Arden and Greater East Midlands
Commissioning Support Unit

NHS Birmingham and Solihull & NHS Sandwell and West Birmingham, Clinical Commissioning Groups

Harmonised Treatment Policies – Phase 3b

'YOU SAID, WE DID' SUMMARY REPORT

November 2019

Contents

Treatment Policies Clinical Development Group: YOU SAID – WE DID Report

Background

In July 2018 the Birmingham and Solihull CCG & Sandwell and West Birmingham CCG committed to working together to develop a further 10 treatment policies to build on the work being undertaken in Phase 3a across Birmingham and the Black Country. The membership of the Birmingham & Solihull and Sandwell and West Birmingham Treatment Policies Clinical Development Group includes clinical and management stakeholders who have met monthly in 2019 to discuss and assess the Evidence Reviews related Draft Policies, Patient Leaflets and Equality Impact Assessments.

The Treatment Policies Clinical Development Group provides the required governance and oversight of the policy programme by:

- Providing direct clinical input and examination of nationally and, where appropriate, internationally available contemporary evidence research.
- Monitoring project planning, timelines and progress of all treatment policy areas.
- Initial engagement with a range of relevant stakeholders including local provider clinical subject matter experts, council members of the Birmingham and Solihull Councils' Joint Health and Oversight Committee and the Sandwell Council Health Oversight Committee, and patient and public representatives.
- Ensuring the appropriate input, endorsement and sign off of the updated policies.

Public and Clinical Engagement

A core element of the policy harmonisation programme has been the public and clinical engagement period. For a six-week period (*September 2nd – October 11th2019*) – Birmingham & Solihull and Sandwell & West Birmingham Clinical Commissioning Groups undertook a joint clinical and public consultation exercise. The purpose of the engagement was both to share 10 draft policies (and accompanying literature including draft patient leaflets, Equality Impact Analyses and Evidence Reviews) and gather feedback on the proposals. Upon conclusion of the engagement period – a full summary report of the feedback was prepared and presented to the Treatment Policies Clinical Development Group (TPCDG) for their discussion and consideration. The full summary report is available upon request and will be published on the CCGs' treatment policies web pages following Governing Body adoption in February 2020.

Using the seven commissioning principles to underpin their evaluation and consideration of the feedback – the TPCDG members assessed all the public and clinical feedback received and responded accordingly.

- CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
- CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
- The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
- CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
- CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community;
- CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance; and
- Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered.

The high level components of these discussions for each of the policies are set out below in the form of a 'You Said -We Did' report.

All of the 10 Policies received feedback from either the public or clinical colleagues.

Policy for the use of Liposuction in Lymphoedema

You Said
Public Feedback:

1. Any help is better than none
2. I personally have lymphoedema but under control. I would like to think that if circumstances change then I would like access to treatment.
3. Don't treat
4. Evidence based change
5. If it's an effective treatment
6. Lymphoedema can be a distressing ailment and the Patient should be given any help possible to make their condition more tolerable
7. Makes treatment options available to wider patient group
8. I see people with this terrible condition, and it makes sense to offer treatment if other treatment has failed
9. see generic comment about readability etc
10. It sounds like a sound policy.
11. Leave the decision to the Patient, GP and Doctor/Nurse specialist
12. Seeking evidence always best answer
13. The addition of Liposuction as treatment option for patients with Lymphedema that are no longer responding to traditional treatments such as bandaging, compression wraps, MLD etc would be life changing for those group of patients this procedure is suitable for. Liposuction for Lymphedema is recognised in NICE guidance.

Clinical Feedback:

14. Studies indicate that Liposuction in lymphoedema where conservative treatments have been exhausted can be beneficial and successful. Clinically in practice I have experience of the positive impact of this procedure on a primary lymphoedema patient. Is new policy going to accept both primary and secondary lymphoedema patients to access this procedure?
15. Good to consider a defined group of patients for this service however there is a lack of lymphoedema specialists so there could be delays in assessment and treatment. This needs to be addressed to meet patient needs

We Did

Public Feedback:

1. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence. There is evidence which shows some clinical interventions do the patient more harm than good and it is the CCG's priority to prevent clinical interventions causing harm to patients. However, liposuction in lymphoedema has been shown to have good success rates.
2. The CCGs welcomed the public feedback. The policy for the use of liposuction in lymphoedema is designed specifically so that when conservative treatment can no longer control the patient's symptoms and the patient is well enough to have liposuction then this may be an option for the patient and her/ his clinician to discuss.
3. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence, which demonstrates that the intervention to be funded has a high rate of improving the patient's quality of life.

   4.; 5; 6. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence and so this policy change is based on up to date evidence.
7. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence and so this policy change is based on up to date evidence which demonstrates that the most effective use of liposuction in patient with lymphoedema is n those patients where conservative treatment is no longer effective.
8. & 10. The CCGs welcomed the public feedback.
9. The CCGs welcomed the public feedback, the patient leaflets will be reviewed in light of this feedback.
11. The CCGs have a finite amount of resources to fund all of the CCG funded services across at area. Therefore, if a service is to increase the clinical options available to a patient, then the CCG have to agree to fund the increase in clinical options, i.e. the liposuction. The policy was drafted with assistance from clinical specialists to ensure that the patients had access. to the most appropriate clinical treatment.
12. & 13. The CCGs welcomed the public feedback.

Clinical feedback:

14. The CCGs welcomed the clinical feedback, the policy will apply to patients with both primary and secondary lymphoedema and the policy has been clarified to reflect this.
15. The CCGs welcomed the clinical feedback, there is currently a bespoke community lymphoedema service commissioned for the patients within Birmingham & Solihull CCG and Sandwell and West Birmingham CCG footprints to meet the patient demand for assessment, conservative management and assessment for suitability for potential liposuction surgery.

