National Institute for Health and Care Excellence

Medical technologies evaluation programme

MT366 Mepilex Border Heel and Sacrum dressings for preventing pressure ulcers

Consultation comments table

Final guidance MTAC date: 21 September 2018

There were 12 consultation comments from 2 consultees:

- 1 NHS Professional
- 1 Manufacturer

The comments are reproduced in full, arranged in the following groups:

- pressure ulcer incidence rates
- draft recommendations
- description of technology
- EAC critique of evidence and meta-analysis
- patient selection

#	Consultee ID	Role	Section	Comments	NICE/ EAC response
Theme 1: Pressure ulcer incidence rates					
1	1	NHS professional	4.2	The EAC provided estimates of pressure ulcer incidence from NHS safety thermometer data: The document is based on data provided by Safety Thermometer. ST offers prevalence data and not incidence data as stated in the draft paper. Furthermore, what is submitted on ST is very different from what occurs in acute care. ST data are grossly underreported and this is acknowledge by the DoH.	Thank you for your comment. The committee was aware of the limitations of the NHS safety thermometer data. However based on expert advice (see Appendix 1) it agreed with the EAC that the safety thermometer is the best data source available. The committee decided to change the wording in section 4.2 to clarify that the safety thermometer is a point prevalence tool.
2	2	Manufacturer	3.6	Section 3.6 states: "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' At a later point in the consultation document (section 4.2), it states: "the committee concluded that the baseline incidence rate of pressure ulcers in the NHS is likely to be close to 3.8%...' The document points out that this figure is based on estimates of pressure ulcer incidence provided by the EAC. It goes on to state: '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' The issue of under-reporting is a commonly discussed topic in the literature. For example, researchers at the Leeds Institute of Clinical Trials Research (University of Leeds, Leeds, United Kingdom) and Mid Yorkshire Hospital NHS Trust (Wakefield, United Kingdom) undertook an audit to assess the accuracy of pressure ulcer monitoring systems across NHS in-patient facilities in England (Smith, I.L., Nixon, J., Brown, S., Wilson, L., Coleman, S. Pressure ulcer and wounds reporting in NHS hospitals in England part 1: audit of monitoring systems. Journal of Tissue Viability 2016;25(1):3-15). The survey involved a stratified random sample of NHS Trusts; 24/34 (72.7%) invited NHS Trusts participated, from which 121 randomly selected	Thank you for your comment. The committee considered this comment carefully alongside others about the under reporting in the NHS safety thermometer data. The committee sought further expert advice (see Appendix 1) which highlighted that though this data source had its limitations, it is the best the NHS has to offer for routine care data. Regarding the prevalence of pressure ulcers in the UK, an expert adviser cited a 2017 paper by Clark et al. The EAC analysed the data in this paper to account for the baseline incidence of heel and sacral pressure ulcers and this was estimated to be 3.82% (see appendix 2) The EAC commented that the paper by Smith et al. is already used within the EAC's assessment report to inflate the number of pressure ulcers occurring given the known under reporting of the NHS safety thermometer data.as described on page 83 of the assessment report The committee decided not to change the guidance.

