

**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)*

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## 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 policies. 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.

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**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 them 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 five 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	<b>YMCA</b> 38 Carter's Green, West Bromwich, B70 9LG
Tuesday 24 September 2019	1.30-5pm	<b>Nishkam Civic Association</b> 6 Soho Road, Handsworth, Birmingham, B21 9BH
Thursday 3 October 2019	9.30am-12.30pm	<b>Midlands Arts Centre (MAC)</b> Cannon Hill Park, Birmingham, B12 9QH
Thursday 3 October 2019	1.30-5pm	<b>St Mary and St Margaret Church</b> Chester Road, Birmingham, B36 9DE
Monday 7 October 2019	9.30am-12.30pm	<b>Solihull Royal British Legion</b> 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 patients 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 than 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 Bariatric 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 that 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**

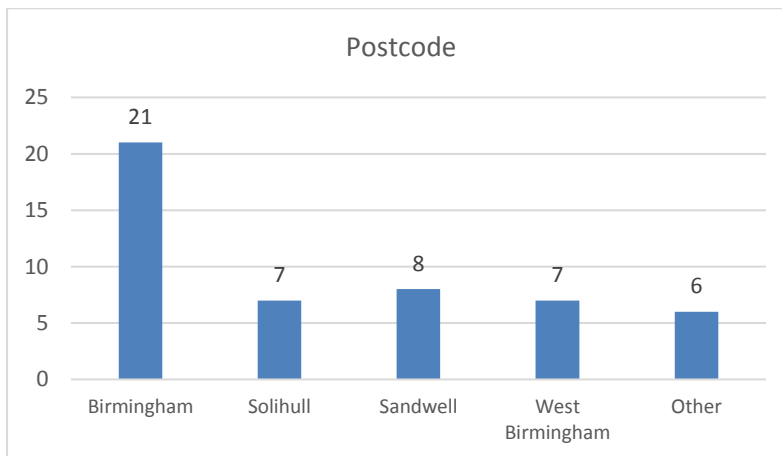
The following statement was received from Muscular Dystrophy UK: *“Muscular Dystrophy UK (MDUK) support the implementation of the non-invasive ventilation (NIV) policy which Birmingham and Solihull CCG & Sandwell & West Birmingham CCG have developed. MDUK note that the term ‘neuromuscular disorders which 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 5<sup>th</sup> September until the 11<sup>th</sup> 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

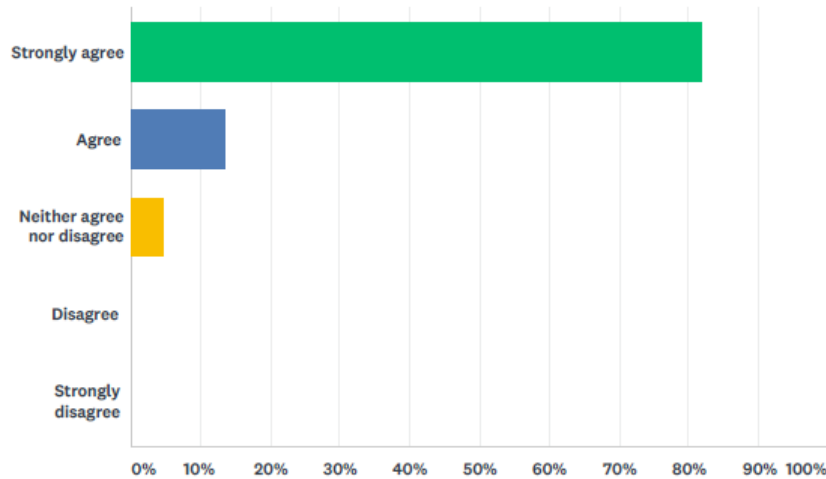


Birmingham	Solihull	Sandwell	West Birmingham	Other	Total
21	7	8	7	6	49
43%	14%	16%	14%	12%	

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



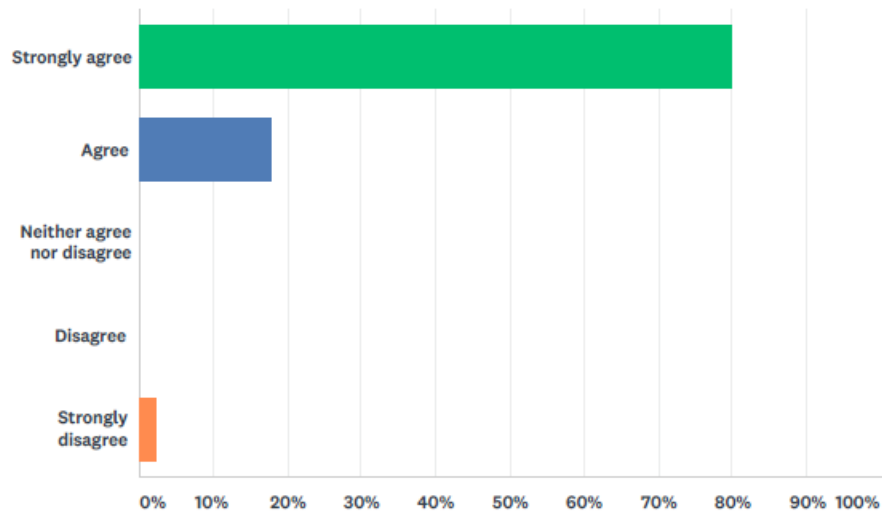
ANSWER CHOICES	RESPONSES	
Strongly agree	81.82%	36
Agree	13.64%	6
Neither agree nor disagree	4.55%	2
Disagree	0.00%	0
Strongly disagree	0.00%	0
TOTAL		44

**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
<b>TOTAL</b>		<b>45</b>

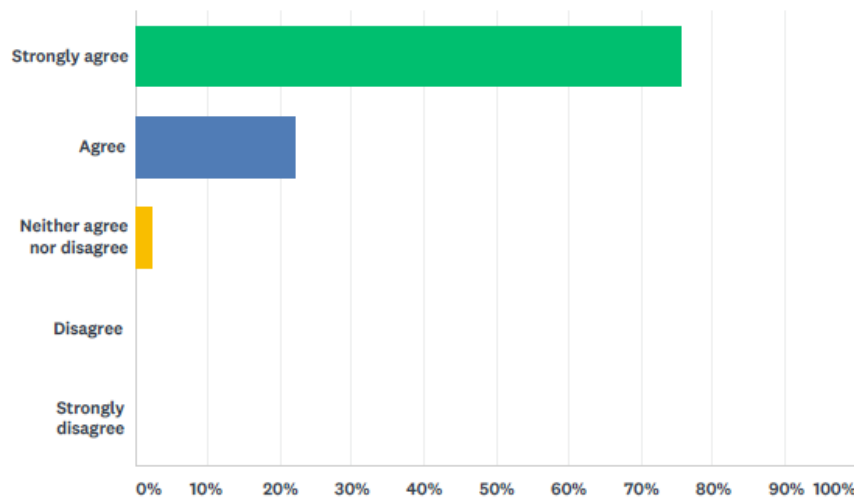
**Analysis:**

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



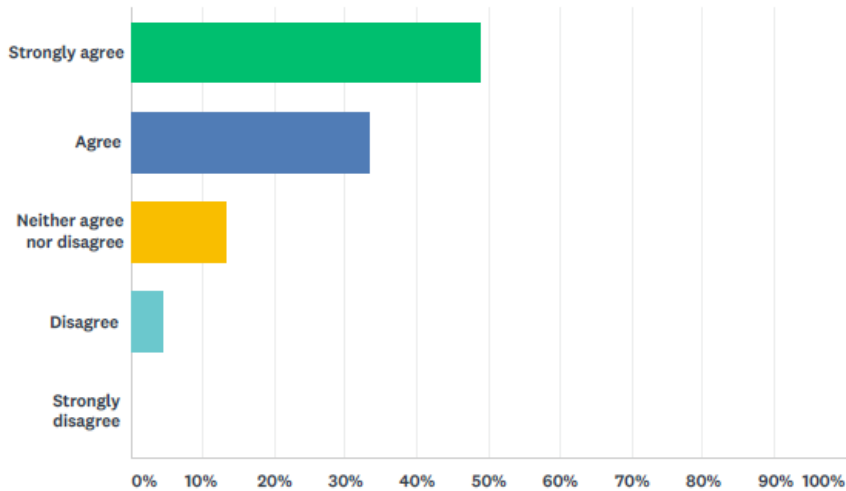
ANSWER CHOICES	RESPONSES	
Strongly agree	75.56%	34
Agree	22.22%	10
Neither agree nor disagree	2.22%	1
Disagree	0.00%	0
Strongly disagree	0.00%	0
<b>TOTAL</b>		<b>45</b>

**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



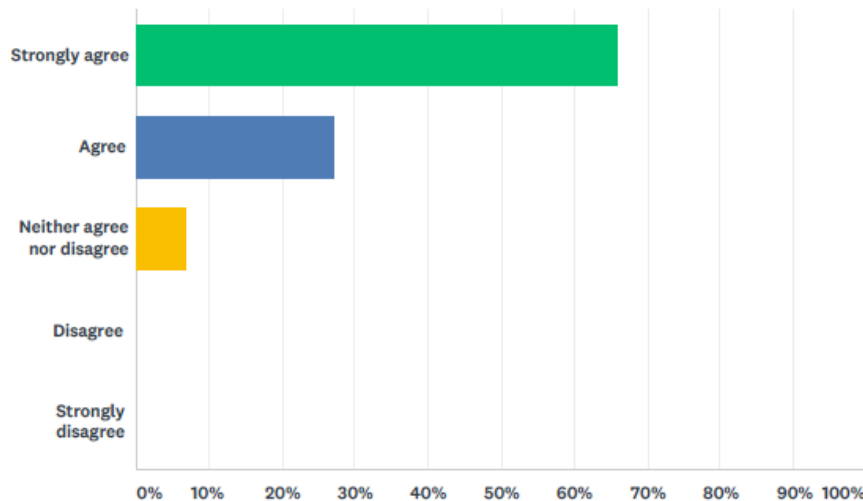
ANSWER CHOICES	RESPONSES	
Strongly agree	48.89%	22
Agree	33.33%	15
Neither agree nor disagree	13.33%	6
Disagree	4.44%	2
Strongly disagree	0.00%	0
TOTAL		45

**Analysis:**

Over 82% strongly agreed or agreed that clinical practices should not be offered if there is limited clinical evidence to support effectiveness.

## Q6 To prioritise treatments which provide the greatest benefits to patients.

Answered: 44 Skipped: 5



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:**

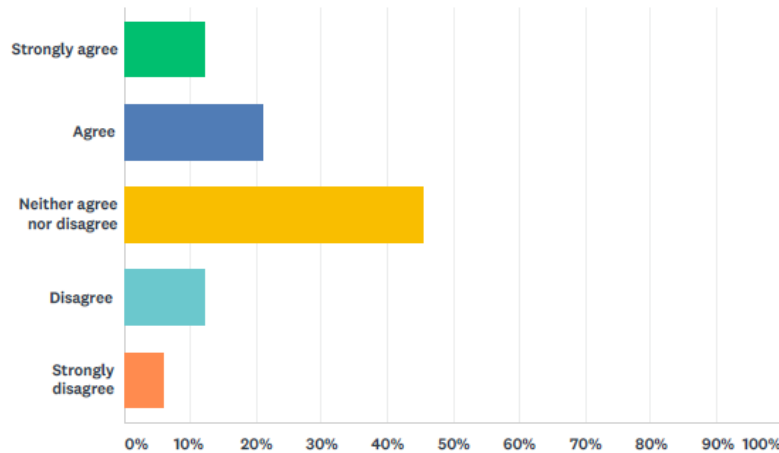
Due to the clinical evidence which fails to demonstrate clinical effectiveness of this intervention in these clinical circumstances the proposed change is not to offer Arthroscopic sub-acromial decompression as a clinical treatment.

#### **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.

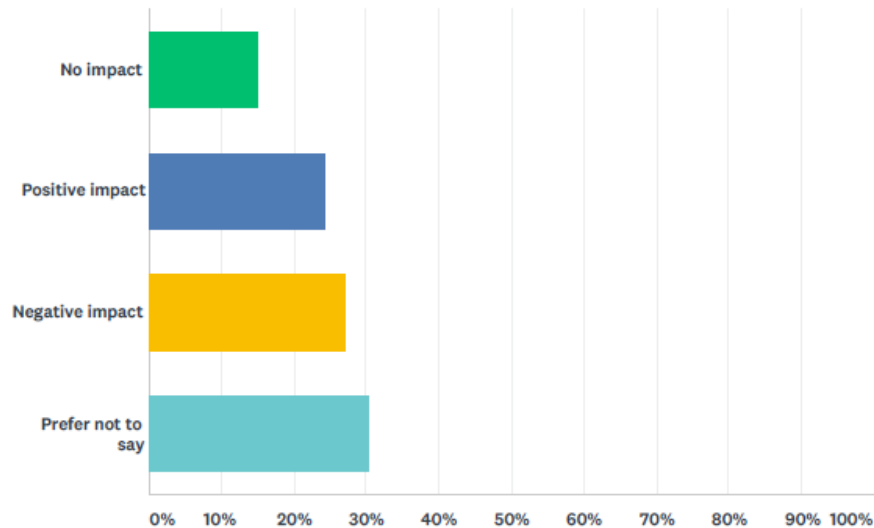
In addition, those who provided further comments half of those received mention in some cases this could be of benefit to a patient in pain and an individual need, needs to be assessed.