Policy Outcome

- **The draft policy with minor amendments following clinical review is endorsed by the TPCDG and will proceed to the next stage of CCG governance for sign off and implementation.**

Policy for the Liposuction in Lipoedema

You Said:

Public Feedback:

1. More research and trials should be considered and reviewed
2. if it helps them only good can come of it
3. I feel that there needs to be more evidence gathered before a final decision made
4. Don't treat
5. Evidence based decision
6. The sooner a trial gets underway the better
7. Need for more clinical evidence and therefore option for limited treatments should be left open
8. Not sure if this should be used or not, surely another larger trial should be commissioned.
9. If it shown to have clinical benefit, it should be recommended by health care professionals, if medically appropriate. This should be left to the Pt, GP and specialist If the CCG wants to withhold - ration- treatment - the CCG should inform the patient and explain its reasons, as well as indemnify health professionals.

Clinical Feedback:

1. I am a Nurse Consultant for Lipoedema UK and have been a Clinical Nurse Specialist in lymphoedema and Lipoedema for several years. I have been to the Hanse Clinic as part of my previous role as Director of LymphCare UK and saw the positive results the specialist Tumescent Liposuction had on Women. It was life-changing. The outcomes with improved range of movement, mobility, pain, psychologically and physically were very evident. Circumferential Limb volumes were greatly reduced. I have also had a patient on my previous caseload who was struggling to carry on working and interacting with her children. Following a series of Tumescent Liposuction procedures she was able to return to work, play with her children and become more mobile and active. This patient still continues to reap the benefits of this procedure after 9 years. Numerous surveys from Lipoedema UK have highlighted that women are in dire need of services and an option in some cases should be Medical Tumescent Liposuction. There is currently a post-code lottery of service provision generally for this condition. Women are often mis-diagnosed as obese or suffering for lipoedema and spend several years suffering with the condition prior to being referred to a specialist Lymphoedema service. However, I think this is a positive step to put Lipoedema on the agenda for improving services. I agree that there needs to be more investment into further research and this is a priority moving forward.

2. I am a Lymphedema nurse specialist and Lipoedema UK Nurse consultant and also suffer from this condition myself. This is NOT for a cosmetic purpose but treatment of a now recognised medical condition. Lipoedema does not respond to conservative treatments. Ladies with Lipoedema have fatty doughy abnormal distribution of fat that is not usual obesity fat and is impossible to loose through healthy eating and fat burning exercise. This condition has physical and psychological long term complications . These include significant reduction in mobility often leading to joint problems and orthopaedic surgeries. Some ladies have significant low self esteem and depressive illness. A complication can be Lymphedema secondary to Lipoedema There is 10 years of evidence from Hanse clinic in Germany that Liposuction is life changing Lipoedema UK have produced a series of four articles from focus groups women in Dire need of Liposuction.

We Did:

Public Feedback

1. The CCGs welcomed the public feedback and agreed then when more research is available the policy development group would review the newly published research for the use of liposuction in patients with lipoedema.
2. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence. There is evidence which shows some improvement in patients with lipoedema who have had liposuction, but the numbers of patients involved in these research studies were very small and cannot be relied on to show that the majority of patients with lipoedema will benefit from liposuction. As new evidence becomes available, which demonstrates the benefits of liposuction in patients with lipoedema, then the CCGs will review this policy.
3. The CCGs welcomed the public feedback and agreed then when more research is available the policy development group would review the newly published research for the use of liposuction in patients with lipoedema.
4. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence, which demonstrates that the clinical intervention to be funded has a high rate of improving the patient's clinical condition.
5. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence and so this policy change is based on up to date evidence.
6. As new evidence becomes available, which demonstrates the benefits of liposuction in patients with lipoedema, then the CCGs will review this policy.
7. The CCGs have a finite amount of resources to fund all of the CCG funded services across the area. Therefore, if a service is to increase the clinical options available to a patient, then the CCG have to agree to fund the increase in clinical options, i.e. the liposuction. There was not enough clinical research on the use of liposuction in lipoedema for the CCG to agree to fund the surgery at this time.
8. The CCGs welcomed the public feedback and agreed then when more research is available the policy development group would review the newly published research for the use of liposuction in patients with lipoedema.
9. The CCGs have a finite amount of resources to fund all of the CCG funded services across the area. Therefore, if a service is to increase the clinical options available to a patient, then the CCG have to agree to fund the

increase in clinical options, i.e. the liposuction. There was not enough clinical research on the use of liposuction in lipoedema for the CCG to agree to fund the surgery at this time.

Clinical Feedback:

1. The CCGs welcomed the clinical feedback, the development of clinical policies is based on review of the most up to date clinical evidence for the area to be reviewed. There is evidence which shows some improvement in patients with lipoedema who have had liposuction, but the numbers of patients involved in these research studies were very small and cannot be extrapolated out to demonstrate a benefit to a larger cohort. The CCG would welcome further research being undertaken. As new clinical evidence becomes available, which demonstrates the benefits of liposuction in patients with lipoedema, then the CCGs will review this policy.
2. The CCGs welcomed the clinical feedback, the policy has been reviewed as it was identified that the CCGs previously only had a policy which relates to cosmetic liposuction which was inappropriate for patients with lipoedema, hence the evidence review was undertaken to review the clinical evidence available to support the use of NHS resources in these clinical circumstances. All clinical evidence which was reviewed by the committee was presented in the engagement phase in the evidence review, and all articles submitted during the clinical engagement were reviewed by the policy development group. However, the level of robust clinical evidence required for the CCG to commission a service was not met at this time. The CCG would be keen to review this policy as new robust clinical evidence is published.

