NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology consultation supporting documentation

The enclosed documents were considered by the NICE medical technologies advisory committee (MTAC) alongside the assessment report and assessment report overview.

Documents included are:

1. Adoption scoping report – produced by the adoption team at NICE to provide a summary of levers and barriers to adoption of the technology within the NHS in England.

2. Sponsor submission of evidence – the evidence submitted to NICE by the notifying company.

3. Company fact check – the response from the company on the factual accuracy of the EAC assessment report submitted to NICE.

4. Expert questionnaires – expert commentary gathered by the NICE team on the technology.

5. EAC correspondence log – a log of all correspondence between the external assessment centre (EAC) and the company and/or experts during the course of the development of the assessment report.

Please use the bookmarks included in this PDF file to navigate to each of the above documents.

Medicines and Technologies Programme

Adoption Scoping Report

MTG 366 Mepilex Border dressings for preventing pressure ulcers (Mepilex Border Heel and Mepilex Border Sacrum)

SUMMARY – for MTAC1 meeting

Adoption Levers

- Prevention of pressure ulcers in select groups with associated cost savings
- Potential reduction in shear, friction and moisture-related injuries
- Clinician satisfaction with ease of use

Adoption Barriers

- Initial cost
- Cost of sacrum and heel dressings compared to Mepilex standard shape
- Clinical uncertainty about whether the sizing of the heel and sacrum dressing will be appropriate for all patients
- Change in practice (placing dressings on intact skin)

1. Introduction

The Adoption team has collated information from healthcare professionals working within NHS organisations who have experience of using or plan on using Mepilex Border dressings for the prevention of pressure ulcers. Information from the expert commentators to the NICE medtech innovation briefing (MIB) on Mepilex Border dressings for preventing pressure ulcers has also been included where relevant.

This adoption scoping report includes some of the benefits and difficulties that may be faced by organisations when planning to adopt the technology into routine NHS use.

2. Contributing organisations

The company provided the Adoption team with contact details of 13 current users of Mepilex Border dressings. Three NHS tissue viability nurses, 1 nurse consultant and 1 pressure ulcer prevention nurse agreed to contribute to this adoption scope.

3. Use of Mepilex border dressings in practice

NICE guidance on pressure ulcers recommends carrying out an assessment of pressure ulcer risk. For those at high risk the following is recommended:

- skin assessment
- change of position 4 hourly
- use of high specification foam mattresses
- strategies to offload heel pressure
- barrier cream (specified situations)

These recommendations were embedded in the care pathways of all of the contributor's organisations. Some reported additional measures for patients at high risk such as: dynamic bed frames, air mattresses, pressure relieving equipment and Parafricta bootees to reduce skin breakdown on heels.

The manufacturer identifies that Mepilex Border dressings are intended for use as a component of standard preventive measures on 'at-risk' patients. Mepilex Border dressings are available in a range of shapes and sizes, including:

- Mepilex Border Sacrum
- Mepilex Border Heel
- Mepilex Border (standard shape)

- Mepilex Border Lite (standard shape)
- Mepilex Border Flex

To align with the proposed medtech guidance, this scope concentrates on the sacrum and heel specific dressings, where possible.

Contributors' reported the following experience of using the dressings:

- 2 use either the heel or standard shape dressing for pressure ulcer prevention, either on a trial basis or in current practice.
- 1 uses a standard shape dressing for pressure ulcer prevention in their intensive care unit (ICU).
- 1 uses the standard shape dressing for treatment of pressure ulcers and occasionally for prevention on bony spines. In January 2018, they will be trialling the sacrum dressings for prevention of pressure ulcers on fractured neck of femur and trauma patients.
- 1 does not currently use the technology for prevention of pressure ulcers but is planning a trial in community care.

Reported benefits

The benefits of adopting Mepilex Border dressings, as reported to the Adoption team by the healthcare professionals using the technology are that it:

- improves patient outcomes through pressure ulcer prevention
- is cost saving through prevention of pressure ulcers
- reduces shear, friction and moisture-related injuries
- reduces length of stay
- is well tolerated by patients
- generally adheres well to skin

4. Levers and barriers to adoption

The key considerations for adoption highlighted through discussions with expert contributors are:

Care pathway and patients selection

The expert commentators on the MIB identified several groups of people who would most benefit from the technology, including those who can't move, have sensory and cognitive impairment, are critically ill, have had major surgery or are frequently moved.

The 4 contributors with experience of using this technology reported that the dressings were used for pressure ulcer prevention in addition to standard care.

One contributor's organisation has introduced the heel dressings as standard pressure ulcer prevention for people receiving spinal anaesthesia for fractured neck of femur. This patient group tend to regain motor function before sensory perception, enabling movement (causing friction) with no discomfort, potentially causing damage to the skin. The case for adoption was supported by the findings of a locally run trial and cost analysis.

Another organisation has recently started to use the standard dressings as routine practice for pressure ulcer prevention in high risk ICU patients. The standard shape dressing is used and cut to shape depending on the patient.

Another organisation uses the standard dressings for prevention in patients who have a bony spine, as they are deemed to be at high risk of pressure ulcer formation. This organisation also plans to trial the sacrum shaped dressings for prevention of pressure ulcers on patients with a fractured neck of femur.

The contributor who is planning the community care trial for pressure ulcer prevention stated that they will consider using them for patients receiving end of life care, those who are non-compliant with pressure relieving equipment and advice and in prevention of recurrent pressure ulcers, where incidences are increasing.

Application

Contributors reported that the dressings are applied by qualified nurses, assistant nurses and healthcare assistants.

One contributor commented on how easy the heel dressings are to use and how the recently updated design and shape of the heel dressing applies better and is less likely to wrinkle at the margins.

The trust that uses the dressings for people with fractured neck of femur generally use 1 dressing for a maximum of 48 hours. This is because the risk of pressure ulcer development reduces after 1 or 2 days due to mobilisation. This contributor reported that they had once used a heel dressing on a patient for 72 hours and recalled no issues with this.

The contributor who uses the standard shape dressing on intensive care patients, reported that patients have a daily skin assessment with the dressing peeled back for skin inspection and re-applied in line with the manufacturer's instructions. Nursing staff have reported occasional issues in re-applying the dressing as the borders can become wrinkled.

The trust that plans to trial the sacrum shaped dressings expects that they will be able to use the same dressing for 5 days, with daily inspection.

Clinician confidence / acceptance

The manufacturer highlighted that historically, it is not standard practice for tissue viability nurses to advise that dressings are applied to intact skin, the concern being that generalist nurses may fail to inspect the skin underneath the dressing daily.

One contributor reported the results of a local trial using Mepilex Border heel dressings to prevent pressure ulcers. In a group of patients with fractured neck of femur who had received spinal anaesthesia, the heel dressings were applied to 87 patients and compared with 60 patients who received standard care. None of the patients that received the heel dressing developed a pressure ulcer, whereas 12 pressure ulcers, grade 2 or worse, developed within 24-48 hours in the comparator group.

An expert commentator on the medtech innovation briefing for Mepilex Border dressings stated that there have been no pressure ulcers in their practice since their introduction. Another specialist commentator stated that they had seen less shear and friction injuries resulting in less damage to skin since using the dressing to prevent pressure ulcers.

Resource Impact

Three contributors reported that cost (initial and ongoing) could be regarded as a barrier to the use of Mepilex Border dressings for the prevention of pressure ulcers as they are an additional cost to standard care. Two contributors who currently use the dressings believe that the benefits outweigh the cost implications.

The organisation that conducted the local trial used the Department of Health pressure ulcer productivity calculator, to calculate that treatment of the 12 pressure ulcers sustained in the control group cost around £72,000, or £6,000 per ulcer.

The contributor who is planning a community trial, stated that the cost of adopting these dressings compared to pressure relief and barrier creams was initially discouraging. They have done further estimates on selected groups of patients (end of life, those non-compliant with equipment and advice) and have calculated potential savings in those groups.

One organisation has managed the cost impact by using the cheaper standard shaped Mepilex Border dressings reporting that the quality of the foam, and not the shape, prevents pressure ulcers.

The trust that plans to trial the sacrum shaped dressings on fractured neck of femur patients does not expect a significant resource impact until they expand their use to other patient groups.

Training

The manufacturer supports education in pressure ulcer prevention through publication of research articles, consensus documents, product training, and general training in wound care, They also provide independent CPD modules in pressure ulcer prevention.

None of the contributors currently using this technology reported that they had received any formal training in its use. However, one contributor reported that their trust provides wound care training to new staff on induction and that the application of the Mepilex Border dressings is included in this programme. Another contributor reported that they have held practice and awareness sessions specifically in the use of these dressings for all nursing staff working on the wards using the technology.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical Technologies Evaluation Programme

Sponsor submission of evidence

Evaluation title: Mepilex® Border Heel and Mepilex® Border Sacrum dressings for preventing pressure ulcers.

Sponsor: Mölnlycke Health Care

Date sections A and B submitted: 21 March 2018

Date section C submitted: 16 April 2018

August 2011 (Version 1.1)

Contents

Instructions for sponsors

This is the template for submission of evidence to the National Institute for Health and Care Excellence (NICE) as part of the Medical Technologies Evaluation Programme process for developing NICE medical technologies guidance. Use of the submission template is mandatory.

The purpose of the submission is for the sponsor to collate, analyse and present all relevant evidence that supports the case for adoption of the technology into the NHS in England, within the scope defined by NICE. Failure to comply with the submission template and instructions could mean that the NICE cannot issue recommendations on use of the technology.

The submission should be completed after reading the 'Medical Technologies Evaluation Programme Methods guide' and the 'Medical Technologies Evaluation Programme Process guide' available at www.nice.org.uk/mt. After submission to, and acceptance by, NICE, the submission will be critically appraised by an External Assessment Centre appointed by NICE.

Under exceptional circumstances, unpublished evidence is accepted under agreement of confidentiality. Such evidence includes 'commercial in confidence' information and data that are awaiting publication ('academic in confidence'). When data are 'commercial in confidence' or 'academic in confidence', it is the sponsor's responsibility to highlight such data clearly. For further information on disclosure of information, submitting cost models and equality issues, users should see section 11 of this document 'Related procedures for evidence submission'.

The submission should be concise and informative. The main body of the submission should not exceed 100 pages (excluding the pages covered by the template and appendices). The submission should be sent to NICE electronically in Word or a compatible format, not as a PDF file.

The submission must be a stand-alone document. Additional appendices may only be used for supplementary explanatory information that exceeds the level of detail requested, but that is considered to be relevant to the case for adoption. Appendices will not normally be presented to the Medical Technologies Advisory Committee when developing its recommendations. Any additional appendices should be clearly referenced in the body of the submission. Appendices should not be used for core information that has been requested in the specification. For example, it is not acceptable to attach a key study as an appendix and to complete the economic evidence section with 'see appendix X'.

All studies and data included in the submission must be referenced. Identify studies by the first author or trial ID, rather than by relying on numerical referencing alone (for example, 'Trial 123/Jones et al.[126], rather than 'one trial[126]').Please use a recognised referencing style, such as Harvard or Vancouver.

The sponsor should provide a PDF copy of full journal articles or reports – in electronic or hard copy form – included in the submission, if the sponsor is either the copyright owner or has adequate copyright clearance to permit the intended use by NICE. This clearance must be wide enough to allow NICE to make further copies, store the article electronically for a limited period of time on a shared drive to be accessed by a limited number of staff. Additionally, any full article obtained and submitted in electronic format must be done so in a manner compliant with the relevant contractual terms of use permitting the sponsor electronic access to the article. If the sponsor does not have sufficient copyright clearance, they are asked to submit references or links only, or details of contacts for unpublished research. NICE will then itself obtain full copies of all relevant papers or reports, paying a copyright fee where necessary. For unpublished studies for which a manuscript is not available, provide a structured abstract about future journal publication. If a structured abstract is not available, the sponsor must provide a statement from the authors to verify the data provided.

If a submission is based on preliminary regulatory recommendations, the sponsor must advise NICE immediately of any variation between the preliminary and final approval.

Document key

Boxed text with a grey background provides specific and/or important guidance for that section. This should not be removed.

Information in highlighted black italic is to help the user complete the submission and may be deleted.

The user should enter text at the point marked 'Response' or in the tables as appropriate. 'Response' text may be deleted.

List of tables and figures

Glossary of terms

Term	Definition
CVICU	Cardiovascular intensive care unit
CVOR	Cardiovascular operating room
DTI	Deep tissue injury
ED	Emergency department
HAPU	Hospital acquired pressure ulcer
IABP	Intra-aortic balloon pump
IADS	Incontinence Associated Dermatitis and its Severity
ICU	Intensive care unit
LVAD	Left ventricular assist device
MODS	Multiple organ dysfunction syndrome
NICE	National Institute for Health and Care Excellence
NPUAP	National Pressure Ulcer Advisory Panel
OPCABG	Off-pump coronary artery bypass graft
OR	Operating room
PMS	Post-marketing surveillance
RCT	Randomised controlled trial
RR	Relative risk
RVAD	Right ventricular assist device
SD	Standard deviation
SIRS	Systemic inflammatory response syndrome
STICU	Surgical trauma intensive care unit
TEWL	Transepidermal water loss
WOCN	Wound, ostomy, and continence nurse
WUWHS	World Union of Wound Healing Societies

Section A – Decision problem

Section A describes the decision problem, the technology and its clinical context. There is also information about ongoing studies, regulatory information and equality issues.

Sponsors should submit section A before the full submission (for details on timelines, see the NICE document 'Guide to the Medical Technologies Evaluation Programme process', available from www.nice.org.uk/mt

1 Statement of the decision problem

The decision problem is specified in the final scope issued by NICE. The decision problem states the key parameters that should be addressed by the information in the evidence submission. All statements should be evidence based and directly relevant to the decision problem.

Table A1: Statement of the decision problem

	Scope issued by NICE	Variation from scope	Rationale for variation
Population	Patients at risk or at high risk of pressure ulcers in acute care settings.	Also includes aged care setting	Whilst most of the studies address acute care settings, one randomised controlled trial (RCT) assesses the use of Mepilex® Border dressings in an aged care facility (Santamaria, 2018).

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.	Also includes use of Mepilex® Border as an adjunct to standard NHS clinical practice for patients considered 'at risk' of pressure ulcers. Mepilex® Border has the same multi-layered structure as Mepilex® Border Sacrum and Heel dressings. Mepilex® or Mepilex® Heel was also used in 3 included studies. Whilst the 5-layer, adherent, Mepilex Border is the dressing of choice the less complex 3-layer, non-adherent, dressing, Mepilex Heel, provides supporting evidence of performanc e and safety.	A prospective comparative cohort study by Yoshimura et al. (2016) demonstrated the effectiveness of Mepilex® Border when used in spinal surgery to prevent intraoperative pressure ulcers. The non-comparative observational studies by Bateman and Roberts (2013) and Sullivan (2013) also demonstrated the effectiveness of Mepilex® Border dressings in the prevention of pressure ulcers in hospitalised subjects.

Comparator(s)	Standard NHS clinical practice for patients considered 'at risk' of pressure ulcers. This includes: • Risk assessment with 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		

Cost analysis	Comparator(s): Standard of care (as listed in Comparator[s]) Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.			
Subgroups to be considered	None			
Special considerations, including issues related to equality	The device is likely to be beneficial to diabetic patients who may be at an increased risk of foot ulcers, patients who have had spinal injuries and people with restricted mobility. These groups of patients may be considered disabled if their conditions have a long term and substantial effect on their daily lives. Disability is a protected characteristic covered by the Equality Act 2010.			
Special considerations, specifically related to equality issues	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics?	No		
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No		
	Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?	No		

2 Description of technology under assessment

2.1 Give the brand name, approved name, and details of any different versions of the same device.

Mepilex® Border dressings (Mölnlycke Health Care) are self-adherent, multilayer foam dressings which include proprietary soft silicone technology (called Safetac®). They are available in various sizes; the company also provides variants which are specifically designed for use on the heel and sacrum, areas where there is a high risk of pressure ulcer formation.

Mepilex® Border dressings can be used for treating a wide range of wound types in people of all ages, but this submission focuses specifically on their use for preventing pressure ulcers and on the 3 variants designed for this indication (Mepilex® Border, Mepilex® Border Heel, and Mepilex® Border Sacrum).

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 is designed to allow the dressing to be easily peeled back and reapplied, thereby enabling multiple inspections of the skin site without needing to fully replace the dressing. The other 4 layers are variously designed to cushion, prevent stretch or tear, absorb moisture and allow moisture to evaporate.

The available dressings with CE marking and UK regulatory approval are:

Mepilex® Border Heel (18.5 x 24 cm)

Mepilex® Border Sacrum (15 x 15 cm)

Mepilex® Border Sacrum (18 x 18 cm)

Mepilex® Border Sacrum (23 x 23 cm)

Mepilex® Border (7 x 7.5 cm)

Mepilex® Border (10 x 12.5 cm)

Mepilex® Border (10 x 20 cm)

Mepilex® Border (10 x 30 cm)

Mepilex® Border (15 x 17.5 cm)

Mepilex® Border (17 x 20 cm)

2.2 What is the principal mechanism of action of the technology?

Independently conducted laboratory studies have demonstrated the ability of Mepilex® Border dressings to:

- **Displace pressure forces** from skin at risk of pressure injury (Call et al. 2015, Miller et al. 2015)
- **Reduce shear and friction** forces at point of application (De Wert et al. 2016)
- **Provide optimal microclimate** management (Call et al. 2013)

The primary cause of pressure ulcers is sustained mechanical load that is applied to tissue, generally in the vicinity of a bony prominence. Ischaemia, reperfusion injury, impaired lymphatic drainage and sustained cell deformation all contribute to pressure ulcers (National Pressure Ulcer Advisory Panel [NPUAP], 2014). Extrinsic risk factors for pressure ulcers include the direct application of pressure and three other elements – friction, shear, and microclimate (humidity / moisture and temperature) – that can potentiate the effects of pressure and are cross-linked to each other (NPUAP, 2014; World Union of Wound Healing Societies [WUWHS], 2016).

Research suggests that 'superficial' pressure ulcers (i.e. Category/Stage I and II) and 'deep' pressure ulcers (i.e. Category/Stage III and IV, and deep tissue injuries [DTIs]) result from different mechanisms (Sibbald, 2011; Oomens, 2013; Black, 2015). Friction and shear forces applied to the skin are thought to be important contributors to superficial pressure ulcers. The damage at the skin surface may progress to affect deep tissue (i.e. superficial pressure

ulcers develop ‘outside in’, ‘top down’. In contrast, deep pressure ulcers and DTIs are thought to be due mainly to deformation of deeper tissues resulting from pressure and shear. The damage occurs initially at the muscle/bone interface, and skin breakdown occurs late in the process, i.e. deep pressure ulcers develop ‘inside out’, ‘bottom up’ (WUWHS, 2016).

Based on the above, a prophylactic dressing for the prevention of pressure ulcers should be capable of providing considerable protection by reducing internal loading levels in deep soft tissues and on the skin. It should be able to dissipate tissue loads through a mechanism of deformations within the dressing layers and be durable enough to deliver these effects continuously over multiple days, even in a moist environment (Levy and Gefen, 2017).

Finite element modelling has been used to demonstrate the ability of Mepilex® Border dressings to reduce exposure of weight-bearing soft tissue to elevated strains and stress, highlighting the importance of the multi-layer construction to the efficacy of the dressings (Levy et al, 2015). However, not all multi-layer dressings can be expected to exert the same effects. For example, in finite element modelling studies by Lancon (2016) and Lancon (2016[a]), differences were observed between Mepilex® Border and comparative dressings in relation to pressure and shear in both dry and wet conditions. While Mepilex® Border was able to successfully reduce the pressure and stresses inside soft tissue when exposed to compression and in the case of shear induced by elevated positioning, the other two dressings did not perform as well, especially in the case of shear induced by elevated positioning. In offering an explanation for what sets Mepilex® Border apart from the other dressings in terms of durability and reducing pressure and sheer, the researchers referred to the presence of a ‘backbone’ (non-woven) layer in Mepilex® Border which gives the dressing anisotropic features. Anisotropy is the property of being directionally dependent, which implies different properties in different directions, such as machine dependent (i.e. axis longitudinal to the dressing) and cross dependent (i.e. axis perpendicular to the dressing), as opposed to isotropy where properties are the same in all directions. The anisotropy of

Mepilex® Border allows it to be more stretchable in the lateral (buttock cheeks) direction than along the direction of the spine when loaded, thereby protecting the soft tissues from deformation-inflicted tissue damage (Levy and Gefen, 2017). When exposed to a small amount of water, Mepilex® Border is able to retain its anisotropic features and, therefore, its durability. In contrast, the researchers observed some degradation with the other dressings tested in the presence of water (Lancon, 2016; Lancon, 2016[a]).

3 Clinical context

3.1 Provide a brief overview of the disease or condition for which the technology is being considered in the scope issued by NICE.

Pressure ulcers are caused when an area of skin and the underlying tissues are damaged as a result of being placed under pressure sufficient to impair its blood supply. Ischaemia, reperfusion injury, impaired lymphatic drainage and sustained cell deformation all contribute to pressure ulcers (NPUAP, 2014). Pressure ulcers typically occur in a person confined to bed or a chair by an illness (NICE, 2014). All patients 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. As pressure ulcers can arise in a number of ways, interventions for prevention and treatment need to be applicable across a wide range of settings including community and secondary care (NICE, 2014).

Pressure ulcers are often preventable and their prevention is included in domain 5 of the Department of Health's NHS outcomes framework 2014/15 (NICE, 2014). It has been reported that the prevalence of pressure ulcers in health-care settings around the world ranges from 0% to 72.5% (NPUAP, 2014), with large variations observed between different geographical regions and clinical settings. Data on pressure ulcer occurrence rates outside of acute care are relatively lacking. Hence, simply counting people with pressure ulcers

in hospital settings may considerably underestimate the total number affected (NPUAP, 2014).

Table A2: Pressure ulcer prevalence and incidence (adapted from NPUAP, 2014)

Setting / population	Prevalence rates	Incidence and facility acquired rates
Acute care	0–46%	0–12%
Critical care	13.1–45.5%	3.3–53.4%
Aged care	4.1–32.2%	1.9–59%
Paediatric care	0.47–72.5%	0.25–27%
OR	—	5–53.4%

3.2 Give details of any relevant NICE or other national guidance or expert guidelines for the condition for which the technology is being used. Specify whether the guidance identifies specific subgroups and make any recommendations for their treatment. If available, these should be UK based guidelines.

The following UK based guidelines are of relevance for the condition:

- Pressure ulcers: prevention and management. NICE clinical guideline 179 (2014)

The guideline identifies that all patients 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, or poor posture or a deformity. Also, the use of equipment such as seating or beds, which are not specifically designed to provide pressure relief, could cause pressure ulcers.

- Diabetic foot problems: prevention and management. NICE guidance 19 (2015, updated 2016)

The guideline identifies 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. On discharge they should be referred or notified to the foot protection service.

In addition, in line with the NICE guideline on pressure ulcers, the use of pressure-redistributing devices and strategies to minimise the risk of pressure ulcers developing are recommended.

The following international guidelines are also of relevance for the condition:

- NPUAP, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline. Haesler E. (Ed.). Cambridge Media: Perth, Australia, 2014.

The guidelines include the recommendation: '*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*'. The results of four clinical studies are cited in support of this recommendation, three of which investigated the efficacy of multi-layer Mepilex® Border dressings with Safetac® (Brindle and Wegelin, 2012; Walsh et al. 2012; Santamaria et al. 2015). A similar recommendation has been added to the section entitled 'Medical Device Related Pressure Ulcers': '*Consider using a prophylactic dressing for preventing medical device related pressure ulcers.*' Importantly, the Guideline also recommends that clinicians '*Continue to use all other preventive measures necessary when using prophylactic dressings*'.

- 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 2015;12(4):484-488.

The recommendations of a consensus panel on the use of prophylactic dressings as an adjunct to pressure injury prevention strategies included the following recommendations:

- Consider using a five-layer soft-silicone bordered foam dressing to enhance, but not replace, pressure ulcer prevention strategies for the sacrum, buttock and heel

- Consider placing a five-layer soft-silicone bordered foam dressing onto the buttocks and sacrum before prolonged procedures or anticipated events when the patient cannot move or be moved from the supine position

- Consider placing soft-silicone dressings onto the buttocks and sacrum when the head of the bed must be continuously elevated

- Consider placing multi-layer soft-silicone foam dressings on the heels before prolonged procedures or anticipated events when the patient's leg(s) cannot move or be moved from the supine position

- Consider placing multi-layer soft-silicone foam dressings to the heels of patients at risk of shear injury

- WUWHS Consensus Document. Role of dressings in pressure ulcer prevention. Wounds International, 2016.

The WUWHS consensus document on the role of dressings in pressure ulcer prevention suggested recommendations for prevention of pressure ulcers including:

If the patient has any of the following, then a prophylactic dressing should be applied to areas of the skin at risk:

- Immobility / planned immobility

- Loss of sensation that reduces spontaneous movement

- Reduced / restricted mobility, or atypical movement

- Medical device in situ
- Scarring due to a previous pressure ulcer

Once a prophylactic dressing has been applied, the skin underneath the dressing should be assessed at least daily and the dressing changed in line with the manufacturer's instruction. In the case of dressings applied beneath medical devices, the skin should be assessed when and if the device can be moved or removed.

The prophylactic dressing should continue to be used until the risk of pressure ulcer development has reduced significantly.

3.3 Describe the clinical pathway of care that includes the proposed use of the technology.

The NICE guideline on the prevention and management of pressure ulcers (2014) recommends that a documented risk assessment for pressure ulcers should be performed in certain adults. It recommends using a validated scale to support clinical judgement, and that risk be reassessed if there is a change in the patient's clinical status.

The guideline recommends various strategies for preventing pressure ulcers, including regular patient repositioning, foam mattresses and pressure redistribution cushions.

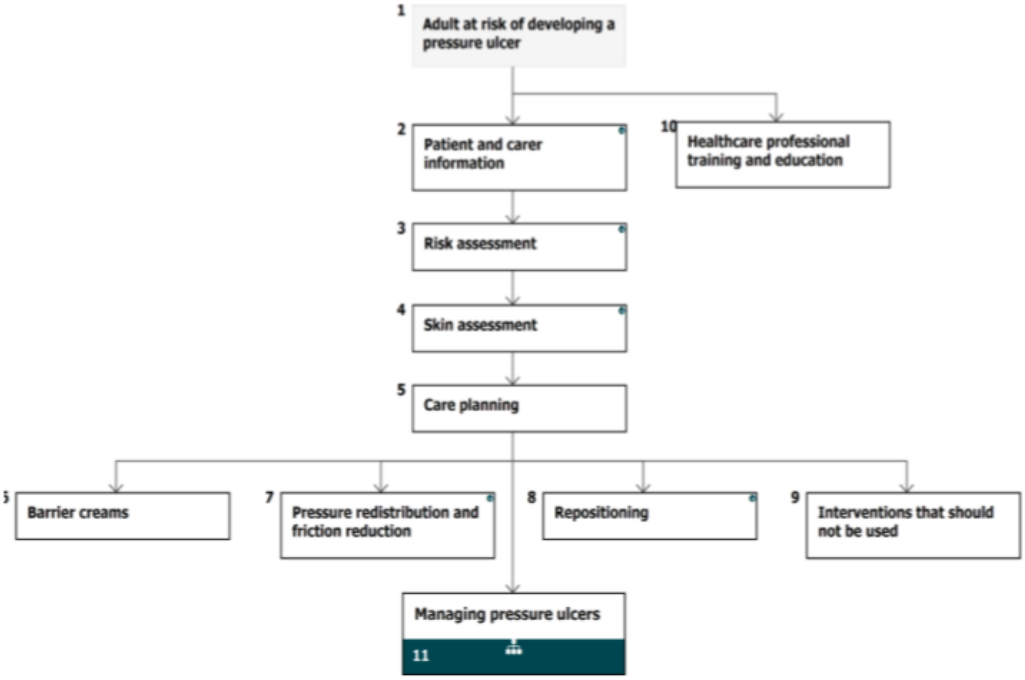
The NICE Pathway for preventing pressure ulcers in adults (2017, **Figure A1**) assesses pressure redistribution and friction reduction in section 7 and states that NICE has published a medtech innovation briefing on Mepilex® Border dressings for preventing pressure ulcers.

It is proposed that the addition of the use of prophylactic Mepilex® Border dressings to standard preventive measures will help to reduce the risk of pressure ulcers. For the patient in an acute care setting, this means:

- Greater satisfaction with overall care

- Lower risk of delayed hospitalisation (length of stay)
- Lower risk of wound infection
- Less pain and discomfort
- Less stress, anxiety and depression
- Greater autonomy and security
- Less impact on social functioning

Figure A1: NICE Pathways: Preventing pressure ulcers in adults (2017)



3.4 Describe any issues relating to current clinical practice, including any uncertainty about best practice.

New interventions that are increasingly being used for pressure ulcer prevention include:

- Establishment of accurate mechanisms for pressure ulcer incidence reporting (WUWHS, 2016)

- Adoption of SSKIN (Surface, Skin inspection, Keep moving (repositioning), Incontinence and moisture, Nutrition and hydration) bundles (an evidence-based set of preventive interventions; Whitlock, 2013)

- Provision of education and training (WUWHS, 2016)

- Adoption of change management principles to implement and sustain new evidence-based practices (WUWHS, 2016)

3.5 Describe the new pathway of care incorporating the new technology that would exist if the technology was adopted by the NHS in England.

Mepilex® Border dressings are intended for use as a component of standard preventive measures on 'at-risk' patients. The new pathway of care has recently been amended to include the medtech innovation briefing on Mepilex® Border dressings for preventing pressure ulcers in adults in section 7 of the pathway. If the technology was adopted by the NHS in England then this could be expanded to include the following guidance, as recommended by the WUWHS (2016).

The WUWHS consensus document includes an algorithm to guide clinicians as to when prophylactic dressings should be used. The algorithm is summarised below:

- If a patient is at risk of developing a pressure ulcer, a prevention protocol should be implemented (e.g. SSKIN pressure-redistributing support surface, regular skin inspection, repositioning, incontinence management and optimisation of nutrition)

- If the patient has any of the following, then a prophylactic dressing should be applied to areas of the skin at risk:

    - Immobility / planned immobility

    - Loss of sensation that reduces spontaneous movement

- Reduced / restricted mobility, or atypical movement
- Medical device in situ
- Scarring due to a previous pressure ulcer

➢ Once a prophylactic dressing has been applied, the skin underneath the dressing should be assessed at least daily and the dressing changed in line with the manufacturer's instruction. In the case of dressings applied beneath medical devices, the skin should be assessed when and if the device can be moved or removed

- The prophylactic dressing should continue to be used until the risk of pressure ulcer development has reduced significantly.

Mepilex® Border dressings could also be used in neonates, infants, children and young people as this population is also at risk of pressure ulcers and may benefit from the prophylactic use of these dressings. Whilst the clinical evidence has concentrated on the adult population the evidence could be extrapolated to younger age groups who are also at risk of developing pressure ulcers. At present there is no discussion of use of these devices in the NICE pathway for preventing pressure ulcers in neonates, children, and young people (2017).

3.6 Describe any changes to the way current services are organised or delivered as a result of introducing the technology.

It is not envisaged that the introduction of prophylactic Mepilex® Border dressings would require changes to the way in which current services are organised or delivered, nor would it require additional facilities or products. We would recommend that all staff involved in the use of prophylactic dressings are adequately trained in the dressing application and skin inspection techniques.

It is proposed that the addition of the use of prophylactic Mepilex® Border dressings to standard preventive measures will help to reduce the risk of pressure ulcers. For the health and social care system, this means:

- Reduced treatment / nursing / hospitalisation costs
- Reduced risk of incurring financial penalties
- Reduced risk of litigation

3.7 Describe any additional tests or investigations needed for selecting or monitoring patients, or particular administration requirements, associated with using this technology that are over and above usual clinical practice.

The use of prophylactic Mepilex® Border dressings would be an additional component of standard preventive measures, which would help to reduce the incidence of pressure ulcers. However, prophylactic dressings are intended to augment existing preventive measures, not to replace them.

An algorithm, developed by the WUWHS (2016) to guide clinicians as to when prophylactic dressings should be used, is summarised in section 3.5.

3.8 Describe any additional facilities, technologies or infrastructure that need to be used alongside the technology under evaluation for the claimed benefits to be realised.

It is not envisaged that the introduction of prophylactic Mepilex® Border dressings would require changes to the way in which current services are organised or delivered, nor would it require additional facilities or products.

3.9 Describe any tests, investigations, interventions, facilities or technologies that would no longer be needed with using this technology.

The use of prophylactic Mepilex® Border dressings would be an additional component of standard preventive measures, which would augment existing preventive measures, but not replace them.

3.10 Describe how the NHS in England can disinvest from tests, investigations, interventions, facilities or technologies described in section 3.9 that would no longer be needed with using this technology.

The use of prophylactic Mepilex® Border dressings would be an additional component of standard preventive measures so there would be no opportunity to disinvest from existing measures.

4 Regulatory information

4.1 Provide PDF copies of the following documents:

- instructions for use
- CE mark certificate or equivalent UK regulatory approval such as EC declaration of conformity
- quality systems (ISO 13485) certificate (if required).

PDF copies of these documents have been submitted at the same time as section A.

4.2 Does the technology have CE mark for the indication(s) specified in the scope issued by NICE? If so, give the date that authorisation was received. If not, state current UK regulatory status, with relevant dates (for example, date of application and/or expected approval dates).

Mepilex® Border was CE marked as a class IIb medical device in 2001. It has been indicated to be used as part of a prophylactic therapy to help prevent

skin damage (e.g. pressure ulcers, postoperative blistering) since 2011, as listed in the products' instructions for use.

4.3 Does the technology have regulatory approval outside the UK? If so, please provide details.

Mepilex® Border dressings have regulatory approval and are sold in over 70 countries across the world.

4.4 If the technology has not been launched in the UK provide the anticipated date of availability in the UK.

Mepilex® Border, Mepilex® Border Sacrum, and Mepilex® Border Heel dressings are all currently available in the UK.

4.5 If the technology has been launched in the UK provide information on the use in England.

Mepilex® Border dressings are currently being used at:

- University College London Hospitals NHS Trust (use on ICU patients)
- Queen Victoria Hospital, Brighton (use on burns patients)
- Royal Liverpool and Broadgreen Hospital, Liverpool (use on critical care patients)
- Countess of Chester Hospital, Chester (use on critical care patients)
- County Durham & Darlington NHS Foundation Trust, Darlington (use on orthopaedic patients as part of fractured neck of femur pathway following spinal anaesthesia)
- Papworth Hospital NHS Foundation Trust, Cambridge (use on patients undergoing transplantation or receiving extracorporeal membrane oxygenation)

5 Ongoing studies

5.1 Provide details of all completed and ongoing studies on the technology from which additional evidence relevant to the decision problem is likely to be available in the next 12 months.

Santamaria (2018). A randomised controlled trial of the clinical effectiveness of multi-layer silicone foam dressings for the prevention of pressure injuries in high-risk aged care residents: The Border III Trial.

Jin (2018, unpublished). [redacted]

[redacted]

Both of these studies are discussed in section 7 in more detail.

5.2 If the technology is, or is planned to be, subject to any other form of assessment in the UK, please give details of the assessment, organisation and expected timescale.

There is no planned or ongoing evaluation of this product by a UK national organisation, to the best of our knowledge.

6 Equality

NICE is committed to promoting equality of opportunity and eliminating unlawful discrimination on the grounds of age, disability, gender reassignment, race, religion or belief, sex, and sexual orientation, and to comply fully with legal obligations on equality and human rights.

Equality issues require special attention because of NICE's duties to have due regard to the need to eliminate unlawful discrimination, promote equality and foster good relations between people with a characteristic protected by the equalities legislation and others.

Any issues relating to equality that are relevant to the technology under assessment should be described. This section should identify issues described in the scope and also any equality issues not captured in the final scope.

Further details on equality may be found in section 11.3 of this document.

6.1.1 Describe any equality issues relating to the patient population and condition for which the technology is being used.

The device is likely to be beneficial to diabetic patients who may be at an increased risk of foot ulcers, patients who have had spinal injuries and people with restricted mobility. These groups of patients may be considered disabled if their conditions have a long term and substantial effect on their daily lives. Disability is a protected characteristic covered by the Equality Act 2010.

6.1.2 Describe any equality issues relating to the assessment of the technology that may require special attention.

There are no equality issues relating to the assessment of the technology that require special attention.

6.1.3 How will the submission address these issues and any equality issues raised in the scope?

The submission will address all clinical evidence in relation to the decision problem including high risk groups, such as diabetic patients, patients who have had spinal injuries, and people with restricted mobility.

Section B – Clinical evidence

7 Published and unpublished clinical evidence

Section B requires sponsors to present published and unpublished clinical evidence for their technology.

Sponsors should read section 6 of the Medical Technologies Evaluation Programme methods guide on published and unpublished evidence, available from www.nice.org.uk/mt

All statements should be evidence-based and directly relevant to the scope. Reasons for deviating from the scope should be clearly stated and explained in table A1.

Sponsors are required to submit section B in advance of the full submission (for details on timelines, see the NICE document 'Guide to the Medical Technologies Evaluation Programme process', available from www.nice.org.uk/mt

7.1 Identification of studies

Published studies

7.1.1 Describe the strategies used to retrieve relevant clinical data from the published literature. Exact details of the search strategy used should be provided in section 10, appendix 1.

The review process was conducted and the results were reported following the PRISMA statement. The search strategy comprised the following main elements: A search of two electronic bibliographic databases (MEDLINE and Embase) was performed on 5th January 2018 for studies that met the

inclusion criteria. The full search strategy is provided in section **10.3**, appendix 1, but a summary of the strategy was:

S1 (bed sore* or bedsore*) OR (pressure (ulcer* or sore* or injury) OR (decubitus (ulcer* or sore* or injury)

S2 mepilex OR (foam dressing)

S1 AND S2 AND prevent*

Bibliographies of included studies were searched for further relevant studies.

