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

Clinical Treatment Policies

‘YOU SAID, WE DID’ COUGH ASSIST REPORT

October 2018

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

Background: 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 template below sets out (policy by policy) an overview of the key information received and the decision outcomes agreed by the TPCDG.

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
e. Period of published evidence to be reviewed: Oct 2007-Oct 2017.

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 up 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.**

Appendix 1 – References submitted during the engagement period. May – June 2018.

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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 qualifies 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 he 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.
- There is no acknowledgement of recent literature which recommends the use of MI-E, including: Toussaint et al (2018), Finkel et al (2018), Chatwin (2018), Birnkrant et al (2018), Hov (2017), Stehling (2015), Phillips (2014), Schroth (2009), Chatwin (2003).
- 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, page10 [1] 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[2] 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.

1. Eugenio Mercuri, et al., Diagnosis and management of spinal muscular atrophy: Part 1 Recommendations for diagnosis, rehabilitation, orthopedic and nutritional care. Neuromuscular Disorders (2017), doi: 10.1016/j.nmd.2017.11.005 www.sciencedirect.com/science/article/pii/S0960896617312841?via%3Dihub

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 www.sciencedirect.com/science/article/pii/S0960896617312907?via%3Dihub

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.