Policy Outcome

- **The draft policy is endorsed by the TPCDG and will proceed to the next stage of CCG governance for sign off and implementation.**

Bariatric Surgery Policy

You Said
Public Feedback:

1. To be used with support for patient in life-style changes and possible emotional support
2. Don’t treat

3. Obesity is a major problem and some people need this help
4. Not qualified to comment
5. Obviously prevention should be the first thing tried but is sometimes difficult to achieve. It seems ludicrous that a Patient of45Kg is deemed "too small" for the surgery so has to put more weight on. The impact on health seems more important to me than the actual weight
6. Benefit to patients overall health and well being who fall within the eligible groups
7. everything must be tried before this costly procedure which we think is self inflicted
8. see generic comment about readability etc
9. Sounds reasonable.
10. Limits not based on sound evidence and considerable morbidity at BMI in 40s for some people

Clinical Feedback:

11. NICE 2014: BMI of 35 or over NICE recommends that all patients with a BMI of 35 or over who have recent-onset type 2 diabetes should be assessed for surgery. Patients must have tried and failed to achieve clinically beneficial weight loss by all other appropriate non-surgical methods and be fit for surgery. You appear to block doctors from fulfilling their medical obligation - and be in breach of the duties of a Dr -GMC
12. If patient has BMI 48, do we need to tell them to eat more to hit 50, so that they are eligible.

We Did:

1. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence. The Bariatric Surgery Policy has been development in line with the service for patients with obesity which has a patient pathway. The final stage of the pathway would be potential surgery, but in earlier stages the patient are supported by a multi-disciplinary team to loose weight.
2. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence, which demonstrates that the clinical intervention to be funded has a high rate of improving the patient's clinical condition.
3. The CCGs welcomed the public feedback.
4. The CCGs welcomed the public feedback.
5. The CCGs welcomed the public feedback. Currently there is only a certain capacity available for bariatric surgery within the local health economy and the CCGs therefore prioritised the patients who could clinically benefit the most from the bariatric surgery.
6. The CCGs welcomed the public feedback.
7. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence. The Bariatric Surgery Policy has been development in line with the service for patients with obesity which has a patient pathway. The final stage of the pathway would

be potential surgery, but in earlier stages the patient are supported by a multi-disciplinary team to loose weight.

8. The CCGs welcomed the public feedback, the patient leaflets will be reviewed in light of this feedback.
9. The CCGs welcomed the public feedback.
10. The CCGs welcomed the public feedback. Currently there is only a certain capacity available for bariatric surgery within the local health economy and the CCGs therefore prioritised the patients who could clinically benefit the most from the bariatric surgery.

Clinical Feedback

11. The CCG will fund all patients who have a BMI of >35 with Type 2 Diabetes onset in the last 10 years for surgery, but the CCG wants to ensure the patient is clinically well enough to undergo surgery, hence the need to be fit for surgery and that the patient has tried other options for weight loss before undergoing a surgical procedure with the ensuing risks of general anaesthesia.
12. If a patient has a BMI of 48, then they may be referred to the Tier 3 Weight Loss service where they will be reviewed by a multidisciplinary weight loss team and provided with an individual care plan. If they meet the criteria for surgery, then the patient will be referred to the Tier 4 service for clinical review. Currently there is only a certain capacity available for bariatric surgery within the local health economy and the CCGs therefore prioritised the patients who could clinically benefit the most from the bariatric surgery.

Policy Outcome

- **The draft policy is endorsed by the TPCDG and will proceed to the next stage of CCG governance for sign off and implementation.**

Policy for the use of Knee Arthroscopy in Acute Knee Injury

You Said:
Public Feedback:

1. Widens the policy to include acute knee injury when more conservative treatments have failed. However, the policy seems to exclude degenerative knee injury- which may occur across a range of adult age groups. Reconsider this group?
2. If it works great
3. Because it worked for me. After injury had 6 months of conservative management; leg in brace and other pain management treatments. Then had surgery with supported physio and feels a lot better
4. If it is thought to have little benefit, then to carry out this procedure would be wasting funds
5. Don't treat
6. Evidence based change
7. Seems sensible
8. If no benefit pointless to proceed
9. If it's not beneficial it shouldn't be used.
10. Where is the evidence that it does not help in trauma? Leave this to Patient, GP and specialist

Clinical Feedback:

11. Consultant in Sport Medicine: The biggest thing that needs clarity is what is meant by "failed physiotherapy". There needs to be a quick route to get IFR approval and this circulated to clinicians - ie within 1-2 weeks. There needs to be specific feedback from physiotherapy and pain teams obtained on this given the likely impact on their services
12. Provider Contract Team Feedback: The draft patient leaflet states that over 35s are automatically excluded. This is at odds with the draft policy, whereby age is an indicator of possible degenerative knee disease, but not an automatic exclusion. The exclusion of all patients with degenerative knee disease means that patients who have a degenerative knee disease but then experience an acute injury would be ineligible for treatment. There are patients for whom surgical treatment for the acute injury would greatly improve quality of life and this is not related to underlying disease. It is unclear from the policy whether patients should only be referred to secondary care following a period of rehab etc. There is a recognised pathway at UHB for acute knee clinic/physio
    Consultant Knee Surgeon suggested that all acute knee injuries should be seen by a knee specialist rather than FCP. It is confusing to have the definition of degenerative knee disease in the 'eligibility criteria' box. These definitions should be elsewhere. Furthermore the definition of degenerative knee disease is difficult to audit against (patients may be over 35, and may

