Derby and Derbyshire
Clinical Commissioning Group

CLINICAL POLICY ADVISORY GROUP (CPAG)

Mechanical Insufflation-exsufflation Policy

Statement

There is currently insufficient evidence to support the use of Mechanical Insufflation-exsufflation (MI-E) for patients with neuron muscular dystrophy (NMD) or spinal cord problems. Derby and Derbyshire CCG therefore do not routinely fund MI-E.

Guidance from a range of professional bodies has supported its use, based on low quality evidence or expert opinion. Further research is needed to establish the effects relating to reducing infections, safety, its use in the longer term and its cost effectiveness. Some of this has started to be addressed at a national and international level but will take some time to be available.

There may be exceptional circumstances where a clinician can demonstrate that a patient can derive significantly greater benefit from the technology than other patients. In these circumstances please read the Individual Funding Request (IFR) policy and complete the relevant form.

This policy statement applies to both children and adults.

1. Background

Patients for a wide variety of reasons are unable to cough or clear airway secretions effectively due to reduced peak cough flow. A number of techniques (e.g. glossopharyngeal breathing and manual assisted cough) are currently available to assist patients with an ineffective cough. MI-E devices can help patients to mobilise and clear bronchial secretions, providing an alternative to suctioning with decreased mucosal trauma and increased patient comfort. MI-E would extend the current pathway for treatment of patients with an ineffective cough, providing another option for attempting to achieve an effective cough in patients for whom existing cough augmentation techniques are unsuccessful.

2. Rationale for Recommendation

In 2013 a Cochrane Systematic Review of the effectiveness of MI-E for clearing airway secretions in people with NMD identified limited evidence to support the routine use of MI-E in clinical practice (Morrow et al. 3012). At that time, the only research available was low quality, short-term trials of less than 2 days, which measured the immediate (e.g. peak cough flow) rather than longer-term effects (e.g. hospital admissions, length of stay) of the device. The review did not clearly show that MI-E improves cough expiratory flow more than other cough augmentation techniques.

Since 2013, a number of small studies have examined the impact of MI-E on a range of outcomes in children and adults. Table 1 (see Appendix 4) presents a summary of this research. The evidence base to support the use of MI-E for preventing hospital admissions, reducing length of stay and reducing community antibiotic prescribing remains of low quality. Most of the findings reported are non-significant, although this may in part be due to small sample sizes. However, even slightly larger studies report non-significant findings. The exception is one study that found a significant decrease in Emergency Department (ED) presentations for patients with MI-E (Mahede et al. 2015). However, the study also noted that due to missing ED data it was not known whether all of the ED presentations were respiratory related. Research suggests that there are perceived physical, social and emotional benefits of MI-E, including that it provides peace of mind and reassurance. There are no reported adverse events.

One of the challenges of research on the effectiveness of MI-E is the absence of a control group of patients with whom to compare outcomes. MI-E is used to support patients with degenerative conditions who might be expected to experience an increase in hospital admissions over time. The studies in Table 1 mostly compare hospital admissions etc. before and after MI-E use in the same patients; however, it is plausible that MI-E prevents an escalation in the number of hospital admissions. Without a control group to compare changes in admissions over time between patients with and without the machine, any effect will be harder to identify.

Whilst the current scientific evidence does not support the use of MI-E for cough

augmentation in patients with neuromuscular diseases, health-care professionals are faced with the reality of medical practice and the absence of alternatives. Many European and American guidelines recommend the use of MI-E despite low-level evidence of effectiveness (Morrow et al. 2013; Auger et al. 2017). See Appendix 3 for some of the guidelines that recommend use of MI-E.

To date there is no published cost-effectiveness data for the use of MI-E.

3. References

British Thoracic Society. (2009) Concise BTS/ACPRC guidelines Physiotherapy management of the adult, medical, spontaneously breathing patient. Available at: https://www.brit-thoracic.org.uk/document-library/clinical-information/physiotherapy/physiotherapy-guidelines/physiotherapy-concise-guideline/.

Cookson, R. McCabe, C. Tsuchiya, A. (2008) Public Healthcare Resource Allocation and the Rule of Rescue. *Journal of Medical Ethics*; 34(7).

Kim, S. Choi, W. Won, Y. Kang, S. (2016) A Comparison of Cough Assistance Techniques in Patients with Respiratory Muscle Weakness. *Yonsei Medical Journal*; 57(6).

Lacombe, M. Castrillo, L. Boré, A. et al. (2014) Comparison of Three Cough-Augmentation Techniques in Neuromuscular Patients: Mechanical Insufflation Combined with Manually Assisted Cough, Insufflation-Exsufflation Alone and Insufflation-Exsufflation Combined with Manually Assisted Cough. *Respiration;* 88: 215-222.

Mahede, T. Davis, G. Rutkay, A. et al. (2015) Use of mechanical airway clearance devices in the home by people with neuromuscular disorders: effects on health service use and lifestyle benefits. *Orphanet Journal of Rare Diseases*; 10(54).

Moran, F. Spittle, A. Delany, C. et al. (2013) Effect of home mechanical in-exsufflation on hospitalisation and life-style in neuromuscular disease: A pilot study. *Journal of Paediatrics and Child Health;* 49: 233-237.

Morrow, B. Zampoli, M. van Aswegen, H. Argent, A. (2013) Mechanical insufflation-exsufflation for people with neuromuscular disorders. *Cochrance Database of Systematic Reviews*; 12:CD010044.

Moses, R. (2015) The use of MI-E as a cost effective admission avoidance strategy for patients with advanced multiple sclerosis. *Physiotherapy*; 101(S1).