Unpublished studies

7.1.2 Describe the strategies used to retrieve relevant clinical data from unpublished sources.

Hand-searching of internal company documentation was performed to identify any relevant unpublished data. Any evidence generated by Mölnlycke Health Care in any country, including confidential and unpublished evidence, was included.

Searching of the Mölnlycke database of all known published or unpublished papers assessing Mepilex® Border dressings.

7.2 Study selection

Published studies

7.2.1 Complete table B1 to describe the inclusion and exclusion criteria used to select studies from the published literature. Suggested

headings are listed in the table below. Other headings should be used if necessary.

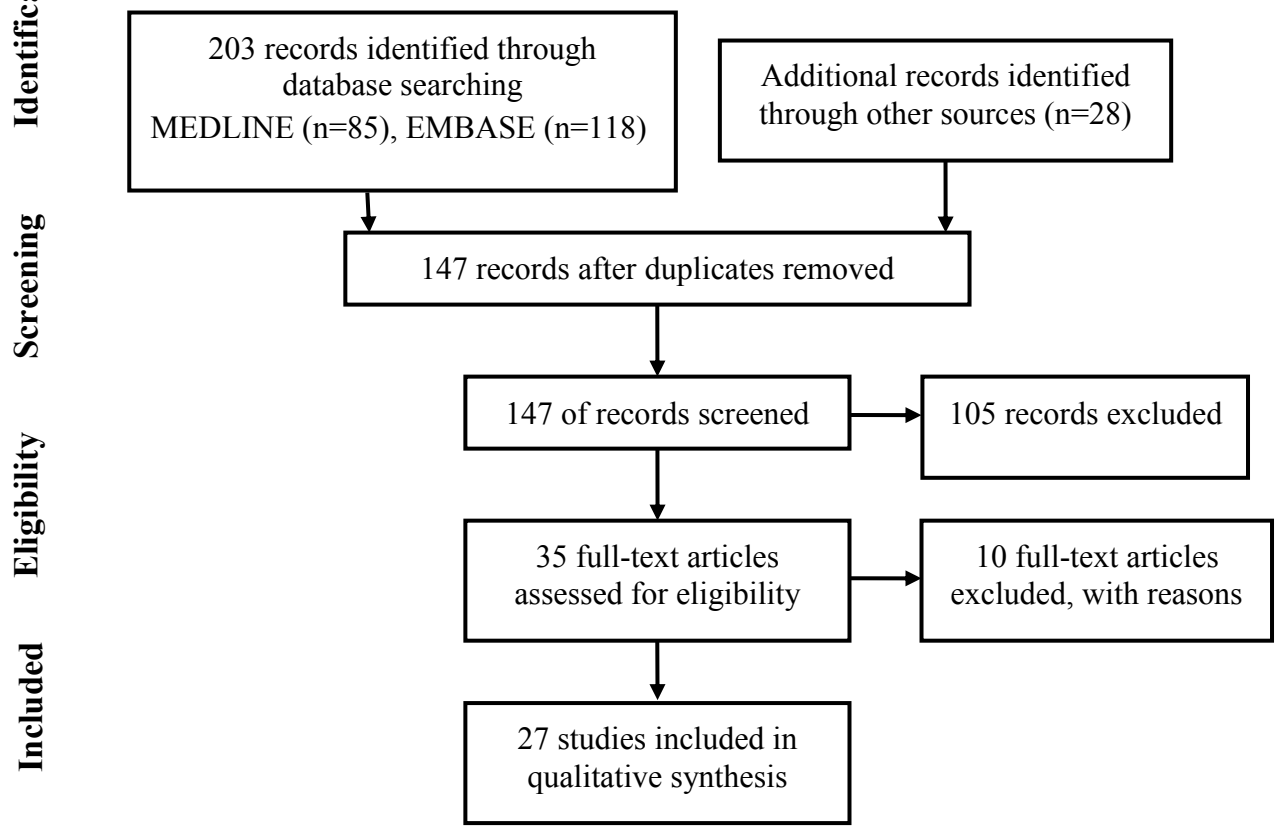
Table B1: Selection criteria used for published studies

Inclusion criteria	
Population	People at risk of developing pressure ulcers but with no signs of established pressure damage (≤category 1 pressure ulcers, as defined by NPUAP et al. [2014] or equivalent validated scale).
Interventions	Use of any Mepilex® Border dressing to assist pressure ulcer prevention as an adjunct to standard pressure ulcer prevention procedures.
Outcomes	• Incidence of developing pressure ulcers • Incidence of skin breakdown at the heel and sacrum • Level of patient satisfaction • Length of hospital stay • Patient compliance with pressure ulcer prevention strategies • Level of pain and discomfort and impact on quality of life • Patients ability to self-reposition in bed • Complications avoided from pressure ulcer prevention e.g. infection, abscess, septicaemia, bone infections, meningitis • Ease of use of product • Cost effectiveness
Study design	Systematic reviews, randomised, non-randomised, cohort, case studies, observational and qualitative studies.
Language restrictions	No language restrictions.
Search dates	The databases (MEDLINE and EMBASE) were searched from inception to the date of the search, but studies were only considered if published after the introduction of Mepilex® dressings (2001).
Exclusion criteria	
Population	People at risk of developing pressure ulcers but who already have established pressure damage (>category 1 pressure ulcers, as defined by NPUAP et al. [2014] or equivalent validated scale).
Interventions	Any intervention that was not a Mepilex® Border dressing being used as part of a pressure ulcer prevention programme.
Outcomes	Any outcomes that were unrelated to pressure ulcer prevention (e.g. pressure ulcer healing, the prevention and treatment of other chronic and acute wounds).
Study design	Studies not using Mepilex® Border dressings to augment pressure ulcer prevention, testimonials, non-systematic reviews containing no primary data, editorials, in vitro, healthy volunteer studies.
Language restrictions	None

Search dates	Studies published before the introduction of Mepilex® dressings (2001). Any studies published after 4th January 2018, any studies not indexed in MEDLINE or EMBASE on 4th January, 2018.

7.2.2 Report the numbers of published studies included and excluded at each stage in an appropriate format.

Figure A2: PRISMA flow diagram of included and excluded published studies



Unpublished studies

7.2.3 Complete table B2 to describe the inclusion and exclusion criteria used to select studies from the unpublished literature. Suggested

headings are listed in the table below. Other headings should be used if necessary.

Table B2 Selection criteria used for unpublished studies

Inclusion criteria	
Population	People at risk of developing pressure ulcers but with no signs of established pressure damage (≤category 1 pressure ulcers, as defined by NPUAP et al. [2014] or equivalent validated scale).
Interventions	Use of any Mepilex® Border dressing to assist pressure ulcer prevention as an adjunct to standard pressure ulcer prevention procedures.
Outcomes	• Incidence of developing pressure ulcers • Incidence of skin breakdown at the heel and sacrum • Level of patient satisfaction • Length of hospital stay • Patient compliance with pressure ulcer prevention strategies • Level of pain and discomfort and impact on quality of life • Patients ability to self-reposition in bed • Complications avoided from pressure ulcer prevention e.g. infection, abscess, septicaemia, bone infections, meningitis • Ease of use of product • Cost effectiveness
Study design	Systematic reviews, randomised, non-randomised, cohort, case studies, observational and qualitative studies.
Language restrictions	No language restrictions.
Search dates	Databases were searched from before the introduction of Mepilex® dressings (2001) to the date of the search (4th January, 2018).
Exclusion criteria	
Population	People at risk of developing pressure ulcers but who already have established pressure damage (>category 1 pressure ulcers, as defined by NPUAP et al. [2014] or equivalent validated scale).
Interventions	Any intervention that was not a Mepilex® Border dressing being used as part of a pressure ulcer prevention programme.
Outcomes	Any outcomes that were unrelated to pressure ulcer prevention (e.g. pressure ulcer healing, the prevention and treatment of other chronic and acute wounds).
Study design	Studies not using Mepilex® Border dressings to augment pressure ulcer prevention, testimonials, non-systematic reviews containing no primary data, editorials, in vitro, healthy volunteer studies.
Language restrictions	None

Search dates	Studies published before the introduction of Mepilex® dressings (2001). Any studies published after 4th January 2018.

7.2.4 Report the numbers of unpublished studies included and excluded at each stage in an appropriate format.

Nine unpublished studies were considered and included.

7.3 Complete list of relevant studies

The sponsor should provide a PDF copy of all studies included in the submission if the sponsor is either the copyright owner or has adequate copyright clearance to permit the intended use by NICE. If the sponsor does not have sufficient copyright clearance, they are asked to submit references or links only, or details of contacts for unpublished studies. For unpublished studies for which a manuscript is not available, provide a structured abstract about future journal publication. If a structured abstract is not available, the sponsor must provide a statement from the authors to verify the data provided.

7.3.1 Provide details of all published and unpublished studies identified using the selection criteria described in tables B1 and B2.

Table B3 List of relevant published studies

Primary study reference	Study name (acronym)	Population	Intervention	Comparator
Aloweni et al. (2017)	A randomised controlled trial to evaluate the incremental effectiveness of a prophylactic dressing and fatty acids oil in the prevention of pressure injuries.	High-risk (Braden score ≤14) patients from medical and surgical wards.	1. Standard care plus Mepilex® Border Sacrum	2. Fatty acids oil spray plus standard care 3. Standard care only
Bateman and Roberts (2013)	Moisture lesions and associated pressure ulcers - getting the dressing regime right.	Acute wound care service referrals with reduced skin integrity due to incontinence, sweat, or wound exudate resulting in erythema, maceration, or combined with pressure ulcer formation	Depending on skin or wound type, patients commenced on standard care plus management regimen of: (i) skin-protecting barrier product as primary layer; overlain by (ii) Mepilex® Border	No comparator
Black et al. (2014)	Dressings as an adjunct to pressure ulcer prevention: consensus panel recommendations	High-risk patients, emergency department (ED), intensive care unit (ICU) and operating room (OR)	Standard care plus any prophylactic dressing	Standard care ± any prophylactic dressing
Black (2016)	Medical device-related pressure ulcers.	Hospital adult and paediatric populations	Standard care plus Mepilex® Border Sacrum	No comparator
Brindle (2010)	Outliers to the Braden Scale: identifying high-risk ICU patients and the results of prophylactic dressing use.	STICU	Standard care plus Mepilex® Border Sacrum	No comparator
Brindle and Wegelin (2012)	Prophylactic dressing application to reduce pressure ulcer formation in cardiac surgery patients.	Cardiac surgery ICU	Standard care plus Mepilex® Border Sacrum	Standard care

Cano (2011)	Efficacy of the prophylactic use of silicone foam dressing for the prevention of pressure ulcers in patients: an observational study in a 24 bed cardiovascular and cardiac intensive care unit.	Cardiovascular intensive care unit (ICU) and critical care unit	Standard care plus soft silicone foam applied to sacral area	No comparator
Chaiken et al. (2012)	Reduction of sacral pressure ulcers in the intensive care unit using a silicone border foam dressing.	ICU	Standard care plus Mepilex® Border Sacrum	No comparator
Clark et al. (2014)	Systematic review of the use of prophylactic dressings in the prevention of pressure ulcers.	Primary and secondary care patients at risk of developing pressure ulcers but with no signs of established pressure damage including category 1 pressure ulcers.	Standard care plus any prophylactic dressing	Standard care ± any prophylactic dressing Comparing dressings (not relevant to Mepilex® Border studies)
Cooper (2015)	In our unit. Against all odds: preventing pressure ulcers in high-risk cardiac surgery patients.	Cardiac surgery ICU	Mepilex® Border and Mepilex® Border Sacrum used as part of bundle of measures to reduce pressure ulcer incidence.	No comparator
Cornish (2017)	The use of prophylactic dressings in the prevention of pressure ulcers: a literature review.	All studies assessing *in vitro* and clinical evidence of prophylactic dressings in the prevention of pressure ulcers.	All studies where prophylactic dressings used.	All prophylactic dressings

Cubit et al. (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.	High risk or very high risk medical patients >65 years of age without existing pressure ulcer.	Standard care plus any prophylactic dressing	No comparator
de Wert (2016)	Improving the effect of shear on skin viability with wound dressings.	Healthy volunteers	Mepilex® Border	Aquacel (ConvaTec, UK), Allevyn Adhesive (Smith and Nephew, UK).
Huang et al. (2015)	Dressings for preventing pressure ulcers: a meta-analysis.	Any care settings (e.g, acute care, homecare, long-term care, rehabilitation, palliative care).	Any topical application of dressings or skin preparation for pressure ulcer prevention.	Any topical application of dressings or skin preparation for pressure ulcer prevention.
Johnstone and McGown (2013)	Innovations in the reduction of pressure ulceration and pain in critical care.	Critical care	Standard care plus Mepilex® Border Sacrum dressings	No comparator
Kalowes et al. (2016)	Five-layered soft silicone foam dressing to prevent pressure ulcers in the intensive care unit.	Medical/Surgical/ Trauma ICU, Cardiac ICU	Standard care plus silicone foam dressing (Mepilex® Border Sacrum)	Standard care
Kiely (2012)	Cultural transformation in pressure ulcer prevention and care.	Acute care, long-term care, and ambulatory facilities	Mepilex® Border Sacrum used as part of bundle of measures to reduce pressure ulcer incidence.	No comparator

Koerner and Adams (2011)	Save our sacrums (S.O.S.) Does the use of an absorbent soft silicone self-adherent bordered foam dressing decrease the incidence of hospital acquired pressure ulcers (HAPUs)?	Medical/Cardiac and Surgical ICU	Standard care plus soft silicone dressing (Mepilex® Border Sacrum)	No comparator
Miller et al. (2015)	Analysis of the pressure distribution qualities of a silicone border foam dressing.	Healthy volunteer study	Mepilex® Border Heel	Without heel dressing
Moore and Thorpe (2015)	Dressings for pressure ulcer prevention. Made Easy.	Critical care unit	Standard care plus Mepilex® Border Sacrum	No comparator
Moore and Webster (2013)	Dressings and topical agents for preventing pressure ulcers.	ICU and critical care unit	All dressings and topical agents	Any intervention
NPUAP et al. (2014)	Prevention and treatment of pressure ulcers: Clinical Practice Guideline.	All patients	All preventive strategies	No comparator or any relevant comparator
Padula (2017)	Effectiveness and value of prophylactic 5-layer foam sacral dressings to prevent hospital-acquired pressure injuries in acute care hospitals.	Acute care settings	Standard care plus Mepilex® Border Sacrum	Standard care plus no prophylactic 5-layer foam sacral dressings (Mepilex® Border Sacrum)
Park (2014)	The effect of a silicone border foam dressing for prevention of pressure ulcers and incontinence associated dermatitis in intensive care unit patients.	ICU patients	Standard care plus Mepilex® Border Sacrum	Standard care

Qiuli and Qiongyu (2010)	[Observation on effect of Mepilex® on the prevention and treatment of pressure sores].	High-risk neurosurgical patients (Waterlow score = 18-23)	Standard care plus Mepilex® or Mepilex® Border	Standard care with no dressings
Richard-Denis et al. (2017)	Effectiveness of a multi-layer foam dressing in preventing sacral pressure ulcers for the early acute care of patients with a traumatic spinal cord injury: comparison with the use of a gel mattress.	Traumatic spinal cord injury	Self-adherent multi-layer sacral foam dressing (Mepilex® Border Sacrum)	Gel mattress
Santamaria et al. (2015)	A randomised controlled trial of the effectiveness of soft silicone multi-layered foam dressings in the prevention of sacral and heel pressure ulcers in trauma and critically ill patients: the border trial.	ED and ICU admission for critical illness and/or major trauma	Standard care plus Mepilex® Border Sacrum and Mepilex® Heel dressing plus Tubifast® retention bandage	Standard care with no dressings
Santamaria et al. (2014)	An estimate of the potential budget impact of using prophylactic dressings to prevent hospital-acquired PUs in Australia.	High-risk patients in public hospitals across Australia	Standard care plus Mepilex® Border Sacrum and Mepilex® Heel dressing plus Tubifast® retention bandage	Standard care with no dressings
Santamaria et al. (2015[a])	Clinical effectiveness of a silicone foam dressing for the prevention of heel pressure ulcers in critically ill patients: Border II Trial.	ICU	Standard care plus Mepilex® Border Heel plus Tubifast® retention bandage	Standard care with no dressings

Santamaria et al. (2015[b])	The cost-benefit of using soft silicone multi-layered foam dressings to prevent sacral and heel pressure ulcers in trauma and critically ill patients: a within-trial analysis of the Border Trial.	ED and ICU admission for critical illness and/or major trauma	Standard care plus Mepilex® Border Sacrum and Mepilex® Heel dressing plus Tubifast® retention bandage	Standard care with no dressings
Sullivan (2015)	Use of a soft silicone foam dressing to change the trajectory of destruction associated with suspected deep tissue pressure ulcers.	Hospitalised subjects	Standard care plus Mepilex® Border Sacrum, Mepilex® Border Heel, Mepilex® Border.	No comparator
Tariq (2014)	Pressure ulcer prevalence and prevention in Sheikh Khalifa Medical City, Abu Dhabii.	ICU	Mepilex® Border Sacrum applied as part of a bundle of measures.	No comparator
Tayyib and Coyer (2016)	Effectiveness of pressure ulcer prevention strategies for adult patients in intensive care units: a systematic review.	ICU	Single strategies designed to reduce the incidence and prevalence of HAPU development in ICUs	Any comparator
Walsh et al. (2012)	Use of a sacral silicone border foam dressing as one component of a pressure ulcer prevention program in an intensive care unit setting.	ICU	Standard care plus Mepilex® Border Sacrum	No comparator

Yoshimura et al. (2016)	Soft silicone foam dressing is more effective than polyurethane film dressing for preventing intraoperatively acquired pressure ulcers in spinal surgery patients: the Border operating room Spinal Surgery (BOSS) trial in Japan.	Spinal surgery	Standard care plus Mepilex® Border applied to the left sides of the chest and iliac crest.	Polyurethane film dressings (Opsite Flexifix, Smith and Nephew) applied to the right sides of the chest and iliac crest.

Table B4 List of relevant unpublished studies

Data source	Study name (acronym)	Population	Intervention	Comparator
Baker (2014)	Nursing driving excellence: preventing pressure ulcers in the high-risk population.	Cardiovascular Intensive Care Unit (CVICU), Surgical Trauma Intensive Care Unit (STICU), Cardiovascular OR (CVOR)	Standard care plus Mepilex® Border and Mepilex® Border Heel	No comparator
Daukste (2014)	Mepilex® Border Sacrum dressing use for pressure ulcers prevention in period of open heart surgery and in intensive care unit.	Open heart surgery and ICU	Standard care plus Mepilex® Border Sacrum dressing	No comparator
Edwards and Lynch (2014)	Head over heels for prevention: use of a silicone bordered foam heel dressing in the prevention of pressure ulcers.	High-risk patients on ICU	Standard care plus Mepilex® Border Heel dressings	No comparator
Gentry and Wright (2010)	The 'Sacral Heart' Dressing Study: use of an absorbent self-adherent soft silicone sacral foam dressing across acute care settings.	High-risk patients on critical care unit.	Standard care plus Mepilex® Border Sacrum dressings (not named in paper)	No comparator
Haisley et al. (2015)	An ounce of prevention: the use of an absorbent soft silicone self-adherent bordered foam heel dressing to decrease the incidence of hospital-acquired heel pressure ulcers in an acute care setting.	Coronary care and SVICU	Standard care plus Mepilex® Border Heel dressings	Standard care as retrospective group

Lientz (2013)	Dollars and sense: economic value in HAPU/sDTI prevention.	Coronary care unit, ICU, CVICU and CVOR	Standard care plus Mepilex® Border Sacrum	No comparator
Muldoon (2010)	Initial use absorbent soft silicone self-adherent bordered foam dressing reduces sacral pressure ulcers in the cardiovascular ICU.	Surgical Trauma ICU	Standard care plus Mepilex® Border Sacrum	No comparator
Santamaria (2018)	A randomised controlled trial of the clinical effectiveness of multi-layer silicone foam dressings for the prevention of pressure injuries in high-risk aged care residents: The Border III Trial	High-risk aged care residents	Standard care plus Mepilex® Border Sacrum and Mepilex Heel plus Tubifast® retention bandage	Standard care
Jin (2018)	[redacted]	[redacted]	[redacted]	[redacted]

7.3.2 State the rationale behind excluding any of the published studies listed in tables B3 and B4.

Table B5: List of excluded studies

Study name	Reason for Exclusion
Black (2016)	Review article with no details on sample size for any original research.
Cano (2011)	Limited information from conference abstract available. Silicone foam dressing placed over sacral skin to reduce pressure ulcer levels.

Cooper (2015)	Study assessed the introduction of a bundle of measures to reduce pressure ulcer levels, which included Mepilex® Border and Mepilex® Border Sacrum. No data regarding the contributory effect of Mepilex® Border Sacrum dressing.
de Wert (2016)	Healthy volunteer study, demonstrates how the dressing improves the effect of shear on skin, but not in indicated population group.
Kiely (2012)	Mepilex® Border Sacrum used as part of bundle of measures to reduce pressure ulcer incidence. No details on number of patients treated with dressing.
Miller et al. (2015)	Healthy volunteer study, demonstrates mode of action of dressing, but not in indicated population group.
Moore and Thorpe (2015)	Study assessed the introduction of a bundle of measures to reduce pressure ulcer levels, which included Mepilex® dressings. No details on number of patients treated with dressing.
Santamaria et al. (2014)	Study assessed cost-effectiveness of dressings compared with standard care for all high-risk patients in public hospitals across Australia, but all primary performance data was taken from the RCT by Santamaria et al. (2015).
Santamaria et al. (2015[b])	Study assessed cost-effectiveness of dressings compared with standard care for the within-study population from the RCT by Santamaria et al. (2015).
Tariq (2014)	Study assessed the introduction of a bundle of measures to reduce pressure ulcer levels, which included Mepilex® Border Sacrum. No data regarding the contributory effect of Mepilex® Border Sacrum dressing.

7.4 Summary of methodology of relevant studies

7.4.1 Describe the study design and methodology for each of the published and unpublished studies using tables B5 and B6 as appropriate. A separate table should be completed for each study.

Table B5.1: Summary of methodology for RCTs: Aloweni et al. (2017)

Study name	A randomised controlled trial to evaluate the incremental effectiveness of a prophylactic dressing and fatty acids oil in the prevention of pressure injuries.
Objectives	To evaluate the incremental effectiveness of silicone foam dressing and fatty acids oil spray, in addition to standard care, in preventing sacral pressure injuries among high-risk patients.
Location	Singapore

Design	RCT
Duration of study	Up to 14 days or duration of hospital stay.
Sample size	461
Inclusion criteria	≥21 years of age, no pre-existing pressure injuries, high risk of developing pressure injuries (≤14 using the Braden Scale).
Exclusion criteria	Existing sacral pressure injury, allergy to fatty acids oil or silicone dressing, faecal incontinence at time of hospital admission.
Method of randomisation	Using a computer-generated table of simple random sampling (ratio 1:1:2), patients were allocated into 1 of 3 treatment arms.
Method of blinding	Patients and data collectors were not blinded.
Intervention(s) (n = 129) and comparator(s) (1: n = 130, 2: n = 202)	Intervention: standard care plus Mepilex® Border Sacrum Comparators: 1. Fatty acids oil spray plus standard care 2. Standard care (included repositioning of patients every 2 to 3 hours when in bed, use of positioning devices, use of alternating air mattress, use of slide sheets, elimination rounds and incontinence pads, skin care e.g. barrier cream or emollient cream).
Baseline differences	Groups were comparable on all major physiological and demographic characteristics upon admission.
Duration of follow-up, lost to follow-up information	Patients were followed up every 3 days to 14 days. End point data collection was when a pressure ulcer developed or when the patient was discharged home or to another institute. Patients who developed diarrhoea or sensitivity reactions to the dressing material or the fatty acids oil were considered as dropped-out. Consort patient flow provided, drop-out rate provided.
Statistical tests	Descriptive statistics were used to describe characteristics of participants. Chi-square tests used to evaluate differences in demographic variables and incidence of pressure injuries among the 3 treatment groups. Participants were also categorised according to their Braden score, and Fisher's exact test with a two-sided significance level of 0.05 used to evaluate statistical significance of incidence of pressure injuries within each subgroup.
Primary outcomes (including scoring methods and timings of assessments)	Pressure ulcers were assessed according to NPUAP (2014) with any event ≥ stage I pressure ulcer reported. Sacra were assessed at least once a day and the conditions were documented by the registered nurses. A study investigator also assessed patients' sacra every 3 days.

Secondary outcomes (including scoring methods and timings of assessments)	Analysis of sub-groups according to association of Braden score and incidence of pressure ulcers.

Table B5.2: Summary of methodology for RCTs: Kalowes et al. (2016)

Study name	Five-layered soft silicone foam dressing to prevent pressure ulcers in the intensive care unit.
Objectives	- To determine the effectiveness of a silicone foam dressing in preventing sacral pressure ulcers in comparison with standard care in critically ill patients. - To examine the role of multiple variables as potential correlates to pressure ulcers.
Location	USA
Design	RCT
Duration of study	Duration of ICU stay.
Sample size	366
Inclusion criteria	≥ 18 years of age, Braden score of ≤ 13, intact sacral skin
Exclusion criteria	Braden score ≥ 14, existing sacral pressure ulcers, moisture-related skin damage on admission, receiving end-of-life care, undergoing withdrawal of life-sustaining treatments.
Method of randomisation	Randomly permuted block design was used with 1:1 randomisation of patients within randomly selected blocks of 2, 4, or 6 patients. The ordering of patients within each block was also randomly assigned by using a computerised research randomiser.
Method of blinding	Non-blinded.
Intervention(s) (n = 184) and comparator(s) (n = 182)	Intervention: standard care plus Mepilex® Border Sacrum. Comparator: standard care (included the use of a low-air-loss bed, regular repositioning, and skin care).
Baseline differences	The 2 groups did not differ significantly in demographics or major physiological variables, including the Acute Physiology and Chronic Health Evaluation III severity-of-illness score.
Duration of follow-up, lost to follow-up information	Patients were followed-up within 24 hours of admission to the ICU throughout their ICU stay. No patients lost to follow-up.
Statistical tests	Descriptive statistics were used to analyse patients' characteristics and all physiological and demographic variables. Pressure ulcer cumulative incidence was compared between the 2 groups and by anatomical site per patient through the calculation of inferential statistics and use of the Fisher exact test. Poisson regression analysis was used to analyse the

	significance of incidence rate ratio, comparing specific factor level (variables) against a reference category to identify final high-risk variables. A survival analysis was used to determine the difference in pressure ulcer incidence rates per group and time to provide a hazard ratio between the groups. Hazard ratios were estimated by using Cox proportional hazard models.
Primary outcomes (including scoring methods and timings of assessments)	To determine the difference in the incidence rate of sacral HAPU formation between 2 groups of critically ill patients. Pressure ulcers were staged according to NPUAP (2014). All patients were seen each day of their ICU stay by a member of the research team who checked to see if a HAPU had developed. When patients were transferred to medical/surgical units, the experimental dressing was removed. Pressure ulcer outcome data (incidence of pressure ulcers, ICU unit, location/stage of pressure ulcers, number of pressure ulcers per patient, length of stay, mortality) were tracked throughout the hospital stay via the electronic medical record. Patients were followed up for 6 months after discharge; any readmissions with pressure ulcers or deaths were noted.
Secondary outcomes (including scoring methods and timings of assessments)	To examine risk factors for HAPUs in critically ill patients and to explicate cost savings related to prevention of pressure ulcers. The hospital's electronic billing/receiving management system was used to retrieve data on ICU and hospital length of stay, expressed in days.

Table B5.3: Summary of methodology for RCTs: Qiuli and Qiongyu (2010)

Study name	Observation on Effect of Mepilex® on the Prevention and Treatment of Pressure Sores
Objectives	Incidence of HAPUs
Location	China
Design	RCT
Duration of study	7 days
Sample size	52
Inclusion criteria	Not stated.
Exclusion criteria	Not stated.
Method of randomisation	Not stated.
Method of blinding	Not stated.

Intervention(s) (n = 26) and comparator(s) (n = 26)	Intervention: standard care plus Mepilex® applied after skin cleansing, mainly at sacrococcygeal region, followed by the hip. Mepilex® was used on the heel in cases of paralysis of lower limbs and where it could not closely adhere to the ankles and fell off, Mepilex® Border was used. Comparator: standard care (air-cushion beds and patients repositioned every 2 to 3 hours. Patients that could not be repositioned every 2 to 3 hours were given a hand massage at their pressed site of the body every 2 to 3 hours).
Baseline differences	No significant differences between the two groups in terms of gender, age, and condition (p>0.05). Both groups: Waterlow pressure sore score = 18 to 23, haemoglobin = 90g/l to 110g/1, fasting blood glucose = 4.2 to 6.5mmol/l. There were 16 patients suffering from incontinence. Patients were randomly divided into two groups: 26 were in the intervention group with 14 males and 12 females and 26 were in the comparator group with 11 males and 15 females. Not stated if there were other areas matched, e.g. levels of incontinence.
Duration of follow-up, lost to follow-up information	Not stated.
Statistical tests	Not stated.
Primary outcomes (including scoring methods and timings of assessments)	Incidence of HAPUs. The dressing was replaced every 1 to 3 days according to the wound conditions. Treatment effect scale 'cure, excellence, improvement, ineffectiveness' described. No further details on scoring methods or time of assessments for assessing effect of dressings for prevention.
Secondary outcomes (including scoring methods and timings of assessments)	None stated.

Table B5.4: Summary of methodology for RCTs: Santamaria et al. (2015)

Study name	A randomised controlled trial of the effectiveness of soft silicone multi-layered foam dressings in the prevention of sacral and heel pressure ulcers in trauma and critically ill patients: the border trial.
Objectives	To determine the effectiveness of multi-layered soft silicone foam dressings in preventing sacral and heel pressure ulcer development in trauma/critically ill ICU patients by applying the dressings on admission to the ED.
Location	Australia
Design	RCT
Duration of study	Dressings applied on admission to ED and were maintained during duration of ICU stay.

Sample size	440
Inclusion criteria	> 18 years of age, ED and ICU admission for critical illness and/or major trauma.
Exclusion criteria	Suspected or actual spinal injury precluding the patient being turned, pre-existing sacral or heel pressure ulcer, trauma to sacrum and/or heels.
Method of randomisation	Retrieving the next envelope in a pre-prepared series of envelopes that had been randomised using a computer generated set of random numbers to determine group allocation.
Method of blinding	Not possible to blind data collectors to the nature of the treatment intervention.
Intervention(s) (n = 219) and comparator(s) (n = 221)	Intervention: standard care plus one Mepilex® Border Sacrum dressing applied to sacrum and one Mepilex® Heel dressings to each heel and retained with Tubifast® (Molnlycke Healthcare) elastic tubular bandages on admission to ED. Dressings were maintained on the sacrum and heels throughout the patients ICU stay and changed every three days unless they became soiled or dislodged. Trauma patients maintained dressings for duration of OR procedure. Comparator: standard care (included ongoing Braden pressure ulcer risk assessment and regular repositioning and skin care, Hill-Rom Versa Care (Hill-Rom, USA) low air loss bed [whilst in ICU]).
Baseline differences	The groups were comparable on major physiological and demographic characteristics on admission to ED.
Duration of follow-up, lost to follow-up information	Throughout ICU stay. Lost to follow-up included patients who were transferred or not for ICU admission.
Statistical tests	Development of pressure ulcers per group and pressure ulcers by anatomical site per group were compared using Fishers Exact test. A survival analysis was used to determine the difference in pressure ulcer incidence development rates per group and time to provide a hazard ratio between the groups.
Primary outcomes (including scoring methods and timings of assessments)	Incidence rates of HAPUs in ICU expressed as the total number of pressure ulcers developed in both groups. Pressure ulcers were defined according to the 4 point staging system of the Australian Wound Management Association (2001). In ICU, all patients were reviewed every 24-hours for the duration of their ICU stay by a member of the research team to determine if a HAPU had developed. In the intervention group this involved partially peeling back the dressings so that the skin could be visualised and assessed and then reapplying the dressing.
Secondary outcomes (including scoring	None stated.

methods and timings of assessments)

Table B5.5: Summary of methodology for RCTs: Santamaria (2018, unpublished)

Study name	**Border III Trial**
Objectives	To determine the clinical effectiveness of multi-layer soft silicone foam dressings in preventing sacral and heel pressure injury development in high-risk residential aged care patients.
Location	Australia
Design	RCT
Duration of study	4 weeks, or until development of pressure ulcer, patient died, or discharged from facility.
Sample size	288
Inclusion criteria	Classified as “high risk”; recently admitted to the facility bed bound; Braden Scale score of ≤ 12; expected length of stay in the facility of > 4 weeks.
Exclusion criteria	Pre-existing sacral and/or heel pressure injuries; life expectancy < four weeks; classed as palliative care or end of life.
Method of randomisation	Computer programme generated a series of random numbers. These random numbers were then used to allocate each facility to either the intervention (dressings) or control group (standard pressure ulcer prevention).
Method of blinding	Following the randomisation, centre managers of the facilities were informed by the chief investigator whether their facility was an intervention or control group facility. The study was limited by inability to blind both the subject and the assessor to the presence or absence of the intervention.
Intervention(s) (n = 138) and comparator(s) (n = 150)	Intervention: standard care plus Mepilex® Border Sacrum and Mepilex® Heel secured with Tubifast® retention bandage. Comparator: standard care (included pressure risk screening; skin inspection; skin care and pressure area care, such as 2-hourly repositioning and the use of alternating air mattresses).
Baseline differences	Participants were comparable on demographic and physiological parameters.
Duration of follow-up, lost to follow-up information	4 weeks.
Statistical tests	Random effects Poisson regression analysis

Primary outcomes (including scoring methods and timings of assessments)	The incidence of pressure ulcers expressed as the total number of pressure ulcers developed in both intervention and comparator groups during the study period.
Secondary outcomes (including scoring methods and timings of assessments)	None stated.

Table B6.1: Summary of methodology for observational studies: Baker (2014)

Study name	Nursing Driving Excellence: Preventing Pressure ulcers in the High-Risk Population
Objective	To decrease and prevent sacral and heel HAPUs, thus decreasing hospital cost in the high-risk patient population.
Location	USA
Design	Prospective cohort study
Duration of study	45 days
Patient population	CVICU, STICU, CVOR
Sample size	110
Inclusion criteria	All CVOR patients with perioperative time ≥ 4 hours, all CVICU patients meeting inclusion criteria, and all STICU patients placed on rotational prone positioning beds. Apply heel & sacral dressing if any of the following are present: strict bed rest > 4 hours, cardiac surgical procedure >4 hours, Apply sacral dressing if any of the following are present: cardiac arrest this admission, vasopressor use >24 hours, shock, multiple organ dysfunction syndrome (MODS), systemic inflammatory response syndrome (SIRS), Braden score ≤17. Apply sacral dressing if on bed rest with limited mobility (i.e. bathroom privileges) and ≥3 of the following are present: weeping oedema/anasarca; traction; morbid obesity (BMI of ≥ 35 and experiencing obesity-related health conditions or ≥ BMI 40–44.9); >65 years of age; diabetes mellitus; liver failure; malnutrition (pre-albumin <20, albumin < 2.5, nil by mouth >3 days); sedation/paralytic >24 hours; mechanical ventilation >24 hours; quadriplegia or spinal cord injury; nitric oxide ventilation; restraints; drive lines (left ventricular assist device [LVAD], right ventricular assist device [RVAD], intra-aortic balloon pump [IABP]); past history of pressure ulcers; faecal or urinary incontinence not controlled with foley catheter or bowel management system.

Exclusion criteria	None
Intervention(s) (n = 110) (no comparator)	Standard care (including rotational prone positioning beds, where appropriate) plus education on pressure ulcer prevention plus Mepilex® Border Sacrum and/or Mepilex® Border Heel. No other devices (e.g., specialty surface, boot) were used in addition to the dressings).
Baseline differences	No details.
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	Skin assessments completed every shift by peeling back the dressing, examining the skin, and replacing the dressing. 45 days, no details on any patients lost to follow-up.
Statistical tests	Not stated.
Primary outcomes (including scoring methods and timings of assessments)	Pressure ulcer incidence. Skin assessments completed every shift by peeling back the dressing, examining the skin, and replacing the dressing. Pressure ulcer staging not specified.
Secondary outcomes (including scoring methods and timings of assessments)	None stated.

Table B6.2: Summary of methodology for observational studies: Bateman and Roberts (2013)

Study name	Moisture lesions and associated pressure ulcers - getting the dressing regime right.
Objective	To evaluate the efficacy of combined dressing regimen in management of moisture lesions and associated pressure ulcer development, with regards to wound healing and pressure ulcer prevention, along with the patient and clinician perspectives.
Location	UK
Design	Prospective non-comparative cohort study
Duration of study	4 weeks
Patient population	Acute wound care service referrals with reduced skin integrity due to incontinence, sweat, or wound exudate resulting in erythema, maceration, or combined with pressure ulcer formation.
Sample size	20
Inclusion criteria	Acute wound care service referrals with diagnosis of reduced skin integrity due to incontinence, sweat, or wound exudate. Skin integrity assessed using a classification tool for assessment of skin integrity (Bateman et al. 2011). (All patients deemed at either medium or high risk with regards to skin integrity and nutrition status via Braden

	scale and Malnutrition Universal Screening Tool [BAPEN, 2003], but was reported in results not methods).
Exclusion criteria	Patients not fulfilling inclusion criteria.
Intervention(s) (n = 20) (no comparator)	Depending on skin or wound type, patients commenced on standard care (not stated) plus management regimen of: (i) skin-protecting barrier product as primary layer; overlain by (ii) Mepilex® Border Sacrum or Mepilex® Border to: buttock (n=8), sacrum (n=7), thigh (n=2), abdomen (n=2), anus (n=1).
Baseline differences	N/A
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	Patients were pro-actively followed up by use of assessment tool, which dictated treatment, but no timings of assessment given. However, paper states all 20 patients had various cleansing, dressing, and management regimens in place prior to study commencing. In the first week the dressing regimen was applied to all patients every 48 hours, reducing to 72 hours thereafter unless incontinence contaminated the dressing products, in which case patients were redressed.
Statistical tests	Not stated.
Primary outcomes (including scoring methods and timings of assessments)	Level of pain according to McGill pain score (Melzack, 1975), Duration of therapy, and skin outcome (designated as healed, healing, static, or deteriorating). Deterioration or development of further pressure ulcers Skin integrity was assessed using the Bateman et al. (2011) skin assessment tool, which directs assessment and treatment of skin and classifies the patient as either healthy, erythemic, or having epidermal damage in regards to lesions, and recognises combined reduced skin integrity and pressure ulcer presence. Patients were monitored over a 4-week period to evaluate the benefits of the regimen, but timings of assessment not stated.
Secondary outcomes (including scoring methods and timings of assessments)	Outcomes not listed as primary or secondary.

