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

Clinical Treatment Policies

‘YOU SAID, WE DID’ SUMMARY REPORT

October 2018
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Treatment Policies Clinical Development Group: YOU SAID – WE DID Report

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 to oversee the review and development of a number of clinical policies. Membership of the TPCDG includes clinical and management stakeholders who have met monthly (2017-18) to discuss and assess Evidence Reviews and related draft policies. Membership has included representation from NHS Sandwell and West Birmingham Clinical Commissioning Group.

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 historic and more 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, local politician members of the Birmingham and Solihull Councils’
Joint Health and Oversight Committee and the Sandwell Council equivalent, and patient and public representatives.

- Ensuring the appropriate input, endorsement and sign off of the updated policies.
- Interconnecting with existing Birmingham and Solihull CCG Governance frameworks by submitting updated policies to the Clinical Policies Advisory Group (CPAG) and the Clinical Policies Quality Sub Committee.

**Public and Clinical Engagement**

A core element of the policy harmonisation programme has been the public and clinical consultation and engagement period. For a 6 week period (May 14th – June 22nd 2018) – Birmingham & Solihull and Sandwell Clinical Commissioning Groups undertook a clinical and public consultation exercise. The purpose of the engagement was both to share 22 DRAFT policies (and accompanying literature including DRAFT patient leaflet, Equality Impact Analyses and Evidence Review) 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)

Using the 7 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.

**Policies with no clinical or public feedback**

Seven of the 22 DRAFT policies received no clinical or public feedback engagement during the consultation.

The TPCDG members received presentations covering both the clinical and public engagement processes and expressed confidence in the engagement mechanisms and approach.
As a result the TPCDG members agreed that the following DRAFT policies would be endorsed in their current version and proceed to the next stage of CCG governance for sign off and implementation.

1. DRAFT Policy Treatment for Snoring
2. DRAFT Policy Painless Rectal Bleed
3. DRAFT Policy Lithotripsy/Renal Calculi
4. DRAFT Policy Breast Implant Revision
5. DRAFT Policy Reversal Male Sterilisation
6. DRAFT Policy Reversal Female Sterilisation
7. DRAFT Policy for the use of Upright / Open MRI Scanning

Policy: Carpal Tunnel Syndrome

You Said:
1. No public feedback received
2. Clinical Feedback - Clarification requested as to the appropriate location for undertaking Nerve Conduction Studies (NCS) (Primary or Secondary Care)
3. Clinical Feedback – queries and suggestions reference the appropriate management and process for reviewing revision/failed carpal tunnel procedures.

We Did:
1. Noted by TPCDG
2. Nerve conduction studies can be undertaken either by the GP or the secondary care provider. However, it was noted that if the GP is to request NCS, then this is a separate referral and so the patient will have to wait for this diagnostic test and then results and then be referred to the secondary care provider for assessment and management. If the patient is referred directly to the secondary care provider, then they can undertake the NCS at the assessment appointment in outpatients and reduce the wait time for the patient.
3. TPCDG agreed that revision surgery for failed carpal tunnel surgery needs due consideration. This will therefore be developed as a stand-alone policy (not an addendum to the current policy) and added to the Phase 3 of the Treatment Policy Harmonisation Programme which is due to commence in late 2018.

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: Arthroscopy Hip Surgery for Femoral Acetabular Impingement (FAI)

You Said:
1. These Policies seem to be in line with the current evidence and NICE guidelines. We are already following them.
2. Is it possible to involve and engage with the Local GPs so that the criteria and policies can be implemented at the GP referral level please.
3. Policy was discussed by the young adult hip MDT. Overall the group welcomed the draft proposals, are in agreement and supportive.
4. Of note the issue of an MDT was raised and that the requirements for an effective MDT needs to be specified. Recognise that the CCG may not be able to be too didactic around
how the internal clinical business is run, it was felt that there is a need for a defined minimum requirement for MDT meeting (possible membership proposals were included)

5. In addition an important point to note is that the patients should be input onto the non-arthroplasty hip registry. This ensures continued mid and long term monitoring of outcomes and is a driver for clinical effectiveness and quality. It is important to note that the study was not designed for cost effectiveness of FAI surgery.

6. Concerns were voiced about the proposal to limit availability of hip arthroscopy to provider trusts able to fully support patients with a multidisciplinary team due to the ability of some patients to then access such services.

7. The preferred choice of arthroscopic surgery over open surgery is perceived as limiting patient choice. One of the eligibility criteria for hip arthroscopy is that patients are offered choice of modality of surgery. However, the consultation document states that ‘where surgery is considered appropriate following an assessment, an arthroscopic surgery should be promoted as the treatment of choice over open surgery’. It is difficult to see whether patients will be offered real choice when one method is being promoted over another.

8. Some people aren’t suitable to have hip arthroscopy, some patients should have physio instead of arthroscopies. Anything that aids the patient’s movement and it would help with patient isolation issues.

9. For instance, the hip arthroscopy policy aims to limit availability to provider trusts able to fully support patients with a multidisciplinary team. If services are then limited to particular locations, what plans are in place to ensure that all Birmingham residents regardless of location are able to access these services. Especially taking into consideration transport, parking, age of users and other issues that might affect those with lesser economic means or those that would have to rely on public transport.

10. Hip waiting list for Dudley is 4 weeks whereas Sandwell is 20-30 week, this needs reviewing.

We Did:

1. The CCGs welcomed the clinician support and feedback.
2. Birmingham and Solihull CCG & Sandwell and West Bromwich CCG have created a video which provides information for GPs regarding the proposed 22 new Treatment Policies. During the engagement period the DRAFT policies were highlighted to GPs.
3. The CCGs welcomed the clinical support and feedback.
4. The CCGs noted the request for specification regarding the requirements for an effective MDT, however it was felt that this would be difficult to mandate as this was within the remit of the provider organisations to ensure correct governance. However, the policy states that this should be a verifiable MDT and the CCG would request evidence of this from any providers undertaking this procedure.
5. The CCG agreed that for patient safety and monitoring of efficacy then it would be added to the policy that inputting patients into the non-arthroplasty hip register would be a requirement of a provider trust.
6. Limiting the availability of hip arthroscopy to certain provider trusts who are fully equipped to undertake this procedure has been made on the basis of patient safety. With this surgical intervention, ensuring that providers are fully resourced to support a patient undergoing such an invasive operation in the safest most clinically effective environment.
7. As stated in the policy, it is a preferred choice, not a mandated choice, the CCG have enabled a suitably qualified clinician with the support of the MDT to have an individual conversation with each patient to ensure that a shared-decision making process is undertaken and the most appropriate plan of care is jointly made for that individual.
8. This is a reason why the CCG have commissioned only trust with a supporting MDT (surgeons; physiotherapists; radiographers; allied health professionals) to undertake these procedures so that following a referral a patient may be holistically assessed and the most appropriate plan of care made for that individual by appropriately qualified clinicians, which
may be a plan for conservative treatment (physiotherapy, pain management etc) as opposed to surgery.
9. All provider trusts have to have parking and disabled access facilities in place. For patients who do not drive and have mobility issues, then there is the option for patient transport for those who meet the eligibility criteria for this service.
10. Waiting lists are a constant challenge for provider trusts, ensuring that operating theatre time is used in the most efficient and effective manner enables these waiting times to be alleviated and ensuring that specialist clinicians can assess complex patients and undertake a shared decision with the individual patient can ensure that operating theatre time is maximised and that surgeons' time is used in the most efficient manner.