				wards and 2239 patients agreed to take part. One of the key findings of the audit was the identification of 160 (7.1%) patients with an existing pressure ulcer, compared to 105 (4.7%) on the Safety Thermometer. The subject of pressure ulcer incidence / prevalence was discussed at some length during the NICE Medical Technologies Advisory Committee meeting on 22 June 2018. One point to note is that the Chair of the meeting made reference to a personal communication he had had with a leading wound care expert based in the United Kingdom who believes that the true prevalence rate in the United Kingdom is likely to be in the region of 15%. This figure is more in line with the baseline incidence rate of 13.1% (taken from the Australian RCT reported by Santamaria et al. 2015a) used in the economic model submitted by the Sponsor. Based on the above, it would seem appropriate for NICE to re-consider the baseline rate used in its model.	
3	2	Manufacturer	4.2	Section 4.2 states: "the baseline incidence rate of pressure ulcers in the NHS is likely to be close to 3.8% (as estimated by the EAC)". It is hoped that NICE will consider using a higher baseline rate in its model based on the earlier comments about section 3.6	Thank you for your comment. Please refer to the response to comment 2.
4	2	Manufacturer	4.7	Section 4.7 states: "The committed recalled that pressure ulcer incidence rates may be lower in the NHS than those used in the model". It is hoped that NICE will re-consider the appropriateness of this statement based on the earlier comments about section 3.6.	Thank you for your comment. Please refer to the response to comment 2.
Theme 2: Draft recommendations					
5	1	NHS professional	1.1	there is currently insufficient evidence to support the case for routine adoption in the NHS: Whilst I agree with the conclusion, the Santamaria paper incidence rate reflects what is happening in the UK, however in a number of Trusts, a high number of PU are not reported as deemed 'unavoidable'. The new NHSi guidance on definition and reporting should help with developing a UK-wide standard and improve the quality of ST data.	Thank you for your comment. The committee was aware that there is under-reporting of pressure ulcers and it welcomed the new NHSi guidance. The committee decided not to change the guidance.
6	2	Manufacturer	1.1	Section 1.1. states "there is currently insufficient evidence to support the case for routine adoption in the NHS" of Mepilex Border Heel and Sacrum dressings for the prevention of pressure ulcers in people who are considered to be at risk in acute care. This recommendation seems to be somewhat at odds with a number of	Thank you for your comment. The EAC noted that the international guidelines quoted were already included within the company's submission. This guideline does not change the fact that the committee consider

				key publications relating to the role of prophylactic dressings as an adjunct to pressure ulcer prevention strategies. These are discussed in turn below. Firstly, in the section entitled 'Prophylactic Dressings' of the second edition of their clinical practice guideline on the prevention and treatment of pressure ulcers published in 2014, the National Pressure Ulcer Advisory Panel (NPUAP), the European Pressure Ulcer Advisory Panel (EPUAP) and the Pan Pacific Pressure Injury Alliance (PPPIA) recommend "Consider applying a polyurethane foam dressing to bony prominences (e.g. heels, sacrum) for the prevention of pressure ulcers in anatomical areas frequently subjected to friction and shear." (NPUAP, EPUAP and PPPIA. Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline. Cambridge Media: Perth, Australia, 2014). According to the rating system utilised by the NPUAP, EPUAP and PPPIA to classify the strength of evidence, this particular recommendation is "supported by direct scientific evidence from properly designed and implemented clinical series on [pressure ulcers] in humans (or humans at risk of [pressure ulcers]) providing statistical results that consistently support the recommendation." The results of four clinical studies are cited in support of this recommendation, three of which investigated the efficacy of Mepilex Border dressings. As can be seen from the Sponsor submission of evidence (contained within part 2 of the 'supporting documentation' file), the evidence base in support of Mepilex Border dressings for pressure ulcer prevention has grown substantially since the publication of the NPUAP, EPUAP and PPPIA clinical guideline in 2014. With this in mind, it seems reasonable to assume that a stronger recommendation for using polyurethane foam dressings for the prevention of pressure ulcers can be expected when the next edition of the NPUAP, EPUAP and PPPIA clinical practice guideline is published in 2019. In 2014, the recommendations of an international consensus panel on the role of dressings as an adjunct to pressure ulcer prevention strategies were published (Black, J., Clark, M., Dealey, C., Brindle, C.T., Alves, P., Santamaria, N., Call E. Dressings as an adjunct to pressure ulcer prevention: consensus panel recommendations. International Wound Journal 2014;doi:10/1111/iwj.12197). Following	there is insufficient evidence to support the case for adoption in a UK/NHS setting, which is the basis of the current draft recommendations in section 1. Further, the recommendations are based on the methods used by EPUAP and NPUAP rather than following NICE processes which consider patient and system benefits. The committee also considered expert advice regarding the impact of the NPUAP, EPUAP and PPIA guideline (see Appendix 1). None of the responses received from experts suggests that the committee should amend section 1.1 in light of the recommendations in the guideline. Medical technologies guidance only refers to a single intervention. The associated process for guidance development at NICE focuses on the evidence available to support the claimed advantages of that technology compared with standard care as described in the MTEP Process guide. The committee decided not to change the guidance.