Table B6.3: Summary of methodology for observational studies: Brindle (2010)

Study name	Outliers to the Braden Scale: Identifying high-risk ICU patients and the results of prophylactic dressing use.

Objectives	Assessment of novel risk assessment tool to identify highest risk ICU patient. Assessment of Mepilex® Border Sacrum for pressure ulcer prevention in addition to standard care.
Location	USA
Design	Prospective comparative study
Duration of study	3 months or until discharge from ICU.
Patient population	STICU patients
Sample size	93
Inclusion criteria	Prophylactic product if patient: 1. Had a surgical procedure >8hours (including cumulative surgeries = 8hrs). 2. Had cardiac arrest on admission 3. Had vasopressors >48hours 4. Was in shock, SIRS, MODS Prophylactic product applied if patient had five or more of the following: weeping oedema / anasarca, traction; morbid obesity; >65 years of age; diabetes mellitus; bed rest; liver failure; malnutrition (prealbumin <20, albumin <2.5 or nil by mouth > 3 days); sedation / paralytics >48hours; mechanical ventilation >48 hours; quadraplegia or spinal cord injury; nitric oxide ventilation; restraints; drive lines (LVAD, RVAD, IABP); past history of pressure ulcers.
Exclusion criteria	Patient admitted to STICU, but did not meet inclusion criteria
Intervention(s) (n = 41) comparator(s) (n=52)	Intervention: standard care* plus Mepilex® Border Sacrum. If dressing does not stay intact >24hr due to incontinence, discontinue and use barrier cream or alternative management. *Standard care included the following: All patients were on a low air loss surface. Interventions for daily practice: Patients were turned ≤2 hours and as required; if on continuous lateral rotation therapy: rotation 18 hours per day; manual turn every 2 hours: stop rotation, reposition right or left x 30 minutes, place supine, resume rotation. Weight shift: if full 30-degree turn not possible due to traction or haemodynamic instability, if patient up in chair, shift weight every 30 minutes to 1 hour; Pressure/shear/friction bundle: float heels using vertical pillows from knee to ankle, use heel offload device if patient agitated; lift sheet/turn sheet to reposition in bed; if

	bariatric specialty bed needed: consult wound care team; chair-bound patients: order 4-inch foam wheelchair pad. Skin bundle: skin checks every shift and as required with each turn; limit number of linens, no plastic chux or nappies. Educate patient/family/caregivers on pressure ulcer risk, interventions, and encourage participation in care. Nutrition bundle: registered dietician to determine blood tests required; encourage water/hydration; assist patient with meals if taking orally. Device check: ensure no devices under patient: intravenous lines, tubing, etc.; evaluate need for endotracheal tube repositioning. Comparator: Standard care plus barrier cream, moisturiser every 12 hours, and as required for incontinence care.
Baseline differences	Only assessed if high-risk or not. If high-risk then dressing used.
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	Dressing peeled back daily, skin assessed and existing dressing resealed, findings documented. Dressing removed and discarded every 3 days. Document daily: Braden score, interventions provided, new interventions used, status changes, or new risk factors determined). For 3 months all STICU patients were monitored for skin breakdown and followed up using a tracking form created by the author. No details on patients lost to follow-up.
Statistical tests	None
Primary outcomes (including scoring methods and timings of assessments)	Number of pressure ulcers developing on patients Scoring methods for pressure ulcer staging not discussed. See daily interventions above.
Secondary outcomes (including scoring methods and timings of assessments)	None

Table B6.4: Summary of methodology for observational studies: Brindle and Wegelin (2012)

Study name	Prophylactic dressing application to reduce pressure ulcer formation in cardiac surgery patients.
Objective	To determine if application of Mepilex® Border Sacrum would reduce pressure ulcer incidence when compared with standard preventive interventions.
Location	USA
Design	Prospective cohort study
Duration of study	Duration of ICU stay.
Patient population	Cardiac surgery ICU

Sample size	56
Inclusion criteria	Enrol patient as 'high risk' if they have had: 1. a surgical procedure >6 hours (may be cumulative surgeries = 6 hours). 2. Cardiac arrest this admission 3. Vasopressors >48hours 4. In shock, SIRS, MODS. Or enrol if patient has five or more of the following: weeping oedema / anasarca; traction; morbid obesity; >65 years of age; diabetes mellitus; bed rest; liver failure; malnutrition (prealbumin <20, albumin <2.5 or nil by mouth >3 days); sedation/paralytics >48hours; mechanical ventilation >48 hours; quadraplegia or spinal cord injury; nitric oxide ventilation; restraints; drive lines (LVAD, RVAD, IABP); past history of pressure ulcers.
Exclusion criteria	Have existing pressure ulcer on admission >stage I (scale not stated), <18 years of age, pregnant, inmate/prisoner, admitted to cardiac surgery ICU but does not meet inclusion criteria.
Intervention(s) (n = 56) comparator(s) (n = 39)	Intervention: standard care plus Mepilex® Border Sacrum (depending on body size, 18 x 18 cm or 23 x 23 cm). Application primarily focused on covering the sacrum, but the coccyx and proximal gluteal cleft were also covered when possible. If dressing does not stay intact >24 hours due to incontinence, discontinue and use barrier cream or alternative management. Comparator: Standard care (full details listed in paper, including low air loss bed, turning and repositioning, nutritional checks, skin checks, repositioning of medical devices, education, documentation [including Braden score]) plus zinc-based skin protectant (Calmoseptine, Huntington Beach, California) twice daily and as needed, for incontinence.
Baseline differences	No significant difference among demographic characteristics was found between the groups (all p>0.058). Over both groups, mean age was 61.8 years (standard deviation [SD] ±13.2), and 65.9% were male; mean Braden Scale risk score = 11.2 (SD ±2.12).
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	During study all ICU patients were monitored for skin breakdown and followed up using a tracking form. Any suspected skin breakdown occurring around the sacrum, coccyx, or gluteal fold was immediately reported and assistance from a trained skin integrity team member was available and a nursing treatment plan. Patients were followed-up until they left the ICU or were removed from study if they expired/left ICU before 48 hours from admission. Data collection forms of 5 patients were lost and their group assignment was not known. Six out of 56 subjects in the intervention group did not complete the study and 4

	out of 39 control subjects failed to complete the study. Analysis was based on 50 subjects in the intervention group and 35 subjects in the comparison group.
Statistical tests	Fisher exact test for nominal covariates and Mann-Whitney U test for continuous covariates. A Kaplan-Meier estimate of time until incident (occurrence of a HAPU) was computed for each group. Cox proportional hazards regression model (comparison of adjusted and unadjusted hazard ratios between groups)
Primary outcomes (including scoring methods and timings of assessments)	Incidence of any stage of pressure ulcer, hours in the ICU. Pressure ulcer staging scale not stated. Both groups had skin inspected daily and the intervention dressing was changed every 3 days throughout the duration of their ICU stay. If the patient's dressing was found to be displaced, a new dressing was applied.
Secondary outcomes (including scoring methods and timings of assessments)	Hours in the ICU. 21 covariates were summarised within the intervention and standard care groups by percent for nominal variables and by mean (SD) for continuous variables.

Table B6.5: Summary of methodology for observational studies: Chaiken et al. (2012)

Study name	Reduction of sacral pressure ulcers in the intensive care unit using a silicone border foam dressing.
Objective	To determine if the use of a silicone border foam dressing in the general ICU population could reduce the incidence of sacral HAPUs.
Location	USA
Design	Non-experimental prospective study with retrospective control.
Duration of study	6 month prospective period, 35 month retrospective comparator.
Patient population	ICU
Sample size	564
Inclusion criteria	Intervention: All ICU patients admitted during observation period. Comparator: Prevalence of sacral HAPUs over a 35-month period by examining each patient's skin monthly. All pressure ulcers were reported to the skin care committee in a written document supplied by the National Database for Nursing Quality Indicators and subsequently verified by a wound, ostomy, and continence nurse (WOCN).
Exclusion criteria	Intervention and comparator groups: Any ulcers present on admission (stage not specified).

6 month prospective intervention(s) (n = 273) 35 month retrospective comparator(s) (n = 291)	Intervention: standard care plus educational intervention plus daily visits to the ICU by the WOCN plus Mepilex® Border Sacrum (9.2 x 9.2 inches). Comparator: standard care (included low-air loss pressure-reduction mattress, defined skin care regimen, proper completion of the Braden Scale, and additional preventive interventions including turning and repositioning patients on a regular schedule every 2 hours).
Baseline differences	Diagnoses and length of ICU stay were comparable between groups. Nurse to patient ratio in the ICU remained constant.
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	Subjects' sacral skin was examined every shift by the nursing staff within each 24-hour period. The dressing was changed twice a week on prescheduled days, but more frequent changes were often required due to incontinence and diaphoresis. The wound nurse was alerted of any sacral skin alternation and was then able to determine if the skin changes were due to pressure or other factors such as incontinent dermatitis.
Statistical tests	Descriptive statistics. Authors initially measured sacral HAPU, using National Database for Nursing Quality Indicators procedures, as compared with measuring HAPU incidence, so authors were not able to directly compare results using inferential statistics.
Primary outcomes (including scoring methods and timings of assessments)	Comparing baseline sacral HAPU prevalence over a 35 month period with sacral HAPU incidence measured during a 6-month prospective data collection period. The WOCN was alerted of any sacral skin alteration and all pressure ulcers were reported to the skin care committee in a written document and subsequently verified by a WOCN. No staging system stated. Subjects' sacral skin was examined every 24 hours by the nursing staff by peeling back the dressing and inspecting the underlying skin.
Secondary outcomes (including scoring methods and timings of assessments)	Not stated.

Table B6.6: Summary of methodology for observational studies: Cubit et al. (2013)

Study name	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.
Objective	To examine the effectiveness of using Mepilex® Border Sacrum to reduce the prevalence of sacral pressure injuries caused by friction, shearing and changes to the

	microclimate in older, high-risk patients admitted via the ED with a medical condition.
Location	Australia
Design	Non-randomised one sample experimental design
Duration of study	For duration of stay from ED admission to end of hospital stay or end of trial (January to May, 2010).
Patient population	Admitted to 3 medical wards via the ED.
Sample size	109
Inclusion criteria	Male and female patients who were admitted via the ED, ≥65 years of age, presented with a medical condition, assessed to be 'at high risk' or 'very high risk' for developing a pressure injury according to the Waterlow Pressure Ulcer Risk Assessment Tool and did not have an existing sacral pressure injury.
Exclusion criteria	Patients who presented to the ED with a sacral pressure injury.
Intervention(s) (n = 51) and comparator(s) (n = 58)	Intervention: standard care plus Mepilex® Border Sacrum. Comparator: standard care (included prevention plan documented in the patient notes including documentation of risk factors, details of pressure relieving devices and written schedules for frequency of repositioning based on the patient's level of risk plus pressure injury education by researchers and Molnlycke Health Care).
Baseline differences	Paper states 'matched sample' chosen as control group, demographics shown, but not statistically analysed.
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	Nursing staff undertook sacral skin integrity checks on the participating patients three times every 24 hours by lifting a portion of the sacral dressing away from the intact skin. The dressing was changed every 3 days or when soiled. Any change in the patient's skin integrity was reviewed by the Wound Management Clinical Nurse Consultant and an appropriate management plan was implemented and recorded in the nursing care and data collection form. Patients followed-up for duration of hospital stay or end of trial. Patients lost to follow-up not stated.
Statistical tests	Descriptive statistics were used to describe and summarise data. The Chi square test was used to compare the intervention and the control group results.
Primary outcomes (including scoring methods and timings of assessments)	Prevalence of sacral pressure injuries. Pressure injuries were graded using the four stage system approved by the Australian Wound Management Association. The development of any pressure injury was documented and reported in the RiskMan online incident reporting tool. Pressure injury in the control group was recorded from the medical record and RiskMan.
Secondary outcomes (including scoring	Not stated.

methods and timings of assessments)

Table B6.7: Summary of methodology for observational studies: Daukste et al. (2014)

Study name	Mepilex® Border Sacrum dressing use for pressure ulcers prevention in period of open heart surgery and in intensive care unit.
Objective	To evaluate Mepilex® Border Sacrum effect on maintaining skin entirety (pressure ulcers prevention) for patients during open heart surgery and in ICU.
Location	Riga, Latvia
Design	Single cohort, prospective.
Duration of study	For duration of surgery and in ICU. Study duration was for 19 days.
Patient population	During open heart surgery and ICU
Sample size	16
Inclusion criteria	Not stated.
Exclusion criteria	Not stated.
Intervention(s) (n = 16)	Mepilex® Border Sacrum and Mepilex® Border for prevention and treatment of pressure ulcers. Two patients with sacral pressure ulcers at start of study.
Baseline differences	N/A
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	Pro-actively by nurses assessing skin integrity. Skin assessed before surgery when dressing applied. Skin integrity was inspected after surgery in ICU, and again when transferred to the clinical heart surgery department. No pressure ulcer staging method stated.
Statistical tests	None stated.
Primary outcomes (including scoring methods and timings of assessments)	Pressure ulcer development/incidence. No pressure ulcer staging methods detailed. Evaluation of skin before surgery/after surgery, in ICU.
Secondary outcomes (including scoring methods and timings of assessments)	Not stated.

Table B6.8: Summary of methodology for observational studies: Edwards and Lynch (2014)

Study name	Head over heels for prevention: use of a silicone bordered foam heel dressing in the prevention of pressure ulcers.

Objective	Assess effectiveness of silicone bordered foam heel dressing in reducing the incidence/development of heel pressure ulcers.
Location	USA
Design	Single cohort observational study.
Duration of study	Initially, 'approximately' 2 months, re-initiated for additional 2 months to validate the results.
Patient population	ICU
Sample size	102
Inclusion criteria	Heel dressings were placed upon arrival to the unit on patients who had no breakdown noted to the heel for prevention of pressure ulcers. The dressing was also applied to treat patients who had a DTI, Stage I, or Stage II pressure ulcer, as deemed appropriate by the WOCN.
Exclusion criteria	Did not meet inclusion criteria.
Intervention for prevention (n = 100) Treatment (n = 2)	Prevention and treatment: Standard care plus Mepilex® Border Heel dressing.
Baseline differences	N/A
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	Using a data collection form, the date and condition of the heel(s) were documented by the WOCN at the time of placement. Dressings were changed twice per week with the exception of two weeks with circumstances beyond our control. At each dressing change, the date and condition of the heel(s) was recorded again. The heel dressings were left in place and were not peeled back to observe the heel between dressing changes. Dressing changes continued for the duration of the patient's hospital stay and continued after transfer out of the ICU until the patient became self-ambulatory.
Statistical tests	None stated.
Primary outcomes (including scoring methods and timings of assessments)	Incidence of pressure ulcers in non-ambulant patients without pressure ulcers wearing Mepilex® Border Heel dressing. Pressure ulcer staging method not stated. Heels assessed at dressing changes (twice/week).
Secondary outcomes (including scoring methods and timings of assessments)	Wound healing in patients with pressure ulcers wearing Mepilex® Border Heel dressing. Scoring method not stated. Heels assessed at dressing changes (twice/week).

Table B6.9: Summary of methodology for observational studies: Gentry and Wright (2010)

Study name	The 'Sacral Heart' Dressing Study: use of an absorbent self-adherent soft silicone sacral foam dressing across acute care settings.

Objective	To assess Mepilex® Border Sacrum in high-risk, mixed critical care population at a rural hospital as part of a process improvement study to reduce sacral pressure ulcer incidence. To observe the effect of the dressing in suspected DTI and in treating stage I-IV pressure ulcers present on admission.
Location	USA
Design	Single cohort observational study.
Duration of study	2 weeks.
Patient population	Critical care unit
Sample size	59
Inclusion criteria	Braden score <18, history of pressure ulcers, cardiac arrest this admission, morbidly obese, open wounds on admission. Apply dressing if 3 or more apply: faecal or urinary incontinence not controlled by Foley catheter or faecal management system, diabetic, > 65 years of age, restrained, mechanical ventilation > 48 hours, traction, weeping oedema/anasarca, paralysis/paraplegia/spinal cord injury, pre-albumin < 20, nil by mouth > 3 days, on vasopressor medication, liver failure, patient sedated or paralytic medications administered.
Exclusion criteria	Not stated.
Intervention for prevention (n = 31) Treatment (n = 28, pressure ulcers present on admission [n=26], incontinence-associated dermatitis [n=1], sacral abrasion [n=1])	Prevention and treatment: Standard care plus Mepilex® Border Sacrum.
Baseline differences	N/A
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	Pro-active follow-up. Sacral dressing applied to high-risk patients at admission to unit and continue use on transfer until discharge from hospital. Inspect skin under dressing daily, re-adhere dressing, change the dressing every 3 days or as required.
Statistical tests	None stated.
Primary outcomes (including scoring methods and timings of assessments)	Incidence of pressure ulcers in patients with intact skin wearing Mepilex® Border Sacrum dressing. Pressure ulcer staging method not stated. Inspect skin under dressing daily.
Secondary outcomes (including scoring methods and timings of assessments)	Wound healing in patients with pressure ulcers wearing Mepilex® Border Sacrum dressing. Pressure ulcer staging method not stated. Skin was inspected under the dressing daily.

Table B6.10: Summary of methodology for observational studies: Haisley et al. (2015)

Study name	An ounce of prevention: the use of an absorbent soft silicone self-adherent bordered foam heel dressing to decrease the incidence of hospital-acquired heel pressure ulcers in an acute care setting.
Objective	To evaluate an intervention aimed at reducing friction, shear, and improving skin microclimate, thereby reducing the incidence of heel HAPUs in a high risk population.
Location	USA
Design	Pilot single cohort observation study
Duration of study	3 month duration, all included patients followed-up from patient admission to coronary care/CVICU until discharge from coronary care/CVICU.
Patient population	Coronary care and CVICU
Sample size	31
Inclusion criteria	Admitted to coronary care unit and CVICU who were non-ambulant or at high risk for heel pressure ulcers 'due to diabetes mellitus, peripheral vascular disease, poor nutritional status, constant heel friction etc.'
Exclusion criteria	Not directly admitted to coronary care unit/CVICU, ambulatory, pre-existing heel pressure ulcers or pre-existing trauma to heels.
Intervention(s) (n = 31) and comparator(s) (n = not stated)	Intervention: standard care (constituents not stated) plus Mepilex® Border Heel to both heels. Comparator: Standard care
Baseline differences	"Similar based on age, body mass index, and history of diabetes mellitus".
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	Dressings were lifted daily to check skin integrity. Prior to discharge from ward, patient's heels were checked for signs and symptoms of pressure ulcer development.
Statistical tests	None stated.
Primary outcomes (including scoring methods and timings of assessments)	Pressure ulcer incidence. Pressure ulcer staging method not stated. Skin was inspected under dressing daily.
Secondary outcomes (including scoring methods and timings of assessments)	Pressure ulcer incidence - trial extended for 3 months to validate outcome. Pressure ulcer staging method not stated. Skin was inspected under the dressing daily.

THIS INFORMATION IS ACADEMIC IN CONFIDENCE.

Table B6.11: Summary of methodology for observational studies: Jin (2018, unpublished)

Study name	[redacted]
Objective	[redacted]
Location	[redacted]
Design	[redacted]
Duration of study	[redacted]
Patient population	[redacted]
Sample size	[redacted]
Inclusion criteria	[redacted]
Exclusion criteria	[redacted]
Intervention(s) (n = [redacted] and comparator(s) (n = [redacted]	[redacted]
Baseline differences	[redacted]
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	[redacted]
Statistical tests	[redacted]
Primary outcomes (including scoring methods and timings of assessments)	[redacted]
Secondary outcomes (including scoring	[redacted]

methods and timings of assessments)

Table B6.12: Summary of methodology for observational studies: Johnstone and McGown (2013)

Study name	Innovations in the reduction of pressure ulceration and pain in critical care.
Objective	To determine whether the application of a prophylactic five-layer foam dressing would: prevent the incidence of ulceration caused by moisture, friction, and shear; reduce the incidence of pain associated with skin damage; be cost-effective in the prevention of sacral lesions.
Location	Glasgow Royal Infirmary, Scotland.
Design	Single cohort product evaluation
Duration of study	3 months
Patient population	Critical care units
Sample size	75
Inclusion criteria	High-risk (Waterlow score >15), bariatric surgery, immobility, spinal cord injury (i.e. paralysis), liver failure, cardiac instability, diabetes, sedation, malnutrition, mechanical ventilation, age >65 years, surgical procedure >8 hours, heart disease, vasopressor medication >48 hours, peripheral vascular disease, past history of pressure ulcers, major trauma, traction, haemodynamically unstable.
Exclusion criteria	None stated, but 7 patients excluded for severe faecal incontinence.
Intervention(s) (n = 75)	Standard care (constituents not stated) plus Mepilex® Border Sacrum.
Baseline differences	N/A
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	Pro-active follow-up. The sacral area was checked every 24 hours and the sacral dressing was discontinued on discharge from the critical care unit. Patients continued to be followed up by the tissue viability nurses for a further 7 days to monitor skin integrity.
Statistical tests	None stated.
Primary outcomes (including scoring methods and timings of assessments)	Pressure ulcer incidence. Pressure ulcer staging method not stated. Skin was inspected under dressing daily. A questionnaire collected data on condition of the skin.
Secondary outcomes (including scoring methods and timings of assessments)	Incidence of pain associated with skin damage. A questionnaire collected data on pain, condition of the skin, ability of the dressing to stay in place and conform to the sacrum.

	Cost effectiveness of prophylactic dressings. A questionnaire collected data on quantity of dressings used for each patient until discharge from unit.

Table B6.13: Summary of methodology for observational studies: Koerner and Adams (2011)

Study name	Save our sacrums (S.O.S.) Does the use of an absorbent soft silicone self-adherent bordered foam dressing decrease the incidence of HAPUs?
Objective	To improve the quality of care for high risk patients in the medical ICU and surgical ICU by standardising care interventions which will lead to the decreased incidence of HAPUs and improve pressure ulcer prevention study results.
Location	USA
Design	Single cohort, quality improvement project.
Duration of study	Two phases that spanned a 2 month period.
Patient population	Medical/cardiac ICU and the surgical ICU
Sample size	81
Inclusion criteria	Braden score <18, any Braden subscale < 3, presence/ history of pressure ulcers, cardiac/respiratory arrest this admission, surgery>4 hours. Apply dressing if 3 or more apply: > 65 years of age, diabetic, faecal or urinary incontinence not controlled by Foley catheter or faecal management system, no nutritional support ≥ 24 hours, weeping oedema/anasarca, paralysis/paraplegia/spinal cord injury, on vasopressor medication, patient sedated or paralytic medications administered, morbidly obese, restrained, liver failure.
Exclusion criteria	Not stated.
Intervention(s) (n = 81) Phase 1 (n = 42) Phase 2 (n = 39)	Standard care (full details provided, but included regular turning/weight distribution protocol, pressure/friction/shear precautions, regular skin care protocol, patient and family education, nutritional support, device check, and documentation of Braden score, interventions provided, status changes, and new risk factors) plus Mepilex® Border Sacrum.
Baseline differences	N/A
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	Phase 1 (18 days): Apply dressing and change every 4 days, or as required, while patient in surgical ICU or medical/cardiac ICU. Phase 2 (40 days): Dressing remained in place upon transfer from ICU to medical/surgical wards. Dressing was changed and sacrum assessed every 4 days by enterostomal therapy nurses.
Statistical tests	Not stated.

Primary outcomes (including scoring methods and timings of assessments)	Pressure ulcer incidence in patients with intact skin (baseline number not stated). Skin checks every shift and as needed with each turn. Pressure ulcer staging method not stated. Skin was inspected under dressing daily.
Secondary outcomes (including scoring methods and timings of assessments)	Deterioration in pressure ulcers in patients presenting with pressure ulcers (baseline number not stated). Skin checks every shift and as needed with each turn. Pressure ulcer staging method not stated. Skin was inspected under dressing daily.

Table B6.14: Summary of methodology for observational studies: Lientz (2013)

Study name	Dollars and sense: economic value in HAPU/sDTI prevention.
Objective	To decrease HAPUs/suspected DTIs in critical care unit, ICU, CVICU and the CVOR population; initiate a prevention protocol to address friction, shear, and manage microclimate; and decrease hospital costs through reduction of HAPU's/suspected DTIs with the addition of application of a multi-layered soft silicone sacral dressing.
Location	USA
Design	Single cohort observational study.
Duration of study	Duration of patient use of dressing not stated, but patients had to meet the study inclusion criteria whilst being followed-up. Study duration: 15 months.
Patient population	Coronary care unit, ICU, CVICU and CVOR
Sample size	58
Inclusion criteria	Automatically apply dressing if patients: Had a surgical procedure >4 hours (including cumulative surgeries > 4 hours). Cardiac arrest on admission. Vasopressor medications >48 hours. Drive lines (LVAD, RVAD, IABP) Shock, systemic inflammatory response syndrome, multiple organ dysfunction syndrome Apply if patient had ≥3 of the following: weeping oedema / anasarca; traction; morbid obesity: body mass index ≥35; >65 years of age; diabetes mellitus; bed rest; liver failure; malnutrition (prealbumin <20, albumin <2.5, or nil by mouth >3 days); sedation / paralytics >48 hours; mechanical ventilation >48 hours; quadriplegia or spinal cord injury; nitric oxide ventilation; restraints; past history of pressure ulcers; faecal or urinary

	incontinence not controlled by Foley catheter or faecal management system device.
Exclusion criteria	Not stated.
Intervention(s) (n = 58)	Standard care (including regular turning; off-loading; reduction of pressure, friction, shear; skin care, nutritional support; and checks to avoid medical device related pressure ulcers. Further details provided in small print on poster) plus Mepilex® Border Sacrum.
Baseline differences	N/A
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	Daily skin assessments by peeling the dressing back, inspecting the skin and then replacing the dressing. The dressing was changed every 3 days or as needed for dislodgement or soiling. Two patients were dropped from the study because the protocol was not followed. Exclusions can introduce a bias as patients may be excluded who are not doing well in a particular arm.
Statistical tests	Not stated.
Primary outcomes (including scoring methods and timings of assessments)	Pressure ulcer incidence. Skin inspected daily, dressing peeled back then replaced. Dressing changed every 3 days and as required. Reapply as long as patient meets inclusion criteria. Pressure ulcer staging method not stated.
Secondary outcomes (including scoring methods and timings of assessments)	Cost effectiveness of Mepilex® Border Sacrum as part of pressure ulcer prevention regimen. Estimated cost/HAPU used cost calculation of Brindle and Wegelin (2012) for the treatment of 1 pressure ulcer. Cost effectiveness covered the cost of the dressings for the 15 month study period.

Table B6.15: Summary of methodology for observational studies: Muldoon et al. (2010)

Study name	Initial use absorbent soft silicone self-adherent bordered foam dressing reduces sacral pressure ulcers in the cardiovascular ICU.
Objective	Not stated.
Location	USA
Design	Case series
Duration of study	As long as patients stayed on unit (between 2 to 6 weeks).
Patient population	Cardiovascular ICU
Sample size	3
Inclusion criteria	All high-risk and pre-operative patients
Exclusion criteria	Not stated.

Intervention(s) (n = 3)	Standard care (constituents not specified) plus Mepilex® Border Sacrum.
Baseline differences	N/A
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	Mepilex® Border Sacrum applied to sacral area. The patient's skin was inspected daily under the dressing and the dressing was changed on the third day until the patient left the unit. 3 cases followed-up until discharge from ward.
Statistical tests	None stated.
Primary outcomes (including scoring methods and timings of assessments)	Duration of product use and pressure ulcer incidence. The patient's skin was inspected daily, pressure ulcer staging not stated, but NPUAP et al. (2007) referenced.
Secondary outcomes (including scoring methods and timings of assessments)	-

Table B6.16: Summary of methodology for observational studies: Padula (2017)

Study name	Effectiveness and value of prophylactic 5-layer foam sacral dressings to prevent hospital-acquired pressure injuries in acute care hospitals.
Objective	To examine the effectiveness and value of prophylactic 5-layer foam sacral dressings to prevent hospital-acquired pressure injury rates in acute care settings.
Location	USA
Design	Retrospective observational cohort.
Duration of study	6 years (2010 to 2015)
Patient population	Acute and critically ill patients.
Sample size	1,031,564
Inclusion criteria	Stage 3, 4, or unstageable HAPUs not present on admission after 5 days of length of stay in patients 18 years and older. (Met the inclusion criteria of [USA] Agency for Healthcare Research and Quality Patient Safety Indicator number 3 [PSI03 {identified as having a pressure injury} v. 5.0] for acute and critically ill patients).
Exclusion criteria	Met the exclusion criteria of the Agency for Healthcare Research and Quality Patient Safety Indicator number 3 [PSI03 {identified as having a pressure ulcer ≥stage 3} v. 5.0] for acute and critically ill patients.
Intervention(s) (n = 631 hospital quarters) and	Intervention: standard care (not specified) plus period after Mepilex® Border Sacrum purchased for use at hospitals.

comparator(s) (n = 912 hospital quarters)	Comparator: standard care plus period before Mepilex® Border Sacrum purchased for use at hospitals.
Baseline differences	Not known
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	Retrospective follow-up according to hospital data. 6 year follow-up, patients lost to follow-up not assessed.
Statistical tests	The average rates of PSI-03 pre- and post-dressing purchase were compared using a student t test at the 95% confidence level. The authors used 2-level mixed-effects negative binomial regression models to perform longitudinal data analysis of PSI-03 counts over each quarter from 2010 to 2015 associated with adoption of prophylactic 5-layer foam sacral dressings. They applied a random-intercept to the regression model to allow hospitals to vary naturally by their baseline rates of PSI-03 prior to dressing adoption since hospitals began using prophylactic dressings at different points in the process toward improving pressure injury prevention.
Primary outcomes (including scoring methods and timings of assessments)	Average HAPU (≥stage 3) incidence during quarters when prophylactic foam sacral dressings were available compared with HAPU (≥stage 3) during quarters when there were no dressings in a hospital. Hospital-level data from University Health System Consortium, which provided aggregate hospital data on patient outcomes by quarter, including case-mix index (hospital-level case-mix per quarter), as well as hospitalised patient discharges and HAPU cases (counts of each). Hospital-level data provided by Mölnlycke Health Care on the amount of Mepilex® Border Sacrum dressings purchased in terms of total volume and cost of each quarterly purchase under the stock-keeping unit.
Secondary outcomes (including scoring methods and timings of assessments)	Budget impact analysis and return-on- investment calculation of the value of Mepilex® Border dressings. The retail cost per prophylactic foam sacral dressing, the estimated cost per HAPU ($70,000 per PSI-03), and the estimated cost of a HAPU prevention protocol ($55/ patient/day).

Table B6.17: Summary of methodology for observational studies: Park (2014)

Study name	The effect of a silicone border foam dressing for prevention of pressure ulcers and incontinence associated dermatitis in intensive care unit patients.

Objective	To examine the effect of a silicone border foam dressing on the development of pressure ulcers and incontinence-associated dermatitis in ICU patients.
Location	South Korea
Design	Nonrandomised comparison cohort (quasi-experimental) study
Duration of study	Dressing was applied to subjects in the intervention group for 9 days.
Patient population	ICU
Sample size	102
Inclusion criteria	(1) Patients did not have IAD or pressure ulcer before participation in the study. (2) Braden Scale score ≤16.
Exclusion criteria	Patients with contraindication to changing positions.
Intervention(s) (n = 52) and comparator(s) (n = 50)	Intervention: standard care plus Mepilex® Border sacral dressing. Comparator: standard care (including pressure redistribution mattress [Hill-Rom KCI, USA] and regular turning and repositioning).
Baseline differences	The homogeneity of the 2 groups was analysed using a $\chi 2$ test or independent groups t test to compare patient demographics, IAD risk factors, and risk factors for pressure ulcer development. No significant differences were found between the 2 groups.
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	Dressings were changed every 3 days or more often if found to be soiled or inadvertently detached. At each dressing change, the surrounding skin was cleaned and dried. Skin assessments, including staging (according to NPUAP et al. 2009) and presence of pressure ulcers and IAD, were evaluated by 2 wound care nurses every 3 days. No patients lost to follow-up.
Statistical tests	Chi-square test for primary outcome. Independent t test for secondary outcome.
Primary outcomes (including scoring methods and timings of assessments)	The number of patients who developed pressure ulcers in the experimental group was compared with that from the control group. Pressure ulcer development was determined based on 2009 Guidelines from the National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel. Incontinence-associated dermatitis was measured using the IADS instrument. The worst scores for the pressure ulcer and IADS status during the data collection period were used, and the other data were collected using electronic medical recording.

Secondary outcomes (including scoring methods and timings of assessments)	The Incontinence Associated Dermatitis and its Severity (IADS) score of the experimental group was measured and compared with those of the control group.

Table B6.18: Summary of methodology for observational studies: Richard-Denis et al. (2017)

Study name	Effectiveness of a multi-layer foam dressing in preventing sacral pressure ulcers for the early acute care of patients with a traumatic spinal cord injury: comparison with the use of a gel mattress.
Objective	To examine the effectiveness of a multi-layer foam dressing applied to the sacral region compared with transfer on a gel mattress in preventing pressure ulcers in patients with a traumatic spinal cord injury upon arrival at a level I spinal cord injury specialised trauma centre for the period prior to spine surgery.
Location	Canada
Design	Prospective cohort study with retrospective control group.
Duration of study	Patients entered the cohort at the time of admission and were followed up until discharge from the acute care centre.
Patient population	Traumatic spinal cord injuries.
Sample size	315
Inclusion criteria	Spine trauma that involved a spinal cord injury above the L1-L2 intervertebral disc and had surgery performed in the study institution.
Exclusion criteria	Not stated.
Intervention(s) (n = 89) and comparator(s) (n = 286)	Intervention: Basic pressure ulcer prevention protocol (including log roll mobilisation once every 2 hours during the pre-operative period and skin assessment) plus Mepilex® Border Sacrum plus local gel pads under the heels and occiput (i.e. no gel mattress across other body areas). Mepilex® Border Sacrum in place during pre-operative period and was removed in surgery. Comparator: basic pressure ulcer prevention protocol plus transfer on a foam stretcher pad with a viscoelastic polymer gel mattress (Blue Cloud™; Batrik Medical Manufacturing, Montreal, Canada) upon arrival at the emergency room until spine stabilisation surgery. Intervention and comparator: in the post-operative period patients were cared for on a low air loss pressure-relieving mattress (Versacare A.I.R.® Surface; Rom-Hill, Mississauga, Canada), with regular repositioning (every 2 hours) and skin care/assessment.

Baseline differences	No significant differences when potential predictors of sacral pressure ulcer from 12 potential predictors were compared between groups in a multivariate logistic regression.
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	Dressing repositioned after skin assessment every 8 hours, if needed, and replaced if soiled. Skin evaluation was collected in a routine data sheet assessing evaluation, observation and treatment. The dressing was removed during surgery and not put back in place afterwards.
Statistical tests	Continuous data were compared between groups using Student t-tests, while categorical data were compared using chi-square tests.
Primary outcomes (including scoring methods and timings of assessments)	Occurrence of sacral pressure ulcer developed during acute hospitalisation. Pressure ulcers located on the sacrum, coccyx and/or gluteal cleft were included in the analyses as sacral pressure ulcers. Pressure ulcer development and staging was based on NPUAP et al. (2007). Pressure ulcers were categorised as stages I–IV, suspected DTI, or unstageable.
Secondary outcomes (including scoring methods and timings of assessments)	Severity of sacral pressure ulcer.

Table B6.19: Summary of methodology for observational studies: Santamaria et al. (2015a)

Study name	Clinical effectiveness of a silicone foam dressing for the prevention of heel pressure ulcers in critically ill patients: Border II Trial.
Objective	To evaluate the clinical effectiveness of a new multi-layer, self-adhesive soft silicone foam heel dressing to prevent pressure ulcer development in trauma and critically ill patients in the ICU.
Location	Australia
Design	Prospective cohort study with retrospective comparator group.
Duration of study	From admission in ED until duration of ICU stay. Mean length of ICU stay for intervention group: 107 hours (SD 123), comparator group: 86 hours (SD 101).
Patient population	ICU
Sample size	412
Inclusion criteria	All major trauma and critically ill patients who were admitted to the ED and subsequently transferred to the ICU.

