NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

Assessment report overview

Mepilex Border Heel and Sacrum dressings for preventing pressure ulcers

This assessment report overview has been prepared by the Medical Technologies Evaluation Programme team to highlight the significant findings of the External Assessment Centre (EAC) report. It includes **brief** descriptions of the key features of the evidence base and the cost analysis, any additional analysis carried out, and additional information, uncertainties and key issues the Committee may wish to discuss. It should be read along with the company submission of evidence and with the EAC assessment report. The overview forms part of the information received by the Medical Technologies Advisory Committee when it develops its recommendations on the technology.

Key issues for consideration by the Committee are described in section 6, following the brief summaries of the clinical and cost evidence.

This report contains no confidential information. This overview also contains:

- Appendix A: Sources of evidence
- Appendix B: Comments from professional bodies
- Appendix C: Comments from patient organisations
- Appendix D: Claimed benefits and decision problem

1 The technology

Mepilex Border dressings (Mölnlycke Health Care) are self-adherent, multilayer foam dressings which include proprietary soft silicone technology (called Safetac). There are 3 variants available (Mepilex Border Heel, Mepilex Border Sacrum and Mepilex Border) in various sizes. Mepilex Border dressings can be used for treating a wide range of wound types, but the scope for this evaluation is the prevention of pressure ulcers.

The dressings are made up of 5 layers. The layer closest to the skin is designed to reduce friction between the skin and the dressing itself. The Safetac technology contained in this layer is designed to allow the dressing to be easily peeled back and be reapplied thereby enabling multiple inspections of the skin site. The other 4 layers are variously designed to cushion, prevent stretch or tear, absorb moisture and allow moisture to evaporate. Mepilex Border dressings are CE marked as class IIb medical device. Other Mepilex dressings which consist of 3 layers and have no border were not considered part of this evaluation.

2 Proposed use of the technology

2.1 Disease or condition

Pressure ulcers are injuries to the skin and underlying tissue, primarily caused by prolonged pressure on an area of bony prominence which is capable of impairing the skin's blood supply. Generally, people confined to bed or a chair by an illness are potentially at risk of developing a pressure ulcer. However, they are more likely to occur in people who are seriously ill, have a neurological condition, impaired mobility, impaired nutrition, poor posture or a deformity. Also, the use of equipment such as seating or beds, which are not specifically designed to provide pressure relief, can cause pressure ulcers. Pressure ulcers are often preventable and their prevention is included in domain 5 of the Department of Health's NHS outcomes framework 2014/15

2.2 Patient group

Mepilex Border dressings are indicated as part of a prophylactic regimen for the prevention of pressure ulcers. The scope of this evaluation is prevention of pressure ulcers in patients at risk or at high risk in acute care settings.

An NHS Safety Thermometer report notes that from April 2014 - March 2015, just under 25,000 patients developed a new pressure ulcer within the NHS in England. Some patients are considered to be at increased risk of developing pressure ulcer. The NICE guideline on pressure ulcers: prevention and management notes that adults considered to be 'at high risk' of developing pressure ulcers will usually have multiple risk factors (such as significantly limited mobility, nutritional deficiency, inability to reposition themselves, and significant cognitive impairment) identified during risk assessment with or without a validated scale. Also considered to be at high risk are patients who have a history of pressure ulcers or those who already have a pressure ulcer.

2.3 Current management

The NICE guideline on pressure ulcers: prevention and management recommends that a documented risk assessment for pressure ulcers be done in adults admitted to secondary care or adults with defined risk factors receiving care in other settings. It recommends using a validated scale to support clinical decision-making, and proposes that risk be reassessed if there is a change in the patient's clinical circumstances.

Strategies recommended by the guideline for preventing pressure ulcers in adults assessed as being at risk, include a combination of regular repositioning and pressure redistribution using high specification foam mattresses or pressure redistributing cushions. The guideline also makes related recommendations specifically tailored at neonates, infants, children and young people at risk of developing a pressure ulcer. This includes skin assessment, repositioning, pressure redistribution, information and use of barrier creams. The NICE guideline on Diabetic foot problems: prevention and

management recommends that people in hospital who are at moderate or high risk of developing a diabetic foot problem should be given a pressure redistribution device to offload heel pressure.

2.4 Proposed management with new technology

The Mepilex Border dressings are intended to be used in addition to standard pressure ulcer prevention strategies for people at risk of developing pressure ulcers in acute care settings.

3 Company claimed benefits and the decision problem

Details of the company's claimed benefits and the decision problem are described in Appendix D. The company proposed some variations from the scope as presented in table 1.

