59 [7]mmHg) were randomized. Sixty-four patients (28 in home oxygen alone and 36 in home oxygen plus home NIV) completed the 12-month study period. The median time to readmission or death was 4.3 months (IQR, 1.3-13.8 months) in the home oxygen plus home NIV group vs 1.4 months (IQR, 0.5-3.9 months) in the home oxygen alone group, adjusted hazard ratio of 0.49 (95% CI, 0.31-0.77; *P* = .002). The 12-month risk of readmission or death was 63.4%in the home oxygen plus home NIV group vs 80.4%in the home oxygen alone group, absolute risk reduction of 17.0%(95%CI, 0.1%-34.0%). At 12 months, 16 patients had died in the home oxygen plus home NIV group vs 19 in the home oxygen alone group. Among patients with persistent hypercapnia following an acute exacerbation of COPD, adding home noninvasive ventilation to home oxygen therapy prolonged the time to readmission or death within 12 months.

B. NMD

Very strong recent NICE guidance, and repeated studies which found clinically and statistically significant benefits. Radunovic et al 2017 stated that it would be unethical to have a control group in future RCTs, indicating that equipoise is no longer a question.

A systematic review by Radunovic et al 2017 found good basis for the use of non-invasive ventilation in certain Motor Neurone Disease cohorts of patients:

The conclusions of the review were based on a single RCT on 41 participants. The study provided modest quality evidence that overall median survival was significantly different between the group treated with NIV and the standard care group.
Low-quality evidence indicates that it improves or maintains quality of life in people with ALS.
Survival and quality of life were significantly improved in the subgroup of people with better bulbar function, but not in those with severe bulbar impairment. Adverse effects related to NIV should be systematically reported, as at present there is little information on this subject. More RCT evidence to support the use of NIV in ALS will be difficult to generate, as not offering NIV to the control group is no longer ethically justifiable.

This is also supported by D' Cruz et al. 2018

NIV has been shown to improve quality of life for patients with MND. In a randomised controlled trial, Bourke and colleagues randomised MND patients with orthopnoea, MIP <60% predicted or symptomatic daytime hypercapnia to NIV or standard care. NIV was associated with sustained improvements in quality of life, with the greatest improvements observed in the domains relating to sleep problems, despite an observed reduction in REM sleep. This supports the findings of smaller prospective studies which have demonstrated sustained improvements in patient-reported outcomes amongst MND patients, including sleep quality, duration and efficiency, reduced sleep disturbance and improved and daytime somnolence, following initiation of NIV.

Similar positive impacts have also been identified within the paediatric population by Katz et al 2004:

NPPV can decrease hospitalisations for children with neuromuscular disease and improves sleep related respiratory parameters. A prospective study is now needed to further delineate the role of NPPV in this population of children.

This was supported by Falsaperla et al. in 2014: We found a statistically significant improvement of the lowest oxygen desaturation (nadir SaO2), apnoea-hypopnoea index (AHI) and oxygen desaturation index (ODI) after NIV treatment in all patients. Mean SaO2 also improved, although this result was not statistical significant, while the percentage of episodes of desaturation with a SaO2 <90% and <80% decreased with a statistical significance (P < 0.0001). After NIV, only one patient showed an episode of desaturation lasting more than 5 min (10.6 min length), and we also found an improvement of daytime blood gas parameters with a normalization of these indexes.

C. OSA

Extensive NICE guidance (NICE 2007;2012; 2017) supported by meta-analyses, Cochrane review, and primary studies supports the use of Continuous Positive Airway pressure for the treatment of moderate to severe obstructive sleep apnoea and mild sleep apnoea with certain presenting symptoms. Alternative treatments to CPAP are discussed however the evidence of efficacy for surgery is, as yet, inconclusive.

In the NICE 2012 guidance 139, the Assessment Group identified 23 RCTS that compared CPAP with placebo or usual care using the Epworth Sleepiness Scale (ESS). A meta-analysis of these studies identified a statistically significantly greater reduction in daytime sleepiness with CPAP compared with placebo or usual care (weighted mean difference in ESS score −2.7; 95% confidence interval [CI] −3.5 to −2.0).

The NICE Assessment Group undertook a series of meta-analyses that compared the effect of CPAP on levels of daytime sleepiness in different populations. This showed a statistically significantly greater reduction in daytime sleepiness with CPAP compared

with placebo for moderate and severe categories of OSAHS. For mild OSAHS (meta-analysis of 3 studies; AHI = 5–14 episodes per hour) a weighted mean difference in ESS score of −1.5 (95% CI −3.4 to 0.4) was found. For moderate OSAHS (meta-analysis of 7 studies; AHI = 15–30 episodes per hour) a weighted mean difference in ESS score of −2.0 (95% CI −3.0 to −1.1) was found. For severe OSAHS (meta-analysis of 13 studies; AHI = over 30 episodes per hour) a weighted mean difference in ESS score of −3.4 (95% CI −4.6 to −2.3) was found.

4.1.2 Trials in progress

A search of clinicaltrials.gov using the search terms domiciliary non-invasive ventilation found the following trials currently recruiting:

Terms	Search Results*	Entire Database**
Synonyms		
domiciliary	11 studies	73 studies
non-invasive ventilation	10 studies	402 studies
ventilation	11 studies	6,696 studies
Respiration	6 studies	4,908 studies
breathing	--	894 studies
respiratory assist	--	6 studies
Respiratory function	--	144 studies
non-invasive	11 studies	2,231 studies

1. Assist Control Versus Pressure Support Modes for **Domiciliary Noninvasive Ventilation** in Chronic Respiratory Failure. ClinicalTrials.gov Identifier: NCT00189527
2. Impact of Early **Non Invasive Ventilation** in Amyotrophic Lateral Sclerosis (ALS) Patients
3. Effect of the Integrated Tele-monitoring Management of NIV Treatment
4. Autotitrating Versus Standard **Non-invasive Ventilation** (NIV) in Newly Diagnosed Patients
5. Trial of **Non-invasive Ventilation** for Stable COPD

6. Assesment of Muscular Unloading in Chronic Obstructive Pulmonary Disease (COPD) Patients With NIV
7. **on-invasive Ventilation** Versus Sham **Ventilation** in Chronic Obstructive Pulmonary Disease (COPD)
8. What do built-in Softwares in Home Ventilators Tell us?
9. Prospective Cohort of Respiratory Insufficiency Outcome
10. **Non-invasive** Ventilator Modems: a Qualitative Study
11. Tracheostomized COPD Patients and **Non Invasive** Mechanical **Ventilation**

4.1.3 Cost-effectiveness

A. COPD

None of the studies identified contained QALY measures, however reduction in repeated hospital admissions with the use of domiciliary NIV within this patient cohort was shown in a number of studies. (Murphy et al 2017)

B. NMD

None of the studies identified contained QALY measures so cost effectiveness could not be determined.

C. OSA

NICE assessment group (2012) identified four published economic evaluations all of which compared CPAP with a 'do nothing' alternative. The resulting incremental cost-effectiveness ratios (ICERs) were: (1) US $3354 (approximately £1688; currency conversions were calculated in August 2007) per quality-adjusted life year (QALY) gained from a third-party payer perspective and US $314 (£158) per QALY gained from a societal perspective; (2) €7861 (£5348) per QALY gained over a 5-year time horizon and €4938 (£3359) per QALY gained for a lifetime time horizon; (3) £8300 per QALY gained at 1 year and £5200 per QALY gained at 2 years; (4) Can $9809 (£4654) per QALY gained for the high-cost estimate and Can $3523 (£1672) per QALY gained for the low-cost estimate.

Only two of the NICE Assessment Group's subgroup and scenario analyses resulted in pronounced changes to the base-case ICERs. When the lifespan of the device was changed from 7 to 5 years and an auto-titrating device plus humidifier was used instead of a fixed-pressure device, the ICER was £16,362 per QALY gained. When cardiovascular events and road traffic accidents were excluded in the analysis for the total population (all severities of OHAHS), the ICER was approximately £8000 per QALY gained.

4.2 Safety

NICE
Support of use in: a subset of section B. patients with Motor Neurone Disease & C. OSA

Medicines and Healthcare Products Regulatory Authority (MHRA) support the use of a number of NIV devices.

5 Equity issue

A. COPD

Major risk factors for developing COPD are smoking, and occupation dust exposure in patients over the age of 40 years old. Ensuring good smoking cessation support in all ages may help to reduce any inequity issues. Due to the links to smoking and exposure to dust and chemicals more likely to be found in manual labour roles, this would indicate indirect links with deprivation.

B. NMD

None of the studies identified discussed health inequality measures.

C. OSA

Major risk factors for developing OSAHS are increasing age, obesity and being male. OSAHS is also associated with certain specific craniofacial characteristics (such as retrognathia), enlarged tonsils and enlarged tongue. Use of alcohol or sedatives can also increase the risk or severity of the condition. OSAHS has been reported to affect up to 4% of middle-aged men and 2% of middle-aged women in the UK. It is estimated that 1% of men in the UK may have severe OSAHS.

6 Discussion and conclusions

A. COPD

There is evidence to support the addition to patients with persistent hypercapnia following an acute exacerbation of COPD, of home non-invasive ventilation to home oxygen therapy prolonged the time to readmission or death within 12 months.

B. NMD

High quality evidence to support the use of non-invasive ventilation within certain patient groups within this cohort of patients. Clinical review should be ensured with patients with severely impaired bulbar function to ensure tolerance of the intervention.

C. OSA

Clinical and cost-effective use of CPAP in more moderate / severe instances of OSA are clearly demonstrated within the literature. Use in those with a mild diagnosis of OSA is demonstrated when the patient is symptomatic.

7 Search Strategy

A. COPD

Population: Person with COPD (and similar conditions) Breathing Impairment Having Experienced a Recent Exacerbation

Intervention: Self-Administered / Home-Based Routine Non-Invasive Ventilation / Continuous Positive Airway Pressure (excludes acute episodes and Long Term Oxygen Therapy)

Comparator / Control: No intervention / Alternative treatments
Outcome: Quality of Life and Survival Benefit

B. NMD

Population: Person with Neurologically Dependent Breathing Impairment
Intervention: Self-Administered / Home-Based Routine Non-Invasive Ventilation / Continuous Positive Airway Pressure (excludes acute episodes and Long Term Oxygen Therapy)
Comparator / Control: No intervention
Outcome: Quality of Life and Survival Benefit

C. OSA

Population: Persons with Sleep Apnoea
Intervention: Self-Administered / Home-Based Routine Non-Invasive Ventilation / Continuous Positive Airway Pressure (excludes acute episodes and Long Term Oxygen Therapy)
Comparator / Control: No intervention / Alternative treatments
Outcome: Quality of Life and Wider Health Benefits

8 References

1. British Lung Foundation (BLF) 2019. Chronic obstructive pulmonary disease (COPD) statistics. https://www.blf.org.uk/?_ga=2.219377177.1205961109.1564051606-1530561031.1560162537&_gac=1.247269040.1564051606.EAIaIQobChMI5q78tfLP4wIVzLTtCh3j-QJkEAAYASAAEgLKnfD_BwE

2. British Lung Foundation (BLF) 2015 Obstructive Sleep Apnoea: Toolkit for commissioning and planning local NHS services in the UK. https://www.blf.org.uk/sites/default/files/OSA_Toolkit_2015_BLF_0.pdf

3. Deenen et al. 2015 The Epidemiology of Neuromuscular Disorders: A Comprehensive Overview of the Literature. Journal of Neuromuscular Diseases 2 (2015) 73–85 DOI 10.3233/JND-140045 https://pdfs.semanticscholar.org/edf8/cb210b7371b45811ab221dd1c31233079191.pdf

4. NICE 2017 Hypoglossal nerve stimulation for moderate to severe obstructive sleep apnoea (2017) - ttps://www.nice.org.uk/guidance/ipg598

5. NICE 2007 Soft-palate implants for obstructive sleep apnoea (2007) - https://www.nice.org.uk/guidance/ipg241

6. NICE 2012 Continuous positive airway pressure for the treatment of obstructive sleep apnoea/hypopnoea syndrome (2008, reviewed 2012) - https://www.nice.org.uk/guidance/ta139

7. Khan et al. 2018. A meta-analysis of continuous positive airway pressure therapy in prevention of cardiovascular events in patients with obstructive sleep apnoea. *European Heart Journal*, Volume 39, Issue 24, 21 June 2018, Pages 2291–2297, https://doi.org/10.1093/eurheartj/ehx597

8. Corrado A, Gorini M, Melej R, et al. Iron lung versus mask ventilation in acute exacerbation of COPD: a randomised crossover study. *Intensive Care Med*. 2009 Apr. 35(4):648-55.

9. Parke RL, McGuinness SP. Pressures delivered by nasal high flow oxygen during all phases of the respiratory cycle. *Respir Care*. 2013 Oct. 58 (10):1621-4.

10. Spoletini G, Alotaibi M, Blasi F, Hill NS. Heated Humidified High-Flow Nasal Oxygen in Adults: Mechanisms of Action and Clinical Implications. *Chest*. 2015 Jul. 148 (1):253-61.
11. Ozsancak A, Sidhom S, Liesching TN, Howard W, Hill NS. EVALUATION OF THE TOTAL FACE MASKTM FOR NONINVASIVE VENTILATION TO TREAT ACUTE RESPIRATORY FAILURE. *Chest*. 2011 Feb 17.
12. Wysocki M, Richard JC, Meshaka P. Noninvasive proportional assist ventilation compared with noninvasive pressure support ventilation in hypercapnic acute respiratory failure. *Crit Care Med*. 2002 Feb. 30 (2):323-9.
13. Fernández-Vivas M, Caturla-Such J, González de la Rosa J, Acosta-Escribano J, Alvarez-Sánchez B, Cánovas-Robles J. Noninvasive pressure support versus proportional assist ventilation in acute respiratory failure. *Intensive Care Med*. 2003 Jul. 29 (7):1126-33.
14. Hoo, G. 2018. Noninvasive Ventilation. Medscape. https://emedicine.medscape.com/article/304235-overview#a5
15. British Thoracic Society/Intensive Care Society Acute Hypercapnic Respiratory Failure Guideline Development Group. 2016. BTS/ICS Guidelines for the Ventilatory Management of Acute Hypercapnic Respiratory Failure in Adults. Journal of the British Thoracic Society. http://thorax.bmj.com/site/about/guidelines.xhtml#open
16. National Institute for Health and Clinical Excellence (NICE). Motor neurone disease: assessment and management**.** NICE guideline [NG42] Published date: February 2016 Last updated: July 2019
17. National Institute for Health and Clinical Excellence (NICE). *Chronic Obstructive Pulmonary Disease in Over 16s: Diagnosis and Management [CG101]*. London, England: NICE; 2010. https://www.nice.org.uk/guidance/ng42

18.Guidance – A: COPD

19. Brochard L, Mancebo J,Wysocki M, et al. Noninvasive ventilation for acute exacerbations of chronic obstructive pulmonary disease. *N Engl J Med*. 1995;333(13):817-822.
20. Bott J, Carroll MP, Conway JH, et al. Randomised controlled trial of nasal ventilation in acute ventilatory failure due to chronic obstructive airways disease. *Lancet*. 1993;341(8860):1555-1557.
21. Connors AF Jr, Dawson NV, Thomas C, et al; SUPPORT Investigators (Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments). Outcomes following acute exacerbation of severe chronic obstructive lung disease. *Am J Respir Crit Care Med*. 1996;154(4 pt 1): 959-967.
22. 4. Murray I, Paterson E, Thain G, Currie GP. Outcomes following non-invasive ventilation for hypercapnic exacerbations of chronic obstructive pulmonary disease. *Thorax*. 2011;66(9):825-826.

23. 5. Chu CM, Chan VL, Lin AW,Wong IW, LeungWS, Lai CK. Readmission rates and life threatening events in COPD survivors treated with non-invasive ventilation for acute hypercapnic respiratory failure. *Thorax*. 2004;59(12):1020-1025.
24. Suh ES, Mandal S, Harding R, et al. Neural respiratory drive predicts clinical deterioration and safe discharge in exacerbations of COPD. *Thorax*. 2015;70(12):1123-1130.
25. Nickol AH, Hart N, Hopkinson NS, et al. Mechanisms of improvement of respiratory failure in patients with COPD treated with NIV. *Int J Chron Obstruct Pulmon Dis*. 2008;3(3):453-462.
26. Meecham Jones DJ, Paul EA, Jones PW, Wedzicha JA. Nasal pressure support ventilation plus oxygen compared with oxygen therapy alone in hypercapnic COPD. *Am J Respir Crit Care Med*. 1995;152(2):538-544.
27. ElliottMW, Mulvey DA,Moxham J, Green M, Branthwaite MA. Domiciliary nocturnal nasal intermittent positive pressure ventilation in COPD: mechanisms underlying changes in arterial blood gas tensions. *Eur Respir J*. 1991;4(9):1044-1052.
28. Lloyd-Owen SJ, Donaldson GC, Ambrosino N, et al. Patterns of home mechanical ventilation use in Europe: results from the Eurovent survey. *Eur Respir J*. 2005;25(6):1025-1031.
29. Clini E, Sturani C, Rossi A, et al; Rehabilitation and Chronic Care Study Group, Italian Association of Hospital Pulmonologists (AIPO). The Italian multicentre study on noninvasive ventilation in chronic obstructive pulmonary disease patients. *Eur Respir J*. 2002;20(3):529-538.
30. McEvoy RD, Pierce RJ, Hillman D, et al; Australian trial of non-invasive Ventilation in
31. Chronic Airflow Limitation (AVCAL) Study Group. Nocturnal non-invasive nasal ventilation in stable hypercapnic COPD: a randomised controlled trial. *Thorax*. 2009;64(7):561-566.
32. 13. WindischW. Noninvasive positive pressure ventilation in COPD. *Breathe*. 2011;8(2):114-123.
33. Köhnlein T, WindischW, Köhler D, et al. Non-invasive positive pressure ventilation for the treatment of severe stable chronic obstructive pulmonary disease: a prospective, multicentre, randomised, controlled clinical trial. *Lancet Respir Med*. 2014;2(9):698-705.
34. Struik FM, Sprooten RT, Kerstjens HA, et al. Nocturnal non-invasive ventilation in COPD patients with prolonged hypercapnia after ventilatory support for acute respiratory failure: a randomised, controlled, parallel-group study. *Thorax*. 2014;69(9):826-834.
35. Altman DG, Bland JM. Treatment allocation by minimisation. *BMJ*. 2005;330(7495):843.
36. Murphy PB, Brignall K, Moxham J, Polkey MI, Davidson AC, Hart N. High pressure versus high intensity noninvasive ventilation in stable hypercapnic chronic obstructive pulmonary disease: a randomized crossover trial. *Int J Chron Obstruct Pulmon Dis*. 2012;7:811-818.
37. National Institute for Health and Clinical Excellence (NICE). Motor neurone disease: assessment and management**.** NICE guideline [NG42] Published date: February 2016 Last updated: July 2019