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: Knee Arthroscopy for degenerative Knee Disease

You Said:
1. Public Feedback:
2. Knee arthroscopy should still be considered if pain control was unsuccessful and that further alternative treatments for knee arthroscopy in degenerative knee disease be explored.
3. If pain killers cannot limit the pain then this procedure of washing out joints eg: knees should be considered.
4. What is the cost and if inexpensive, why not still consider the procedure? If it even gives short term benefit then it should be considered.
5. Clinical evidence shows that it is not best practice as it does not always relieve for long periods of time but group still thinks it should be considered for some cases.
6. Need to know how long it would last once a washout is done could determine whether it should still be considered.
7. For the policies that will no longer be funded, are there alternative treatments that should be considered. For instance the ‘Knee Arthroscopy for Degenerative Knee Disease’, are there other arthroscopy techniques that might be useful and be of benefit than arthroscopic debridement?
8. Can you outline how many patients would be affected by the proposed changes to each policy? For example, you propose to limit the availability of knee arthroscopy for degenerative knee disease. How many people have received a knee arthroscopy in the last year and how many of these patients would no longer be eligible under your proposed policy change? Is this in line with NICE guidelines?
9. Clinical Feedback - These Policies relating to T&O seem to be in line with the current evidence and NICE guidelines. We are already following them.
10. Is it possible to involve and engage with the Local GPs so that the criteria and policies can be implemented at the GP referral level please?
11. I've circulated to all the hip and knee surgeons at XXX but haven’t received a single response. I guess we must assume that they are entirely happy with commissioning proposals.

We Did:
1. Noted by TPCDG
2. Items 2-7. Confirmation the policy is in line with NICE Guidance. Rather than revising the policy based on the request to keep the procedure – the public should have full information about the procedure so that they can understand the impact of post-surgical infections,
repeat surgery, poor surgical outcomes, and limited/short-lived impact on pain/mobility, as well as increasing the risk/likelihood of needing an arthroscopy sooner than otherwise would have been the case.

3. Items 8 – the CCG have responded to the Birmingham MP with the information requested.

4. Items 9-11. TPCDG noted the feedback and flagged the engagement work undertaken with GP’s (also noted that the referral communication can be a 2-way process with providers also communicating referral requirements with GP’s)

**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.

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### Policy: Dupuytren’s Contracture

**You Said:**

1. Is it possible to involve and engage with the Local GPs so that the criteria and policies can be implemented at the GP referral level pls?

2. These Policies relating to T&O seem to be in line with the current evidence and NICE guidelines. We are already following them. Dupuytren Injections which are also in line. However, we will strongly recommend that Bluteq is unnecessary.

3. P4 is inconsistent with the DD leaflet (at least it suggests that disease more severe than moderate disease can be treated). This has functional AND MCP AND PIPj OR 1st web contracture. I think it should be functional AND MCP OR PIPj OR 1st web contracture….Isolated PIPj contracture which causes functional problems should not be restricted from treatment – it is these contracture that are more difficult to manage than the isolated MCPjs. (Though I notice that the NICE guidelines state the former, this is not what is stated in your DD leaflet).

4. The NICE guidelines go into a fair bit of detail about PNF, and how it was not sure how a cord could be suitable for CCH but not PNF. I cannot see in the guidance anywhere that it does not think that PNF is appropriate. The recommendations 1.2 “…. CCH is recommended as an option …only if all of the following apply….. Percutaneous needle fasciotomy (PNF) is not considered appropriate, but limited fasciectomy is considered appropriate by the treating hand surgeon…..” ie you can only use CCH if PNF is not considered appropriate. It isn’t removing the possibility of using PNF. I speaks as a surgeon who doesn’t use PNF as I have no experience of it, so I have no vested interest, but I cannot see why PNF is now not commissioned.

5. In response to the guidelines I think it just needs to be made clear that severe disease can be treated – in the first section it says ‘at least moderate disease’ then only includes moderate disease not ‘at least’ moderate disease the final section.

6. DD leaflet: page 2 ….“any contracture…..(inter-phalangeal joint...)” I think this should be proximal inter-phalangeal joint. Is this leaflet for patients or clinicians. It seems too simple for clinicians and too complex for patients. There is a muddle between “patients should…” and “you”. There are a lot of “often”’s when I think “usually”, “commonly”, “frequently” or “normally” might read better. Recurrence is quoted at 40%, but it depends on when your end point is. 50% at 5 years is commonly quoted (probably cos it’s easy to remember), but I suspect that practically all patients will experience recurrence or extension of their disease if they live long enough after intervention. However this recurrence doesn’t always cause functional problems. There is inconsistency in the criteria. Page 2 top part says contracture 30-60… shouldn’t it be a contracture of at least 30 degrees. After all a contracture of over 60 degrees would be eligible. But then at the bottom any contracture of the PIPj is
eligible. Therefore what I think you mean is any contracture over 30 degrees at MCPj or any contracture of PIPj or symptomatic contracture of the first web space so long as it is causing functional problems. It seems from the leaflet that severe disease is not eligible for treatment, which I am sure is not the case, but if it’s only discussing DD management where the use of CCH is an option against surgery, then I guess that this is reasonable. CCH isn’t really the correct thing to use in most severe cases.

We Did:
1. Birmingham and Solihull CCG & Sandwell and West Bromwich CCG have created a video which provides information for GPs regarding the proposed 22 new Treatment Policies. During the engagement period the DRAFT policies were highlighted to GPs.
2. The CCGs welcomed the clinical support and feedback and will forward the Bluteq feedback to contract managers.
3. This has functional AND MCP AND PIPj OR 1st web contracture. Has now been amended to: functional AND MCP OR PIPj OR 1st web contracture
4. National Institute for Health and Care Excellence (NICE) 2017 - Collagenase clostridium histolyticum for treating Dupuytren’s contracture. Technology appraisal guidance # 459. TPCDG reviewed and revised the draft policy as per NICE guidance and specialist clinical steer.
5. TPCDG welcomed the clinical review and the policy wording was amended.
6. TPCDG welcomed the clinical review of the patient leaflet and amendments were made to simplify the leaflet for patients and ensure clinical continuity.

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: Management of Chronic Fatigue Syndrome/ME

You Said:
1. Public Feedback:
2. Is it being put under the umbrella of a mental health condition?
3. Is it wasted money if someone is on a CBT programme when it’s a mental health related condition?
4. Pathways need to be made more clear in the leaflet.
5. Clinical Feedback
6. Queries raised about the referral pathway

We Did:
1. Noted by TPCDG
2. Items 2-5. TPCDG noted that the questions appeared to link to the location of where the current CFS/ME service is provided as the condition is not put under the umbrella of a mental health condition. All patient leaflets will undergo a final review for clarity before implementation.
3. Item 5-6. The Clinical Lead Nurse clarified the queries directly with the Neuropsychiatry department.

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: Port Wine Stain**

**You Said:**
1. Public Feedback:
2. Some treatments such as port wine stain removal shouldn’t be treated as cosmetic as it has a massive impact on the mental health and wellbeing of an individual, especially if they are young and in school therefore more likely to be teased or bullied for how they look.
3. What if a child that looks differently is bullied? The social stigma that comes with it and the long term effects of bulling might cost the NHS more than the actual treatment to reduce the birthmark.
4. This isn’t a cosmetic treatment due to the potentially social stigma that comes with it.
5. Is the laser treatment not funded because it’s generally linked to underlying treatments? It’s not clear in the leaflet
6. What if it’s a little boy? Men and boys don’t like wearing make-up so the psychological effect could be huge. If laser can reduce how obvious the birth mark is then surely it should be used.
7. Comments received on the draft policy for port wine birthmark raised concerns on the psychological impact of not having laser treatment. It was felt that particularly for children, bullying could result and that offering only camouflage makeup when laser treatment could reduce the birthmark was inappropriate.
8. Port Wine stains should be funded if in a visible place
9. It is cruel to refuse to treat all port wine stains - placement and severity should determine need.
10. Apart from port wine stain agree with all
11. Clinical Feedback
12. Main issue raised by the team discussing the document was if the policy applies to all ages and if the role of laser to treat Children with PWS had been scoped.

**We Did:**
1. Noted by TPCDG
2. Items 2-10. Members noted the mental health impact/concerns raised by the public – when a psychological condition is cited – then an IFR request can be made.
3. Item 11-12. Lead Clinical Nurse for the project responded to the query.