or may not have the following symptoms). There is an ongoing discussion between clinicians at UHB and the CCGs around the definition of locked/locking knee. The definition of functional impairment should include ability to perform one's job. The EIA is unclear. The summary says 'The restriction of this policy may have an impact on those who would wish to receive the treatments for a degenerative condition such as osteoarthritis' but this policy is about acute knee injury. The national EBI policy does not have an age limit of 35 but this is stated in the evidence review.
We Did: 1. The Policy currently under development is for : Knee Arthroscopy In Acute Knee Injury. A review of clinical evidence has determined the pathway of evidence-based treatment for this group of patients with Acute Knee Injury. The CCGs have a separate policy for patient with degenerative knee disease. 2. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence. The clinical evidence reviewed by the policy development group demonstrated that in patients where physiotherapy and other conservative treatments have not worked in the first 3 months, the knee arthroscopy can be clinically effective in patients with acute knee injury. 3. 4. 5. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence. The clinical evidence reviewed by the policy development group demonstrated that in patients where physiotherapy and other conservative treatments have not worked in the first 3 months, the knee arthroscopy can be clinically effective in patients with acute knee injury. 6.7.8.9.The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence, which demonstrates that the clinical intervention to be funded has a high rate of improving the patient's clinical condition. 10. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence, which demonstrates that the clinical intervention to be funded has a high rate of improving the patient's clinical condition, but only when physiotherapy for 3 months has failed. The CCG does not want patients to undergo unnecessary surgery and so wants to ensure that all conservative management options have been tried and have filed before the patient proceeds to surgery. **Clinical Feedback** 11. We have reviewed the patient pathway with the main NHS provider and the planned care surgical knee team currently provides a rapid assessment MDT clinic for patient with acute knee injury who are then seen by physiotherapy within that MDT Clinic and undertake conservative management. Only when this conservative management (including physiotherapy) had failed are patients listed for surgery. 12. The main NHS provider provides a rapid assessment MDT clinic for patient with acute knee injury who are then seen by physiotherapy within that MDT Clinic and undertake conservative management for at least 3 months following the acute knee injury. Only when this conservative management

(including physiotherapy) had failed are patients listed for surgery, these patients, must meet the eligibility criteria for surgery.
In Phase 2 2018 a Knee Arthroscopy in Degenerative Knee Disease was developed and followed a similar engagement phase as has been undertaken in Phase 3. Following implementation of the Knee Arthroscopy in Degenerative Knee Disease Policy which is in line with NHSE EBI Knee Arthroscopy Policy for Degenerative Knee Disease, further discussions are currently being undertaken with providers outside of the Phase 3 engagement to work together to resolve the issues surrounding the Knee Arthroscopy in Degenerative Knee Disease Policy.

Policy Outcome

- **The draft policy is endorsed by the TPCDG and will proceed to the next stage of CCG governance for sign off and implementation.**

Policy for the use of Domiciliary Ventilation in
A. Chronic Obstructive Pulmonary Disease (COPD)
B. Neuro-Muscular Disease (NMD)

You Said:
Public Feedback:

1. Do not use this service to be able to comment
2. This treatment is vital to patients with respiratory conditions. It offers them a better quality of life which can only have a positive outcome
3. Don't treat
4. These policies must be put in place in order to speed up process of giving patients their own machinery and make it easier for GPs and walk in centres to know how to refer patients with relevant illness directly to a respiratory specialist instead of putting breathlessness and other symptoms down to asthma/anxiety
5. More education and guidelines are needed to prevent Muscular dystrophy patients becoming very ill or dying through lack of knowledge
6. This is a needed treatment, provision is long overdue
7. Not qualified to comment

8. Being unable to breathe to having difficulty in breathing May make the Patient very anxious. Anything that can alleviate their anxiety and help their breathing can only be a good thing
9. Do whatever is best for the patient
10. See generic comment about readability etc
11. My mother in law had COPD and had this service at home towards the end. It helped her breathe till she died. Obviously but it eased her breathing till she died.
12. What is the change?

Clinical Feedback:

13. Lead Consultant Respiratory Ventilation Team: Thank you for your initiative in addressing Domiciliary NIV in the Birmingham area, for which hopefully our patients will be thankful. Attached are the 2 documents with our comments embedded. The most important single point in both documents is the inclusion of CPAP and Bi-Level Ventilation under the umbrella term NIV. The 2018 NCEPOD recommendation is to separate CPAP and NIV (bi-level ventilation, also loosely called BiPAP but BiPAP being a commercial brand the current UK consensus is to call it NIV). The recommendation of the NCEPOD to the NHS Digital and the Association of Clinical Coders is as follows: "Continuous positive airways pressure (CPAP) and non-invasive ventilation (NIV) should be coded separately. They are two distinct treatments given for different conditions and separate coding will reduce clinical confusion and improve reporting of outcomes."
    - Therefore it is crucial that to align with the latest (2018) NCEPOD recommendations, the section on Continuous Positive Airways Pressure is EITHER taken out OR the policy is renamed the Policy for the use of domiciliary Continuous Positive Airways Pressure (CPAP) and Non-Invasive Ventilation (NIV).
    - All other comments are there on the comments list of the attached documents but the two others I would like to highlight are:

1. The ordering of the Neuromuscular conditions should be unambiguous and reflect the order of prevalence/clinical relevance. This is why we recommend the ordering on Page 16 of the draft Policy as follows:
    a. • Motor Neurone Disease
    b. • Muscular Dystrophies including Duchenne Muscular Dystrophy and Spinal Muscular Atrophy
    c. • Spinal cord injury
    d. • Multiple Sclerosis
    e. • Guillain-Barre Syndrome

f. • Post-polio syndrome with respiratory impairment

g. • Syringomyelia

h. • Tuberculosis infection with residual respiratory insufficiency

2. The only UK-based HTA report (NIHR commissioned) on the cost-effectiveness of Domiciliary NIV in COPD, which included a systematic review is conspicuous by its absence:

Dretzke J, et al. The cost-effectiveness of domiciliary non-invasive ventilation in patients with end-stage chronic obstructive pulmonary disease: a systematic review and economic evaluation. Health technology assessment. 10/2015; 19(81):1-246. doi: 10.3310/hta19810. [PubMed ID: 26470875 PMCID: PMC4781210]

14. SMAUK:

In general, it is good to see that patients with SMA are included on the restricted list. Non-invasive Ventilation (NIV) is necessary and effective for many patients who have SMA

The SoC for SMA are read and included as an essential reference.