38. National Institute for Health and Clinical Excellence (NICE). *Chronic Obstructive Pulmonary Disease in Over 16s: Diagnosis and Management [CG101]*. London, England: NICE; 2010. https://www.nice.org.uk/guidance/ng42
39. Bestall JC, Paul EA, Garrod R, Garnham R, Jones PW,Wedzicha JA. Usefulness of the Medical Research Council (MRC) dyspnoea scale as a measure of disability in patients with chronic obstructive pulmonary disease. *Thorax*. 1999;54(7): 581-586.
40. Ghosh D, Rzehak P, ElliottMW, WindischW. Validation of the English Severe Respiratory Insufficiency Questionnaire. *Eur Respir J*. 2012;40 (2):408-415.
41. Jones PW, Quirk FH, Baveystock CM. The St George's Respiratory Questionnaire. *Respir Med*. 1991;85(suppl B):25-31.
42. Jones PW. St George's Respiratory Questionnaire: MCID. *COPD*. 2005;2(1):75-79.
43. Kahan BC, Morris TP. Improper analysis of trials randomised using stratified blocks or minimisation. *Stat Med*. 2012;31(4):328-340.
44. Costello R, Deegan P, Fitzpatrick M, McNicholasWT. Reversible hypercapnia in chronic obstructive pulmonary disease: a distinct pattern of respiratory failure with a favourable prognosis. *Am J Med*. 1997;102(3):239-244.
45. Seemungal TA, Donaldson GC, Paul EA, Bestall JC, Jeffries DJ,Wedzicha JA. Effect of exacerbation on quality of life in patients with chronic obstructive pulmonary disease. *Am J Respir Crit Care Med*. 1998;157(5 pt 1):1418-1422.
46. De Backer L, VosW, Dieriks B, et al. The effects of long-term noninvasive ventilation in hypercapnic COPD patients: a randomized controlled pilot study. *Int J Chron Obstruct Pulmon Dis*. 2011;6:615-624.
47. Gates KL, Howell HA, Nair A, et al. Hypercapnia impairs lung neutrophil function and increases mortality in murine pseudomonas pneumonia. *Am J Respir Cell Mol Biol*. 2013;49(5):821-828.
48. Pepperell JC, Ramdassingh-Dow S, Crosthwaite N, et al. Ambulatory blood pressure after therapeutic and subtherapeutic nasal continuous positive airway pressure for obstructive sleep apnoea: a randomised parallel trial. *Lancet*. 2002;359(9302):204-210.
49. Saatci E, Miller DM, Stell IM, Lee KC, Moxham J. Dynamic dead space in face masks used with noninvasive ventilators: a lung model study. *Eur Respir J*. 2004;23(1):129-135.
50. Rodway GW,Weaver TE, Mancini C, et al. Evaluation of sham-CPAP as a placebo in CPAP intervention studies. *Sleep*. 2010;33(2):260-266.
51. Djavadkhani Y, Marshall NS, D'Rozario AL, et al. Ethics, consent and blinding: lessons from a placebo/sham controlled CPAP crossover trial. *Thorax*. 2015;70(3):265-269.
52. Schwartz SW, Cimino CR, Anderson WM. CPAP or placebo-effect? *Sleep*. 2012;35(12):1585- 1586.
53. Murphy, P. Rehal, S. et al. 2017. Effect of Home Noninvasive Ventilation With Oxygen Therapy vs Oxygen Therapy Alone on Hospital Readmission or Death After an Acute COPD Exacerbation: A Randomized Clinical Trial. *JAMA.* 2017;317(21):2177-2186. doi:10.1001/jama.2017.4451. https://jamanetwork.com/journals/jama/issue/317/21
54. Murphy P, Arbane G, Phillips R, Hart N. S37 Home mechanical ventilation (HMV) and home oxygen therapy (HOT) following an acute exacerbation of COPD in patients with persistent hypercapnia: results of the per protocol analysis from the HOT-HMV

UK trial. *Thorax* 2017; 72: A25– A6.
https://onlinelibrary.wiley.com/doi/full/10.1111/resp.13484

Guidance B. - NMD

55. Joshua O. Benditt1 and Louis J. Boitano. Pulmonary Issues in Patients with Chronic Neuromuscular Disease. Am J Respir Crit Care Med Vol 187, Iss. 10, pp 1046–1055, May 15, 2013
56. Miller RG, Jackson CE, Kasarskis EJ, England JD, Forshew D, Johnston W, Kalra S, Katz JS, Mitsumoto H, Rosenfeld J, et al.; Quality Standards Subcommittee of the American Academy of Neurology. Practice parameter update: the care of the patient with amyotrophic lateral sclerosis: drug, nutritional, and respiratory therapies (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology 2009;73: 1218–1226.
57. Bourke SC, Gibson GJ. Sleep and breathing in neuromuscular disease. Eur Respir J 2002;19:1194–1201.
58. Birnkrant DJ, Panitch HB, Benditt JO, Boitano LJ, Carter ER, Cwik VA, Finder JD, Iannaccone ST, Jacobson LE, Kohn GL, et al. American College of Chest Physicians consensus statement on the respiratory and related management of patients with Duchenne muscular dystrophy undergoing anesthesia or sedation. Chest 2007; 132:1977–1986.
59. Mehta S, Hill NS. Noninvasive ventilation. Am J Respir Crit Care Med 2001;163:540–577.
60. Eagle M, Baudouin SV, Chandler C, Giddings DR, Bullock R, Bushby K. Survival in Duchenne muscular dystrophy: improvements in life expectancy since 1967 and the impact of home nocturnal ventilation. Neuromuscul Disord 2002;12:926–929.
61. Toussaint M, Steens M, Wasteels G, Soudon P. Diurnal ventilation via mouthpiece: survival in end-stage Duchenne patients. Eur Respir J 2006; 28:549–555
62. Radunovic A, Annane D, Jewitt K, Mustfa N. Mechanical ventilation for amyotrophic lateral sclerosis/motor neuron disease. Cochrane Database Syst Rev 2009;4:CD004427. Update in: Cochrane Database Syst Rev 2013;3:CD004427.
63. Motor neurone disease: assessment and management (2016) - https://www.nice.org.uk/guidance/ng42/chapter/Recommendations#non-invasiv ventilation
64. Outcome of non-invasive positive pressure ventilation in paediatric neuromuscula disease (2004) - https://www.ncbi.nlm.nih.gov/pubmed/14736624
65. Effects of non-invasive ventilation on survival and quality of life in patients with ar yotrophic lateral sclerosis: a randomised controlled trial (2006) - https://www.ncbi.nlm.nih.gov/pubmed/16426990
66. Non-invasive ventilation in amyotrophic lateral sclerosis: a 10 year population bas study (2012) - https://www.ncbi.nlm.nih.gov/pubmed/22013242

67. Mechanical ventilation for amyotrophic lateral sclerosis/motor neuron disease (2017) - https://www.ncbi.nlm.nih.gov/pubmed/28982219

68. Outcome of non-invasive positive pressure ventilation in paediatric neuromuscular disease (2004) - https://www.ncbi.nlm.nih.gov/pubmed/14736624

69. Polysomnographic evaluation of non-invasive ventilation in children with neuromuscular disease (2014) - https://www.ncbi.nlm.nih.gov/pubmed/24033486

70. Mechanical ventilation for amyotrophic lateral sclerosis/motor neuron disease (2017) - https://www.ncbi.nlm.nih.gov/pubmed/28982219

71. Sleep disordered breathing in motor neurone disease (2018) - http://jtd.amegroups.com/article/view/18178/14526

72. The use of non-invasive ventilation at end of life in patients with motor neurone disease: a qualitative exploration of family carer and health professional experiences (2013) - https://www.ncbi.nlm.nih.gov/pubmed/23462702

73. Sheehan, D. Birnkrant, J. et al. 2018. Respiratory Management of the Patient With Duchenne Muscular Dystrophy Paediatrics, October 2018, vol 142 https://pediatrics.aappublications.org/content/142/Supplement_2/S62

74. Hamada et al. 2011. Indicators for ventilator use in Duchenne muscular dystrophy. Respiratory Medicine. Volume 105, Issue 4, April 2011, Pages 625-629. https://www.sciencedirect.com/science/article/pii/S0954611110005317#tbl1

75. Birnkrant et al 2010. The Respiratory Management of Patients With Duchenne Muscular Dystrophy: A DMD Care Considerations Working Group Specialty Article. Pediatric Pulmonology. DOI 10.1002/ppul.21254. http://muscle.ca/wp-content/uploads/2012/11/Respirarory_Management_DMD_Publication_2010.pdf

Guidance – C. - OSA

76. NICE. 2008. Continuous positive airway pressure for the treatment of obstructive sleep apnoea/hypopnoea syndrome. Technology appraisal guidance. Published: 26 March 2008. Updated Feb 2014. nice.org.uk/guidance/ta139

77. Hypoglossal nerve stimulation for moderate to severe obstructive sleep apnoea (2017) - https://www.nice.org.uk/guidance/ipg598

78. Soft-palate implants for obstructive sleep apnoea (2007) - https://www.nice.org.uk/guidance/ipg241

79. A meta-analysis of continuous positive airway pressure therapy in prevention of cardiovascular events in patients with obstructive sleep apnoea (2017) - https://academic.oup.com/eurheartj/article-abstract/39/24/2291/4563763?redirectedFrom=fulltext

80. Sleep-disordered Breathing in Heart Failure (2015) - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6159414/

81. The official website of The Epworth Sleepiness Scale (ESS) - http://epworthsleepinessscale.com/about-the-ess/

82. The Epworth Sleepiness Scale: Minimum Clinically Important Difference in Obstructive Sleep Apnea (2018) - https://www.atsjournals.org/doi/abs/10.1164/rccm.201704-0672LE

83. Minimum important difference of the Epworth Sleepiness Scale in obstructive sleep apnoea: estimation from three randomised controlled trials (2018) - https://thorax.bmj.com/content/early/2018/08/11/thoraxjnl-2018-211959

84. Cardiorespiratory interaction with continuous positive airway pressure (2018) - http://jtd.amegroups.com/article/view/18553/14525

85. Continuous positive airway pressure for the treatment of obstructive sleep apnoea/hypopnoea syndrome (2008, reviewed 2012) - https://www.nice.org.uk/guidance/ta139

Evidence Review for the use of Hysteroscopy as a First Line Investigation

Question to be addressed

1. In female adults, are there clinical circumstances where the use of hysteroscopy would be clinically more effective than ultrasound as a first line investigation?

Reason for review

NHS Birmingham and Solihull CCG, Sandwell and West Birmingham CCG, requested a rapid evidence review of the clinical and cost effectiveness of the use of hysteroscopy as a first line investigation and identification of the clinical circumstances in which use as a first line investigative tool this intervention would be most clinically effective to inform their decisions on commissioning policy development.

Options for commissioners:

1. The Committee considers that due to the limited quality of evidence of clinical and cost effectiveness for the use hysteroscopy as a first line intervention, its use should be considered a low priority.
2. The Committee recommends that, due to the limited quality of evidence of its clinical and cost effectiveness in all clinical circumstances, the use of hysteroscopy as a first line intervention should ONLY be offered to patients who have suspected submucosal fibroids OR polyps OR endometrial pathology AND one of the following: persistent intermenstrual bleeding OR risk factors for endometrial pathology.
3. The Committee considers that there is sufficient evidence to suggest that the use of hysteroscopy as a first line treatment is at least as effective as alternative treatment options and the costs are comparable, therefore the decision about which approach to proceed with should be made after an informed discussion between the clinician and the individual person about the risks and benefits of each procedure.

Summary:

Background

- Heavy periods are common, but they can have a big effect on a woman's everyday life. HMB does not always have an underlying cause but can result from problems such as fibroids or endometriosis.
- Heavy menstrual bleeding is defined as losing 80ml or more in each period, having periods that last longer than 7 days, or both.
- A hysteroscopy is a procedure used to examine the inside of the womb (uterus).

Clinical effectiveness

- Evidence including the NICE review 2018 demonstrated clinically robust evidence to support the use of hysteroscopy as a first line intervention should ONLY be offered to patients who have suspected submucosal fibroids OR polyps OR endometrial

pathology AND one of the following: persistent intermenstrual bleeding OR risk factors for endometrial pathology.

- Evidence including the NICE evidence review 2018 enabled a review of the diagnostic tests to be used to direct treatment according to the woman's underlying pathology. In the NICE 2018 model, diagnostic test accuracy was used to estimate the proportion of women who would be correctly identified and receive the appropriate first line treatment.

Safety

- NICE supports the use of hysteroscopy as a first line intervention should ONLY be offered to patients who have suspected submucosal fibroids OR polyps OR endometrial pathology AND one of the following: persistent intermenstrual bleeding OR risk factors for endometrial pathology in NG 88.

Cost effectiveness

- A high quality economic evaluation from the UK (Cooper 2014) concluded that either outpatient hysteroscopy or outpatient hysteroscopy in combination with endometrial biopsy represented cost-effective strategies for HMB.
- NICE NG 88 established that whilst outpatient hysteroscopy was the most expensive diagnostic test but the least expensive diagnostic strategy. An important contributing factor to this is that hysteroscopy can facilitate a one stop 'see-and-treat' approach which reduces treatment cost.

Equity issues

NICE identified the following groups of women whom may require special consideration, but equity issues were not identified:

- women who have difficulties communicating in English
- women with learning difficulties
- women from some minority ethnic groups (because women from some minority ethnic group might find it difficult to talk about HMB with health care professionals)
- women from disadvantaged socio-economic groups.

Context

1.1 Introduction

In about half of women with heavy menstrual bleeding, no underlying reason is found. But there are several conditions and some treatments that can cause heavy menstrual bleeding.

Some conditions of the womb and ovaries can cause heavy bleeding, including:

- fibroids – non-cancerous growths that develop in or around the womb and can cause heavy or painful periods

- endometriosis – where the tissue that lines the womb (endometrium) is found outside the womb, such as in the ovaries and fallopian tubes (although this is more likely to cause painful periods)
- adenomyosis – when tissue from the womb lining becomes embedded in the wall of the womb; this can also cause painful periods
- pelvic inflammatory disease (PID) – an infection in the upper genital tract (the womb, fallopian tubes or ovaries) that can cause symptoms like pelvic or abdominal pain, bleeding after sex or between periods, vaginal discharge and fever
- endometrial polyps – non-cancerous growths in the lining of the womb or cervix (neck of the womb)
- cancer of the womb – the most common symptom is abnormal bleeding, especially after the menopause
- polycystic ovary syndrome (PCOS) – a common condition that affects how the ovaries work; it causes irregular periods, and periods can be heavy when they start again

Other conditions that can cause heavy periods include:

- blood clotting disorders, such as Von Willebrand disease
- an underactive thyroid gland (hypothyroidism) – where the thyroid gland does not produce enough hormones, causing tiredness, weight gain and feelings of depression
- diabetes

Medical treatments that can sometimes cause heavy periods include:

- an IUD (intrauterine contraceptive device, or "the coil") – this can make your periods heavier for the first 3 to 6 months after insertion
- anticoagulant medication – taken to prevent blood clots
- some medicines used for chemotherapy
- some herbal supplements, which can affect your hormones and may affect your periods – such as ginseng, ginkgo and soya

1.2 Management

A hysteroscopy is a procedure used to examine the inside of the womb (uterus). It is carried out using a hysteroscope, which is a narrow telescope with a light and camera at the end. Images are sent to a monitor so the doctor or specialist nurse can see inside the womb. The hysteroscope is passed into the womb through the vagina and cervix.

NICE Guideline 88 states:

In Women with suspected submucosal fibroids, polyps or endometrial pathology

1.3.4 Offer outpatient hysteroscopy to women with HMB if their history suggests submucosal fibroids, polyps or endometrial pathology because:

- they have symptoms such as persistent intermenstrual bleeding or

- they have risk factors for endometrial pathology

Women with possible larger fibroids

1.3.12 Offer pelvic ultrasound to women with HMB if any of the following apply:

- their uterus is palpable abdominally
- history or examination suggests a pelvic mass
- examination is inconclusive or difficult, for example in women who are obese.

Women with suspected adenomyosis

1.3.13 Offer transvaginal ultrasound (in preference to transabdominal ultrasound or MRI) to women with HMB who have:

- significant dysmenorrhoea (period pain) **or**
- a bulky, tender uterus on examination that suggests adenomyosis.

1.3.14 If a woman declines transvaginal ultrasound or it is not suitable for her, consider transabdominal ultrasound or MRI, explaining the limitations of these techniques.

1.3.15 Be aware that pain associated with HMB may be caused by endometriosis rather than adenomyosis (see NICE's guideline on endometriosis).

Other diagnostic tools

1.3.16 Do not use saline infusion sonography as a first-line diagnostic tool for HMB.

1.3.17 Do not use MRI as a first-line diagnostic tool for HMB.

1.3.18 Do not use dilatation and curettage alone as a diagnostic tool for HMB

1.3 Existing national policies and guidance

- National Institute for Health and Care Excellence (NICE) Guidance

Guidance was published in 2018 on the use of hysteroscopy as a first line treatment, which states that a hysteroscopy should be used as a first line treatment in women who have suspected submucosal fibroids OR polyps OR endometrial pathology AND one of the following: persistent intermenstrual bleeding OR risk factors for endometrial pathology.

2 Epidemiology

HMB is one of the most common reasons for gynaecological consultations in both primary and secondary care. About 1 in 20 women aged between 30 and 49 years consult their GP each year because of heavy periods or menstrual problems, and menstrual disorders comprise 12% of all referrals to gynaecology services.

The focus of this review is on women of reproductive age (after puberty and before the menopause) with HMB, including women with suspected or confirmed fibroids, and women with suspected or confirmed adenomyosis. The guideline does not primarily cover women with gynaecological bleeding other than HMB (for example, intermenstrual bleeding or postcoital bleeding) or with gynaecological conditions in which HMB is not the main symptom (such as endometriosis).

Since 2007, equipment and software for transvaginal ultrasound have improved. Outpatient hysteroscopy has become more widely available, and is more acceptable to women with the advent of modern equipment such as miniature hysteroscopes.
Therefore, the relative clinical and cost effectiveness of diagnostic strategies have changed. Improvements in diagnostic imaging in recent years have resulted in an increase in the reported prevalence of certain conditions, e.g. adenomyosis.

3 The interventions

3.1 Ultrasound scan

3.1.1 Abdominal

Ultrasound imaging involves sending high-frequency sound waves into the body. These waves reflect off of organs and other structures inside the body. A receiver then picks up these response signals.

It is possible to create images by analyzing the data that these signals create.

The abdominal ultrasound scan is undertaken with a probe moving over the stomach to identify structures within the abdominal and pelvic areas.

3.1.2 Transvaginal

The transvaginal (internal) ultrasound scan does not require a full bladder as the scan probe is placed inside the vagina and is closer to the pelvic organs being examined.
This type of scan is used to help provide clearer pictures of the womb, ovaries and surrounding structures.

3.2 Hysteroscopy

A hysteroscopy is a procedure used to examine the inside of the womb (uterus). It's carried out using a hysteroscope, which is a narrow telescope with a light and camera at the end. Images are sent to a monitor so that the inside the womb may be examined. The hysteroscope is passed into the womb through the vagina and cervix.

4 Findings

4.1 Evidence of effectiveness

In reviewing the evidence NICE 2018 considered the following requirements:

- that the correct identification of the cause of HMB is important as this can impact the treatment options offered to women.
- If a test is sensitive, it may help the clinicians to choose the right initial treatment to be offered to women.
- It is important to avoid false positives because unnecessary treatment, especially surgical treatment, can cause harm.
- The evidence on diagnostic accuracy was assessed using adapted GRADE methodology.
- The evidence on patient satisfaction or acceptability was assessed using Cochrane Collaboration's tool for assessing risk of bias.

NICE in their evidence review accepted that the quality of evidence in these reviews ranged from very low to moderate with most evidence being of very low quality. The NICE committee recognised that the evidence was fragmented and with several limitations. The NICE committee agreed that the quality of evidence was most often downgraded because of unclear sampling, unclear inclusion and exclusion criteria, unclear diagnostic criteria, and at times, considerable number of drop-outs.

4.1.1 Clinical effectiveness

It was noted that there was a lack of robust evidence to support the intervention.

The NICE committee agreed that many women presenting to primary care with symptoms of HMB can be offered treatment without the need for further examination or investigation. However, investigation via a diagnostic technique might be warranted for women for whom history or examination suggests a structural or endometrial pathology or for whom the initial treatment has failed.