Table 1 Details of variation from the scope

Decision problem	Variation proposed by company	EAC's view of the variation
Population	The company expanded the scope to include patients in an aged care setting	The EAC has considered the population included within the scope only.
Comparator	The company expanded the scope to include both Mepilex Border dressing (not specific to heel and sacrum) and the 3-layer Mepilex dressing	The EAC has included Mepilex Border Heel dressing, Mepilex Border Sacrum dressing and Mepilex Border dressing when cut to size for use on the heel or sacrum. The 3-layer Mepilex dressing and dressings used on other sites of the body have not been considered.

4 The evidence

4.1 Summary of evidence of clinical benefit

The company presented 34 studies, 25 published and 9 unpublished studies for qualitative synthesis of clinical evidence. The EAC considered that the company search strategy was not appropriate because the eligible population differed from the scope, details of which can be found in section 3.2 of the assessment report. The EAC undertook a de novo search using a search strategy in line with the scope. The EAC identified all the studies included by the company and considered that 13 studies, reported across 23 publications were relevant. Summary information on the included and excluded studies is in table 2; further details can be found in section 3.3 of the assessment report.

Table 2: Included studies, company and EAC

Study	**Type of publication**	**Type of study**	
Studies included by both EAC and company			
12 studies included by both	*Full paper*	*Randomised controlled trials*	*Aloweni et al. 2017, Kalowes et al. 2016, Santamaria et al. 2015a*
	Full paper	*Observational studies*	*Brindle and Wegelin 2012, Chaiken 2012, Cubit et al. 2013, , Jin 2018 (Unpublished contains academic in confidence information), Park 2014, Richard-Denis et al. 2017a, Santamaria et al. 2015b, Yoshimura et al. 2016*
	Poster		*Haisley et al. 2015*
Studies not in submission included by EAC			

Walker et al. 2017	*Full paper*	*Randomised controlled trial*	
Studies in submission excluded by EAC			**Comment**
Bao and Ji 2010, *Santamaria et al. 2015b,*	*Full paper*	*Randomised controlled trials*	*Ineligible population* *Ineligible setting (i.e. aged not acute care)*
Koerner 2011,	*Abstract*	*Non-randomised comparative observational studies*	*Insufficient information on population and intervention.*
Padula 2017	*Full paper*		*Ineligible study design*
Bateman and Roberts 2013, Walsh et al. 2012,	*Full paper*	**Single arm studies*	*Insufficient information reported on intervention*
Gentry and Wright 2010	*Poster*		
Baker 2014, Daukste 2013, Edwards and Lynch 2014, Gentry and Wright 2010, Lientz 2013, Muldoon et al. 2010,	*Poster*		*Did not report device-related adverse event data*
Brindle 2010, , Johnstone and McGown 2013a, Sullivan 2015	*Full paper*		
Black J et al.2014, Clark et al. 2014, Cornish 2017, Huang et al. 2015, Moore and Webster 2013, National Pressure Ulcer Advisory Panel 2014a, Tayyib and Coyer 2016	*Full paper*	*Systematic reviews*	*Inappropriate study design not fully aligned to the scope*

* Single arm studies were considered for adverse events only and not clinical effectiveness.

EAC critical appraisal of the clinical evidence

From the EAC's critical appraisal of the included studies, it concluded that all the RCT's had an acceptable rating for both internal and external validity with

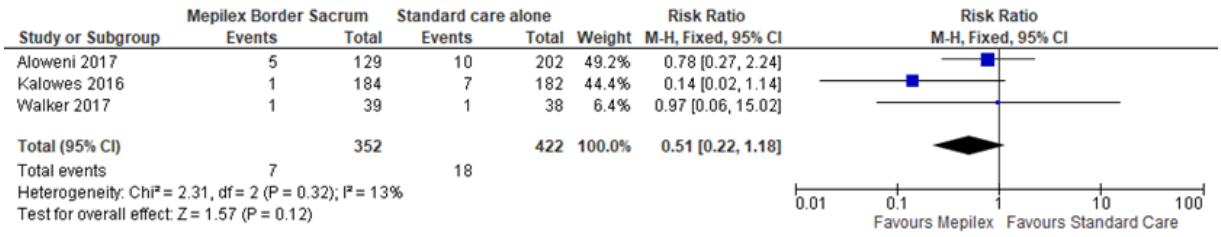
the exception of the study by Kalowes et al. 2016 which had a high internal validity. The EAC noted that with respect to external validity, results from these studies were generalisable to patients in acute care settings who were at risk or at high-risk of pressure ulceration. However, the EAC noted the variation in the definition of standard care across these studies. The EAC considered that only 3 observational studies (Park 2014, Richard-Denis et al. 2017a, Santamaria et al. 2015b) had an acceptable rating for both internal and external validity. However, the main focus for the clinical evidence was on the RCT's as this study design was deemed most appropriate in assessing the effectiveness of an intervention and minimising bias.