That NIV for non-sitters (SMA Type 1 and pre-symptomatic) is considered as a pro-active treatment for respiratory management.

That the CCG consider separate eligibility for those with SMA Type 1 and pre-symptomatic as reflected in the SoC for SMA.

15. Paediatric Ventilation Team

Section B: What do you mean by 'Neuro-dependant'?? and then the wording is then 'neuromuscular' patients for section B when you arrive at that section. Consider changing to Neuromuscular

Also in regards to benefits - improvement of quality of life and longevity of life are also key and hugely important benefits.

The list of conditions that are appropriate for NIV does not include Duchenne Muscular Dystrophy or any other paediatric Neuromuscular conditions know to affect ventilation. eg: congential myasthenia, Merosin deficiency, nemaline. Congenital myopathy.

Considerations for multiple admissions due to respiratory failure/ chest infections leading to type 2 respiratory failure.

In regards to the evidence review - most of the evidence base is around MND - no evidence listed for DMD or SMA although is available .

We Did:

Public Feedback

1. – 12. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence. The clinical evidence reviewed by the policy development group demonstrated

the strong evidence basis for the use of non-invasive ventilation in clinically appropriate patients who had COPD or Neuromuscular disease. The current pathway is determined through assessment of patients at respiratory centres without an overarching review of the clinical evidence. With leading ventilation specialist, the policy development committee want to ensure provision of non-invasive ventilation in adults for these groups of patients was secured and the process of gaining funding for these patients was streamlined across the footprint of the 2 CCGs.

Clinical Feedback

13., 14. & 15. The CCGs welcomed the clinical feedback, the support of specialist ventilation clinical colleagues has been invaluable in enabling these policies to be developed.
The policy development committee took on board the recommendation to separate the NIV and CPAP policies into two and this was approved by the whole committee following the engagement.
The change ordering of the NMD condition was agreed by the policy development committee, however it was noted by the committee that patients with Spinal Muscular Atrophy have a specialised service commissioned by NHS England and therefore these patients do not fall into the commissioning responsibility of the CCG and therefore have not been included in the policy.

The committee would like to thank the clinician for submitting the following article, which has been taken into consideration: The Dretzke J, et al. The cost-effectiveness of domiciliary non-invasive ventilation in patients with end-stage chronic obstructive pulmonary disease: a systematic review and economic evaluation. Health technology assessment. 10/2015; 19(81):1-246. doi: 10.3310/hta19810. [PubMed ID: 26470875 PMCID: PMC4781210].

The policy development committee also agreed that a separate policy for the use of NIV in children would be beneficial and recommended that such a policy is explored in the next phase of policy development.

Policy Outcome

- **The draft policy has been amended in line with the clinical feedback received regarding clinical assessment of patients and is endorsed by the TPCDG and will proceed to the next stage of CCG governance for sign off and implementation.**

Policy for the use of domiciliary CPAP in Obstructive Sleep Apnoea Hypocapnia Syndrome

You Said:
Public Feedback:

1. Widens access to a treatment for an increasing common complaint
2. Haven't used this to be able to comment

3. It offers peace of mind and a better quality of life both for the patient and their partner
4. Don't treat
5. As above
6. It is not just the Patient who suffers in this condition their partner is often kept awake by the snoring of the Patient (although the machine can be noisy too) Anything that can help the Patient can only be a good thing
7. Should work using up to date recommendations
8. See generic comment about readability etc
9. I was quite a bad case of sleep apnoea, but for mild cases, they may still need a machine, particularly if they are doing jobs where they need to stay sharp.
10. This should be left to the pt, GP and specialist with regard to NICE guidelines, if any. If the CCG wishes to ration this against clinical advice of GP and specialists, it should contact affected patients direct and indemnify drs.
11. To be able to sleep without the worry that you could stop breathing at any time, brings peace of mind to patient and family
12. Don't treat
13. As above
14. It could have a negative impact if some people are denied a machine, but I do think maybe weight loss should be explored with some sleep apnoea patients?
15. This should be left to the pt, GP and specialist with regard to NICE guidelines, if any. If the CCG wishes to ration this against clinical advice of GP and specialists, it should contact affected patients direct and indemnify drs.

Clinical Feedback:

16. UHB Sleep Medicine: I have looked through these documents again, and read and concur with the comments of my colleagues

    My thoughts include:

    - I agree with regards to the confusion between 'NIV' and 'CPAP'. Dr XXX has emphasised the NCEPD recommendations to separate these indications. Clinically the services for each (and frequently the staffing personnel) are different. There is a strong argument for separating a policy for patients with type II respiratory failure (indications COPD, neuromuscular disease, thoracic cage deformity, obesity related respiratory failure, rarely other indications) who will generally require 'NIV' from a policy for obstructive sleep apnoea (OSA) for which the treatment will usually be CPAP, and only very occasionally will NIV be required.

- ‘CPAP’ for OSA falls under the remit of a ‘sleep’ service. I am hopeful that you have included specialists working within sleep (responsible for a huge workload both numerically and financially) in this proposed policy harmonisation. (Eg and most notably Dr XXX at Birmingham Heartlands Hospital, as well as people like Dr XXX at the Queen Elizabeth Hospital.)
- The draft policy proposes limiting the use of CPAP in mild OSA to those in whom it causes ‘severe functional impairment.’ This is later defined as sleeping, eating, walking driving etc. This is a much higher bar than that set by current relevant NICE guidelines: “CPAP is only recommended as a treatment option for adults with mild OSAHS if: they have symptoms that affect their quality of life and ability to go about their daily activities, and lifestyle advice and any other relevant treatment options have been unsuccessful or are considered inappropriate” (my italics.) In my experience a significant proportion of patients with mild sleep apnoea have considerable benefit from the use of CPAP if carefully selected, and I feel that this wording will strongly discourage practitioners from offering appropriate treatment from which patients may benefit.
- It is also worth noting that new NICE guidelines for OSA are currently being developed, and the West Midlands policy may require revision in the light of them when published (expected August 2020.)
- Long term follow up of patients with OSA is not necessary to ensure adherence once regular usage has been established, although the provision of a service to troubleshoot problems, offer consumables/service machines as necessary and provide a route to clinical review if required is offered in many centres and I think is valued.
- I do not see why patient smoking should preclude offering NIV – although as Dr XXX points out, many of these patients will also be receiving oxygen.
- I worry the patient leaflets may confuse rather than inform and may benefit from a rewrite. The ‘OSAHS’ leaflet for example seems to suffer from confusion with obesity related respiratory failure, and talks about hypoventilation and hypercapnia which is not appropriate in an OSAHS leaflet. Again it discussed ‘NIV’, which is not really appropriate in an OSAHS document.