The NICE committee considered outpatient hysteroscopy to be an efficient and safe technique with a low risk of complications, and acceptable to most women if done according to best practice guidance. It would also allow for services to be developed to offer women the option of see-and-treat by having submucosal fibroids or polyps identified and removed in one process when appropriate.

4.1.2 Trials in progress

Review of *clinicaltrials.gov* provided no current trials being undertaken to evaluate the use of hysteroscopy and the clinical circumstances in which hysteroscopy would be a first line treatment.

4.1.3 Cost-effectiveness

A high quality economic evaluation from the UK (Cooper 2014) compared a number of diagnostic strategies for HMB. This analysis took an NHS perspective and the setting was a 'one-stop' secondary care clinical setting. The study concluded that either outpatient hysteroscopy or outpatient hysteroscopy in combination with endometrial biopsy represented cost-effective strategies for HMB. Treatment effectiveness was estimated through patient satisfaction although the authors also derived a cost per QALY estimate based on this.

Outpatient hysteroscopy is a more expensive investigation than pelvic ultrasound but there are potential off-setting savings to treatment costs as the technique can allow a 'see and treat' approach.

4.2 Safety

National Institute for Health and Care Excellence (NICE) Guidance 88 supports the use of hysteroscopy as a first line investigation to patients who have suspected submucosal fibroids OR polyps OR endometrial pathology AND one of the following: persistent intermenstrual bleeding OR risk factors for endometrial pathology.

4.3 Summary of findings

The evidence identified in the NICE review and the paucity of reliable evidence which was found within this evidence review, appears to be a result of a lack of quality/ strong evidence, not evidence which does not support hysteroscopy as a first line intervention.

The safety and cost effectiveness of hysteroscopy as a first line treatment, particularly in a see and treat scenario are documented by NICE (2018).

5 Equity issues

This issue solely relates to women. However, further equity issues have not been identified.

6 Discussion and conclusions

A paucity of robust, current evidence, has meant that NICE Guidance 88 has been heavily relied on in reviewing this intervention. The guidance has identified that the most appropriate clinical circumstances in which hysteroscopy should be used is as a first line investigation. NICE recognise the limited evidence available and have used clinical experts to guide the development of this guidance.

Further research in this area, would be welcomed.

7 Search Strategy

- PubMed

("hysteroscopy"[MeSH Terms] OR "hysteroscopy"[All Fields]) AND first[All Fields] AND ("long interspersed nucleotide elements"[MeSH Terms] OR ("long"[All Fields] AND "interspersed"[All Fields] AND "nucleotide"[All Fields] AND "elements"[All Fields]) OR "long interspersed nucleotide elements"[All Fields] OR "line"[All Fields]) AND ("therapy"[Subheading] OR "therapy"[All Fields] OR "treatment"[All Fields] OR "therapeutics"[MeSH Terms] OR "therapeutics"[All Fields]) AND ("menorrhagia"[MeSH Terms] OR "menorrhagia"[All Fields] OR ("heavy"[All Fields] AND "menstrual"[All Fields] AND "bleeding"[All Fields]) OR "heavy menstrual bleeding"[All Fields])

8 References

Abd Elkhalek, Y. I., Kamel, O. F., El-Sabaa, H., Comparison of 3 dimensional sonohysterography and hysteroscopy in Premenopausal women with abnormal uterine bleeding, Egyptian Journal of Radiology and Nuclear Medicine, 47, 1117-22, 2016

Abdel Hak, A. M., Accuracy of sonographic criteria for diagnosis of adenomyosis in perimenopausal women with menorrhagia, Middle East Fertility Society Journal, 15, 35-8, 2010

Abe, M., Ogawa, H., Ayhan, A., The use of non-three-layer ultrasound in biopsy recommendation for premenopausal women, Acta Obstetricia et Gynecologica Scandinavica, 87, 2008

Alborzi, S., Parsanezhad, M. E., Mahmoodian, N., Alborzi, S., Alborzi, M., Sonohysterography versus transvaginal sonography for screening of patients with abnormal uterine bleeding, International Journal of Gynaecology & Obstetrics, 96, 20-3, 2007

Bazot, M., Darai, E., Rouger, J., Detchev, R., Cortez, A., Uzan, S., Limitations of transvaginal sonography for the diagnosis of adenomyosis, with histopathological correlation, Ultrasound in Obstetrics and Gynecology, 20, 605-11, 2002

Botsis, D., Kassanos, D., Antoniou, G., Pyrgiotis, E., Karakitsos, P., Kalogirou, D., Adenomyoma and leiomyoma: differential diagnosis with transvaginal sonography, Journal of Clinical Ultrasound, 26, 21-5, 1998

Champaneria, R., Abedin, P., Daniels, J., Balogun, M., Khan, K.S., Ultrasound scan and magnetic resonance imaging for the diagnosis of adenomyosis: systematic review comparing test accuracy, Acta Obstetricia et Gynecologica, 89, 1374–84, 2010

Cicinelli, E., Romano, F., Anastasio, P. S., Blasi, N., Parisi, C., Galantino, P., Transabdominal sonohysterography, transvaginal sonography, and hysteroscopy in the evaluation of submucous myomas, Obstet GynecolObstetrics and gynecology, 85, 42-7, 1995

Cooper, N. A., Barton, P. M., Breijer, M., Caffrey, O., Opmeer, B. C., Timmermans, A., Mol, B. W., Khan, K. S., Clark, T. J., Cost-effectiveness of diagnostic strategies for the management of

abnormal uterine bleeding (heavy menstrual bleeding and post-menopausal bleeding): a decision analysis, Health Technology Assessment, 18, 1-201, 2014

Critchley, H. O. D., Warner, P., Lee, A. J., Brechin, S., Guise, J., Graham, B., Evaluation of abnormal uterine bleeding: Comparison of three outpatient procedures within cohorts defined by age and menopausal status, Health Technology Assessment, 8, iii-77, 2004

Dakhly, D. M. R., Abdel Moety, G. A. F., Saber, W., Gad Allah, S. H., Hashem, A. T., Abdel Salam, L. O. E., Accuracy of Hysteroscopic Endomyometrial Biopsy in Diagnosis of Adenomyosis, Journal of Minimally Invasive Gynecology, 23, 364-71, 2016

Dasgupta, S., Chakraborty, B., Karim, R., Aich, R. K., Mitra, P. K., Ghosh, T. K., Abnormal uterine bleeding in peri-menopausal age: Diagnostic options and accuracy, Journal of Obstetrics and Gynecology of India, 61, 189-94, 2011a

Dasgupta, S., Sharma, P. P., Mukherjee, A., Ghosh, T. K., Ultrasound assessment of endometrial cavity in perimenopausal women on oral progesterone for abnormal uterine bleeding: comparison of diagnostic accuracy of imaging with hysteroscopy-guided biopsy, The journal of obstetrics and gynaecology research, 37, 2011b

Dueholm, M., Forman, A., Jensen, M. L., Laursen, H., Kracht, P., Transvaginal sonography combined with saline contrast sonohysterography in evaluating the uterine cavity in premenopausal patients with abnormal uterine bleeding, Ultrasound in Obstetrics and Gynecology, 18, 54-61, 2001a

Dueholm, M., Lundorf, E., Hansen, E. S., Sorensen, J. S., Ledertoug, S., Olesen, F., Magnetic resonance imaging and transvaginal ultrasonography for the diagnosis of adenomyosis, Fertility and Sterility, 76, 588-94, 2001b

Erdem, M., Bilgin, U., Bozkurt, N., Erdem, A., Comparison of transvaginal ultrasonography and saline infusion sonohysterography in evaluating the endometrial cavity in pre- and postmenopausal women with abnormal uterine bleeding, Menopause, 14, 2007

Exacoustos, C., Brienza, L., Di Giovanni, A., Szabolcs, B., Romanini, M. E., Zupi, E., Arduini, D., Adenomyosis: three-dimensional sonographic findings of the junctional zone and correlation with histology, Ultrasound in obstetrics & gynecology : the official journal of the International Society of Ultrasound in Obstetrics and Gynecology, 37, 471-9, 2011

Fakhar, S., Mahmud, G., Validity of hysteroscopy and histopathology in patients with menstrual irregularity, Journal of Ayub Medical College, Abbottabad: JAMC, 22, 129-32, 2010

Gkrozou, F., Dimakopoulos, G., Vrekoussis, T., Lavasidis, L., Koutlas, A., Navrozoglou, I., Stefos, T., Paschopoulos, M., Hysteroscopy in women with abnormal uterine bleeding: a meta-analysis on four major endometrial pathologies, Arch Gynecol Obstet, 291, 1347-54, 2015

Krampl, E., Bourne, T., Hurlen-Solbakken, H., Istre, O., Transvaginal ultrasonography sonohysterography and operative hysteroscopy for the evaluation of abnormal uterine bleeding, Acta Obstetricia et Gynecologica Scandinavica, 80, 616-622, 2001

Meredith, S. M., Sanchez-Ramos, L., Kaunitz, A. M., Diagnostic accuracy of transvaginal sonography for the diagnosis of adenomyosis: systematic review and metaanalysis. American Journal of Obstetrics and Gynecology, 201:107, e1-6, 2009

Mukhopadhayay, S., Bhattacharyya, S. K., Ganguly, R. P., Patra, K. K., Bhattacharya, N., Barman, S. C., Comparative evaluation of perimenopausal abnormal uterine bleeding by transvaginal sonography, hysteroscopy and endometrial biopsy, Journal of the Indian Medical Association, 105, 2007

Najeeb, R., Awan, A. S., Bakhtiar, U., Akhter, S., Role of transvaginal sonography in assessment of abnormal uterine bleeding in perimenopausal age group, Journal of Ayub Medical College, Abbottabad : JAMC, 22, 2010

Nanda, S., Chadha, N., Sen, J., Sangwan, K., Transvaginal sonography and saline infusion sonohysterography in the evaluation of abnormal uterine bleeding, Australian and New Zealand Journal of Obstetrics and Gynaecology, 42, 530-4, 2002

NICE 2018 NICE Guidelines: Heavy menstrual bleeding: Assessment and Management. Published: 14 March 2018 nice.org.uk/guidance/ng88

NICE 2018 NICE Guideline 88: Evidence Reviews.
March 2018. https://www.nice.org.uk/guidance/ng88/evidence/a-diagnostic-test-accuracy-pdf-4782293101

Pennant, M. E., Mehta, R., Moody, P., Hackett, G., Prentice, A., Sharp, S. J., Lakshman, R., Premenopausal abnormal uterine bleeding and risk of endometrial cancer, BJOG, 124, 404-11, 2017

Royal Coll Royal College of Obstetricians and Gynaecologists, British Society for Gynaecological Endoscopy, Management of Endometrial Hyperplasia, Green-top Guideline No. 67, London: RCOG, 2016

Royal College of Obstetricians and Gynaecologists, British Society for Gynaecological Endoscopy, Best Practice in Outpatient Hysteroscopu, Green-top Guideline No. 59, London: RCOG, 2011

Soguktas, S., Cogendez, E., Kayatas, S. E., Asoglu, M. R., Selcuk, S., Ertekin, A., Comparison of saline infusion sonohysterography and hysteroscopy in diagnosis of premenopausal women with abnormal uterine bleeding, European Journal of Obstetrics, Gynecology, & Reproductive BiologyEur J Obstet Gynecol Reprod Biol, 161, 2012

Taylor, S., Jones, S., Dixon, A. M., O'Donovan, P., Evaluation of ultrasound in an outpatient hysteroscopy clinic: Does it alter management in premenopausal women?, Gynaecological Endoscopy, 10, 173-8, 2001

Vercellini, P., Cortesi, I., De Giorgi, O., Merlo, D., Carinelli, S. G., Crosignani, P. G., Transvaginal ultrasonography versus uterine needle biopsy in the diagnosis of diffuse adenomyosis, Human Reproduction, 13, 1998

Vercellini, P., Cortesi, I., Oldani, S., Moschetta, M., De Giorgi, O., Crosignani, P. G., The role of transvaginal ultrasonography and outpatient diagnostic hysteroscopy in the evaluation of patients with menorrhagia, Human Reproduction, 12, 1768-71, 1997

Williams, C. D., Marshburn, P. B., A prospective study of transvaginal hydrosonography in the evaluation of abnormal uterine bleeding, Am J Obstet GynecolAmerican journal of obstetrics and gynecology, 179, 292-8, 1998

Yildiz, A., Koksal, A., Ates, P. F., Ivit, H., Keklik, A., Cukurova, K., Hysteroscopy in the evaluation of intrauterine cavity. Is it more valuable than dilatation and curettage?, Turkiye Klinikleri Journal of Medical Sciences, 29, 2009

Evidence Review for the Use of Biological Mesh in hernia repair in comparison to synthetic surgical mesh.

Questions to be addressed

1. In adults with a non-healed wound following hernia repair surgery using synthetic surgical mesh, is there evidence to support the use of biological mesh?
2. In adults are there clinical circumstances where the use of biological mesh in hernia repair would be clinically more effective than the use of synthetic surgical mesh?

Reason for review

NHS Birmingham and Solihull CCG, Sandwell and West Birmingham CCG, requested a rapid evidence review of the clinical and cost effectiveness of biological surgical mesh for hernia repair compared to alternative treatment options, in particular synthetic surgical mesh to inform their decisions on commissioning policy development.

Options for commissioners:

1. The Committee considers that due to the limited quality of evidence of clinical and cost effectiveness for the use of biological mesh compared to alternative treatment options, its use should be considered a low priority.
2. The Committee recommends that, due to the limited quality of evidence of its clinical and cost effectiveness, the use of biological mesh should be offered ONLY to patients who have failed wound healing following hernia repair using standard surgical mesh.
3. The Committee considers that there is sufficient evidence to suggest that the use of biological mesh in surgical hernia repair is at least as effective as alternative treatment options and the costs are comparable, therefore the decision about which approach to proceed with should be made after an informed discussion between the clinician and the individual person about the risks and benefits of each procedure.

Summary

Background

- Hernia most frequently occurs when an organ or internal tissue pokes through a hole or weakness in the abdominal muscle wall.
- Hernia repair surgery is one of the most common surgeries to be performed.
- Different types of mesh can be used in hernia repair: standard surgical mesh and biological mesh.

Clinical effectiveness

- Clinical effectiveness of biological mesh above synthetic mesh was not identified within the literature.
- 2 systematic reviews demonstrated a lack of clinically robust evidence to support the use of biological mesh above the use of synthetic mesh.
- The currently available clinical evidence demonstrated a lack of blinding within the studies and often retrospective studies of low to moderate quality.

Safety

NICE & MHRA support the use of surgical synthetic mesh in hernia repair surgery.

Cost effectiveness

Synthetic mesh is not excluded from National Tariff and the cost of synthetic mesh is within tariff and not funded separately.

Biological Mesh is currently excluded from PbR tariff. This is because of the variable and often high cost associated with its use; the product can range in cost from £750 to in excess of £8,500 per patient, depending on intended use, size of wound and product choice. All items listed as PbR exclusions are subject to locally agree payments taking into consideration existing tariff charges.

Equity issues

None were identified within the course of this review.

Context

1.1 Introduction

- A hernia occurs when an internal part of a body pushes through a weakness in the muscle or surrounding tissue wall. It usually takes the form of a lump, or swelling with or without some discomfort that may limit daily activities, including the ability to work.

- There are different types of hernia, inguinal hernias are the most common and the majority of these (approximately 98%) are found in men due to their particular anatomical structure.

- Other types include femoral (also in the groin), umbilical and incisional (this type occurs following surgery in the upper abdomen where an incision has caused weakness in tissue)

- Hernias cannot be treated medically and often require surgical repair if the patient is fit enough. Without surgery, there are risks of strangulation, bowel obstruction and incarceration, which could require emergency surgical intervention.

Management

- Hernia repair is a very common surgical intervention and significantly more patients have undergone hernia mesh procedures than have undergone vaginal mesh

procedures [with approximately 70,000 inguinal hernia repairs performed every year in England and 6,000 each year in Wales].

- Until the 1950's, the repair took the form of a suture technique at the site of weakness or defect. The stitching of such weak areas did not result in long lasting repair which led to the recurrence of the hernia.

- The use of prosthetic mesh has become increasingly common since then as a 'tension-free' or patching method for strengthening and reinforcing weak tissue, resulting in longer lasting repair.

- There has been significant change in the design and manufacture of synthetic mesh over the years, with a move to larger pore, lighter weight mesh, with early data suggesting better tolerance of such implants by the patient.

- There are broadly two techniques for mesh hernia repair - open or laparoscopic.

    - In an open repair, the defect through which the hernia is protruding is identified and mesh placed over the defect and stitched in place, in effect creating a scaffold for the tissue to grow through to strengthen the weak area.

    - In a laparoscopic repair, a small incision is made near the umbilicus as well as two small incisions in the lower abdomen. Carbon dioxide is used to inflate the abdomen and a camera is inserted via one of the incisions so that the defect is viewed from the interior abdominal wall and mesh introduced.

- As with all types of surgery, there are associated risks. These include inter-operative complications such as bleeding or damage to surrounding structures as well as post-operative complications such as infection, pain (which can become chronic), thromboembolic complications as well as hernia recurrence.

There are 2 types of surgical mesh:

1. Standard Surgical Synthetic Mesh
2. Biological Mesh

Standard Surgical Synthetic mesh is made of either non-absorbable synthetic polymers (polypropylene) or absorbable synthetic polymers (polyglycolic acid or polycaprolactone).

A number of Biological Meshes are currently available on the market. Biological Meshes are derived from human (allograft) or animal (xenograft) dermis, pericardium or intestinal submucosa. These tissues are processed to remove any immunogenic material and, as a result, are rendered acellular. After processing, the extracellular matrix remains and is used as a scaffold by host tissues.

1.2 Existing national policies and guidance

National Institute for Health and Care Excellence (NICE) Guidance

- Guidance was published in 2004 on laparoscopic hernia repair which states that a laparoscopic repair should only be carried out by trained surgeons who perform the procedure regularly.

- The use of mesh in hernia repair is considered by NICE to be an 'Interventional Procedure', and therefore is not 'approved' as may be the case for a drug or procedure subject to technology appraisal. NICE do not examine interventional procedures which are considered established practice unless there are data demonstrating uncertainty about their efficacy or safety.

- The guidance with regard to laparoscopic repair was reviewed in 2016 but there was no new evidence to suggest a change in the guidelines was required.

Medicines and Healthcare Products Regulatory Authority (MHRA)

- It is understood that the MHRA broadly agrees with NICE's position outlined above and considers that the main determinant of success of an operation seems to be patient selection and surgical technique rather than choice of device. MHRA continues to encourage the reporting of adverse events following the use of surgical mesh.

2 Epidemiology

Groin hernia repairs are amongst the most commonly performed general surgical operations with over 71,000 inguinal and femoral hernias repairs carried out in England in 2014/15.

There is more than a 2-fold variation in the rate of inguinal hernia repair across the NHS. Patients and surgeons have the choice between various techniques and materials.
There is no national system of audit or follow-up, and the overall low reported recurrence rate following inguinal hernia repair makes it difficult to determine which procedure is best. However, outcomes should not be judged in only terms of hernia recurrence, but also wound complications, length of hospital stay, chronic pain, patient experience, quality of life and cost2.

The British Association of Day Surgery has suggested that 80% of inguinal hernia repairs should be carried out as day case procedures. In 2014/15 77.8% of primary inguinal hernia repairs (unilateral) were carried out as a day case, and rates varied from 67% to 88% across providers. (RCS, 2016).