The EAC noted that standard care varied across the 4 RCTs, but that some specific components of standard care in each study aligned with the scope. The recruited population across the 4 RCTs aligned with the scope and these were adult patients at high-risk of pressure ulcers in intensive care units, medical/surgical wards and emergency departments. Three RCTs reported the level of risk of the recruited population as part of the eligibility criteria; Braden scale risk score ≤14 (Aloweni et al. 2017); Braden score ≤13 (Kalowes et al. 2016); Waterloo risk score of 15+ (Walker et al. 2017). The Santamaria (2015a) study reported a mean Braden score of 12 across both intervention and control groups. Generalisability of the evidence may be limited because all 4 RCTs are single site studies conducted outside of the UK: in Australia (Santamaria et al. 2015a, Walker et al. 2017); Singapore (Aloweni et al. 2017); and the USA (Kalowes et al. 2016).

The EAC noted that the most commonly reported outcomes were the incidence rate and severity of pressure ulcers, as assessed using established guidelines (NPUAP/EPUAP 2014 or unspecified; AWMA 2001). 4 RCTs compared Mepilex Border Sacrum to standard care, 3 of these (Walker et al. 2017, Aloweni et al. 2017, Kalowes et al. 2016) reported the incidence rate of pressure ulcers as a proportion of patients who developed pressure ulcers, whereas the Santamaria (2015a) study reported the number of pressure ulcers developed among patients. The EAC synthesised results from 3 RCTs (Walker et al. 2017, Aloweni et al. 2017, Kalowes et al. 2016) using a fixed

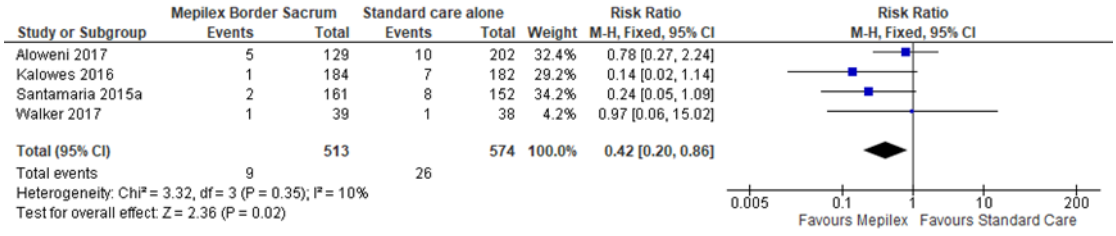
effect meta-analysis and the pooled estimate showed a non-statistically significant relative risk (RR 0.51 95% CI 0.22 to 1.18] p=0.12) in favour of Mepilex Sacrum Border dressing – see figure 1. This pooled estimate informed the treatment effect for Mepilex dressing in the base case analysis.

Figure 1 Pooled analysis: Number of patients who developed pressure ulcers (Mepilex Border Sacrum vs. Standard Care)



The Santamaria et al 2015a RCT reported the number of pressure ulcers developed among patients rather than the number of patients who developed a pressure ulcer. Assuming 1 pressure ulcer per patient the EAC conducted a second meta-analysis including this study. The pooled estimate for all 4 RCTs was statistically significant in the fixed effect meta-analysis (RR: 0.42 [95% CI 0.20 to 0.86], p=0.02) – see figure 2. However, the difference is not significant based on a random effects model (RR: 0.45 [95% CI: 0.20 to 1.04], p=0.06). This pooled estimate was only considered in a scenario analysis.

Figure 2 Pooled analysis: Number of patients who developed pressure ulcers- including Santamaria 2015a (Mepilex Border Sacrum vs. Standard Care)



Results from 1 study assessing Mepilex Border heel (Haisley et al. 2015) and 1 assessing Mepilex Border dressing (Park et al 2014) showed a statistically significant difference in favour of the intervention (p = <0.001). Other

outcomes reported have been detailed in section 3.6 of the assessment report.

In conclusion the EAC considered that despite a relatively large body of clinical evidence, there remains uncertainty in the treatment effect of Mepilex Border dressings. This uncertainty is lower in patients or settings with a relatively high baseline incidence of pressure ulcers and for the Mepilex Border Sacrum dressing intervention specifically

. **Table 3. Pivotal clinical evidence, reproduced from table 3.3 in the assessment report**

Study name (acronym)	Design and intervention(s)	Participants* and setting	Follow-up	Outcomes	Withdrawals	Comments
Comparative studies: Randomized controlled trials						
Aloweni 2017 (Aloweni et al. 2017)	Single-site RCT Mepilex Border Sacrum plus standard care, Fatty acids oil spray plus standard care Standard care (SC)	**Patients**: Adult patients recruited within 48 hours of hospital admission. No pre-existing pressure injuries and a high risk of developing pressure injuries **Mepilex Border Sacrum**: 129 patients **Oil group**:130 patients **SC group**: 202 patients **Setting**: Hospital (medical/surgical wards); Singapore	Patients followed-up every 3 days up to 14 days of hospital stay Mean duration of Santamaria stay was 6.7 days (SD ±4.3)	Incidence rate of any stage I pressure injury (NPUAP/EPUAP 2014). Subgroup analysis by Braden score (≤12, ≥13)	**Mepilex Border Sacrum**: 29 **Oil group**: 18 **SC group**: 17	Study matches scope and provides limited non-UK comparative data