We Did:

Public Feedback

1.-15. The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence and guidelines including NICE guidelines. The clinical evidence reviewed by the policy development group demonstrated the strong evidence basis for the use of continuous positive airway pressure in the home environment in clinically appropriate patients who had obstructive sleep apnoea. The current

pathway is determined through assessment of patients at sleep medicine centres without an overarching review of the clinical evidence. With leading sleep medicine specialists, the policy development committee want to ensure provision of continuous positive airway pressure devices in adults with obstructive sleep apnoea was secured and the process of gaining funding for these patients was streamlined across the footprint of the 2 CCGs.

Clinical Feedback

16. The CCGs welcomed the clinical feedback, the support of specialist ventilation clinical colleagues has been invaluable in enabling these policies to be developed.
    The policy development committee took on board the recommendation to separate the NIV and CPAP policies into two and this was approved by the whole committee following the engagement.
    Further clinicians were contacted directly following the revised policies being drafted to gain further clinical review before being approved by the policy development committee.
    The committee reviewed the definition of functional impairment, which is a standard definition across all of the CCG policies, to ensure a consistent approach for patients. The committee felt that the definition of functional impairment designated within the policy was not dissimilar from the NICE defined cohort of patients with mild OSA and therefore amending this definition was not required at this present time. However, the committee were grateful for the information pertaining to new guidelines for OSA due to be published in August 2020 and would be mindful of this publication in the next phase of policy development.
    The clinical review of the patient leaflet was also gratefully received and the leaflet has been revised in light of this clinical information.

Policy Outcome

- **The draft policy with minor amendments following the clinical review and separation from the NIV policy, is endorsed by the TPCDG and will proceed to the next stage of CCG governance for sign off and implementation.**

Policy for the use of Biological and Biosynthetic Mesh in Hernia Repair

You Said:

Public Feedback:

1. Some evidence that synthetic polymers have migrated/adhered to surgery sites resulting in difficulties for patients? Further evidence needed and research into safe, viable alternatives
2. not clinical experience in this area

3. not enough understanding of procedure
4. Don't treat
5. Evidence based
6. As there are other meshes available not using biological mesh should not have much impact
7. Hearing all the negative complaints about mesh, patients must be worried about what is used. I also believe as many patients have no problems so a difficult decision
8. See generic comment about readability etc
9. If ordinary mesh does the job, then why use other types, particularly animal.
10. This should be left to the pt, GP and specialist with regard to NICE guidelines, if any. If the CCG wishes to ration this against clinical advice of GP and specialists, it should contact affected patients direct and indemnify drs.

Clinical Feedback:

11. Consultant Surgeon: Thank you for asking me to comment. I do not use non-synthetic mesh in any of my inguinal, umbilical or incisional hernia repair operations.
12. Consultant Surgeon: In general, I agree with the findings of the report and have found it to be based on appropriate evidence but would like to make some additional comments.

For the vast majority of surgeons undertaking the vast majority of hernia repairs, there is no need for biological or biosynthetic meshes. Medium-weight macroporous (large pore size) polypropylene meshes have shown to provide good outcomes when used appropriately with lower recurrence rates and no increase in chronic pain as compared to non-mesh alternatives. For simple hernias I would not consider the use of biologic or biosynthetic meshes.
The descriptions of open and laparoscopic hernia repairs in the draft report are really only applicable to inguinal hernias and I would suggest that this is clarified for the sake of completeness.
My personal interest is in complex abdominal wall hernia repairs. This term can be used to describe repairs of very large hernias, mesh infections, contaminated wounds, entero-cutaneous fistulae (uncontrolled holes from the bowel out of the skin) and others. In this context it is not always possible to use a synthetic mesh as the risk of contamination is high although the quality of studies in these cases is limited due to their relative scarcity as discussed in one of the meta-anlalyses[1]. The majority of these patients have had multiple previous operations and often several failed attempts to repair their abdomen. Many have spent long periods of time in hospital due to their problems and months or years of community nursing support prior to definitive surgery.
I have moved over the last few years away from biological meshes to almost exclusively using biosynthetic (long-term absorbable) meshes as they are significantly cheaper than true biologics and appear to give me similar outcomes. I also use these meshes in combination with a synthetic mesh as an adjunct to allow closure and protect the bowel where there is a very large

hernia defect requiring component separation (division and separation of layers of the abdominal wall).[2] If these meshes were also restricted to use via an IFR it would significant reduce my ability to perform these more complex cases. Some recent studies looking at the economic benefit of biosynthetic meshes in this complex subgroup of patients would suggest that they may be cost-effective.

There has been discussion with colleagues in the British Hernia Society and with the GIRFT group regarding accreditation of centres for different grades of hernia repair. If this comes to fruition then it may be possible to limit these more expensive meshes to centres accredited for complex abdominal wall repair.

13. I am one of the Colorectal Surgeons over at UHB and I do a lot of work with complex abdominal wall repairs. My colleague, XXX forwarded these documents to me and there are a few issues I wanted to highlight about Biological meshes. Please find these points in the email below.