Further data and analysis for England is yet to be undertaken, but Wales has undertaken a review of the use of surgical mesh and has found the following:

- In Wales between 2011/12 and 2017/18, 43,646 patients had a hernia repair
- Of those, 78.8% underwent a mesh-based technique
- A small number of patients will require removal of mesh due to complications, for example, chronic infection.
- The data showed that a very small minority of patients suffer complications that necessitates removal and those figures do not change dramatically on an annual basis
- Obviously some patients will have complications that do not warrant mesh removal but the interpretation is that those who undergo mesh removal suffer the most severe complications. The likelihood of the mesh being removed appears to be around 0.007%, consistent with international data and extremely low for any surgical complication. This is a rate which appears to have been largely consistent over the 5 year period of this review.

3 The interventions

Most hernias are found in the abdomen. Areas of weakness in the abdominal wall where hernias are commonly found include the groin, upper stomach, belly button and, where you have a surgical scar.

The most frequently seen types of hernia include:

• Inguinal hernias – the most common hernia, seen more in men, causes a bulge in your groin. The inguinal hernia appears through your inguinal canal, a narrow passage that blood vessels pass through in your abdominal wall and, may reach your scrotum.
• Femoral hernias – also a bulge in your groin, relatively uncommon and seen more in women. The femoral hernia happens at the hole in your abdominal wall where the femoral artery and vein pass from the abdomen into your leg.
• Hiatus hernias - occur in your upper chest area when part of your stomach pushes up into your chest by squeezing through a gap in your diaphragm called the hiatus.
• Umbilical/periumbilical hernias – occur at the umbilicus, a natural weakness in your abdominal wall, when fatty tissue or a part of your bowel pokes through your abdomen near your naval.
• Incisional hernia – occurs through a scar from past abdominal surgery as tissue pokes through the weak healed site in your abdominal wall.

Hernia surgery is a routine procedure, but as with all surgeries there are risks of complications. These may vary depending upon the exact hernia operation required and the individual patient' health.

Often the greatest complication risk is a reoccurrence of the hernia. Other hernia surgery side effects include: build-up of seroma or a fluid-filled sac under the surface of the skin, inability or difficulty urinating, organ or tissue damage, wound infection and, rejection of the mesh.

4 Findings

4.1 Evidence of effectiveness

- A Cochrane systematic review was published in 2018 comparing mesh procedures and non-mesh procedures for the repair of inguinal and femoral hernias (which included 6,293 participants)

- It found that mesh repairs are associated with a reduced rate of hernia recurrence (hence reduced amount of patients needing more surgery) as well as reduced risk of visceral and neurovascular damage but non-mesh procedures carried a lower risk of seroma (pocket of serous fluid) formation.

- In terms of chronic pain a large systematic review published in 2018 found no statistical difference in the rates of chronic pain between mesh and non-mesh procedures in the first post-operative year. There is no evidence that the use of mesh increases the risk of pain

    - There are reports that moderate-severe chronic pain can affect 10-12% post-operatively, but that the risk is less with mesh than non-mesh repair. Reports from England also noted that up to 5 % of those undergoing inguinal hernia repairs can experience long-term discomfort or pain, lasting for more than three months after their operations.

    - An original piece of research looked at the rate of chronic infection following mesh insertion with only 0.005% requiring mesh removal due to chronic infection.

There is good evidence to support the use of synthetic mesh in hernia repair operations. Further evidence was reviewed to ascertain the clinical and cost effectiveness of synthetic vs biological mesh.

4.1.1 Clinical effectiveness

Con et al undertook a systematic review in 2019, , which aimed to review potential bias in the literature which reviewed the use of biological mesh in hernia repair:

A literature search in PubMed, Embase and Cochrane databases of systematic reviews on biologic mesh for ventral hernia repair. The literature review was conducted using the Population, Intervention, Comparisons, Outcomes and Design approach. 40 studies were identified which matched the stringent criteria set. A 13-point instrument was set to assess for bias and applied on the primary studies that were analyzed.

Most primary studies are case series or case reports of patients undergoing abdominal hernia repair with biologic mesh, without any comparison group, and the inclusion of cases was only specified to be consecutive in 6 out of 40 cases. In terms of assessing outcomes, in none of the 40 articles were the outcome assessors blinded to the intervention or exposure status of participants.

The instrument that created could allow assessment of the risk of bias in different kind of studies. The assessment of the studies based on the criteria set up in the instrument clearly identified that further research needs to be done due to the lack of unbiased studies regarding the use of biologic meshes for abdominal hernia repair.

Other earlier systematic reviews also support the need for further research in this area.

2017 Systematic Review of synthetic vs biological mesh (Knappen et al 2017) found the following: Forty-four studies were included: 5 reporting biologic mesh repairs; 21, synthetic mesh repairs; and 18, prophylactic mesh repairs. Most of the studies were retrospective cohorts of low to moderate quality. The hernia recurrence rate was higher after undergoing biologic compared to synthetic mesh repair (24.0% vs 15.1%, P = 0.01). No significant difference was found concerning wound and mesh infection (5.6% vs 2.8%; 0% vs 3.1%). Open and laparoscopic techniques were comparable regarding recurrences and infections. Prophylactic mesh placement reduced the occurrence of a parastomal hernia (OR = 0.20,

P < 0.0006) without increasing wound infection [7.8% vs 8.2% (OR = 1.04, P = 0.91)] and without differences between the mesh types.

Further research in this area is required to identify the clinical circumstances in which the use of biological mesh would be clinically superior and cost effective.

4.1.2 Trials in progress

A search of clinicaltrials.gov found the following trials currently recruiting:

1. https://clinicaltrials.gov/ct2/show/NCT03034213?cond=biological+surgical+mesh&rank=2

The hypothesis for this study is complex incisional hernia repair using the separation of

components technique reinforced with retrorectus placement of Gentrix™ Surgical Matrix will lead to fewer incisional hernia recurrences and fewer wound complications compared to the same incisional hernia repair techniques reinforced with other prosthetic or biologically-derived mesh.

2. Performance of biological mesh materials in abdominal wall reconstruction: study rotocol for a randomised controlled trial

Carver DA, *et al*. *BMJ Open* 2019;9:e024091. doi:10.1136/bmjopen-2018-024091

3. Seedfelt et al (2019) BIOLAP: biological versus synthetic mesh in laparo-endoscopic inguinal hernia repair: study protocol for a randomized, multicenter, self-controlled clinical trial. Trials. 2019 Jan 16;20(1):55. doi: 10.1186/s13063-018-3122-5.

https://www.ncbi.nlm.nih.gov/pubmed/30651127

4.1.3 Cost-effectiveness

Biological meshes are excluded from National Tariff.

Biological Mesh is currently excluded from PbR tariff. This is because of the variable and often high cost associated with its use; the product can range in cost from £750 to in excess of £8,500 per patient, depending on intended use, size of wound and product choice. All items listed as PbR exclusions are subject to locally agree payments taking into consideration existing tariff charges.

For a device to be considered as an exclusion from PbR it must meet all 3 of the following criteria:
I. high cost and represent a disproportionate cost relative to the relevant HRG
II. used in a subset of cases within an HRG and/or used in a subset of providers delivering services under a specific HRG
III. relatively high cost in terms of volume and cost.

Synthetic mesh is not excluded from National Tariff and the cost of synthetic mesh is within tariff and not funded separately.

Synthetic Equivalents This wording was included within PbR exclusions and is intended to allow for the possibility that there are synthetic materials in use which may represent a similar disproportionate cost as biological mesh – synthetic equivalents to biologic mesh are therefore also excluded.

4.2 Safety

National Institute for Health and Care Excellence (NICE) Guidance

- Guidance was published in 2004 on laparoscopic hernia repair which states that a laparoscopic repair should only be carried out by trained surgeons who perform the procedure regularly.

- The use of mesh in hernia repair is considered by NICE to be an 'Interventional Procedure', and therefore is not 'approved' as may be the case for a drug or procedure subject to technology appraisal. NICE do not examine interventional procedures which are considered established practice unless there are data demonstrating uncertainty about their efficacy or safety.

- The guidance with regard to laparoscopic repair was reviewed in 2016 but there was no new evidence to suggest a change in the guidelines was required.

Medicines and Healthcare Products Regulatory Authority (MHRA)

- It is understood that the MHRA broadly agrees with NICE's position outlined above and considers that the main determinant of success of an operation seems to be patient selection and surgical technique rather than choice of device. MHRA continues to encourage the reporting of adverse events following the use of surgical mesh.

4.3 Summary of findings

There is a significant amount of evidence to currently support the use of surgical synthetic mesh in hernia repair surgery at the present time. However, there is a lack of evidence to support the use of biological mesh above standard synthetic mesh in hernia repair surgery. The evidence to support the use of biological mesh when standard surgical mesh has failed is also scant and the disproportionate higher cost of biological mesh is also a factor to be considered.

5 Equity issues

Whilst there is a greater occurrence rates of inguinal hernia in men, there is currently insufficient evidence to support a wider equity issue.

6 Discussion and conclusions

Systematic reviews of the use of biological mesh found that there were issues with many of the studies carried out in this area. Many studies had no comparison group, assessors were not blinded to either the intervention or exposure status of participants.

Further unbiased studies are required to identify the true clinical effectiveness of biological mesh and the most cost effective clinical circumstances for use should be identified.

7 Search Strategy

Medline:

Surgical mesh

Biological mesh

Hernia repair

Synthetic mesh

PubMed:

Surgical mesh

Biological mesh

Hernia repair

Synthetic mesh

8 References

1. Con J[1], Zarain L[2], Gogna S[3], Samson DJ[4], Prabhakaran K[5], Gashi S[6], Tilley E[6], Latifi R (2019) A novel tool to evaluate bias in literature on use of biologic mesh in abdominal wall hernia repair. Hernia. 2019 Apr 8. doi: 10.1007/s10029-019-01935-7. https://www.ncbi.nlm.nih.gov/pubmed/30963425

2. Fitzgerald, F. & Kumar, A. 2014. Biologic versus Synthetic Mesh Reinforcement: What are the Pros and Cons? Clin Colon Rectal Surg. 2014 Dec; 27(4): 140–148.doi: 10.1055/s-0034-1394155. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4477030/

3. Winder, M. et al. 2016. Comparative analysis of biologic versus synthetic mesh outcomes in contaminated hernia repairs. Surgery. 2016 Oct;160(4):828-838. doi: 10.1016/j.surg.2016.04.041. Epub 2016 Jul 21. https://www.ncbi.nlm.nih.gov/pubmed/27452954

4. Carver DA, Kirkpatrick AW, Eberle TL, *et al* Performance of biological mesh materials in abdominal wall reconstruction: study protocol for a randomised controlled trial BMJ Open 2019;9:e024091. doi: 10.1136/bmjopen-2018-024091

5. Seefeldt, C. et al. 2019. IOLAP: biological versus synthetic mesh in laparo-endoscopic inguinal hernia repair: study protocol for a randomized, multicenter, self-controlled clinical trial. Trials.Vol 20 (55). https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-018-3122-5

7. McCormack et al. 2003. Laparoscopic techniques versus open techniques for inguinal hernia repair. Cochrane Systematic Review - Intervention Version. Published 20 January 2003. Collaboration the EU Hernia Trialists

8. EU Hernia Trialist Collaboration. 2002. Repair of Groin Hernia with Synthetic Mesh. Meta-Analysis of Randomized Controlled Trials. Ann Surg. 2002 Mar; 235(3): 322–332. https://www.ncbi.nlm.nih.gov/pubmed/11882753

9. Lockhart et al. 2108. Mesh versus non-mesh for inguinal and femoral hernia repair. Cochrane Database Syst Rev. 2018 Sep 13;9. https://www.ncbi.nlm.nih.gov/pubmed/30209805

10. Öberg, S. et al. 2018. Chronic pain after mesh versus non-mesh repair of inguinal hernias: A systematic review and a network meta-analysis of randomized controlled trials Surgery: Official Journal of the Society of University Surgeons, Central Surgical Association, and the American Association of Endocrine Surgeons, 2018-05-01, Volume 163, Issue 5, Pages 1151-1159

11. Rossenberg et al. 2011. Danish Hernia Database recommendations for the management of inguinal and femoral hernia in adults. Dan Med Bull. 2011 Feb;58(2):C4243. https://www.ncbi.nlm.nih.gov/pubmed/21299930

12. European Hernia Society guidelines on the treatment of inguinal hernia in adult patients, August 2009, Volume 13, Issue 4, pp 343–403 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2719730/

13. Hernia Surge. 2018 International guidelines for groin hernia management, Hernia. 2018 Feb;22(1):1-165. doi: 10.1007/s10029-017-1668-x. Epub 2018 Jan 12.https://www.ncbi.nlm.nih.gov/pubmed/29330835

14. Akyol et al. 2013. Outcome of the patients with chronic mesh infection following open inguinal hernia repair. J Korean Surg Soc. 2013 May; 84(5): 287–291 https://www.ncbi.nlm.nih.gov/pubmed/23646314

15. Courtney et al. 2001. Outcome of patients with severe chronic pain following repair of groin hernia British Journal of Surgery 2002, 89, 1310±1314 https://www.ncbi.nlm.nih.gov/pubmed/12296903

16. Kokotovic, D. et al. 2016. Hernia Repair. JAMA. 2016 Oct 18;316(15):1575-1582. https://www.ncbi.nlm.nih.gov/pubmed/27750295

17. Burger et al. 2004. Long-term Follow-up of a Randomized Controlled Trial of Suture versus Mesh Repair of Incisional Hernia Ann Surg. 2004 Oct; 240(4): 578–585. https://www.ncbi.nlm.nih.gov/pubmed/15383785

18. Aasvang, E. et al. 2005. Chronic postoperative pain: the case of inguinal herniorrhaphy British Journal of Anaesthesia. Volume 95, Issue 1, July 2005, Pages 69-76
https://doi.org/10.1093/bja/aei019

19. RCS 2016. Commissioning guideline Groin Hernia.*https://www.rcseng.ac.uk/standards-and-research/commissioning/commissioning-guides/topics/*

20. NICE 2004. Laparoscopic surgery for inguinal hernia repair

Technology appraisal guidance [TA83] Published date: 22 September 2004
https://www.nice.org.uk/guidance/ta83

NHS Birmingham and Solihull CCG
NHS Sandwell and West Birmingham CCG

DRAFT
Policy for Hysteroscopy for Heavy Menstrual Bleeding.

Document Details:

Version:	DRAFT v1.
Ratified by (name and date of Committee):	Treatment Policy Clinical Development Group
Date issued for Public Consultation:	02.09.2019
Equality & Diversity Impact Assessment	

The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decisions are considered within the wider constraints of the CCG's legally responsibility to remain fiscally responsible.

Category: Restricted

Heavy Menstrual Bleeding (HMB/ Heavy Periods)

Heavy Menstrual Bleeding (HMB) is common but can have a big effect on a woman's everyday life. HMB does not always have an underlying cause but can result from problems such as fibroids or endometriosis.

It's difficult to define exactly what a heavy period is because it varies from woman to woman. Heavy for one woman may be normal for another.

Most women will lose less than 16 teaspoons of blood (80ml) during their period, with the average being around 6 to 8 teaspoons.

Heavy menstrual bleeding is defined as losing 80ml or more in each period, having periods that last longer than 7 days, or both.

However, it's not usually necessary to measure blood loss. Most women have a good idea of how much bleeding is normal for them during their period and can tell when this changes.

A good indication that your periods are heavy is if you:

- are having to change your sanitary products every hour or two
- are passing blood clots larger than 2.5cm (about the size of a 10p coin)
- are bleeding through to your clothes or bedding
- need to use two types of sanitary product together – for example, tampons and pads

In about half of women with heavy menstrual bleeding, no underlying reason is found. But there are several conditions and some treatments that can cause heavy menstrual bleeding.

Some conditions of the womb and ovaries can cause heavy bleeding, including:

- fibroids – non-cancerous growths that develop in or around the womb and can cause heavy or painful periods
- endometriosis – where the tissue that lines the womb (endometrium) is found outside the womb, such as in the ovaries and fallopian tubes (although this is more likely to cause painful periods)
- adenomyosis – when tissue from the womb lining becomes embedded in the wall of the womb; this can also cause painful periods
- pelvic inflammatory disease (PID) – an infection in the upper genital tract (the womb, fallopian tubes or ovaries) that can cause symptoms like pelvic or abdominal pain, bleeding after sex or between periods, vaginal discharge and fever

- endometrial polyps – non-cancerous growths in the lining of the womb or cervix (neck of the womb)
- cancer of the womb – the most common symptom is abnormal bleeding, especially after the menopause
- polycystic ovary syndrome (PCOS) – a common condition that affects how the ovaries work; it causes irregular periods, and periods can be heavy when they start again

Other conditions that can cause heavy periods include:

- blood clotting disorders, such as Von Willebrand disease
- an underactive thyroid gland (hypothyroidism) – where the thyroid gland does not produce enough hormones, causing tiredness, weight gain and feelings of depression
- diabetes

Medical treatments that can sometimes cause heavy periods include:

- an IUD (intrauterine contraceptive device, or "the coil") – this can make your periods heavier for the first 3 to 6 months after insertion
- anticoagulant medication – taken to prevent blood clots
- some medicines used for chemotherapy
- some herbal supplements, which can affect your hormones and may affect your periods – such as ginseng, ginkgo and soya

Hysteroscopy

A hysteroscopy is a procedure used to examine the inside of the womb (uterus).

It is carried out using a hysteroscope, which is a narrow telescope with a light and camera at the end. Images are sent to a monitor so your doctor or specialist nurse can see inside your womb.

The hysteroscope is passed into your womb through your vagina and cervix (entrance to the womb), which means no cuts need to be made in your skin.

In deciding whether to offer the woman a hysteroscopy or ultrasound scan NICE Guidance 88 should be taken into consideration:

Women with suspected submucosal fibroids, polyps or endometrial pathology
Offer outpatient hysteroscopy to women with HMB if their history suggests submucosal fibroids, polyps or endometrial pathology because:

- they have symptoms such as persistent intermenstrual bleeding or
- they have risk factors for endometrial pathology

Women with possible larger fibroids

Offer pelvic ultrasound to women with HMB if any of the following apply:

- their uterus is palpable abdominally
- history or examination suggests a pelvic mass
- examination is inconclusive or difficult, for example in women who are obese.

Women with suspected adenomyosis

Offer transvaginal ultrasound (in preference to transabdominal ultrasound or MRI) to women with HMB who have:

- significant dysmenorrhoea (period pain) or
- a bulky, tender uterus on examination that suggests adenomyosis.

If a woman declines transvaginal ultrasound or it is not suitable for her, consider transabdominal ultrasound or MRI, explaining the limitations of these techniques.

Be aware that pain associated with HMB may be caused by endometriosis rather than adenomyosis (see NICE's guideline on endometriosis).

Other diagnostic tools

Do not use saline infusion sonography as a first-line diagnostic tool for HMB.

Do not use MRI as a first-line diagnostic tool for HMB.

Do not use dilatation and curettage alone as a diagnostic tool for HMB

Evidence Review

In reviewing the evidence NICE 2018 considered the following requirements:

- that the correct identification of the cause of HMB is important as this can impact the treatment options offered to women.
- If a test is sensitive, it may help the clinicians to choose the right initial treatment to be offered to women.
- It is important to avoid false positives because unnecessary treatment, especially surgical treatment, can cause harm.
- The evidence on diagnostic accuracy was assessed using adapted GRADE methodology. GRADE is a systematic approach to rating the certainty of evidence in systematic reviews and other evidence syntheses.
- The evidence on patient satisfaction or acceptability was assessed using Cochrane Collaboration's tool for assessing risk of bias.

NICE in their evidence review accepted that the quality of evidence in these reviews ranged from very low to moderate with most evidence being of very low quality. The NICE committee recognised that the evidence was fragmented and with several limitations. The NICE committee agreed that the quality of evidence was most often downgraded because of unclear sampling, unclear inclusion and exclusion criteria, unclear diagnostic criteria, and at times, considerable number of drop-outs.