				an extensive literature review process, the panel identified 28 eligible publications which formed the basis of the discussions. The panel concluded that there is adequate evidence to recommend the use of multi-layer foam dressings with Safetac (i.e. Mepilex) for pressure ulcer prevention on the sacrum, buttocks, and heels in high-risk patients in the emergency department (ED), intensive care unit (ICU) or operating room (OR). In 2016, researchers at the Queensland University of Technology in Australia published the results of a systematic review that was undertaken to assess the effectiveness of pressure ulcer prevention strategies in the intensive care unit setting (Tayyib, N., Coyer, F. Effectiveness of pressure ulcer prevention strategies for adult patients in intensive care units: a systematic review. Worldviews on Evidence-Based Nursing 2016;13(6):432-444). A literature search was undertaken to retrieve articles published between 2000 and 2015 that describe randomised controlled trials, quasi-experimental and comparative studies. The meta-analysis of those studies that were considered as being methodologically valid revealed a statistically significant effect of a silicone foam dressing strategy in reducing hospital acquired pressure ulcer (HAPU) incidence (p=0.00001). In contrast, the analysis revealed that the evidence of the effectiveness of nutrition, skin-care regimen, positioning and repositioning schedule, support surfaces, and the role of education in prevention of HAPUs development is limited. In the section of the consultation document entitled 'Why the committee made these recommendations' it states: "Standard care to prevent pressure ulcers in acute care settings includes risk assessment, skin assessment, regular repositioning and the use of special devices'. In view of the relative strengths of the supporting evidence reported by Tayyib and Coyer, the recommendation in section 1.1 is somewhat surprising.	
Theme 3: Description of technology					
7	2	Manufacturer	2	In the 'Overview' row of the table, it states: "They [Mepilex Border dressings] are intended for use as part of a care bundle in patients in an acute care setting that are at risk of developing pressure ulcers." Whilst the scope of the consultation document is restricted to an evaluation of the technology in an acute care setting, it is incorrect to state that the dressings are intended for use in just acute care settings. There now exists robust evidence (from a randomised controlled trial) to show that the technology can be expected to be efficacious in other	Thank you for your comment. Section 2 has been amended in response to this comment.

				settings. Removal of 'acute care setting' in the 'Overview' column would, therefore, seem like an appropriate amendment. In the same row, it states: "The company claims that the dressings reduce shear and friction, displace pressure and create an environment that encourages healing' Whilst the creation of an environment that encourages healing is highly relevant to the dressings when they are applied to open wounds, it has little relevance to the explanation of their mode of action in helping to reduce pressure ulceration. Furthermore, there is no mention of the ability of the dressings to manage microclimate which is key to the scope of the consultation document. The replacement of 'create an environment that encourages healing' with 'manages microclimate' would, therefore, seem appropriate.	
Theme 4: EAC critique of evidence and meta-analysis					
8	2	Manufacturer	3.2	Section 3.2. states "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 ulcer 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' The sample size of the Walker et al. 2017 study (n=77) was considerably smaller than that for the other three studies 'Aloweni et al. 2017, n=461; Kalowes et al. n=366; Santamaria et al. 2015a, n=440). As highlighted in Table 3.3 and Section 3.4 of the EAC's report, the Walker et al. 2017 RCT provides only limited data as this was a pilot study involving a sample size that, although large enough for the purpose of the study (i.e. to determine the feasibility and effect size to inform a larger RCT), was insufficient to determine an effect of the intervention. On this basis, the inclusion of the Walker et al. 2017 study in the meta-analysis is questionable. One other minor point to raise is in relation to the stated settings of the RCTs. Whilst the statement is correct in reporting that the Singapore and USA studies were undertaken in the intensive care unit (ICU) setting, the Australian study involved the application of the dressings to	Thank you for your comment. The EAC considered that as the trial by Walker et al. 2017 meets the inclusion criteria it cannot be omitted from the meta-analysis. The fact that there are fewer patients in this study means that it will have low weighting within the meta-analysis, thus only contributing to the result proportionally. In terms of the setting for the Australian study, this is correctly reported within the assessment report. The committee was aware that in the Australian study, the use of the dressing commenced in the Emergency Department and was maintained during the patients stay in the intensive care unit. The committee decided not to change the guidance.