Exclusion criteria	Under 18 years of age, had a pre-existing heel pressure ulcer, had trauma to the heels, or had spinal injuries which precluded repositioning.
Intervention(s) (n = 191) and comparator(s) (n = 221)	Intervention: standard care plus Mepilex® Border Heel retained on each heel by Tubifast retention bandage. Comparator: standard care (Hill-Rom Versa-Care low air loss bed (Hill-Rom, USA), pressure ulcer risk assessment, regular repositioning, nutritional support, and incontinence management).
Baseline differences	Significant difference in ICU length of stay (p=0.007), but intervention and control cohorts comparable on all other variables.
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	Mepilex® Border was applied to each heel on admission to the ED and changed every 3 days or when soiled or dislodged. Data included the ED electronic patient information system (Ascribe-Symphony) and the ICU Australian & New Zealand Intensive Care Society databases used to retrieve data on patients' length of stay in the ED, OR and ICU expressed in hours. Patients were reviewed to determine if a HAPU had developed every 24 hours, for the duration of their ICU stay or until they were ambulant, by a member of the research team. The daily review involved partially peeling back the adhesive border of the dressings so that the heel skin could be visualised and assessed for HAPUs. Lost to follow-up or not for ICU transfers: Intervention group (n=24). Control group (n=29).
Statistical tests	Descriptive statistics were calculated for all physiological and demographic variables and differences in these were analysed with chi-squared where data was not normally distributed. Pressure ulcer incidence rates between the two cohorts were explored through the calculation of inferential statistics (inferences from the data to more general populations).
Primary outcomes (including scoring methods and timings of assessments)	Incidence rate of HAPUs in the ICU expressed as the total number of heel pressure ulcers developed in the study group. HAPUs were identified and categorised according to the four-point category system of the Australian Wound Management Association (2001).
Secondary outcomes (including scoring methods and timings of assessments)	Not stated.

Table B6.20: Summary of methodology for observational studies:

Sullivan (2015)

Study name	A two-year retrospective review of suspected deep tissue injury evolution in adult acute care patients.
Objective	To identify the role of absorbent soft silicone self-adherent multi-layer bordered foam in improved patient outcomes.
Location	USA
Design	Narrative literature review and secondary analysis of data from observational retrospective study.
Duration of study	1 day to 14 weeks
Patient population	Adult, hospitalised subjects.
Sample size	77 (including 12 patients with suspected DTIs).
Inclusion criteria	Hospitalised subjects ≥18 years of age with wound care nurse identified suspected DTIs.
Exclusion criteria	None.
Intervention(s) (n = 77)	All patients used Mepilex® Border Sacrum, Mepilex® Border Heel, Mepilex® Border as part of pressure ulcer prevention programme.
Baseline differences	N/A
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	Wound care nurse assessments occurred once or twice weekly depending on the condition of the ulcer. All ulcers had at least two wound care nurse assessments. The study sample initially consisted of 122 patients. Of those, 45 were excluded from analysis due to incomplete data (n=13), evolution on initial presentation (n=2), and loss of follow-up (n=30).
Statistical tests	Descriptive statistics and observational data.
Primary outcomes (including scoring methods and timings of assessments)	Effect of soft silicone foam dressings in the treatment of suspected DTIs. A median time for wound care nurse follow-up of 6 days (range 1–41 days), for a total of 377 visits. Pressure ulcers staged according to NPUAP et al. (2007). The data collection tool was developed by the principal investigator and validated through consensus by the Institutional Nursing Research Council.
Secondary outcomes (including scoring methods and timings of assessments)	The percentage of change in size for each ulcer was determined at the same visit, using the following standard formula: $\frac{\text{initial surface area - endpoint surface area} \times 100}{\text{endpoint surface area}} = \%\ \text{change}$

Table B6.21: Summary of methodology for observational studies: Walsh

et al. (2012)

Study name	Use of a sacral silicone border foam dressing as one component of a pressure ulcer prevention program in an intensive care unit setting.
Objective	(Not clearly stated, but appears to have been to achieve additional reduction in pressure ulcer incidence).
Location	USA
Design	Single cohort observational study.
Duration of study	From admission to ICU until duration of ICU stay or until development of pressure ulcer, when appropriate management was considered. Three month study duration.
Patient population	ICU
Sample size	69
Inclusion criteria	No pressure ulcers on admission. Automatically apply the dressing if: length of surgery >6 hours; vasopressor use; cardiac arrest at the time of admission; shock (septic, hypovolaemic, cardiogenic), SIRS, MODS; mechanical ventilation > 24 hours; use of paralytics/continuous sedation >24 hours; generalised oedema/anasarca; faecal incontinence not controlled by faecal management system; spinal cord injury; drive lines (LVAD, RVAD, IABP). Apply the dressing if the patient has ≥3 of the following: diabetes; traction; morbid obesity; >65 years of age; history of pressure ulcers; liver failure; restraint use; malnutrition; ethanol toxicity/drug use active withdrawal.
Exclusion criteria	None stated.
Intervention(s) (n = 69)	Standard care plus Mepilex® Border Sacrum. Standard care included use of a single absorbent breathable incontinent pad and avoidance of all use of cloth pads for incontinence. Patients were placed on a single draw sheet, and placed on the Total Care Sport Bed with low air loss surface and a pulmonary module [Hill Rom, Batesville, Indiana). Education was provided to the nursing and medical staff regarding the study.
Baseline differences	N/A
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	The dressing was applied to the sacral area and maintained through the patients' ICU stay. The dressing was changed every 3 days to allow for assessment of the sacral area. If no pressure ulcer was assessed, a new dressing was applied. If evidence of a pressure ulcer was observed, care was evaluated and appropriate treatment initiated. The pressure ulcer was

	also noted as an outcome and the patient's record was reviewed for contributing factors. No data on length of ICU stay. The intervention was discontinued prematurely in 7 patients, including 5 who expired during their ICU stay, 1 who was agitated resulting in friction against the dressing and frequent displacement, and 1 who did not fulfil inclusion criteria after the dressing was initially applied.
Statistical tests	None stated.
Primary outcomes (including scoring methods and timings of assessments)	Incidence of pressure ulcers. Skin inspected every 3 days and pressure ulcers staged according to NPUAP et al. (2007) guidelines.
Secondary outcomes (including scoring methods and timings of assessments)	None stated.

Table B6.22: Summary of methodology for observational studies: Yoshimura et al. (2016)

Study name	Soft silicone foam dressing is more effective than polyurethane film dressing for preventing intraoperatively acquired pressure ulcers in spinal surgery patients: the Border Operating room Spinal Surgery (BOSS) trial in Japan.
Objective	1. To determine the clinical effectiveness of soft silicone foam dressings in the prevention of intraoperative pressure ulcers in patients undergoing spinal surgery under general anaesthesia in the prone position using the Relton-Hall frame. 2. To clarify the different effects of soft silicone foam dressings and polyurethane film dressings in the prevention of intraoperative pressure ulcers.
Location	Japan
Design	Prospective, dual-centre, open-label, split-body comparison sham study.
Duration of study	Dressings applied for duration of surgery. Mean procedure duration = 2·6 hours (SD ± 1·2).
Patient population	Spinal surgery
Sample size	100
Inclusion criteria	Undergoing elective spinal surgery in the prone position using a Relton-Hall frame.
Exclusion criteria	Undergoing emergency surgery, presence of skin disorders or scars in the area to be observed, remarkable spondylosis deformation, <20 years of age.

Intervention(s) (n = 100) and comparator(s) (n = 100)	Intervention: standard positioning protocol plus Mepilex® Border to the left side of the chest and iliac crest. Comparator: standard positioning protocol plus polyurethane film dressings (Opsite Flexifix®, control; Smith and Nephew) to the right side of the chest and iliac crest.
Baseline differences	The treatment and control groups were similar with respect to the patient characteristics at the start of the trial. This was a sham study, which did not require matching in the statistical analysis and had high reliability because the left and right sides were compared in the same patient. The validity of the sham study was confirmed by a preliminary test.
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	After the application of the dressings, the patient was moved from the supine position into the prone position on the Relton-Hall frame. Thirty minutes after the completion of surgery, and after shifting the patient back into the supine position, the OR nurses determined whether or not intraoperative pressure ulcers had developed.
Statistical tests	The categorical variables associated with the presence or absence of intraoperative pressure ulcers on each side were compared using the $\chi 2$ test or Fisher's exact test, while the continuous variables were compared using the unpaired t-test or Mann–Whitney U test. Variables with P values of <0·05 were included in a subsequent multivariate analysis. A multivariate logistic regression analysis was conducted with selected variables. Prior to the analyses, the correlations between the potential independent variables were assessed for multicollinearity. If the correlation coefficients exceeded 0·4, either variable was selected.
Primary outcomes (including scoring methods and timings of assessments)	The difference in the intraoperative pressure ulcer incidence rates when using soft silicone foam dressings compared with polyurethane film dressings during surgery in patients with intraoperative pressure ulcers and patients without intraoperative pressure ulcers. The relative risk (RR) of developing intraoperative pressure ulcers was analysed based on the patients' characteristics and the intraoperative factors. The condition of the skin that had been in contact with the Relton-Hall frame was evaluated by two operating room nurses using the finger pressure method at 30 minutes after the patient was returned to the supine position from the prone position in order to distinguish non-blanchable erythema from blanchable erythema. The results were confirmed by agreement between these two nurses.

	All of the patients were followed-up by a review of their medical records to ascertain whether or not they had developed any new pressure ulcers on the chest or iliac crest. Patients who developed a pressure ulcer or DTI within 1 week after surgery were classified as having intraoperative pressure ulcers.
Secondary outcomes (including scoring methods and timings of assessments)	Not stated.

Table B6: Summary of methodology for systematic reviews

Study reference	Study title	Study Design & location	Population	Sample size	Objective	Outcomes reported
Black et al. (2014)	Dressings as an adjunct to pressure ulcer prevention: consensus panel recommendations.	Systematic review USA	High-risk patients, ED, ICU, and OR.	Not all sample sizes included.	Assess use of wound dressings for pressure ulcer prevention. Provide evidence based guidelines using graded recommendations depending on strength of evidence (A: RCT's, B: other studies, C: expert opinion, other sources).	Thirteen studies considered clinical outcomes of wound dressing use on pressure ulcer prevention. Eleven studies reported measurements of pressure, shear or friction where wound dressings were applied to the skin.
Clark et al. (2014)	Systematic review of the use of prophylactic dressings in the prevention of pressure ulcers.	Systematic review UK	Primary and secondary care patients at risk of developing pressure ulcers but with no signs of established pressure damage including category I pressure ulcers.	Not clearly stated.	Assess evidence supporting the use of prophylactic dressings for the prevention of pressure ulcers.	Number and severity of new pressure ulcers.
Cornish et al. (2017)	The use of prophylactic dressings in the prevention of pressure ulcers: a literature review.	Quasi-systematic review (no inclusion/exclusion, narrative review, but used systematic search strategy). UK	All studies assessing *in vitro* and clinical evidence of prophylactic dressings in the prevention of pressure ulcers.	Not clearly stated.	Assess evidence supporting the use of prophylactic dressings for the prevention of pressure ulcers.	Number and severity of new pressure ulcers.

Huang et al. (2015)	Dressings for preventing pressure ulcers: a meta-analysis.	Meta-analysis China	Any care settings	5401 subjects analysed	Determine effectiveness of dressings in the prevention of pressure ulcers.	Not clearly stated, but pressure ulcer incidence routinely reported in results.
Moore and Webster (2013)	Dressings and topical agents for preventing pressure ulcers.	Systematic Cochrane review Australia / Ireland	ICU or critical care unit	Dressings applied over bony prominences assessing pressure ulcer incidence (4 trials, n=561).	Identify effectiveness of single strategies designed to reduce the incidence and prevalence of HAPU development in ICUs in comparison to no strategy, other strategies, or usual practice.	HAPU incidence, HAPU prevalence, pressure ulcer severity, time to occurrence, and number of pressure ulcers per patient. Secondary outcome measure was any adverse effect caused by, or associated with, the use of the preventive strategy.
NPUAP et al. (2014)	Prevention and treatment of pressure ulcers: Clinical Practice Guideline.	Systematic review International Guidelines	All patients	Not clearly stated.	International review of pressure injury evidence.	Research to support clinical recommendations

Tayyib and Coyer (2016)	Effectiveness of pressure ulcer prevention strategies for adult patients in intensive care units: a systematic review.	Systematic review Australia	ICU	Effectiveness of the prophylactic silicone foam dressings in decreasing incidence of sacral HAPUs (3 trials, n=500). Effectiveness of similar dressings in reducing incidence of heel HAPUs (2 trials, n=742).	Synthesise the best available evidence regarding the effectiveness of single strategies designed to reduce the incidence and prevalence of HAPU development in ICUs.	HAPU incidence, HAPU prevalence, pressure ulcer severity, time to occurrence, and number of pressure ulcers per patient. Secondary outcome measure was any adverse effect caused by, or associated with, the use of the preventive strategy.

7.4.2 Provide details on data from any single study that have been drawn from more than one source (for example a poster and unpublished report) and/or when trials are linked this should be made clear (for example, an open-label extension to randomised controlled trial).

The observational quality improvement study by Koerner et al. (2011) was originally a poster presentation and the abstract from the study was later published. Data from the poster and the abstract have been used in reporting the results of this study.

The comparative cohort study by Santamaria et al. (2015[a]) used the same control sample that was used in the RCT by Santamaria et al. (2015). The RCT by Santamaria et al. (2015) was also the source of 2 cost-effectiveness studies (Santamaria et al. 2014 and Santamaria et al. 2015[b]), which were excluded from section 7 as they provided no new clinical effectiveness data, but are reviewed in section 8.

The observational study by Sullivan (2015) was a secondary analysis of data from a previously published observational retrospective study (Sullivan, 2013).

7.4.3 Highlight any differences between patient populations and methodology in all included studies.

In all of the 5 RCTs and 21 of the 22 observational studies, Mepilex® dressings were used as an adjunct to standard care for pressure ulcer prevention, which varied according to the study and setting. All studies assessed adult populations. Difference in the appearance of dressings in the 16 comparative trials (11 observational studies, 5 RCTs) made blinding impossible.

Two RCTs by Santamaria et al. (2015) and Santamaria et al. (2018) used a Mepilex® Heel dressing secured with Tubifast dressing. In addition, the RCT by Qiuli and and Qiongyu (2010) used Mepilex® on the sacrococcygeal and heel regions and where it could not closely adhere to the ankles and fell off, Mepilex® Border was used. The Mepilex® Heel dressing is a comparably

shaped, soft, and conformable foam dressing designed for use on the heel. The Mepilex® and Mepilex® Heel dressings are 3-layered dressings which utilise the same Safetac technology used in the Mepilex® Border dressings. Mepilex® Border is the dressing of choice as it is based on the five-layer design that has been reported to be key to the prevention of tissue deformation (Call et al. 2015, Miller et al. 2015, De Wert et al. 2016, Call et al. 2013) and is recommended in the consensus recommendations by Black et al. (2014), whereas Mepilex® Heel has a less complex three-layer structure. Mepilex® Border dressings are also self-adherent, whereas Mepilex® dressings require some form of retention device (bandage or adhesive tape) to keep them in place.

The control and intervention groups in the 5 RCTs (n=1,607) were well matched according to baseline patient characteristics. All of the patients were from high-risk settings: neurosurgical patients (Aloweni et al. 2017), patients across hospital settings (Qiuli and Qiongyu, 2010), trauma and ICU patients (Kalowes et al. 2016), critical illness or trauma patients (Santamaria et al. 2015), and high-risk aged care residents (Santamaria et al. 2018, unpublished).

All 5 of the RCTs assessed outcomes measuring incidence of sacral pressure ulcers and 3 of the studies also assessed the incidence of heel pressure ulcers. All of the RCTs had primary outcomes which were designed to detect incidence rates of HAPUs expressed as the total number of pressure ulcers developed in both groups.

Six of the 11 non-randomised comparative observational studies included high-risk patients from an ICU setting. The other settings were: [redacted], patients with spinal injuries (n=2 studies), and hospitalised patients (n=2 studies). Nine of the 11 observational studies, which were non-comparative in nature, included patients from a high-risk ICU or critical care setting.

7.4.4 Provide details of any subgroup analyses that were undertaken in the studies included in section 7.4.1. Specify the rationale and state whether these analyses were pre-planned or post-hoc.

The RCT by Aloweni et al. (2017) carried out pre-planned subgroup analysis evaluating the association of Braden score with incidence of pressure ulcers within each of the 3 intervention and comparator groups.

The observational retrospective study by Richard-Denis et al. (2017) included stratified analyses on patients with complete tetraplegia and complete paraplegia evaluating the association of these conditions with incidence of pressure ulcers within the standard care group and the standard care plus Mepilex® Border Sacrum group.

7.4.5 If applicable, provide details of the numbers of patients who were eligible to enter the study(s), randomised, and allocated to each treatment in an appropriate format.

There were 1,607 participants in control and intervention groups in the 5 RCTs. CONSORT flow charts for 4 of the 5 RCTs are attached below. The RCT by Qiuli and Qiongyu (2010) contained minimal information on randomisation and patient flow. In that study the patients were randomly divided into two groups: 26 were in the observation group with 14 males and 12 females and 26 were in the control group with 11 males and 15 females.

Figure B1: CONSORT flow chart for Santamaria et al. (2015)

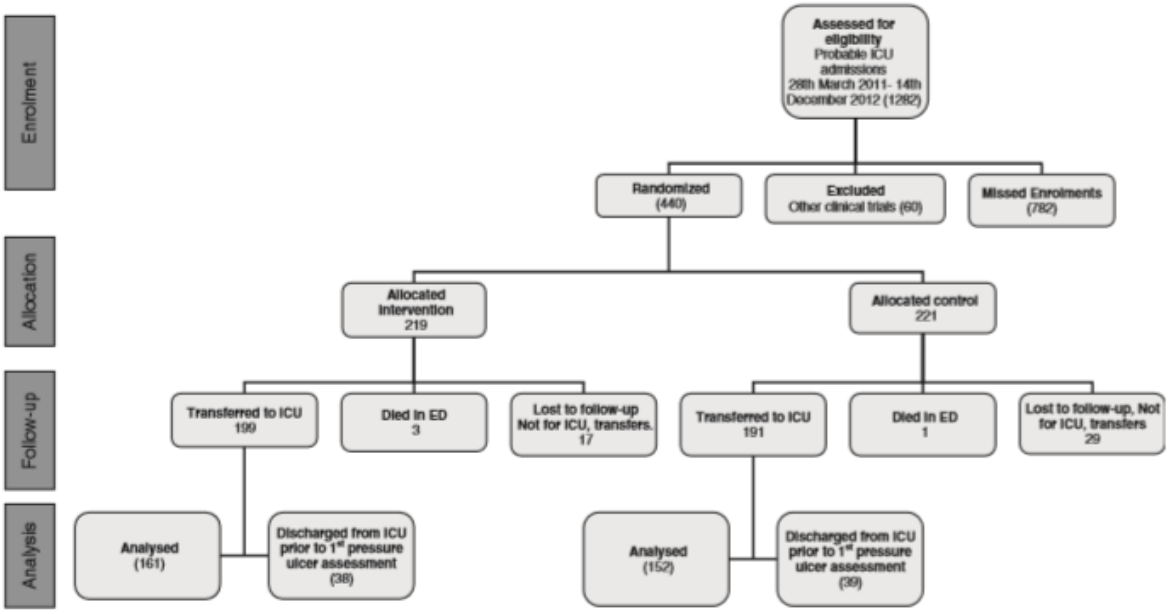


Figure B2: CONSORT flow chart for Kalowes et al. (2016)

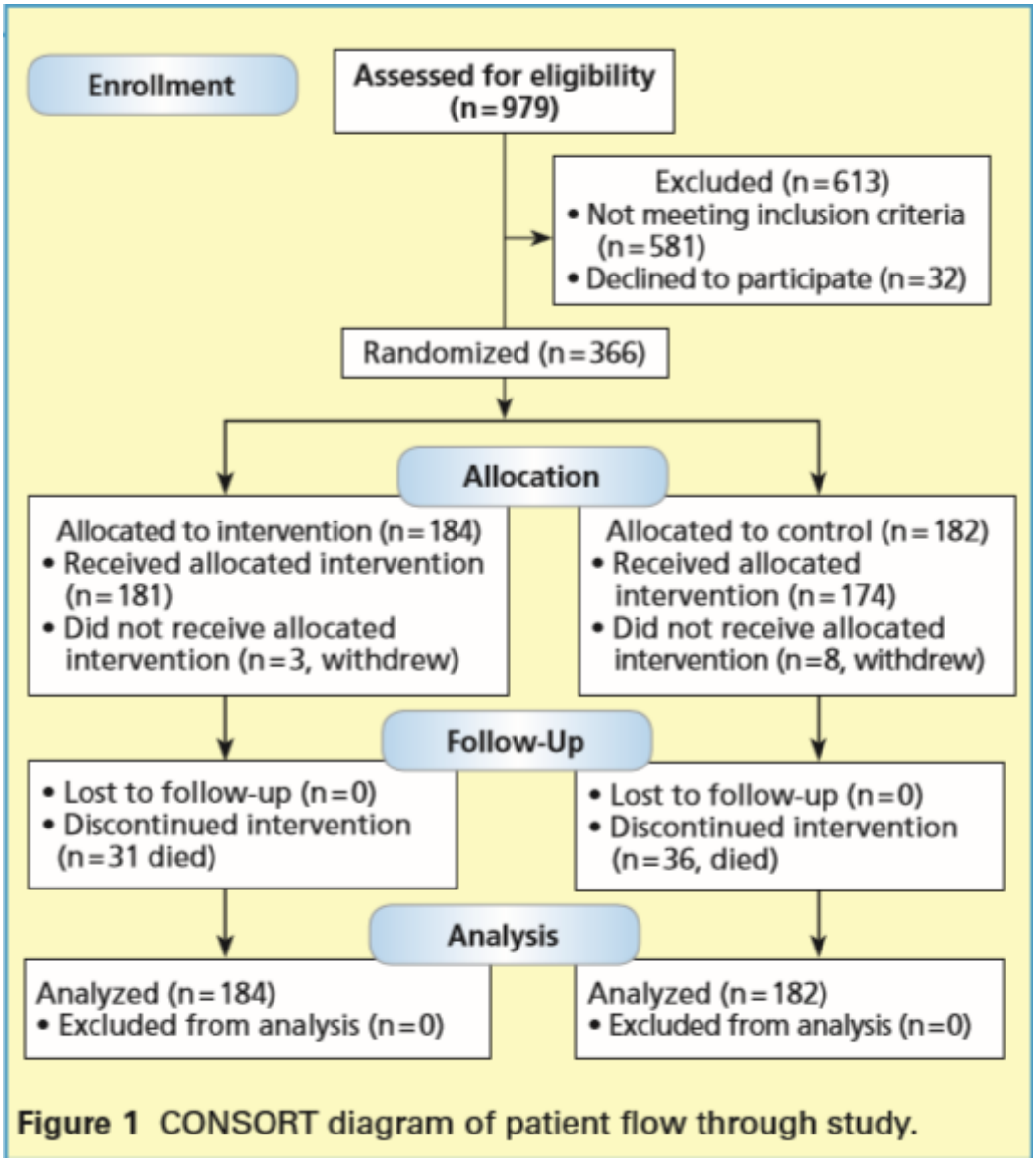


Figure 1 CONSORT diagram of patient flow through study.

Figure B3: CONSORT flow chart for Aloweni et al. (2017)

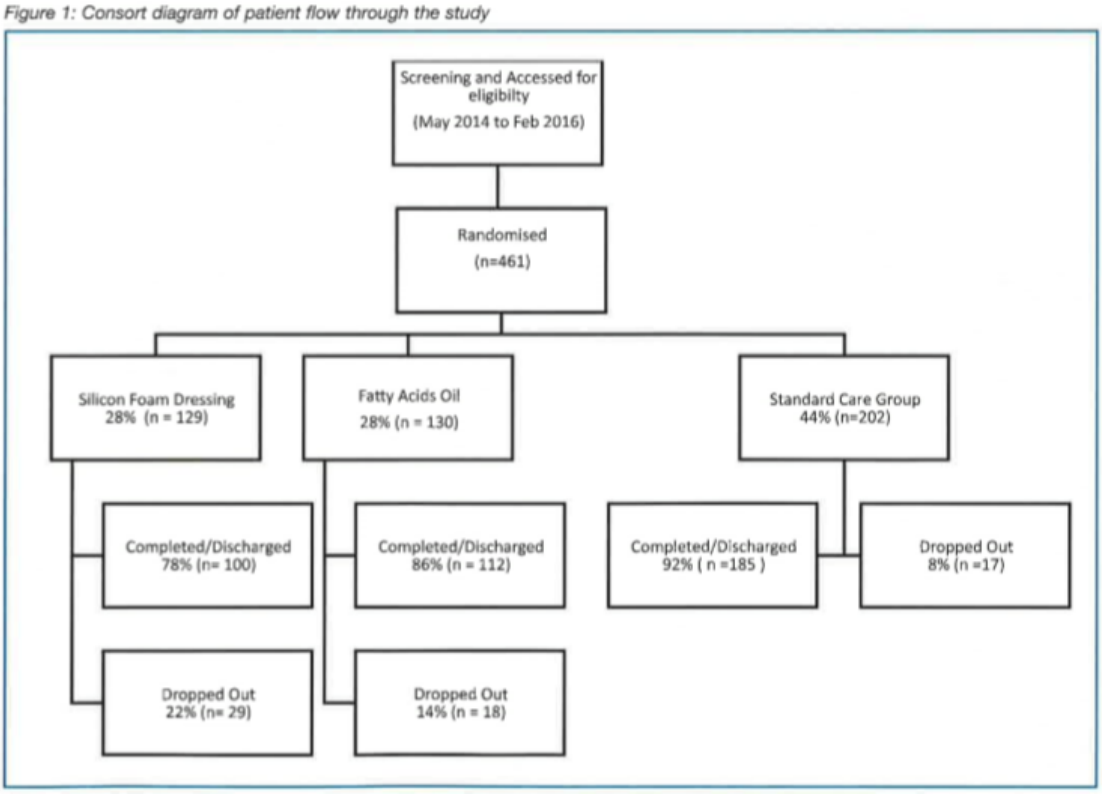
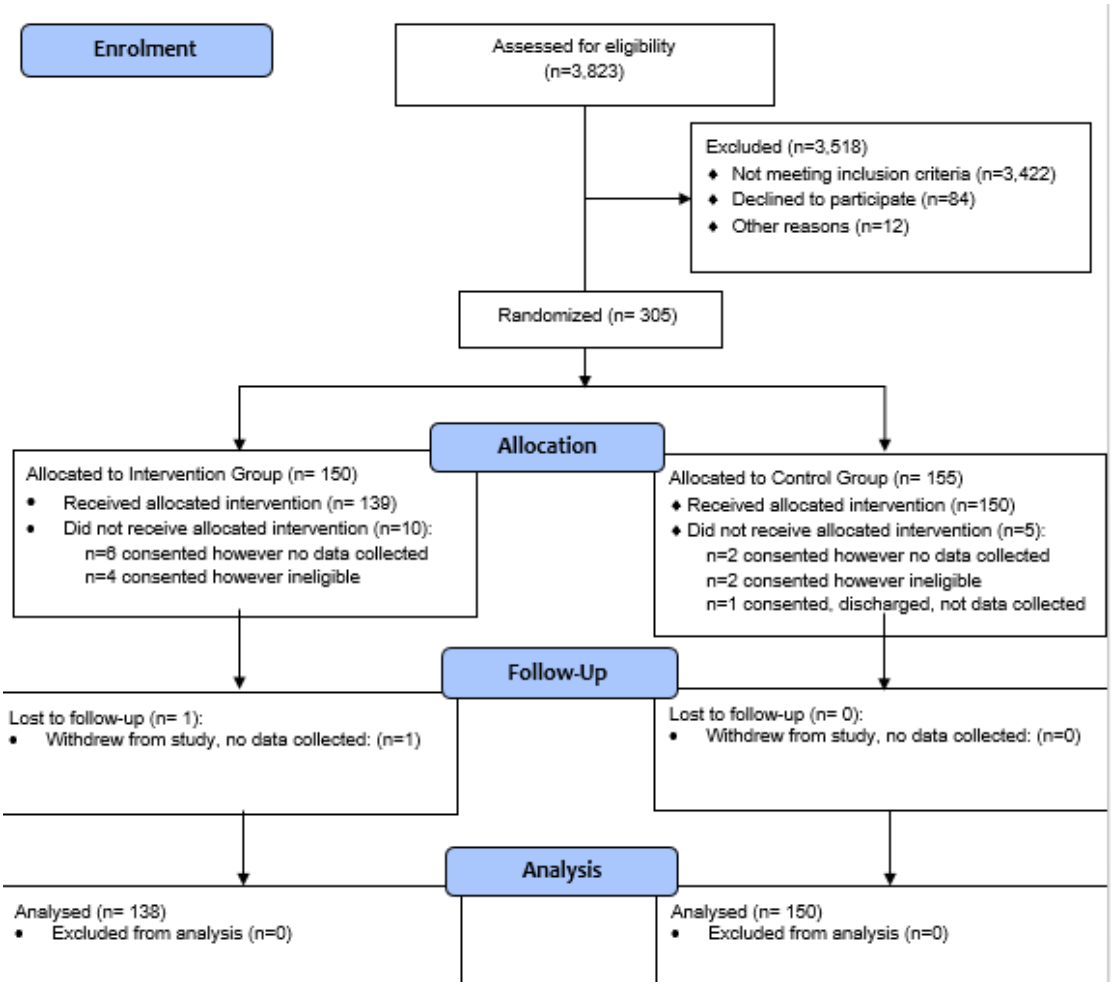


Figure B4: CONSORT flow chart for Santamaria et al. (2018,)



7.4.6 If applicable provide details of and the rationale for, patients that were lost to follow-up or withdrew from the studies.

All of the lost to follow-up information is detailed in the relevant appraisal, methodology, or outcomes tables.

7.5 Critical appraisal of relevant studies

7.5.1 Complete a separate quality assessment table for each study. A suggested format for the quality assessment results is shown in tables B7 and B8.

Table B7.1: Critical appraisal of RCTs: Aloweni et al. (2017)

Study name	A randomised controlled trial to evaluate the incremental effectiveness of a prophylactic dressing and fatty acids oil in the prevention of pressure injuries.	
Study question	**Response (yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was randomisation carried out appropriately?	Yes	Adequate generation of the randomisation sequence.
Was the concealment of treatment allocation adequate?	Yes	Allocation list performed by research coordinator not involved in study. Opaque sealed envelopes used to maintain allocation concealment. Allocation assignment only made known to ward nurses after patients successfully enrolled in study.
Were the groups similar at the outset of the study in terms of prognostic factors, for example, severity of disease?	Yes	No significant difference in terms of age, Braden score, nutrition status, skin colour, presence of heart disease or diabetes.
Were the care providers, participants and outcome assessors blind to treatment allocation? If any of these people were not blinded, what might be the likely impact on the risk of bias (for each outcome)?	No	Patients and care providers/data collectors (nurses) were not blinded. Difference in the appearance of dressings made blinding impossible.
Were there any unexpected imbalances in drop-outs between groups? If so, were they explained or adjusted for?	Yes	Drop-outs: dressing group = 29 (sacral excoriation = 3, diarrhoea = 6, dying/death = 6, contamination of treatment = 9, requested withdrawal = 5) Fatty acids oil group = 18 Standard care = 17

		Reasons for drop-out provided, no adjustments made.
Is there any evidence to suggest that the authors measured more outcomes than they reported?	No	
Did the analysis include an intention-to-treat analysis? If so, was this appropriate and were appropriate methods used to account for missing data?	Yes	Intention-to-treat analysis provided an unbiased estimate of the treatment effect and reflected clinical practice.
Adapted from Centre for Reviews and Dissemination (2008) Systematic reviews. CRD's guidance for undertaking reviews in health care. York: Centre for Reviews and Dissemination		

Table B7.2: Critical appraisal of RCTs: Kalowes et al. (2016)

Study name	Five-layered soft silicone foam dressing to prevent pressure ulcers in the intensive care unit.	
Study question	**Response (yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was randomisation carried out appropriately?	Yes	The randomisation of participants was undertaken by the principal investigator or study nurse, when patients were admitted to the ICU, and following eligibility screening. Enrolment and randomisation procedures were carried out by the study nurse: (1) study team rounds daily, screens for new patients admitted to the ICU who meet inclusion criteria; (2) determine group allocation by accessing the randomisation programme (3) if patient is randomised to the treatment group, the Mepilex® Border Sacrum foam dressing is applied to the patient's sacrum following the protocol, recording the time and date on the dressing.
Was the concealment of treatment allocation adequate?	Yes	See (2) above. Difficult to conceal treatment given the nature of the treatments.
Were the groups similar at the outset of the study in	Yes	Baseline characteristics of all 366 patients showed that the groups did not differ significantly.

terms of prognostic factors, for example, severity of disease?		
Were the care providers, participants and outcome assessors blind to treatment allocation? If any of these people were not blinded, what might be the likely impact on the risk of bias (for each outcome)?	No	The risk for bias in reporting findings was reported by the authors however they stated that it was impossible to blind data collectors because of the nature of the treatment intervention.
Were there any unexpected imbalances in drop-outs between groups? If so, were they explained or adjusted for?	No	No drop-outs in study.
Is there any evidence to suggest that the authors measured more outcomes than they reported?	No	
Did the analysis include an intention-to-treat analysis? If so, was this appropriate and were appropriate methods used to account for missing data?	Yes	The intention-to-treat analysis was appropriate. The number of patients who died during the study were accounted for (31 in the intervention group and 36 in the control group). There was no other missed data.
Adapted from Centre for Reviews and Dissemination (2008) Systematic reviews. CRD's guidance for undertaking reviews in health care. York: Centre for Reviews and Dissemination		

Table B7.3: Critical appraisal of RCTs: Qiuli and Qiongyu (2010)

Study name	[Observation on effect of Mepilex® on the prevention and treatment of pressure sores].	
Study question	**Response (yes/no/not clear/N/A)**	**How is the question addressed in the study?**

Was randomisation carried out appropriately?	Not clear	No details on randomisation process. It was not stated how many patients used Mepilex® dressings and how many used Mepilex® Border dressings.
Was the concealment of treatment allocation adequate?	Not clear	No details presented.
Were the groups similar at the outset of the study in terms of prognostic factors, for example, severity of disease?	Yes	No significant differences between the two groups in terms of gender, age, condition ($p>0.05$). However, 16 patients were reported as being incontinent, but it is not clear which group these patients were in.
Were the care providers, participants and outcome assessors blind to treatment allocation? If any of these people were not blinded, what might be the likely impact on the risk of bias (for each outcome)?	Not clear	No details on blinding in the study. Difference in the appearance of dressings made blinding impossible. Therefore, the outcome or outcome measurement may be influenced by a lack of blinding.
Were there any unexpected imbalances in drop-outs between groups? If so, were they explained or adjusted for?	Not clear	Drop-outs not assessed in study.
Is there any evidence to suggest that the authors measured more outcomes than they reported?	No	
Did the analysis include an intention-to-treat analysis? If so, was this appropriate and were appropriate methods used to account for missing data?	Not clear	Minimal information given regarding the results of the study. (There were no numbers of patients who completed the trial, the number of patients followed-up, and the number of drop-outs).

Adapted from Centre for Reviews and Dissemination (2008) Systematic reviews. CRD's guidance for undertaking reviews in health care. York: Centre for Reviews and Dissemination

Table B7.4: Critical appraisal of RCTs: Santamaria et al. (2015)

Study name	A randomised controlled trial of the effectiveness of soft silicone multi-layered foam dressings in the prevention of sacral and heel pressure ulcers in trauma and critically ill patients: the border trial.	
Study question	**Response (yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was randomisation carried out appropriately?	Yes	The randomisation was undertaken by an ED research nurse when the patient was admitted to ED and following screening to determine if they met the inclusion criteria. The following procedure was used by the ED research nurse to enrol each participant into the trial: • Potential participant admitted to ED trauma/resuscitation • Assessment to determine if patient meets study inclusion criteria • Group allocation determined by retrieving randomisation envelope If randomised to trial group: • Mepilex® Border Sacrum dressings applied to sacrum and Mepilex® Heel dressing applied to both heels • Time of dressing application recorded
Was the concealment of treatment allocation adequate?	N/A	Not possible due to dressing being applied if in intervention group.
Were the groups similar at the outset of the study in terms of prognostic factors, for example, severity of disease?	Yes	The groups were comparable on major physiological and demographic characteristics on admission to ED.
Were the care providers, participants and outcome assessors blind to treatment allocation? If any of these people were not blinded, what	Not clear	Difference in the appearance of dressings made blinding impossible. Therefore, the outcome or outcome measurement may have been influenced by a lack of blinding. All members of the research team underwent inter-rater reliability testing prior to data collection to ensure consistency in pressure ulcer identification and staging.

might be the likely impact on the risk of bias (for each outcome)?		
Were there any unexpected imbalances in drop-outs between groups? If so, were they explained or adjusted for?	No	There were 17 patients in the intervention group and 29 patients in the control group lost to follow-up. No adjustments made, but patients lost to follow-up explained in the CONSORT flow chart.
Is there any evidence to suggest that the authors measured more outcomes than they reported?	Yes	The study by Santamaria et al. (2015[b]) evaluates the cost-effectiveness of the Mepilex® dressings used in the study.
Did the analysis include an intention-to-treat analysis? If so, was this appropriate and were appropriate methods used to account for missing data?	Yes	All patients followed-up or lost to follow-up explained.
Adapted from Centre for Reviews and Dissemination (2008) Systematic reviews. CRD's guidance for undertaking reviews in health care. York: Centre for Reviews and Dissemination		

Table B7.5: Critical appraisal of RCTs: Santamaria et al. (2018, unpublished)

Study name	**Santamaria et al. 2018**	
Study question	**Response (yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was randomisation carried out appropriately?	Yes	Facilities randomised by a member of the research team
Was the concealment of treatment allocation adequate?	Yes	The member of the research team was blinded to the identity of the facilities.
Were the groups similar at the outset of the study in terms of prognostic factors, for	Yes	Participants were comparable on demographic and physiological parameters.

example, severity of disease?		
Were the care providers, participants and outcome assessors blind to treatment allocation? If any of these people were not blinded, what might be the likely impact on the risk of bias (for each outcome)?	No	Authors acknowledge inability to blind both the subject and the assessor to the presence or absence of the intervention. Authors state this is a general limitation in wound care trials investigating a specific product or device and as such it should be regarded as a pragmatic trial of the clinical effectiveness of the dressings to prevent the development of a pressure ulcer in high-risk aged care residents. Difference in the appearance of dressings made blinding impossible. Therefore, the outcome or outcome measurement may be influenced by a lack of blinding.
Were there any unexpected imbalances in drop-outs between groups? If so, were they explained or adjusted for?	No	Drop-outs included in CONSORT flow chart of participants.
Is there any evidence to suggest that the authors measured more outcomes than they reported?	No	
Did the analysis include an intention-to-treat analysis? If so, was this appropriate and were appropriate methods used to account for missing data?	Intention-to-treat	Missing data described in CONSORT flow chart, but not explained in analysis.
Adapted from Centre for Reviews and Dissemination (2008) Systematic reviews. CRD's guidance for undertaking reviews in health care. York: Centre for Reviews and Dissemination		

Table B8.1: Critical appraisal of observational studies: Baker (2014)

Study name		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**

Was the cohort recruited in an acceptable way?	Not clear	Limited information from poster presentation. All CVOR patients with perioperative time ≥ 4 hours, all CVICU patients meeting inclusion criteria (not specified), and all STICU patients placed on rotational prone positioning beds. No details on pressure ulcer risk scale of patients or specific conditions.
Was the exposure accurately measured to minimise bias?	Not clear	Limited information from poster presentation. Skin assessments completed every shift by peeling back dressing, examining skin, and replacing dressing. No details of what stages of pressure ulcers were being measured. No details of what standard care constituted. Poster states that Mölnlycke Health Care US, LLC. provided support for this project.
Was the outcome accurately measured to minimise bias?	Not clear	Poster states HAPU/DTI incidence rate decreased to 0% for all patients included in the trial. Unclear if this referred to all stages of pressure ulcers or only those with full thickness skin loss (stage III or IV).
Have the authors identified all important confounding factors?	Not clear	Limited information from poster presentation.
Have the authors taken account of the confounding factors in the design and/or analysis?	Not clear	Limited information from poster presentation.
Was the follow-up of patients complete?	Not clear	Limited information from poster presentation. No pressure ulcers from any of the high-risk patients during the 45 day study period.
How precise (for example, in terms of confidence interval and p values) are the results?	-	HAPU/DTI incidence rate by number (%) No details on confidence intervals or p values.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Table B8.2: Critical appraisal of observational studies: Bateman and Roberts (2013)

Study name: Moisture lesions and associated pressure ulcers - getting the dressing regime right.