**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: IVF/Assisted Conception**

**Policy: Provision of NHS funded Gamete Retrieval and Cryopreservation for the Preservation of Fertility**

**You Said:**
1. No clinical feedback was received during the engagement period.
2. We note that assisted conception is now only limited to those under 40 years of age and that only one cycle of IVF will be funded. Although the age limit is in line with NICE guidelines, we note that the CCG has failed to adhere to NICE Guidance that recommends that up to three IVF cycles should be available on the NHS. According to NICE, the
cumulative effect of three full cycles of IVF increases the chances of a successful pregnancy to 45-53%. Three IVF cycles are the most cost effective and clinically effective number for women under the age of 40. As a result of the CCGs plans, this will mean that only those who can afford to continue treatment privately will be able to do so. Thus the outcome for those from poorer backgrounds will be worse off as they might not be able to afford private treatment.

3. We note that IVF treatment will not be offered to women over the age of 40 contrary to NICE guidance that recommends that women between 40 and 42 should have at least one IVF cycle.

4. It is not clear from the documents provided whether the change of eligibility age from 42 to 40 will be the same for patients under Birmingham South Central and Solihull CCG. As it seems from the document that the change only applies to patients under Cross City CCG. Unless this has been brought in line with the other two CCGs, having different eligibility ages under the same CCGs will lead to inequality in access to services and health outcomes.

5. We note that assisted conception is now only limited to those under 40 years of age and that only one cycle of IVF will be funded. Although the age limit is in line with NICE guidelines, we note that the CCG has failed to adhere to NICE Guidance that recommends that up to three IVF cycles should be available on the NHS. According to NICE, the cumulative effect of three full cycles of IVF increases the chances of a successful pregnancy to 45-53%. Three IVF cycles are the most cost effective and clinically effective number for women under the age of 40. As a result of the CCGs plans, this will mean that only those who can afford to continue treatment privately will be able to do so. Thus the outcome for those from poorer backgrounds will be worse off as they might not be able to afford private treatment.

6. The proposed restricted age limit for assisted conception was unfair to women who had suffered illnesses such as cancer, meaning they were unable to have children until they had recovered and subsequently received assisted conception treatment.

7. I worked and became financially secure before I thought about having children. I wanted to buy a house by the time I was 40. I’ve done that. I’m 41 now, married and financially very secure so I’m ready to have a baby. I’ve done everything to prepare myself for the moment and now we’re ready. However, we’ve been having problems trying to have a baby and we’ve now discovered that we are not covered on the NHS for IVF treatment. I’m 41 and will be 42 in a few weeks, so I’m already too old to be covered – although I might be if I was in the other area where it’s currently up to 42 now.

8. If they’re healthy then why not allow them to have IVF? Up to 45 would be ok but I supposed that would only be ok if you had some evidence that there was a chance of success at that age. But I suppose if you showed that you could prioritise to help younger people have a baby, if they had a better chance, then maybe that’s a better thing.

9. We’ve had two rounds of IVF previously paid for by the NHS. We’re now on our third and have to pay for it ourselves. I think that there should be no age at all. People want to get their homes and education first. They want to be fit and health, so they’re leaving it later to have a child.

10. Even though the evidence is there about age it should be based on health rather that how old you are. Some people may be 40 but have a body age of 30.

11. Some of the statistics behind IVF treatment are misleading. The difference between a 30 year old conceiving through IVF and a 43 year old is very narrow.

12. The considered proposal for assisted conception was felt by some not to have considered modern lifestyles where women have children later in life.

13. I think that IVF should be fair across the whole country. I have a friend who has relocated in order to be offered three cycles of IVF. It doesn’t seem fair that in some areas you are offered none at all.
14. Most people agreed that the assisted conception proposed policy in terms of age for treatment should be the same across the CCG geographical areas; some even felt it should be applied nationally to prevent a postcode lottery.

15. However, some people fed back their concern on access to treatment being based on age, it was felt that the policy was unfair to same sex couples and feedback on future relationships when those bearing children had failed, other aspects of the proposed policy were discussed and comments made for consideration when final decisions were made.

16. Eligibility for assisted conception for same sex couples was raised as being unfair. Fairness and equality, particularly with regard to sexual orientation was raised several times.

17. Childlessness – Every relationship should be sacred. We should all have the choice as humans to have the chance to have a child. If you could still have a child naturally then why can’t you have a child through IVF? I totally disagree with the idea that if you’ve already had a child in a previous relationship you can’t try for a child in a new relationship. If you’re in love and you have a bright future then why shouldn’t you be offered the treatment?

18. Previous sterilisation – I think this is quite shocking and very unfair that you can’t have IVF if you have been sterilised and it’s then been reversed.

19. IVF isn’t just about getting pregnant, it would also help ensure that you have a healthy baby and screen for any problems.

20. Contentious (regarding IVF) but where does it stop. Might be cruel and heartless but there needs to be rules behind it.

We Did:

1. TPCDG acknowledged the lack of clinical feedback, the policy was written with significant input from local clinical experts who had previously reviewed a number of drafts of the DRAFT policy document before it was release for engagement.

2.-12. TPCDG acknowledged the clarity which was required regarding the rationale for the age restrictions.

With regard to the current Birmingham and Solihull CCG, alignment was required as prior to the CCG merging in April 2018, the four CCGs (Birmingham Cross City CCG; Birmingham South central CCG; Solihull CCG & Sandwell & West Birmingham CCG) had differing age limits for IVF:

- Birmingham Cross City CCG: one cycle of IVF was funded for couples / single women who met all of the eligibility criteria up to the age of 42 years.
- Birmingham South Central CCG: one cycle of IVF was funded for couples / women who met all of the eligibility criteria up to the age of 40 years
- Solihull CCG: one cycle of IVF was funded for couples / women who met all of the eligibility criteria up to the age of 40 years
- Sandwell and West Birmingham CCG: one cycle of IVF was funded for couples / single women who met all of the eligibility criteria up to the age of 42 years.

Following the CCG merger, Birmingham and Solihull CCG drafted a policy following review of the clinical evidence:

- There is high quality evidence from the 2013 NICE Clinical Guideline, more recently published evidence and the HFEA, all of which confirm that increasing maternal age is a key predictor of failure to have a live birth following IVF treatment.

<table>
<thead>
<tr>
<th>Maternal age</th>
<th>Live birth rate per treatment cycle started using patients’ fresh eggs in 2013 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All ages</td>
<td>26.5</td>
</tr>
<tr>
<td>18-34</td>
<td>32.8</td>
</tr>
<tr>
<td>35-37</td>
<td>29.5</td>
</tr>
</tbody>
</table>
Therefore, based on the clinical data, the CCGs wanted to align the age limit for access to funding for one cycle of IVF treatment across the region of responsibility. This was based on enabling the largest number of women to have the greatest chance of a live birth within the financial resources available.

13. & 14. Birmingham and Solihull CCG and Sandwell & West Birmingham CCGs would welcome the introduction by NHS England of a national policy regarding IVF treatment in order to tackle the ‘postcode lottery’ funding issue currently evident with regard to this treatment. NHS England have recently released a consultation document for national treatment policies and as part of this feedback, the CCGs will recommend that NHS England develop a national policies regarding Assisted Conception and Gamete Retrieval and Cryopreservation.

15. & 16. The (CCG) will not provide routine funding for the medical treatment required to give effect to a surrogacy arrangement because: (a) this treatment is not considered by the CCG to be a priority for NHS investment, (b) the CCG is unlikely to be in a position to be able to reach an assessment as to whether the parties have concluded a lawful surrogacy arrangement, and (c) the CCG is concerned that the funding of such treatment raises substantial risks that NHS bodies and clinicians providing care connected to surrogacy arrangements would be exposed to unknown medico-legal risks. IVF treatment will not be provided as part of surrogacy arrangements.