				patients on admission to an Emergency Department and maintained during their stay in an ICU.	
9	2	Manufacturer	3.3	Section 3.3 states “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.” Whilst RCTs and systematic reviews are generally considered to be the ‘gold standards’, i.e. the pinnacle of the so-called hierarchy of clinical evidence, some experts have expressed concerns about the over-reliance on RCTs in decision-making, focusing on their limitations and the practical difficulties in undertaking them (Kaplan, B.J., Giestrecht, G., Shannon, S., McLeod, K. Evaluating treatments in health care: the insanity of a one-legged stool. BMC Medical Research Methodology 2011;11:65. Available at: http://biomedcentral.com/content/pdf/1471-2288-11-65.pdf). Concerns have also been raised that evidence from RCTs does not easily inform day-to-day clinical decision-making relating to individual patient needs (White, R., Jeffery, S. The evidence debate in wound care. Is patient welfare an issue? Wounds UK 2010;6(3):10. White, R., Maylor, M., Iversen, C. Evidence is ‘in’, ignorance is ‘out’: a dilemma for advanced wound care products. Wounds UK 2010;6(3):114-116). In relation to wound management, it has been suggested that the extended definition of evidence-based medicine by Sackett et al: “Evidence-based medicine is not restricted to randomised trials and meta-analyses, but involves exploration of all types of the best available evidence with which to answer our clinical question” (Sackett, D.L., Rosenberg, W.M.C., Gray, J.A.M., et al. Evidence-based medicine what is and what isn’t. British Medical Journal 1996;312:71) On this basis, it could be argued that the evidence from the 9 observational studies should be given a greater weighting in the analysis.	Thank you for your comment. As described in the MTEP methods guides all types of evidence are considered in the assessment of the case for adoption. The committee considered that the EAC applied appropriate selection criteria and assessment of the quality of the studies to determine which studies presented the most relevant evidence to the decision problem.. The results of the three observational studies referred to in the comment were not included in the meta-analysis for a number of key reasons relating to both their study design and their eligibility for pooling e.g. in terms of the outcome reported. The committee decided not to change the guidance.

10	2	Manufacturer	4.1	Section 4.1. states: “Having considered the various meta-analysis done by the EAC, the committee showed preference for the meta-analysis of 3 RCTs’’ It is hoped that NICE will re-consider its selection of studies for the meta-analysis based on the earlier comments about sections 3.2 and 3.3.	Thank you for your comment. Please refer to the reply to comments 8 and 9.
11	2	Manufacturer	4.6	Section 4.6 states: “The committee accepted the EAC’s changes to the company’s cost model and considered that the revised parameters better reflected cost and resource use in an NHS acute care setting’ It is hoped that NICE will re-consider the appropriateness of this statement based on the earlier comments about section 3.6.	Thank you for your comment. Please refer to the reply to comment 2.
Theme 5: Patient selection					
12	2	Manufacturer	4.5	Section 4.5 states: “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’ It is important to note that an international expert working group has published a consensus document that aims to help clinicians and healthcare budget holders to understand which dressings may protect against pressure ulcer development and which patients may benefit from the use of prophylactic dressings (World Union of Wound Healing Societies (WUWHS) Consensus Document. Role of dressings in pressure ulcer prevention. Wounds International 2016). Within this document, there is an easy-to-follow algorithm to help determine whether or not prophylactic dressings are appropriate for patients. This algorithm is covered in detail during the product training offered by the Sponsor.	Thank you for your comment. The committee sought expert advice (see Appendix 1) regarding the potential use of the WUWHS consensus document for patient selection within the NHS. None of the responses received suggests that this algorithm is widely used in the NHS as care is often individualised. The committee decided not to change the guidance.