Study name (acronym)	Design and intervention(s)	Participants* and setting	Follow-up	Outcomes	Withdrawals	Comments
Santamaria 2015a (Santamaria et al. 2015a) (BORDER)	Single-site, open-label RCT Standard care plus Mepilex Border Sacrum and Mepilex Heel with Tubifast Standard care	**Patients:** Patients aged >18 years who were admitted to the ED and ICU **Mepilex Border Sacrum/ Mepilex Heel**: 219 patients; mean age 54 (SD 20.8) **Standard care**: 221 patients; mean age 56 (SD 20.5) years **Setting**: Hospital Trauma Centre; Australia	Patients were reviewed every 24 hours for the duration of their ICU stay. Follow-up was until discharge from ICU. Mean duration of ICU stay was 91 (SD 112) hours in Mepilex group and 86 (SD 101) hours in the standard care group	Incidence rate of pressure ulcers in the ICU (AWMA 2001), by cases and anatomical site. Adverse events were not a pre-specified outcome but were discussed	**Mepilex Border Sacrum/ Mepilex Heel**: 3 deaths in ED, 17 lost to follow-up/not for ICU/transferred, and 38 transferred from ICU prior to first pressure ulcer assessment **Standard care:** 1 death in ED, 29 lost to follow-up/not for ICU/transferred, 39 discharged from ICU prior to first pressure ulcer assessment	Single-site study Authors commented that it was not possible to determine whether the success of the intervention was due solely to dressing use being commenced in the ED. Study matches scope for sacrum application only (Mepilex Border Sacrum), and provides limited non-UK comparative data on 1 outcome
Walker 2017 (Walker et al. 2017)	Single-site, , pilot RCT Mepilex Border Sacrum plus standard care	**Patients:** Patients admitted to surgical care unit and ED,	Baseline high-resolution digital photograph of sacral area.	Feasibility criteria, incidence and severity of pressure injury based on	3 patients allocated to the dressing were excluded (2 for protocol violations	Limitations reported by the authors included lack of generalizability to

	Standard care	aged ≥18 years, and at high risk or greater of pressure injury (Waterloo risk score15+) on hospital admission. Overall, median age 75 years (IQR 49-91) **Mepilex Border Sacrum**: 39 patients; **Standard care**: 38 patients; **Setting**: Tertiary health facility Australia	guided by the NPUAP/EPUAP pressure injury and staging classification system (reported by AWMA 2012) Study duration 5 months. Follow-up duration not explicitly reported but likely on discharge from ward. Median time (days) the dressings remained in situ was 2 (IQR: 1-3). Median time (hours) from recruitment to discharge **Mepilex Border Sacrum**: 121 (IQR 73-171) **Standard care:** 122 (IQR 88-198)	digital photos (NPUAP/EPUAP). Patient comfort (self-assessment) and costs were not pre-specified outcomes but were reported	and 1 consent withdrawal). 5 patients in each group without outcome assessment due to early discharge from ward, dressing could not be applied (lumbar spinal block or spinal surgery), or patient removed dressing due to discomfort	other settings (single-site pilot study with small sample size), participant attrition, and protocol inconsistency due to disparity in body weight assessment and probably mattress variation. At the time of the study, the larger size dressing was unavailable for patients assessed as obese Authors noted that blinding of the outcome assessor was considered a challenge as the dressing left atraumatic skin marks; use of a sham dressing (if approved) may have left similar markings

						Study matches scope and provides limited non-UK comparative data

* Age and gender was not consistently reported in the studies. Where data were reported, details of age and gender have been included.
Abbreviations: AWMA, Australian Wound Management Association; ED, emergency department; EPUAP, European Pressure Ulcer Advisory Committee; HAPU, hospital-acquired pressure ulcer; ICU, intensive care unit; IQR, interquartile range; LOS, length of stay NPUAP, National Pressure Ulcer Advisory Association;

4.2 Summary of economic evidence

The company carried out a search for economic evidence and identified 7 relevant studies. The EAC found no further evidence in its search and considered that 2 studies reported in 3 publications were relevant.

- Santamaria et al. 2015 presents a cost-benefit analysis based on their RCT which was undertaken in the emergency department and ICU of a large teaching hospital in Australia comparing Mepilex Border Sacrum with standard care. Cost data were collected during the trial based on a total of 313 patients (intervention n = 161, control n = 152) on hospital resources and time used to provide pressure ulcer care. The EAC considered that although this economic study was well reported, it had poor external validity to the decision problem and the NHS because the costs relate to an Australian health care system. The study was however useful in presenting resource utilization associated with the use of the dressing in the company's de novo analysis.