Study question	Response yes/no/not clear/N/A)	How is the question addressed in the study?
Was the cohort recruited in an acceptable way?	Yes	All patients recruited had an initial diagnosis of reduced skin integrity due to incontinence, sweat, or wound exudate.
Was the exposure accurately measured to minimise bias?	Yes	In the first week, the dressing regimen was applied to all patients with moisture or combined lesions every 48 hours, reducing to 72 hours thereafter unless incontinence contaminated the dressing products, in which case redressing was immediate.
Was the outcome accurately measured to minimise bias?	Yes	Skin integrity assessed using Bateman et al. (2011) classification tool. If reduced skin integrity noted then Braden scale and MUST scale required.
Have the authors identified all important confounding factors?	Not clear	Many confounding factors identified: nutrition, shear, friction, pressure, repositioning.
Have the authors taken account of the confounding factors in the design and/or analysis?	Yes	A number of scales utilised to measure contributing/confounding factors.
Was the follow-up of patients complete?	Yes	Patients were followed-up for 4 weeks.
How precise (for example, in terms of confidence interval and p values) are the results?	-	No further deterioration of existing pressure ulcers or development of new pressure ulcers in 17 patients using Mepilex® Border. Confidence intervals or p values not stated.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Table B8.3: Critical appraisal of observational studies: Brindle (2010)

Study name: Outliers to the Braden Scale: Identifying high-risk ICU patients and the results of prophylactic dressing use.		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Yes	All patients admitted to STICU included in 3 month period.

Was the exposure accurately measured to minimise bias?	Yes	Clear definition of skin assessment detailed.
Was the outcome accurately measured to minimise bias?	Not clear	Pressure ulcer staging not detailed.
Have the authors identified all important confounding factors?	Yes	Controllable and uncontrollable risk factors detailed and factors for high-risk detailed in inclusion criteria.
Have the authors taken account of the confounding factors in the design and/or analysis?	Yes	Assessment tool developed with confounding factors included.
Was the follow-up of patients complete?	Not clear	States all patients followed-up, but 3 of the control group patients who experienced pressure ulcers were 'either not included in study due to low risk, or were missed during evaluation'.
How precise (for example, in terms of confidence interval and p values) are the results?	Not precise	No confidence intervals or p numbers stated.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Table B8.4: Critical appraisal of observational studies: Brindle and Wegelin (2012)

Study name: Prophylactic dressing application to reduce pressure ulcer formation in cardiac surgery patients.		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Yes	The assignment of subjects to groups was done in a non-random manner, via pre-study room designation (7 intervention rooms/7 standard practice rooms) and room availability on call from the OR. The charge nurse and bed management staff were unaware of room designation and staff did not know which group the subjects were assigned to until they admitted the patient

		and opened the bedside chart that indicated group assignment.
Was the exposure accurately measured to minimise bias?	Yes	Clear definition of skin assessment detailed. Peel back dressing daily, assess skin and reseal existing dressing, document findings, remove & discard dressing every 3 days for duration of ICU stay. During study all ICU patients were monitored for skin breakdown and followed up using a tracking form. Any suspected skin breakdown occurring around the sacrum, coccyx, or gluteal fold was immediately reported and assistance from a trained skin integrity team member was available and a nursing treatment plan. Patients were followed-up until they left the ICU or if they expired/left ICU before 48 hrs.
Was the outcome accurately measured to minimise bias?	Not clear	No reporting of scoring assessment used, but different stages of developing pressure ulcers stated.
Have the authors identified all important confounding factors?	Yes	21 covariate factors compared between groups.
Have the authors taken account of the confounding factors in the design and/or analysis?	Yes	21 covariate factors compared between groups.
Was the follow-up of patients complete?	No, for intention-to-treat. Yes, for per protocol.	Data collection forms of 5 patients were lost and their group assignment was not known. Six out of 56 subjects in the intervention group did not complete the study and 4 out of 39 control subjects also failed to complete the study.
How precise (for example, in terms of confidence interval and p values) are the results?	-	Incidence of pressure ulcers in study period provided. Confidence intervals and p values presented.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Table B8.5: Critical appraisal of observational studies: Chaiken et al. (2012)

Study name: Reduction of sacral pressure ulcers in the intensive care unit using a silicone border foam dressing.		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Not clear	Minimal inclusion/exclusion criteria. Different durations of treatment for the intervention (6 months) and control (35 months) groups.
Was the exposure accurately measured to minimise bias?	Yes	Subjects' sacral skin was examined every shift by the nursing staff within each 24-hour period by peeling back the silicone dressing and inspecting the underlying skin. The dressing was changed twice a week on prescheduled days.
Was the outcome accurately measured to minimise bias?	Not clear	The WOCN was alerted of any sacral skin changes and determined if skin changes were due to pressure or other factors such as incontinent dermatitis. There was no discussion of staging scale, although results did state what stages of pressure ulcers developed.
Have the authors identified all important confounding factors?	Yes	Preventive practices discussed.
Have the authors taken account of the confounding factors in the design and/or analysis?	Not clear	Most of preventive practices used for both groups, but authors admit limitation that education sessions only introduced for intervention group as well as daily visits to the ICU by the WOCN.
Was the follow-up of patients complete?	Not clear	Limited follow-up data, 4 of 5 patients who developed sacral HAPU's in intervention group died, but no other data on lost patients.
How precise (for example, in terms of confidence interval and p values) are the results?	-	Initially, the study measured sacral HAPU, using National Database for Nursing Quality Indicators procedures, compared with measuring HAPU incidence during prospective study, so not able to directly compare results using inferential statistics.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Table B8.6: Critical appraisal of observational studies: Cubit et al. (2013)

Study name: 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.		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Not clear	Defined inclusion and exclusion criteria, but not clear why some patients invited to be part of intervention group and some patients not, i.e. control group.
Was the exposure accurately measured to minimise bias?	Not clear	Presence and stage of pressure injury in the intervention group was through actual skin assessment on the patient, while pressure injury in the known group was recorded from the medical record and RiskMan.
Was the outcome accurately measured to minimise bias?	Yes	Pressure ulcers were graded using the four stage system approved by the Australian Wound Management Association.
Have the authors identified all important confounding factors?	Not clear	Standard care not well defined.
Have the authors taken account of the confounding factors in the design and/or analysis?	No	Authors state that further research is needed to explore associations of other factors including nutrition, continence, mobility and comorbidities.
Was the follow-up of patients complete?	Not clear	Lack of follow-up details.
How precise (for example, in terms of confidence interval and p values) are the results?	-	P value presented, but no confidence interval presented.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Table B8.7: Critical appraisal of observational studies: Daukste et al. (2014)

Study name: Mepilex® Border Sacrum dressing use for pressure ulcers prevention in period of open heart surgery and in intensive care unit.		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Not clear	No inclusion, exclusion criteria detailed.
Was the exposure accurately measured to minimise bias?	Not clear	Specific timings of assessment not stated.
Was the outcome accurately measured to minimise bias?	Not clear	Specific timings of assessment and scoring methods not stated.
Have the authors identified all important confounding factors?	Not clear	Not stated in poster.
Have the authors taken account of the confounding factors in the design and/or analysis?	Not clear	Not stated in poster.
Was the follow-up of patients complete?	Not clear	Skin integrity of all patients accounted for, but minimal details of follow-up.
How precise (for example, in terms of confidence interval and p values) are the results?	-	No confidence intervals or p numbers presented.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Table B8.8: Critical appraisal of observational studies: Edwards and Lynch (2014)

Study name: Head over heels for prevention: use of a silicone bordered foam heel dressing in the prevention of pressure ulcers.		
Study question	**Response**	**How is the question addressed in the study?**

	yes/no/not clear/N/A)	
Was the cohort recruited in an acceptable way?	Yes	On admission to ward.
Was the exposure accurately measured to minimise bias?	Not clear	Dressing change twice/week, but not detailed how many days between changes.
Was the outcome accurately measured to minimise bias?	Not clear	Staging of pressure ulcer method not stated.
Have the authors identified all important confounding factors?	Not clear	Minimal information from poster, but confounding factors addressed, e.g. mattress, albumin level, leg elevation, heel suspension device.
Have the authors taken account of the confounding factors in the design and/or analysis?	Yes	Patients wearing heel dressing not used in conjunction with heel suspension device.
Was the follow-up of patients complete?	Not clear	No details on any patients lost to follow-up.
How precise (for example, in terms of confidence interval and p values) are the results?	-	No confidence intervals or p values stated.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Table B8.9: Critical appraisal of observational studies: Gentry and Wright (2010)

Study name: The 'Sacral Heart' Dressing Study: use of an absorbent self-adherent soft silicone sacral foam dressing across acute care settings.		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Yes	Clear inclusion and exclusion criteria.
Was the exposure accurately	Yes	Skin inspected daily.

measured to minimise bias?		
Was the outcome accurately measured to minimise bias?	Not clear	Staging of pressure ulcer method not stated.
Have the authors identified all important confounding factors?	Yes	Confounding factors addressed in data collection form and medical complications addressed in poster.
Have the authors taken account of the confounding factors in the design and/or analysis?	Yes	Confounding factors addressed in data collection form.
Was the follow-up of patients complete?	Not clear	No details on any patients lost to follow-up.
How precise (for example, in terms of confidence interval and p values) are the results?	-	No confidence intervals or p values stated.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Table B8.10: Critical appraisal of observational studies: Haisley et al. (2015)

Study name: An ounce of prevention: the use of an absorbent soft silicone self-adherent bordered foam heel dressing to decrease the incidence of hospital-acquired heel pressure ulcers in an acute care setting.		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Yes	Clear inclusion/exclusion criteria.
Was the exposure accurately measured to minimise bias?	Yes	Dressings lifted daily to check skin integrity and heels checked before patient discharge from ward.
Was the outcome accurately measured to minimise bias?	Not clear	Staging of pressure ulcer method not stated.

Have the authors identified all important confounding factors?	Not clear	Some factors detailed in inclusion criteria, but not all factors listed.
Have the authors taken account of the confounding factors in the design and/or analysis?	Yes	Matched some confounding factors with control group.
Was the follow-up of patients complete?	Not clear	No details on any patients lost to follow-up.
How precise (for example, in terms of confidence interval and p values) are the results?	-	No confidence intervals or p values stated.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

THIS INFORMATION IS 'ACADEMIC IN CONFIDENCE'

Table B8.11: Critical appraisal of observational studies: Jin (2018, unpublished)

Study name: [redacted]		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	[redacted]	[redacted]
Was the exposure accurately measured to minimise bias?	[redacted]	[redacted]
Was the outcome accurately measured to minimise bias?	[redacted]	[redacted]
Have the authors identified all important	[redacted]	[redacted]

confounding factors?		
Have the authors taken account of the confounding factors in the design and/or analysis?	[redacted]	[redacted]
Was the follow-up of patients complete?	[redacted]	[redacted]
How precise (for example, in terms of confidence interval and p values) are the results?	[redacted]	[redacted]
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Table B8.12: Critical appraisal of observational studies: Johnstone and McGown (2013)

Study name: Innovations in the reduction of pressure ulceration and pain in critical care.		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Yes	Clear inclusion criteria.
Was the exposure accurately measured to minimise bias?	Yes	Sacral area checked daily to check skin integrity.
Was the outcome accurately measured to minimise bias?	Yes	Staging of pressure ulcer method not stated. Clinical information was recorded daily on OpenVista® CareVue (Medsphere®) – an electronic patient recording system – and a questionnaire was completed daily by the clinician on the clinical performance of the dressing.
Have the authors identified all important confounding factors?	Not clear	Standard care not detailed.

Have the authors taken account of the confounding factors in the design and/or analysis?	Not clear	Some factors detailed in inclusion criteria, but not all factors listed.
Was the follow-up of patients complete?	Not clear	No details on any patients lost to follow-up.
How precise (for example, in terms of confidence interval and p values) are the results?	-	No confidence intervals or p values stated.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Table B8.13: Critical appraisal of observational studies: Koerner and Adams (2011)

Study name: Save our sacrums (S.O.S.) Does the use of an absorbent soft silicone self-adherent bordered foam dressing decrease the incidence of hospital acquired pressure ulcers?		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Yes	Clear inclusion criteria.
Was the exposure accurately measured to minimise bias?	Not clear	Sacral area only checked every 4 days or as required.
Was the outcome accurately measured to minimise bias?	Not clear	Staging of pressure ulcer method not stated. Data collection form detailed on poster.
Have the authors identified all important confounding factors?	Yes	Standard care detailed on poster.
Have the authors taken account of the confounding factors in the design and/or analysis?	Yes	Data collection form detailed alongside standard care provision.

Was the follow-up of patients complete?	Not clear	No details on any patients lost to follow-up.
How precise (for example, in terms of confidence interval and p values) are the results?	-	No confidence intervals or p values stated.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Table B8.14: Critical appraisal of observational studies: Lientz (2013)

Study name: Dollars and sense: economic value in HAPU/sDTI prevention.		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Yes	Clear inclusion criteria.
Was the exposure accurately measured to minimise bias?	Yes	Dressing applied and dated. Sacral area checked daily to check skin integrity. Dressing changed every 3 days or as required.
Was the outcome accurately measured to minimise bias?	Not clear	Staging of pressure ulcer method not stated.
Have the authors identified all important confounding factors?	Yes	Standard care detailed on poster.
Have the authors taken account of the confounding factors in the design and/or analysis?	Yes	Inclusion criteria detailed alongside standard care provision.
Was the follow-up of patients complete?	Not clear	Two patients lost to follow-up as protocol not followed.
How precise (for example, in terms of confidence interval and p values) are the results?	-	No confidence intervals or p values stated.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence		

12 questions to help you make sense of a cohort study

Table B8.15: Critical appraisal of observational studies: Muldoon et al. (2010)

Study name: Initial use absorbent soft silicone self-adherent bordered foam dressing reduces sacral pressure ulcers in the cardiovascular ICU.		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Not clear	Minimal information on inclusion/exclusion criteria.
Was the exposure accurately measured to minimise bias?	Yes	Sacral area checked daily to check skin integrity. Dressing changed every 3 days or as required.
Was the outcome accurately measured to minimise bias?	Not clear	Staging of pressure ulcer method not stated.
Have the authors identified all important confounding factors?	Not clear	Insufficient information on poster.
Have the authors taken account of the confounding factors in the design and/or analysis?	Not clear	Methods and procedures “consistent with Osceola Regional standards of care and evidence-based pressure ulcer prevention protocols”.
Was the follow-up of patients complete?	Yes	Length of stay of 3 case studies stated.
How precise (for example, in terms of confidence interval and p values) are the results?	-	No confidence intervals or p values stated.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Table B8.16: Critical appraisal of observational studies: Padula (2017)

Study name: Effectiveness and value of prophylactic 5-layer foam sacral dressings to prevent hospital-acquired pressure injuries in acute care hospitals.		
Study question	**Response**	**How is the question addressed in the study?**

	yes/no/not clear/N/A)	
Was the cohort recruited in an acceptable way?	Not clear	There are acknowledged limitations to the recruitment. Author assumed that the Mepilex® Border Sacrum dressings were used as indicated and assumed that hospitals could act as their own controls, since PSI-03 counts were regressed between hospitals at times when hospitals had purchased different amounts of these sacral dressings, to predict a trajectory of HAPU rates.
Was the exposure accurately measured to minimise bias?	Not clear	The size (38 hospitals) and retrospective, longitudinal (6 year) nature of the study meant that it was not possible to assess how well the exposure was measured. Due to an abundance of missing data from the University Health System Consortium clinical database/resource manager in the third quarter of 2012, this quarter was omitted from the analysis.
Was the outcome accurately measured to minimise bias?	Not clear	The rates of HAPUs are dependent upon accurate coding and reporting of PSI-03.
Have the authors identified all important confounding factors?	Not clear	There are a number of confounding factors detailed, but study focussed on difference between hospitals using, or not using, Mepilex® Border Sacrum so confounding factors may have varied from one hospital to another.
Have the authors taken account of the confounding factors in the design and/or analysis?	Not clear	Study had limited discussion of other forms of HAPU prevention.
Was the follow-up of patients complete?	Not clear	Patients lost to follow-up not assessed.
How precise (for example, in terms of confidence interval and p values) are the results?		Confidence intervals not presented, but SDs and p values stated.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Table B8.17: Critical appraisal of observational studies: Park (2014)

Study name: The effect of a silicone border foam dressing for prevention of pressure ulcers and incontinence associated dermatitis in intensive care unit patients.		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Yes	Clear inclusion and exclusion criteria.
Was the exposure accurately measured to minimise bias?	Yes	Sacral area checked and dressing changed every 3 days or as required.
Was the outcome accurately measured to minimise bias?	Yes	Pressure ulcer development staged according to NPUAP et al. (2009).
Have the authors identified all important confounding factors?	Yes	Discussion of confounding factors in introduction.
Have the authors taken account of the confounding factors in the design and/or analysis?	Yes	Both groups received same pressure redistribution mattress (Hill-Rom/KCI, USA) and turning and repositioning protocols.
Was the follow-up of patients complete?	Yes	Follow-up information described and all patients accounted for.
How precise (for example, in terms of confidence interval and p values) are the results?	-	P values presented, but no confidence interval stated for primary outcome.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Table B8.18: Critical appraisal of observational studies: Richard-Denis et al. (2017)

Study name: Effectiveness of a multi-layer foam dressing in preventing sacral pressure ulcers for the early acute care of patients with a traumatic spinal cord injury: comparison with the use of a gel mattress.

Study question	Response yes/no/not clear/N/A)	How is the question addressed in the study?
Was the cohort recruited in an acceptable way?	No	Clear inclusion criteria and patients entered at admission and were followed up until discharge from the acute care centre. However, dressings only in place during pre-operative period until surgery. Mepilex® Border Sacrum group did not receive standard care. The groups were not well matched in terms of number of participants in each group.
Was the exposure accurately measured to minimise bias?	Not clear	Dressing inspected every 8 hours pre-operatively, but routine data sheet used post-operatively and timing of assessment unclear.
Was the outcome accurately measured to minimise bias?	Not clear	Pressure ulcer development and staging was based on NPUAP et al. (2007). Not clear on timings of skin assessment post-operatively.
Have the authors identified all important confounding factors?	Yes	12 potential predictors of sacral pressure ulcer were compared between groups in a multivariate logistic regression.
Have the authors taken account of the confounding factors in the design and/or analysis?	Not clear	Discussion of contributory factors and analysis of different factors contributing to pressure ulcer development, but patients in Mepilex® Border Sacrum group not using gel mattress as part of standard care.
Was the follow-up of patients complete?	Not clear	No data on any patients lost to follow-up.
How precise (for example, in terms of confidence interval and p values) are the results?	-	P values presented, confidence intervals not presented for main outcomes.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Table B8.19: Critical appraisal of observational studies: Santamaria et al. (2015[a])

Study name: Clinical effectiveness of a silicone foam dressing for the prevention of heel pressure ulcers in critically ill patients: Border II Trial.

Study question	Response yes/no/not clear/N/A)	How is the question addressed in the study?
Was the cohort recruited in an acceptable way?	Not clear	Patients entered at admission and were followed up until discharge from the ICU. Patients were matched on most variables, but length of ICU stay significantly different between groups (p=0.007).
Was the exposure accurately measured to minimise bias?	Yes	Skin and dressings were checked daily until patients were ambulant or left the ICU.
Was the outcome accurately measured to minimise bias?	Yes	All members of the research team underwent inter-rater reliability testing before the study started. HAPUs were identified and categorised according to the four-point category system of the Australian Wound Management Association (2001).
Have the authors identified all important confounding factors?	Yes	Confounding factors were discussed in the study. The length of stay in ICU was stated as a limitation of the study.
Have the authors taken account of the confounding factors in the design and/or analysis?	Yes	Confounding variables considered in matching groups, standard care defined and comparable in both groups.
Was the follow-up of patients complete?	Yes	Detailed in patient flow chart and discussed in analysis. Due to the nature of the recruitment large number of patients lost to follow-up or not for ICU transfers (n=53) and discharged from ICU before 1st pressure ulcer assessment (n=55).
How precise (for example, in terms of confidence interval and p values) are the results?	-	P values were presented, but no confidence intervals stated.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Table B8.20: Critical appraisal of observational studies: Sullivan (2013)

Study name: A two-year retrospective review of suspected deep tissue injury evolution in adult acute care patients.		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Yes	Clear inclusion and exclusion criteria stated.
Was the exposure accurately measured to minimise bias?	Yes	Wound care nurse assessments occurred once or twice weekly depending on the condition of the suspected DTI. All ulcers had at least two wound care nurse assessments.
Was the outcome accurately measured to minimise bias?	Yes	Pressure ulcer development staged according to NPUAP et al. (2007).
Have the authors identified all important confounding factors?	Yes	Confounding factors were discussed in the study.
Have the authors taken account of the confounding factors in the design and/or analysis?	Yes	Contributory risks included in data collection and confounding factors part of analysis.
Was the follow-up of patients complete?	No	Some patients were lost to follow-up. Forty-five were excluded from analysis due to incomplete data (n=13), evolution on initial presentation (n=2), and loss of follow-up (n=30).
How precise (for example, in terms of confidence interval and p values) are the results?	-	No confidence intervals or p values presented.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Table B8.21 Critical appraisal of observational studies: Walsh et al. (2012)

Study name: Use of a sacral silicone border foam dressing as one component of a pressure ulcer prevention program in an intensive care unit setting.		
Study question	**Response**	**How is the question addressed in the study?**

	yes/no/not clear/N/A)	
Was the cohort recruited in an acceptable way?	Yes	Patients entered at admission and were followed up until discharge from the ICU. Clear inclusion criteria.
Was the exposure accurately measured to minimise bias?	Yes	The ICU staff were educated on the correct use of the dressing. Skin was inspected when dressings were changed every 3 days.
Was the outcome accurately measured to minimise bias?	Yes	HAPUs were identified and categorised according to the NPUAP et al. (2007).
Have the authors identified all important confounding factors?	Yes	Yes, confounding factors are discussed in the study.
Have the authors taken account of the confounding factors in the design and/or analysis?	Yes	Successive quality improvement plans had seen implementation of different skin management practices. Mepilex® Border Sacrum was evaluated as a potential addition to standard care. Its use was restricted to patients considered at risk of pressure ulcers according to specified inclusion criteria.
Was the follow-up of patients complete?	Not clear	Minimal data provided. Follow-up data provided for patients who discontinued the study prematurely.
How precise (for example, in terms of confidence interval and p values) are the results?	-	No p values or confidence intervals stated.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Table B8.22: Critical appraisal of observational studies: Yoshimura et al. (2016)

Study name: Soft silicone foam dressing is more effective than polyurethane film dressing for preventing intraoperatively acquired pressure ulcers in spinal surgery patients: the Border Operating room Spinal Surgery (BOSS) trial in Japan.		
Study question	**Response** **yes/no/not clear/N/A)**	**How is the question addressed in the study?**

Was the cohort recruited in an acceptable way?	Yes	Clear inclusion and exclusion criteria and the standard positioning protocol was well defined.
Was the exposure accurately measured to minimise bias?	Yes	Dressings applied at the start of surgery and 30 minutes after surgery nurses checked for signs of any intraoperative pressure ulcers.
Was the outcome accurately measured to minimise bias?	Yes	The skin checks after surgery were confirmed by agreement between two nurses and pressure ulcers staged according to NPUAP et al. (2014).
Have the authors identified all important confounding factors?	Yes	Numerous internal and external risk factors evaluated and several pressure redistributing devices used in the study, in addition to review of literature.
Have the authors taken account of the confounding factors in the design and/or analysis?	Yes	Interface pressure mapping used to evaluate areas of body at risk of pressure ulcers whilst using Relton-Hall frame prior to study. Intraoperative warming device used to maintain core temperature. Urethane foam mattress and protective helmet system used to redistribute the pressure. Univariate and multivariate analysis of pressure ulcer risk factors assessed and analysed.
Was the follow-up of patients complete?	Yes	Patient flow chart presented, no patients lost to follow-up.
How precise (for example, in terms of confidence interval and p values) are the results?	-	P values presented, confidence intervals presented for the RR of developing intraoperative pressure ulcers based on the patients' characteristics and the intraoperative factors.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Table B8: Critical appraisal of systematic reviews

Study name	Was the cohort recruited in an acceptable way?	Was the exposure accurately measured to minimise bias?	Was the outcome accurately measured to minimise bias?	Have the authors identified all important confounding factors?	Have the authors taken account of the confounding factors in the design and/or analysis?	Was the follow-up of patients/studies complete?	Are the results precise (for example, in terms of confidence interval and p values)?
Black et al. (2014)	Inclusion criteria appropriate for systematic review	Not clear, critical appraisal tool not discussed.	Yes, outcomes measured depending on quality of the trials.	Not clear, confounding factors considered specific to dressing use.	Yes, pressure, shear, and microclimate frequently assessed as contributory factors to pressure ulcer development.	Not clear, follow-up not discussed.	No meta-analysis performed, but p values of individual studies discussed.
Clark et al. (2014)	Inclusion and exclusion listed and criteria appropriate for systematic review	Yes, studies were assessed for internal and external validity according to the criteria suggested by Scottish Intercollegiate Guidelines Network based on study type.	Yes, analysis was carried out using Review Manager (RevMan) v5 (Cochrane Collaboration).	Yes, content of standard care discussed.	Yes, pressure, shear and microclimate frequently assessed as contributory factors to pressure ulcer development.	Yes, length of follow-up in included studies addressed: until people receiving pressure ulcer prevention left the study or developed pressure ulcers. Study flow chart included.	Yes, the principal summary measure was RR with 95% confidence intervals using random effects model. No meta-analysis performed.

Cornish et al. (2017)	No details on inclusion or exclusion criteria for assessment of studies.	Not clear, narrative review evaluated aspects of potential bias.	Not clear, narrative review evaluated aspects of potential bias.	Not clear, aspects of standard care discussed, but not on every study.	Yes, pressure, shear and microclimate frequently assessed as contributory factors to pressure ulcer development.	Incomplete reporting of follow-up in studies assessed.	No meta-analysis performed, but p values of individual studies discussed.
Huang et al. (2015)	Not clear, inclusion and exclusion listed and criteria appropriate for meta-analysis although outcomes not listed.	Yes, quality of included trials assessed by a standardised critical appraisal instrument developed by the Cochrane Collaboration.	Yes, methodological quality of included trials assessed by a standardised critical appraisal instrument developed by the Cochrane Collaboration.	Confounding factors of included studies discussed as limitation of the meta-analysis (as its focus was on pressure ulcer incidence).	Confounding factors discussed, but not addressed in the analysis.	Yes, follow-up periods assessed in analysis.	Fixed effects model with confidence intervals used.

Moore and Webster (2013)	Yes, inclusion and exclusion criteria included.	Yes, papers selected for retrieval assessed by two independent reviewers for methodological validity prior to inclusion in review using standardised critical appraisal instruments from the Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument.	Yes, addressed inconsistency in the use of pressure ulcer staging systems as an outcome measure	Confounding factors of included studies discussed as limitation of those studies.	Yes, confounding factors assessed of included studies.	Length of follow-up in included studies not addressed. Study flow chart included.	Yes, overall effect size included for application of prophylactic silicone foam dressings in decreasing incidence of sacral HAPUs.
NPUAP et al. (2014)	Inclusion and exclusion listed and criteria appropriate for systematic review.	Yes, methodological quality of included trials assessed.	Yes, methodological quality of included trials assessed	Confounding factors of included studies discussed.	Confounding factors of included studies addressed in design of systematic review.	Follow-up discussed and addressed.	No meta-analysis performed, but p values of individual studies discussed.
Tayyib and Coyer (2016)	Yes, selection criteria listed. Papers selected for retrieval were assessed by two independent reviewers for methodological validity using standardised critical appraisal instruments from the Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument (2014). Disagreements were resolved by a 3rd reviewer. Studies that	Not clear. Accuracy of measurement of exposure not assessed in review.	Yes, all studies assessed reported accuracy of measurement of outcome (prophylactic silicone foam dressings in decreasing the incidence of sacral or heel pressure ulcers).	Not clear. Confounding factors considered in other aspects of the review, but not considered in relation to the effectiveness of studies assessing dressings.	Not clear. Confounding factors considered in other aspects of the review, but not considered in relation to the effectiveness of studies assessing dressings.	Not clear, follow-up of the 3 included studies not assessed.	Pressure ulcer incidence numbers presented, overall effect size with confidence intervals and p values presented for sacral pressure ulcers.

	met 50% of the JBI-MAStARI checklist tool were included.						

7.6 Results of the relevant studies

7.6.1 Complete a results table for each study with all relevant outcome measures pertinent to the decision problem. A suggested format is given in table B9.

Table B9.1: Outcomes from RCTs: Aloweni et al. (2017)

Study name		A randomised controlled trial to evaluate the incremental effectiveness of a prophylactic dressing and fatty acids oil in the prevention of pressure injuries.
Size of study groups	**Intervention**	Standard care plus Mepilex® Border Sacrum (n=129)
	Control	1. Fatty acids oil spray plus standard care (n=130) 2. Standard care only (n=202)
Study duration	**Time unit**	Up to 14 days or duration of hospital stay. Mean duration of stay = 6.7 days (SD ±4.3).
Type of analysis	**Intention-to-treat/per protocol**	Intention-to-treat
Outcome	**Name**	Any stage I pressure injuries (skin intact, non-blanchable redness) were reported as an incident.
	Unit	Number (n=, %)
Effect size	**Value**	Intervention: standard care plus Mepilex® Border Sacrum (n=5, 3.9%) Controls: 1. Fatty acids oil spray plus standard care (n=7, 5.4%) 2. Standard care only (n=10, 5%)
	95% CI	Not available
Statistical test	**Type**	Chi-square tests
	p value	0.84
Other outcome	**Name**	Incidence rate of pressure injury by Braden score ≤12
	Unit	Number (n=total in group/number with HAPU, %)
Effect size	**Value**	Treatment: standard care plus Mepilex® Border Sacrum (n=0/60, 0%) Control 2: standard care only (n=4/83, 4.8%)
	95% CI	Not available
Statistical test	**Type**	Fisher's exact test
	p value	0.04
Comments		-

Table B9.2: Outcomes from RCTs: Kalowes et al. (2016)

Study name		Five-layered soft silicone foam dressing to prevent pressure ulcers in the intensive care unit.
Size of study groups	**Intervention**	184
	Control	182
Study duration	**Time unit**	Mean ICU stay (all patients) = 7.0 (4-13) days.
Type of analysis	**Intention-to-treat/per protocol**	Intention-to-treat
Outcome	**Name**	Pressure ulcer incidence plus incidence rate is calculated per 1000 patient days at risk and is reported per 1000 patient days
	Unit	Number
Effect size	**Value**	Intervention: n=1, incidence rate = 0.7 Pressure ulcers stages: DTI (n=1) Control: n=7, incidence rate = 5.9 Pressure ulcers stages: DTI (n=1), unstageable (n=2), stage II (n=4).
	95% CI	For incidence rate Treatment: 0.1-5.2 Control: 2.8-12.4
Statistical test	**Type**	Not stated
	p value	<0.001
Other outcome	**Name**	Time-to-injury survival analysis
	Unit	Hazard ratio of patients in intervention group compared with patients in the control group
Effect size	**Value**	0.12
	95% CI	0.02-0.98
Statistical test	**Type**	Cox proportional hazard models
	p value	0.048
Comments		All patients had pressure ulcers develop on the sacrum or buttocks, including 1 suspected DTI. The majority (n = 6, 75%) of the pressure ulcers developed in the first week of ICU admission.

Table B9.3 Outcomes from RCTs: Qiuli and Qiongyu (2010)

Study name		[Observation on effect of Mepilex® on the prevention and treatment of pressure sores].
Size of study groups	**Intervention**	26
	Control	26
Study duration	**Time unit**	7 days.
Type of analysis	**Intention-to-treat/per protocol**	Not stated.
Outcome	**Name**	Incidence of pressure ulcers
	Unit	Number
Effect size	**Value**	Intervention: 0 pressure ulcers. Control: 3 pressure ulcers (site not stated, all stage II).
	95% CI	Not stated.
Statistical test	**Type**	Not stated.
	p value	Not stated.
Other outcome	**Name**	-
	Unit	-
Effect size	**Value**	-
	95% CI	-
Statistical test	**Type**	-
	p value	-
Comments		None

Table B9.4 Outcomes from RCTs: Santamaria et al. (2015)

<table>
<tr><td colspan="2">Study authors name</td><td>A randomised controlled trial of the effectiveness of soft silicone multi-layered foam dressings in the prevention of sacral and heel pressure ulcers in trauma and critically ill patients: the border trial.</td></tr>
<tr><td rowspan="2">Size of study groups</td><td>Intervention</td><td>219 (analysed 161)</td></tr>
<tr><td>Control</td><td>221 (analysed 152)</td></tr>
<tr><td>Study duration</td><td>Time unit</td><td>Mean length of stay in hours (SD):
<table>
<tr><td></td><td>Intervention</td><td>Comparator</td></tr>
<tr><td>ED</td><td>6 (4)</td><td>6 (4)</td></tr>
<tr><td>OR</td><td>4 (2)</td><td>5 (4)</td></tr>
<tr><td>ICU</td><td>91 (112)</td><td>86 (101)</td></tr>
</table></td></tr>
<tr><td>Type of analysis</td><td>Intention-to-treat/per protocol</td><td>Intention-to-treat</td></tr>
<tr><td rowspan="2">Outcome</td><td>Name</td><td>Overall pressure ulcer incidence</td></tr>
<tr><td>Unit</td><td>Number</td></tr>
<tr><td rowspan="2">Effect size</td><td>Value</td><td>Intervention: 7
Control: 27</td></tr>
<tr><td>95% CI</td><td>Not stated</td></tr>
<tr><td rowspan="2">Statistical test</td><td>Type</td><td>Fishers Exact test</td></tr>
<tr><td>p value</td><td>0.002</td></tr>
<tr><td rowspan="2">Other outcome</td><td>Name</td><td>Heel pressure ulcer incidence
Sacral pressure ulcer incidence</td></tr>
<tr><td>Unit</td><td>Number</td></tr>
<tr><td rowspan="2">Effect size</td><td>Value</td><td>Sacral pressure ulcers:
Intervention = 2, Control = 8.
Heel pressure ulcers:
Intervention = 5, Control = 19.</td></tr>
<tr><td>95% CI</td><td>Not stated</td></tr>
<tr><td rowspan="2">Statistical test</td><td>Type</td><td>Fishers Exact test</td></tr>
<tr><td>p value</td><td>Sacrum: 0·05
Heel: 0·002</td></tr>
<tr><td rowspan="2">Other outcome</td><td>Name</td><td>Rate at which each group developed pressure ulcers expressed in days: Cox regression analysis.</td></tr>
<tr><td>Unit</td><td>Hazard ratio for developing a pressure ulcer in the intervention group compared with the control group.</td></tr>
<tr><td>Effect size</td><td>Value</td><td>0·198.</td></tr>
<tr><td></td><td>95% CI</td><td>0·065–0·555</td></tr>
<tr><td>Statistical test</td><td>Type</td><td>Fishers Exact test</td></tr>
<tr><td></td><td>p value</td><td>0·002</td></tr>
</table>

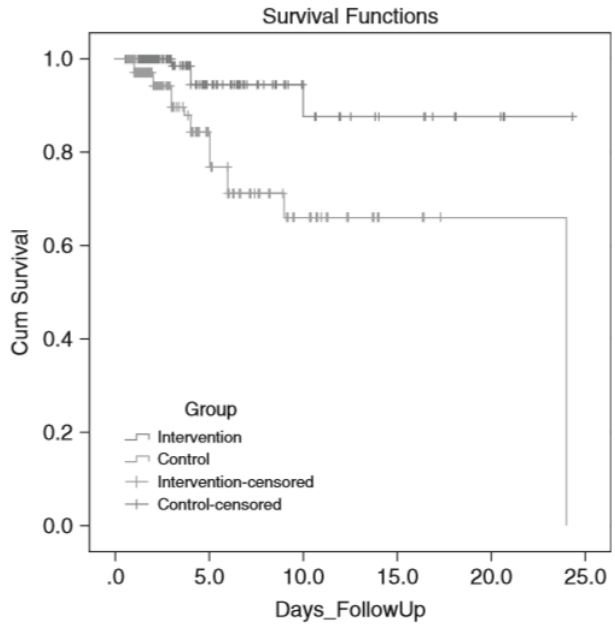
Other outcome	**Name**	The rate at which each group developed pressure ulcers.
	Unit	Days until development of pressure ulcer.
Effect size	**Value**	
	95% CI	N/A
Statistical test	**Type**	Kaplan–Meier survival analysis
	p value	N/A
Comments		-

Table B9.5: Outcomes from RCTs: Santamaria (2018)

Study authors name		A randomised controlled trial of the clinical effectiveness of multi-layer silicone foam dressings for the prevention of pressure injuries in high-risk aged care residents: The Border III Trial
Size of study groups	**Intervention**	138
	Control	150
Study duration	**Time unit**	4 weeks, or until development of pressure ulcer, patient died, or discharged from facility.
Type of analysis	**Intention-to-treat/per protocol**	Intention-to-treat
Outcome	**Name**	Incidence of pressure ulcers expressed as the total number of pressure ulcers developed in both intervention and control groups during the study period.
	Unit	Numbers of pressure ulcers (%)
Effect size	**Value**	Intervention = 3 (2.1%), Control = 16 (10.6%) 2 sacral pressure ulcers in the intervention group (1 stage I and 1 stage II) and 13 in the standard care group (5 stage I, 6 stage II, 2 stage IV). 3 heel ulcers in the intervention group (2 stage I, 1 stage II) and 5 in the standard care group (4 stage I, 1 stage II). (Some patients experienced >1 pressure ulcer). RR reduction of 80% for residents treated with the dressings and a number needed to treat of 12.
	95% CI	Not available.
Statistical test	**Type**	Random effects Poisson regression analysis
	p value	0.004
Other outcome	**Name**	Incidence of sacral pressure ulcers expressed as the total number of sacral pressure ulcers developed in both intervention and control groups during the study period.
	Unit	Number
Effect size	**Value**	Intervention = 2, Control = 13.
	95% CI	Not available
Statistical test	**Type**	Not stated
	p value	0.007
Other outcome	**Name**	The rate at which each group developed pressure ulcers.
	Unit	Days until development of pressure ulcer.