Appendix 1

Additional expert advice following consultation on draft guidance

Following the public consultation on the draft Mepilex guidance, expert advice was collected on issues raised in the consultation comments to help the committee address the comments and review the draft guidance if necessary.

1. Expert advice collected by the External Assessment Centre

Expert #1	Professor Michael Clark, Commercial Director, Welsh Wound Innovation Centre
Expert #2	Lisa Robson, Tissue Viability Nurse, Royal Liverpool Hospital
Expert #3	Gillian MacLean, Staff Nurse, The Royal Infirmary of Edinburgh, NHS Lothian
Expert #4	Carol Johnson, Clinical Matron – Tissue Viability County Durham and Darlington NHS Foundation Trust

Questions	Expert responses
Comment 1 Section 1.1 of NICE's draft guidance states that there is currently insufficient evidence to support the case for routine adoption in the NHS of Mepilex Border Heel and Sacrum dressings for the prevention of pressure ulcers in people who are considered to be at risk in acute care. A comment from a stakeholder states that "in the second edition of their clinical practice guideline on the prevention and treatment of pressure ulcers published in 2014, the National Pressure Ulcer Advisory Panel (NPUAP), the European Pressure Ulcer Advisory Panel (EPUAP) and the Pan Pacific Pressure Injury Alliance (PPPIA) recommend 'Consider applying a polyurethane foam dressing to bony prominences (e.g. heels, sacrum) for the prevention of pressure ulcers in anatomical areas frequently subjected to friction and shear.' (NPUAP, EPUAP and PPPIA. Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline. Cambridge Media: Perth, Australia, 2014)"	**Expert #1:** The international guidelines in 2014 did recommend use of prophylactic dressings in pressure ulcer prevention. This recommendation was contained in a section on emerging technologies in prevention. The recommendation was scored as a weak positive recommendation using GRADE and so in the realm of 'probably do this' rather than definitely do this. **Expert #2**: The document below does inform our practice it is included in our clinical policy but it is used as a guideline, we do not routinely use mepilex borders on all at risk patients. It is guidance for registered professionals who decide using clinical judgement and not solely because of the guidance which is not prescriptive **Expert #3**: I agree with the comments made by Nice draft guidance, we do not have a high incidence of PU development in critical care therefore it would not be cost effective to apply dressings to every at risk patient. I think it's fair to say it should be considered in certain cases, but even in our high risk category for PU development we seem to manage with

Please can you comment on the impact of this guideline on the draft recommendation made by NICE?	standard care procedures and no routine dressing application. Nearly all the patients that come through critical care flag up as at risk **Expert #4:** Within CDDFT we have already adopted the 5 layer dressing as standard practice for the prevention of heel blistering, where shear & friction may be a clinical issue for patient who have a fractured neck of femur and as a subsequent have seen a decrease in incidences when applied in the initial admission phase of the care delivery
Comment 2 Section 4.5 of NICE's draft guidance states: "The clinical experts [those attending the Committee meeting] 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". A comment from a stakeholder states that "It is important to note that an international expert working group has published a consensus document that aims to help clinicians and healthcare budget holders to understand which dressings may protect against pressure ulcer development and which patients may benefit from the use of prophylactic dressings (World Union of Wound Healing Societies (WUWHS) Consensus Document. Role of dressings in pressure ulcer prevention. Wounds International 2016). Within this document, there is an easy-to-follow algorithm to help determine whether or not prophylactic dressings are appropriate for patients. This algorithm is covered in detail during the product training offered by the Sponsor." ***Please can you comment on whether this document informs the approach used in NHS acute care ?***	**Expert #1**: The consensus document was authored by an impressive cohort of wound healing experts including authors working in the NHS. The consensus recommendations appear sensible however the impact of their implementation in the NHS is unknown with the clinical algorithm untested to **Expert #2**: Care is individualised. **Expert #3:**:If we were to use the algorithm from this document, all our patients would require dressings for PU prevention. Most of our patients , have reduced mobility and have 2-3 hr periods in the same position. They are often sedated and have reduced spontaneous movement, and nearly all have invasive lines insitu. This algorithm doesn't give us any new guidance, therefore PU dressings would end up being applied to everyone and this is not required. We would consider PU dressing prevention in patients who are extremely emaciated, obese, unable to receive regular pressure area care or be nursed on an air mattress **Expert #4:** Having reviewed the algorithm it is applicable within my organisation and would be easy enough for clinicians to understand and adopt going froward.