*“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
<b>TOTAL</b>		<b>33</b>

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.

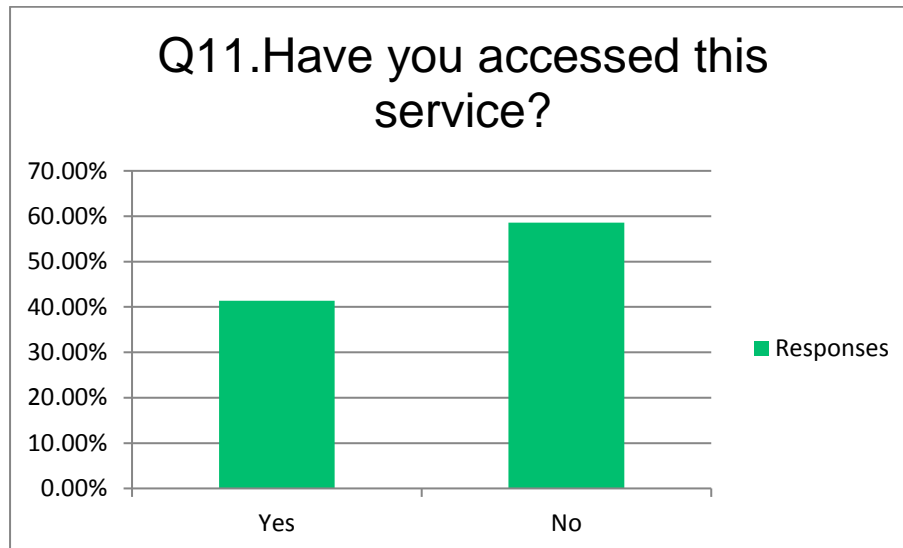
## Summary of survey responses: Image guided therapeutic intra-articular joint injections with corticosteroids with/without local anaesthetic

### 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):

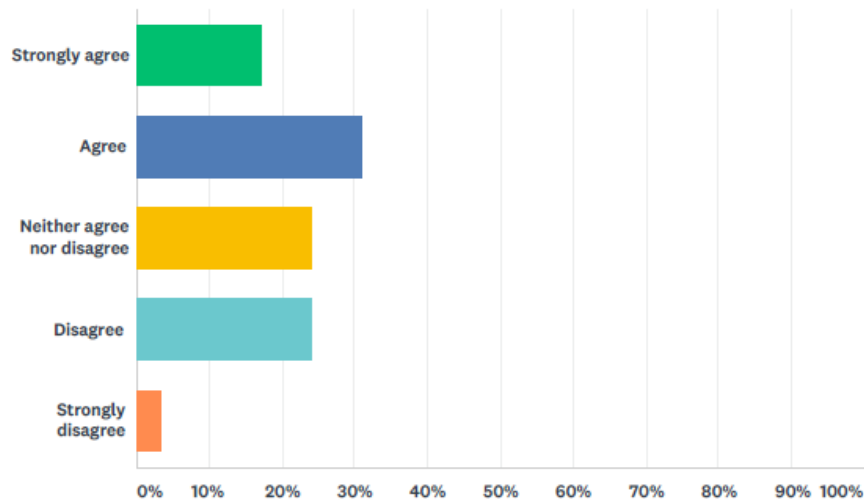
Image guided injections should only be offered to patients where other treatments have failed and should only be undertaken in the small joints (defined as joint of the hands and feet).



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
<b>TOTAL</b>		<b>29</b>

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 performing treatment.

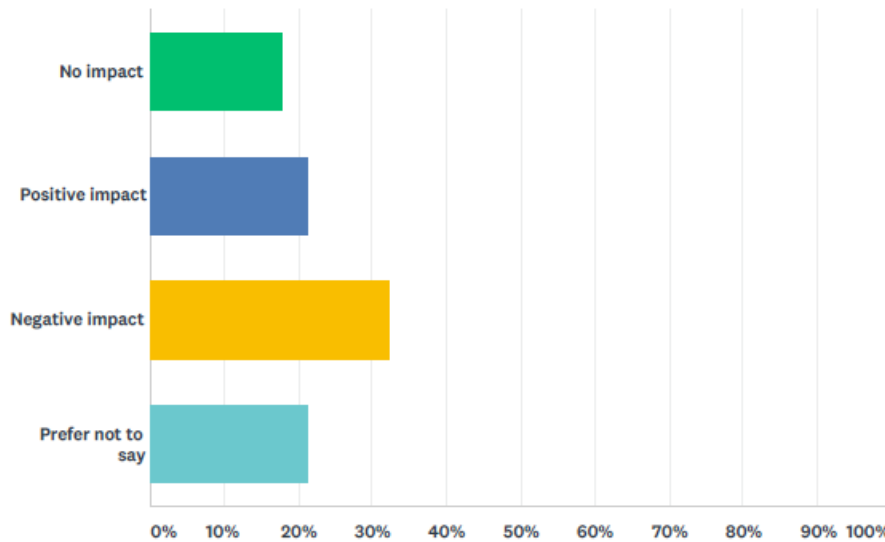
*“it is very difficult to administer an injection into the hip especially if the anatomy is also altered and hence safer and also beneficial to inject under imaging guidance. Hence, I would support injections under guidance for hips for this reason. knee joint injections can be done without imaging due 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

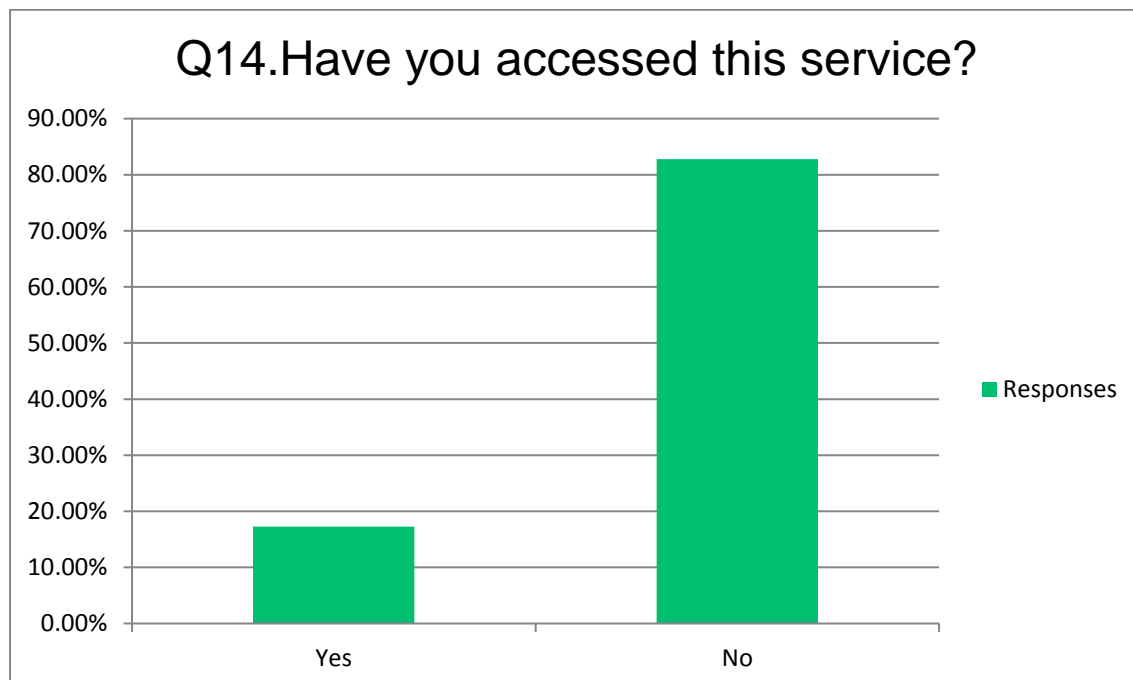
In this procedure, high volume injections (10-55mls of saline solution) are injected into joints using imaging guidance through an x-ray (fluoroscopy), ultrasound or computed tomography (CT) to identify the correct location to insert the needle.

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.

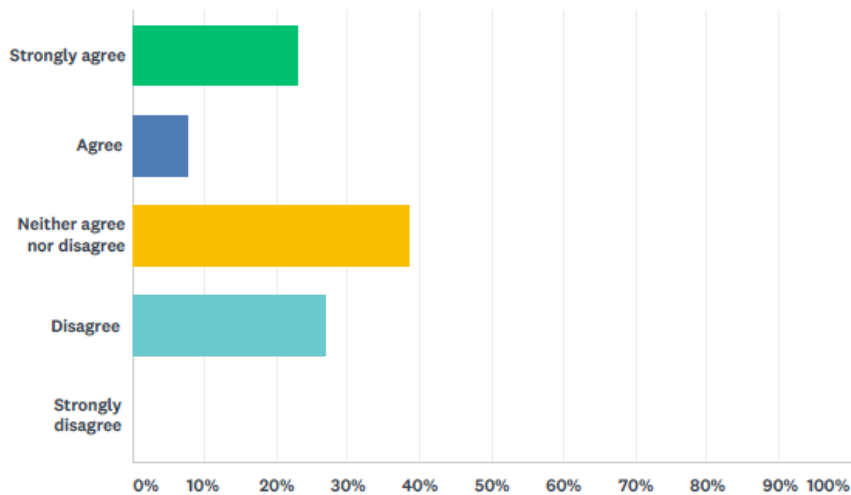
From the 29 responders who completed this question, 17.24% had accessed this service.





## 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
<b>TOTAL</b>		<b>26</b>

Below are the exact comments received from the respondents:

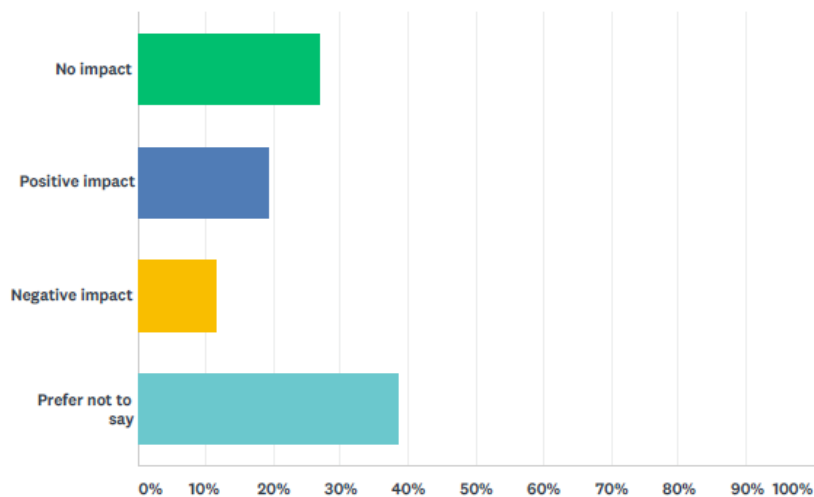
- I understand that further research into the use of saline injections is on-going?
- Not enough evidence to go one way or another
- Until there is clinical evidence to either support or stop this procedure then i feel the individual clinical has the say over whether to continue or not.
- Don't treat 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.