- The second included study, (Santamaria and Santamaria 2014), presents a budget impact estimate of using Mepilex Border dressings to prevent hospital acquired pressure ulcers in Australia, based on the Santamaria et al. 2015 cost benefit analysis

The EAC concluded that based on the published studies, Mepilex Border may be cost saving compared with standard care. However, both studies were based on a single trial conducted in Australia with Australian costs applied. Therefore, there is insufficient evidence to draw any robust conclusions for the NHS without a de novo analysis. For a full description of the EAC's consideration of the economic evidence see section 4.1 of the assessment report.

De novo analysis

The company submitted a single level decision tree model. The EAC agreed that the model structure was correct but it considered some of the data used

to populate the model were not appropriate. The company model data was largely based on 1 RCT (Santamaria et al. 2015a) and a cost-benefit analysis (Santamaria et al. 2015). The EAC highlighted that the trial informing primary outcome of pressure ulcer incidence was based on a majority of high risk patients and had both Mepilex Border Sacrum and the 3-layer Mepilex heel with Tubifast as interventions. The time horizon of the model was set to <1 year because pressure ulcers are expected to heal within this period.

Clinical parameters

The main clinical parameter in the model is the incidence of pressure ulcer with standard care and with standard care plus Mepilex Border dressings. The company's model used incidence rates from an Australian study for both the comparator and intervention. The EAC felt this was not appropriate and used UK specific sources and literature considered more generalisable to the NHS, to estimate the incidence rate of pressure ulcers with standard care as 3.8% (further details in section 4.2.5 of the assessment report). The incidence rate of pressure ulcers with Mepilex was 1.9% based on the treatment effect taken from the pooled estimate in figure 1. Table 4 shows parameters revised by the EAC as noted in table 4.7 of the assessment report. Details of the rationale for these changes can be seen in section 4.2 of the assessment report.

Table 4: EAC revisions to the company's model (inputs used in the base case)

Parameter	Company base-case	Company source	EAC value	EAC source
Incidence of pressure ulcer – standard care	13.1%	(Santamaria et al. 2015a)	3.8%	NHS safety thermometer data (NHS Improvement 2017-2018) for ICU adjusted to account for poor sensitivity (Smith et al. 2016), missed stage 1 pressure ulcers and only heel and sacrum ulcers (Clark et al. 2017). (Section 4.2.5)
Incidence of pressure ulcer – Mepilex Border dressings	3.1%	(Santamaria et al. 2015a)	1.9%	Combined standard care pressure ulcer incidence with pooled relative risk calculated by EAC (Section 3.8)
Cost of pressure ulcer treatment – standard care	£3,111	NHS pressure ulcer treatment productivity calculator (NHS Improvement 2018a) weighted by stages from (Santamaria et al. 2015a)	£4,823	Costs from Dealey 2012 (Dealey et al. 2012). Weighted by NHS safety thermometer data (NHS Improvement 2017-2018), adjusted for stage 1 pressure ulcers (Clark et al. 2017) (Section 4.2.6)
Cost of pressure ulcer treatment – Mepilex Border dressings	£3,858	NHS pressure ulcer treatment productivity calculator (NHS Improvement 2018a) weighted by stages from (Santamaria et al. 2015a)	£4,823	Costs from Dealey 2012 (Dealey et al. 2012). Weighted by NHS safety thermometer data (NHS Improvement 2017-2018), adjusted for stage 1 pressure ulcers (Clark et al. 2017) (Section 4.2.6)
Total number of Mepilex Border Sacrum dressings per patient	2	(Santamaria et al. 2015)	4	(Johnstone and McGown 2013b)
Total number of Mepilex Border Heel dressings per patient	4	(Santamaria et al. 2015)	6	Assumption based on (Johnstone and McGown 2013b) and (Santamaria et al. 2015)
Cost of nurse time per minute	£0.51	NHS Agenda for change pay bands 2015, band 6 nurse cost used, adjusted for national insurance, superannuation, annual leave, overheads and full time working hours.	£0.62	Band 5 nurse cost (Personal Social Services Research Unit (PSSRU) 2017), validated by clinical experts.
Total number of minutes allowed for all dressing changes per patient	12 minutes	2 minutes per dressing change for 6 dressing (2 sacrum, 4 heel) (Santamaria et al. 2015)	20 minutes	2 minutes per dressing change (10 dressings, 4 sacrum, 6 heel) (Santamaria et al. 2015). Validated by clinical experts

Cost and resource use

The cost of pressure ulcer in the UK used by the company was sourced from the NHS pressure ulcer productivity calculator. The EAC considered this source to be appropriate but noted that tool inflated costs from a fairly old paper (Bennett et al. 2004). The EAC updated the model using a more recent source. It considered that the costs in the Dealey et al. 2012, inflated to current prices better reflected costs in UK clinical practice. The EAC considered the weighted data from NHS safety thermometer to be the most appropriate for this patient population in an acute care setting. Table 5 shows the cost of pressure ulcer treatment calculated by the EAC and the value of £4,823 was used in the base case analysis.