Additional expert advice collected by the NICE team

The response to the following questions raised in consultation comments were provided during a teleconference on 14 September, 2018.

Present: Professor Keith Harding CBE FRCGP FRCP FRCS FLSW (Clinical Professor, School of Medicine Cardiff University), Dr Peter Groves (MTAC chair), Dr Avril McCarthy (MTAC lead team member), Jae Long (MTEP Project Manager), Tosin Oladapo (MTEP technical lead), Chris Marshall and Judith Shore (Newcastle and York External Assessment Centre).

1) Safety thermometer

- What is the strength and reliability of this as a data source and metric for estimating the incidence or prevalence of pressure wounds (or the patients at risk of developing them) in a UK acute care setting?

  ***Response**: The safety thermometer is a weak data source which is not robust as it relies on self-reporting. In addition this data source is not routinely audited. A study published in the BMJ (2017) showed that about 20% of pressure ulcers were not reported.*

- What is the professional opinion and credibility of this as a data source on which to build conclusions about the value of an innovative technology (such as Mepilex) in the setting of the UK NHS?

  ***Response:** The safety thermometer is currently the best data source in routine care. However, like any self-reporting system it is likely to be inaccurate. In secondary care services at any one time 10% of patients are at risk.*

2) Incidence/prevalence of pressure ulcers and patients at risk?

- What is the best estimate (%) of pressure ulcers in a UK acute care setting and is the data available to differentiate between care levels within hospital ward, HDU and ITU?

  ***Response**: Based on experience in Cardiff and South Wales incidence rates in:*

  - *ITU – 10%*
  - *HDU – 6%*
  - *General ward – 4%*
  - *Community care – Unknown*

- *Aged care setting – Data is emerging*

Estimate in draft guidance based on the safety thermometer is low even though this has been inflated and deflated to account for sacral and heel pressure ulcers using UK literature. The THIN database should be considered for data.

- What is the best estimate in a European and Australian acute care setting i.e. is there any reason to believe that the UK should be different from other countries?

***Response**: There are similarities across Australia and the UK in terms of morbidity. A multi-country research done by EPUAP showed that figures across 5 European countries were consistent. However, Italy had lower values.*

3) What is the explanation for differences in the reported incidence/prevalence of pressure ulcers across published studies and guidelines?

- Differences in standard of care?

***Response**:*

- *Lack of interest*
- *Variation in standard care*
- *Lack of focus*
- *Variation in standard of reporting*
- *Poor management support*
- *No sanctions for institutions with high PU rates*

In addition, there is currently no tool that is sensitive enough for risk scoring. A new scoring system developed in Leeds shows promise but has not been widely adopted. There exists a big disparity in standard care across the country.

- Differences in reporting - is this voluntary or mandatory in different settings?

***Response**: A robust and transparent system is required. Reporting is mandatory in US, Belgium and Czech Republic. In Wales a system is being developed that makes it mandatory to report categories 3 and 4 pressure ulcers. In England reporting of pressure ulcers is not mandatory and needs to be adopted widely*.