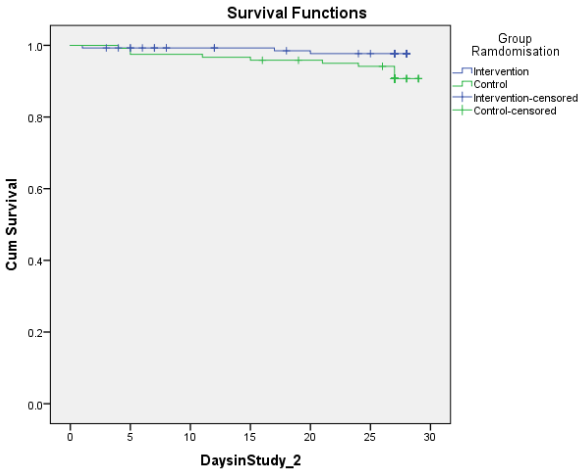
Effect size	Value	
		
	95% CI	N/A
Statistical test	**Type**	Kaplan–Meier survival analysis
	p value	N/A
Comments		Levels of heel ulcers (left and right) were not significant between groups.

Table B9.6: Outcomes from observational studies: Baker (2014)

Study name		Nursing driving excellence: preventing pressure ulcers in the high-risk population.
Size of study groups	**Intervention**	110
	Control	No control
Study duration	**Time unit**	45 days.
Type of analysis	**Intention-to-treat/per protocol**	Intention-to-treat
Outcome	**Name**	HAPUs/DTIs incident rate
	Unit	Number (%)
Effect size	**Value**	Decreased to 0 (0%) for all 110 patients included in the trial.
	95% CI	N/A
Statistical test	**Type**	None
	p value	None
Other outcome	**Name**	-
	Unit	-
Effect size	**Value**	-
	95% CI	-
Statistical test	**Type**	-
	p value	-
Comments		-

Table B9.7: Outcomes from observational studies: Bateman and Roberts

(2013)

Study name		Moisture lesions and associated pressure ulcers - getting the dressing regime right.
Size of study groups	**Intervention**	20
	Control	No control
Study duration	**Time unit**	4 weeks.
Type of analysis	**Intention-to-treat/per protocol**	Intention-to-treat
Outcome	**Name**	Level of pain
	Unit	McGill pain score
Effect size	**Value**	Pain: Pre-intervention = 2/10-8/10 Post-intervention = 0/10–1/10
	95% CI	Not stated.
Statistical test	**Type**	None
	p value	None
Other outcome	**Name**	Skin condition
	Unit	Healed, healing, static, or deteriorating.
	Value	Healed (n=16), healing (n=4)
	95% CI	Not provided.
Other outcome	**Name**	Ulcer status
	Unit	No further deterioration of existing pressure ulcers or development of new pressure ulcers.
	95% CI	Not provided.
Statistical test	**Type**	None
	p value	None
Comments		None

Table B9.8: Outcomes from observational studies: Brindle (2010)

Study name		Outliers to the Braden Scale: Identifying high-risk ICU patients and the results of prophylactic dressing use.
Size of study groups	**Intervention**	41
	Control	52
Study duration	**Time unit**	3 months or until discharge from ICU.
Type of analysis	**Intention-to-treat/per protocol**	Intention-to-treat
Outcome	**Name**	Number of pressure ulcers developing on patients
	Unit	Number of high-risk STICU patients who developed pressure ulcer while sacrum dressing in use compared with non-high-risk patients not wearing prophylactic dressing.
Effect size	**Value**	Intervention = 0 pressure ulcers Control = 6 pressure ulcers (4 DTI, 2 unstageable)
	95% CI	Not available
Statistical test	**Type**	None
	p value	None
Other outcome	**Name**	-
	Unit	-
Effect size	**Value**	-
	95% CI	-
Statistical test	**Type**	-
	p value	-
Comments		-

Table B9.9: Outcomes from observational studies: Brindle and Wegelin

(2012)

Study name		Prophylactic dressing application to reduce pressure ulcer formation in cardiac surgery patients.
Size of study groups	**Intervention**	56
	Control	39
Study duration	**Time unit**	Subjects followed until discharge from ICU and final skin evaluation performed on day of discharge.
Type of analysis	**Intention-to-treat/per protocol**	Per protocol
Outcome	**Name**	Pressure ulcer incidence. Intervention: 1 out of 50 subjects (2.0%) developed a pressure ulcer (classified as suspected DTI, but it did not evolve into a higher stage pressure ulcer). Comparator: 4 out of 35 subjects (11.7%) developed 8 pressure ulcers (5 classified as suspected DTIs; 3 evolved into stage III pressure ulcers, and 3 evolved into stage II pressure ulcers).
	Unit	Cox proportional hazards regression model
Effect size	**Value**	4.4
	95% CI	0.49-39.4
Statistical test	**Type**	Hazard ratio
	p value	0.185
Other outcome	**Name**	To adjust for effect of any imbalance in covariates between the 2 groups on the hazard ratio
	Unit	Adjusted Cox proportional hazards model
Effect size	**Value**	3.6
	95% CI	0.32-40.7
Statistical test	**Type**	Adjusted hazard ratio
	p value	0.296
Comments		None

Table B9.10: Outcomes from observational studies: Chaiken (2012)

Study name		Reduction of sacral pressure ulcers in the intensive care unit using a silicone border foam dressing.
Size of study groups	**Intervention**	273
	Control	291
Study duration	**Time unit**	6 months for intervention group. 35 months for retrospective control group.
Type of analysis	**Intention-to-treat/per protocol**	Intention-to-treat
Outcome	**Name**	Pressure ulcer incidence
	Unit	Incidence and prevalence of pressure ulcers n = (%).
Effect size	**Value**	Intervention group incidence: n = 5 (1.8%) Control group prevalence: n = 36 (12.3%)
	95% CI	N/A
Statistical test	**Type**	None
	p value	None
Other outcome	**Name**	-
	Unit	-
Effect size	**Value**	-
	95% CI	-
Statistical test	**Type**	-
	p value	-
Comments		None

Table B9.11: Outcomes from observational studies: Cubit et al. (2013)

Study name		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.
Size of study groups	**Intervention**	51
	Control	58
Study duration	**Time unit**	Intervention: Mean length of stay = 15.2 days (SD 16.1) Comparator: Mean length of stay = 12.8 days (SD 15.1)
Type of analysis	**Intention-to-treat/per protocol**	Intention-to-treat
Outcome	**Name**	Incidence of pressure ulcers
	Unit	Number of sacral pressure ulcers.
Effect size	**Value**	Treatment group: 1 of 51 patients developed a stage II sacral pressure ulcer. Control group: 6 of 58 patients developed sacral pressure ulcer (stage I or stage II). Neither group developed a DTI. Control group was 5·4 times more likely to sustain a pressure ulcer than the treatment group.
	95% CI	N/A
Statistical test	**Type**	Chi-square test showed application of sacral dressing had effect on prevention of sacral pressure injury $\chi^2(1, n = 109) = 3{\cdot}26$
	p value	≤0·08
Other outcome	**Name**	-
	Unit	-
Effect size	**Value**	-
	95% CI	-
Statistical test	**Type**	-
	p value	-
Comments		None

Table B9.12: Outcomes from observational studies: Daukste (2014)

Study name		Mepilex® Border Sacrum dressing use for pressure ulcers prevention in period of open heart surgery and in intensive care unit.
Size of study groups	**Intervention**	16
	Control	N/A
Study duration	**Time unit**	Duration of surgery was from 2 to 11 hours.
Type of analysis	**Intention-to-treat/per protocol**	Intention-to-treat.
Outcome	**Name**	Number of patients who maintained skin integrity
	Unit	Number
Effect size	**Value**	1st stage pressure ulcers were healed in 17 hours and 2nd stage pressure ulcers were fully healed in 19 days using one dressing.
	95% CI	N/A
Statistical test	**Type**	N/A
	p value	N/A
Other outcome	**Name**	Period of dressing use Dressing use (total number used, average duration per dressing, maximum duration of single dressing time).
	Unit	Days
Effect size	**Value**	Period of using one dressing was 3 – 7 days Total use of dressings: 19 Average one dressing usage time: 1.5 days (7 days max).
	95% CI	N/A
Statistical test	**Type**	N/A
	p value	N/A
Comments		Minimum details available from poster presentation.

Table B9.13: Outcomes from observational studies: Edwards and Lynch

(2014)

Study name		Head over heels for prevention: use of a silicone bordered foam heel dressing in the prevention of pressure ulcers.
Size of study groups	**Intervention**	102
	Control	N/A
Study duration	**Time unit**	Initially, 'approximately' 2 months, re-initiated for additional 2 months to validate the results.
Type of analysis	**Intention-to-treat/per protocol**	Intention-to-treat
Outcome	**Name**	Prevention of heel pressure ulcers
	Unit	Incidence number
Effect size	**Value**	4 pressure ulcers from 102 patients
	95% CI	N/A
Statistical test	**Type**	N/A
	p value	N/A
Other outcome	**Name**	-
	Unit	-
Effect size	**Value**	-
	95% CI	-
Statistical test	**Type**	-
	p value	-
Comments		Heel dressings part of standard care after end of study.

Table B9.14: Outcomes from published and unpublished studies: Gentry

and Wright (2010)

Study name		The 'Sacral Heart' Dressing Study: use of an absorbent self-adherent soft silicone sacral foam dressing across acute care settings.
Size of study groups	**Intervention**	31
	Control	N/A
Study duration	**Time unit**	2 weeks.
Type of analysis	**Intention-to-treat/per protocol**	Intention-to-treat
Outcome	**Name**	Prevention of pressure ulcers
	Unit	Incidence number
Effect size	**Value**	0 pressure ulcers from 31 patients.
	95% CI	N/A
Statistical test	**Type**	N/A
	p value	N/A
Other outcome	**Name**	-
	Unit	-
Effect size	**Value**	-
	95% CI	-
Statistical test	**Type**	-
	p value	-
Comments		-

Table B9.15: Outcomes from observational studies: Haisley et al. (2015)

Study name		An ounce of prevention: the use of an absorbent soft silicone self-adherent bordered foam heel dressing to decrease the incidence of hospital-acquired heel pressure ulcers in an acute care setting.
Size of study groups	**Intervention**	31
	Control	Not stated
Study duration	**Time unit**	3 months.
Type of analysis	**Intention-to-treat/per protocol**	Intention-to-treat
Outcome	**Name**	Prevention of pressure ulcers
	Unit	Incidence number
Effect size	**Value**	Intervention: 0 heel pressure ulcers from 31 patients Control: 3 heel pressure ulcers in same 3 month period.
	95% CI	N/A
Statistical test	**Type**	N/A
	p value	N/A
Other outcome	**Name**	Pressure ulcer incidence - trial extended for 3 months to validate outcome.
	Unit	Incidence number
Effect size	**Value**	Intervention: 0 heel pressure ulcers (n=not stated).
	95% CI	Not stated.
Statistical test	**Type**	Not stated.
	p value	Not stated.
Comments		-

THE FOLLOWING INFORMATION IS 'ACADEMIC IN CONFIDENCE'

Table B9.16 Outcomes from published and unpublished studies: Jin

(2018, unpublished)

Study name		[redacted]
Size of study groups	**Treatment**	[redacted]
	Control	[redacted]
Study duration	**Time unit**	[redacted]
Type of analysis	**Intention-to-treat/per protocol**	[redacted]
Outcome	**Name**	[redacted]
	Unit	[redacted]
Effect size	**Value**	[redacted]
	95% CI	[redacted]
Statistical test	**Type**	[redacted]
	p value	[redacted]
Other outcome	**Name**	[redacted]
	Unit	[redacted]
Effect size	**Value**	[redacted]
	95% CI	[redacted]
Statistical test	**Type**	[redacted]
	p value	[redacted]
Comments		-

Table B9.17: Outcomes from observational studies: Johnstone and

McGown (2013)

Study authors		Innovations in the reduction of pressure ulceration and pain in critical care.
Size of study groups	**Intervention**	75
	Control	N/A
Study duration	**Time unit**	Until discharge from critical care unit. Mean duration = 9 days.
Type of analysis	**Intention-to-treat/per protocol**	Intention-to-treat
Outcome	**Name**	Pressure ulcer incidence
	Unit	0
Effect size	**Value**	Not stated.
	95% CI	Not stated.
Statistical test	**Type**	Not stated.
	p value	Not stated.
Other outcome	**Name**	Pain
	Unit	Not reported
Effect size	**Value**	Feedback from the questionnaires revealed no reports of pain.
	95% CI	Not stated.
Statistical test	**Type**	Not stated.
	p value	Not stated.
Other outcome	**Name**	Cost effectiveness per day of using Mepilex® Border Sacrum in comparison with standard pressure ulcer treatment
	Unit	Cost savings in £/day
Effect size	**Value**	£29.56/day saving
Comments		-

Table B9.18: Outcomes from observational studies: Koerner and Adams

(2011)

Study name		Save our sacrums (S.O.S.) Does the use of an absorbent soft silicone self-adherent bordered foam dressing decrease the incidence of hospital acquired pressure ulcers (HAPUs)?
Size of study groups	**Intervention**	Mepilex® Border Sacrum plus standard care 1) n=42, 2) n=39
	Control	N/A
Study duration	**Time unit**	2 months in 2 stages 1) limited to Medial/Cardiac ICU and Surgical ICU 2) Dressing in place when patients transferred to other wards
Type of analysis	**Intention-to-treat/per protocol**	Not stated.
Outcome	**Name**	Pressure ulcer incidence.
	Unit	Number.
Effect size	**Value**	1) 0 2) 0
	95% CI	Not stated.
Statistical test	**Type**	Not stated.
	p value	Not stated.
Other outcome	**Name**	Not stated.
	Unit	Not stated.
Effect size	**Value**	Not stated.
	95% CI	Not stated.
Statistical test	**Type**	Not stated.
	p value	Not stated.
Comments		Improvement noted for these units which reported prior results of 20% incidence for surgical ICU and 40% incidence for medical/cardiac ICU.

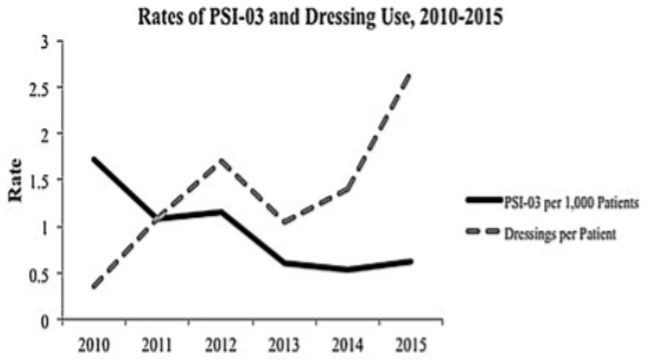
Table B9.19: Outcomes from observational studies: Lientz (2013)

Study authors name		Dollars and sense: economic value in HAPU/sDTI prevention.
Size of study groups	**Intervention**	56
	Control	N/A
Study duration	**Time unit**	Duration of patient use of dressing not stated, but patients had to meet the study inclusion criteria whilst being followed-up. Study duration = 15 months
Type of analysis	**Intention-to-treat/per protocol**	Per protocol
Outcome	**Name**	Pressure ulcer incidence
	Unit	Number
Effect size	**Value**	1) 0 2) 0
	95% CI	Not stated
Statistical test	**Type**	Not stated
	p value	Not stated
Other outcome	**Name**	Cost effectiveness of Mepilex® Border Sacrum as part of pressure ulcer prevention regimen.
	Unit	Estimated cost ($) of Mepilex® Border Sacrum over 15 months
Effect size	**Value**	$21,590*.
	95% CI	Not stated.
Statistical test	**Type**	Not stated.
	p value	Not stated.
Comments		* The author calculated that this was nearly half the cost of treating one HAPU/suspected DTI. (Author stated that each HAPU/suspected DTI on these cardiovascular surgical patients could have potentially cost the facility $43,1802).

Table B9.20: Outcomes from observational studies: Muldoon (2010)

Study name		Initial use absorbent soft silicone self-adherent bordered foam dressing reduces sacral pressure ulcers in the cardiovascular ICU.
Size of study groups	**Intervention**	3
	Control	N/A
Study duration	**Time unit**	2 weeks
Type of analysis	**Intention-to-treat/per protocol**	Not stated.
Outcome	**Name**	Pressure ulcer incidence
	Unit	Number
Effect size	**Value**	0
	95% CI	Not stated
Statistical test	**Type**	Not stated
	p value	Not stated
Other outcome	**Name**	-
	Unit	-
Effect size	**Value**	-
	95% CI	-
Statistical test	**Type**	-
	p value	-
Comments		-

Table B9.21 Outcomes from observational studies: Padula (2017)

Study authors name		Effectiveness and value of prophylactic 5-layer foam sacral dressings to prevent hospital-acquired pressure injuries in acute care hospitals.
Size of study groups	**Intervention and Control**	1,031,564
Study duration	**Time unit**	6 years.
Type of analysis	**Intention-to-treat/per protocol**	N/A
Outcome	**Name**	Average hospital-level PSI-03 count (HAPU stages 3, 4, and unstageable) during a quarter when prophylactic foam sacral dressings were available compared with PSI-03 (HAPI stages 3, 4, and unstageable) during quarters when there were no dressings in a hospital.
	Unit	Average number of HAPUs per hospital quarter.
Effect size	**Value**	When prophylactic foam sacral dressings were available: 1.2 (SD=0.045) When there were no dressings: 1.5 (SD=0.125)  **Decreasing rates of hospital-acquired pressure injury (Patient Safety Indicator #3) coinciding with increased use of prophylactic dressings per patient, 2010-2015.**
	95% CI	No, but SD presented above.
Statistical test	**Type**	T test
	p value	0.0063
Other outcome	**Name**	Longitudinal data analysis using a mixed-effects negative binomial regression with random intercept assessing the purchase of prophylactic 5-layer foam sacral dressing units and association with reductions in PSI-03 (HAPI stages 3, 4, and unstageable), while controlling for case-mix index.
	Unit	Numerical reduction in PSI-03 (HAPI stages 3, 4, and unstageable)

Effect size	**Value**	The average hospital experienced a 1.0 case reduction in PSI-03 (HAPI stages 3, 4, and unstageable) per quarter.
	95% CI	N/A
Statistical test	**Type**	Student t test
	p value	<0.05
Other outcome	**Name**	Cost effectiveness of Mepilex® Border Sacrum dressings.
	Unit	$ per case
Effect size	**Value**	There were 1.72 HAPU cases per 1000 in 2010 compared to 0.62 cases in 2015 at an estimated cost of $70,000 per case.
	95% CI	Not stated.
Statistical test	**Type**	Not stated.
	p value	Not stated.
Comments		The author states that the average hospital in 2010 purchased 355 prophylactic foam sacral dressings per 1000 compared to 2662 per 1000 in 2015 at a cost of $7.50 per dressing. Given the authors understanding of the patients admitted to these hospitals over 5 years, spending on pressure ulcers decreased from $120/patient to $43/patient, while the investment in prophylactic foam sacral dressings increased from $2.60/patient to $20/patient.

Table B9.22 Outcomes from observational studies: Park (2014)

<table>
<tr><td colspan="2">Study name</td><td>The effect of a silicone border foam dressing for prevention of pressure ulcers and incontinence associated dermatitis in intensive care unit patients.</td></tr>
<tr><td rowspan="2">Size of study groups</td><td>Intervention</td><td>52</td></tr>
<tr><td>Control</td><td>50</td></tr>
<tr><td>Study duration</td><td>Time unit</td><td>9 days.</td></tr>
<tr><td>Type of analysis</td><td>Intention-to-treat/per protocol</td><td>Intention-to-treat</td></tr>
<tr><td rowspan="2">Outcome</td><td>Name</td><td>The number of patients who developed pressure ulcers in the experimental group was compared with the control group.</td></tr>
<tr><td>Unit</td><td>χ^2 n (%)</td></tr>
<tr><td rowspan="2">Effect size</td><td>Value</td><td>χ^2 = 21.722

<table><tr><td></td><td>Control</td><td>Intervention</td></tr><tr><td>Stage I</td><td>17 (34%)</td><td>1 (2%)</td></tr><tr><td>Stage II</td><td>6 (12%)</td><td>1 (2%)</td></tr><tr><td>DTI</td><td>0 (0%)</td><td>1 (2%)</td></tr><tr><td>Total</td><td>23 (46%)</td><td>3 (6%)</td></tr><tr><td>Intact</td><td>27 (54%)</td><td>34 (65%)</td></tr><tr><td>Blanching erythema</td><td>0 (0%)</td><td>15 (29%)</td></tr></table></td></tr>
<tr><td>95% CI</td><td>Not stated.</td></tr>
<tr><td rowspan="2">Statistical test</td><td>Type</td><td>Chi-square test (χ^2)</td></tr>
<tr><td>p value</td><td><0.001</td></tr>
<tr><td rowspan="2">Other outcome</td><td>Name</td><td>The IADS score of the experimental group was measured and compared with those of the control group.</td></tr>
<tr><td>Unit</td><td>t</td></tr>
<tr><td rowspan="2">Effect size</td><td>Value</td><td>2.166</td></tr>
<tr><td>95% CI</td><td>Not stated.</td></tr>
<tr><td rowspan="2">Statistical test</td><td>Type</td><td>Independent t test</td></tr>
<tr><td>p value</td><td><0.033</td></tr>
<tr><td>Outcome</td><td>Name</td><td>Relationship between IADS score and pressure ulcer occurrence.</td></tr>
<tr><td></td><td>Unit</td><td>Odds ratio</td></tr>
<tr><td>Effect size</td><td>Value</td><td>1.900</td></tr>
<tr><td></td><td>95% CI</td><td>1.237-2.917</td></tr>
<tr><td rowspan="2">Statistical test</td><td>Type</td><td>Logistic regression analysis</td></tr>
<tr><td>p value</td><td>0.003</td></tr>
<tr><td colspan="2">Comments</td><td>-</td></tr>
</table>

Table B9.23 Outcomes from observational studies: Richard-Denis et al.

(2017)

Study name		Effectiveness of a multi-layer foam dressing in preventing sacral pressure ulcers for the early acute care of patients with a traumatic spinal cord injury: comparison with the use of a gel mattress.
Size of study groups	**Intervention**	89
	Control	226
Study duration	**Time unit**	From time of admission until discharge from acute care centre. Mean length of stay approx. 1 month in both groups.
Type of analysis	**Intention-to-treat/per protocol**	Intention-to-treat
Outcome	**Name**	Occurrence of sacral pressure ulcer
	Unit	Number (%)
Effect size	**Value**	Dressing: 17 (19·1%) Gel mattress: 40 (17·7%)
	95% CI	Not available
Statistical test	**Type**	chi-square tests
	p value	0·77
Other outcome	**Name**	Severity of sacral pressure ulcer
	Unit	%
Effect size	**Value**	Dressing: stage I = 29·4, stage II = 70·6, stage III = 0·0, stage IV = 0.0 Gel mattress: stage I = 30·0, stage II = 62·5, stage III = 2·5, stage IV = 5.0
	95% CI	N/A
Statistical test	**Type**	Chi-square tests
	p value	0.71
Comments		Results were criticised by Levy and Santamaria (2017) who questioned why gel pads were placed under patient's heels and occiput in the dressing group rather than these patients being treated with a good mattress. As such, standard care was insufficient in the dressings group, where dressings should have been an addition to standard care, but appear to have been a replacement for standard care. The author replied to these queries and stated that the use of Mepilex® Border Sacrum alone at the sacrum, instead of a gel mattress, preoperatively does not decrease the incidence of pressure ulcers. Essential preventive measures of pressure ulcers, such as frequent repositioning and assessment of skin integrity, are crucial even in the presence of an optimal surface/interface in contact with the skin at risk of a pressure ulcer (Richard-Denis et al. 2017).

Table B9.24 Outcomes from observational studies: Santamaria et al.

(2015[a])

Study name		Clinical effectiveness of a silicone foam dressing for the prevention of heel pressure ulcers in critically ill patients: Border II Trial.
Size of study groups	**Intervention**	191
	Control	221
Study duration	**Time unit**	For length of ICU stay Mean = 107 hours (SD 123 hours).
Type of analysis	**Intention-to-treat/per protocol**	Intention-to-treat
Outcome	**Name**	Incidence of heel pressure ulcers in patients
	Unit	Patient numbers
Effect size	**Value**	Intervention: 0 (0%) Control: 14 (9.2%)
	95% CI	Not stated
Statistical test	**Type**	Chi-squared
	p value	<0.001
Other outcome	**Name**	Total number of pressure ulcers
	Unit	Pressure ulcer numbers
Effect size	**Value**	Intervention: 0 Control: 19
	95% CI	Not stated
Statistical test	**Type**	Chi-squared
	p value	<0.001
Comments		Of the 19 pressure ulcers developing, 15 were category I, 2 were category II, and 2 were category IV. The study was funded through an unrestricted research grant from Mölnlycke Health Care.

Table B9.25 Outcomes from observational studies: Sullivan (2015)

Study name		A two-year retrospective review of suspected DTI evolution in adult acute care patients.
Size of study groups	**Treatment**	77 with 128 suspected DTIs.
	Control	None
Study duration	**Time unit**	1 day to 14 weeks.
Type of analysis	**Intention-to-treat/per protocol**	Per protocol.
Outcome	**Name**	Healing rate of suspected DTIs progressing to pressure ulcers (≥category I as defined by NPUAP [2007]).
	Unit	Number of ulcers (%)
Effect size	**Value**	Recovery from suspected DTI: 85/128 (66.4%) No deterioration: 31/128 (24.2 %) Deterioration to ≥category I pressure ulcer: 12/128 (9.3%)
	95% CI	Not stated.
Statistical test	**Type**	Not stated.
	p value	Not stated.
Other outcome	**Name**	Healing rate of suspected DTIs progressing to pressure ulcers.
	Unit	Size of pressure ulcers (cm^2).
Effect size	**Value**	Resolved: 45 Decreased: 48 Unchanged: 12 Increased: 20
	95% CI	N/A
Statistical test	**Type**	N/A
	p value	N/A
Comments		Author is a member of staff of the manufacturer of the product under investigation.

Table B9.26 Outcomes from observational studies: Walsh et al. (2012)

Study name		Use of a sacral silicone border foam dressing as one component of a pressure ulcer prevention program in an intensive care unit setting.
Size of study groups	**Intervention**	69
	Control	No control.
Study duration	**Time unit**	Three month study duration.
Type of analysis	**Intention-to-treat/per protocol**	Per protocol (n=62)
Outcome	**Name**	Incidence of pressure ulcers.
	Unit	Number of sacral pressure ulcers (%)
Effect size	**Value**	3 (4.8%)
	95% CI	Not stated.
Statistical test	**Type**	Not stated.
	p value	Not stated.
Other outcome	**Name**	-
	Unit	-
Effect size	**Value**	-
	95% CI	-
Statistical test	**Type**	-
	p value	-
Comments		Mölnlycke Health Care provided the Mepilex® Border dressings and staff education during the quality improvement initiative.

Table B9.27 Outcomes from observational studies: Yoshimura et al.

(2016)

Study name		Soft silicone foam dressing is more effective than polyurethane film dressing for preventing intraoperatively acquired pressure ulcers in spinal surgery patients: the Border Operating room Spinal Surgery (BOSS) trial in Japan.
Size of study groups	**Intervention**	100 (split-body trial)
	Control	100 (split-body trial)
Study duration	**Time unit**	30 minutes after surgery
Type of analysis	**Intention-to-treat/per protocol**	Intention-to-treat
Outcome	**Name**	The difference in the intraoperative pressure ulcer incidence rates when using soft silicone foam dressings compared with polyurethane film dressings during surgery in groups. The patients were classified into two groups: the 'with intraoperative pressure ulcers group' and the 'without intraoperative pressure ulcer s group'. The RR of developing intraoperative pressure ulcers was analysed based on the patients' characteristics and the intraoperative factors.
	Unit	Univariate analysis of perioperative pressure ulcers' location (all chest).
Effect size	**Value**	Intervention: 3 Control: 11
	95% CI	N/A
Statistical test	**Type**	Chi-square test or Fisher's exact probability test
	p value	0.027
Other Outcome	**Name**	Soft silicone foam dressings as one of the risk factors associated with perioperative pressure ulcers.
	Unit	Odds ratio
Effect size	**Value**	0·23
	95% CI	0·05–0·79
Statistical test	**Type**	Multivariate logistic regression analysis on 200 regions of the chest.
	p value	0·019
Other outcome	**Name**	Severity and location of pressure ulcers
	Unit	Number and body location.
Effect size	**Value**	Ten patients had Category I intraoperative pressure ulcers, and one patient had a Category II intraoperative pressure ulcer with a blister. The intraoperative pressure ulcers developed on the chest in all 11 patients (14 locations) and healed without deterioration before discharge.

	95% CI	N/A
Statistical test	**Type**	N/A
	p value	N/A
Comments		

Table B9.28: Outcomes from systematic reviews: Black et al. (2014)

Study name		Dressings as an adjunct to pressure ulcer prevention: consensus panel recommendations.
Size of study groups	**Treatment**	Not stated. (Studies included any dressing plus standard care).
	Control	Not stated. (Studies included standard care with or without any dressing).
Study duration	**Time unit**	Varied between studies
Type of analysis	**Intention-to-treat/per protocol**	Not stated.
Outcome	**Name**	Dressings for pressure ulcer prevention in the sacrum, buttocks and heels in high-risk patients, those in ED, ICU, and OR.
	Unit	Adequate evidence from 13 included studies to recommend the use of five-layer silicone bordered dressings (Mepilex® Border Sacrum and Mepilex® Heel dressings)
Effect size	**Value**	Not presented – narrative review of evidence
	95% CI	Not presented – narrative review of evidence
Statistical test	**Type**	Not presented – narrative review of evidence
	p value	Not presented – narrative review of evidence
Other outcome	**Name**	-
	Unit	-
	Value	-
	95% CI	-
Other outcome	**Name**	-
	Unit	-
	95% CI	-
Statistical test	**Type**	-
	p value	-
Comments		-

Table B9.29: Outcomes from systematic reviews: Clark et al. (2014)

Study name		Systematic review of the use of prophylactic dressings in the prevention of pressure ulcers.
Size of study groups	**Treatment**	Not stated. (Studies included prophylactic dressings).
	Control	Not stated. (Studies included standard care with or without alternative dressings).
Study duration	**Time unit**	Until people receiving pressure ulcer prevention left the study or developed pressure ulcers.
Type of analysis	**Intention-to-treat/per protocol**	Both types of studies could be included.
Outcome	**Name**	Number and severity of new pressure ulcers at sacrum
	Unit	RR of 4 studies, 3 of which used Mepilex® Border Sacrum (Santamaria et al. 2013; Brindle and Wegelin, 2012; Cubit et al. 2012) described incidence of sacral pressure ulcers where the skin was protected with a prophylactic dressing compared with skin which was not protected. (The fourth study used a polyurethane film dressing, which was applied to the sacrum during surgery [Imanishi et al. 2006])
Effect size	**Value**	The four studies had a RR of 0·37.
	95% CI	(95% CI 0·21–0·67)
Statistical test	**Type**	Statistical heterogeneity was tested using the I2 measure of inconsistency within RevMan 5 (Cochrane Collaboration) where an I^2 below 40% might indicate that statistical heterogeneity may not be important.
	Value	The heterogeneity of these four studies was calculated (I^2=0%)
Other outcome	**Name**	Two studies reported the incidence of new heel ulcers irrespective of whether the heel was covered with a prophylactic dressing or not. Studies were not combined due to differences in reported outcome measures. One study used Mepilex® Heel (Santamaria et al. 2013)
	Unit	N, % having new heel ulcers
Effect size	**Value**	Mepilex® Border Heel = 3/161; 1·9% No dressing = 12/152 (7·9%)
	95% CI	N/A
Statistical test	**Type**	-
	p value	-

Comments	Authors concluded that the single high-quality RCT (Santamaria et al. 2013) and the growing number of cohort, weak RCT, and case series all suggest that the introduction of a dressing as part of pressure ulcer prevention may help reduce pressure ulcer incidence associated with medical devices and in immobile ICU patients. There was no firm clinical evidence at the time to suggest that one dressing type was more effective than other dressing types.

Table B9.30: Outcomes from systematic reviews: Cornish et al. (2017)

Study name		The use of prophylactic dressings in the prevention of pressure ulcers: a literature review.
Size of study groups	**Intervention**	Not stated. (Studies included prophylactic dressings).
	Control	Not stated (Studies included standard care with or without alternative dressings).
Study duration	**Time unit**	Until people receiving pressure ulcer prevention left the study or developed pressure ulcers.
Type of analysis	**Intention-to-treat/per protocol**	Both types of studies could be included.
Outcome	**Name**	Number and severity of new pressure ulcers
	Unit	Number, %
Effect size	**Value**	Variable, narrative review
	95% CI	Not presented
Statistical test	**Type**	Not presented
	p value	Not presented
Other outcome	**Name**	-
	Unit	-
Effect size	**Value**	-
	95% CI	-
Statistical test	**Type**	-
	p value	-
Comments		All dressings evaluated were Mepilex® Border dressings. The authors concluded that the combined results of this evidence should be viewed in the context of those critically ill patients in the ED and ICU settings, and cannot be generalised to other patient populations, i.e. the community. However, the results do support the use of prophylactic dressings combined with standard methods in the prevention of pressure ulcers.

Table B9.31: Outcomes from systematic reviews: Huang et al. (2015)

Study name		Dressings for preventing pressure ulcers: a meta-analysis.
Size of study groups	**Treatment**	2090
	Control	-
Study duration	**Time unit**	1 day to 8 weeks.
Type of analysis	**Intention-to-treat/per protocol**	Not clear.
Outcome	**Name**	Pressure ulcer incidence from 8 trials (including 4 English language papers assessing Mepilex® Border) that compared foam dressings with standard care and 2 trials that compared foam dressings with padded bandages in patients at risk of pressure ulcers. Data pooled and analysed using a fixed-effects model.
	Unit	RR
Effect size	**Value**	Significant difference with fewer pressure ulcers found in foam dressing group (RR, 0.17).
	95% CI	0.12-0.26
Statistical test	**Type**	RR with 95% CIs was calculated for dichotomous data in each outcome measured
	p value	No p values available.
Other outcome	**Name**	Four trials (*3 papers in Chinese language and 1 paper concerning facial pressure ulcers) evaluated use of foam dressings compared with hydrocolloid dressings pooled by using a fixed-effects model.
	Unit	RR
Effect size	**Value**	Significantly fewer pressure ulcers among those allocated to foam dressings (RR, 0.16)
	95% CI	0.07-0.38
Statistical test	**Type**	The RR with 95% CIs was calculated for dichotomous data in each outcome measured
	p value	No p values available.
Comments		*Specific dressings used not clear.

Table B9.32: Outcomes from systematic reviews: Moore and Webster

(2013)

Study name		Dressings and topical agents for preventing pressure ulcers.
Size of study groups	**Treatment**	Mepilex® Border dressings applied over heel and sacrum plus standard care (4 trials, n=413).
	Control	Standard care 4 trials (n=389)
Study duration	**Time unit**	Varied
Type of analysis	**Intention-to-treat/per protocol**	Intention-to-treat
Outcome	**Name**	Three studies reported the effectiveness of the application of prophylactic silicone foam dressings in decreasing the incidence of sacral HAPUs (Brindle and Wegelin, 2012; Park, 2014; Santamaria et al., 2015)
	Unit	Odds ratio (overall effect size across 3 studies)
Effect size	**Value**	0.12
	95% CI	0.05-0.29
Statistical test	**Type**	Z test
	p value	<0.00001
Other outcome	**Name**	Heel HAPUs and dressings
	Unit	Effectiveness of prophylactic silicone border foam dressings (Mepilex® Border) in reducing incidence of heel HAPUs (Santamaria et al. 2015, Santamaria et al. 2015a).
Effect size	**Value**	Two studies demonstrated that heel HAPU incidence significantly decreased after implementation of the dressing.
	95% CI	See separate studies for full results.
Statistical test	**Type**	Statistical pooling not conducted as both studies had same control group.
	p value	See separate studies for full results.
Comments		Linking evidence to action: • This review revealed the effectiveness of using silicone foam dressing for preventing sacral HAPUs in ICU settings. • RCTs for preventing HAPUs in ICUs that follow standardised criteria for reporting intervention are needed. • Future RCTs should include a standard pressure ulcer definition, staging systems, and intervention and comparative care integrity.

