NICE advice

The Vest for delivering high-frequency chest wall oscillation in people with complex neurological needs

Medtech innovation briefing
Published: 14 September 2018
nice.org.uk/guidance/mib159

Summary

- The **technology** described in this briefing is The Vest. It is intended to deliver high-frequency chest wall oscillation for clearing airways. The focus of this briefing is its use in adults and children with complex neurological needs, such as cerebral palsy and motor neurone disease (also known as amyotrophic lateral sclerosis).
- The **innovative aspects** are that it delivers therapy in a more standardised and consistent way compared with manual therapy.
- The intended **place in therapy** would be as an alternative to chest wall percussion – a manual airway clearance technique used as part of chest wall physiotherapy by respiratory physiotherapists or trained carers.
- The **main points from the evidence** summarised in this briefing are from 5 US studies: 4 in cerebral palsy (including 54 people) and 1 in motor neurone disease (including 36 people). All studies in cerebral palsy showed that The Vest reduced the number of hospital admissions, but the reduction was not significant. The study in motor neurone disease showed that The Vest significantly reduced the number of infections.
- **Key uncertainties** around the evidence are that it is limited in quality and quantity. A randomised controlled trial with relevant outcomes comparing The Vest with manual airway

clearance techniques in an NHS pathway would improve the evidence base. Also, there is no established place in therapy for high-frequency chest wall oscillation in this patient group.

- The **cost** of The Vest is £6,995 per unit (excluding VAT). The **resource impact** would be greater than standard care but costs might be offset by reducing the number of hospital admissions.

The technology

The Vest (Hill-Rom) is an airway clearance system that delivers high-frequency chest wall oscillation (HFCWO). An air-pulse generator rapidly inflates and deflates a garment (available in different styles and sizes), which gently compresses and releases the chest wall. This action is designed to mobilise mucus from smaller to larger airways, which can then be coughed up or removed by suction.

The Vest has 3 programmes with different combinations of frequency, pressure and treatment time. A treatment session usually takes 10 to 30 minutes. The system can be used by the person having treatment, but people who are immobile may need help from a carer. Specialist commentators noted that The Vest and manual techniques should not be used until at least 1 hour after the person having treatment has eaten.

If The Vest were adopted, it would replace chest wall percussion, which is physically demanding and time-consuming for the carer.

The Vest is contraindicated in people with a head or neck injury that has not been stabilised or in people with an active haemorrhage with haemodynamic instability. It should be used with caution in some people, as described in the company's instructions for use; this includes people with rib fractures or people with osteomyelitis of the ribs.

Innovations

The company claims The Vest is unique from other manual airway clearance therapy because it delivers a standardised therapy in a consistent way.

Current care pathway

There are no published guidelines on airway clearance in people with complex neurological needs. Specialist commentators confirmed that they are usually referred to community respiratory physiotherapy teams. Chest wall physiotherapy is the standard treatment for managing airway clearance and involves manual techniques aimed at clearing the lungs by percussion (clapping),

vibration, deep breathing and huffing or coughing. Community respiratory physiotherapy teams train carers to do chest wall percussion. A typical session takes about 30 minutes but can range from 10 to 60 minutes. People will usually need 2 to 4 sessions a day, but if they have a respiratory infection they may need up to 6 sessions. There are other complementary treatments used to help with airway clearance including cough assist devices, suction devices and nebulisers. People who have repeat respiratory infections or recurrent or prolonged hospital admissions may be offered treatment with The Vest.

Population, setting and intended user

People with complex neurological needs and airway clearance problems usually have their care managed by a community respiratory physiotherapy team, but their day-to-day needs are typically met by carers. Specialist respiratory physiotherapy teams, where these exist, would need to train users or carers in how to use The Vest, and design specific respiratory care plans. The Vest would most likely be used in a person's home to replace chest wall percussion done by respiratory physiotherapists or trained carers. The Vest should only be considered on the recommendation of an experienced respiratory physiotherapist.

Costs

Technology costs

The list price of The Vest is £6,995 per device, excluding VAT; volume discounts may apply. The air-pulse generator has an expected lifespan of between 5 and 10 years. The inflatable garments come in various styles and sizes and need to be replaced about every 2 to 4 years (garment prices range from £275 to £295). An estimated annual cost for treatment with The Vest is £817.50 (based on 10 years of use with 4 garment replacements) to £1,517 (based on 5 years of use with 2 garment replacements) per person. The company claims that The Vest does not need routine maintenance.

Costs of standard care

The company states that chest wall physiotherapy is usually done by carers so there is no ongoing cost to the NHS. However, there are costs associated with specialist training of carers to use The Vest. One specialist commentator said that in their service, it takes 3 sessions to train a carer. Repeated training sessions and monitoring of the effectiveness of the therapy may also be needed.

