NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology consultation document

Mepilex Border Heel and Sacrum dressings for preventing pressure ulcers

The National Institute for Health and Care Excellence (NICE) is producing guidance on using Mepilex Border Heel and Sacrum dressings for preventing pressure ulcers in the NHS in England. The medical technologies advisory committee has considered the evidence submitted by the company and the views of expert advisers.

This document has been prepared for public consultation. It summarises the evidence and views that have been considered, and sets out the recommendations made by the committee. NICE invites comments from the public. This document should be read along with the evidence (see the committee papers).

The advisory committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and resource savings reasonable interpretations of the evidence?
- Are the recommendations sound and a suitable basis for guidance to the NHS?
- Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?

Note that this document is not NICE's final guidance on Mepilex Border Heel and Sacrum dressings for preventing pressure ulcers. The recommendations in section 1 may change after consultation.

After consultation the committee will meet again to consider the evidence, this document and comments from the public consultation. After considering the comments, the committee will prepare its final recommendations which will be the basis for NICE's guidance on the use of the technology in the NHS in England. For further details, see the medical technologies evaluation programme process and methods guides.

The key dates for this guidance topic are:

Closing date for comments: 24 August 2018

Second committee meeting: 21 September 2018

Details of the advisory committee are given in section 5.

NICE medical technologies guidance addresses specific technologies notified to NICE by companies. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This case is reviewed against the evidence submitted and expert advice.

If the case for adopting the technology is supported, the specific recommendations are not intended to limit use of other relevant technologies that may offer similar advantages. If the technology is recommended for use in research, the recommendations are not intended to preclude the use of the technology in the NHS but to identify further evidence which, after evaluation, could support a recommendation for wider adoption.

1 Recommendations

1.1 Mepilex Border Heel and Sacrum dressings show promise for preventing pressure ulcers in people who are considered to be at risk in acute care settings. However, there is currently insufficient evidence to support the case for routine adoption in the NHS.

1.2 Research is recommended to address uncertainties about the claimed benefits of using Mepilex Border Heel and Sacrum dressings. This research should also explore the incidence of sacrum and heel pressure ulcers in NHS acute care settings, and the outcomes from using Mepilex Border Heel and Sacrum dressings in addition to standard care.

Why the committee made these recommendations

Standard care to prevent pressure ulcers in acute care settings includes risk assessment, skin assessment, regular repositioning and the use of special devices.

Pressure ulcers are most common on the heel and sacrum. Mepilex Border Heel and Mepilex Border Sacrum dressings are designed to prevent pressure ulcers in these areas by reducing pressure, friction, shear and humidity.

There is limited evidence for the clinical effectiveness of Mepilex Border Heel dressings. Evidence from clinical trials suggest that that Mepilex Border Sacrum dressings may reduce the incidence of pressure ulcers but there is still uncertainty. Also, it is not clear if the results are generalisable to patients in NHS acute care settings. Because of the uncertainty in the clinical evidence, the estimates of cost saving are very uncertain. Therefore further research is recommended to address the uncertainties in the clinical and cost evidence.

2 The technology

Mepilex Border Heel and Mepilex Border Sacrum dressings (Mölnlycke Health Care)	
Overview	Mepilex Border dressings are self-adherent, 5-layer foam dressings that include a patented soft silicone technology (known as Safetac). They are intended for use as part of a care bundle to prevent pressure ulcers in patients in an acute care setting that are at risk of developing pressure ulcers. The current standard of care, and relevant comparators, are described by the NICE pressure ulcer pathway. The company claims that the dressings reduce shear and friction, displace pressure and create an environment that encourages healing. Mepilex Border dressings are available in 3 variants: for use on the heel and sacrum (Mepilex Border Heel and Mepilex Border Sacrum), or as standard dressings (Mepilex Border) for use on any part of the body. This guidance specifically considers the variants designed to prevent pressure ulcers of the heel and sacrum (Mepilex Border Heel and Mepilex Border Sacrum).
Innovative aspects	The proprietary Safetac technology allows the dressings to be easily removed and reapplied. The dressings also have a non-woven redistribution layer designed to lessen the effect of shear forces.
Costs	The costs stated in the company's submission are £6.47 to £7.21 for Mepilex Border Heel and £3.06 to £7.26 for Mepilex Border Sacrum, depending on size.
For more details, see the website for Mepilex Border Heel and Sacrum dressings.	

3 Evidence

Clinical evidence

Relevant evidence comes from 13 studies, 4 of which are randomised controlled trials

3.1 Of the studies that met the inclusion criteria defined in the scope, 4 were randomised controlled trials (n=1,344) and 9 were non-randomised comparative observational studies (n=1,767). The 4 randomised controlled trials were based on the prevention of sacral pressure ulcers in

adults, and none was done in the UK. For full details of the clinical evidence, see section 3 of the assessment report.