For heterosexual couples, single women or women in same sex relationships, IVF is only available to those who are defined as clinically infertile. If clinical investigations so not show that a woman in a same-sex relationship is infertile, then she will have to demonstrate as a heterosexual couple would have to through the failure to conceive after regular unprotected sexual intercourse for a period of 2 years. Single women or women in a same sex relationship are asked to demonstrate infertility in the absence of known infertility through undertaking 6 rounds of self-funded donor insemination via IUI as this is the most clinically effective method of achieving a donor pregnancy.

17. The eligibility requirement for both partners to be childless, has been reviewed by the CCGs, with limited resources, the CCG hopes to enable through this policy that the greatest number of people will have the opportunity to become parents.

18. Sterilisation: before undergoing a sterilisation procedure, a patient will be advised that this is a permanent procedure and has a very low success rate of reversal and the patient will the outcome of the procedure will be that the patient will have no further chance of parenting a biological child. Therefore, a patient who has undergone sterilisation has made an informed decision to not have any further children. The NHS does not fund reversal of sterilisation and therefore will not fund IVF when a patient has been sterilised.

19. This policy reviews the eligibility criteria for funding for patients who have been demonstrated to be clinically infertile. With a successful pregnancy following IVF, screening for any foetal anomalies would then proceed in the same way as it would for any pregnancy along the NHS ante-natal care pathway. For patients who require Pre-Implantation Genetic Diagnosis (PGD), this is not covered by this commissioning policy as it is the commissioning responsibility of NHS England. Patients should be referred to the Genetic Centre at Birmingham Women’s & Children’s Hospital.

20. TPCDG noted the feedback.

**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: Acupuncture for Indications other than Back Pain

You Said:
1. Public Feedback:
2. Question 4- Have you or a loved one had any experience of the procedures currently being proposed in the new draft harmonised treatment policies with RESTRICTED CRITERIA?
3. Acupuncture for Indications other than Back Pain 15.09% 8
4. No clinical feedback received

We Did:
1. Noted by TPCDG
2. No further clinical feedback received following the Headache Team at Royal Stoke Hospital (UHNMC) having previously submitted information for the draft policy. Public feedback was non-specific for this policy. The policy is consistent with NICE.

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: Management of Ear Wax

You Said:
7. Just to say that the ear wax referral policy was discussed in ENT Quality Improvement Half Day Meeting last week and it was thought to be ok.
8. Thank you for sending me these documents to work with and address our secondary care service, they are most useful.
10. Group discussion:
   - The group listed variation between their practices on the removal of ear wax. Some patients had been offered this and other hadn’t.
   - There are some GPs that did not know of a policy and sends them to a specialist therefore more money is spent – this needs to stop
   - How do you make sure that GPs offer these services to patients in a consistent manner?
11. Questionnaire:
   - Question 4- Have you or a loved one had any experience of the procedures currently being proposed in the new draft harmonised treatment policies with RESTRICTED CRITERIA?
   - The majority of those that answered (43.40%) had experienced procedures relating to Treatment for ear wax
   - Question 5- Do you agree with the list of procedures that are proposed to be not normally funded?
     Ear Wax as this may lead to more problems
   - Question 6 - Do you think any of the proposed changes would have a negative impact on your care/ the care of your family/ any particular group of patients within the community?
     Yes. Nobody knows how or when they might develop such conditions or may need to reapply for treatment e.g. in my case, ear wax treatment.

We Did:
1.& 2. Clinical feedback was welcomed by the TPCDG.
3. Amendments will be made to the patient leaflet
4.5. & 6. Birmingham and Solihull CCG and Sandwell and West Birmingham CCG are currently reviewing the commissioning arrangements regarding the management of ear wax in line with the newly drafted policy which reflects NICE Guidance 2018.

**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.

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**Policy: Management of Umbilical, Para-Umbilical and Incisional Hernias.**

**You Said:**

1. **The issue of wound infection after open hernia repair is complex and there is no clear guidance.**
   - I have investigated this in my own clinical practice and have successfully reduced SSI (surgical site infection) in open hernia repair by over 80% (p<0.05) using a care bundle design as part of a Safety and Quality improvement project and integrated it into the WHO checklist.
   - This was a pilot study and does not represent Level 1 (RCT) evidence but the results were so large that I feel I should share the case study because it suggests that open repairs can be done with acceptably low infection rates using a care bundle approach.

2. **Comments on draft hernia policy and leaflet**
   - Post-operative advice would be helpful. Needs to be on the flyer, for example; will symptoms come back, what to do if it does and how do they avoid return illness?
   - Doctors’ communication is quite vague in surgeries and they have scored low. This needs to be addressed immediately to regain confidence with the patients.

3. **Question 4- Have you or a loved one had any experience of the procedures currently being proposed in the new draft harmonised treatment policies with RESTRICTED CRITERIA? Management of Hernias 24.53% 13**

4. **Question 5 - Do you agree with the list of procedures that are proposed to be not normally funded?**
   - More detail required before I would say yes or no especially around management of hernia and hip arthroscopy.
   - In some cases the appearance of a hernia can affect daily life, it’s not just about pain, walking, sleeping.

5. **Question 7 - Do you agree with the list of procedures that are proposed to have restricted criteria? Not sure about changing hernia as husband needed it**

**We Did:**

4. The TPCDG welcomed the clinical feedback, the proposed policy does not rule out open hernia repair, the proposed policy encourages clinicians to have an open shared decision making review of the individual patient’s circumstances in order to ensure that the surgical method which is best suited to the patient is undertaken to enable the best possible outcome for that patient. The information received is extremely useful in supporting the clinician in offering a choice of surgical repair to the patient which best suits the patient and the surgical expertise of the clinician.
5. Post-operative advice will be given to the patient by the surgical team on discharge from hospital following the procedure being undertaken.

6. 4. & 5. The policy has been created to ensure that patients are able to access surgical repair of hernias in the safest circumstances. There will always be a very low clinical risk in undertaking a surgical procedure and so the need for surgery must out weigh this risk.

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: Complementary and Alternative Therapies

You Said:

1. Attached anecdotal and paper evidence from patients with regard to cupping and some research papers to support.

2. Indicated further anecdotal evidence for aromatherapy (which is extremely patient focused and is generating excellent outcomes) would be supplied but was not received during engagement period.

3. I’m emailing you my testimony of the benefits of cupping as requested. After having ACDF and fusion surgery of C3/4 on my spine in October 2016 I was referred to XXXX for physiotherapy. After several sessions XXXX suggested trying cupping on my neck as I have suffered severe pain and stiffness to my neck area since the surgery. Following the cupping sessions I have experienced some relief in the stiffness of the neck and a reduction of the intensity of the headaches. During the sessions I experience relaxation of the muscles in my neck and shoulders. The cupping used alongside my medication has made a marked difference in the intensity of my symptoms and gives me some relief from the pain and stiffness.

4. I am currently undergoing a course of cupping at XXXX Trust. When it was first suggested as a treatment option, I said no as I didn’t realise that cupping was under the acupuncture umbrella. As I am needle phobic, I know that I wouldn’t be able to tolerate needles and it was not an option I could consider. Luckily my physiotherapist has been trained in cupping and as I know it’s non-invasive I said yes. On my second session I had woken with a cricked neck and after having my cupping session I had immediate relief and the tight muscles had reduced significantly afterwards. I am now half way through my treatment plan and would highly recommend cupping to anyone as it’s not painful, non-invasive, cost effective and very effective. I have worked in the NHS for 17 years and I know that costing is a major factor in developing and implementing packages of care, this ancient art of cupping stands alone as once you have the cupping equipment you don’t need extra supplies, such as single use only equipment, thus reducing storage requirements, by not ordering equipment and using cupping more within the physiotherapy department you are reducing your carbon foot print, thus making it cost effective. However as a patient myself I much prefer a holistic approach to patient care which is very important to me. Overall I feel extremely lucky that I was paired with the right physiotherapist who was trained in cupping enabling me to gain more movement in my neck and reduce pins and needles in my hands after being told I could have surgery but there was not a guarantee it would work, so for me cupping has been very beneficial.