Resource consequences

The Vest would represent an additional cost compared with standard care; the subsequent resource consequences are uncertain and depend on the patient group in which it is used, and the configuration and availability of local specialist physiotherapy services. The additional costs might be offset if using The Vest resulted in fewer respiratory complications needing treatment or admission to hospital. There is no published economic evidence to judge this.

People with complex neurological needs and their carers would usually have 1 or 2 training sessions at their home on how to use the technology and 1 or 2 follow-up calls to make sure treatment is being delivered correctly. Training and follow-up calls would be done by the community respiratory physiotherapy team or specialist centre if community teams do not offer this; they would have had training from the company. The company offers training at no additional cost using a 'train-the-trainer' approach. The Vest is usually used for 6 weeks on a trial basis before a decision is made on longer-term treatment.

The company has stated that The Vest is currently being used in at least 36 NHS organisations across the UK. Specialist commentators have said that where The Vest is funded by the NHS, it is usually through an individual funding request.

Several specialists commented that The Vest is being used infrequently in NHS clinical practice but 1 stated that it is being used in children with complex neurological needs who have frequent chest infections or hospital admissions.

Regulatory information

The Vest was CE marked as a class IIa medical device in 2005.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

The prevalence of cerebral palsy is higher in males than females.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

Five studies are summarised in this briefing: 1 pilot randomised controlled trial, 1 retrospective review and 2 before-and-after studies involving 54 people with cerebral palsy in the US. Three of the studies were in children, 1 study included adults and children. An additional before-and-after study in the US included 36 people with motor neurone disease.

Table 1 summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

The evidence for the effectiveness of The Vest for airway clearance in people with complex neurological needs is limited in quality and quantity. Two of the studies were reported as abstracts only so there was limited reporting of their methods and results. All the studies recruited a small number of people and were done in the US, limiting their relevance to the NHS care pathway. Only 1 study included adults, but it is not reported how many. The total study sample size was 7 so the number of adults is likely to be small so there is very limited evidence to support the effectiveness of using The Vest in adults.

Specialist commentators suggested that relevant outcomes to show the clinical effectiveness of The Vest would include the number of hospital admissions, antibiotic use, the number of chest infections and lung function. In people with cerebral palsy, 4 studies showed non-significant reductions in the number of hospital admissions after using The Vest. In 2 studies, there was reduced antibiotic use and a reduced number of chest infections (only 1 study showed a significant reduction in infections). Only 1 study reported oxygen saturation as an outcome. In people with amyotrophic lateral sclerosis, there was a significant reduction in the number of infections.

One specialist commentator suggested that The Vest needs to be used for 6 to 12 months before patient benefit can be clearly shown. In people with cerebral palsy, the duration of treatment was

12 months in 2 of the studies, and in 1 study it was at least 6 months. In the randomised controlled trial (Yuan et al. 2010), it was only 5 months. In the motor neurone disease study, the duration of treatment is not reported.

There is only 1 study which compared The Vest with chest wall physiotherapy; the other studies did not have a comparator. A large study comparing The Vest with chest wall percussion in adults and children with a range of complex neurological needs in a UK setting would give more robust evidence for its effectiveness.

Table 1 Summary of selected studies

Yuan et al. (2010)	
Study size, design and location	Single-site, prospective pilot randomised controlled trial of 23 children with ND (n=14) and CP (n= 9) in the US.
Intervention and comparator(s)	Intervention: HFCWO using The Vest (n=11; CP=4, ND=7). Comparator: standard chest physiotherapy (n=12; CP=5, ND=7).
Key outcomes	There was a trend in the chest physiotherapy group for more hospital admissions and antibiotics for pulmonary infection but there was no statistically significant difference between groups. There was a statistically significant difference in maximum saturation level of oxygen in haemoglobin after therapy in the HFCWO group (p=0.01) but no difference in the overnight saturation levels. The post-therapy apnoea-hypopnoea index was lower in the chest physiotherapy group (median 4.9; IQR 1.8, 77.65) compared to the HFCWO group (median 11.2; IQR 6.58, 39.0) but the difference was not statistically significant. There were no therapy-related adverse events in either group.