However, national clinical consensus under NG 88 has recommended the use of hysteroscopy as a first line intervention in a limited number of clinical circumstances:

The patient must have suspected submucosal fibroids OR polyps OR endometrial pathology

AND

The patient has one of the following symptoms:

- persistent intermenstrual bleeding OR
- risk factors for endometrial pathology

Due to this national clinical expertise, the use of hysteroscopy will be commissioned in specified clinical circumstances in line with the clinical consensus achieved through NICE NG 88.

Eligibility Criteria: Restricted

Hysteroscopy for Heavy menstrual Bleeding is commissioned as a first line investigation in the following clinical circumstances:

The patient must have suspected submucosal fibroids OR polyps OR endometrial pathology

AND

The patient has one of the following symptoms:

- persistent intermenstrual bleeding OR
- risk factors for endometrial pathology

Risk factors for endometrial pathology are defined as:

- the patient has persistent intermenstrual or persistent irregular bleeding, and the patient has infrequent heavy bleeding and is obese or has polycystic ovary syndrome
- the patient taking tamoxifen
- the patient for whom treatment for HMB has been unsuccessful.

In other clinical circumstances diagnostic hysteroscopy is commissioned in the following clinical circumstances:

- First -line investigation using ultrasound scan has provided inconclusive results. For example, hysteroscopy is clinically required to determine the exact location of a fibroid or the exact nature of the abnormality.

N.B. investigation for suspected or proven malignancy is outside the scope of this policy and should in investigated in line with the relevant cancer pathway.

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Guidance

1. Abd Elkhalek, Y. I., Kamel, O. F., El-Sabaa, H., Comparison of 3 dimensional sonohysterography and hysteroscopy in Premenopausal women with abnormal uterine bleeding, Egyptian Journal of Radiology and Nuclear Medicine, 47, 1117-22, 2016
2. Abdel Hak, A. M., Accuracy of sonographic criteria for diagnosis of adenomyosis in perimenopausal women with menorrhagia, Middle East Fertility Society Journal, 15, 35-8, 2010
3. Abe, M., Ogawa, H., Ayhan, A., The use of non-three-layer ultrasound in biopsy recommendation for premenopausal women, Acta Obstetricia et Gynecologica Scandinavica, 87, 2008
4. Alborzi, S., Parsanezhad, M. E., Mahmoodian, N., Alborzi, S., Alborzi, M., Sonohysterography versus transvaginal sonography for screening of patients with abnormal uterine bleeding, International Journal of Gynaecology & Obstetrics, 96, 20-3, 2007
5. Bazot, M., Darai, E., Rouger, J., Detchev, R., Cortez, A., Uzan, S., Limitations of transvaginal sonography for the diagnosis of adenomyosis, with histopathological correlation, Ultrasound in Obstetrics and Gynecology, 20, 605-11, 2002
6. Botsis, D., Kassanos, D., Antoniou, G., Pyrgiotis, E., Karakitsos, P., Kalogirou, D., Adenomyoma and leiomyoma: differential diagnosis with transvaginal sonography, Journal of Clinical Ultrasound, 26, 21-5, 1998
7. Champaneria, R., Abedin, P., Daniels, J., Balogun, M., Khan, K.S., Ultrasound scan and magnetic resonance imaging for the diagnosis of adenomyosis: systematic review comparing test accuracy, Acta Obstetricia et Gynecologica, 89, 1374–84, 2010
8. Cicinelli, E., Romano, F., Anastasio, P. S., Blasi, N., Parisi, C., Galantino, P., Transabdominal sonohysterography, transvaginal sonography, and hysteroscopy in the evaluation of submucous myomas, Obstet GynecolObstetrics and gynecology, 85, 42-7, 1995
9. Cooper, N. A., Barton, P. M., Breijer, M., Caffrey, O., Opmeer, B. C., Timmermans, A., Mol, B. W., Khan, K. S., Clark, T. J., Cost-effectiveness of diagnostic strategies for the management of abnormal uterine bleeding (heavy menstrual bleeding and post-menopausal bleeding): a decision analysis, Health Technology Assessment, 18, 1-201, 2014
10. Critchley, H. O. D., Warner, P., Lee, A. J., Brechin, S., Guise, J., Graham, B., Evaluation of abnormal uterine bleeding: Comparison of three outpatient procedures within cohorts defined by age and menopausal status, Health Technology Assessment, 8, iii-77, 2004
11. Dakhly, D. M. R., Abdel Moety, G. A. F., Saber, W., Gad Allah, S. H., Hashem, A. T., Abdel Salam, L. O. E., Accuracy of Hysteroscopic Endomyometrial Biopsy in Diagnosis of Adenomyosis, Journal of Minimally Invasive Gynecology, 23, 364-71, 2016
12. Dasgupta, S., Chakraborty, B., Karim, R., Aich, R. K., Mitra, P. K., Ghosh, T. K., Abnormal uterine bleeding in peri-menopausal age: Diagnostic options and accuracy, Journal of Obstetrics and Gynecology of India, 61, 189-94, 2011a
13. Dasgupta, S., Sharma, P. P., Mukherjee, A., Ghosh, T. K., Ultrasound assessment of endometrial cavity in perimenopausal women on oral

progesterone for abnormal uterine bleeding: comparison of diagnostic accuracy of imaging with hysteroscopy-guided biopsy, The journal of obstetrics and gynaecology research, 37, 2011b
14. Dueholm, M., Forman, A., Jensen, M. L., Laursen, H., Kracht, P., Transvaginal sonography combined with saline contrast sonohysterography in evaluating the uterine cavity in premenopausal patients with abnormal uterine bleeding, Ultrasound in Obstetrics and Gynecology, 18, 54-61, 2001a
15. Dueholm, M., Lundorf, E., Hansen, E. S., Sorensen, J. S., Ledertoug, S., Olesen, F., Magnetic resonance imaging and transvaginal ultrasonography for the diagnosis of adenomyosis, Fertility and Sterility, 76, 588-94, 2001b
16. Erdem, M., Bilgin, U., Bozkurt, N., Erdem, A., Comparison of transvaginal ultrasonography and saline infusion sonohysterography in evaluating the endometrial cavity in pre- and postmenopausal women with abnormal uterine bleeding, Menopause, 14, 2007
17. Exacoustos, C., Brienza, L., Di Giovanni, A., Szabolcs, B., Romanini, M. E., Zupi, E., Arduini, D., Adenomyosis: three-dimensional sonographic findings of the junctional zone and correlation with histology, Ultrasound in obstetrics & gynecology : the official journal of the International Society of Ultrasound in Obstetrics and Gynecology, 37, 471-9, 2011
18. Fakhar, S., Mahmud, G., Validity of hysteroscopy and histopathology in patients with menstrual irregularity, Journal of Ayub Medical College, Abbottabad: JAMC, 22, 129-32, 2010
19. Gkrozou, F., Dimakopoulos, G., Vrekoussis, T., Lavasidis, L., Koutlas, A., Navrozoglou, I., Stefos, T., Paschopoulos, M., Hysteroscopy in women with abnormal uterine bleeding: a meta-analysis on four major endometrial pathologies, Arch Gynecol Obstet, 291, 1347-54, 2015
20. Krampl, E., Bourne, T., Hurlen-Solbakken, H., Istre, O., Transvaginal ultrasonography sonohysterography and operative hysteroscopy for the evaluation of abnormal uterine bleeding, Acta Obstetricia et Gynecologica Scandinavica, 80, 616-622, 2001
21. Meredith, S. M., Sanchez-Ramos, L., Kaunitz, A. M., Diagnostic accuracy of transvaginal sonography for the diagnosis of adenomyosis: systematic review and metaanalysis. American Journal of Obstetrics and Gynecology, 201:107, e1-6, 2009
22. Mukhopadhayay, S., Bhattacharyya, S. K., Ganguly, R. P., Patra, K. K., Bhattacharya, N., Barman, S. C., Comparative evaluation of perimenopausal abnormal uterine bleeding by transvaginal sonography, hysteroscopy and endometrial biopsy, Journal of the Indian Medical Association, 105, 2007
23. Najeeb, R., Awan, A. S., Bakhtiar, U., Akhter, S., Role of transvaginal sonography in assessment of abnormal uterine bleeding in perimenopausal age group, Journal of Ayub Medical College, Abbottabad : JAMC, 22, 2010
24. Nanda, S., Chadha, N., Sen, J., Sangwan, K., Transvaginal sonography and saline infusion sonohysterography in the evaluation of abnormal uterine bleeding, Australian and New Zealand Journal of Obstetrics and Gynaecology, 42, 530-4, 2002
25. NHS. 2018 Hysteroscopy. Last reviewed 05.12.2018. https://www.nhs.uk/conditions/hysteroscopy/
26. NHS. 2018. Heavy Menstrual Bleeding. Last updated 07.06.2018. https://www.nhs.uk/conditions/heavy-periods/

27. NICE 2018 NICE Guidelines: Heavy menstrual bleeding: Assessment and Management.
Published: 14 March 2018 nice.org.uk/guidance/ng88
28. NICE 2018 NICE Guideline 88: Evidence Reviews.
March 2018. https://www.nice.org.uk/guidance/ng88/evidence/a-diagnostic-test-accuracy-pdf-4782293101
29. Pennant, M. E., Mehta, R., Moody, P., Hackett, G., Prentice, A., Sharp, S. J., Lakshman, R., Premenopausal abnormal uterine bleeding and risk of endometrial cancer, BJOG, 124, 404-11, 2017
30. Royal Coll Royal College of Obstetricians and Gynaecologists, British Society for Gynaecological Endoscopy, Management of Endometrial Hyperplasia, Green-top Guideline No. 67, London: RCOG, 2016

31. Royal College of Obstetricians and Gynaecologists, British Society for Gynaecological Endoscopy, Best Practice in Outpatient Hysteroscopu, Green-top Guideline No. 59, London: RCOG, 2011
32. Soguktas, S., Cogendez, E., Kayatas, S. E., Asoglu, M. R., Selcuk, S., Ertekin, A., Comparison of saline infusion sonohysterography and hysteroscopy in diagnosis of premenopausal women with abnormal uterine bleeding, European Journal of Obstetrics, Gynecology, & Reproductive BiologyEur J Obstet Gynecol Reprod Biol, 161, 2012
33. Taylor, S., Jones, S., Dixon, A. M., O'Donovan, P., Evaluation of ultrasound in an outpatient hysteroscopy clinic: Does it alter management in premenopausal women?, Gynaecological Endoscopy, 10, 173-8, 2001
34. Vercellini, P., Cortesi, I., De Giorgi, O., Merlo, D., Carinelli, S. G., Crosignani, P. G., Transvaginal ultrasonography versus uterine needle biopsy in the diagnosis of diffuse adenomyosis, Human Reproduction, 13, 1998
35. Vercellini, P., Cortesi, I., Oldani, S., Moschetta, M., De Giorgi, O., Crosignani, P. G., The role of transvaginal ultrasonography and outpatient diagnostic hysteroscopy in the evaluation of patients with menorrhagia, Human Reproduction, 12, 1768-71, 1997
36. Williams, C. D., Marshburn, P. B., A prospective study of transvaginal hydrosonography in the evaluation of abnormal uterine bleeding, Am J Obstet GynecolAmerican journal of obstetrics and gynecology, 179, 292-8, 1998

37. Yildiz, A., Koksal, A., Ates, P. F., Ivit, H., Keklik, A., Cukurova, K., Hysteroscopy in the evaluation of intrauterine cavity. Is it more valuable than dilatation and curettage?, Turkiye Klinikleri Journal of Medical Sciences, 29, 2009

NHS Birmingham and Solihull CCG
NHS Sandwell and West Birmingham CCG

DRAFT
Policy for the use of Liposuction in Lymphoedema

Document Details:

Version:	DRAFT v1.
Ratified by (name and date of Committee):	Treatment Policy Clinical Development Group
Date issued for Public Consultation:	2nd September 2019
Equality & Diversity Impact Assessment	

The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decisions are considered within the wider constraints of the CCG's legally responsibility to remain fiscally responsible.

Liposuction

Liposuction is normally deemed to be a cosmetic procedure used to remove unwanted body fat.

It involves sucking out small areas of fat that are hard to lose through exercise and a healthy diet. It's carried out on areas of the body where deposits of fat tend to collect, such as the buttocks, hips, thighs and tummy.

The aim is to alter body shape, and the results are generally long-lasting, providing you maintain a healthy weight.

It works best in people who are a normal weight and in areas where the skin is tight.

Liposuction carried out for cosmetic reasons is not normally available on the NHS. However, liposuction can sometimes be used by the NHS to treat certain health conditions.

Liposuction is usually carried out under general anaesthetic, although an epidural anaesthetic may be used to enable treatment on lower parts of the body.

The surgeon would mark on your body the area where fat is to be removed. He or she would then:

- **inject this area** with a solution containing anaesthetic and medication, to reduce blood loss, bruising and swelling
- **break up the fat cells** using high-frequency vibrations, a weak laser pulse or a high-pressure water jet
- **make a small incision (cut) and insert a suction tube attached to a vacuum machine** (several cuts may need to be made if the area is large)
- **move the suction tube back and forth** to loosen the fat and suck it out
- **drain** any excess fluid and blood
- **stitch up and bandage** the treated area

It usually takes one to three hours. Most people need to stay in hospital overnight.

After the procedure, you would be fitted with a compression garment. This helps to reduce swelling and bruising, and should be worn constantly for several weeks after the operation.

You may need to take antibiotics straight after the procedure to reduce the risk of infection. Most people also take mild painkillers to ease any pain and swelling.

Recovery

It may take up to 12 weeks to make a full recovery.

If you had a general anaesthetic, someone would need to drive you home and stay with you for the first 24 hours. You would not be able to drive for a few days.

The compression garment may be taken off while you shower.

You would need to avoid strenuous activity for up to four weeks (but walking and general movement should be fine).

The results of the procedure are not always noticeable until the swelling has gone down or depending on the care plan for the individual patient, it may take more than one surgical episode before results are visible. It can take up to six months for the area to settle completely.

After about a week: Stitches would be removed (unless you had dissolvable stitches).

At four to six weeks: You should be able to resume any contact sports or strenuous activities you would normally do.

- Side effects to expect

It is common after liposuction to have:

- **bruising and swelling**, which may last up to a couple of months
- **numbness**, which should go away in six months
- **scars**
- **inflammation** of the treated area, or the veins underneath
- **fluid** coming from the cuts
- **swollen ankles** (if the legs or ankles are treated)and it may require long-term compression garments to be worn.
- **Pain which may last for up to a month**
- **Skin laxity**

- What could go wrong

Liposuction can occasionally result in:

- **lumpy and uneven results, which is often due to skin laxity and cannot be resolved by further episodes of liposuction.**
- **Seroma which is a collection of fluid under the skin**
- **bleeding under the skin** (haematoma)
- **persistent numbness** that lasts for months
- **changes in skin colour** in the treated area

- **a build-up of fluid in the lungs** (pulmonary oedema) from the fluid injected into the body
- **a blood clot in the lungs** (pulmonary embolism)
- **damage to internal organs** during the procedure

Any type of operation also carries a small risk of:

- **excessive bleeding**
- **developing a blood clot** in a vein
- **infection**
- **an allergic reaction** to the anaesthetic

The surgeon should explain how likely these risks and complications are, and how they would be treated if they occurred.

.

Liposuction in Lymphoedema: Category: Restricted

Lymphoedema

Lymphoedema is a long-term (chronic) condition that causes swelling in the body's tissues. It can affect any part of the body, but usually develops in the arms or legs.

It develops when the lymphatic system does not work properly. The lymphatic system is a network of channels and glands throughout the body that helps fight infection and remove excess fluid.

There are two main types of lymphoedema:

- **primary lymphoedema** – caused by faulty genes that affect the development of the lymphatic system; it can develop at any age, but usually starts during infancy, adolescence, or early adulthood
- **secondary lymphoedema** – caused by damage to the lymphatic system or problems with the movement and drainage of fluid in the lymphatic system; it can be the result of an infection, injury, cancer treatment, inflammation of the limb, or a lack of limb movement

Lymphoedema is thought to affect more than 200,000 people in the UK. Primary lymphoedema is rare and is thought to affect around 1 in every 6,000 people. Secondary lymphoedema is much more common.

Secondary lymphoedema affects around 2 in 10 women with breast cancer, and 5 in 10 women with vulval cancer. About 3 in every 10 men with penile cancer get lymphoedema.

People who have treatment for melanoma in the lymph nodes in the groin can also get lymphoedema. Research has shown around 20-50% of people are affected.

Treating lymphoedema

There is no cure for lymphoedema, but it's usually possible to control the main symptoms using techniques to minimise fluid build-up and stimulate the flow of fluid through the lymphatic system.

These include wearing compression garments, taking good care of your skin, moving and exercising regularly, and having a healthy diet and lifestyle.

The recommended treatment for lymphoedema is decongestive lymphatic therapy (DLT).

DLT isn't a cure for lymphoedema, but it can help control the symptoms. Although it takes time and effort, the treatment can be used to bring lymphoedema under control.

Decongestive lymphatic therapy (DLT)

There are four components to DLT:

- **compression garments** – to complement exercise by moving fluid out of the affected limb and minimise further build-up
- **skin care** – to keep the skin in good condition and reduce the chances of infection
- **exercises** – to use muscles in the affected limb to improve lymph drainage
- **specialized massage techniques** – known as manual lymphatic drainage (MLD); this stimulates the flow of fluid in the lymphatic system and reduces swelling however, this technique is only appropriate for patients with cancer-related or primary lymphoedema.

DLT is an intensive phase of therapy, during which you may receive treatment up to 3 times per week for several weeks to help reduce the volume of the affected body part.

This is followed by a second phase called the maintenance phase. You will be encouraged to take over your care using simple self-massage techniques, wearing compression garments, and continuing to exercise.

This treatment phase aims to maintain the reduced size of the affected body part.

Surgery

In a small number of cases, surgery may be used to treat lymphoedema. There are three main types of surgery that may be useful for the condition:

- removal of sections of excess skin and underlying tissue (debulking)
- removal of fat from the affected limb (liposuction)
- restoration of the flow of fluid around the affected section of the lymphatic system – for example, by connecting the lymphatic system to nearby blood vessels (lymphaticovenular anastomosis)
- Lymph node transfer

These treatments may help reduce the size of areas of the body affected by lymphoedema, but some are still being evaluated – particularly lymphaticovenular anastomosis – and aren't in widespread use.

This policy ONLY covers the use of Liposuction for Lymphoedema.

Liposuction

Liposuction is where a thin tube is inserted through small cuts (incisions) in the skin to suck fat out of tissue. It can be used to remove excess fat from an affected limb to help reduce its size.

After surgery, you'll have to wear a compression garment on the affected limb day and night for at least a year to help keep the swelling down.

Evidence Review

Searches in the Cochrane Database and the identification of a number of systematic reviews show, good quality of evidence, which support the use of liposuction in patient diagnosed with lymphoedema in certain clinical circumstances.

The evidence demonstrated clear prevention of future illness, due to the nature of lymphoedema and the reduction in the likelihood of serious infections.

Moderate to large health improvement using this procedure was supported within the evidence review by long term follow up which demonstrated on-going clinical benefit to patients.

Current evidence on the safety and efficacy of liposuction for chronic lymphoedema is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.

However, patient selection should only be done by a specialist lymphoedema multidisciplinary team as part of a lymphoedema service pathway.

Eligibility Criteria: Restricted

For patients with either Primary or Secondary Lymphoedema who have failed conservative management in line with the currently commissioned patient pathway for the treatment of lymphoedema, patients will be eligible for treatment of their lymphoedema with liposuction.