5. just wanted to write a testimony about the cupping therapy XXXX is having with you. As you
know X has pots syndrome & suffers with chronic pain in the back, shoulders & neck. X is definitely feeling the benefits of the cupping therapy, her shoulders, back & neck feel lighter & less knotted up & tight after a session. I really hope X can carry on with these cupping therapy sessions.

6. Any relieve from pain for a period, is helpful as there is nothing worse than being in chronic pain as well as all X symptoms especially for a child it's heart-breaking to see X suffering so much.

7. I have been seeing XXXX since March 2018 to help manage my pain in my neck & shoulders. X has been using an acupuncture technique named cupping to help manage and reduce the pain. After my physiotherapy sessions with X my neck pain is lighter and the pain is reduced by 30/40%. I am a holistic been who believes in traditional natural remedies. I am person centred and believe this cupping technique is really aiding me.

8. Members of the public asked for the benefits of such therapies to be further considered, for example in cases of mental health illness, children’s diseases such as Potts syndrome, neck and back pain and Parkinson’s diseases if alternative pain relief has been tried and hasn’t worked then if the patient prefers they should be allowed to go with Acupuncture. Electrical impulse is also used, if in-effective then patient should be offered alternatives such as acupuncture. There should be evidence that shows this procedure is clinically proven to work. The leaflet should explain why these therapies are not offered as some of them definitely have benefits to patients.

9. Hypnotherapy/Yoga; at least one person felt that it was positive so they should still be considered. If you are a practitioner can you offer this; can there be clarity? Also, is there evidence that Yoga/Hypnotherapy works for mental health patients – will this still be offered in special cases?

10. The CCG is funding for dance therapy to help elderly eg: Parkinson. What evidence was done to stop this funding?

11. Tai Chi is very good and is not on the list; is this still being supported. It’s great for balance for older people. More clarity required as to why these have been stopped.

12. Art therapy being stopped is contentious due to the positive outcomes that there has been seen in social prescribing, particularly with mental health patients and maybe palliative care.

13. Acupuncture worked extremely well for one patient. Her operation scar hasn’t hurt since she had the acupuncture treatment.

14. What is the clinical effectiveness of these treatments? Might not be great but from a holistic and wellbeing point of view, might not be the right way to look at these policies. Don’t just look at policies through a hard clinical point of view.

15. Interventions are just as important as policies. Is there evidence that shows that some of these therapies prevent others?

We Did:

7. The TPCDG welcomes the feedback and supporting clinical papers which were reviewed by Public health colleagues. The submitted clinical papers were of an evidential grade which did not support the use of NHS resources.

8. – 15. Anecdotal information was supplied regarding cupping; acupuncture; electrical impulse; hypnotherapy; yoga; Tai Chi. Acupuncture is not part of the complementary and alternative therapies policy, a separate policy has been developed in relation to the use of acupuncture, which enables a course of acupuncture to be funded in certain clinical circumstances. With regard to the other interventions mentioned above, there was insufficient evidence found by the initial evidence review or submitted in the engagement phase to warrant the use of NHS resources to fund these interventions.

Policy Outcome

- The draft policy is endorsed by the TPCDG and will proceed to the next stage of CCG
**Policy: Vasectomy**

**You Said:**

1. Draft policy for vasectomy. We have read through – it looks comprehensive and accurate. Nothing to edit or add here.
2. EIA and patient leaflet – edits and suggestions made for the content.
3. *I think that counselling should be in place before somebody has a vasectomy because things and people change in the future.*

**We Did:**

9. TPCDG welcomed the clinical feedback regarding the assessment of the draft policy and thanked the clinicians for taking the time to review the draft.
10. The comments and suggestions regarding the patient leaflet and EIA were also welcomed and will be reviewed and amendments made as required.
11. As outlined in the policy and the service specification for the vasectomy services across Birmingham and Solihull CCG and Sandwell & West Birmingham CCG, counselling is a mandatory requirement prior to a vasectomy procedure being undertaken.

**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.

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**Policy: Asymptomatic & Symptomatic Bunions**

**You Said:**

1. These Policies relating to T&O seem to be in line with the current evidence and NICE guidelines. We are already following them. New ones are about Bunion surgery & Dupuytren Injections, which are also in line
2. Is it possible to involve and engage with the Local GPs so that the criteria and policies can be implemented at the GP referral level pls?
3. Patient experience of having problems with bunions. He went for an x-ray and then then had to wait for next steps. Told to self-care first before going through with any type of operation but was in pain in the meantime.

**We Did:**

12. The TPCDG welcomed the clinical review and feedback regarding the policy and thanked the clinicians for their time. Birmingham and Solihull CCG and Sandwell and west Birmingham CCG are currently redesigning the Musculoskeletal Triage Services and all referrals from primary and secondary care will in the future be reviewed through this service to ensure
that patients meet the policy criteria before being referred to secondary care services.

13. The TPCDG will forward the Blueteq feedback to contract managers.

14. The pathway which the patient outlined is in line with National Guidance regarding the management of bunions. If a patient is in pain, then he/she should visit their GP for a review regarding their pain relief requirements.

**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.

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**Policy: Cough Assist**

**You Said:**
During the engagement period a substantial amount of evidence and clinical and public opinion were received from the sources below:

- Submission of 65 pieces of further clinical evidence (appendix 1)
- Submission of supporting letter from local Clinical Specialist Respiratory MDT to accompany the above mentioned evidence (appendix 2)
- Submission of letter from clinician and supporting evidence (appendix 3)
- Submission of letter from West Midlands Neuromuscular Disease Network. (appendix 4)
- Email Submission from MND Association (appendix 5)
- Email submission from Spinal Muscular Atrophy Support UK (appendix 6)
- Email submission from public member (appendix 7)

From the above submissions the following themes were highlighted for review by the TPCDG:

1. Submission of evidence which has not been included within the CCG evidence review undertaken in 2017 and issues raised in regard to the initial evidence review.
2. Expert clinical opinion has not been given due consideration.
3. The issues surrounding undertaking Randomised Control Trials within this specific patient group.
4. Postcode lottery which patients experience in accessing these devices nationally.
5. Appropriate assessment and on-going support to these patients to ensure that those who might benefit clinically from using the machines have access to them.
6. Minimising hospital admissions and length of stays through the use of the cough assist machine.
7. Clinical support for those using cough assist machines in the community.
8. Patient numbers.

**We Did:**
The TPCDG welcomed and thanked all of those who submitted clinical evidence, clinical opinion and public opinion during the engagement period. The time taken to contribute to this policy development process has been greatly appreciated.

1. The clinical evidence submitted, was further reviewed by NHS Solutions for Public Health (SPH). The original remit of the initial evidence review undertaken in November 2017 was as follows:
   a. Research Question: What is the evidence for the clinical and cost effectiveness of using a mechanical insufflator-exsufflator machine (MI-E) (also referred to as cough assist machines) compared to manual assisted coughing and other breathing methods in adults who have ineffective cough due to weak or abnormal musculature.
   b. Population: Children and adults who are living in the community, who are unable to
clear secretions due to ineffective cough (PCEF >160L/min and <270L/min)
a. Indication: Ineffective cough due to paralytic and/or restrictive disorders associated with weak and/or abnormal musculature e.g.:Neurological disease; Neuromuscular disorders; Spinal cord injury; Kyphoscoliosis; Post-polio syndrome. (NB excludes patients with ineffective cough due to respiratory disorders e.g. cystic fibrosis, chronic obstructive pulmonary disease (COPD))
b. Intervention: Mechanical insufflator-exsufflator (MI-E) machine in home setting
c. Comparator: Standard treatment Any other intervention to help patients mobilise and clear bronchial secretions e.g. Manual assisted coughing; Other breath methods e.g. Frog breathing; Non-invasive ventilation (NIV); Bag assisted breaths
d. Outcomes: Clinical effectiveness including: Peak cough expiratory flow; Respiratory infections; Pneumonias; Antibiotic treatment; Quality of life; Activities of daily living; Emergency intubation; Cost effectiveness including Resource utilisation; Early discharge to home; length of stay; Hospital admissions

SPH standard rapid evidence review methodology involves searching EMBASE, Medline and Cochrane databases for 10 years prior to the search date, which was 3rd October 2017. This is because the technologies in question tend to improve over time and older studies with older technology may provide less favourable results that are no longer applicable and may bias the overall result of the evidence review. (Comments received regarding the changes in the machines over the years and greater ease of use support this, as appliances that can be used more easily are likely to be used more regularly by patients and, if effective, are likely to provide better outcomes as a result.)