Table 5: Cost of pressure ulcer treatment as calculated by the EAC

Stage of pressure ulcer	Cost from Dealey (inflated)	Weighting from NHS safety thermometer (NHS Improvement 2017-2018)*	Weighting from Richardson 2017 (Richardson et al. 2017) (2015 year)	Weighting from NHS Pressure ulcer productivity calculator (NHS Improvement 2018a)	Clark 2017 (Clark et al. 2017)**
1	£1,299	0.33	0.11	0.35	0.33
2	£5,608	0.54	0.86	0.41	0.44
3	£9,675	0.11	0.04	0.13	0.14
4	£15,097	0.02	0.00	0.11	0.09
Pressure ulcer treatment cost	-	£4,823	£5,352	£5,672	£5,609

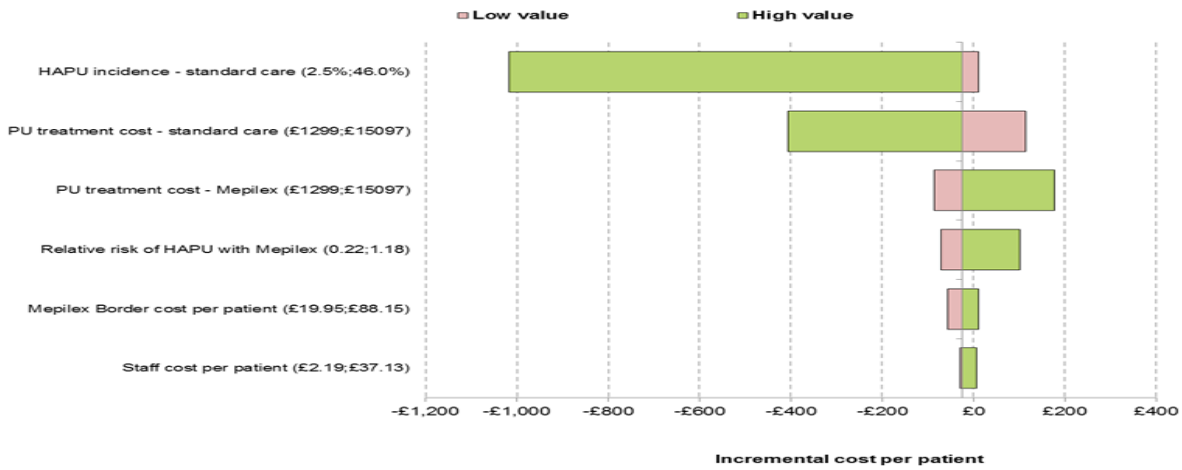
*Note these figures have been adjusted to account for stage 1 pressure ulcers which are not reported by NHS safety thermometer, using Clark 2017 (Clark et al. 2017).
** Note this study reports prevalence not incidence. Unstageable and unknown pressure ulcers have been excluded for the purpose of calculating the distribution. Deep tissue injuries have been classified as stage 4.

Results

The base case results from the company's model showed cost savings of £177 per patient. In the model with EAC revised parameters, base case model showed cost savings of £19 per patient, (see tables 4.4 and 4.8 of assessment report). The EAC conducted a number of sensitivity analyses (the detail of these and the limits applied can be seen in section 4.4 and

appendix K of the assessment report). The deterministic sensitivity analysis showed that the key drivers of the model are pressure ulcer incidence with standard care, pressure ulcer treatment costs and relative risk of pressure ulcer with Mepilex Border dressings. The tornado diagram in figure 3 shows the results of the deterministic sensitivity analysis.

Figure 3: Tornado diagram based on EAC sensitivity analysis



The EAC considered the combined uncertainty of all parameters in a probabilistic sensitivity analysis (PSA). The base case assumed Mepilex Border dressings reduces the incidence of pressure ulcer uniformly across all stages of pressure ulcer. The PSA resulted in a cost saving of £6.55 per patient. This saving was lower than the saving in the base case analysis, because the average probabilistic relative risk of pressure ulcer was 0.56 compared with 0.51 used in the base case. The estimated probability of being cost saving is 57% which means that the results from 57% of iterations were cost saving. The EAC explored a scenario analysis where the proportions of each grade of pressure ulcer were varied independently to account for any uncertainty around Mepilex Border dressings reducing the incidence of pressure ulcer more for lower or higher stages of pressure ulcer. The PSA results of this scenario is a cost saving of £8.94 per patient with and estimated probability of being cost saving of 57%.