AND

Patient selection should only be undertaken by a specialist lymphoedema multidisciplinary team as part of a lymphoedema service pathway.

Conservative management of lymphoedema is defined as:

Current conservative treatments for lymphoedema include decongestive lymphatic therapy (DLT). DLT combines MLD massage techniques with compressive bandaging, skin care and decongestive exercises. Once DLT sessions are stopped the patient is fitted with a custom-made compression garment, which is worn every day.

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that request is supported by the CCG.

Guidance

1. Stuiver Martijn M, ten Tusscher Marieke R, McNeely Margaret L. Which are the best conservative interventions for lymphoedema after breast cancer surgery? BMJ 2017; 357 :j233

2. Carl, H. M., Walia, G., Bello, R., Clarke-Pearson, E., Hassanein, A. H., Cho, B.Sacks, J. M. (Accepted/In press). Systematic Review of the Surgical Treatment of Extremity Lymphedema (. Journal of Reconstructive Microsurgery. https://doi.org/10.1055/s-0037- 1599100

3. Schaverien MV, Munnoch DA, Brorson H. Liposuction Treatment of Lymphedema. Semin Plast Surg. 2018;32(1):42–47. doi:10.1055/s- 0038-1635116

4. Greene AK and Maclellan Reid A (2016) Operative treatment of lymphedema using suction-assisted lipectomy. Annals of Plastic Surgery 77: 337-340.

5. Lamprou DAA, Voesten HG, Damstra RJ et al. (2017) Circumferential suction-assisted lipectomy in the treatment of primary and secondary end-stage lymphoedema of the leg. The British journal of surgery 104, 84-89.

6. Hoffner M, Bagheri S, Hansson E et al. (2017) SF-36 Shows Increased Quality of Life Following Complete Reduction of Postmastectomy Lymphedema with Liposuction. Lymphatic Research and Biology 15, 87-9

7. https://www.nhs.uk/conditions/Lymphoedema/

8. https://www.mayoclinic.org/diseases-conditions/lymphedema/symptoms-causes/syc-20374682

NHS Birmingham and Solihull CCG
NHS Sandwell and West Birmingham CCG

DRAFT
Policy for the use of Liposuction in Lipoedema

Document Details:

Version:	DRAFT v2
Ratified by (name and date of Committee):	Treatment Policy Clinical Development Group
Date issued for Public Consultation:	2nd September 2019
Equality & Diversity Impact Assessment	

The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decisions are considered within the wider constraints of the CCG's legally responsibility to remain fiscally responsible.

Liposuction in Lipoedema: Category: Not Routinely Commissioned

Liposuction

Liposuction is normally deemed to be a cosmetic procedure used to remove unwanted body fat.

It involves sucking out small areas of fat that are hard to lose through exercise and a healthy diet. It is usually carried out on areas of the body where deposits of fat tend to collect, such as the buttocks, hips, thighs and tummy.

The aim is to alter body shape, and the results are generally long-lasting, providing a healthy weight is maintained.

It works best in people who are a normal weight and in areas where the skin is tight.

Liposuction carried out for cosmetic reasons is not normally available on the NHS. However, liposuction can sometimes be used by the NHS to treat certain health conditions.

Liposuction is usually carried out under general anaesthetic, although an epidural anaesthetic may be used to enable treatment on lower parts of the body.

The surgeon would mark on your body the area where fat is to be removed. He or she would then:

- **inject this area** with a solution containing anaesthetic and medication, to reduce blood loss, bruising and swelling
- **break up the fat cells** using high-frequency vibrations, a weak laser pulse or a high-pressure water jet
- **make a small incision (cut) and insert a suction tube attached to a vacuum machine** (several cuts may need to be made if the area is large)
- **move the suction tube back and forth** to loosen the fat and suck it out
- **drain** any excess fluid and blood
- **stitch up and bandage** the treated area

It usually takes one to three hours. Most people need to stay in hospital overnight.

Lipoedema

Lipoedema is a long-term (chronic) condition where there is an abnormal build-up of fat cells in the legs, thighs and buttocks, and sometimes in the arms.

The condition usually only affects women, although in rare cases it can also affect men.

In lipoedema, the thighs, buttocks, lower legs, and sometimes the arms, become enlarged due to a build-up of abnormal fat cells. Both legs and/or the arms are usually enlarged at the same time and to the same extent.

The feet and hands are not affected, which creates a "bracelet" effect or "band-like" appearance just above the ankles and wrists.

Leg and arm size can vary between individuals with lipoedema, and the condition can gradually get worse over time.

As well as becoming enlarged, affected areas of the body may:

- feel soft, "doughy" and cold
- bruise easily
- ache or feel painful or tender
- have small broken veins under the skin

Someone with lipoedema may eventually get fluid retention (lymphoedema) in their legs. This type of swelling can worsen by the end of the day and may improve overnight, whereas the fatty swelling of lipoedema is constant.

Treatments for lipoedema

There has been little research into lipoedema, so there is some uncertainty about the best way to treat the condition.

If you have lipoedema it is important to avoid significant weight gain and obesity because putting on weight will make the fatty swelling worse.

Compression tights are helpful for some people because they support the fatty swelling and may reduce the pain.

Liposcution is the surgical option for the removal of fat.

Tumescent liposuction

Tumescent liposuction involves sucking out the unwanted fat through a tube. A liquid solution is first injected into the legs to help numb the area and reduce blood loss.

Fatty swelling of the legs may return after having the procedure if you subsequently gain weight.

Non-surgical treatments may also be needed for a long period after having tumescent liposuction. For example, you'll need to wear compression garments after surgery to prevent complications such as lymphoedema.

Treatments to prevent lipoedema progression

Non-surgical treatments can sometimes help improve pain and tenderness, prevent or reduce lipoedema, and improve the shape of affected limbs – although they often have little effect on the fatty tissue.

Several different treatments are designed to improve the management of the lipoedema, such as:

- compression therapy – wearing bandages or garments that squeeze the affected limbs
- exercise – usually low-impact exercises, such as swimming and cycling
- massage – techniques that help relieve the aching and heaviness often felt by patients

Treatments that do not work

Treatments used for some types of tissue swelling are generally unhelpful for lipoedema.

Lipoedema doesn't respond to:

- raising the legs
- diuretics (tablets to get rid of excess fluid)
- dieting – this tends to result in a loss of fat from areas not affected by lipoedema, with little effect on the affected areas

Causes of lipoedema

The cause of lipoedema is not known, but in some cases, there is a family history of the condition. It seems likely that the genes you inherit from your parents play a role.

Lipoedema tends to start at puberty or at other times of hormonal change, such during pregnancy or the menopause, which suggests hormones may also have an influence.

Although the accumulation of fat cells is often worse in obese people, lipoedema is not caused by obesity and can affect people who are a healthy weight. It should not be mistaken for obesity and dieting often makes little difference to the condition.

Evidence Review

There is no evidence available which directly compares liposuction with conservative management – where evidence testing the intervention is found, it is applied to patient cohorts that have already received conservative management.

The evidence identified during the evidence review consisted of three trials (totalling 274 patients), along with the NHS website (https://www.nhs.uk/conditions/lipoedema/) which states that this is a relatively new and under researched condition.

The largest study consisting of 164 patients, clearly stated that they had “undergone conservative therapy over a period of years” and as such the benefits stated can be viewed as over and above those offered by conservative treatment.

The results from all of the identified studies, suggests that there are both short and long-term sustained improvements in almost all dimensions around pain and Quality of Life measurements, and one study substantiates this as over and above conservative treatment. However, the number of patients across the research areas are very low and no randomised control trials were identified.

Whilst the three studies seem consistent in their findings, the evidence identified within the review reflects the lack of RCTs (or direct comparison to no treatment on two of the studies) and the need for further research in this area.

Therefore, in light of the paucity of evidence to support this intervention, liposuction for this clinical indication cannot be supported at the present time.

Eligibility Criteria: Not Routinely Commissioned

For patients with Lipoedema, Liposuction is Not Routinely Commissioned in these clinical circumstances due to a lack of evidence to support this intervention.

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Guidance

Lipoedema (2017) - https://www.nhs.uk/conditions/lipoedema/

Dadras M[1,2], Mallinger PJ[3], Corterier CC[1], Theodosiadi S[1], Ghods M[1] (2017) Liposuction in the Treatment of Lipedema: A Longitudinal Study. Arch Plast Surg. 2017 Jul;44(4):324-331. doi: 10.5999/aps.2017.44.4.324. Epub 2017 Jul 15. https://www.ncbi.nlm.nih.gov/pubmed/28728329

Schmeller W[1], Hueppe M, Meier-Vollrath I. (2012) Tumescent liposuction in lipoedema yields good long-term results. r J Dermatol. 2012 Jan;166(1):161-8. doi: 10.1111/j.1365-2133.2011.10566.x. Epub 2011 Nov 17. https://www.ncbi.nlm.nih.gov/pubmed/21824127

Baumgartner A[1], Hueppe M[2], Schmeller W[1].(2015) Long-term benefit of liposuction in patients with lipoedema: a follow-up study after an average of 4 and 8 years. Br J Dermatol. 2016 May;174(5):1061-7. doi: 10.1111/bjd.14289. Epub 2015 Dec 26https://www.ncbi.nlm.nih.gov/pubmed/26574236

NHS Birmingham and Solihull CCG
NHS Sandwell and West Birmingham CCG

DRAFT
Policy for the use of Non-Cosmetic Body Contouring Surgery.

Document Details:

Version:	DRAFT v1.
Ratified by (name and date of Committee):	Treatment Policy Clinical Development Group
Date issued for Public Consultation:	02.09.2019
Equality & Diversity Impact Assessment	

The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decisions are considered within the wider constraints of the CCG's legally responsibility to remain fiscally responsible.

Category: Restricted

Body Contouring Surgery

The Surgical Procedures included in Body Contouring Surgery may including the following:

- **Full abdominoplasty:**

For patients who have significant skin laxity, excess fat and separation of the muscles, a classic tummy tuck is the most common procedure. Performed under general anaesthetic, this operation can require patients to be in hospital for two or three days.

During the operation, an incision is made from hip to hip and around the umbilicus. The excess skin and fat is excised from the umbilicus to just above the pubic hair. The muscles above and below the umbilicus are tightened. The skin is then sewn up to give a circular scar around the umbilicus and a long scar across the lower abdomen. Although this operation leaves a large scar, it does provide the greatest improvement in abdominal shape.

Patients who are thinking about becoming pregnant should not undergo this procedure and should wait until they are sure they are not having any more children. All the skin and fat below the umbilicus can be removed in a standard abdominoplasty. This results in a scar across the lower abdomen and a scar around the umbilicus.

- **Mini abdominoplasty**

For patients with only a small amount of excess skin a lesser abdominoplasty might be appropriate. A general anaesthetic is still needed.

During the operating, a wedge of skin and fat is excised from the lower tummy leaving a horizontal scar above the pubic hair. Sometimes the muscles will also be tightened. No scar is left around the umbilicus, which may be stretched slightly to become a different shape. A mini abdominoplasty will give a smaller effect than a full abdominoplasty.

- **Extended abdominoplasty**

Surplus skin and fat of the loins and back are removed at the same time as the abdomen.

- **Endoscopic abdominoplasty**

Tightens the muscles of the abdominal wall. Skin is not removed but liposuction can be carried out at the same time.

- **Apronectomy (Panniculectomy)**

An Apronectomy is a modified mini-abdominoplasty, mainly for patients who have a large excess of skin and fat hanging down over the pubic area and only the surplus skin and fat is removed. A modification to an abdominoplasty might also be necessary when the patient has problems with scars from previous operations.

A panniculus is excess adipose tissue hanging downward from the abdomen and resembles an "apron of skin" overlying the front of the pelvic girdle. A large panniculus can interfere with normal activities such as walking, and lead to serious medical problems. The heavy overhanging tissue can cause chronic skin inflammation under the flap, and subsequently, skin breakdown and infection.

The panniculus hanging below the symphysis pubis when the individual is standing normally can cause significant functional impairment and other complications such as intertrigo.

- **Arm reduction and lift (Brachioplasty):**

Brachioplasty, or upper arm reduction or arm lift is a surgical procedure which removes and tightens loose skin and excess fat in the upper arm. It is usually performed under a general anaesthetic. The surgeon makes a long incision between the elbow and axilla. Segments of skin and fat are removed and the remaining skin and tissue lifted resulting in a tight, smooth look.

- **Buttock and/or Thigh lift (Thighplasty):**

Thighplasty is aesthetic reshaping surgery with the removal of excess skin and fat. Buttock or thigh lift surgery is performed to lift the excess skin to firm and tighten the skin around the buttocks and/or thighs. Liposuction may also be performed during this procedure. Sometimes a buttock lift is combined with this procedure.

- **Liposuction / Liposculpture / Suction Assisted Lipectomy**

Liposuction is also known as liposculpture or suction assisted lipectomy. It is a technique most commonly performed to remove unwanted fat deposits. Liposuction can be performed on other areas of the body, including the neck, arms, tummy, loins, thighs, inner side of the knees and the ankles.

Evidence Review

The results from the search strategy found 3 systematic reviews, 1 economic systematic review and 4 clinical trials & guidance which directly informed 'Body Contouring' in reference to the effectiveness measurable by physical, physiological, and/or qualitative patient reported outcomes.

The BAPRAS UK Commissioning Guide 2017 highlights an expert interpretation of various papers to inform NICE and clinical commissioners in the UK health care sector. All results highlighted in the evidence review are also utilised within the commissioning guide.

The 'BODY-Q' systematic review provides strong evidence to support the method in measuring the effectiveness of body contouring from patient-reported outcomes (PRO. 'BODY-Q' method is the framework of the BODY-Q scales, presented below, is comprised of three overarching themes as follows: 1) Appearance; 2) Health-Related Quality of Life; and 3) Patient Experience. Under these domains, there are 18 independently functioning scales that measure important Central Obesity Index. In addition to the 18 scales, there is 1 obesity-specific symptom checklist.

Due to the statistically significant health improvement benefits both in relation to Quality of Life and clinical outcomes of more than 30%, and that the evidence has demonstrated the potential of removal of excess skin to prevent both 1st and 2nd prevention of future illness such as mobility, Quality of Life concerns, infection, lymphoedema and other illnesses, it was deemed within certain clinical circumstances that excess skin removal could be an effective surgical intervention.

Glossary

Term	Definition
Body mass index (BMI)	A measure for human body shape based on an individual's weight and height. BMI = body weight in kilograms / height in meters squared
Excess body weight	Calculation of change of BMI relative to a maximum normal BMI of 25kg/m_2
Massive weight loss	Loss of 50% or more excess body weight
BODY-Q	The Patient-Reported Outcome Instrument for Weight Loss and Body Contouring Treatments

Eligibility Criteria: Restricted

Removal of excess skin is commissioned in the following clinical circumstances:

The patient is 18 or over at the time of application

AND

The patient has lost at least 50% of their original excess weight and maintained their weight for at least two years, both of which have been recorded and documented by a clinician in the patient's medical notes

AND the patient has one of the following:

Skin folds are causing severe functional impairment which is impacting on the patient's ability to carry out activities of daily living.

OR

Recurrent skin infections are present in the patient's skin folds which fail to resolve, despite appropriate medical treatment for at least 6 months.

N.B. Functional impairment is defined as preventing activities of daily living to be undertaken independently, i.e. sleeping; eating; walking.
Each patient will have access to funding for one course of surgical treatment to remove excess skin. All surgical interventions for removal of the excess skin must be undertaken as part of the original treatment plan and in line with the above eligibility criteria. Further applications for body contouring surgery will not be routinely funded and revision surgery to improve the cosmetic appearance will not be accepted. Funding is for surgical procedures to remove excess skin from an area of the body, which is causing functional impairment / recurrent skin infections. Procedures to aid weight loss or muscle tightening e.g. full abdominoplasty are not commissioned under this policy.

Other procedures which are not included within the Body Contouring Surgery policy are:

- Breast Surgery
- Liposuction
- Cosmetic Surgery

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

.

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG

Guidance

[1] British Association of Plastic Reconstructive and Aesthetic Surgeons (BAPRAS), Royal College of Surgeons: UK Commissioning Guide: Massive Weight Loss Body Contouring, 2017. http://www.bapras.org.uk/docs/default-source/commissioning-and-policy/2017--draft-for-consultation--body-contouring-surgery-commissioning.pdf?sfvrsn=0

[2] Measuring Quality of Life and Patient Satisfaction After Body Contouring: A Systematic Review of Patient-Reported Outcome Measures, Patrick L. Reavey et al, Aesthetic Surgery Journal September 2011 vol. 31 no. 7 807-813 https://academic.oup.com/asj/article/31/7/807/176334

[3] Recommendations on the most suitable quality-of-life measurement instruments for bariatric and body contouring surgery: a systematic review. C.E.E. de Vries, et al. – https://www.ncbi.nlm.nih.gov/pubmed/29883059

[4] Quality of life among adults following bariatric and body contouring surgery: a systematic review. J. Gilmartin, et al. JBI Database of Systematic Reviews and Implementation Reports November 2016 vol.14 no.11 240-270 https://journals.lww.com/jbisrir/Abstract/2016/11000/Quality_of_life_among_adults_following_bariatric.16.aspx

[5] Diverse approaches to the health economic evaluation of bariatric surgery: a comprehensive systematic review. J.A. Campbel, et al. https://www.ncbi.nlm.nih.gov/pubmed/27383557

[6] Body image and quality of life in patients with and without body contouring surgery following bariatric surgery: a comparison of pre- and post-surgery groups. M. de Zwaan, et al - https://www.frontiersin.org/articles/10.3389/fpsyg.2014.01310/full

[7] The impact of reconstructive procedures following bariatric surgery onpatient well-being and quality of life. Van der Beek ES, et al. - https://www.ncbi.nlm.nih.gov/pubmed/19688408

[8] The BODY-Q: A Patient-Reported Outcome Instrument for Weight Loss and Body Contouring Treatments. A.F. Klassen, et al. - https://www.ncbi.nlm.nih.gov/pubmed/27200241

[9] Body-Q User Manual, Royal College of Surgeons - https://tinyurl.com/y53b9xmn

[10] Body Image and Quality of Life in Post Massive Weight Loss Body Contouring Patients. AY. Song, et al. - https://www.ncbi.nlm.nih.gov/pubmed/17030974

[11] Mukherjee,S.,Kamat,S.,Adegbola,S.,andAgrawal,S.(2014). Funding for post-bariatric body contouring (bariplastic) surgery in England: a post code lottery. Plast.Surg.Int.

2014:153194. doi:10.1155/2014/153194
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3980931/

[12] NHS Digital: Statistics on Obesity, Physical Activity and Diet - England, 2018 [PAS] https://digital.nhs.uk/data-and-information/publications/statistical/statistics-on-obesity-physical-activity-and-diet/statistics-on-obesity-physical-activity-and-diet-england-2018

NHS Birmingham and Solihull CCG
NHS Sandwell and West Birmingham CCG
NHS Dudley CCG
NHS Walsall CCG
NHS Wolverhampton CCG

DRAFT
Policy for the use of Image Guided Therapeutic Intra-Articular Joint Injections.

Document Details:

Version:	DRAFT v1.
Ratified by (name and date of Committee):	Treatment Policy Clinical Development Group 23.05.2019
Date issued for Public Consultation:	02.09.2019
Equality & Diversity Impact Assessment	

The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decisions are considered within the wider constraints of the CCG's legally responsibility to remain fiscally responsible.

The causes of joint pain are numerous. Joint pain can be related to osteoarthritis or inflammatory joint disorders such as rheumatoid arthritis and psoriatic arthritis. Joint pain can also be as a result of traumatic injury, joint surgery or crystal deposition in the joints such as gout or chondrocalcinosis. Other causes of joint pain include sports injuries, general sprains and strains, frozen or unstable shoulder, and bleeding into joint spaces caused by torn ligaments.