**Q16 Please indicate the impact of the proposed change(s).**

Answered: 26 Skipped: 23



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

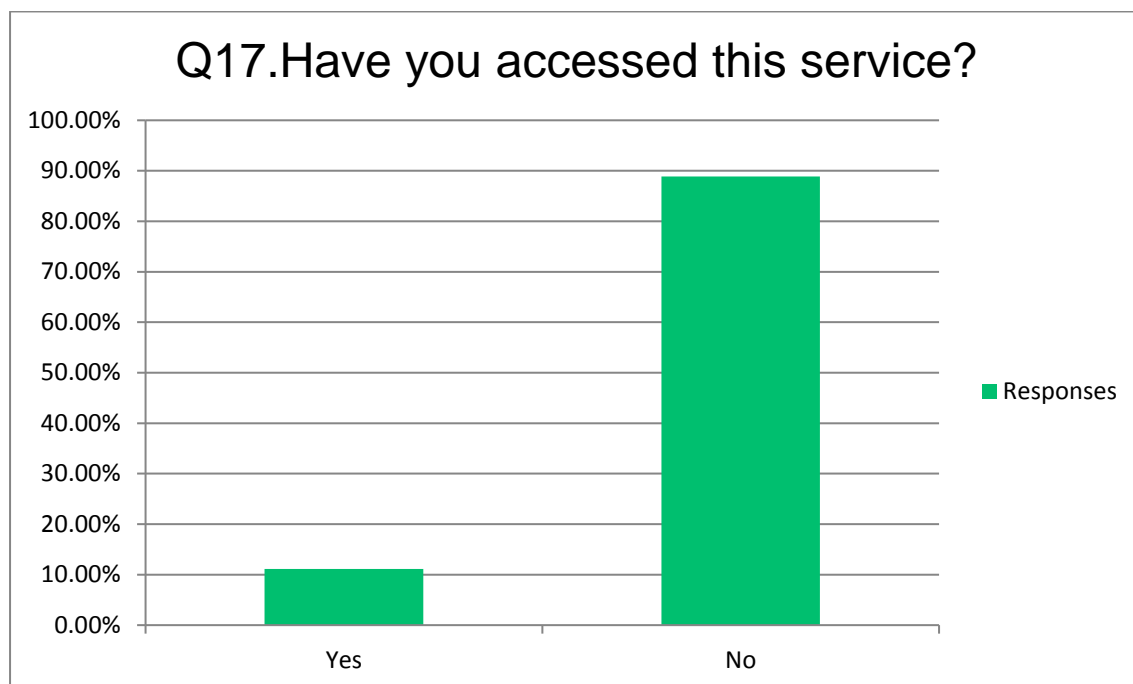
### Overview:

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):

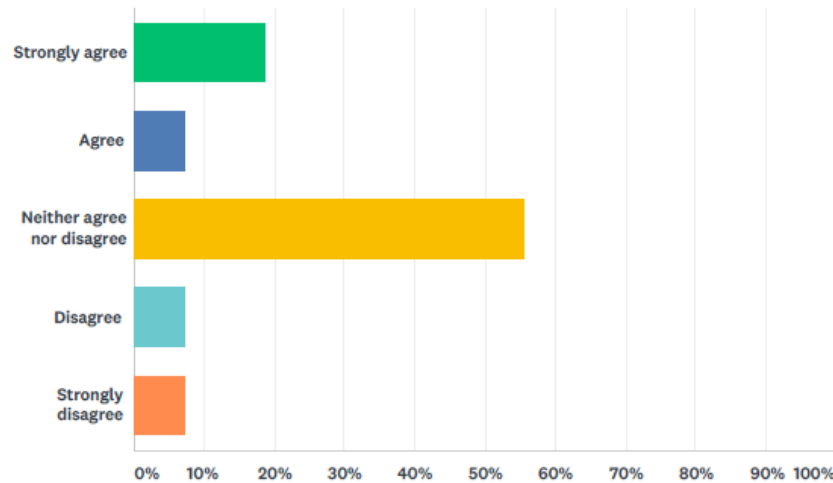
Currently, there is no policy for this clinical treatment. Therefore, based on the lack of robust clinical evidence to support this clinical treatment it is proposed that a policy is developed stating that the treatment is not routinely commissioned.

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

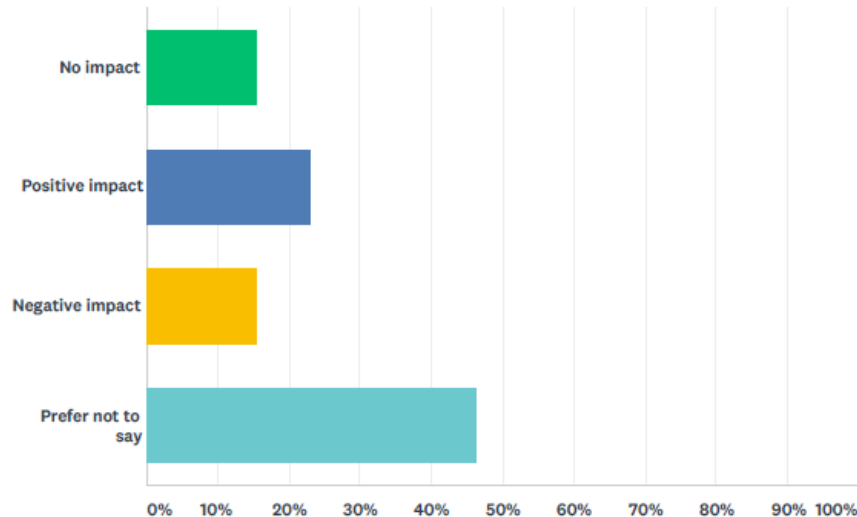
- Evidence presented in non-union if long bones as included in the info reviewed
- lack of evidence for its use
- Not qualified to comment
- I presume that "it is not routinely commissioned" does not mean that it will never be commissioned (or am I incorrect in this assumption?!
- Personal lack of investigation 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.



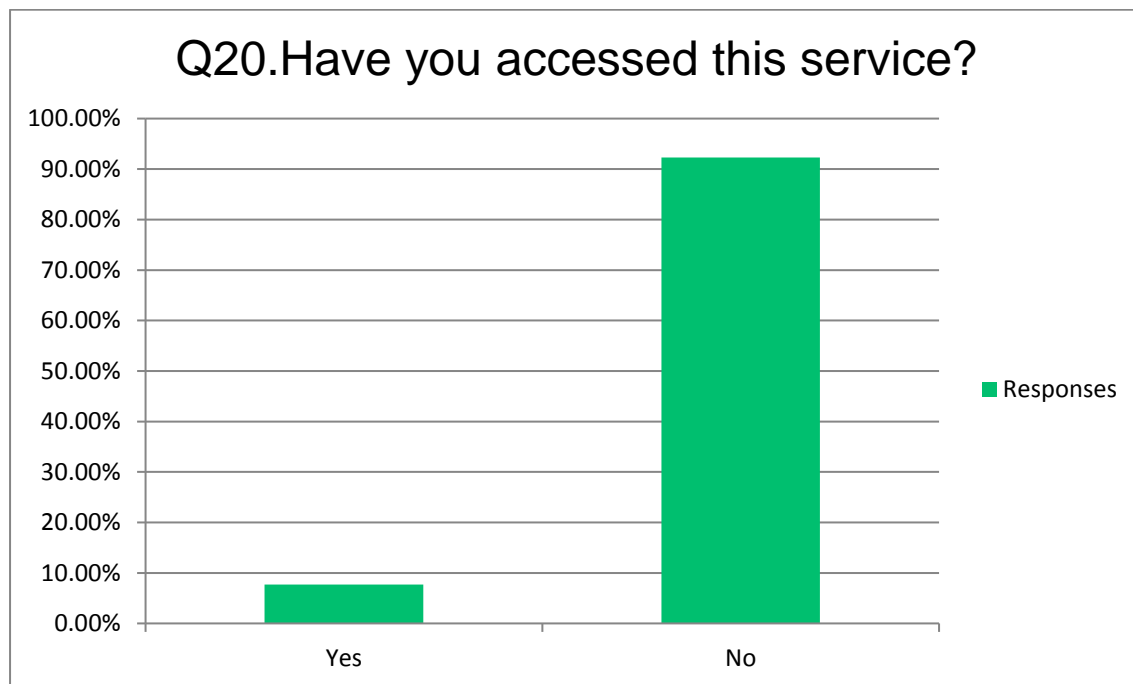
## Summary of survey responses: The use of liposuction in lymphoedema

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):

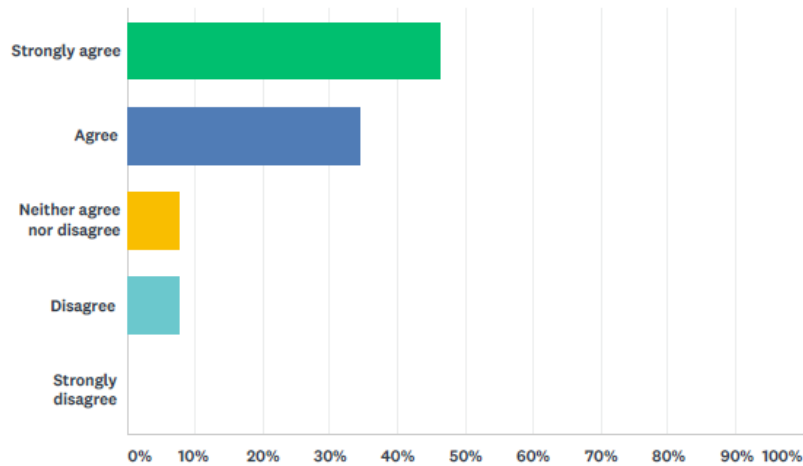
Currently, there is no policy for this clinical treatment. Therefore, a draft policy will be developed stating that this treatment will be available for patients with lymphoedema who have failed conservative management in line with the current patient pathway for treatment of lymphoedema. Patient selection 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

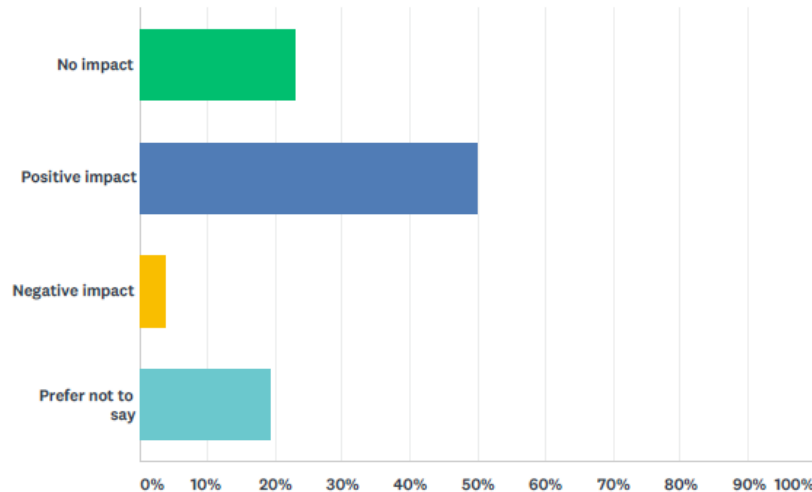
**Analysis:**

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

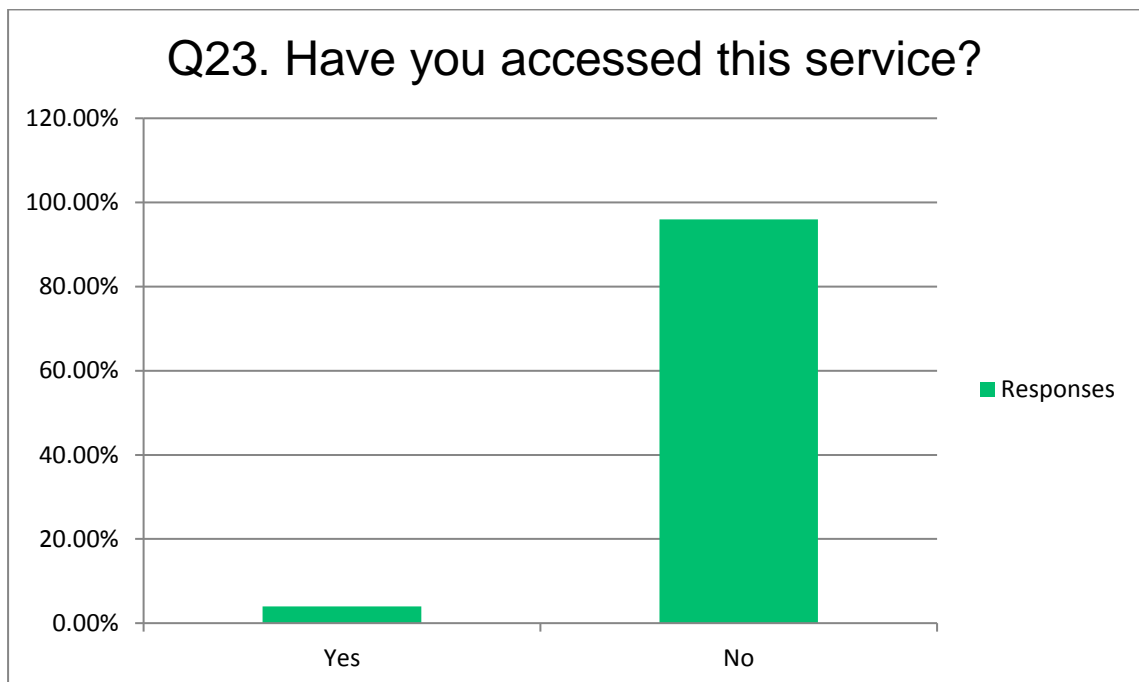
Lipoedema is a long-term (chronic) condition where there is an abnormal build-up of fat cells in the legs, thighs and buttock areas, and sometimes in the arms.