NICE (2016) Assessing and managing respiratory function in motor neurone disease. Available at: https://pathways.nice.org.uk/pathways/motor-neurone-disease/assessing-and-managing- respiratory-function-in-motor-neurone-disease

NICE (2016) Motor neurone disease: assessment and management. Available at: https://www.nice.org.uk/guidance/ng42/resources/motor-neurone-disease-assessment-and- management-1837449470149.

North Derbyshire CCG (2014) Policy Statement for the Commissioning of Mechanical Insufflation / Exsufflation – MI-E (Cough Assist Device) for Neuromuscular Disorders and Cervical Spinal Cord Injury Patients. Available at: http://www.northderbyshireccg.nhs.uk/assets/Clinical Guidelines /August 2016/Neuromuscular Weakness Cough Assist PolicyFinal.docx

Phillips, R. Edwards, E. McNamara, D. Reed, P. (2017) Does use of the Cough Assist Machine reduce respiratory morbidity for children with neuromuscular disease? *New Zealand Journal of Physiotherapy;* 42(3).

Rafiq, M. Proctor, R. McDermott, C. Shaw, P. (2017) Respiratory management of motor

neurone disease: a review of current practice and new developments. *Practical Neurology*; 12: 166- 176.

Travlos, V. Drew, K. Patman, S. (2016) The value of the CoughAssist® in the daily lives of children with neuromuscular disorders: Experiences of families, children and physiotherapists. *Developmental Neurorehabilitation*; 19(5).

4. Appendices

Appendix 1- Consultation

Consultee	Date
Public Health Input– Consultant in Public Health and Public Health Specialty Registrar	March and April 2017
Derbyshire Affiliated Commissioning Committee	April and May 2017
Clinical engagement – Adult Respiratory Team	5th April 2017
Clinical engagement – Specialist Physiotherapist UHDBFT	17th May 2019
Clinical engagement – Paediatric Consultant with respiratory interest UHDB	19th June 2019
Clinical engagement – Clinical Specialist Physiotherapist NUH	19th June 2019
Clinical Policies Advisory Group	20th June 2019
Clinical and Lay Commissioning Committee	11th July 2019
Discharge Co-ordinator, Specialist Spinal Injury Centre, Sheffield Teaching Hospital.	15th July 2019
Specialised Commissioning Pharmacist, Sheffield CCG	June-July 2019
Clinical Team Leader, Continuing Healthcare	15th July 2019

Appendix 2- Document Update

Document Update	Date Updated
First produced –Version 1	June 2017
Updated format and wording to reflect new organization –version 2	June 2019

Appendix 3– Guidelines that Recommend Use of MI-E

British Thoracic Society, Guidelines for respiratory management of children with

neuromuscular weakness, *Thorax* 2012; 67: i1-i40. Available at: https://www.brit-thoracic.org.uk

BTS/ACPRC: Joint guidelines for the Physiotherapy management of the adult, medical, spontaneously breathing patient, *Thorax* 2009; 64: i1-i52. Available at: http://thorax.bmj.com/content/64/Suppl_1/i1.full

Ching H. Wang, Richard S. Finkel, Enrico S. Bertini, Mary Schroth, Anita Simonds, Brenda Wong, Annie Aloysius, Consensus Statement for Standard of Care in Spinal Muscular Atrophy *J Child Neurol* 2007; 22; 1027.

NHS England's Service Specification for Neurosciences: Specialised Neurology (Adult). Available at: https://www.england.nhs.uk/commissioning/spec-services/npc-crg/group-d/d04/

NICE guidelines for NMD 2016 (1.13.4) suggest considering a mechanical cough assist device if assisted breath stacking is not effective, and/or during a respiratory tract infection, or for any patient who is unable to increase peak cough flow < 160L/min with other strategies. Available at: https://www.nice.org.uk/guidance/NG42/chapter/Recommendations#cough-effectiveness

Appendix 4 – Summary of Research Evidence

Table 1: Summary of research evidence published since Morrow et al. 2013

Author & Date	Study Size	Study Design	Inclusion	Outcomes Measured	Results
Moran et al. 2013	7	Retrospective (non-randomised) before and after study. Australia.	Children with NMD using MI-E at home, with at least 6 months of hospital data pre-intervention.	Hospital records used for number of admissions, length of stay (LOS) and hours of ventilation. Parental survey of impact of MI-E on lifestyle for child and family.	N.S. effect on presentations or admissions. May have slight impact on length of stay at 6 and 12 months (but interpret with caution due to moderate p values and multiple testing). No complications reported.
Travlos et al. 2014	9	Qualitative. Australia.	Children in care of a specialist neuromuscular service regularly using MI-E at home.	Experiences of regular MI-E use. Perceptions of value as adjunct to daily home respiratory management.	Perceived physical, social and emotional benefits of MI-E. Poor adherence a barrier to effective use: issues were child's resistance, treatment preference, time constraints, practitioner support, fear of pressure trauma.
Mahede et al. 2015	37	Non-randomised before and after study. Australia.	NMD patients	ED presentations, hospital separations and LOS.	Machine provided reassurance and peace of mind. Not all patients used it regularly. N.S. impact on LOS or admissions. Not using device associated with significant increase in ED presentations (1.76; 95%CI 1.10-2.84).
Kim et al. 2016	40	Randomised crossover trial. South Korea.	Patients with stable NMD.	Peak cough flow.	MIE improves peak cough flow compared to manual thrust alone.
Phillips et al. 2017	6	Retrospective (non-randomised) before and after study. New Zealand.	NMD & significant respiratory morbidity	Hospital admissions, lung function, community antibiotic prescriptions and chest radiology reports for 2 years before and after MI-E initiation.	General trend towards fewer days hospitalised for respiratory infections and reduced community antibiotic prescribing, but all results N.S. No adverse events reported.