Results of the randomised controlled trials are mixed

3.2 The 4 randomised controlled trials (Aloweni et al. 2017, Kalowes et al. 2016, Santamaria et al. 2015a and Walker et al. 2017) compared Mepilex Border Sacrum with standard care in adults at risk of developing pressure ulcers in an intensive care unit in Singapore, USA and Australia. The external assessment centre (EAC) considered these studies to have acceptable internal and external validity and to provide relevant evidence for the use of Mepilex Border Sacrum. Pooled treatment effect estimates from the fixed-effect meta-analysis of the 3 studies that reported pressure ulcer incidence rates as the number of patients with a pressure ulcer, showed a non-statistically significant relative risk in favour of Mepilex Border Sacrum (RR 0.51, 95% confidence interval [CI] 0.22 to 1.18; p=0.12). Based on the assumption of 1 pressure ulcer per patient in the Santamaria (2015a) study, pooled treatment effect estimates from a fixed-effect meta-analysis of the 4 studies showed a statistically significant relative risk in favour of Mepilex Border Sacrum (RR 0.42, 95% CI 0.20 to 0.86; p=0.02). However, a random-effect meta-analysis of the 4 studies showed a non-statistically significant relative risk with Mepilex Border Sacrum (RR 0.45, 95% CI 0.20 to 1.04; p=0.06).

Evidence from most observational studies is low quality and less relevant

3.3 The EAC considered 3 of the 9 observational studies (Park 2014, Richard-Denis et al. 2017a and Santamaria et al. 2015b) to have acceptable levels of both internal and external validity. However, the observational studies overall had lower internal and external validity compared with the randomised controlled trials, because of unacceptable cohort recruitment, inconsistencies in describing procedures and measurements, and unclear presentation and precision of results. Because of this, the EAC concluded that the evidence from the 9 observational studies was less relevant to the decision problem.

There is less evidence for Mepilex Border Heel

3.4 The EAC noted that the clinical effectiveness of Mepilex Border Heel is uncertain because of the limited comparative evidence. Only 2 observational studies assessing the heel dressing were identified (Haisley et al. 2015 and Santamaria et al. 2015b), and only the Santamaria study had acceptable levels of internal and external validity. This study (n=412) showed a statistically significant difference in the proportion of patients who developed a pressure ulcer, in favour of Mepilex Border Heel (p=<0.001).

Cost evidence

The structure of the model is adequate for decision making

3.5 The company's cost model included only patients at high risk of pressure ulcers from Santamaria (2015a). The time horizon was less than 1 year. The model was a single-level decision tree comprising health states for 2 possible outcomes, specifically whether or not a patient develops a pressure ulcer. The model assumed that:

- standard care and reductions in pressure ulcer incidence rates are generalizable from the Australian RCTs to NHS practice
- the cost of pressure ulcer management in the UK is known and that the estimates are reliable
- the costs of implementation and managing adverse events are negligible
- the treatment effect is comparable across different types of Mepilex Border dressing.

The EAC agreed that the structure of the model accurately depicts the patient pathway and any possible changes that may result from the use of Mepilex Border dressings. The company model showed that using Mepilex Border Heel and Sacrum dressings results in a cost saving of £177 per patient. For full details of the cost evidence, see section 4 of the assessment report.

The EAC's changes to the cost model make Mepilex Border dressings less cost saving

3.6 The EAC identified limitations in the company's model and made changes to better reflect NHS costs, specifically:

- Applying baseline incidence rates of pressure ulcers from UK sources.
- Calculating the cost of pressure ulcer treatment by appropriately weighting treatment cost for different pressure ulcer stages.
- Updating the number of dressing changes and the cost of nursing time.

Clinical effectiveness estimates in the EAC's model was informed by the pooled treatment effect of the meta-analysis of 3 RCT's. These changes to the model decreased the cost savings associated with Mepilex Border Heel and Sacrum dressings to £19 per patient. For full details of the changes, see section 4.2 of the assessment report.

4 Committee discussion

Clinical effectiveness

The effectiveness of Mepilex Border dressings is uncertain

4.1 Having considered the various meta-analysis done by the EAC, the committee showed preference for the meta-analysis of 3 RCTs and concluded that any benefit provided by Mepilex Border Sacrum in preventing sacral pressure ulcers was of borderline statistical significance. The committee also noted that there was limited robust evidence on the clinical effectiveness of Mepilex Border Heel; indeed, only 1 observational study reported positive results for the Mepilex Border dressing. The committee concluded that Mepilex Border Sacrum is at best marginally effective, and that the effectiveness of Mepilex Border Heel remains uncertain.

Pressure ulcer incidence rates in the NHS may be lower than those in the published evidence

4.2 The incidence of pressure ulcers with standard care is an important factor in determining the potential of Mepilex Border dressings. The clinical experts highlighted that there is variation in reported pressure ulcer incidence rates across the NHS; this is likely because of variation in how best practice to prevent pressure ulcers is implemented. However, they explained that preventing pressure ulcers is a priority for all NHS trusts and the incidence of pressure ulcers seems to be reducing through the widespread use of standard bundles of care. The EAC provided estimates of pressure ulcer incidence from NHS safety thermometer data, but the committee concluded that there remains uncertainty because of the failure to capture grade 1 pressure ulcers and the voluntary nature of data submission. Based on the available data, the committee concluded that the baseline incidence rate of pressure ulcers in the NHS is likely to be close to 3.8% (as estimated by the EAC) but that this is likely to decrease over time.