Standard practice for rapid evidence reviews also involves using the most recent good quality/comprehensive systematic review of evidence as an anchor, retrieving data from that study for the studies that predate it and then including other studies if they were published subsequently or if, for example, they cover a different in-scope indication. Only peer reviewed original studies or systematic evidence reviews are in scope of an evidence review, and it does not include a review of information from other types of publications such as letters, presentations, general reviews or guidance documents.

The 65 references which were submitted during the engagement period were reviewed by SPH and the following findings made as to why they were not included within the original evidence review:

- 22 were published before 2007
- 5 were published after 3rd October 2017.
- Of the remaining 38 papers (published between 2007 and 2017):
  - 5 were included in the evidence review, in some cases using the information provided for that study within the “anchor” systematic review as described above
  - 31 were not original research or systematic reviews of evidence and/or were out of scope of the agreed PICO (Note: The PICO acronym stands for: P – patient, problem or population. I – intervention. C – comparison, control or comparator) for other reasons (the population, indication or intervention in the study did not match that defined in the PICO for the SPH evidence review, for example some studies looked at the use of MI-E within an in-patient setting rather than a community setting).
  - 1 study could not be identified from the limited information provided and it is not possible to comment on its applicability to the review
  - 1 study was not picked up by the SPH search (Phillips et al 2014). This study was in a journal that is not included in Medline or EMBASE (New Zealand Journal of
Physiotherapy) and was not highlighted during the initial evidence review consultation period in December 2017/January 2018. It does appear to be an original study that is in scope of the SPH evidence review, although it is a small non-comparative study which included only six patients. SPH will revise the evidence review to include this study and issue the review later in the summer (end August/early September).

2. & 3. The 5 pieces of clinical evidence published after 3rd October 2017 were reviewed by the TPCDG in light of the feedback from clinicians regarding the ability of clinicians to undertake randomised control trials due to financial and ethical considerations and the clinical opinion which was submitted during the engagement phase. The TPCDG welcome the support and continued engagement of their clinical colleagues in all areas of policy development. The CCG highly values the expert clinical opinion of the clinical specialist from all areas of the multi-disciplinary team, local, national and international. In light of the evidence submitted during the engagement period, the newly published information regarding clinical opinion, e.g. Touissant et al. (2018) 228th ENMC International Workshop: Airway clearance techniques in neuromuscular disorders, Naarden, The Netherlands, 3-5 March, 2017. Neuromuscul Disord. 2018 Mar;28(3):289-298. doi: 10.1016/j.nmd.2017.10.008. Epub 2017 Nov 7; was reviewed by the TPCDG.

4. The TPCDG acknowledges the ‘postcode lottery’ which many through England face. The CCG has worked hard to merge the previous 3 CCGs which covered the Birmingham and Solihull area to enable equality of treatment across the patch and is now working closely with Sandwell and West Birmingham CCG through the Harmonised Treatment Policy Programme to enable greater equality of treatment for all patients across an even larger area. In addition the CCG welcomes NHS England’s new consultation on harmonised treatment policies and, in the submission by the CCG during this consultation, will raise with NHS England the need for a unified national policy for the use of cough assist machines.

5. The TPCDG wishes to ensure that only those patients who might benefit clinically from using a cough assist machine may be able to gain access to them, and the on-going support of clinical colleagues in undertaking this policy development process to ensure that patients are offered clinically effective treatment in a cost effective manner which makes the best use of NHS resources is paramount.

6. The TPCDG acknowledged the evidence which suggest a reduction in the number of hospital bed days per patient/per year but also noted the lack of evidence or impact demonstrating improvements to the patient’s condition and clinical outcomes (i.e. same number of infections/exacerbations). The improvement to quality of life argument stems from patients being kept out of hospital for longer periods rather than improvements to the clinical condition.

7. The importance of ensuring that patients were fully supported clinically within a community setting if the cough assist machines were to be funded, was discussed by the TPCDG and the requirement of the specialist team to be able to monitor and advise these patients within the in-patient and community setting would be paramount to patient safety.

8. The numbers of patients across the area were acknowledged following information provided by specialist clinical teams as being approximately 20 patients per year per CCG.

**Policy Outcome**

- **Following further internal discussion within the CCG, it was agreed that the Cough Assist Machine Policy would be redrafted with a restricted criteria and set out for review with local specialist respiratory clinicians.**
- **Once agreed the patient leaflet will be redrafted in alignment with the revised policy.**


16. Mayer et al (2017) DMD: Annual Rate of hospitalizations respiratory events on behalf of the Cooperative International Neuromuscular Research Group (CINRG) and the DELOS study group Advances in Pulmonary Care in Duchenne Muscular Dystrophy


https://www.atsjournals.org/doi/full/10.1513/AnnalsATS.201507-475BC#readcube-epdf


http://rc.rcjournal.com/content/54/3/359.short


35. Chatwin


52. Sivasothy P, Brown L, Smith IE, Shneerson JM. Effect of manually assisted cough and mechanical insufflation on cough flow of normal subjects, patients with chronic obstructive pulmonary disease (COPD), and patients with respiratory muscle weakness. Thorax 2001;56(6):438-44


Appendix 2 – Email from Local Respiratory MDT

Thank you for your email. I have actually seen this policy and there are quite a few fundamental points that I do not agree with that I have listed below.

The cough patient information leaflet

'A cough is a reflex action to clear your airways of mucus and irritants such as dust or smoke.
It's rarely a sign of anything serious.'

I would disagree with this statement as cough is one of the key things we look for clinically in the neuromuscular cohort - this statement would refer to someone without an ineffective cough and therefore not requiring a cough augmentation device. I don't feel this is an appropriate statement in the context of MIE.

'A 'dry cough' means it's tickly and doesn't produce any phlegm (thick mucus). A 'chesty cough' means phlegm is produced to help clear your airways. Most coughs clear up within three weeks and don't require any treatment.'

Again this statement is not appropriate or true to the neuromuscular patients. Firstly a dry cough is not always indicative of thick mucus and if a neuromuscular patient were to have thick mucus that would cause significant concern and require immediate action. I'm unsure what the statement 'A chesty cough means phlegm is produced to help clear your airways' means?? Clear airways of what? and are we suggesting phlegm is beneficial? The three week time frame - I would not expect a neuromuscular patient to wait 3 weeks before seeking help and I would also be extremely concerned if their cough were to last for that period of time. They would undoubtedly require antibiotics, clinic review and a chest management plan.

This means (for patients who do not meet the above criteria)

There is no above criteria listed the CCG will ONLY fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Although this is the suggested route by the CCG's these funding requests are all being declined based on the fact that NMD patients are not individuals however we are not being given an alternative route for MIE provision.

Evidence summary report

There are currently some key papers that are missing from the research work, in particular 'Diagnosis and management of Duchenne Muscular Dystrophy, part 2: respiratory, cardiac, bone health and orthopaedic management - Birnkrant et al 2018. They state manual and mechanically assisted coughing should be initiated when FVC is <50% predicted, when PCF is <270l/min or MEP <60cmH20.