    The key issue is that complex abdominal wall repairs (these are completely different from your simple and groin hernia) are of various varieties. They cannot all be lumped into the same category. For those of us that get these cases referred to us, we find our use of biologicals are actually fairly limited but steady. I reckon that I might use this about twice a year, but this use is not entirely predictable as some of these might be necessitated as an emergency.

    In the potentially infected wound, no one will stick a synthetic mesh in because they get infected. Infection of these meshes are very difficult to manage, with often disastrous consequences for the patient as well as the cost of management. An example is resecting a tumour in a colostomy that requires excision of the abdominal wall. Unless this is a staged repair (which then costs more to both the trust and the patient), I see no way of using synthetics in that situation.

    We also use biologics for all repairs after an Abdomino-perineal resection. This is fairly standard practice for a routine cancer operation and I don't think anyone will use synthetics in that scenario. Moreover, I have had to repair a complete perineal prolapse, 6 months after anterior exenteration for gynaecological surgery and radiotherapy. This patient presented as an emergency, very unwell and literally sitting on their small bowel!! The only prospect of a repair was a biological…and all this was happening at about 0200.

    So, the case for biologicals is that they are not used often in expert hands but use remains steady. We have to be careful they remain available both for the elective and emergency use, but their use needs to be controlled.

    At UHB-HGS, we have tried to harmonise all the meshes we use in all 4 categories (extraperitoneal, intra-peritoneal, biosynthetics and biologicals) in accordance with both the best evidence we have available to us as well as the difficult cases we encounter in order to save cost. I can provide more of the work we have done on this should you require it.

We Did:

Public Feedback

The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence and expert clinical advice in the use of the most up to date, clinically effective surgical interventions. The committee in light of the concerns regarding the use of synthetic mesh in vaginal surgery wanted to ensure that there was evidence to support the use of synthetic mesh in hernia repair and that in line with Right Care and Get It Right First Time (GRIFT) principles patients were being reviewed by the most appropriate surgical team. The committee was satisfied with the standard of evidence available at the present time to demonstrate the safety of synthetic mesh in standard hernia repair, and following clinical input, the committee agreed to endorse the use of biological / biosynthetic mesh in patients where standard / first line surgical repair if hernia had failed or was inappropriate and the patient had been reviewed by a complex abdominal wall MDT.

Clinical Feedback

11 The CCGs welcomed the clinical feedback.

12 & 13. The CCGs welcomed the clinical feedback, and the time the specialist surgeons had taken to review the proposed policy. The clinical information received from the surgical team was extremely pertinent in enabling the committee to understand the clinical complexities of a small cohort patients where first line hernia repair has failed and the use of biological or biosynthetic mesh may be clinically appropriate, once the patient has been reviewed by a specialist multi-disciplinary complex abdominal wall surgical team. Based on the evidence submitted, the committee agreed to fund biological or biosynthetic mesh for a small cohort of patients with non-healed hernias, who have failed first line treatment and who have been reviewed by a complex abdominal wall MDT.

Policy Outcome

- **The draft policy has been amended to enable surgical members of complex abdominal wall MDTs to have access to biological / biosynthetic mesh for patients where first line surgical treatment to repair a hernia has failed and this revised policy is endorsed by the TPCDG and will proceed to the next stage of CCG governance for sign off and implementation.**

Policy for Non-Cosmetic Body Contouring

You Said:

Public Feedback

1. Positive benefits for those patients who have worked to reduce body mass and maintained lower weight with clinical support. A consequent improvement in quality of life and less impact on their need for further treatment
2. If the patient meets the criteria and has followed the rules laid down then yes

3. Don't treat
4. Improve quality of life for patients
5. If a patient has taken positive and sustainable measures to lose and maintain weight loss
6. Obviously, prevention of obesity at a much earlier stage should be the 1st thing but often hard to do therefore if a Patient has had the willpower to lose a lot of excess weight they should not be discouraged by the excess skin which is left (and often with which they are unaware will happen until it does)
7. Strict criteria must be monitored
8. See generic comment about readability etc
9. Surely the mental state of the patient should be assessed also. This loose skin may affect their body image and impinge on their mental health.
10. This should be left to the pt, GP and specialist with regard to NICE guidelines, if any. If the CCG wishes to ration this against clinical advice of GP and specialists, it should contact affected patients direct and indemnify drs.
11. The impact on the patient has to be positive if they have gone through surgery and weight loss etc.
12. Don't treat
13. Anything that can give a Patient a positive body image after all their hard work in losing weight can only be a good thing
14. I thought this was already the case.
15. You will probably be saying no to more patients.
16. This should be left to the pt, GP and specialist with regard to NICE guidelines, if any. If the CCG wishes to ration this against clinical advice of GP and specialists, it should contact affected patients direct and indemnify drs.

Clinical Feedback:

17. Consultant Surgeon:
    Please could you consider my comments regarding the proposal non-cosmetic body contouring surgery.
    Thank you for making these patients a priority. There are patients who suffer debilitating symptoms as a result of loose skin. I have been involved with a number of cases and I have been trying to get funding in particular for a patient with a chromosomal disorder who is struggling to walk because of her excess skin on her abdomen and surgery has been proposed by a neurologist and myself. This has been rejected despite a number of appeals.
    I think there should be more emphasis on symptoms and not the amount of weight loss which is arbitrary. There are patients who cannot function after

losing less than 50% of excess weight and need an abdominal apron removed to help them exercise and lose further weight.
Also, it cannot be stressed how busy we are as surgeons working in acute hospitals and it would be very helpful to have a streamlined form for requests for funding. Perhaps you could do a bespoke one for these patients which has the important information you need.
Ultimately, I would like to see a situation with trust whereby the clinician decides on surgery based on these criteria and we can avoid IFRs. Audits could then be done of these cases to demonstrate compliance.