It is unclear if the evidence is generalisable to the NHS

4.3 All 4 randomised controlled trials were done outside the UK. The clinical experts explained that because of international guidelines on preventing pressure ulcers, overall standards of care are likely to be relatively consistent across different countries. Nonetheless, there may still be differences in terms of patient selection, length of hospital stay, staff ratios and the exact composition of care bundles. The committee noted the relatively high baseline incidence rate of pressure ulcers in the control arm of the trials compared with the EAC's estimate for the incidence in the NHS. It also noted that any benefits associated with Mepilex Border dressings observed in the trial are based on a small absolute number of pressure ulcer events. Moreover, the committee was aware that identifying and grading of pressure ulcers may vary. The clinical experts confirmed that assessing and grading heel and sacral pressure ulcers is subjective and often depends on individual staff experience. Healthcare

professionals will often seek a second opinion to avoid the consequence of incorrect grading, and the availability of specialist tissue viability nurses across the NHS varies. The clinical experts confirmed that NHS acute care settings include a broad range of patients at risk of pressure ulcers, and that staff across different clinical areas will have different levels of expertise in preventing and recognising early evidence of pressure ulcers. Having considered these factors, the committee concluded that there were uncertainties about the generalisability of the evidence to NHS practice.

NHS considerations

Healthcare professionals should use the appropriate dressing for the specific location of the pressure ulcer

4.4 The clinical experts explained that little training is needed to be able to apply Mepilex Border dressings. Some clinical experts noted that because of the cost of the specific Mepilex Border Sacrum and Heel variants, the less costly standard rectangular Mepilex Border dressings are sometimes used and instead cut to the appropriate shape. However, this may limit the effectiveness of the dressings and mean that they need to be changed more often. The committee noted that this improvised use is not included in the manufacturer's instructions for use. It concluded that healthcare professionals should use the appropriate dressing for the specific location of the pressure ulcer.

Further research would help to inform patient selection

4.5 The clinical experts agreed that not all patients in acute care should have Mepilex Border dressings, but they described uncertainty in terms of best patient selection. They explained that it has not yet been determined how to identify patients for whom Mepilex Border dressings would be most suitable. The committee agreed that the evidence available does not allow for accurate patient selection and that further research would be helpful in this regard. The committee also noted that evidence was generated in other settings which are not covered by the scope of this evaluation.

Cost modelling

The EAC's updated model is more plausible than the company's model but uncertainties remain

4.6 The committee accepted the EAC's changes to the company's cost model (see section 3.6), and considered that the revised parameters better reflected cost and resource use in an NHS acute care setting. However, it noted that uncertainties remained with regard to important factors such as the incidence of pressure ulcers and how often dressings needed to be changed. The committee concluded that the cost consequences associated with Mepilex Border Heel and Sacrum were uncertain and that further research would help to inform more accurate cost modelling.

Pressure ulcer incidence rates and frequency of dressing changes are uncertain and vary across settings

4.7 Cost savings in the updated model were mainly driven by the incidence of pressure ulcers in the standard care arm and the frequency of dressing changes. The committee recalled that pressure ulcer incidence rates may be lower in the NHS than those used in the model (see section 4.2). The committee also understood that according to the instructions for use, Mepilex Border Heel and Sacrum dressings should be changed every 3 days. However, the clinical experts explained that in certain patient groups, such as people with faecal or urinary incontinence, the dressings may need to be changed more often. The committee concluded that resource use data from clinical practice would help to inform more accurate cost modelling.

Cost savings

Mepilex Border Heel and Sacrum dressings may be cost saving compared with standard care

4.8 The EAC's updated cost model reported that compared with standard care, using Mepilex Border Heel and Sacrum may save around £19 per patient. However, the committee concluded that any proposed cost

savings should be interpreted with caution because of the uncertainties in the cost modelling (see section 4.7).

Further research

Mepilex Border dressings show promise and further research would help to address the uncertainties

4.9 The committee concluded that Mepilex Border Heel and Sacrum dressings show promise, and that further research should be done to help resolve the uncertainties about clinical effectiveness and cost modelling. This research should also evaluate the incidence of pressure ulcers in patients at risk or high risk of pressure ulcers in an acute care setting, despite having standard care to prevent pressure ulcers. The research should explore any benefits that Mepilex Border dressings may offer compared with standard care for preventing heel and sacral pressure ulcers. Data from this research, combined with data from use of dressings in clinical practice, should allow conclusions to be drawn about which patients will benefit most, as well as practical considerations such as how often the dressings should be changed.

5 Committee members and NICE project team

Committee members

This topic was considered by the medical technology advisory committee which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each medical technologies guidance topic is assigned to a team consisting of 1 or more technical analysts (who act as technical leads for the topic), a technical adviser and a project manager.

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