Diagnosis and management of spinal muscular atrophy: Part 2: Pulmonary and acute care; medications, supplements and immunisations; other organ systems and ethics. Finkel et al 2018.
When discussing Non Sitters they state that ‘the approach to treating the pulmonary manifestation of SMA has shifted from a reactive approach to a proactive approach’.

‘Manual chest physiotherapy combined with mechanical insufflation-exsufflation should be the primary mode of airway clearance therapy and should be made available for all non sitters’

When discussing sitters they state ‘Manual chest physiotherapy combined with mechanical insufflation-exsufflation should be made available to all patients with an ineffective cough. They should be introduced proactively in patients using either clinical effectiveness of cough or by measuring PCF’

They also briefly refer to the Touissant 2018 paper ‘Airway clearance techniques in neuromuscular disorders: A state of the art review’ in the policy reference list but not in the evidence review document.

Recommendations for MIE in this paper included - 'MIE is the treatment of choice for the weaker group of patients with NMD'. They also state that MIE appears very effective in patients with lower PCFs <160l/min. They also echo the BTS guidelines for Resp care in children with NMW and state. 'MIE should be considered in weak children and those who cannot cooperate with MAC or AS or in whom these methods are not effective'

There is heavy reference to an RCT by Rafiq et al in 2015. I think there are potentially some fundamental flaws within this. Firstly they only looked at ALS patients, these patients have a very different disease progression, presentation and prognosis from the NMD cohort. There were only 40 patients included within the study, so a very small sample size. The patients and investigators were unblinded. I think crucially the MIE group had significantly lower PCF's than the control group using LVR+/or NIV (120l/min vs 215l/min) therefore making it extremely difficult to compare the 2 groups based on the fact that the control group already had PCF deemed likely adequate to clear secretions (>160l/min) before any cough augmentation techniques were introduced v's the MIE group. Also this would lead you to assume that MIE group were likely further along with their disease progression based on their extremely low PCF's therefore again making it difficult to compare the 2 groups. The MIE group also had significant bulbar involvement therefore making it likely MIE would be effective. They also discuss that they aimed to build up to pressures of 40cmH20 with MIE however there is no discussion around actual pressures delivered therefore there is a possibility of ineffective pressures being delivered by MIE making it difficult to accurately assess effectiveness of the device. These points do appear to be acknowledged however they continue to heavily reference this paper.

The clinical opinion of the specialist clinicians involved with these patients appears to be insignificant and does not appear to be being taken in to account within the West Midlands policy. MIE provision for these patients happens all over the country with the same level of evidence base yet there does not appear to be any problems with funding for other areas and the clinicians opinion is respected and listened too. Therefore creating a postcode lottery for West Midlands patients.

This procedure has never been commissioned in the BSOL area and no successful IFR requests have been made since as these were a cohort of patients the requests did not demonstrate sufficient exceptionality

As discussed previously therefore why are the CCG suggesting this route as an option for MIE?
Where a patient's GP feels they would be beneficial an IFR request can be made.

Why is there a suggestion that GP's complete an IFR? The majority of GP's are likely never to have encountered an MIE device. It is unlikely they are able to assess cough strength and know what the most appropriate line of treatment for these patients is. This is a specialist respiratory physiotherapists role alongside the specialist neuromuscular team and only they should be making the decision on whether MIE is required in patients.

The provision of these machines has not been shown to be beneficial to patients (based on clinical evidence).

Based purely on the CCG's evidence review which as discussed above does not include all relevant and recent recommendations, does not include expert opinion in the field and does not take in to account current practice around the rest of the country.
Appendix 3 – Email received from Respiratory Consultant

Thank you for asking me to review the commissioning proposition

I am qualified to given an opinion having set up a 20 bedded ventilatory support / weaning unit at my hospital centre and have authored the specialist commissioning document on home ventilation that includes issues on sputum retention.

This proposal is a major concern for patient care and I cannot support in its current format as I believe it will leave to patient harm. I would add from the literature review that lack of evidence is not lack of effect. Applications through the IFR process would be incorrect, and often denied as use of MIE is not exceptional and in appropriate patients is the norm.

As noted in the literature review, which I will not recap, there are a group of patients for a variety of reasons, eg tracheostomy, neuromuscular disease that are unable to clear their secretions, as best assessed via expert and detailed methods at may include cough peak flow.

While a variety of manual techniques can be used to augment cough, and these should be employed first, there are a significant number of patients who are unable to clear their secretions. As a consequence of this sputum retention patients may experience respiratory distress and troublesome cough, leading to sputum plugging, infections and lobar / lung collapse. This will lead to patient and career distress, hospital admission and potentially premature death.

While MIE does not negate all of these issues, it does reduce some of the above problems. This has been confirmed at both international conferences (international meeting in Lyon 3/18) and recent publications (I can provide if needed) I appreciate the potential for such expensive devices to be handed out without appropriate assessment by staff who are not trained / familiar with the device, so benefit may be limited and expense incurred.

One suggestion may be such devices should only be provided by full assessment in a specialist centre. If there is a need to apply for funding via IFR then not only may it not be available but if approved there will be a delay in obtaining such devices. As a consequence there will be a delay discharging patients, an increased risk of acquiring hospital infection and premature premature death. Moreover patients may not be able to be discharged home and will need to go home but to an institution where regular physiotherapy /cough support using manual techniques are available. Alternatively frequent input from physiotherapists or trained individuals (usually two) will be needed to support patients at home. If they are at home then readmissions for sputum retention / lung collapse / infection will occur, increasing overall cost as well as providing sub-optimal care.

Overall the failure to provide MIE is going to be detrimental to patient care and lead to an increased cost. If a way of reducing spend is to be considered limiting the number of centres / hospitals that can provide such devices may be an alternative option.
Appendix 4 – Letter Received from West Midlands Neuromuscular Network

Re: Birmingham and Solihull CCG & Sandwell and West Birmingham CCG, treatment Policy Harmonisation Programme, Phase 2 – Clinical Engagement Cough Assist Machine

As a team of clinicians working across the West Midlands specialising in patients with neurological and neuromuscular conditions, we write to express our disappointment and frustration at Birmingham and Solihull CCG’s proposed mechanical insufflation-exsufflation (MI-E – Cough Assist machine) policy. The CCG’s current position is that there is a “lack of robust clinical evidence to support the cough assist machine as a clinically effective intervention for this cohort of patients”. This is despite evidence and clinical opinion supporting the use of MI-E for patients with neuromuscular conditions including neuromuscular disease (NMD).

There are multiple flaws in the evidence policy written by Solutions of Public Health in January 2018. Notably, it fails to take into consideration past policies on MI-E which were co-written by respiratory clinicians working with people with muscle-wasting conditions in the West Midlands.

Our key concerns are:

- There appears to be a lack of understanding of the phases of cough and the treatment techniques available. This is demonstrated by the recommendation that Lung Volume Recruitment (LVR) can be utilised instead of an MI-E.
- Cost savings have been identified by suggesting LVR is equal to MI-E. Again, this demonstrates a lack of understanding that LVR can be used in all patient groups. It cannot be used in patients with severe disease progression and reduced bulbar function.
- Item 4.1.1. discusses the results of a randomised control trial (RCT) (Rafiq. et al., 2015) on the use of MI-E to affect survival rates of adults with motor neurone disease (MND). Within this paper there is a clear bias in the randomisation of patients in each cohort, which reduces the credibility of the results. The MI-E group’s patients had ineffective peak cough flow (PCF) values to start and more bulbar dysfunction, indicating a more severe group of patients than the non-MI-E group with higher PCF values and less bulbar dysfunction. As the study looked at survival, the MI-E group baseline was always going to progress more quickly and have poorer survival. However, again this is MND not NMD, and therefore not a reflection on cough effectiveness with MI-E in the NMD population.
- National guidelines such as: MND NICE Guidelines (2016), NHS Neuroscience Service Specification (2013/14), and British Thoracic Society Guidelines (2012), which support the use of MI-E, have been disregarded.
- The evidence review listed studies (Mahede et al 2015, Rafiq et al 2015, and Moran et al 2013) that discussed size concerns and lack of data availability to show compliance. However, machines are now smaller and portable with back-up batteries and capacity for data storage. Morrow et al (2013) also states that appropriate devices should be available.
A recent European Consortium (Toussaint et al 2018) which reviewed expert opinions of treatments and was supportive of MI-E was recorded in your reference list. However neither that, nor the paper by (Toussaint et al 2009), were included in the main document.