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):

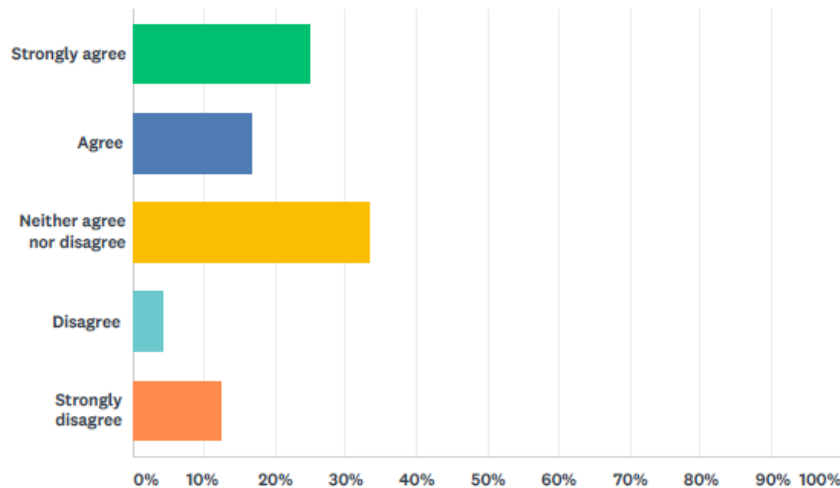
Some research has been undertaken for the use of liposuction in lipoedema, which demonstrated clinical benefit to patients in the study. However, the number of patients in the trials is small. Further research is needed before the CCG may support this intervention. Currently there is no policy for liposuction. 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
<b>TOTAL</b>		<b>24</b>

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 Tumescant 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 Tumescant 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 Tumescant 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.

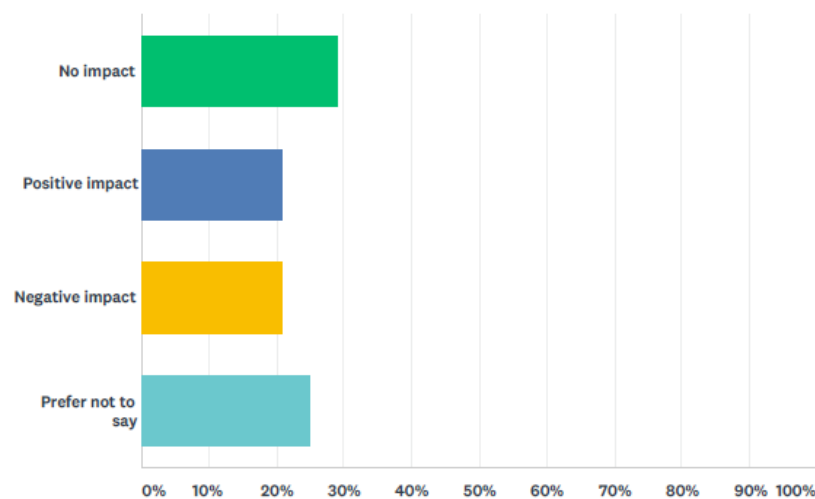
**Analysis:**

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”*

**Q25 Please indicate the impact of the proposed change(s).**

Answered: 24 Skipped: 25



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
<b>TOTAL</b>		<b>24</b>

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/m<sup>2</sup>

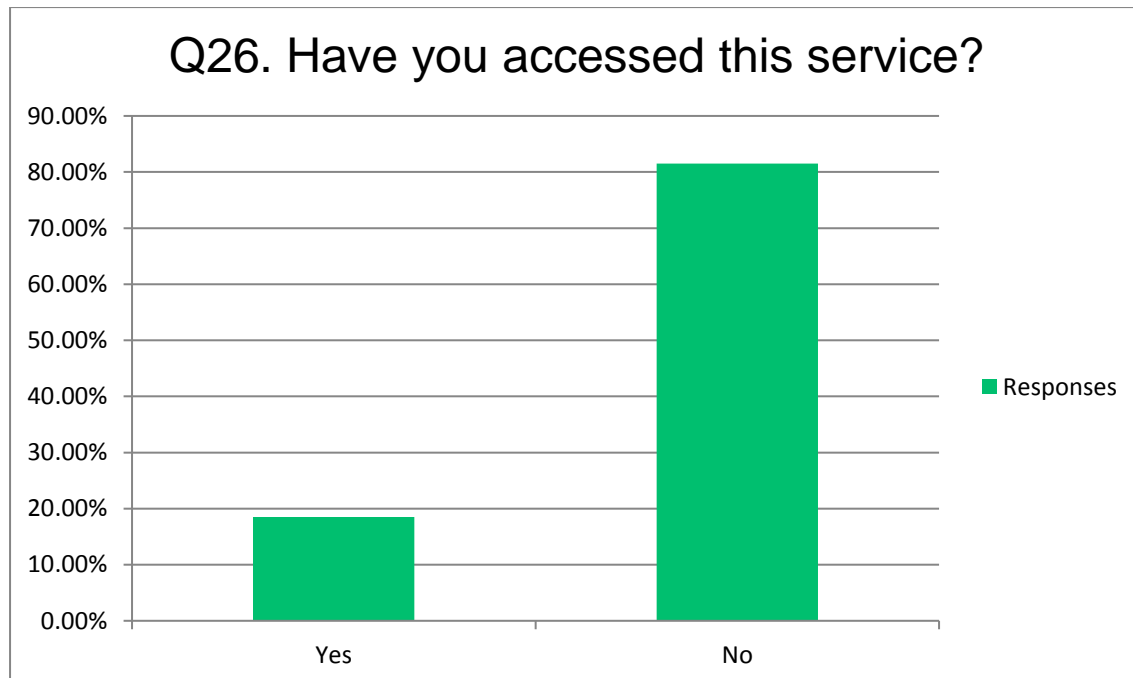
AND

Type 2 diabetes mellitus which has been diagnosed within the last 10 years.

OR

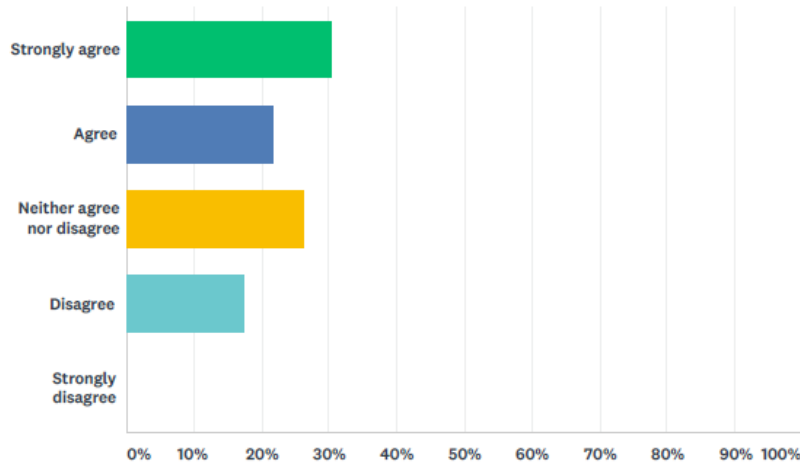
- BMI of >50kg/m<sup>2</sup>

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 are 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 of 45Kg 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:**

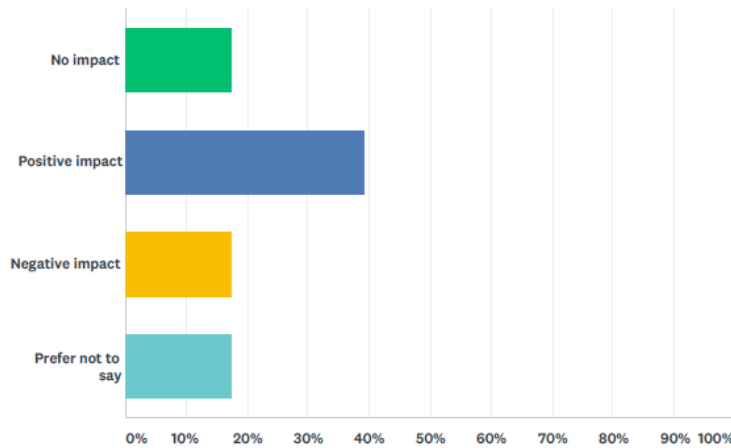
Although over 52% agree with the proposed policy criteria those comments received by healthcare professionals question the eligibility criteria. Particular concerns are also raised that the proposed policy may exclude those who are in drastic need of the surgery and may oppose current NICE guidelines.

*“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:**

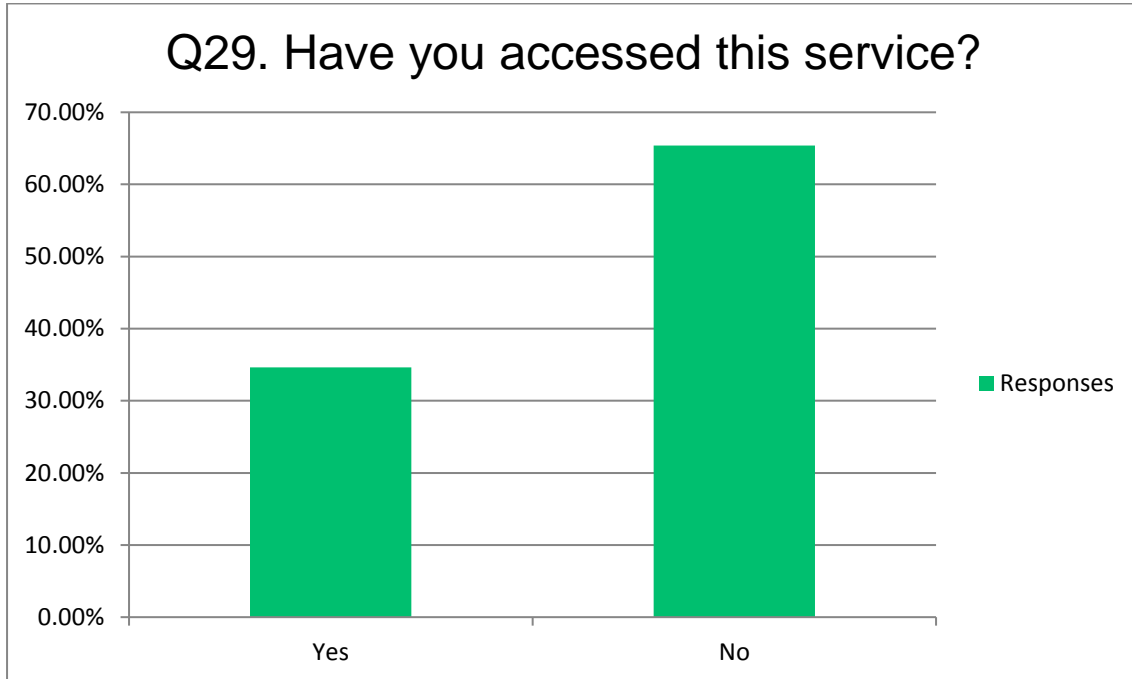
Arthroscopic knee surgery is a treatment which may include:

- 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):**

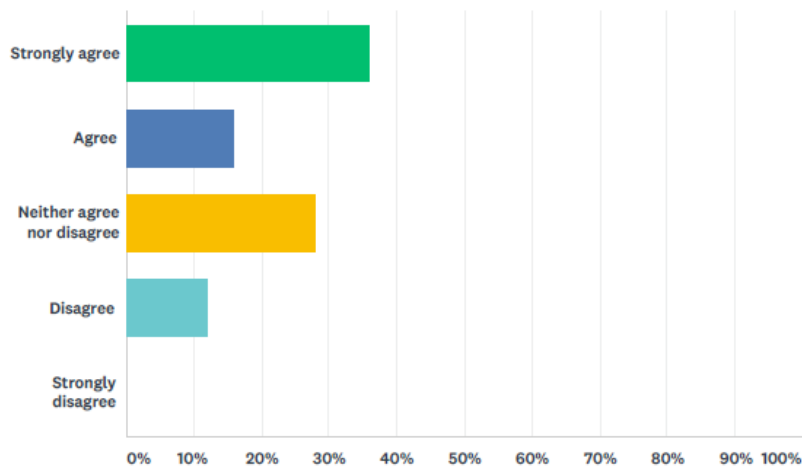
Clinical evidence strongly demonstrates that knee arthroscopy in acute knee injury provides no greater benefit than conservative treatment immediately following injury. The current policy for knee arthroscopy is for degenerative knee disease only. The proposed draft policy will state that arthroscopy 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
<b>TOTAL</b>		<b>25</b>