Strengths and limitations	28 children were enrolled but 5 withdrew after randomisation (2 with ND and 3 with CP). All had been randomised to HFCWO. This is a small pilot study that was not powered to show significance for any primary outcome. It is not reported which HFCWO device was used but the company has confirmed that it was The Vest. The study was partly funded by a grant from the company. The study included children with CP and children with ND but the study does not report the results separately; both subgroups have been combined. Specialist commentators advised that the comparator 'standard chest physiotherapy' as described in this study as '2 minutes in each of 6 positions' would not be considered standard UK chest physiotherapy practice. The mean treatment duration with The Vest was only 5 months.
Overgaard and Radford (2005)	
Study size, design and location	A retrospective review of 13 children with CP in the US.
Intervention and comparator(s)	Intervention: HFCWO using The Vest. No comparator.
Key outcomes	There were fewer hospital admissions while using HFCWO compared to 1 year before using HFCWO (8 versus 5) and fewer emergency room visits (5 versus 1). Parents reported fewer respiratory illnesses and reduced antibiotic use after treatment. 9 parents reported improvement in their child's health and quality of life after treatment.
Strengths and limitations	This is a small retrospective study with no comparator. It is not reported which HFCWO device was used but the company has confirmed that it was The Vest. The study is reported as an abstract only with minimal reporting of the methods and results. Parent recall was used as a measure for respiratory illness, antibiotic use and missed school days, which could be at risk of recall bias.
Fitzgerald (2010)	

Study size, design and location	A before-and-after study of 6 children with tracheostomy and muscle weakness related to CP or genetic syndromes in the US.
Intervention and comparator(s)	Intervention: HFCWO using The Vest. No comparator.
Key outcomes	There was a non-significant trend in the reduction of hospital days while using HFCWO compared to before using it (1.83±1.94 versus 0.50±0.80, p=0.082).
Strengths and limitations	The study is reported as a poster presentation only with minimal reporting of the methods and results. Only 6 children were included in the study. 4/6 children used an additional device to help them cough.
Plioplys et al. (2002)	
Study size, design and location	A before-and-after study of 12 people with quadriplegic CP at 2 nursing facilities in the US.
Intervention and comparator(s)	Intervention: HFCWO using The Vest. No comparator.
Key outcomes	There was a significant reduction in pneumonia after treatment with HFCWO (18 versus 36, p=0.026) and fewer hospital admissions caused by pneumonia (3 versus 9) but this was not statistically significant (p=0.16). The added score of effective suctioning increased from 4,825 to 10,445 after treatment (p=0.008).
Strengths and limitations	The study included children and adults (age range 7 to 28 years) but it was a very small sample size (n=7) and a breakdown of the numbers of children and adults is not given. All had severe quadriplegic CP and were fed by gastrostomy tube so this was a severely unwell patient population. Patients from 2 different nursing facilities were included so there may be a difference in the treatment they had. Patients were also having manual chest physiotherapy and postural drainage programmes before and during treatment. The authors have reported there were differences in how these were delivered.
Brooks et al. (2011)	

Study size, design and location	A before-and-after observational study of 36 people with MND in the US.
Intervention and comparator(s)	Intervention: HFCWO using The Vest. Comparator: no comparator.
Key outcomes	Before HFCWO using The Vest people with MND had 0.07±0.13 infections/ month and after it reduced to 0.02±0.06 infections/ month (t test p=0.0638; Wilcoxon ranked test p=0.0415).
Strengths and limitations	The study is only available as an abstract so there is limited reporting of the methods and results.
Abbreviations: CP, cerebral palsy; HFCWO, high-frequency chest wall oscillation; IQR, interquartile range; MND, motor neurone disease; ND, neuromuscular disease.	

Recent and ongoing studies

No relevant ongoing or in-development trials were identified.

The company stated that it was aware of 3 centres that are currently collecting data and intend to publish within the next 12 months.

Specialist commentator comments

Comments on this technology were invited from clinical specialists working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

All 10 specialists were familiar with this technology and 9 had used or were currently using it in adults or children with complex neurological needs, neuromuscular disease, motor neurone disease or cystic fibrosis.

Level of innovation

Seven specialists noted that The Vest was the only device for high-frequency chest wall oscillation (HFCWO) available in the UK. Three specialists said that it was innovative because it standardised treatment (force, rate, time). One specialist explained there is always human variation with manual

techniques. One specialist stated that devices such as The Vest were not new but that there has been very little reporting on their use in the UK.

Potential patient impact

Four specialists thought that using The Vest would give users more autonomy. They would not need to be as dependent on their carers or on clinicians. Two specialists thought that using The Vest may improve quality of life. Three noted that The Vest would offer a more standardised therapy than manual therapy.

Two specialists stated that The Vest can be administered sitting upright or lying down, which can reduce disruption and physical burden for both patients and carers, particularly if the patient is physically impaired or immobile.