The EAC undertook a subgroup analysis to assess the impact of Mepilex Border dressings on sacral pressure ulcers only. This analysis used pressure

ulcer incidence rates specific to the sacrum and excluded the cost of heel dressings and associated staff time. This analysis resulted in a cost saving of £27. A similar sub group analysis done specifically for the heel estimated a cost saving of £31. A subgroup analysis exploring the impact of varying the cost of a standard Mepilex Border dressing estimated a cost saving of £48 at the lower cost of the dressing (£2.90) and a saving of £25 at a higher cost of the dressing (£5.12).

5 Ongoing research

The EAC identified 2 ongoing studies within the scope of the decision problem (section 3.9 Assessment report). One study compares pressure ulcer incidence in 'at risk' hospitalised patients receiving foam dressings (plus standard care) with patients receiving standard care alone (NCT0344277). The comparators in the 3 arm study are the Allevyn brand silicone adhesive multilayer foam dressings, Mepilex brand silicone adhesive multilayer foam dressings and standard care. The study, based in Belgium, includes 1,662 patients and is estimated to complete in December 2019.

The second study described in a protocol compares the onset of pressure injuries and cost-effectiveness between Allevyn Life Sacrum and with Mepilex Border Sacrum (Gordon 2017). This study, based in Australia, was planned to complete recruitment in August 2017 but the EAC was unable to find any other details.

6 Issues for consideration by the Committee

Clinical effectiveness

Following its review of the evidence the EAC conducted 2 meta-analysis. Which meta-analysis do you believe is most relevant to the effectiveness of Mepilex Border dressings or are there individual study point estimates more believable than any others?

Most of the evidence is for Mepilex Border Sacrum dressing with 1 study for Mepilex Border Heel dressing. Are the results generalisable across the variants of the Mepilex Border dressings?

The RCTs which were included in the meta-analyses are all non-UK studies. Will generalisability to the NHS be an issue, considering that some aspects of preventive care in these non-UK settings are similar to NHS clinical practice?

Cost-saving

The key driver to the cost saving is the incident rate of pressure ulcers with standard care. This was 13.1% in the company's model and revised to 3.8% based on NHS data by the EAC. What is an appropriate value?

The cost of pressure ulcers in the model depends on assumptions made about the distribution of pressure ulcer stages. Do the committee agree with the EAC values?

The EAC revised model base case showed reduced cost savings compared with the company's base case result and the sensitivity analysis done by the EAC suggests that a plausible range of input parameters can result in the technology becoming cost incurring. What key parameter assumptions should be considered?

7 Authors

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Appendix A: Sources of evidence considered in the preparation of the overview

A Details of assessment report:

- Jenks, M., Marshall, C., Arber, M. et al. Mepilex Border Heel and Sacrum dressings for preventing pressure ulcers

B Submissions from the following sponsors:

- Molnlycke Health Care

C Related NICE guidance:

- Pressure ulcers: prevention and management. NICE clinical guideline 179 (2014). Available from www.nice.org.uk/guidance/cg179
- Diabetic foot problems: prevention and management. NICE guideline 19 (2015, updated 2016). Available from www.nice.org.uk/guidance/ng19

D References

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Brindle CT and Wegelin JA (2012) Prophylactic dressing application to reduce pressure ulcer formation in cardiac surgery patients. Journal of Wound, Ostomy, & Continence Nursing 39(2),pp. 133-42.

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Cubit K, McNally B and Lopez V (2013) Taking the pressure off in the Emergency Department: Evaluation of the prophylactic application of a low shear, soft silicon sacral dressing on high risk medical patients. International Wound Journal 10(5),pp. 579-584

Gordon, J., Stankiewicz, M., Pollock, H., Christensen, M., Barker-Gregory, N. and Dulhunty, J., 2017. A trial of two prophylactic sacral dressings (2PSD) in the prevention of Stage 1 sacral pressure injury in the critically ill patient: A study protocol. Wound Practice & Research: Journal of the Australian Wound Management Association, 25(2), p.82.

Haisley V, Potter K, Wallace J, et al. (2015) An ounce of prevention: The use of a soft silicone five-layer bordered foam heel dressing to decrease the incidence of hospital-acquired heel pressure ulcers in an acute care setting. Journal of Wound Ostomy and Continence Nursing 42(3),pp. S48-S49

Jin HE (2018) Pressure ulcer prevention using a multi-layer foam dressing with soft silicone (Mepilex Border) during off-pump coronary artery bypass graft (OPCABG) surgery. (Unpublished contains academic in confidence information)

Kalowes P, Messina V and Li M (2016) Five-layered soft silicone foam dressing to prevent pressure ulcers in the intensive care unit. American Journal of Critical Care 25(6),pp. e108-e119

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Appendix B: Comments from professional bodies

Expert advice was sought from experts who have been nominated or ratified by their Specialist Society, Royal College or Professional Body. The advice received is their individual opinion and does not represent the view of the society.