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

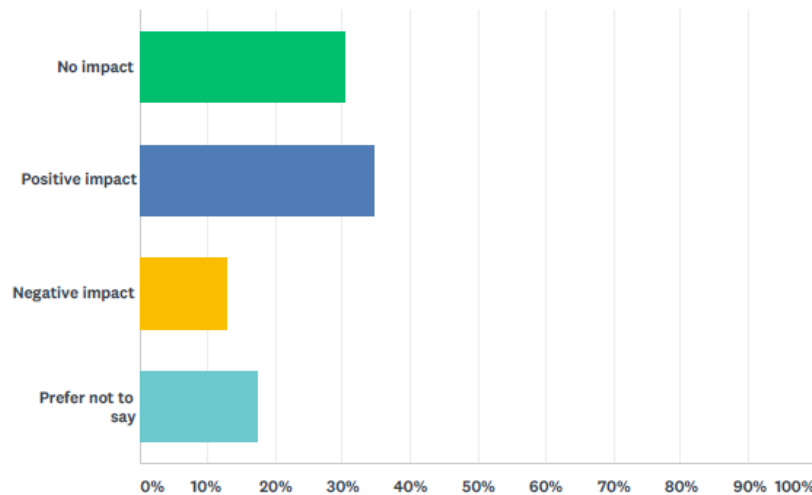
**Analysis:**

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

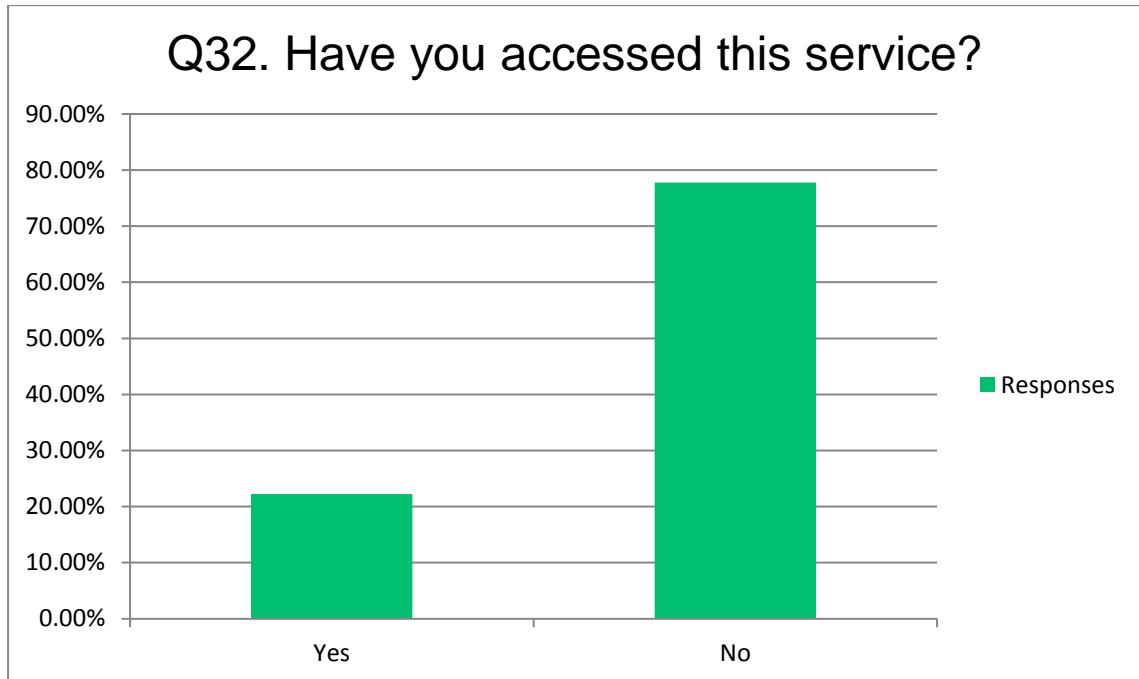
- More than one condition affecting the level of oxygen in the blood which could lead to pulmonary hypertension or heart failure

OR

- Two or more hospital admissions over the past 12 months needing NIV treatment admissions to which the patient has responded well

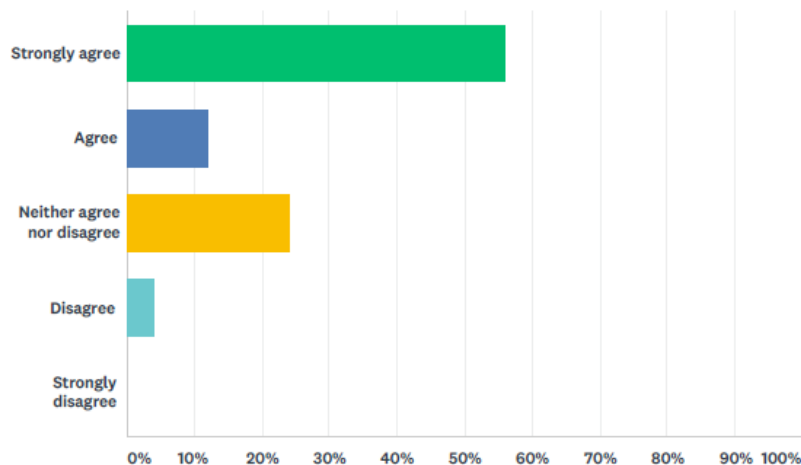
This means the patient's NHS commissioning organisation (CCG), who is responsible for buying healthcare services on behalf of patients, will **only** fund the treatment if an Individual Funding Request (IFR) application has shown exceptional clinical need and the CCG supports this.

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

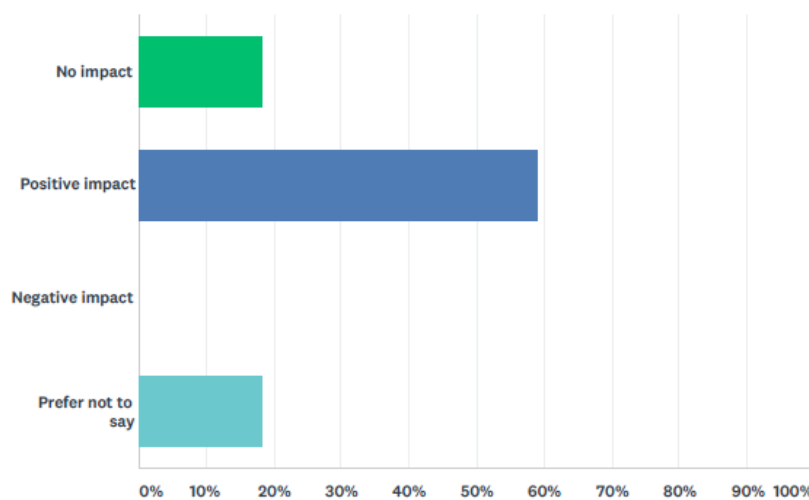
- Being unable to breathe or having difficulty in breathing May make the Patient very anxious. Anything that can alleviate their anxiety and help their breathing can only be a good thing
- Do whatever is best for the patient
- See generic comment about readability etc
- My mother in law had COPD and 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
<b>TOTAL</b>		<b>22</b>

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**

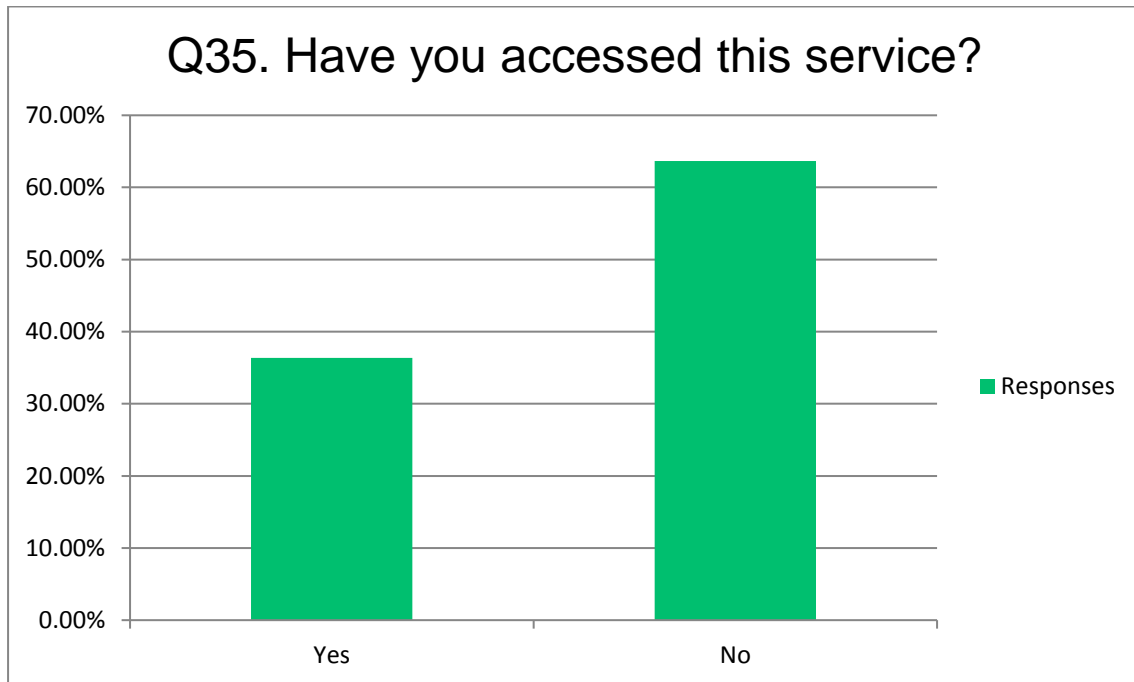
**Overview**

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):**

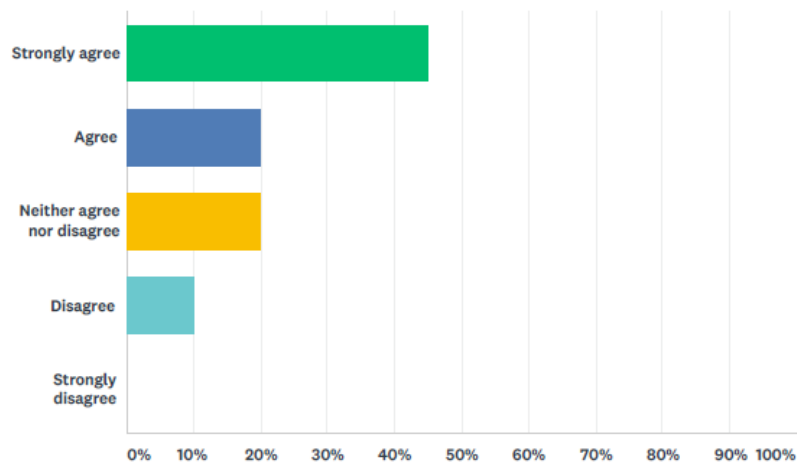
Currently, there is no policy for this treatment. Therefore, a policy will be drafted to reflect the most up to date clinical evidence and clinical expertise stating that CPAP treatment will be commissioned for patients diagnosed with moderate or severe symptomatic obstructive sleep apnoea/hypopnoea syndrome (OSAS). CPAP will only be recommended for patients with mild OSAHS if the condition is impacting on the patient's ability to carry out 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
<b>TOTAL</b>		<b>20</b>

Below are additional comments provided by the respondents:

- Widens access to a treatment for an increasing common complaint



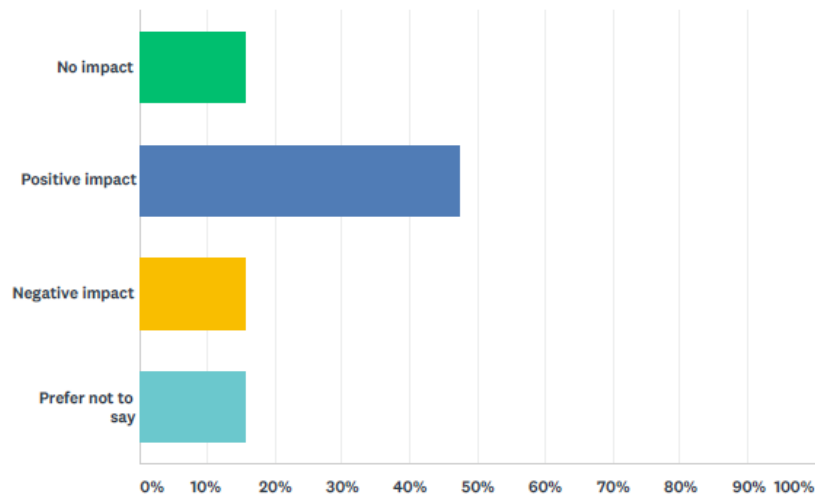
- Haven't used this to be able to comment
- It offers peace of mind and a better quality of life both for the patient and their partner
- Don't treat
- As above
- It is not just the Patient who suffers in this condition their partner is often kept awake by the snoring of the Patient (although the machine 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.