Arthritis is a chronic musculoskeletal disorder, which may be either degenerative or inflammatory in nature and is characterised by involvement of all joint structures including the synovial membrane, cartilage and bone. People often have joint pain, reduced mobility, reduced participation in daily activities and poor quality of life [1].

The joints most commonly affected by arthritis are the knees, hips and small joints of the hand, although most joints can be affected. Pain, reduced function and effects on a person's ability to carry out their day-to-day activities can be important consequences of arthritis. Pain in itself is also a complex biopsychosocial issue, related in part to a person's expectations and self-efficacy (that is, their belief in their ability to complete tasks and reach goals), and is associated with changes in mood, sleep and coping abilities. There is often a poor link between changes visible on an X-ray and symptoms of arthritis: minimal changes can be associated with a lot of pain, or modest structural changes to joints can occur with minimal accompanying symptoms [2].

Contrary to popular belief, arthritis is not just caused by ageing and does not necessarily deteriorate. It is believed that a variety of traumas and inflammation may trigger the need for a joint to repair itself which may result in a structurally altered but symptom-free joint. However, in some people, because of either overwhelming trauma on going inflammation or compromised repair, the process cannot fully compensate, resulting in eventual presentation with symptomatic arthritis.

Treatment options

A range of lifestyle, pharmacological, non-pharmacological, surgical and rehabilitation interventions are effective for controlling symptoms and improving function in both degenerative and inflammatory arthritis (NICE 2012) Conventional conservative therapies include the use of simple analgesics, non-steroidal anti-inflammatory drugs, physical therapy and intra-articular (IA) corticosteroid administration [3].

NICE published Clinical Guideline (CG177) - Osteoarthritis: care and management in February 2014 [2]. The guidelines made the following recommendations regarding intra-articular injections;

- Intra-articular corticosteroid injections should be considered as an adjunct to core treatments for the relief of moderate to severe pain in people with osteoarthritis.

- Do not offer intra-articular hyaluronan injections for the management of osteoarthritis.

Intra-articular injections of corticosteroids have been used for several decades in the management of inflammatory and degenerative joint conditions when first line conservative therapies fail to provide adequate symptom relief [4].

Intra-articular injections are performed using anatomical landmarks to identify the correct trajectory for needle placement. However, inaccurate corticosteroid injections may result in complications such as post-injection pain, crystal synovitis, haemarthrosis, and steroid articular cartilage atrophy, as well as systemic effects, including fluid retention or exacerbation of hypertension or diabetes mellitus. Therefore, identification of methods and proper training to aid in correct needle placement during these procedures is warranted [4, 6].

The purpose of image guidance during corticosteroid joint injections is to allow visualisation, normally of the joint line typically in real time, so that the operator can achieve potentially safer and more effective injection [4, 5].

Clinical Evidence Review.

No high-quality evidence to support the clinical effectiveness of image guided intra-articular corticosteroid injections, compared to non-image guided intra-articular corticosteroid injections, was found, although some lower quality evidence was found.

Evidence from a low quality study (retrospective chart review) [14] suggests that ultra sound guided intra-articular corticosteroid injections for osteoarthritis of the AC joint significantly improves some clinical outcome measures (VNSlp score and SPADI score at six months and VNSaat score at three months and six months), compared to palpation guided intraarticular corticosteroid injections. The clinical relevance of the difference seen in these outcome measures is uncertain.

In addition, a moderate quality study (single-blinded RCT) [16] also suggests that sonographic guided intra-articular corticosteroid injections significantly improves pain relative to palpation guided injections in patients with osteoarthritis of the knee after two weeks (although this was not sustained at six months follow-up), reduces reinjection rates within 12 months and increases the time to the next procedure. However, the lack of blinding of the participants to the treatments they received means that there was potential for bias in the results.

These findings conflict with those from a moderate quality prospective single-blinded randomised controlled study [15] which reported no difference in the clinical outcomes measured between US guided and palpation guided intra-articular corticosteroid injections for patients with distal radioulnar joint disorder (DRUJ).

Evidence from this study of distal radioulnar joint disorder (DRUJ) injections [15] suggests that US guided intra-articular corticosteroid injections into the distal radioulnar joint (DRUJ) have a higher accuracy rate relative to palpation guided intra-articular corticosteroid injections (100% versus 75%; $p<0.05$). The authors also suggest a positive correlation between accuracy and improvement in clinical outcomes measured ($p<0.05$). However, the study may not have been sufficiently powered to show any differences between outcomes for US guided compared to palpation guided injections due to the relatively small number of inaccurate injections in the latter group.

Conclusion

In conclusion there was not a significantly robust evidence base to support the use of image-guidance in delivering intra-articular joint injections.

However, the use of image guidance for hip and spinal intra-articular injections are outside the scope of this policy.

Eligibility Criteria

Therapeutic image guided intra-articular corticosteroid injections are **Restricted**.

Therapeutic image guided intra-articular corticosteroid injections should only be undertaken in the small joints (defined as joint of the hands & feet)

AND

Therapeutic image guided intra-articular corticosteroid injections should be offered ONLY to patients who have failed to respond to conventional pharmacological and non-pharmacological interventions due to the limited quality of evidence of the clinical and cost effectiveness of this intervention.

Pharmacological and non-pharmalogical interventions are defined as:

- Analgesics/nonsteroidal anti-inflammatory drugs (NSAIDs)
- Domestic exercise programme
- Supervised physiotherapy/manual therapy
- Non-image guided (palpated) steroid injections

N.B.

- Diagnostic image –guided injections are not within the remit of this policy.
- The use of image guidance for hip and spinal intra-articular injections is outside the remit of this policy.

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

N.B. investigation for suspected or proven malignancy is outside the scope of this policy and should in investigated in line with the relevant cancer pathway.

Guidance

1. National Institute for Health and Clinical Excellence (NICE). Final Scope Osteoarthritis: the care and management of osteoarthritis. London, UK :NICE; 2012 https://www.nice.org.uk/guidance/cg177/documents/osteoarthritis-update-final-scope2
    a. Last accessed 27 September 2018

2. National Institute for Health and Clinical Excellence (NICE). Osteoarthritis: the care and management of osteoarthritis. Clinical Guideline 177. London, UK: NICE; 2014

3. Griesser MJ, Harris JD et al. Adhesive capsulitis of the shoulder: a systematic review of the effectiveness of intra-articular corticosteroid injections. Joint and Bone Joint Surgical Am 2011; 93: 1727-1733.

4. Berkoff DJ, Miller LE, Block JE. Clinical utility of ultrasound guidance for intra-articular knee injections: a review. Clinical Interventions in Aging. 2012; 7:89-95.

5. Jüni P, Hari R et al. Intra-articular corticosteroid for knee osteoarthritis. Cochrane Database of Systematic Reviews 2015, Issue 10. Art. No.: CD005328

6. Nam SH, Kim J et al. Palpation versus ultrasound guided corticosteroid injections and short-term effect in the distal radioulnar joint disorder: A randomized, prospective single-blinded study. Clinical Rheumatology 2013; 12:1807-1814.

7. Arthritis Research UK, Osteoarthritis in General Practice. 2013.

8. Wluka A, Lombard C, and Cicuttini F. Tackling obesity in knee osteoarthritis. Nature Reviews Rheumatology 2013; 9(4): 225-235.

9. Kearns K, Dee A et al. Chronic disease burden associated with overweight and obesity in Ireland: the effects of a small BMI reduction at population level. BMC Public Health 2014; 14(143)

10. Clemence P, Nguyen C et al. Risk factors and burden of osteoarthritis. Annals of Physical and Rehabilitation Medicine 2016 59 (3): 134–138.

11. Spector T and MacGregor A. Risk factors for osteoarthritis: genetics. Osteoarthritis and Cartilage 2004; 12: 39-44.

12. Berkoff DJ, Miller LE, Block JE. Clinical utility of ultrasound guidance for intra-articular knee injections: a review. Clinical Interventions in Aging. 2012; 7:89-95

13. Jüni P, Hari R et al. Intra-articular corticosteroid for knee osteoarthritis. Cochrane Database of Systematic Reviews 2015, Issue 10. Art. No.: CD005328

14. Park KD, Kim TK et al. Palpation versus ultrasound-guided acromioclavicular joint intra-articular corticosteroid injections: a retrospective comparative clinical study. Pain Physician. 2015;18(4):333–341

15. Nam SH, Kim J et al. Palpation versus ultrasound guided corticosteroid injections and short-term effect in the distal radioulnar joint disorder: A randomized, prospective single-blinded study. Clinical Rheumatology2013; 12:1807-1814.

16. Sibbitt WL Jr, Band PA et al. A randomized controlled trial evaluating the cost effectiveness of sonographic guidance for intra-articular injection of the osteoarthritic knee. Journal of Clinical Rheumatology. 2011; 17(8):409–415.

17. Fraenkel L. Ultrasound (US)-Guided Versus Sham Ultrasound Corticosteroid (CS) Knee Injections. https://clinicaltrials.gov/ct2/show/NCT01032720

18. John Hopkins University. "Blind" vs. Fluoroscopy-Guided Steroid Injections for Knee Osteoarthritis. https://clinicaltrials.gov/ct2/show/NCT02104726

19. National Collaborating Centre for Chronic Conditions (UK). Osteoarthritis: National clinical guideline for care and management in adults. London: Royal College of Physicians (UK), 2008

20. Neogi T. The epidemiology and impact of pain in osteoarthritis. Osteoarthritis Cartilage 2013; 21: 1145-1153.

NHS Birmingham and Solihull CCG
NHS Sandwell and West Birmingham CCG
NHS Dudley CCG
NHS Walsall CCG
NHS Wolverhampton CCG

DRAFT
Policy for the use of Image Guided High Volume Intra-Articular Injections.

950

Document Details:

Version:	DRAFT v1.
Ratified by (name and date of Committee):	Treatment Policy Clinical Development Group 23.05.2019
Date issued for Public Consultation:	02.09.2019
Equality & Diversity Impact Assessment	25.11.2019
Governing Board	

The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decisions are considered within the wider constraints of the CCG's legally responsibility to remain fiscally responsible.

Category: Not Routinely Commissioned

Joint Pain

Pain in the joints affects millions of people worldwide. The causes of joint pain are numerous. Joint pain can be related to osteoarthritis or inflammatory joint disorders such as rheumatoid arthritis and psoriatic arthritis. Joint pain can also be as a result of traumatic injury, joint surgery or crystal deposition in the joints such as gout or chondrocalcinosis. Other causes of joint pain include sports injuries, general sprains and strains, frozen or unstable shoulder, and bleeding into joint spaces caused by torn ligaments.

Depending on the individual, pain might be felt in the joint or in the muscles around the joint. Depending on the cause the pain may be diffuse and constant, occurring at rest or while moving. Despite the wide range of underlying conditions and symptoms, joint pain of different aetiology may share similar mechanisms, manifestations, and potential treatments.

Image Guided High Volume Intra-Articular Injections

Treatment of joint pain consists of both pharmacologic and non-pharmacologic modalities. First-line therapy generally includes analgesia and physiotherapy.

Hydrodilatation (HD) also known as arthrographic capsular distension or distension arthrography is a procedure where a high volume injection of saline solution and/or steroids or air is given into the joint. Dependent upon the contracted state of the joint capsule,hydrodilation usually occurs with an injection of between 10ml and 55ml of normal saline.

The procedure is performed under imaging guidance, using fluoroscopy, ultrasound or Computed Tomography (CT). Hydrodilation is felt to provide benefit via two mechanisms: manual stretching of the capsule and thus disruption of adhesions that might be limiting the movements of the glenohumeral joint and causing pain and disability which are characteristic of adhesive capsulitis; and the introduction of cortisone, which provides a potent anti-inflammatory effect and thus prevents further recurrence of adhesion.

Clinical Evidence Review

From the evidence reviewed, there is no clear benefit of treatment for joint pain with an image-guided high volume intraarticular injection.

Evidence from two systematic reviews of Randomised Controlled Trials (RCTS) comparing hydrodilatation with corticosteroids, and corticosteroid injection only, is conflicting. The systematic review (with meta-analysis) by Saltychev et al (2018) reported that hydrodilatation with corticosteroids has only a small, clinically insignificant effect for pain and Range Of Movement (ROM) (seven RCTs) when treating adhesive capsulitis. Conversely, Catapano et al (2018) reported that the intervention is likely to be effective. However, this conclusion was based on the results from two of five RCTs and three of five RCTs which reported improvements in pain scores and range of movement respectively. The evidence is therefore at best inconsistent. No long term results were reported. Both authors report that the included RCTs were of moderate quality.

Evidence from one small RCT suggests that arthrographic capsular release is associated with a higher Oxford Shoulder Score (OSS) than hydrodilatation at six months follow-up. It is not known for how long this effect is likely to be sustained (Gallacher 2018). In addition, the study may not have been sufficiently powered to show any meaningful differences. The pain scores were reported by the patients who were not blinded to their treatment, this could have introduced bias. It is also unclear whether the Range Of Movement assessors were blinded to the treatments.

Eligibility Criteria

Due to the limited quality of evidence of clinical effectiveness for image-guided high volume intra-articular joint injections, high volume injections are Not Routinely Commissioned.

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Guidance

1. International Association for the Study of Pain (IASP). Treating people with joint pain. Global year against pain in the joint 2016; Fact sheet no 1. https://s3.amazonaws.com/rdcmsiasp/files/production/public/Content/ContentFolders/GlobalYearAgainstPain2/2016/FactSheets/English/1.%20Patients%20and%20Joint%20Pain.pdf Last accessed 15 October 2018

2. NHS Choices [online] https://www.nhs.uk/conditions/joint-pain/ Last accessed 15 October 2018

3. Gallacher S, Beazley JC et al. A randomized controlled trial of arthroscopic capsular release versus hydrodilatation in the treatment of primary frozen shoulder. Journal of Shoulder & Elbow Surgery. 2018 Aug; 27(8):1401-6.

4. Neogi T. Joint pain epidemiology. Global year against pain in the joint 2016; Fact sheet no 11. https://s3.amazonaws.com/rdcmsiasp/files/production/public/Content/ContentFolders/GlobalYearAgainstPain2/2016/FactSheets/English/11.%20Joint%20Pain%20Epidemiology.pdf Last accessed 15 October 2018

5. Duncan R, Francis RM et al. Prevalence of arthritis and joint pain in the oldest old: findings from the Newcastle 85+ Study. Age and Aging 2011; 40(6):752-5.

6. Georgiannos D, Markopoulos G et al. Adhesive Capsulitis of the Shoulder. Is there Consensus Regarding the Treatment? A Comprehensive Review. The open orthopaedics journal. [Review]. 2017; 11:65-76.

7. Buchbinder R, Green S et al. Arthrographic distension for adhesive capsulitis (frozen shoulder). Cochrane Database of Systematic Reviews 2008, Issue 1. Art. No.: CD007005.

8. Saltychev M, Laimi K et al. Effectiveness of Hydrodilatation in Adhesive Capsulitis of Shoulder: A Systematic Review and Meta-Analysis. Scandinavian Journal of Surgery: SJS. 2018:1457496918772367.

9. Catapano M, Mittal N et al. Hydrodilatation with Corticosteroid for the Treatment of Adhesive Capsulitis: A Systematic Review. Pm & R. [Review]. 2018; 10(6):623-35.

10. Maund E, Craig D et al. Management of frozen shoulder: a systematic review and cost-effectiveness analysis. Health Technology Assessment (Winchester, England).[Research Support, Non-U.S. Gov't Review]. 2012; 16(11):1-264.

NHS Birmingham and Solihull CCG
NHS Sandwell and West Birmingham CCG
NHS Dudley CCG
NHS Walsall CCG
NHS Wolverhampton CCG

DRAFT
Policy for Subacromial Pain in Adults.

Document Details:

Version:	2.0
Ratified by (name and date of Committee):	Treatment Policy Clinical Development Group 2nd May 2019.
Date issued for Public Consultation:	2nd September 2019
Equality & Diversity Impact Assessment	25th November 2019
Governing Board	

The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decisions are considered within the wider constraints of the CCG's legally responsibility to remain fiscally responsible.

Category: Not Routinely Commissioned

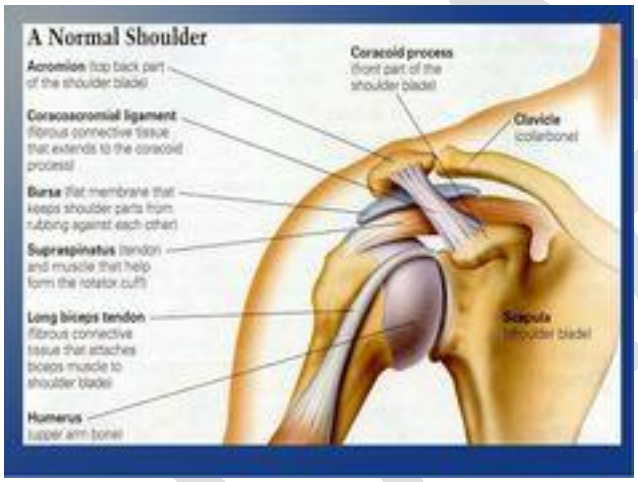
Sub-acromial Pain in Adults

Rotator cuff disease (wear and tear of the rotator cuff tendons) is thought to be a continuum ranging from shoulder impingement syndrome (SIS) through to partial and then full thickness rotator cuff tears [1]. It is one of the most common causes of non-traumatic shoulder pain which presents in primary care and is a normal part of aging [2].

The rotator cuff tendons hold the shoulder joint in place and allow people to lift the arm and reach overhead. When the arm is lifted, the rotator cuff tendon passes through a narrow space at the top of the shoulder, known as the sub-acromial space. The illustration of a healthy shoulder joint below (Figure 1) shows the relationship of tendons, ligaments, soft tissue and bony anatomy of the sub-acromial space.

Arthroscopic sub-acromial decompression is a surgical procedure that involves decompressing the sub-acromial space by removing bone spurs and soft tissue arthroscopically.

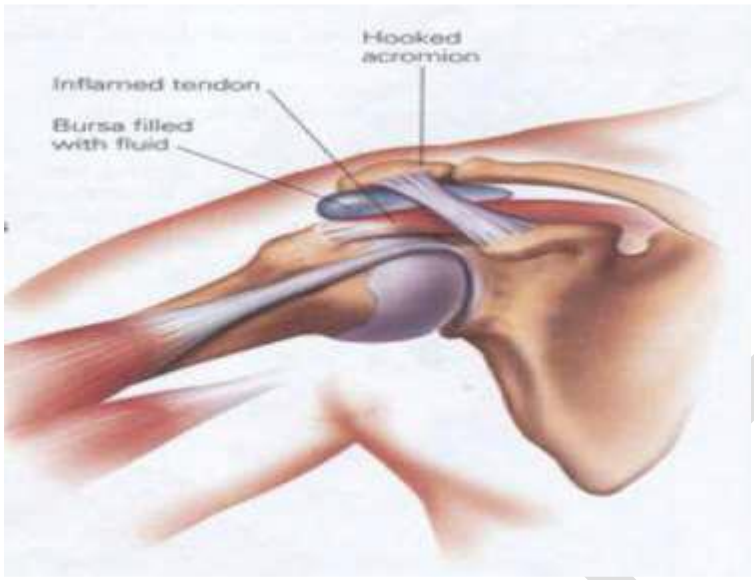
Figure 1: Anatomy of a normal shoulder.