- Follow on question about what impact training in interpretation of pressure ulcers have on incidence reporting

  ***Response**: It has a huge impact as some clinicians are not able to differentiate between categories 1 and 2 pressure ulcer.*

- Differences in the inclusion of different grades of pressure ulcers in incidence reporting e.g. Grade I and II

  ***Response**: Some assessment tools are able to measure moisture damage while others assess skin breakdown. There is no consensus agreement on what tool to use. It is important to report categories 1 pressure ulcers as categories 1 and 2 pressure ulcers account for 85% of all pressure ulcers.*

- Please help us understand the thinking behind 'unavoidable' pressure ulcers and how these are or are not captured

  ***Response**: There is no clear definition of 'unavoidable' pressure ulcers. Though a 0% pressure ulcer incidence rate is not the goal, there is no objective criteria/ rationale for not reporting category 1 pressure ulcers or pressure ulcers labelled 'unavoidable'.*

4) Different national guidelines – where do dressings to prevent pressure ulcers in an acute setting feature?

- NHS Improvement guidance

  ***Response**: This guidance is in its draft stage and yet to be implemented*

- Clinical Practice Guideline 2014 (NPUAP, EPUAP and PPPIA)

  ***Response**: This is the most comprehensive single source of information on the prevention and treatment of pressure ulcers. There was moderate evidence to support a recommendation on the use of dressings and this challenges the paradigm on prevention of pressure ulcers with beds and mattresses.*

- World Union of Wound Healing Societies Consensus Document 2016

  ***Response:** No comment.*

Other comments in discussion

- Feasibility of research in area
  Response: *In theory research is feasible and can be completed in a time frame of 18 months to 2 years. The research question will be split into 3 components*

  - *Prevention – This will look at a case mix and will require adequately powered studies and trained observers.*
  - *Potential treatment- Arguably there is limited reason for this. However, it may be worth looking at the impact of the dressings on wound healing particularly in chronic pressure ulcers*
  - *Health economics/ litigation costs – This is important to look at but might be quite difficult to measure.*

- Opinion on observational studies
  Response*: Cohort studies are not as reliable as randomised controlled trials. However, it is important to have registries of observational studies.*

2.1 Response to the same questions submitted in writing by Professor Michael Clark

- What is the strength and reliability of this as a data source and metric for estimating the incidence or prevalence of pressure wounds (or the patients at risk of developing them) in a UK acute care setting?
- What is the professional opinion and credibility of this as a data source on which to build conclusions about the value of an innovative technology (such as Mepilex) in the setting of the UK NHS?
- What is the best incidence rate estimate (%)of pressure ulcers in a UK acute care setting and is the data available to differentiate between care levels within hospital ward, HDU and ITU?

Responses:

Thank you for the additional questions. I would consider the Safety Thermometer data to probably under-represent the incidence of pressure ulcers, as such it is a weak source of data but remains the only large-scale, frequently updated data source on pressure ulcer occurrence in the UK. So while weak it is the data source we have.

There is limited data on pressure ulcer incidence in any care setting, the Department of Health have often used my 4.0% incidence from acute care gathered in the early 1990's to represent pressure ulcer incidence although this figure is very outdated due to the changes in patient demography over the past twenty years! I'm unaware of robust data giving incidence rates across different departments.

APPENDIX 2

Summary of EAC's review of Clark et al. 2017

Study by Clark et al 2017 found 12.84% of hospitalised patients at medium to high risk of pressure ulcer within Wales had a PU in a study conducted between 28/09/15 to 02/10/15 in 8,365 patients

Note this refers to pressure ulcers on any part of the body, and applies to all pressure ulcers i.e. pressure ulcers could have been acquired outside of the hospital setting or developed within 72 hours of admission (unavoidable), whereas NHS safety thermometer reports new pressure ulcers i.e. those that have occurred 72 hours after admission.

From data presented in the paper we can estimate 63% of pressure ulcers are at the heel or sacrum, and so estimate around 8% of medium/high risk patients have a pressure ulcer at the heel or sacrum.

As a crude estimate of 'new' pressure ulcers we can apply the proportion of 'new' pressure ulcers from the safety thermometer to this Welsh data. According to the safety thermometer data, around 41% of pressure ulcers are 'new' so applying this proportion to the Welsh data gives a value of 3.82%.

Note the welsh data is a few years out of date and campaigns such as "stop the pressure" aim to reduce these values.