One specialist noted that chest wall oscillation can be done at a higher frequency and for a longer time than a carer can do manual percussion. A specialist noted that the frequency of sessions might be reduced if The Vest is more effective.

One specialist said that The Vest may not be suitable in people with osteoarthritis or others who are at risk of fractures, in people who have spinal deformities or pressure damage, and it may have an effect on pacemakers or other monitoring devices. Another specialist commented that the risk compared with the benefit should be considered before starting treatment with The Vest for people with rib fractures, poor bone density or surgical sites or lines that would be affected by the position of The Vest on the chest wall.

One specialist highlighted that HFCWO is a technique to help mobilisation of secretions and still needs an effective cough to clear secretions. If a person has an ineffective cough effort, The Vest would have to be used with assisted cough techniques and suction to clear the secretions.

The specialists identified specific patient populations needing airway clearance who could benefit from The Vest:

- People who are physically impaired or immobile, for example, people who may need to be lifted onto a bed for manual airway clearance.
- People with learning disabilities who are unable to follow instructions for other chest clearance strategies.
- People with low bone density in whom manual airway clearance techniques are unsuitable.

- People who have not had successful airway clearance despite treatment, particularly those with frequent hospital admissions because of chest infections.

Potential system impact

One specialist who has used The Vest in children with complex neurological needs stated that it led to reduced chest infections in children who were frequently admitted to hospital for up to 2 weeks. This resulted in reduced antibiotic use, fewer hospital admissions and shortened length of stay, less invasive suctioning and less time off from school.

Several specialists thought that using The Vest could potentially lead to fewer chest infections or other respiratory illness, reduced antibiotic use and fewer hospital admissions. If it did lead to these reductions, then it would likely be cost saving to the NHS. One specialist said that The Vest could pay for itself if it prevented 1 hospital admission. Three other specialists stated that adopting The Vest is likely to lead to reduced overall costs but there would be a higher upfront cost to the NHS than current treatment. Three specialists stated that there was not currently enough published evidence comparing The Vest with chest wall physiotherapy to support any claims of system benefit.

Two specialists advised that it was easier to train carers in the use of The Vest than to train them to do manual chest wall physiotherapy techniques.

One specialist noted that it would be helpful to have another option for airway clearance available for people that had exhausted all other options.

General comments

One specialist noted that it can be difficult to get approval for funding of The Vest and that if further studies were done in the UK, an improved evidence base would help support future applications. One specialist advised that there is no locking mechanism on The Vest to prevent the settings from being adjusted accidentally.

Patient comments

The carers of 3 children (aged 7, 11 and 13) with complex neurological needs who have been using The Vest 2 to 3 times a day for more than a year gave feedback on their experiences. Two carers commented that it was easy to use. When they do chest wall percussion, they are not always sure they are doing it correctly; using The Vest gave them greater confidence. Carers stated 2 children

experienced fewer chest infections and 1 needed fewer antibiotics. Two also had fewer hospital admissions.

Specialist commentators

The following clinicians contributed to this briefing:

- Ms Caroline Adcock, physiotherapist, Nottinghamshire Healthcare Trust. Did not declare any interests.
- Ms Wendy Browne, principal physiotherapist (paediatric respiratory), Birmingham Women's and Children's NHS Foundation Trust. Did not declare any interests.
- Ms Alexandra Christie, respiratory physiotherapist, Berkshire Healthcare NHS Foundation Trust. Did not declare any interests.
- Mr Gareth Cornell, clinical specialist physiotherapist critical care, Sheffield Teaching Hospitals NHS Foundation Trust. Currently holds a committee position with the Association of Chartered Physiotherapists in Respiratory Care (ACPRC). Hill-Rom have provided corporate sponsorship to ACPRC educational events in the past and may also in the future.
- Mr Matthew Cox, extended scope respiratory physiotherapist, Sheffield Teaching Hospital NHS Foundation Trust. Did not declare any interests.
- Ms Hannah Langman, clinical specialist physiotherapist, Manchester University NHS Foundation Trust. Did not declare any interests.
- Ms Lisa Morrison, principal physiotherapist, Queen Elizabeth University Hospital. Did not declare any interests.
- Mrs Penelope Wilcox, highly specialised paediatric physiotherapist, The Royal London Hospital. Did not declare any interests.
- Professor Mike Morgan, consultant respiratory physician, University Hospitals of Leicester NHS Trust. Did not declare any interests.
- Dr Andrew Bentley, consultant in intensive care and respiratory medicine, clinical lead for North West Ventilation Unit, Manchester University NHS Foundation Trust. Did not declare any interests.

Development of this briefing

This briefing was developed for NICE. The interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

ISBN: 978-1-4731-3010-4