Source: Orthopaedic Surgeons of Long Island Association. Retrieved from http://www.orthomd.com/procedures/impingement_syndrome.html

Previously it was thought that sub acromial pain occurs when the top of the tendon rubs or catches on the acromion and the sub-acromial bursa, however more recent studies have shown that between 76-91% of rotator cuff tears occur within the tendon or on the ‘under-side’ of the tendon. There has been shown to be poor correlation between acromial shape and pain. Furthermore, rotator cuff tears can continue to develop post sub-acromial decompression. To this end subacromial decompression surgery is no longer recommended routinely in any clinical circumstances.

Figure 2: Anatomy of a shoulder affected by shoulder impingement syndrome



The main problem in shoulder impingement syndrome is of pain in the top and outer side of the shoulder, which is worse when the arm is raised overhead [1]. Pain is associated with dysfunction, affecting usual activities of daily living, sporting activities and ability to work full time. Patients often report a significant reduction in terms of health-related quality of life [3].

Shoulder impingement will often improve in a few weeks or months, especially with prescribed shoulder exercises.

Arthroscopic Sub-acromial Decompression.

The term ‘arthroscopic’ describes any surgical procedure which is performed using surgical instruments inserted through a small ‘keyhole’ incision and an endoscope inserted via a separate incision to visualise the area.

Arthroscopic shoulder surgery is not one single surgical procedure; rather it refers to a
wide range of procedures to different parts of the shoulder anatomy. These may repair
damaged cartilage or torn tendons, remove loose fragments of bone or cartilage, drain
excess fluid, or release adhesions.

Arthroscopic sub-acromial decompression (ASD) is the most common surgical procedure in patients with shoulder impingement syndrome (SIS) [3]. The standard procedure is antero-inferior acromioplasty, i.e. the resection of bone spurs under the lateral third of the acromion, as well as the excision of the coracoacromial ligament and the sub-acromial bursa. If a partial or small full-thickness tear of the rotator cuff is present, it may be mildly debrided or left alone [3].

Evidence Review

Shoulder Impingement Syndrome.
Three randomised controlled trials were identified and reviewed, which compared ASD to conservative treatment for patients with SIS (at 24 months in two of the trials and 12 months only in the CSAW RCT). Patients with partial thickness rotator cuff tears were not excluded from these RCTs. The key differences between the study design were that Ketola et al [7] compared ASD plus physiotherapy to physiotherapy alone [7], whereas in the FIMPACT [6] and CSAW [4] RCTs, there were three treatment arms. Both FIMPACT and CSAW included ASD plus physiotherapy and diagnostic arthroscopy plus physiotherapy as two of the three arms. However, in the UK based multicentre RCT known as CSAW, the third arm was no treatment at all, whereas in the FIMPACT RCT, the non-operative third arm was a home exercise regime as well as 15 physiotherapy visits.

- ASD plus physiotherapy versus diagnostic arthroscopy plus physiotherapy. There was no clinically significant difference between ASD plus physiotherapy treatment compared to diagnostic (sham) arthroscopy plus physiotherapy at either 12-month follow-up in the CSAW RCT [4] or at 24 months (FIMPACT RCT) [6]. This was consistent for all of the outcomes measured: OSS, Constant score, pain, depression and anxiety, quality of life, simple shoulder test,15D and patient satisfaction.

- ASD plus physiotherapy versus no treatment: Although small statistical differences were seen in favour of ASD followed by up to four sessions of physiotherapy, there were no clinically important differences for any outcomes measured at 12 months compared to no treatment at all [4].

- ASD plus physiotherapy versus physiotherapy therapy only: There were no clinically important differences reported between these two treatment groups at 24-month follow-up [6,7] even though the physiotherapy protocol for the FIMPACT RCT was for 15 sessions (compared to just one post-operative session for those being treated with ASD). Both the ASD plus PT and PT only groups in the RCT by Ketola et al [7] had a similar number of physiotherapy sessions (6 and 7 sessions respectively). Within each treatment group, all three trials showed clinically significant improvements at 12 or 24 months, when compared to baseline for the OSS, the Constant score and for pain [4,6,7].

These RCTs showed that ASD for SIS was no more effective than physiotherapy alone or no treatment at achieving clinically important differences at 12 months and 24 months (OSS, Constant Score and pain). In addition, all three treatment groups achieved clinically important improvements over time compared to baseline. This suggests that the natural history of non-traumatic shoulder impingement syndrome, which has previously failed conservative treatment, is for the painful and disabling symptoms to resolve without intervention.

Supraspinatus tear.
There was one single RCT where 180 patients with a supraspinatus tear were treated with arthroscopic acromioplasty and physiotherapy, or tendon repair, acromioplasty and physiotherapy and the outcomes were compared to patients who had 10 sessions of physiotherapy alone. All the patients followed the same physiotherapy plan. There were no between group differences in the Constant score at 12 months. Although the ASD was performed concomitantly with repair of the supraspinatus tendon, the results are consistent with the results of the RCTs which assessed the effectiveness of ASD for the management of shoulder impingement syndrome.

Cost Effectiveness.
No studies generalisable to the NHS were found which measured the cost effectiveness of ASD compared to conservative treatment in patients with subacromial shoulder pain.

Conclusion

There has been shown to be poor correlation between acromial shape and pain. Furthermore, rotator cuff tears can continue to develop post sub-acromial decompression. There is no evidence that ASD offers any better outcome than more conservative options. Subacromial decompression surgery is therefore no longer recommended in any clinical circumstances.

Eligibility Criteria

Due to the lack of evidence for the clinical effectiveness of arthroscopic shoulder decompression (ASD) compared to conservative treatment,
ASD in any clinical circumstances,
is not routinely commissioned.

N.B. **Acute Severe Shoulder Pain**

- Any shoulder 'red flags' identified during primary care assessment need urgent secondary care referral. A suspected infected joint needs same day emergency referral.
- An unreduced dislocation needs same day emergency referral.
- Suspected tumour and malignancy will need urgent referral following the local 2-week cancer referral pathway.
- An acute cuff tear as a result of a traumatic event needs urgent referral and ideally should be seen in the next available outpatient clinic.
- Acute calcific tendinopathy is not a red flag, it is severely painful, often mimicking malignant pain and usually necessitates an early secondary care referral.
- It should also be noted that patients with subacromial shoulder pain in which the symptoms and signs suggest a more systemic inflammatory joint disease, should be considered as a 'rheumatological red flag'.
- Any new inflammatory oligo or polyarthritis, with symptoms of inflammation in several joints, should be referred urgently (following local rheumatology referral pathways) because time is of the essence with these diseases and a prompt diagnosis with early commencement of disease modifying drugs where appropriate is essential.

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

N.B. investigation for suspected or proven malignancy is outside the scope of this policy and should be investigated in line with the relevant cancer pathway.

Guidance

1. NHS choices. Shoulder Pain. https://www.nhs.uk/conditions/shoulder-pain/

2. Artus M, Holt T and Rees J. The painful shoulder: an update on assessment, treatment, and referral. British Journal of General Practice. 2014;64(626), e593-e595.

3. Chipchase LS, O'Connor DA, Costi JJ, Krishnan J (2000) Shoulder impingement
syndrome: preoperative health status. J Shoulder Elbow Surg 9:12–15

4. Beard DJ, Rees JL, Cook JA CSAW Study Group et al. Arthroscopic subacromial
decompression for subacromial shoulder pain (CSAW): a multicentre, pragmatic, parallel group, placebo-controlled, three-group, randomised surgical trial. Lancet 2018;391:329-38.

5. Linsell L, Dawson J, Zondervan K, Rose P, Randall T, Fitzpatrick R, Carr A. Prevalence and incidence of adults consulting for shoulder conditions in UK primary care; patterns of diagnosis and referral. Rheumatology (Oxford). 2006;45(2):215-21.

6. Paavola M, Malmivaara A, Taimela S et al. Subacromial decompression versus
diagnostic arthroscopy for shoulder impingement: randomised, placebo surgery controlled clinical trial. BMJ 2018;362:k2860

7. Ketola S, Lehtinen J, Arnala I, et al. Does arthroscopic acromioplasty provide any
additional value in the treatment of shoulder impingement syndrome? a two-year randomised controlled trial. J Bone Joint Surg Br 2009;91:1326-34

8. Ketola S, Lehtinen J, Rousi T et al. Which patients do not recover from shoulder
impingement syndrome, either with operative treatment or with non-operative treatment? Subgroup analysis involving 140 patients at 2 and 5 years in a randomised study. Acta Orthop 2015;86:641-46

9. Ketola S, Lehtinen J, Elo P et al. No difference in long-term development of rotator
cuff rupture and muscle volumes in impingement patients with or without decompression. Acta Orthop 2016;87(4):351-55

10. Ketola S, Lehtinen J, Arnala I. Arthroscopic decompression not recommended in
the treatment of rotator cuff tendinpathy. Bone Joint J 2017;99-B:799-805

11. Kukkonen J, Joukainen A, Lehtinen J et al. Treatment of non-traumatic rotator cuff

tears. Bone Joint J 2014;96-B:75-81

12. Longo UG, Vasta S, Maffulli N, Denaro V. Scoring systems for the functional assessment of patients with rotator cuff pathology Sports Med Arthrosc Rev. 2011;19(3):310-20.doi: 10.1097/JSA.0b013e31820af9b6.

13. Christiansen DH1, Frost P, Falla D, Haahr JP, Frich LH, Svendsen SW. Responsiveness and Minimal Clinically Important Change: A Comparison Between
Shoulder Outcome Measures. J Orthop Sports Phys Ther. 2015 Aug;45(8):620-5.

14. Constant CR, Murley AH. A clinical method of functional assessment of the shoulder. Clin Orthop Relat Res 1987;214:160–164

15. Mathieson S, Lin C. PainDETECT Questionnaire Clinimetrics. Journal of Physiotherapy 2013 Vol. 59

16. Stern AF. Questionnaire Review: The Hospitals Anxiety and Depression Score.
Occupational Medicine 2014;64:393–394

17. EuroQol Research Foundation 2018. EQ-5D Instruments. https://euroqol.org/eq-
5d-instruments/. Accessed 19.11.2018

18. National Clinical Coding Standards OPCS-4 (2017) - NHS Digitalhttps://hscic.kahootz.com/gf2.ti/f/762498/27837541.1/.../-/NCCSOPCS42017.pdf

19. McCormack HM, Horne DJ, Sheather S. Clinical applications of visual analogue
scales: a critical review. Psychol Med 1988;18:1007–1019

20. Beard D, Rees J, Rombach I et al. The CSAW Study (Can Shoulder Arthroscopy
Work?)—a placebo-controlled surgical intervention trial assessing the clinical and cost effectiveness of arthroscopic subacromial decompression for shoulder pain: study protocol for a randomised controlled trial.Trials. 2015; 16: 210

21. Kukkonen J, Kauko T, Vahlberg T et al Investigating minimal clinically important
difference for Constant score in patients undergoing rotator cuff surgery. J Shoulder Elbow Surg 2013;22:1650–1655

22. Salaffi F, Stancati A, Silvestri CA et al. Minimal clinically important changes in chronic musculoskeletal pain intensity measured on a numerical rating scale. Eur J
Pain 2004;8:283-91

23. Beard DJ, Carr AJ, Cook JA et al. Can Shoulder Arthroscopy Work? (CSAW) trial –
Authors' reply. Lancet. July 28, 2018.

24. Kulkarnhi, R. et al. 2015) Sub-acromial Shoulder pain: BESS/BOA Patient CarePathways.http://www.bess.org.uk/media/Research%20Committee/National%20Guidelines/Subacromial%20Shoulder%20Pain.pdf

25. NHS. Shoulder impingement. https://www.nhs.uk/conditions/shoulder-impingement-syndrome/

26. Lewis (2011) Subacromial impingement syndrome: a musculoskeletal condition or a clinical illusion? Physical Therapy Reviews, 16(5), pp. 388 – 398.

27. Lewis (2016) Rotator cuff related shoulder pain: Assessment, management and uncertainties. Manual Therapy, 23, pp. 57 – 68.

Sandwell Metropolitan Borough Council

Agenda Item 6

REPORT TO
HEALTH AND ADULT SOCIAL CARE SCRUTINY BOARD

20 January 2020

Subject:	Proposed change of location for Dental Services under General Anaesthesia for children.
Contribution towards Vision 2030:	
Report	Birmingham Community Healthcare NHS Foundation Trust (BCHC) Dental Services Division

DECISION RECOMMENDATIONS

That Health and Adult Social Care Scrutiny Board:

1. Consider and comment on the proposed change of location for provision of Dental services under General Anaesthesia (GA) for Children from Sandwell General Hospital to Birmingham Dental Hospital in 2022.

1 PURPOSE OF THE REPORT

1.1 A letter outlining the proposed change of location for provision of Dental services under General Anaesthesia (GA) for Children from Sandwell General Hospital to Birmingham Dental Hospital in 2022 is attached at appendix 1.

1.2 The Divisional Director Dental Services, Birmingham Community Healthcare NHS Foundation Trust (BCHC), will be attending the meeting to present further detail around the proposed changes.

1.3 This will be an opportunity to question and comment on the effect of the changes on residents in Sandwell.

Surjit Tour
Director – Law and Governance and Monitoring Officer

NHS
Birmingham
Community Healthcare
NHS Foundation Trust

3rd January 2020

James Sandy
Scrutiny Officer
Sandwell Borough Council
By Email
James_sandy@sandwell.go.uk

Dental Services Division
Birmingham Dental Hospital & School of Dentistry
Birmingham Community Healthcare
NHS Foundation Trust
5 Mill Pool Way
Edgbaston
Birmingham B5 7EG

Tel: 0121 466 5303
Fax: 0121 466 5151

Dear James

I am writing on behalf of Birmingham Community Healthcare NHS Foundation Trust (BCHC) Dental Services Division to follow up on a proposed change of location for where it currently provides services under General Anaesthesia (GA) for Children in Sandwell General Hospital to Birmingham Dental Hospital in 2022.

We informed you about this proposed change on 20th December 2017 and at that point Sandwell MBC did not raise objection or request further information about the proposed change. However, the Trust is now at the point that we are finalising our full business case to develop new Theatres immediately adjacent to Birmingham Dental Hospital and, assuming this is approved by our Board, BCHC will be entering a Heads of Terms agreement to lease, setting into motion the new build project. This letter is therefore being sent as a courtesy to ensure that the Health Over and Scrutiny Committee is aware of progress in relation to this project and provide an opportunity to make comment or seek clarification about the effect on Sandwell patients.

The Trust currently provides Secondary and Community Dental Services for all West Midland patients within Birmingham Dental Hospital as well within community locations across Birmingham, Sandwell, Walsall and Dudley. The Trust has endeavoured to

maintain services under General Anaesthesia not just within Birmingham Dental Hospital, but also through usage of theatres within the following locations:

Paediatric Patients
Birmingham Dental Hospital
Sandwell General Hospital, Sandwell
Walsall Manor Hospital, Walsall

Special Care Patients
Birmingham Dental Hospital

As previously outlined, there are various problems the service faces which pose a risk to the service configuration above:

- Birmingham Dental Hospital Theatre is based within a building with temporary planning permission granted on the basis that a permanent solution would be found.
- Walsall Manor have over the last two years reduced the theatre capacity available to the Dental Service for the last two winters
- Sandwell and West Birmingham NHS Trust have indicated that they will not be able to provide theatre space at Sandwell General Hospital in the long term.

The Trust has identified a preferred option to enter into a lease agreement to take space in a new development being built by Calthorpe Estates on a plot adjacent to the new Dental Hospital. The current proposal being prepared will be to lease space in this new development to provide two theatres and relocate GA services currently from Sandwell General. The Trust is aiming to maintain access to Walsall Manor Hospital.

The following outlines the key benefits of the new facilities and the case for centralising GA services into this location:

- High quality, purpose built facilities to meet the needs of the service and enhance the user's experience. The service at Birmingham Dental Hospital is and will continue to be provided by a specialist Paediatric and Special Care Dental Consultant team supported by Consultant Anaesthetists from both University Hospital Birmingham NHS FT and Birmingham Women's and Children's Hospital NHS FT.

- Provides long term stability of the service and ensure BCHC has the capacity to provide this service in the same location for many years to come

- Increased theatre capacity to help reduce waiting times for Sandwell patients as well as across the West Midlands

- Create a centre of excellence for these services and support the Dental Hospital training programme

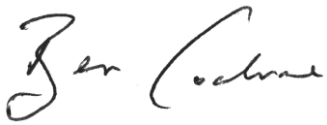
It is also important to make the Committee aware that this does not mean the complete withdrawal of BCHC outpatient Dental services from Sandwell General Hospital. The Trust will continue to provide all other services including those provided under sedation and have recently enjoyed the benefit of upgraded facilities within the hospital. The ideal pathway for both adults and children is to only receive dental services under GA as a last resort. BCHC is therefore well placed to ensure that all other services including those provided under sedation are provided locally either at Sandwell General Hospital, the Lyng Health Centre, Oldbury Health Centre or Glebefields Health Centre.

The downside to this course of action is that these services will no longer be provided as close to home for some Sandwell patients. However, to a large extent the option to continue to deliver services in its current form is not a viable option.

I have copied this letter to NHS England Commissioners and Public Health England colleagues who are fully aware and supportive of this project.

If you could please let me know if you have any further question or if this does or does not need to go to HOSC (my contact details are shown below), we would be grateful for a response as soon as possible in January due to the timescales we are working to. We are aiming to approve our Business Case by the end of March 2020.

Yours Sincerely



Ben Cochrane
Divisional Director Dental Services

Tel: [redacted]
Mobile: [redacted]
Email: Ben.Cochrane2@bhamcommunity.nhs.uk

NHS
Sandwell and
West Birmingham
Clinical Commissioning Group

6 January 2020

NHS Sandwell and West Birmingham Clinical Commissioning Group (SWB CCG) are undertaking a listening exercise from 6 January to 14 February 2020 on the future of walk-in centres in Sandwell and West Birmingham.

We want to hear from as many people as possible during the listening exercise on our proposals for the future of the Summerfield Urgent Care Centre in West Birmingham and the Parsonage Street Walk-in Centre in Sandwell.

For more information and to let us know your views please visit our website at:

https://sandwellandwestbhamccg.nhs.uk/

Please cascade this information to colleagues, friends and family members on our behalf so that as many people as possible can have their say.

As the Clinical Commissioning Group (CCG) responsible for buying and planning healthcare services in Sandwell and West Birmingham, we have been on a journey for over a decade to plan for the future of healthcare services for the local area which has included an extensive amount of engagement. We have made a lot of progress:

- We have extended access to primary care, meaning more appointments are now available with a GP, practice nurse or other healthcare professional.
- We have improved NHS 111, with more access to clinical advice via this service.
- We have planned and commissioned the new Midland Metropolitan Hospital which will be a major asset for healthcare locally.

However, alongside all these positive developments, we have also seen the demand for walk-in centres increase, as has demand for all urgent care services. This has occurred despite the significant investment in primary care services which has enabled us to offer more appointments with a range of clinicians and extend opening hours for local GP practices and we wish to continue our conversation on this topic.

We now need to make some changes to urgent care services because:

- There are new national requirements for urgent care which means we are required to change and improve how we provide walk-in centre services and they will be called urgent treatment centres.

- The contracts for our two local walk-in centres are coming to an end and we need to review how these services are provided in future. The two walk-in centres are: Parsonage Street Walk-in Centre and Summerfield Urgent Care Centre
- There has been a delay in the build of the Midland Metropolitan Hospital.

People can complete the questionnaire online at:

https://www.surveymonkey.co.uk/r/SWB_UTC

We highly value your feedback and input and we look forward to hearing your views.

In anticipation thank you for completing the questionnaire and cascading this information as requested.

Yours sincerely,

Dr Sommiya Aslam

Clinical lead for Urgent Care
Sandwell and West Birmingham CCG