### Q37 Please indicate the impact of the proposed change(s).

Answered: 19 Skipped: 30



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:

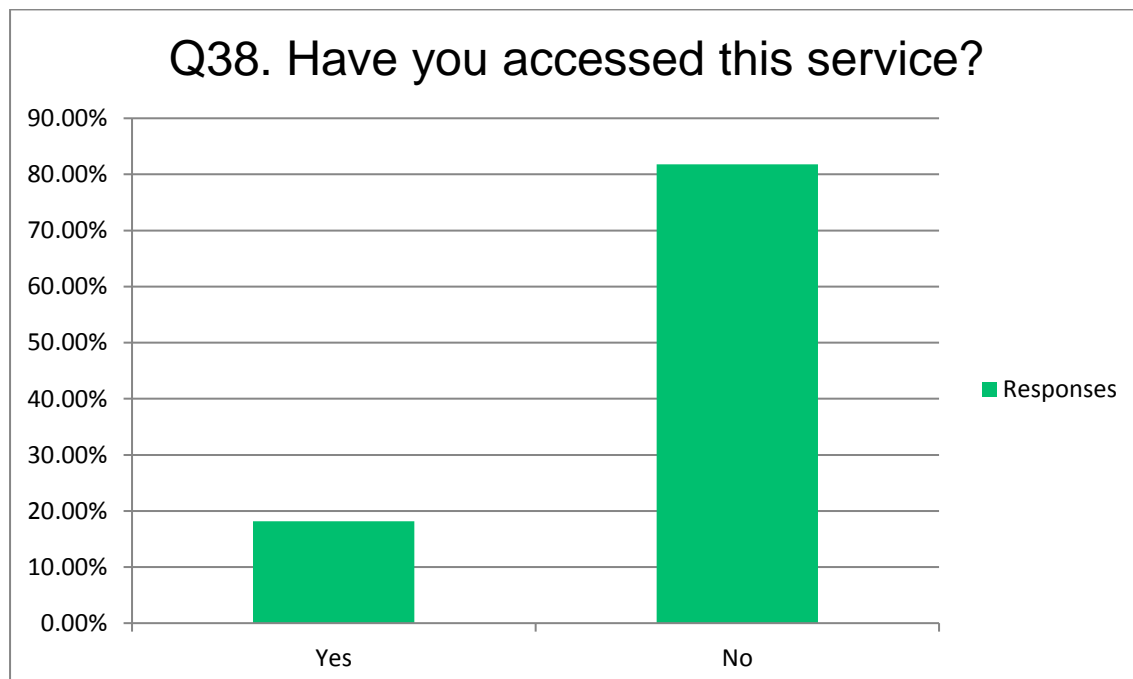
- **Non-absorbable synthetic polymers** (polypropylene)
- **Absorbable synthetic polymers** (polyglycolic acid or polycaprolactone)
- **Biologic** (acellular collagen sourced from cows or pigs)
- **Composite** (a combination of any of the three previous materials)

**The policy relates to the use of biologic mesh in hernia repair.**

### Policy review:

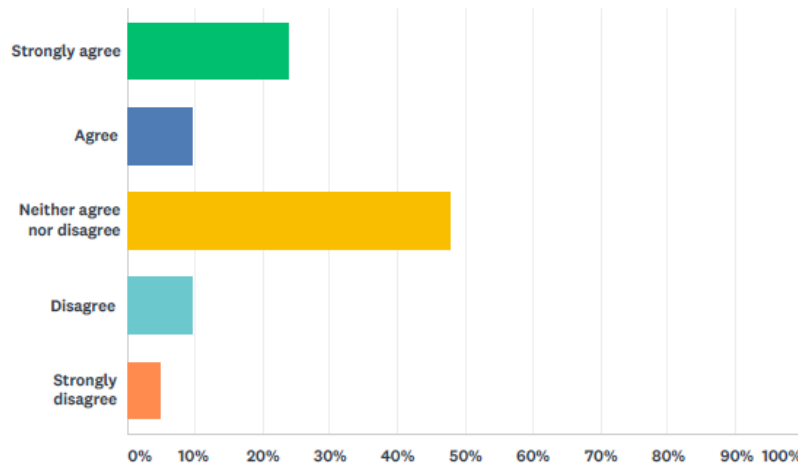
Currently there is no policy for the use of biological mesh in hernia repair meaning it is not commissioned by the NHS as a clinical treatment. Due to the lack of evidence to support biological mesh over standard mesh, a draft policy will be developed stating that the use of biological mesh is not routinely 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 from 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.

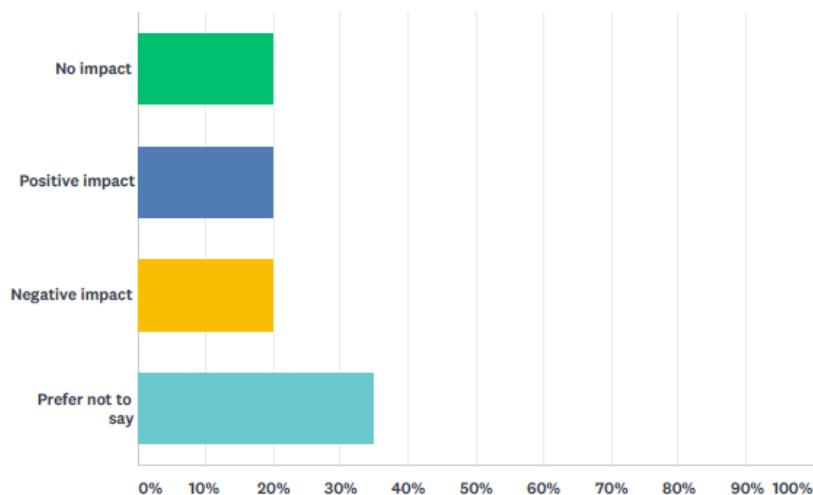
- This should be left to the patients, GP and specialist with regard to NICE guidelines, if any. If the CCG wishes to ration this against clinical advice of GP and specialists, it should contact affected patients direct and indemnify Drs.

**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:

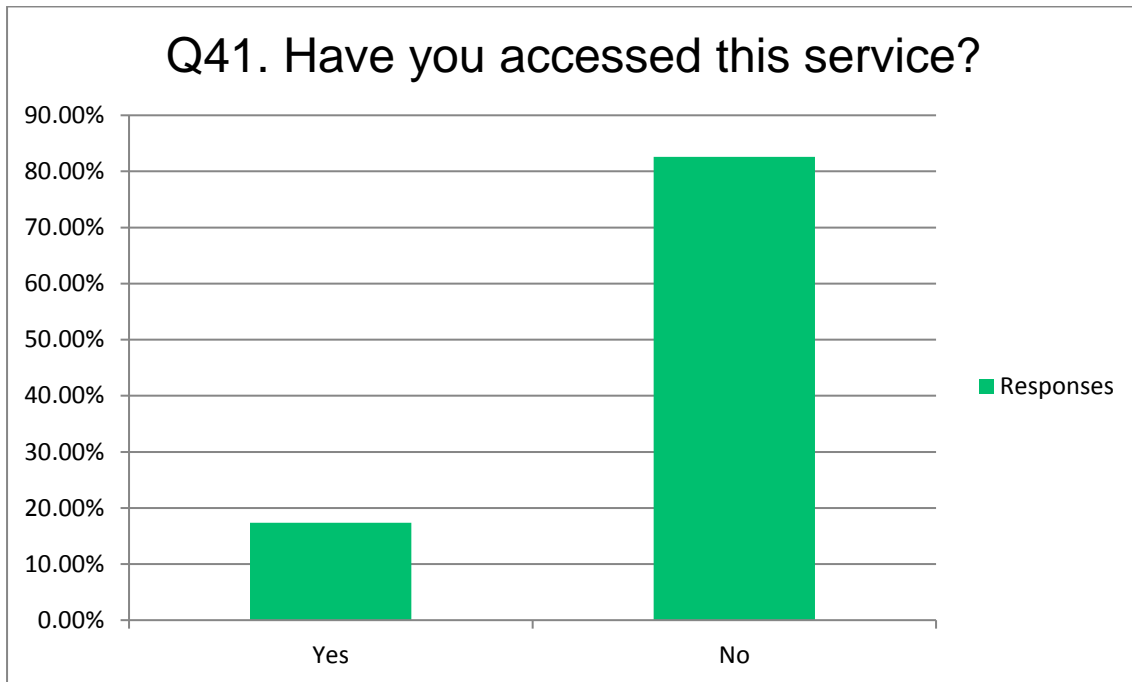
- The patient is 18 or over at the time of application

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:

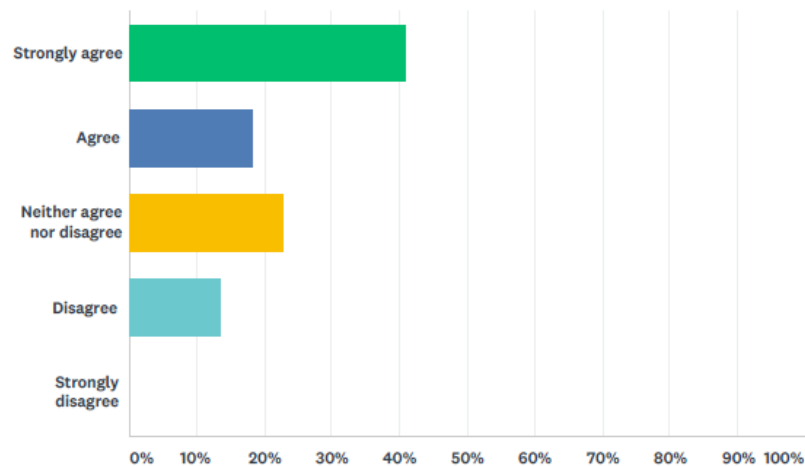
- Skin folds are causing severe functional impairment, which is impacting on the patient's ability to carry out activities of daily living
- From the 23 responses to this question, 17.39% have accessed this service





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

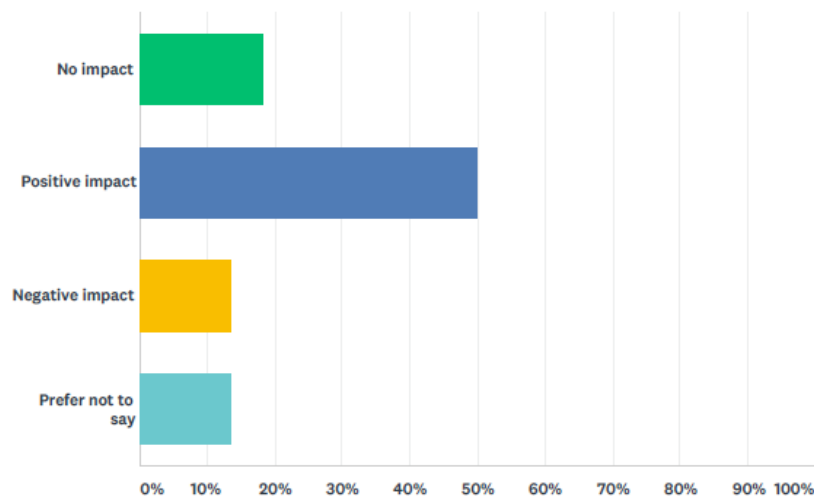
- Surely the mental state of the patient should be assessed also. This loose skin may affect their body image and impinge on their mental health.
- This should be left to the pt, GP and specialist with regard to NICE guidelines, if any. If the CCG wishes to ration this against clinical advice of GP and 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

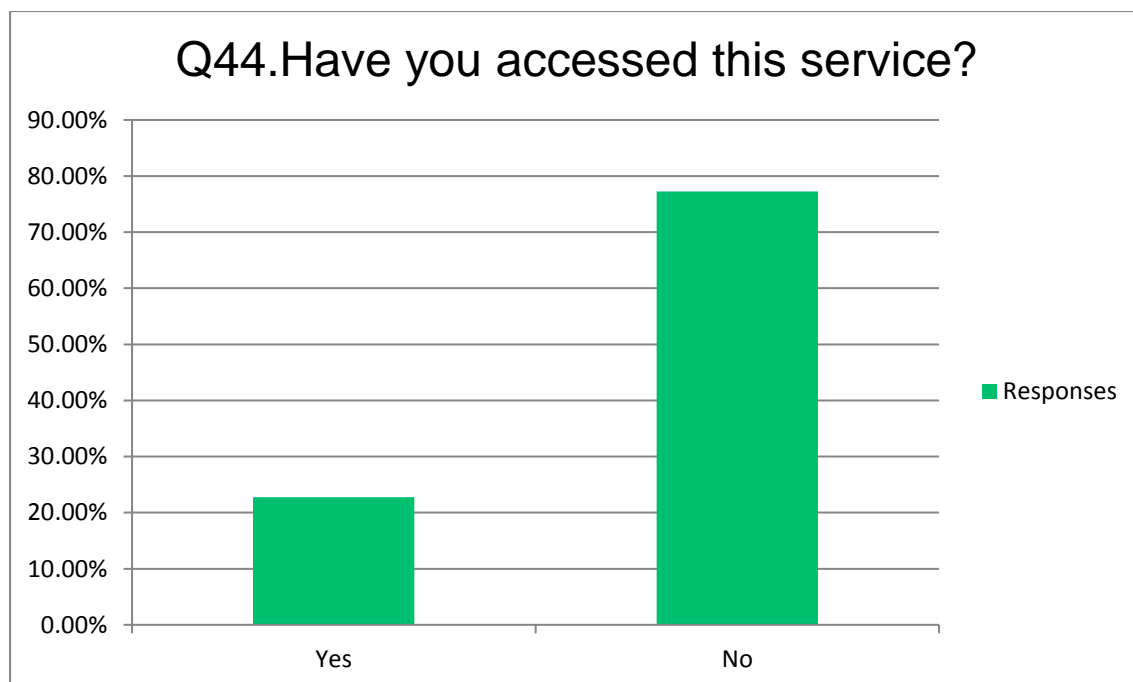
### Overview

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):

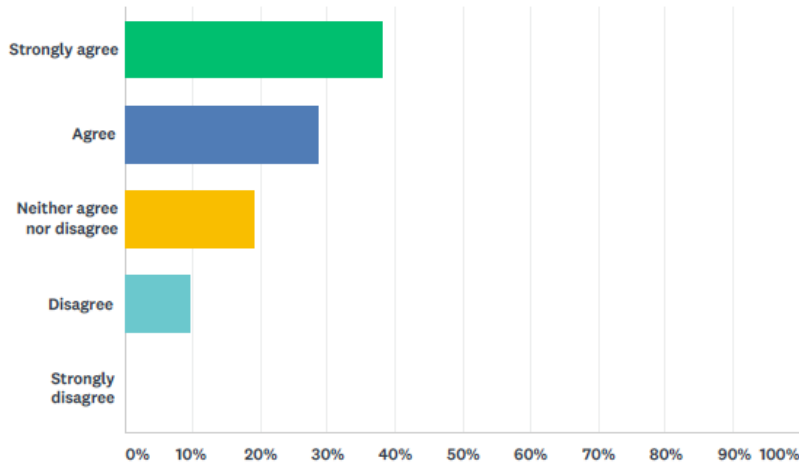
The current policy only relates to children. The proposed new policy widens the scope to incorporate the small cohort of adult patients where the adenoids are enlarged. Adenoidectomy will then be available to adults and children when there is documented medical problems caused by obstruction of the airway by enlarged adenoids and all conservative treatments have been exhausted.