Table B9.33 Outcomes from systematic reviews: NPUAP et al. (2014)

Study name		Prevention and treatment of pressure ulcers: Clinical Practice Guideline.
Size of study groups	**Treatment**	Not stated.
	Control	Not stated.
Study duration	**Time unit**	Literature search covering the period 1 January 2008 until 1 July 2013.
Type of analysis	**Intention-to-treat/per protocol**	Both types of study could be included.
Outcome	**Name**	Pressure ulcer incidence in 3 studies: (1) Santamaria et al. 2015; (2) Brindle and Wegelin, 2012; (3) Walsh et al. 2012). For all studies, Mepilex® Border plus standard care (Intervention) was compared with standard care alone (Control).
	Unit	Number
Effect size	**Value**	(1) Intervention: 4.3%; Control 17.8%. (2) Intervention: 2%; Control: 11.4%. (3) Intervention: 4.8%; Control: 20%.
	95% CI	Not stated.
Statistical test	**Type**	See separate studies for details.
	p value	(1) 0.002; (2) Not stated; (3) Not stated.
Other outcome	**Name**	-
	Unit	-
Effect size	**Value**	-
	95% CI	-
Statistical test	**Type**	-
	p value	-
Comments		The guideline states the following: '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'. The results of 4 studies are cited in support of this recommendation, 3 of which relate to the use of Mepilex® Border dressings.

Table B9.34 Outcomes from systematic reviews: Tayyib and Coyer

(2016)

Study name		Effectiveness of pressure ulcer prevention strategies for adult patients in intensive care units: a systematic review.
Size of study groups	**Treatment**	Not stated. (Included studies which assessed prophylactic dressings for the prevention of sacral and heel HAPUs).
	Control	Not stated (Included studies assessed standard care).
Study duration	**Time unit**	Not stated.
Type of analysis	**Intention-to-treat/per protocol**	Intention-to-treat.
Outcome	**Name**	Overall effect size across 3 studies which assessed the effectiveness of prophylactic silicone foam dressings in the prevention of pressure ulcer incidence of sacral HAPUs: Brindle and Wegelin, 2012; Park, 2014; Santamaria et al., 2015.
	Unit	Odds ratio, forest plot presented.
Effect size	**Value**	0.12
	95% CI	0.05-0.29
Statistical test	**Type**	Z test
	p value	<0.00001
Other outcome	**Name**	Prophylactic silicone foam dressings in decreasing incidence of heel HAPUs. (2 studies: Santamaria et al., 2015, and 2015a).
	Unit	Descriptive data only.
Effect size	**Value**	Santamaria et al., 2015: 5 vs.19 Santamaria et al., 2015a: 0 vs.19
	95% CI	Not stated. (see original study)
Statistical test	**Type**	Not stated. (see original study)
	p value	Santamaria et al., 2015: 0.002 Santamaria et al., 2015a: <0.001
Comments		-

7.6.2 Justify the inclusion of outcomes in table B9 from any analyses other than intention-to-treat.

There were 4 trials which included per protocol analyses. The remaining 23 primary research studies were intention-to-treat or did not clearly state the type of analysis used.

The observational cohort study by Brindle and Wegelin (2012) used a per protocol analysis. One hundred subjects were enrolled in the study, data collection forms of 5 patients were lost and their group assignment was not known, 6 out of 56 subjects in the intervention group did not complete the study, and 4 out of 39 control subjects also failed to complete the study. Analysis was therefore based on 50 subjects in the intervention group and 35 subjects in the comparison group. The reason for patients not completing the study was not stated.

In the observational study by Lientz (2013) two patients were dropped from the study because the protocol was not followed. The analysis was provided for the per protocol population.

In the observational study by Sullivan (2015) 45 patients were excluded from analysis due to incomplete data (n=13), evolution on initial presentation (n=2), and loss to follow-up (n=30). The analysis was provided for the per protocol population.

In the observational study by Walsh et al. (2012) the intervention was discontinued prematurely in 7 patients, including 5 who expired during their ICU stay, 1 who was agitated resulting in friction against the dressing and frequent displacement, and 1 who did not fulfil inclusion criteria after the dressing was initially applied. The analysis was provided for the per protocol population.

Whilst per protocol analyses are limitations of these studies, this type of analysis provides an estimate of the true efficacy of an intervention

(Ranganathan et al. 2016) and the studies should be viewed alongside all the other included studies which were intention-to-treat, where stated.

7.7 Adverse events

In section 7.7 the sponsor is required to provide information on the adverse events experienced with the technology being evaluated in relation to the scope.

For example, post-marketing surveillance data may demonstrate that the technology shows a relative lack of adverse events commonly associated with the comparator.

THE FOLLOWING INFORMATION IS 'COMMERCIAL IN CONFIDENCE'

Post-marketing surveillance (PMS) data for Mepilex® Border

[redacted]

[redacted]

7.7.1 Using the previous instructions in sections 7.1 to 7.6, provide details of the identification of studies on adverse events, study selection, study methodologies, critical appraisal and results.

All of the included studies assessed in sections 7.1 to 7.6 were reviewed in terms of adverse events. A number of these studies included data on safety outcomes, although none of them were primarily designed to capture safety differences between treatments. Those studies that contained relevant data are discussed in section 7.7.2 below.

The adverse event review process was conducted and the results were reported following the PRISMA statement. The search strategy comprised the following main elements: A search of two electronic bibliographic databases (MEDLINE and EMABASE) was performed on 15th January 2018 for studies that met the inclusion criteria. The full search strategy is provided in section **10.4**, appendix 2, but a summary of the strategy was:

S1 adverse (event or effect or reaction)

AND

mepilex or (soft silicone foam dressing)

Table B10: Selection criteria used for published studies – adverse

events

Inclusion criteria	
Population	People at risk of developing pressure ulcers but with no signs of established pressure damage (<category 1 pressure ulcers, as defined by NPUAP et al. [2014] or equivalent assessment).
Interventions	Use of any Mepilex® Border dressing to assist pressure ulcer prevention as an adjunct to standard pressure ulcer prevention procedures.
Outcomes	• Incidence of skin breakdown at the heel and sacrum • Length of hospital stay • Level of pain and discomfort and impact on quality of life • Device related adverse events
Study design	Systematic reviews, randomised, non-randomised, cohort, case studies, observational and qualitative studies.
Language restrictions	No language restrictions.
Search dates	The databases (MEDLINE and EMBASE) were searched from inception to the date of the search.
Exclusion criteria	
Population	People at risk of developing pressure ulcers but who already have established pressure damage (≥category 1 pressure ulcers, as defined by NPUAP et al. [2014] or equivalent validated scale).
Interventions	Any intervention that was not a Mepilex® Border dressing being used as part of a pressure ulcer prevention programme.
Outcomes	Any outcomes that were unrelated to pressure ulcer prevention (e.g. pressure ulcer healing, the prevention and treatment of other chronic and acute wounds).
Study design	Studies not using Mepilex® Border dressings to augment pressure ulcer prevention, testimonials, non-systematic reviews containing no primary data, editorials, in vitro studies.
Language restrictions	None
Search dates	Studies published before the introduction of Mepilex® Border dressings (2001). Any studies published after 4th January 2018, any studies not indexed in MEDLINE or EMBASE on 4th January, 2018.

Figure B5: PRISMA flow diagram of included and excluded published

studies assessing Mepilex® Border adverse events

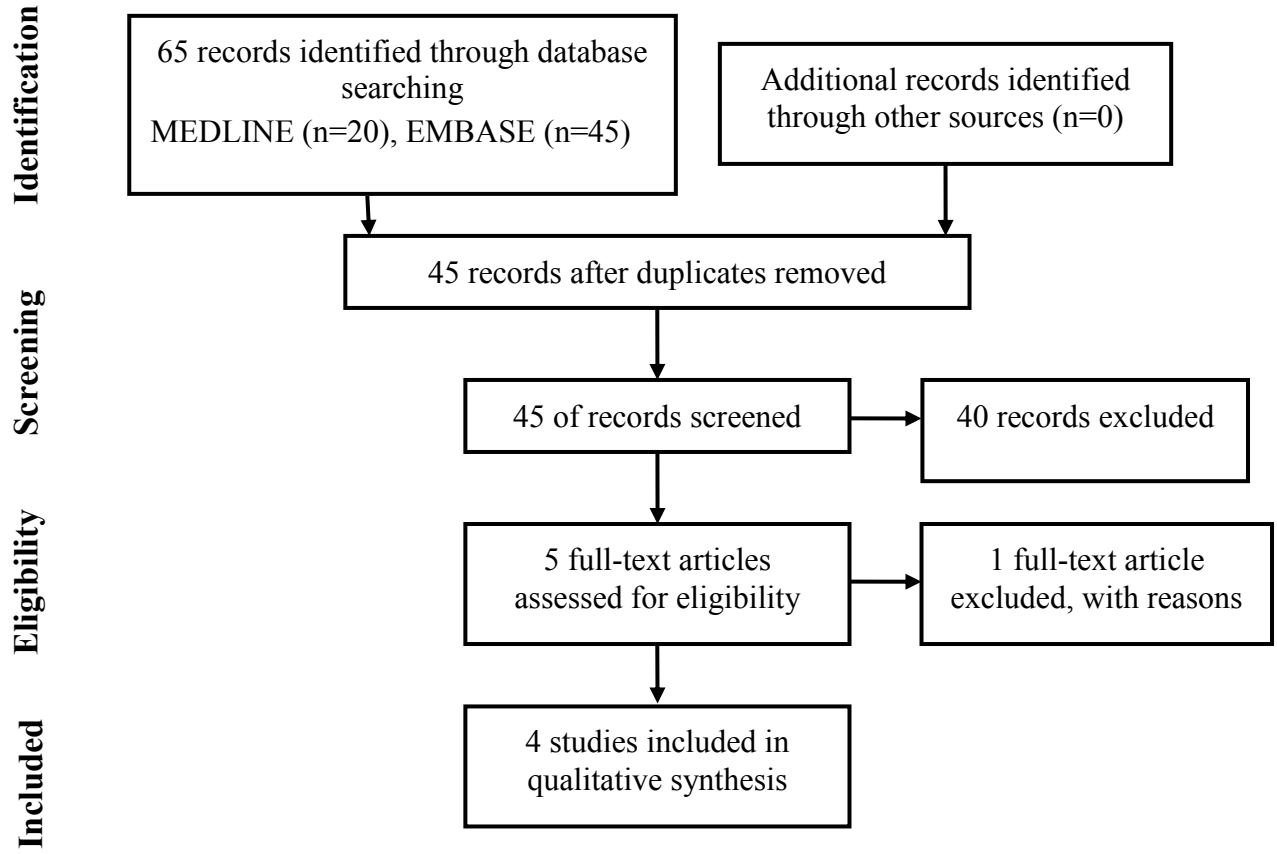


Table B11: List of relevant published studies – adverse events

Primary study reference	Study name	Population	Intervention	Comparator
Dykes and Hill (2001)	Effects of adhesive dressings on the stratum corneum of the skin.	Healthy adult volunteers	Mepilex® Border	- DuoDERM Extra Thin (ConvaTec, UK) - Allevyn Adhesive - Biatain Adhesive (Coloplast, Denmark) - Tielle Hydropolymer (Johnson and Johnson, USA)
Dykes and Heggie (2003)	The link between the peel force of adhesive dressings and subjective discomfort in volunteer subjects.	Healthy adult volunteers	Mepilex® Border	- DuoDERM Extra Thin - Biatain (Coloplast, Denmark) - Tielle - Versiva (ConvaTec, UK) - Allevyn Adhesive
Dykes (2007)	The effect of adhesive dressing edges on cutaneous irritancy and skin barrier function.	Healthy adult volunteers	Mepilex® Border Lite	- Allevyn Adhesive - Biatain Adhesive (Coloplast, Denmark) - Tielle Plus (Johnson and Johnson, USA) - DuoDERM Extra Thin (ConvaTec, UK) - Comfeel Plus Transparent
Spencer et al. (2016)	Dressings: An emerging source of acrylate contact allergy.	Minor traumatic injury (n = 4), leg ulcers (n = 2) and venous stasis (n = 1)	Mepilex® Border	None

Waring et al. (2011)	An evaluation of the skin stripping of wound dressing adhesives.	Healthy adult volunteers	Mepilex® Border	- Untreated - Versiva XC (ConvaTec, UK) - Biatain (Coloplast, Denmark) - Allevyn Adhesive - Comfeel® Plus - Urgotul Trio (Laboratoire Urgo, France)

Table B12: List of excluded studies – adverse events

Study name	Reason for Exclusion
Spencer et al. (2016)	Abstract referred to cases of contact allergic reactions to butyl acrylate contained in the adhesive of a variety of dressings, but all indications were when the device was used as a wound dressing.

Table B13.1: Summary of methodology for RCTs: Dykes and Hill (2001)

Study name	Effects of adhesive dressings on the stratum corneum of the skin.
Objective	To quantify the effect of the adhesive edges of five dressings on the skin.
Location	Wales
Design	Healthy volunteer, open, within subject comparison.
Duration of study	72 hours
Patient population	Healthy volunteers.
Sample size	20
Inclusion criteria	'Appropriate evaluations (medical history and examination) were undertaken to ensure that they were in good health'.
Exclusion criteria	Using concomitant medications likely to interfere with the study; any history of or who presented with an allergy or skin disease; females who were pregnant or lactating, or likely to become pregnant; subjects known to be intolerant to adhesive tapes.
Method of randomisation	Treatments were randomly allocated to five out of six test sites (3 x 15cm) marked on each subject's back. The sixth site acted as an untreated control and was covered with a non-adherent silicone gauze. The dressings were applied to the test sites according to a randomisation schedule and removed and discarded after 24 hours. Application and removal was repeated twice over 24-hour intervals, amounting to three consecutive applications.

Intervention(s) (n = 20) and comparator(s) (n = 20)	All dressings were applied for 3 successive 24-hour periods at days 2, 3 and 4 to test sites (2 x 2cm) marked on the flexor aspect of both forearms (four sites per arm), one arm corresponding to one 24-hour application and the other arm to three consecutive 24-hour applications. The fourth site on each arm acted as an untreated control site. Intervention: Mepilex® Border Comparators: Duoderm Extra Thin Allevyn Adhesive Biatain Adhesive Tielle Hydropolymer Dressing. Untreated control site covered with a nonadherent silicone gauze.
Baseline differences	None stated, but all healthy volunteers exposed to all of the test materials.
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	The test materials were removed using a device which measured the force needed to peel the test materials off the skin surface at a 135° angle at a constant speed of 25mm per second. Follow-up was for the 3 consecutive 24-hour periods at days 2, 3 and 4 and there was no data on patients lost to follow-up.
Statistical tests	An ANOVA procedure was used to determine treatment and time effects. Subsequent analysis was carried out using the non-parametric Friedman ANOVA procedure followed by a multiple comparison procedure based on the Tukey test.
Primary outcomes (including scoring methods and timings of assessments)	Measurement of removal forces at days 2, 3 and 4. Mean steady state force values (three-day average) for peel force were measured in mNewtons using a transducer calibrated with a series of known weights. Output from the transducer was amplified and recorded using a chart recorder. The initial detachment (peak) force and the steady state force achieved once the material had started to detach from the skin were obtained from the output of the chart recorder.
Secondary outcomes (including scoring methods and timings of assessments)	The degree of skin surface damage when dressings removed at days 2, 3 and 4. The superficial stratum corneum in the centre of the test site was stained by applying a 12mm aluminium Finn chamber containing an 11mm filter paper disc wetted with 0.03ml 1% aqueous methylene blue to the skin surface for 60 minutes. This was sufficient to produce an even staining of only the superficial layers of the stratum corneum. The test materials were applied to the test sites on both arms. They were removed and discarded after 24 hours. One arm received one 24-hour application and the other arm three consecutive 24-hour applications.

Table B13.2: Summary of methodology for RCTs: Dykes and Heggie

(2003)

Study name	The link between the peel force of adhesive dressings and subjective discomfort in volunteer subjects.
Objective	The study compared the level of discomfort experienced by healthy volunteers on the removal of a range of adhesive wounds.
Location	Cardiff, Wales.
Design	Open within subject comparative study of the adhesive edges of six adhesive dressings.
Duration of study	24 hours.
Patient population	Healthy volunteers.
Sample size	24
Inclusion criteria	'Appropriate evaluations (medical history and examination) were undertaken to ensure that each subject was in good health before participation'.
Exclusion criteria	Subjects using concomitant medications that were likely to interfere with the study, those with any history or presence of allergy or skin disease, women who were pregnant or lactating or likely to become pregnant, and those who were known to be intolerant to adhesive tapes.
Method of randomisation	Six test sites were identified on the lower back corresponding to the 6 test materials. Allocation of test materials to the test sites was randomised. No further details on randomisation process stated.
Intervention(s) (n =) and comparator(s) (n =)	The 6 dressings (each measuring 15 x 2.5cm) were applied vertically to the 6 test sites on the lower back on day 1 in a parallel array. Intervention: Mepilex® Border Comparators: DuoDERM Extra Thin Biatain (Coloplast) Tielle Versiva Allevyn Adhesive.
Baseline differences	None stated, but all healthy volunteers exposed to all of the test materials.
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	Follow-up was at 24 hours when peel force and visual analogue pain scores were taken. It was not stated whether any patients were lost to follow-up.
Statistical tests	To avoid any assumptions about the normality of the data, the analysis was carried out using a nonparametric multiple-comparison procedure based on the Tukey-HSD test.
Primary outcomes (including scoring	- The peel force of removal was recorded at day 2 (24 hours). Peel force was measured in Newtons using a transducer, which had been calibrated using a series of known weights. The output

methods and timings of assessments)	from the transducer was amplified and recorded using a chart recorder (1mm on chart recorder = 0.04 Newtons). The initial detachment (peak) force and the steady-state force, which occurs once the material starts to become detached, were obtained from the output of the chart recorder. The test materials were removed under standardised conditions. A purpose-built device was used to measure the force required to peel the test strips from the skin at an angle of 135° to the surface at a constant speed of 25mm per second. - Discomfort experienced by the subject at each removal was assessed using an electronic 100mm visual analogue scale (0=no discomfort, 100=extreme discomfort).
Secondary outcomes (including scoring methods and timings of assessments)	-

Table B13.3: Summary of methodology for RCTs: Dykes (2007)

Study name	The effect of adhesive dressing edges on cutaneous irritancy and skin barrier function.
Objective	To assess the effect of repeated application and removal of adhesive edges from wound- care products on cutaneous irritancy and barrier function in normal volunteer subjects.
Location	Cardiff, Wales
Design	An open RCT, repeat-insult patch test on human volunteers where all dressings were exposed to all dressings.
Duration of study	15 days.
Patient population	Healthy volunteers.
Sample size	30
Inclusion criteria	A medical history and examination were undertaken to ensure each subject was in good health before participation.
Exclusion criteria	Subjects using concomitant medications likely to interfere with the study, those with any history or presence of allergy or skin disease, females who were pregnant or lactating or likely to become pregnant, and those known to be intolerant to adhesive tapes.
Method of randomisation	The six test products were randomly allocated to the test sites. No further details on randomisation process stated.
Intervention(s) (n = 30) and comparator(s) (n = 30)	Intervention: 2.5 cm x 2.5 cm adhesive edges from Mepilex® Border Lite (Mölnlycke, Sweden) applied, removed and reapplied repeatedly under occlusion, to the same site. (The adhesive edges are made from the same materials as used in the other Mepilex® Border dressings). Comparators: The 2.5 cm x 2.5 cm adhesive edges from: Allevyn Adhesive Biatain Adhesive Tielle Plus

	DuoDERM Extra Thin Comfeel® Plus Transparent.
Baseline differences	None stated, but all healthy volunteers exposed to all of the test materials.
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	The materials were applied, removed and reapplied repeatedly under occlusion to the same site over a 14-day period using a repeat-insult schedule of applications and assessments (six applications over a 14-day period, with removal and reapplication every two to three days). Cumulative irritancy scores for each test site were determined by adding the erythema scores on days 3, 5, 8, 10, 12 and 15. The test sites were assessed for cutaneous irritation at product re-application by trained study nurses who routinely carry out repeat-insult patch tests. At the end of the study, one hour after removal of the test products, the barrier function of each test site was assessed by measuring transepidermal water loss (TEWL).
Statistical tests	To avoid assumptions about the normality of the data, analysis was carried out using a non-parametric Friedman two-way ANOVA procedure, followed by a multiple comparison procedure based on the Tukey HSD test. All statistical analyses were done using Unistat for Windows version 5.5.
Primary outcomes (including scoring methods and timings of assessments)	The primary sign of cutaneous irritancy was taken to be erythema, and this was assessed using an established 0–6 ranking scale for cutaneous erythema (grade 2 reaction [moderate, uniform erythema] is considered a noteworthy indication of cutaneous irritancy). If ≥ grade 2 reaction was recorded and application of study material stopped, a score of ≥grade 2 was used at subsequent time points in the data analysis.
Secondary outcomes (including scoring methods and timings of assessments)	TEWL was measured using a Tewameter (Courage & Khazaka, GmbH). Control measurements were made at adjacent normal skin sites that were untreated.

Table B13.4: Summary of methodology for RCTs: Waring et al. (2011)

Study name	An evaluation of the skin stripping of wound dressing adhesives.
Objective	To investigate how likely six different modern wound dressings are to cause skin stripping and impairment of the skin's barrier function.
Location	Germany
Design	A human volunteer repeat-insult RCT where all comparative dressings were randomly allocated to the backs of all volunteers.
Duration of study	15 days.
Patient population	Healthy volunteers.
Sample size	22
Inclusion criteria	Over 18 years old and had uniform skin colour, with no erythema or dark pigmentation in the test area; willingness to conform to the

	study protocol; any underlying medical conditions, such as diabetes, had to be under control, with the volunteer currently receiving appropriate medical attention.
Exclusion criteria	Pregnancy or lactation, drug addiction, alcoholism, AIDS or infections hepatitis (if known), documented allergies to cosmetic products, intolerance to plasters in the past, conditions that exclude participation or might influence the test reaction/evaluation, systematic therapy with immunosuppressive drugs and/or antihistamines within the previous 7 days or antiphlogistic agents or analgesics within the previous 3 days.
Method of randomisation	The dressings were given a code letter and randomly allocated, with the participant blinded to the dressing allocation.
Intervention(s) (n = 22) and comparator(s) (n = 22)	Intervention: Mepilex® Border to back of volunteers. Comparators: All placed on back of volunteers. Untreated Versiva XC (hydrocolloid) Biatain (hydrocolloid) Allevyn adhesive (acrylate) Comfeel® Plus (hydrocolloid) Urgotul Trio (hydrocolloid petrolatum mixture)
Baseline differences	None stated, but all healthy volunteers exposed to all of the test materials.
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	Baseline measurements were taken in a controlled environment, the skin on the back was divided into test areas. On 7 areas, a circular stain was applied using an occlusive patch system with dihydroxyacetone for 8 hours. On day 2, an overview photograph of all test areas was taken. The test products were then applied according to a randomisation scheme. One area was left untreated to act as a visual control. After 24 hours, the test products were removed, following a predetermined technique to ensure consistency, and one overview image of all test areas was taken. The volunteers were then acclimatised for at least 60 minutes before measurements were taken. This complete procedure was repeated on days 5, 8, 10 and 12. The study was completed on day 15, with no further dressings applied.
Statistical tests	For TEWL and chromameter measurements the baseline values and treatments were tested for statistical differences using ANOVAs, while differences between dressings at each time point were tested using paired t-tests. For volunteer and technician assessment the data were tested using the Wilcoxon signed-rank tests.
Primary outcomes (including scoring methods and timings of assessments)	Skin barrier function was investigated using the amount of TEWL and then related to the amount of skin stripping, investigated by measuring stained skin removal, the thickness of the stratum corneum after treatment, and the amount of skin attached to the removed dressings. TEWL was measured on every assessed day of the trial, using DermaLab skin testing (Cortex, Denmark).

	The removal of stratum corneum was assessed using a dye (dihydroxyacetone) to stain the skin and measuring the subsequent stain removal with the skin layers. Skin colour of the stained area was measured on days 2, 3, 5, 8, 10, 12 and 15 using a chromameter, and compared with baseline readings of the unstained skin on day 1. The L*a*b* colour space was used, taking the mean of three repetitive measurements.
Secondary outcomes (including scoring methods and timings of assessments)	General signs of trauma, such as skin dryness and erythema, were investigated by subjective and objective parameters using a visual assessment scale (0 [no results] to 3 [strong results]). An objective visual evaluation of the test areas was carried out by a trained technician for the presence of erythema, dryness, fissures, papules, pustules, oedema, vesicles and weeping. Subjective volunteer assessments were made for itching, burning, tightness and a feeling of dryness. Overview photographs were also taken at each dressing change to record the response of the skin to repeated dressing removal and application.

Table B14.1: Critical appraisal of RCTs: Dykes and Hill (2001)

Study name		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Yes	The study was approved by a local health authority ethics committee. Written, informed consent was obtained from each volunteer and appropriate evaluations (medical history and examination) were undertaken to ensure that volunteers were in good health.
Was the exposure accurately measured to minimise bias?	Yes	Treatments were randomly allocated to five out of six test sites (3 x 15cm) marked on each subject's back. The sixth site acted as an untreated control and was covered with a non-adherent silicone gauze. Dressings were applied to the test sites according to a randomisation schedule and removed and discarded after 24 hours. Application and removal was repeated twice over 24-hour intervals, amounting to three consecutive applications.
Was the outcome accurately measured to minimise bias?	Yes	Peel force was measured in mNewtons using a transducer calibrated with a series of known weights. Output from the transducer was amplified and recorded using a chart recorder. The initial detachment (peak) force and the steady state force achieved once the material had started to detach from the skin were obtained from the output of the chart recorder.
Have the authors identified all important	Not clear	Confounding factors and the relevance of healthy volunteer studies to clinical settings is discussed in the analysis, but limited discussion of clinical setting.

confounding factors?		
Have the authors taken account of the confounding factors in the design and/or analysis?	Not clear	The authors stated that it has yet to be determined whether this model is predictive of actual clinical use as data from comparative trials are not currently available.
Was the follow-up of patients complete?	Not clear	The number of volunteers who completed follow-up was not reported.
How precise (for example, in terms of confidence interval and p values) are the results?	-	P values stated, but confidence intervals not presented.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Table B14.2: Critical appraisal of RCTs: Dykes and Heggie (2003)

Study name		
Study question	**Response** **yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Yes	The local health authority ethics committee approved the study. Volunteers were recruited from the test panel of Cutest. Written informed consent was obtained from each volunteer before enrolment into the study and appropriate evaluations (medical history and examination) were undertaken to ensure that each subject was in good health before participation.
Was the exposure accurately measured to minimise bias?	Yes	Allocation of test materials to the test sites was randomised. For peel force measurement the dressings were removed under standardised conditions. The visual analogue scale meter was set at approximately 50mm before each assessment. The value recorded from the position on the scale was displayed on the back of the meter, so the subject was unaware of the exact value they had given. Subjects were not aware of the order in which the dressings were removed to avoid bias.
Was the outcome accurately measured to minimise bias?	Yes	Both visual analogue scales and peel force measures recorded mechanically.

Have the authors identified all important confounding factors?	Not clear	Minimal discussion of confounding factors and the relevance of healthy volunteer studies to clinical settings.
Have the authors taken account of the confounding factors in the design and/or analysis?	Not clear	Limitations of the human volunteer study are stated in the study and the authors state that clinical studies are needed to support these results.
Was the follow-up of patients complete?	Not clear	No details on patient follow-up stated.
How precise (for example, in terms of confidence interval and p values) are the results?	-	P values presented, but no confidence intervals stated.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Table B14.3 Critical appraisal of RCTs: Dykes (2007)

Study name		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Yes	Inclusion and exclusion criteria clearly defined. Ethical approval was obtained from the Cardiff Independent Research Ethics Review Committee. Healthy volunteers recruited from the test panel of Cutest. Informed consent obtained.
Was the exposure accurately measured to minimise bias?	Not clear	Suitable qualified nurses assessed test products using an established scale. However, where the adhesive border was <2.5cm wide, two parallel strips of adhesive border were used to cover an equivalent area, so may not be representative of real use of some dressings. Also, authors state that from day 5 of the study the test products were covered with non-occlusive Scanpor tape (Alpharma AS, Norway) because, in a minority of subjects, accidental removal of some products was occurring. The Scanpor tape was 5 x 5cm and completely covered the test product. There is no discussion of whether this may have affected the exposure of the test dressings.
Was the outcome accurately	Yes	The assessment of erythema was observer-blinded in that the study nurse carrying out the assessments was unaware of the product allocation.

measured to minimise bias?		
Have the authors identified all important confounding factors?	Not clear	Confounding factors and the relevance of healthy volunteer studies to clinical settings is discussed in the analysis, but there is no discussion of the limitations of the test method exposures, as discussed above.
Have the authors taken account of the confounding factors in the design and/or analysis?	No	Healthy volunteer study so not able to replicate the clinical environment and co-morbidities that may influence cutaneous irritancy and skin barrier function.
Was the follow-up of patients complete?	Not clear	The number of volunteers who completed follow-up was not reported.
How precise (for example, in terms of confidence interval and p values) are the results?	-	Median cutaneous irritancy scale values and 75% quartiles presented. Mean TEWL values plus SD presented. P values, but no confidence intervals presented.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

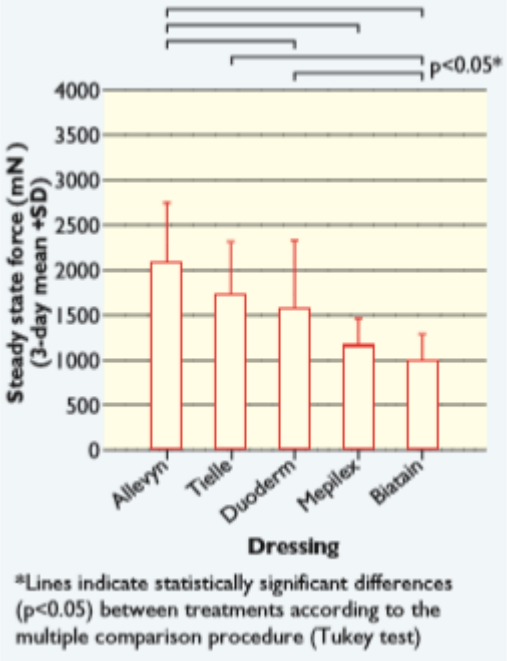
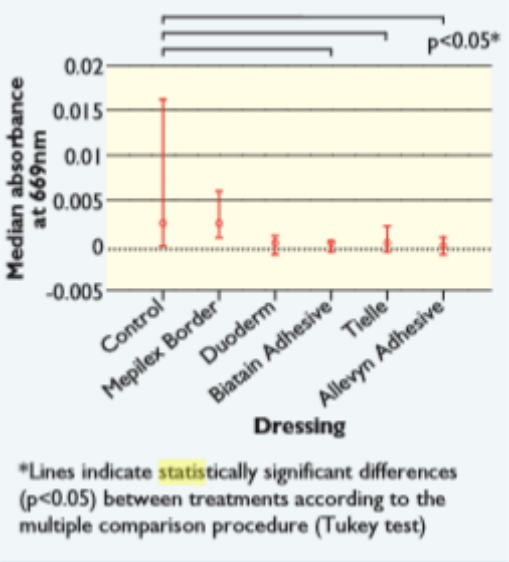
Table B14.4: Critical appraisal of RCTs: Waring et al. (2011)

Study name		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Yes	Inclusion and exclusion criteria clearly defined. As all the wound dressings studied were medical devices with a CE mark, no individual review by an ethics committee was necessary for this study. Protocol explained to all volunteers and informed consent obtained.
Was the exposure accurately measured to minimise bias?	Yes	The dressings were given a code letter and randomly allocated, with the participant blinded to the dressing allocation. 24 hours after application, the test products were removed, following a predetermined technique to ensure consistency. The volunteers were then acclimatised for at least 60 minutes before measurements were taken. This complete procedure was repeated on all test days.
Was the outcome accurately	Yes	Duplicate measurements taken for each test site for TEWL.

measured to minimise bias?		For chromameter measurements the mean of 3 repetitive measurements was taken. Objective visual evaluation of the test areas was carried out by a trained technician. In order to support the instrumental measurements of the skin barrier, the adhesive surface of the removed dressings from two randomly selected volunteers was examined for evidence of stratum corneum removal using a field emission scanning electron microscope. On day 15, the thickness of the stratum corneum was measured on four randomly selected volunteers, using confocal scanning laser microscopy.
Have the authors identified all important confounding factors?	Yes	Limitations of human volunteer study discussed.
Have the authors taken account of the confounding factors in the design and/or analysis?	Yes	The authors have attempted to limit the effect of confounding factors with the variety of established tests used and random inspection of stratum corneal thickness and adhesive material from dressings.
Was the follow-up of patients complete?	Not clear	The number of volunteers who completed follow-up is not reported.
How precise (for example, in terms of confidence interval and p values) are the results?	-	P values reported, but confidence intervals not presented.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Table B15.1 Outcomes from RCTs: Dykes and Hill (2001)

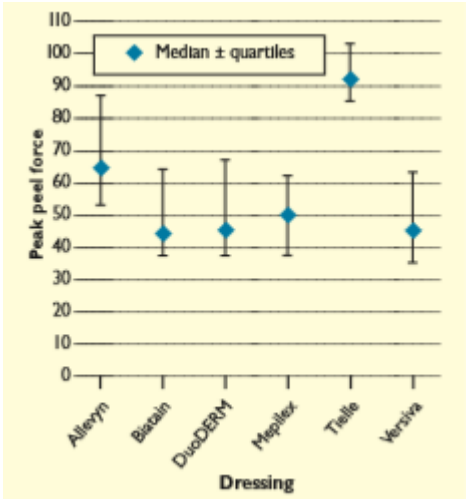
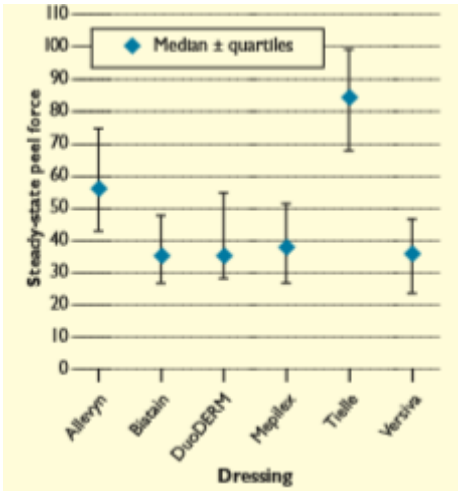
Study name		Effects of adhesive dressings on the stratum corneum of the skin.
Size of study groups	**Treatment**	20
	Control	20
Study duration	**Time unit**	4 days.
Type of analysis	**Intention-to-treat/per protocol**	Not stated.
Outcome	**Name**	Mean steady state force values (three-day average).
	Unit	mNewtons

Effect size	**Value**	Mean steady state peel force values 
	95% CI	N/A
Statistical test	**Type**	An ANOVA procedure was used to determine treatment and time effects. To avoid assumptions about the normality of the data, subsequent analysis was carried out using the non-parametric Friedman ANOVA procedure followed by a multiple comparison procedure based on the Tukey test.
	p value	<0.05
Other outcome	**Name**	Median absorbance values
	Unit	Optical density units
Effect size	**Value**	Median absorbance values and interquartile range 
	95% CI	<0.05

Statistical test	**Type**	An ANOVA procedure was used to determine treatment and time effects. To avoid assumptions about the normality of the data, subsequent analysis was carried out using the non-parametric Friedman ANOVA procedure followed by a multiple comparison procedure based on the Tukey test.
	p value	<0.05
Comments		There were 2 parts to this study, only the second part assessed Mepilex® Border. The study was supported by a grant from Mölnlycke Health Care.

Table B15.2 Outcomes from RCTs: Dykes and Heggie (2003)

Study name		The link between the peel force of adhesive dressings and subjective discomfort in volunteer subjects.
Size of study groups	**Treatment**	24
	Control	24
Study duration	**Time unit**	24 hours
Type of analysis	**Intention-to-treat/per protocol**	Not stated.
Outcome	**Name**	The initial detachment (peak) force and the steady-state force, which occurs once the material starts to become detached, were obtained from the output of the chart recorder.
	Unit	mm (1mm on chart recorder = 0.04 Newtons).

Effect size	**Value**	Peak peel-force values  Steady-state peel-force values 
	95% CI	N/A
Statistical test	**Type**	Nonparametric multiple-comparison procedure based on the Tukey-HSD test.
	p value	Statistical analysis indicated that Tielle had a significantly higher peak peel force than Mepilex® Border, Biatain, DuoDERM Extra Thin and Versiva ($p<0.01$). In addition, Allevyn Adhesive had a higher peak force than DuoDERM Extra Thin and Versiva ($p<0.05$). All other comparisons were not statistically significant. Tielle had a significantly higher steady-state peel force than Mepilex® Border, Biatain, DuoDERM Extra Thin and Versiva ($p<0.01$). Allevyn Adhesive had a higher steady state peel force than Mepilex® Border, Biatain and Versiva ($p<0.05$). All other comparisons were not statistically significantly.
Other outcome	**Name**	Discomfort experienced by the subject at each dressing removal
	Unit	100mm visual analogue scale (0=no discomfort, 100=extreme discomfort).