18. Consultant Surgeon:
It is good and will be good for many patients.
I have few notes
What is the starting BMI. Is for patients with morbid obesity (BMI more than 35) who were able to loss weight and maintain it
As you know, those patient will be referred to us (plastic Surgeons) by their GPs and sometime bariatric surgeon. The referring doctor / surgeon should include in the referring letter that the patient achieved the target weight / the 50% loss of excess weight and maintained for 2 years. It should be documented in the referring letter.
Those patients usually have high BMI, so please include in the policy that the patient should be aware of high risks complications as DVT, wound breakdown, ….
The surgery will be targeting patients to improve function, so please document in the policy that revision surgery to improve appearance will not be accepted. Those patients will have excess skin in multiple parts. And after removing the excess skin and fat from one site (as abdominplasty), the patient will start noticing the excess skin and tissue in other parts as flanks, buttocks, breasts. If the patient would gain weight again, then surgery will not be repeated.

We Did:

Public Feedback

The CCGs welcomed the public feedback, the development of clinical policies is based on review of the most up to date clinical evidence and expert clinical advice in the use of the most up to date, clinically effective surgical interventions. The committee was aware that the currently commissioned policy relating to cosmetic surgery for body contouring meant that patients with a significant amount of excess skin and the resulting medical complications were unable to access surgery for the removal of this skin. The committee was therefore keen to review the evidence in relation to removal of skin where the patient had maintained their weight loss and had significant physical impact from the excessive skin in order to enable these patients to access surgical intervention.

Clinical Feedback

17 & 18. The CCGs welcomed the clinical feedback, the specialist clinical input into the development of policies is essential.
The committee has previously implemented an on-line prior approval process with providers, some providers are using this to streamline the funding application process with good effect.

The committee reviewed the feedback regarding clarification of referral information and will communicate the need for this information to GPs working within the footprints of the CCGs.
The committee also agreed to provide clarification in the policy regarding cosmetic surgery to approve appearance and revision surgery.

Policy Outcome

- **The draft policy is amended in line with clinical feedback, endorsed by the TPCDG and will proceed to the next stage of CCG governance for sign off and implementation.**

Policy for Adenoidectomy

You Said:
Public Feedback:

1. Positive impact on quality of life for patients
2. In both adults I know this can be a problem
3. Don't treat
4. Enable a small number of patients to have the surgery
5. large adenoids can have a negative impact on a patient
6. operation only if necessary agree
7. See generic comment about readability etc
8. As it should be.
9. Good
10. Some children suffer a lot and suffering can be reduced
11. This condition can cause a lot of discomfort in adults and children, if it continues to bother them them I fel it would be positive
12. Don't treat
13. The Patient should feel a lot better
14. Unnecessary operations avoided.
15. Good
16. Dangerous surgery only for the few likely to benefit

Clinical Feedback:

17. ENT UK We have discussed this at our Executive Meeting and are satisfied that the guidance is reasonable.

18. ENT Consultant: There is some evidence that topical nasal steroid (e.g. as spray or drops) can be effective in reducing the symptoms of adenoidal hypertrophy. It may be appropriate to states this in the guidance and patient leaflet

We Did:

Public Feedback

1.-16. The CCGs welcomed the public feedback. The clinical policies are developed based on an evidence review of the most up to date clinical evidence to ensure best practice. The revised policy will enable those with symptoms from enlarged adenoids who have failed conservative treatment to receive clinically appropriate surgical intervention.

Clinical Feedback

17. The CCG welcomed the review provided by ENT UK and would like to thanks the committee for reviewing the proposed policy.
18. The CCG welcomed the clinical feedback and appreciated the submitted piece of robust clinical evidence which enabled a small amendment in the eligibility criteria to be made.

Policy Outcome

- **The draft policy is endorsed by the TPCDG and will proceed to the next stage of CCG governance for sign off and implementation.**

Policy for the use of Hysteroscopy in Heavy Menstrual Bleeding

You Said:

Public Feedback:

1. A speedier diagnostic for patients, especially where there is a risk of endometrial pathology
2. If it is the first line of action it may save the patient from further treatment
3. Don't treat
4. This can impact on the lives of women with this condition
5. Evidence based decision
6. Sometimes just having a hysteroscopy can reduce the heavy blood loss that a patient experiences in the future
7. I had an ultra sound first then a hysteroscopy under sedation. If only a hysteroscopy sedation should be offered as it was the most painful procedure I have ever experienced.
8. See generic comment about readability etc

9. I don't know enough about it to comment, but if the scope does a better job, then use it first and cut the cost, time etc., of the scan.
10. Endometrial polyps can also cause heavy periods. Hysteroscopy helps in those patients.
11. It conciliates or highlighting further treatment. Maybe
12. Don't treat
13. Sometimes can reduce the menstrual flow
14. Saves time and I believe more accurate plus ant problems they can be done at the same time
15. Probably positive in that by using the scope first a patient will get a better diagnosis first time.

Clinical Feedback:

16. US scanning is not always reliable - I have had 2 cases where it missed endometrial cancer
17. Consultant ObGyn: I have looked at the documents and agree with them - they are comprehensive and deal with all points
18. I will also forward to some senior colleagues for their opinion and will let you know - My colleagues have reviewed this - all in agreement

We Did:

Public Feedback

1.-15. The CCGs welcomed the public feedback. The clinical policy has been developed based on an evidence review of the most up to date clinical evidence to ensure best practice in line with NICE Guidance and Right Care to ensure patients who require more invasive investigation may receive this as a first line diagnostic.

Clinical Feedback

16, 17 & 18. The CCG welcomed the clinical feedback. The clinical policy has been developed in line with current clinical evidence and NICE guidelines.

Policy Outcome

- **The draft policy is endorsed by the TPCDG and will proceed to the next stage of CCG governance for sign off and implementation.**