*From the 22 responses who answered this question, 22.73% have accessed this service.*



Q45 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	28.57%	6
Neither agree nor disagree	19.05%	4
Disagree	9.52%	2
Strongly disagree	0.00%	0
<b>TOTAL</b>		<b>21</b>

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.

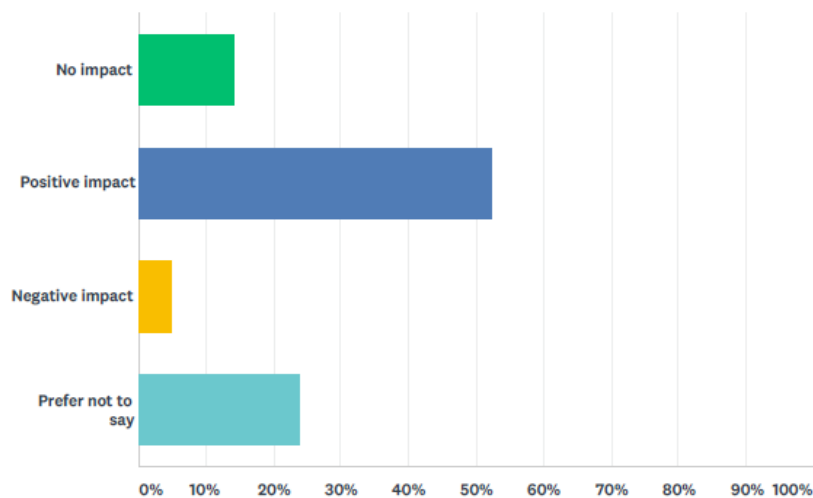
**Analysis:**

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.

### Q46 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	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

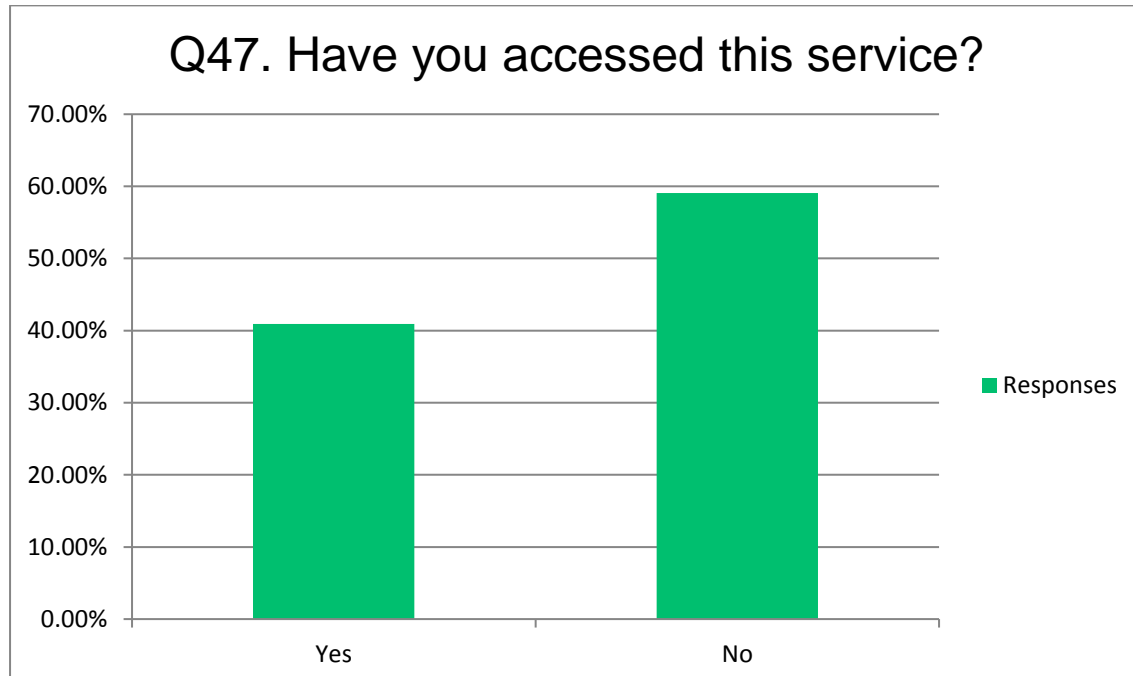
### Overview

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.

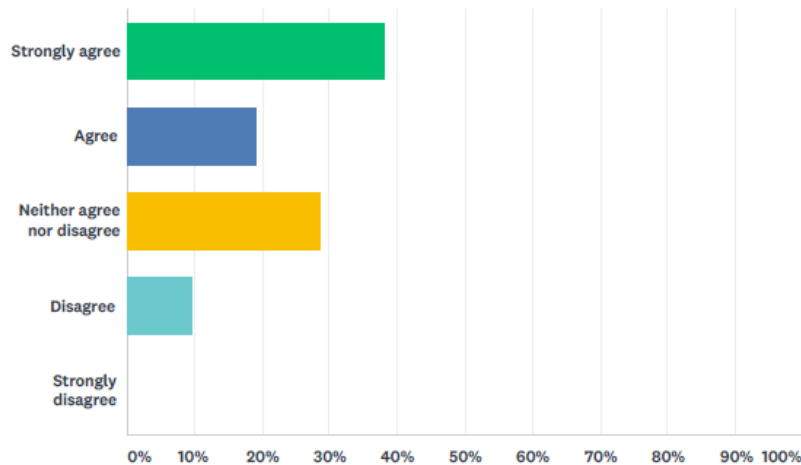
From the 22 responses received for this question, 40.91 have accessed this service





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:

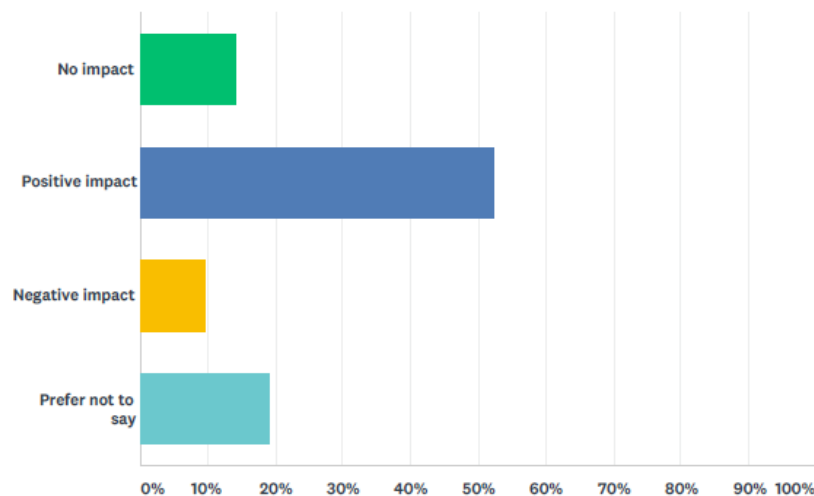
- A speedier diagnostic for patients, especially where there is a risk of endometrial pathology
- If it is the first line of action it may save the patient from further treatment
- Don't treat
- This can impact on the lives of women with this condition
- Evidence based decision
- Sometimes just having 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 2<sup>nd</sup> 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:

- 19<sup>th</sup> September 2019
- 1<sup>st</sup> October 2019
- 8<sup>th</sup> 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	<ul style="list-style-type: none"> <li>UHB Consultant: Thank you. I have been advised by our specialised upper limb experts. Happy with this.</li> <li>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.'</li> </ul>	Lewis (2011) Subacromial impingement syndrome: a musculoskeletal condition or a clinical illusion? Physical Therapy Reviews, 16(5), pp. 388 – 398.	Yes



		<ul style="list-style-type: none"> <li>• 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’.</li> <li>• 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).</li> <li>• Rotator cuff tendinopathy/shoulder impingement syndrome appear to be multi-factorial in nature &amp; 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</li> </ul>	<p>Lewis (2016) Rotator cuff related shoulder pain: Assessment, management and uncertainties. Manual Therapy, 23, pp. 57 – 68.</p>	
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		<p>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)</p> <ul style="list-style-type: none"> <li>• 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).</li> <li>• 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</li> </ul>		
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		<p>policy does not provide a comprehensive pathway for these patients.</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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</li> <li>• 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.</li> </ul> <p>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</p>		
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		<p>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 Dupuytren's 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!</p> <ul style="list-style-type: none"> <li>• 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</li> </ul>		
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		<p>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.</p>		
<p><b>DRAFT</b> Image guided therapeutic intra-articular joint injections with corticosteroids with/without local anaesthetic.</p>	<p>Yes</p>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• GPSI: <b>Ultrasound Guided Injections</b></li> </ul>	<p><a href="https://bjgp.org/content/67/661/378">https://bjgp.org/content/67/661/378</a> USGI shoulder injections significantly greater clinical improvement</p>	<p>Yes</p>

		<p>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</p> <p><b>Viscosupplement Injections</b></p> <p>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.</p> <ul style="list-style-type: none"> <li>• 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:</li> <li>• Large Osteoarthritic joints do not require US-guided injections (exception: Hip joint) <ul style="list-style-type: none"> <li>• Small joints (e.g. in the hand and foot) where accuracy is important would benefit from US-guidance</li> </ul> </li> <li>• Alternative service model: 3 roomed department with a trained specialist nurse, MSK sonographer and Consultant Rheumatologist with special interest in ultrasound. The</li> </ul>	<p>over LMGI - <a href="https://www.ncbi.nlm.nih.gov/pubmed/26590864">https://www.ncbi.nlm.nih.gov/pubmed/26590864</a> USGI Carpal Tunnel Syndrome better for several markers - <a href="https://bjgp.org/content/67/661/378">https://bjgp.org/content/67/661/378</a> USGI shoulder significant improvement in pain and abduction vs LMGI but small and suggests further research - <a href="https://www.ncbi.nlm.nih.gov/pubmed/23275390">https://www.ncbi.nlm.nih.gov/pubmed/23275390</a> USGI improves</p>	
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		<p>department sees approximately 40-50 patients per week for diagnostic scans and provides a similar sized service for ultrasound guided injections and aspirations.</p> <ul style="list-style-type: none"> <li>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:             <ol style="list-style-type: none"> <li>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”</li> <li>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.</li> <li>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</li> </ol> </li> </ul>	<p>efficiency and cost-effectiveness but more research is needed - <a href="https://www.ncbi.nlm.nih.gov/pubmed/29511701">https://www.ncbi.nlm.nih.gov/pubmed/29511701</a></p>	
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		<p>require imaging guidance for injections, and this must remain an exclusion to the policy.</p> <p>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.</p> <p>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?</p> <ul style="list-style-type: none"> <li>• 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.</li> </ul> <p>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.</p>		
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		<p>Page 5, Para 2, 2nd sentence is incorrect as the evidence states that USGI results in better pain and functional status at 6 months.</p> <p>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.</p> <p>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.</p> <p>Citation 2 does not separate USGI (ultrasound-guided injection) and LMGI (landmark-guided injection).</p> <p>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.</p> <p>Citation 4 states USGI is better than LMGI.</p> <p>Citation 5 states there is no real benefit of steroid injections at all.</p> <p>Citation 6 says USGI is more accurate but doesn't conclude the clinical outcome is any different.</p> <p>Citation 7 says USGI gives maximum benefit.</p> <p>Citation 14 says USGI is better at 6 months.</p> <p>Citation 16 says USGI is better tolerated, more effective at 6 months and more cost-effective.</p> <p>Citation 17 says USGI of the knee is no better than LMGI.</p> <p>Citation 18 is not cited and has no relevance to the document.</p>		
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		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	<ul style="list-style-type: none"> <li>• UHB Consultant: Happy with this</li> <li>• Walsall Consultant: I have reviewed the treatment policy of image guided high volume Intra articular injections, and agree with it.</li> <li>• <b>GPSI: High Volume Injections</b> I feel that there is a role for HVI especially in Achilles Tendinopathy again we perform these at no additional premium to our tariffs.</li> </ul> <p><b>Hydro dilatation in Adhesive Capsulitis</b> 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).</p>	No	Yes
DRAFT Exogen Bone healing	No	1. <b>NICE MTG12 – Review Decision 8<sup>th</sup> October 2019 – should be included in Evidence Review</b>	<a href="https://www.nice.org.uk/guidance/mtg12">https://www.nice.org.uk/guidance/mtg12.</a>	Yes