Despite the current public engagement process and the discussion of evidence, Birmingham and Solihull CCG is set to decide not to fund MI-E devices. Vital evidence has been ignored and clinical opinion has not been considered. Muscle-wasting conditions are rare and it can be difficult to gather research on efficacy, therefore clinical consensus should be sufficient. It is also the case that provision of these devices is supported by international consensus (Chatwin et al 2018, Toussaint et al 2018, Finkel et al 2017). Furthermore, the review fails to take into account ethical concerns about undertaking a large-scale study on MI-E. For example, the implications of comparing patients who have benefited from this equipment, compared with a group who have been denied it.

We request that you meet with our network’s representatives to discuss the policy Birmingham and Solihull CCG plans to implement. A full reference list identifying the missed evidence has recently been shared with your colleagues for consideration. We urge your organisation to review this evidence and follow the example of other CCGs in the West Midlands by implementing a best-practice policy on the commissioning of MI-E devices. These are the CCGs we are forced to refer our patients to, at a cost to your organisation and to patients who struggle to access this vital treatment.

Thank you for your taking the time to consider this letter.
Appendix 5 – Email submission from Motor Neurone Disease Association

You’re right that there is little clinical evidence pointing towards the efficacy of MI-E devices but the concluding remarks of this paper are worth noting:

https://www.ncbi.nlm.nih.gov/books/NBK367737/

‘There is a consensus that secretion encumbrance resulting from an ineffective cough is a contributor to morbidity and mortality in MND. However, this has not been established in a clinical study.’

Cough assist machines are loaned to XXX patients from XXX. I have liaised with all physio colleagues across this region and bar one, none of them have the competencies to deliver training on manual cough assist techniques. In XXX respiratory physios can deliver this training but they’re not commissioned to see MND patients. The one specialist palliative physio said she does try breath stacking with patients but this is only ever as a short term measure and all patients then move on to cough assist machines. There is a generalised concern that even if they had the competencies to try manual cough assist techniques that they wouldn’t have capacity to do this as these techniques require more time to educate, and then to monitor for efficacy.

There is concern that use of a LVR bag requires dexterity of the patient and carer. It has been commented that breath stacking can be effective in a calm environment, but not useful in a crisis if the patient is anxious, short of breath, or struggling with secretions. All patients comment that the cough assist machine has helped during a crisis, and they have avoided a hospital admission.

It’s well recognised that there is a high degree of carer burden in MND and it has been noted that the cough assist machine reduces some of this burden.

There has been some research completed at XXX which points in favour of the use of a cough assist machine with MND patients but unfortunately it’s not ready for publication so I’m not able to share this.

As you’ll know, MND patients can deteriorate rapidly so need to have prompt access to equipment, so I am guessing that completing an IFR for every patient is going to be burdensome to XXX who provide the machines, and will delay the provision of the equipment.
Appendix 6 – Email submission from Spinal Muscular Atrophy UK.

To the Commissioning Group

Thank you for the information about the NHS Birmingham and Solihull Clinical Commissioning Group: engagement on proposed changes to health policies.

We had a look at your questionnaire but found that it would not give us the opportunity to give the feedback we think necessary, hence this email.

Use of cough assist machines

We have read in your ‘What is coughing?’ advice that ‘due to the lack of robust clinical evidence to support the use of cough assist machines as clinically effective intervention, cough assist machine are not routinely commissioned’ unless patients meet criteria you have listed.

We are concerned to ensure that your criteria include routine funding of cough assist treatment for patients with spinal muscular atrophy who are ‘non-sitters’ or ‘sitters’

The references you have do not appear to include the new 2017 international standards of care for SMA that have been established by an international group of experts. These standards are described in Part 1, page 10 as ‘assessments or interventions that constitute the minimal care that families should expect to find in any neuromuscular centre’.

A summary of these minimal care interventions in terms of pulmonary care is outlined on Part 2, page 3 where you will see that cough insufflator / exsufflator is very clearly a recommended intervention for anyone with SMA who is either a non-sitter or sitter –this includes those with SMA Type 1 or SMA Type 2.

We are concerned that these patients should have routine access to cough assist machines and that this should be explicit. Their consultant should not have to prove exceptional clinical need. We hope that you can reassure us that this clearly routine need will be reflected in your future policy.


2. Richard S. Finkel, et al., Diagnosis and management of spinal muscular atrophy: Part 2: Pulmonary and acute care; medications, supplements and immunizations; other organs systems; and ethics, Neuromuscular Disorders (2017), doi: 10.1016/j.nmd.2017.11.004
Appendix 7 – Email following conversation with Mr XX

- XX explained the Harmonised Treatment Policy process from evidence review to final policy draft, which included the following: Solutions for Public Health (https://www.sph.nhs.uk/) undertaking a clinical evidence review for the use of cough assist machines in late 2017, the evidence review was presented to the Treatment Policy Clinical Development Group and clinicians from the respiratory speciality were invited to attend the meeting and to provide their clinical expertise on the basis of the evidence review and the specialist clinical input, a DRAFT policy was written the DRAFT policy was submitted to the CCG Clinical Priorities Advisory Group, where another public health review was undertaken of the clinical evidence before the draft policy recommendation was made. DRAFT policy released for public and clinical engagement. Further clinical evidence has been submitted by specialist respiratory clinicians. This further clinical evidence has been submitted to SPH for review against the original evidence review. Once the engagement phase has been completed then the new evidence, SPH review and all feedback received will be re-reviewed by the Treatment Policy Clinical Development Group (TPCDG)

- Mr XX advised that it was widely felt within the patient and clinical community that evidence already submitted was being overlooked.

- Mr XX advised that he would like to ensure that CCG’ should consider the following feedback and look to quality his remarks with those with the necessary respiratory expertise:
  - MI-E devices are considered as part of a ‘cough augmentation strategy’ and not necessarily needed. Proactive Respiratory MDT assessments of patient may mean that a person with developing respiratory complications or on a early radar screening and assessment program can have their condition managed through ‘breath stacking’, manual assisted cough techniques and the use of LVR this is BEFORE the need to use a MI-E. The MI-E however may at some stage be the only effective intervention thereafter to clear secretions. This may be as a series of interventions to stabilise and recover an emergency acute episodes or episodes OR depending on the progression of the respiratory complications, MI-E may be then needed as part of an ongoing pathway of care. Too often so far in these discussions my perception is that there appears to me to be a CCG view that these devices are being requested routinely. This is not the case. (Note there are my views having no clinical expertise but significant knowledge of the journey I have taken on this subject.
  - Mr XX advised that he would like the committee to know that he is sure the devices can save lives and that the cost of the machines is far outweighed by the cost of repeated hospital admissions, which he feels could have been avoided.
  - XX confirmed for Mr XX that cough assist machines within the community setting are part of the CCG commissioning responsibility

- Mr XX advised that he would like to ensure that the TPCDG is aware of the parliamentary questions which have been raised regarding cough assist machines Mr XX advised that from his own lay experience and that of fellow patients and family. The cough assist machines are a suitable answer to this defined cohort of patients with respiratory conditions at a stage when all other cough augmentation strategies have been exhausted OR when Peak Cough Flow and other respiratory factors/complications become expert respiratory clinician concerns.

- XX advised that the meeting arranged at Heartlands Hospital 19/06/2018 for respiratory patients and family / friends / carers was from 2-4pm.