Ms Elaine Thorpe, Critical Care Matron, ratified by Nursing and Midwifery Council

Prof Michael Clark, Commercial Director, Welsh Wound Innovation Centre, ratified by European Wound Management Association

Mrs. Samantha Holloway, Senior Lecturer and Programme Director, ratified by European Wound Management Association.

Fiona Downie, Nurse Consultant Tissue Viability, ratified by Royal College of Nursing

Ms Lisa Robson, Tissue Viability Nurse, ratified by Royal College of Nursing

Ms Deborah Gleeson, Lead nurse tissue viability, ratified by Royal College of Nursing

Ms Gillian Maclean, Staff Nurse, nominated by Scottish Intensive Care Society, ratified by Royal College of Nursing

- The experts considered that although this may be a minor variation from standard care, it is innovative in the use of a dressing for prophylaxis.
- All the experts were familiar with the technology.
- The experts considered that either no or some additional training was required to integrate the use of the technology into existing care bundles.
- The majority of the experts considered that patients will benefit from reduced incidence of pressure ulcers and associated complications.
- Two experts considered it may be beneficial for patients who cannot be repositioned.

- The experts considered that the use of the technology could have an initial increase in per patient cost which may result in cost saving from reduced incidence of pressure ulcers.

Appendix C: Comments from patient organisations

Advice and information was sought from patient and carer organisations. The following patient organisations were contacted and no response was received.

- Action Cerebral Palsy
- Action for Elder abuse
- Age Related Diseases and Health Trust
- Age UK
- Bladder and Bowel UK
- Brain and Spinal Injury Charity (BASIC)
- Brain and Spine Foundation (UK)
- British Obesity Surgery Patients Association (BOSPA)
- Critical Care Patient Liaison Committee (CritPaL)
- Cure Parkinsons Trust, The
- Diabetes Research & Wellness Foundation
- Diabetes UK
- Foot in Diabetes UK (FDUK)
- Hoop UK
- ICU Steps
- Independent Age
- Independent Diabetes Trust
- Juvenile Diabetes Research Foundation (JDRF)
- Leg Ulcer Charity
- Lindsay Leg Club Foundation
- Multiple Sclerosis Society (MS Society)
- Multiple Sclerosis Trust
- Multiple Sclerosis-UK
- National Obesity Forum (NOF)
- National Tremor Foundation (NTF)
- Parkinson's UK
- Pressure Ulcers UK
- Spinal Injuries Association

- The Circulation Foundation
- The Relatives and Residents Association
- Trauma Care
- Vascular Society of Great Britain and Ireland
- Wound Care 4 Heroes

Appendix D: Claimed benefits and decision problem

The claimed benefits to patients in acute care settings from the addition of the Mepilex Border dressings to standard care are:

- A reduction in the occurrence of pressure ulcers
- A reduction in the length of stay in hospital
- Reduced pain and discomfort

The claimed benefits to the healthcare system from the addition of the Mepilex Border dressings to standard care in acute care settings are:

- Reduced costs associated with pressure ulcer treatment, nursing costs and hospitalization costs.
- Reduced risk of incurring financial penalties
- Reduced risk of legal action

	Scope issued by NICE
Population	Patients at risk or at high risk of pressure ulcers in acute care settings.
Intervention	Mepilex Border Heel dressing or Mepilex Border Sacrum dressing or both dressings used as an adjunct to standard NHS clinical practice for patients considered 'at risk' or 'at high risk' of pressure ulcers.
Comparator(s)	Standard NHS clinical practice for patients considered 'at risk' or 'at high risk' of pressure ulcers. This may involve a combination of: • Risk assessment with a validated scale • Skin assessment • Frequent repositioning (at least 6 hourly in people considered to be at risk and 4 hourly in people considered to be at high risk) • Pressure redistribution using devices such as high-specification foam mattress or pressure redistributing cushions. • Other dressings or skin applications to prevent pressure ulcers • Information • Barrier cream (specified situations)
Outcomes	The outcome measures to consider include: Incidence of developing pressure ulcers Incidence of skin breakdown at the heel and sacrum Stage of pressure ulcer developed (stage I – IV, unstageable) Level of patient satisfaction Additional length of hospital stay as a result of pressure ulcers including ICU and conventional ward bed days. Patient compliance with pressure ulcer prevention strategies Level of pain and discomfort and impact on quality of life. Complications avoided from pressure ulcer prevention e.g. Infection, abscess, septicaemia, bone infections, meningitis. Ease of use of product Device related adverse events