		<p>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.</p> <ul style="list-style-type: none"> <li>○ <a href="https://www.nice.org.uk/guidance/mtg12">https://www.nice.org.uk/guidance/mtg12</a>.</li> <li>○ Changes to the guidance after review; <ul style="list-style-type: none"> <li>▪ Cost consequence has been updated – benefit of EXOGEN has more than doubled to £2,407 per patient – previously this was £1164 per patient.</li> <li>▪ Details on the device updated to describe new version which includes patient tracker aimed at improving patient compliance.</li> </ul> </li> <li>○ Cost saving referenced does not account for our performance money back guarantee which is also provided with EXOGEN 250.</li> </ul> <p><b>2. BIOVENTUS Feedback on ‘DRAFT Policy Evidence Review for the use of EXOGEN Ultrasound’</b></p> <p>2.1. Discussions on the detail of EXOGEN do not include the Money Back Guarantee that is provided (subject to T&amp;Cs). Should a non-union fracture fail to unite (where the patient has been compliant), Bioventus will provide a refund.</p> <ul style="list-style-type: none"> <li>● 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.</li> </ul>		
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		<p>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.</p> <p>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.</p> <ul style="list-style-type: none"> <li>• 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. <p>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.</p> <p>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</p> </li> </ul>		
<p><b>DRAFT Non-Cosmetic Liposuction for lymphoedema &amp; lipoedema</b></p>	<p>No</p>	<ul style="list-style-type: none"> <li>• 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.</li> </ul> <p>If you would like to discuss any of the comments with me in more detail please do not hesitate to contact me.</p> <ul style="list-style-type: none"> <li>• UHB Consultant: We've had a look at this document as a department. It's not clear to me, or my colleague Darren,</li> </ul>	<p><a href="https://www.lipoedema.co.uk/wp-content/uploads/2017/05/WUK-Lipoedema-BPS_Web.pdf">https://www.lipoedema.co.uk/wp-content/uploads/2017/05/WUK-Lipoedema-BPS_Web.pdf</a></p>	<p>Yes</p>

		<p>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.</p> <p>I presumes lipoedema was not funded but I couldn't see where it actually said that.</p> <p>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.</p> <ul style="list-style-type: none"> <li>• 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</li> </ul> <p>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</p>	<p><a href="https://www.lipoedema.co.uk/wp-content/uploads/2012/08/Early-lipoedema-diagnosis-and-the-RCGP-e-learning-course.pdf">https://www.lipoedema.co.uk/wp-content/uploads/2012/08/Early-lipoedema-diagnosis-and-the-RCGP-e-learning-course.pdf</a></p> <p><a href="https://www.ncbi.nlm.nih.gov/pubmed/24489474">https://www.ncbi.nlm.nih.gov/pubmed/24489474</a></p> <p><a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5055019/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5055019/</a></p> <p><a href="https://www.semanticscholar.org/paper/English-Translation-Liposuction-of-Lipedema-to-Stutz-">https://www.semanticscholar.org/paper/English-Translation-Liposuction-of-Lipedema-to-Stutz-</a></p>	
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		lipoedema but as lymphoedema has specific criteria an IFR should not be needed.	<a href="https://www.nhs.uk/medicines/ifu/ifu-wald-a4538d84-f421ce4523029-bdaffdc10a24eb-ca1db">Wald/a4538d84f421ce4523029bdaffdc10a24ebca1db</a>	
DRAFT Bariatric Surgery	Yes	<ul style="list-style-type: none"> <li>I have read through these docs and confirm that I am happy with the content and have no further comments to make.</li> </ul>	No	Yes
DRAFT Knee arthroscopy in Acute Knee Injury	Yes	<ul style="list-style-type: none"> <li>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</li> <li>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</li> </ul>	<a href="https://baskonline.com/professional/wp-content/uploads/sites/5/2018/07/BASK-Meniscal-Surgery-Guideline-2018.pdf">https://baskonline.com/professional/wp-content/uploads/sites/5/2018/07/BASK-Meniscal-Surgery-Guideline-2018.pdf</a>  <a href="https://online.boneandjoint.org.uk/doi/full/10.1302/0301-620X.101B6.BJJ-2019-0126.R1">https://online.boneandjoint.org.uk/doi/full/10.1302/0301-620X.101B6.BJJ-2019-0126.R1</a>	Yes

		<p>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</p> <p>Mr Arbuthnot suggested that all acute knee injuries should be seen by a knee specialist rather than FCP</p> <p>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.)</p> <p>There is an ongoing discussion between clinicians at UHB and yourselves around the definition of locked/locking knee.</p> <p>The definition of functional impairment should include ability to perform one's job.</p> <p>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</p> <p>The national EBI policy does not have an age limit of 35 but this is stated in the evidence review.</p>	<p><a href="https://cdn.ymas.com/www.esska.org/resources/resmgr/docs/survey/Degenerative Knee summary.pdf">https://cdn.ymas.com/www.esska.org/resources/resmgr/docs/survey/Degenerative Knee summary.pdf</a></p>	
<p><b>DRAFT Policy for Domiciliary NIV/CPAP</b></p>	<p>Yes</p>	<ul style="list-style-type: none"> <li>Lead Consultant Respiratory Ventilation Team: Thank you for your initiative in addressing Domiciliary NIV in the</li> </ul>	<p>Dretzke J, et al. The cost-effectiveness of domiciliary non-</p>	<p>Yes</p>

		<p>Birmingham area, for which hopefully our patients will be thankful.</p> <p>Attached are the 2 documents with our comments embedded</p> <p>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."</p> <ul style="list-style-type: none"> <li>• 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).</li> <li>• All other comments are there on the comments list of the attached documents but the two others I would like to highlight are:</li> </ul> <ol style="list-style-type: none"> <li>1. The ordering of the Neuromuscular conditions should be unambiguous and reflect the order of</li> </ol>	<p>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 PMID: PMC4781210]</p> <p><a href="https://treat-nmd.org/wp-content/uploads/2019/06/uncat">https://treat-nmd.org/wp-content/uploads/2019/06/uncat</a></p>	
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		<p>prevalence/clinical relevance. This is why we recommend the ordering on Page 16 of the draft Policy as follows:</p> <ol style="list-style-type: none"> <li>a. • Motor Neurone Disease</li> <li>b. • Muscular Dystrophies including Duchenne Muscular Dystrophy and Spinal Muscular Atrophy</li> <li>c. • Spinal cord injury</li> <li>d. • Multiple Sclerosis</li> <li>e. • Guillain-Barre Syndrome</li> <li>f. • Post-polio syndrome with respiratory impairment</li> <li>g. • Syringomyelia</li> <li>h. • Tuberculosis infection with residual respiratory insufficiency</li> </ol> <p>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 PMID: PMC4781210]</p> <ul style="list-style-type: none"> <li>• 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</li> </ul>	<p><a href="#">egorized-A-Guide-to-the-2017-International-Standards-of-Care-for-SMA UKEnglish Digital-v2L.pdf</a></p>	
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		<p>The SoC for SMA are read and included as an essential reference.</p> <p>That NIV for non-sitters (SMA Type 1 and pre-symptomatic) is considered as a pro-active treatment for respiratory management.</p> <p>That the CCG consider separate eligibility for those with SMA Type 1 and pre-symptomatic as reflected in the SoC for SMA.</p> <ul style="list-style-type: none"> <li>• UHB Paediatric Ventilation Team</li> </ul> <p>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</p> <p>Also in regards to benefits - improvement of quality of life and longevity of life are also key and hugely important benefits.</p> <p>The list of conditions that are appropriate for NIV does not include Duchenne Muscular Dystrophy or any other paediatric Neuromuscular conditions known to affect ventilation. eg: congenital myasthenia, Merosin deficiency, nemaline. Congenital myopathy.</p> <p>Considerations for multiple admissions due to respiratory failure/ chest infections leading to type 2 respiratory failure.</p> <p>In regards to the evidence review - most of the evidence base is around MND - no evidence listed for DMD or SMA although is available.</p>		
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		<ul style="list-style-type: none"> <li>• UHB Sleep Medicine: I have looked through these documents again, and read and concur with the comments of my colleagues</li> </ul> <p>My thoughts include:</p> <p>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.</p> <ul style="list-style-type: none"> <li>• ‘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.)</li> <li>•</li> </ul>		
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		<ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.)</li> <li>• 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</li> </ul>		
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		<p>review if required is offered in many centres and I think is valued.</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> </ul>		
<p><b>DRAFT Policy for the use of Biological Mesh</b></p>	<p>No</p>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> </ul> <p>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.</p>	<p>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.</p>	<p>Yes</p>

		<p>For simple hernias I would not consider the use of biologic or biosynthetic meshes.</p> <p>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-analyses<sup>1</sup>. 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.</p> <p>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).<sup>2</sup> 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</p>	<p>Garcia-Urena MA, Lopez-Monclus J et al. Abdominal Wall Reconstruction Utilising the Combination of Absorbable and Permanent Mesh in a Retromuscular Position: A Multicenter Prospective Study. World J Surg. 2019 Jan;43(1):149-158</p> <p>Rognoni C et al. Budget Impact Analysis of a Biosynthetic Mesh for</p>	
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		<p>economic benefit of biosynthetic meshes in this complex subgroup of patients would suggest that they may be cost-effective.<sup>3,4</sup> 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.</p> <ul style="list-style-type: none"> <li>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.</li> </ul> <p>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.</p> <p>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</p>	<p>Incisional Hernia Repair. Clin Ther 2018 Nov; 40(11):1830-1844</p> <p>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</p>	
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		<p>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.</p> <p>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.</p> <p>So, the case for biologics 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.</p> <p>At UHB-HGS, we have tried to harmonise all the meshes we use in all 4 categories (extraperitoneal, intra-peritoneal, biosynthetics and biologics) 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.</p>		
	No	•	No	Yes



<p>DRAFT Policy for Non-Cosmetic Body Contouring</p>		<ul style="list-style-type: none"> <li>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.</li> <li>UHB Consultant: It is good and will be good for many patients.</li> </ul>		
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		<p>I have few notes</p> <p>What is the starting BMI. Is for patients with morbid obesity (BMI more than 35) who were able to lose weight and maintain it</p> <p>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.</p> <p>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, ....</p> <p>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 abdominoplasty), the patient will start noticing the excess skin and tissue in other parts as flanks, buttocks, breasts.</p> <p>If the patient would gain weight again, then surgery will not be repeated.</p>		
DRAFT Policy for Adenoidectomy	Yes		<a href="https://www.cochrane.org/CDO">https://www.cochrane.org/CDO</a>	Yes

		<ul style="list-style-type: none"> <li>• ENT UK We have discussed this at our Executive Meeting and are satisfied that the guidance is reasonable.</li> <li>• 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</li> <li>• <a href="https://www.cochrane.org/CD006286/ENT_topical-steroids-for-nasal-airway-obstruction-in-children-with-moderately-to-severely-enlarged-adenoids">https://www.cochrane.org/CD006286/ENT_topical-steroids-for-nasal-airway-obstruction-in-children-with-moderately-to-severely-enlarged-adenoids</a> 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.</li> </ul>	<a href="#">06286/ENT_topical-steroids-for-nasal-airway-obstruction-in-children-with-moderately-to-severely-enlarged-adenoids</a>	
<p><b>DRAFT Policy for Hysteroscopy for investigation of Heavy Menstrual Bleeding</b></p>	<p>No</p>	<ul style="list-style-type: none"> <li>• 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</li> <li>• SWB Consultant ObGyn: My colleagues have reviewed this - all in agreement</li> </ul>	<p>No</p>	<p>Yes</p>

### 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 policies; 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 with 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 not 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.

Despite not knowing the process from someone else, difficult and painful but ...

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.