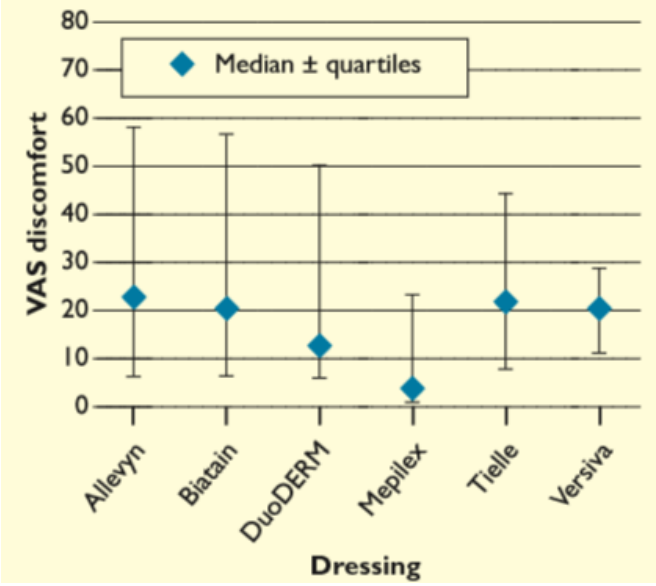
Effect size	**Value**	Visual analogue scale discomfort scores  Statistical analysis indicated that Mepilex® Border had a significantly lower discomfort score than the other products. All other comparisons were not statistically significant.
	95% CI	N/A
Statistical test	**Type**	Nonparametric multiple-comparison procedure based on the Tukey-HSD test.
	p value	p<0.01
Comments		This study was supported by a grant from Mölnlycke Healthcare.

Table B15.3: Outcomes from RCTs: Dykes (2007)

Study name		The effect of adhesive dressing edges on cutaneous irritancy and skin barrier function.
Size of study groups	**Treatment**	30
	Control	30
Study duration	**Time unit**	15 days
Type of analysis	**Intention-to - treat/per protocol**	There is no analysis of patient follow-up.
Outcome	**Name**	Median cutaneous erythema.
	Unit	0–6 ranking scale.

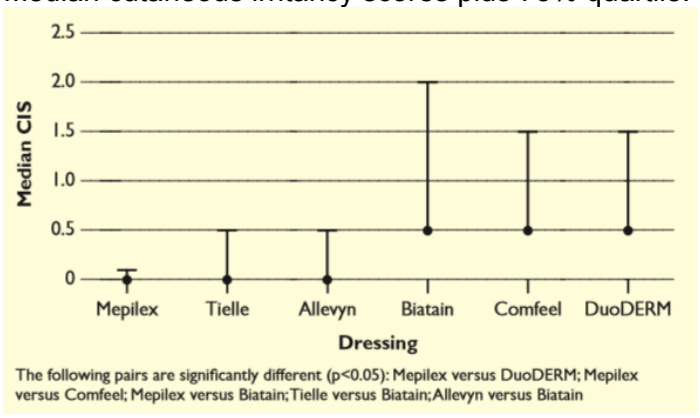
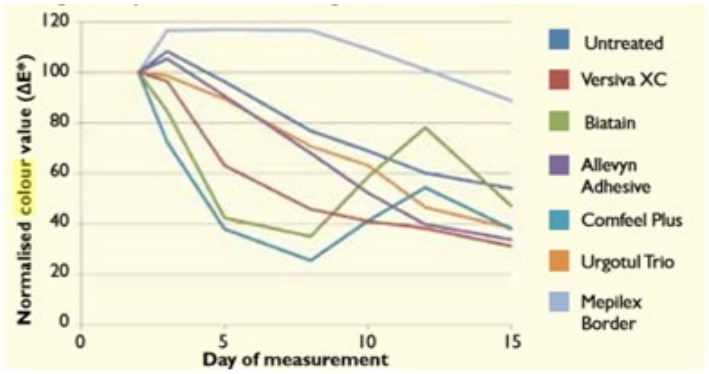
Effect size	**Value**	Median cutaneous irritancy scores plus 75% quartile.  The following pairs are significantly different (p<0.05): Mepilex versus DuoDERM; Mepilex versus Comfeel; Mepilex versus Biatain; Tielle versus Biatain; Allevyn versus Biatain
	95% CI	N/A
Statistical test	**Type**	A non-parametric Friedman two-way ANOVA procedure, followed by a multiple comparison procedure based on the Tukey HSD test.
	p value	<0.05
Other outcome	**Name**	Mean TEWL values.
	Unit	g/m^2/h
Effect size	**Value**	Mean TEWL plus SD Subject / Mepilex / Tielle / Allevyn / Biatain / Comfeel / DuoDERM / Normal adjacent skin Mean / 7.78 / 10.87 / 14.92 / 60.78 / 56.68 / 49.88 / 9.10 Standard deviation / 2.97 / 10.20 / 10.98 / 21.71 / 24.11 / 22.82 / 2.63
	95% CI	N/A
Statistical test	**Type**	A non-parametric Friedman two-way ANOVA procedure, followed by a multiple comparison procedure based on the Tukey HSD test.
	p value	Mepilex®, Tielle and Allevyn were not significantly different from normal skin (p<0.05), whereas Biatain, Comfeel® and DuoDERM were significantly higher than normal skin and higher than the other products tested.
Comments		The study was supported by a research grant from Mölnlycke health care.

Table B15.4: Outcomes from RCTs: Waring et al. (2011)

Study name		An evaluation of the skin stripping of wound dressing adhesives.
Size of study groups	**Treatment**	22
	Control	22

Study duration	**Time unit**	15 days
Type of analysis	**Intention-to - treat/per protocol**	Per protocol
Outcome	**Name**	Mean difference in TEWL from the baseline.
	Unit	$g/m^2/h$
Effect size	**Value**	TEWL values measured on the untreated test area, as well as after application of Urgotul Trio, remained relatively unchanged during the 15 day study period. TEWL values after application of Mepilex® Border decreased slightly (~1$g/m^2/h$) after application, indicating an improvement in the skin barrier. All other dressings displayed an increase in TEWL, with slight increases shown by Allevyn Adhesive (5$g/m^2/h$) and Versiva XC (14$g/m^2/h$); the highest increases in TEWL (Comfeel Plus, 22$g/m^2/h$, and Biatain, 28$g/m^2/h$) indicate damage to the stratum corneum, where the barrier function of the skin resides.
	95% CI	Not presented, but SD error bars presented on graph.
Statistical test	**Type**	Homogeneity of the TEWL baseline values was investigated using a repeated measurements ANOVA for the test areas. No significant differences between baseline values were found (p=0.97). A repeated measurements ANOVA for the test products was performed on area under curve differences from the baseline, from day 3 to day 14.
	p value	<0.001
Other outcome	**Name**	Change in skin colour from baseline.
	Unit	Normalised colour value (∆e*)
Effect size	**Value**	Graph of the total change in stained skin colour 
	95% CI	N/A
Statistical test	**Type**	A repeated measurements ANOVA for the test products was performed on area under the curve from day 3 to day 14.
	p value	Reported as not significant, but stated as <0.001.
Other outcome	**Name**	Subjective parameters: itching, burning, tightness
	Unit	Visual assessment scale (0-3).

Effect size	**Value**	Not stated.
	95% CI	N/A
Statistical test	**Type**	Wilcoxon signed-rank tests
	p value	No statistical differences were seen between treatments.
Other outcome	**Name**	Objective parameters: erythema, dryness.
	Unit	Visual assessment scale (0-3).
Effect size	**Value**	The mean values of the objective parameter erythema showed that the hydrocolloid dressings (Versiva XC, Biatain, Comfeel Plus) displayed a marked increase in erythema over the trial period, while Mepilex® Border, Urgotul Trio and Allevyn Adhesive remained more constant, with Mepilex® Border showing the least redness. The mean values of the objective parameter skin dryness, with the hydrocolloid dressings again showing the greatest increase.
	95% CI	N/A
Statistical test	**Type**	Wilcoxon signed-rank tests
	p value	Erythema: not presented. Skin dryness: p>0.05.
Comments		-

7.7.2 Provide details of all important adverse events reported for each study.

As Mepilex® Border is to be topically applied to intact skin to prevent pressure ulcers a minimal number of adverse events would be expected linked to the use of the device for prophylactic purposes, the use indicated in the decision problem. All of the identified studies assessed in section 7.7.1, from the search assessing adverse events, were from human volunteer studies. The relevance of normal volunteer studies to the clinical situation has to be considered. Although the two- to three-day schedule of a repeat-insult patch test may be similar to that in clinical use, the periwound skin may be abnormal, both structurally and in the way it responds to external stimuli. In addition, the way the dressings are removed in a clinical situation may be different from that used in healthy volunteer studies (Dykes, 2007). Therefore, Table B17, assessing adverse events, does not include these human volunteer results.

The 4 human volunteer studies assessed the skin stripping potential of the adhesive border used in the Mepilex® Border dressings in comparison with a

variety of other wound dressings with adhesive borders (n=96). The study by Waring et al. (2011) used a per protocol analysis due to one volunteer being excluded from the study due to a major protocol violation.

All of the studies used a within-subject design and all studies randomised the location of the dressing to assess the effect of repeated application and removal of adhesive edges from a variety of wound-care dressings assessing peel force, discomfort, cutaneous irritancy, skin stripping, and barrier function in healthy volunteer subjects.

Mepilex® Border demonstrated a comparatively lower peel force required to remove the dressing from the skin in combination with a relatively low absorbance value, indicating less damage to the skin after removal of the dressing (Dykes and Hill, 2001). The relatively low peel force required to remove the dressing was demonstrated in another study combined with a comparatively low discomfort score (Dykes and Heggie, 2003). The same dressing also demonstrated a reduction in TEWL values after application, indicating an improvement in the skin barrier and a reduced level of erythema compared with other dressings, which all showed an increase in TEWL scores compared with measurements of skin where there was no dressing in place (Waring et al. 2011). Mepilex® Border also demonstrated the lowest cutaneous irritancy score compared with other test dressings, as well as confirming the low TEWL values demonstrated previously (Dykes, 2007).

These results show clear differences between dressings with adhesive borders and indicate that Mepilex® Border would be well tolerated on intact skin in clinical settings.

A qualitative review of the adverse event data, derived from the limited number of adverse events from sections 7.1 to 7.6, assessing the product for prevention of pressure ulcers, provides clinical data on adverse events.

The RCT by Santamaria et al. (2015) states that there were no adverse events recorded related to the dressings used throughout the study. Similarly, the RCT by Kalowes et al. (2016) reported no adverse events related to

Mepilex® Border Sacrum. In fact, Kalowes et al. asserted that the dressing remained in place, was atraumatic to skin, and impermeable to urine and faeces. Moreover, the authors reported that there was no evidence of skin fungal infections or dermatitis.

The RCT by Aloweni et al. (2017) detailed the number of drop-outs from their study, assessing all high risk patients admitted to hospital (≤14 on the Braden scale). In this study there was an unexpected number of drop-outs from the dressing group compared to the other comparative groups. There were 18 (14%) drop-outs in the fatty acids oil group, 17 (8%) in the standard care group, and 29 (22%) in the Mepilex® Border group. The reasons for drop-out were provided, no adjustments made, and no assessment of their statistical significance given. In the Mepilex® Border group the reasons for drop-out from the study were: sacral excoriation (n=3), diarrhoea (n=6), dying/dead (n=6), contamination of treatment (n=9), and requested withdrawal (n=5). There were no further details regarding any of these withdrawals. Whilst contamination of treatment would not be viewed as an adverse event it does indicate a potential concern when using the dressing with poorly managed incontinent patients and a number of the included studies in this submission listed poorly managed incontinence as an exclusion criteria. The comparative number of cases of sacral excoriation and contamination of products are considered in Table B.16 below, in comparison with the control groups in that study.

Table B.16: Aloweni et al. (2017): Sacral excoriation and contamination of treatment (Time period: ≤14 days)

	Standard care plus Mepilex Border Sacrum (n = 124)	**Fatty acids oil of patients (n = 123)**	**Standard care of patients (n = 192)**
Sacral excoriation	3	6	2
Contamination of treatment	9	2	1

There was only one other study, assessing Mepilex® Border Sacrum for the prevention of pressure ulcers, where safety concerns were noted. In the observational study by Walsh (2012) the Mepilex® Border Sacrum dressing was discontinued prematurely in one patient, who was agitated resulting in friction against the dressing and frequent displacement.

The systematic review by Clark et al. (2014) alludes to only one case study that contained adverse event data and that study was unrelated to this submission. There was no reference to adverse events in the meta-analysis by Huang et al. (2015). In the systematic review by Tayyib and Coyer (2016) adverse effects were listed as a secondary outcome of the study, but no adverse effects were noted from the use of dressings in the prevention of pressure ulcers. The Cochrane review by Moore and Webster (2013), assessing dressings and topical agents for preventing pressure ulcers, featured the studies by Kalowes et al. (2016 [as a poster presentation, 2012]) and Qiuli and Qiongyu (2010) assessing Mepilex® Border. The review included 9 RCT's and 1501 participants. However, there was only one trial they noted that included any data on adverse events, which was a study assessing an emollient based cream. The authors stated that no studies reported on pain at dressing change and that adverse events were poorly described.

The systematic review and consensus recommendations by Black et al. (2014) reported that skin injury could result from repeated removal of strongly adhesive dressings. If skin was torn, easily bruised or fragile the authors recommend the use of a dressing such as soft silicone which is recognised to prevent skin damage. For patients with fragile skin, use of a retention bandage to hold the dressing securely in place is recommended. Two of the RCT's assessing the Mepilex® Heel dressing did use a Tubifast retention bandage to maintain the dressing in place (Santamaria et al. 2015, Santamaria et al. 2018).

All except one study (the observational study by Richard-Denis, which studied Mepilex® Border Sacrum without some aspects of standard care, rather than

as an adjunct to standard care) demonstrated the effectiveness of the Mepilex® Border dressings in the prevention of pressure ulcers. However, pressure ulcers were still experienced in these prevention studies and their effectiveness in the prevention of pressure ulcers compared with standard care could be assessed in terms of the level of pressure ulcers experienced as an adverse event. Table B17 reviews the number of pressure ulcers experienced by Mepilex® dressings plus standard care in comparison with standard care alone, or with any of the additional treatments considered in included studies in this submission. The incidence figures in Table B17 demonstrate that the Mepilex® dressings are consistently more effective compared with standard care in terms of the reduction of sacral pressure ulcers, heel pressure ulcers, chest pressure ulcers, and the total number of ulcers experienced. Studies assessing the incidence of pressure ulcers will be further analysed in section 7.8.

Table B17: Adverse events: pressure ulcers across all patient groups in all time periods

	Standard care plus Mepilex® Dressings (n = 2243*)	**Standard care ± additional treatment (n = 2072+)**
Sacral pressure ulcers	41	167
Heel pressure ulcers	12	43
Chest pressure ulcers	3	11
Pressure ulcers: site not stated	0	3
Total Pressure ulcers	56	224
*Studies included for intervention population: Aloweni et al. (2017); Kalowes, et al. (2016); Qiuli and Qiongyu (2010); Santamaria, et al. (2015); Santamaria, N. (2018), Brindle and Wegelin (2012), Haisley et al. (2015); Park (2014); Richard-Denis et al. (2017); Santamaria, et al. (2015a); Yoshimura et al. (2016); Jin (2018, unpublished); Brindle (2010); Chaiken (2012); Cubit et al. (2013); Bateman and Roberts (2013); Daukste (2014); Edwards and Lynch (2014); Gentry and Wright (2010); Johnstone, and McGown (2013); Koerner and Adams (2011); Lientz (2013); Muldoon et al. (2010); Walsh et al. (2012); Baker (2014).		
+ Studies included for control population: Aloweni et al. (2017); Kalowes, et al. (2016); Qiuli and Qiongyu (2010); Santamaria, et al. (2015); Santamaria, N. (2018) , Brindle and Wegelin (2012); Park (2014); Richard-Denis et al. (2017); Santamaria, et al. (2015a); Yoshimura et al. (2016); Jin (2018, unpublished); Brindle (2010); Chaiken (2012); Cubit et al. (2013)		

7.7.3 Describe all adverse events and outcomes associated with the technology in national regulatory databases such as those maintained by the MHRA and FDA (Maude).

A search undertaken in the FDA MAUDE database on 11th January, 2018 revealed 4 adverse events from a search of 'brand name': 'Mepilex Border'. Only one of these events was related to Mepilex® Border Sacrum and that case was related to a nurse reported event detailing Mepilex® Border Sacrum being applied prophylactically to prevent pressure ulceration, in December, 2010. The nurse described the patient as elderly with a suspected DTI developing under the dressing. The patient reportedly expired one day later. No further details were available on the incident or the batch details of the dressing so no further assessment on the association of the device with the reported problems was possible.

The MHRA 'Alerts and recalls for drugs and medical devices' were searched on 12th January, 2018 for any reports related to: 'Mepilex' and there were no reports listed.

7.7.4 Provide a brief overview of the safety of the technology in relation to the scope.

[redacted]. However, it should be noted that, in the published literature, the Mepilex® Border dressings are consistently reported as being 'skin friendly' and associated with less trauma and pain than other adhesive dressings.

The human volunteer studies assessed in section 7.7.1 indicate that the Mepilex® Border dressings have a low potential for skin stripping and irritation related to the adhesive on the dressing and have a favourable TEWL level compared with untreated intact skin and competitor dressings.

The pressure ulcer prevention studies for Mepilex® Border, Mepilex® Border Sacrum, and Mepilex® Border Heel dressings (n=34 studies) revealed that the dressings were extremely well tolerated and resulted in very few adverse events, as detailed in section 7.7.2.

The instructions for use for Mepilex® Border dressings state that they should not be used on patients with known sensitivity to the dressing or its components. They also state that Mepilex® Border should not be used together with oxidising agents such as hypochlorite solutions or hydrogen peroxide.

To the best of our knowledge, the use of prophylactic Mepilex® Border dressings pose minimal risks of adverse events that might affect the UK health and social care system, its staff or its facilities.

7.8 Evidence synthesis and meta-analysis

When more than one study is available and the methodology is comparable, a meta-analysis should be considered.

Section 7.8 should be read in conjunction with the 'Medical Technologies Evaluation Programme Methods Guide', available from www.nice.org.uk/mt

7.8.1 Describe the technique used for evidence synthesis and/or meta-analysis. Include a rationale for the studies selected, details of the methodology used and the results of the analysis.

Given the time constraints for this submission we were unable to perform a meta-analysis of the data presented in this submission.

7.8.2 If evidence synthesis is not considered appropriate, give a rationale and provide a qualitative review. The review should summarise the overall results of the individual studies with reference to their critical appraisal.

A qualitative review will allow consideration of some of the observational studies which may not have been suitable for consideration in a meta-analysis, in addition to the RCTs and systematic reviews assessing Mepilex®

Border products. However, evidence synthesis through meta-analysis has been performed in a number of recent systematic reviews included in this submission (Huang et al. 2017; Moore and Webster, 2013; Clark et al. 2014; Tayyib et al. 2016). Both the Cochrane review by Moore and Webster (2013) and the systematic review by Tayyib and Coyer (2016) synthesized the results of the same 3 studies ([1 RCT: Santamaria et al. 2015]; [2 prospective cohort studies: Brindle and Wegelin, 2012; Park, 2014]) assessing standard care plus Mepilex® Border Sacrum. The combined studies had an odds ratio of the overall effect size across 3 studies of 0.12 (95% confidence interval 0.05-0.29) p=0.00001, demonstrating that Mepilex® Border Sacrum was significantly more effective in the prevention of sacral pressure ulcers compared with standard care alone.

In the systematic review by Tayyib and Coyer (2016), assessing the use of pressure ulcer prevention strategies in the ICU, all data relating to prophylactic dressing use included in the meta-analysis related specifically to Mepilex® Border multi-layer foam dressings with Safetac®. In the systematic review of the evidence pertaining to the use of prophylactic dressings in the prevention of pressure ulcers in all settings (Clark et al. 2014), almost half of the studies included in the review relate to the use of Mepilex® Border multi-layer foam dressings with Safetac®. While the review stated that there was no firm clinical evidence (at the time of publication) to suggest that one dressing type was more effective compared with another, the authors did highlight that high-quality evidence relating to pressure ulcer prevention existed for just one group of dressings (i.e. multi-layer foam dressings with Safetac®).

In total, there were 5 RCTs which measured the incidence of pressure ulcers, assessing standard care plus Mepilex® Border or Mepilex® Heel dressings compared with standard care for the prevention of sacral and heel pressure ulcers, (n=1607). Whilst difference in the appearance of dressings made blinding impossible in all of the studies presented in this submission, all of the RCTs demonstrated the effectiveness of Mepilex® Border Sacrum or Mepilex® dressings in preventing sacral pressure ulcers (Santamaria et al. 2015; Aloweni et al. 2017; Kalowes et al. 2016; Qiuli and Qiongyu, 2010;

Santamaria et al. (2018). Four RCTs reported p values demonstrating significant effects for the level of effectiveness of the dressings in comparison with standard care. Three of these RCTs also demonstrated that Mepilex® Border or Mepilex® Heel dressings plus standard care were more effective in the prevention of heel pressure ulcers compared with standard care alone (Santamaria et al. 2015; Qiuli and Qiongyu, 2010; Santamaria et al. 2018). One of the 2 RCTs reporting p values demonstrated that Mepilex® Heel plus standard care was significantly more effective compared with standard care alone (p=0·002) in patients with ED and ICU admission for critical illness and/or major trauma (Santamaria et al. 2015).

All of the RCTs were undertaken in high-risk patients: in all hospital departments (Aloweni et al. 2017); medical/surgical/trauma ICU, and cardiac ICU (Kalowes et al. 2016); neurosurgical patients (Qiuli and Qiongyu, 2010); the ED and ICU (Santamaria et al. 2015); and in aged care residents (Santamaria et al. 2018,). The latter study demonstrating the effectiveness of Mepilex® Border Sacrum and Mepilex® Heel dressings in the aged care community setting in addition to the majority of studies, which were undertaken in hospital settings.

There were 11 non-randomised comparative studies assessing Mepilex® Border dressings. One was a modelling study, which demonstrated the benefits to the USA healthcare system of adopting Mepilex® Border Sacrum in acute care settings (n=1,031,564). The 10 remaining primary research studies assessed Mepilex® Border Sacrum, Mepilex® Border Heel, and Mepilex® Border dressings in a range of settings (n=2021). These included patients in high-risk settings: cardiac surgery ICU, Coronary Care, SVICU, ICU, traumatic spinal cord injury, spinal surgery

Seven of the 11 non-randomised comparative studies assessed Mepilex® Border Sacrum plus standard care in comparison with standard care alone (n=5 studies), with standard care plus alternative dressings (n=1 study), and in comparison with a gel mattress (n=1 study, Richard-Denis et al. 2017). Two

studies assessed Mepilex® Border dressings compared with alternative dressings (n=1 study) and compared with standard care (n=1 study). The remaining 2 studies assessed Mepilex® Border Heel dressings in comparison with standard care.

Ten of the studies assessing the range of Mepilex® Border dressings showed greater effectiveness for the Mepilex® Border dressings compared with the comparator. The only study that failed to show greater effectiveness was the study by Richard-Denis, which was criticised as it evaluated spinal injury patients using Mepilex® Border Sacrum dressings instead of part of the standard care, rather than in addition to standard care (Gefen and Santamaria, 2017). The Mepilex® Border dressing was used in conjunction with standard care in another comparative study assessing patients with spinal injuries and the results showed that standard care plus Mepilex® Border dressings applied to the sides of the chest and the iliac crest reduced the risk of intraoperatively acquired pressure ulcers (p=0·019, odds ratio 0·23, 95% CI 0·05–0·79) and was more effective compared with film dressings (Yoshimura et al. 2016).

Two non-randomised comparative studies assessed Mepilex® Border Heel dressings alone (n=222). The largest prospective cohort study (using a retrospective control cohort) by Santamaria et al. (2015[a]) assessing Mepilex® Border Heel dressings demonstrated a significant effect of standard care plus Mepilex® Border Heel dressings compared with standard care alone in ICU patients (p<0.001).

In addition, there were 11 non-comparative studies, the majority undertaken in high-risk ICU settings, which all demonstrated the effectiveness of Mepilex® Border, Mepilex® Border Sacrum, and Mepilex® Border Heel dressings in comparison with standard care for the prevention of pressure ulcers (n=642).

Two of these studies reported outcomes supporting the use of Mepilex® Border dressings in reducing pain associated with skin damage (Bateman and Roberts, 2013; Johnstone, and McGown, 2013). In addition, the study by

Brindle (2010) reported that the nursing staff found the dressing to be easy to apply, remained in place, was atraumatic to the patient's skin, was resistant to minor faecal incontinence and absorptive.

The RCT by Santamaria et al. (2015) reported on the occurrence of 7 study protocol violations in the dressing group, where sacral dressings were not always in place due to patient/compliance factors. Whilst 1 of these patients developed a stage II sacral pressure ulcer during the time that they did not have the dressing in place, because of the ITT analysis, this patient was analysed with all other intervention group patients.

Three RCTs reported the stages of pressure ulcers, which developed from intact skin during the study. In the RCT by Kalowes et al. (2016) there was only one sacral DTI reported in the Mepilex® Border Sacrum group, but there was 1 DTI, 4 stage II pressure ulcers, and 2 unstageable pressure ulcers reported in the standard care group. The RCT by Qiuli and Qiongyu (2010) reported no pressure ulcers for the Mepilex® or Mepilex® Border group, but there were 3 stage II pressure ulcers (site not stated) recorded in the standard care group. The RCT by Santamaria (2018,) reported 2 sacral pressure ulcers in the intervention group (1 stage I and 1 stage II) and 13 in the standard care group (5 stage I, 6 stage II, 2 stage IV). There were 3 heel pressure ulcers reported in the Mepilex® Heel group (2 stage I, 1 stage II) and 5 pressure ulcers reported in the standard care group (4 stage I, 1 stage II).

Whilst the treatment of pressure ulcers has been previously established to extend the length of hospital stay for patients (NICE, 2014[a]), there was insufficient data to draw conclusions on the association between pressure ulcer incidence and length of ICU or hospital stay from the data evaluated for this submission. The majority of studies were primarily designed to assess the association between pressure ulcer incidence and the use of Mepilex® Border dressings and hospital length of stay was less frequently evaluated. However, 2 RCTs did compare length of stay between groups. There was no significant difference between groups in ICU or hospital stay in the RCT by Kalowes et al. (2016). Whilst length of ICU stay was recorded for both groups in the RCT

by Santamaria et al. (2015) there were no statistical calculations comparing length of stay between groups.

7.9 Interpretation of clinical evidence

7.9.1 Provide a statement of principal findings from the clinical evidence highlighting the clinical benefit and any risks relating to adverse events from the technology.

The principal findings from the clinical evidence summarised in this submission consistently demonstrate that standard care plus Mepilex® Border dressings is more effective than standard care alone in the prevention of pressure ulcers.

Whilst the majority of studies were designed to assess the effectiveness of Mepilex® Border dressings in the prevention of pressure ulcers, by measuring pressure ulcer incidence, there were also two studies that supported use of the dressings in the reduction of pain associated with skin damage. Three RCTs also reported the stages of pressure ulcers, which developed from intact skin during the studies.

The highest quality clinical evidence supporting the range of Mepilex® Border dressings is from 5 RCTs, which demonstrate the clinical benefit of Mepilex® Border dressings for the prevention of sacral and heel pressure ulcers in a range of high-risk patients, both in hospital and community settings, in over 1500 patients.

These findings are supported by primary research in 11 non-randomised comparative studies, the majority assessing the prevention of sacral and heel pressure ulcers in over 2000 high-risk patients.

Although the use of prophylactic Mepilex® Border dressings as an additional component of standard NHS preventive measures for patients ‘at risk’ of pressure ulcers has demonstrated significant reduction in the incidence of pressure ulcers, it is important to stress that prophylactic dressings are intended to augment existing preventive measures, but not to replace them.

The results of these studies indicate that the use of prophylactic Mepilex® Border dressings can reduce the occurrence of pressure ulcers on anatomical locations such as the sacrum and the heel. There is also evidence indicating that other areas of the body that are affected by the same mechanical forces may also benefit from the dressings, such as high-risk surgical settings.

The Mepilex® Border dressings are designed to be used on intact skin as a preventive dressing and have a long established safety record, having been on the market for 15 years with approximately 470 million dressings sold, during which time the level of complaints has been consistently low. The Mepilex® Border dressings also uses the company's proprietary Safetac® technology, which is intended to minimise pain when changing dressings or inspecting the skin.

The PMS data and evidence from the FDA MAUDE and MHRA adverse event databases further support the safe use of Mepilex® Border dressings as an adjunct to standard care in the prevention of pressure ulcers.

7.9.2 Provide a summary of the strengths and limitations of the clinical-evidence base of the technology.

Strengths of the clinical evidence

There is a strong evidence base for Mepilex® Border dressings as an addition to standard pressure ulcer prevention strategies in the prevention of sacral and heel pressure ulcers in high-risk patients in the hospital and community.

There is evidence to suggest that the use of Mepilex® Border dressings plus standard care in other areas of the body, subject to the same mechanical forces, may also benefit high-risk patients in a range of acute settings.

Studies have been undertaken in a range of developed healthcare settings with similarities in principles and practice to the UK healthcare system, including 2 RCT's in Australia, and one in the USA.

Studies assessed are primarily based on the range of Mepilex® Border dressings and not all multi-layer dressings can be expected to exert the same effects.

There were minimal reports of device related adverse events related to pain or discomfort of the dressings, or any negative impact related to ease of use of the product, or on any negative effect on patient quality of life.

Limitations of the clinical evidence

Mepilex® Border dressings are to be used as an adjunct to standard care in the prevention of pressure ulcers and are not to replace standard NHS pressure ulcer prevention strategies.

There is a lack of evidence assessing Mepilex® Border dressings plus standard care in patients at high risk of developing pressure ulcers in the NHS. There were only two non-comparative observational studies assessing the use of Mepilex® Border dressings in the UK.

There is a lack of evidence of effectiveness in children, but Mepilex® Border dressings are indicated to be used in children so further research evaluating the effectiveness of the dressings in children would be useful.

There is a lack of evidence on the use of the device in diabetic patients, as this patient group may benefit from the use of the dressings if they are at an increased risk of foot or heel ulcers.

There was a lack of evidence for some of the outcome measures included in the decision problem: level of patient satisfaction, length of hospital stay, complications avoided from pressure ulcer prevention, and patient compliance with pressure ulcer prevention strategies.

7.9.3 Provide a brief statement on the relevance of the evidence base to the scope. This should focus on the claimed patient- and system-benefits described in the scope.

The Mepilex® Border dressings offer both patient- and system-benefits and the evidence presented is consistent with the statement of the decision problem issued in the scope.

The overwhelming majority of studies demonstrated the effectiveness of Mepilex® Border dressings plus standard care in the prevention of pressure ulcers. However, 2 of the included studies used Mepilex® Heel dressings, rather than Mepilex® Border Heel dressings (Santamaria et al. 2015 and Santamaria et al. 2018). As indicated previously, Mepilex® Border is the adherent dressing of choice as it is based on the five-layer design that has been reported to be key to the prevention of tissue deformation whereas Mepilex® Heel has a less complex non-adherent three-layer structure. These isolated studies should be viewed alongside the results of the 5 studies evaluating Mepilex® Border Heel dressings (Santamaria et al. 2015[a]; Haisley et al. 2015; Edwards and Lynch, 2014; Baker, 2014; Sullivan, 2013). A further RCT by Qiuli and Qiongyu (2010) utilised both Mepilex® and Mepilex® Border in their study without experiencing any pressure ulcer incidence. As indicated above, this isolated study should be viewed alongside the majority of evidence supporting the Mepilex® Border dressings.

7.9.4 Identify any factors that may influence the external validity of study results to patients in routine clinical practice.

The evidence assessed in this submission includes human volunteer studies, which may give an indication of experience in clinical practice, but the majority of evidence comes from clinical studies that reflect real clinical practice in the hospital and community settings. Therefore, there are no issues of external validity/transferability to routine clinical practice.

The majority of studies assessed patients who were at high-risk of developing pressure ulcers, which reflects the greater benefit that this patient group would receive from use of the products.

7.9.5 Based on external validity factors identified in 7.9.4 describe any criteria that would be used in clinical practice to select patients for whom the technology would be suitable.

All patients at risk of pressure ulcers may benefit from the use of Mepilex® Border dressings as an adjunct to standard care in the prevention of pressure ulcers, but high-risk patients would receive the greatest benefit. Therefore, selection of high-risk patients using a validated scale to support clinical judgement may be a consideration for use of the dressings.

Section C – Economic evidence

Section C requires sponsors to present economic evidence for their technology.

All statements should be evidence-based and directly relevant to the decision problem.

The approach to the de novo cost analysis expected to be appropriate for most technologies is cost-consequence analysis. Sponsors should read section 7 of the Medical Technologies Evaluation Programme Methods guide on cost-consequences analysis, available from www.nice.org.uk/mt

Sponsors are requested to submit section C with the full submission. For details on timelines, see the NICE document 'Guide to the Medical Technologies Evaluation Programme process', available from www.nice.org.uk/mt

8 Existing economic evaluations

8.1 Identification of studies

The review of the economic evidence should be systematic and transparent and a suitable instrument for reporting such as the PRISMA statement (www.prisma-statement.org/statement.htm).

A PDF copy of all included studies should be provided by the sponsor.

8.1.1 Describe the strategies used to retrieve relevant health economics studies from the published literature and to identify all unpublished data. The search strategy used should be provided as in section 10, appendix 3.

The economic evidence search was part of the overall search described earlier and the sources are described in section 10, Appendix 3.

8.1.2 Describe the inclusion and exclusion criteria used to select studies from the published and unpublished literature. Suggested headings are listed in the table below. Other headings should be used if necessary.

The economic search was part of the overall search described earlier. However, inclusion in the tabulation was the identified relevant studies that referred primarily to economic outcomes and so some of these had been excluded from the clinical tabulation but are now tabulated here. Studies that considered both clinical and economic evidence are also included.

Studies were included if they calculated or estimated a cost saving (or a consequence computed as a cost-saving) from the identified use of Mepilex® Border products including combination of Mepilex® Border product with another Mepilex® prophylactic dressing (such as Mepilex® non-adhesive dressings with Tubifast® bandages e.g. Mepilex® Heel, as seen in the Clinical section).

8.1.3 Report the numbers of published studies included and excluded at each stage in an appropriate format.

Six studies were identified as relevant to the economic evidence by the data analyst who conducted the main search and 1 newer poster was subsequently found by the manufacturer, making 7 in total. Six studies were included. Two of these (Santamaria 2014;Santamaria 2015b – the latter also published electronically in 2013 with the same doi) were economic studies based on the same RCT that had been excluded from the clinical tabulation (Table B4) because they were primarily economics focussed. Four other economic

studies were also tabulated in Section B (Padula, 2017;Kalowes 2016;Johnstone 2016;Lientz 2013 poster). Kalowes, 2016 is also an RCT (USA setting) which considers costs.

One study (Cooper, 2015) was excluded, similarly to the clinical section (Table B4), because although it assessed and costed overall the introduction of a bundle of measures to reduce pressure ulcer levels, which included Mepilex® Border and Mepilex® Border Sacrum, no data regarding the contributory effect of Mepilex® Border Sacrum dressing was available.

One additional poster, identified by the manufacturer after the main search was conducted, was included (Fimiani, 2017) since it presented a cost-saving estimate based on a longitudinal comparison of a set of preventative interventions using self-adhesive sacral dressings from two manufacturers (and 2 variants of each dressing) with cost comparisons based on the consequence of HAPI incidence conducted after an initial upgrade of the Control. The initial Control Dressing was Allevyn® Gentle Border Sacrum and the Control Dressing Upgrade was Allevyn® Life Sacrum (both manufactured by Smith and Nephew, Inc.) and the final intervention was Mepilex® Border Sacrum, the subject of this submission. Since the poster was included after the Clinical section was submitted to NICE, it has not been added to the PRISMA statement to avoid inconsistency.

8.2 Description of identified studies

8.2.1 Provide a brief review of each study, stating the methods, results and relevance to the scope. A suggested format is provided in table C2.

Table C2 Summary list of all evaluations involving costs

Study name (year)	Location of study	Summary of model and comparators	Patient population *(key characteristics, average age)*	Costs *(intervention and comparator)*	*Patient outcomes (clinical outcomes, utilities, life expectancy, time to recurrence for intervention and comparator)*	*Results (annual cost savings, annual savings per patient, incremental cost per QALY)*
Santamaria N. et al. (2015[b]) The cost-benefit of using soft silicone multi-layered foam dressings to prevent sacral and heel pressure ulcers in trauma and critically ill patients: a within-trial analysis of the Border Trial.	Australia	Cost benefit (or more accurately consequences with reported cost of these to the healthcare system) analysis from healthcare system perspective. Standard care plus Mepilex® Border Sacrum and Mepilex® Heel dressing plus Tubifast® retention bandage vs. Standard care with no dressings	ED and ICU admission for critical illness and/or major trauma. Over 18 years of age. Intervention (N=219, M/F 126/89). Comparator (N=221, M/F 132/82). Mean age 56. Based on the Border Trial.	Cost of HAPU. Intervention: AU$70.82 per patient Comparator: AU$144.56 Marginal cost of intervention AU$36.61 per patient admission.	Significant reduction in incidence of Hospital Acquired Pressure Ulcers (P=0.001) Intervention: 3.1% HAPU incidence. Comparator: 13.1% HAPU incidence.	Annual savings per patient AU$73.74 ($70.82 intervention vs. $144.56 comparator) derived from cost per day of a 20 day average patient stay for PU treatment following ICU admission.

Santamaria N. et al. (2014) An estimate of the potential budget impact of using prophylactic dressings to prevent hospital-acquired PUs in Australia.	Australia	Cost-consequences of standard care plus Mepilex® Border Sacrum and Mepilex® Heel dressing plus Tubifast® retention bandage vs. Standard care with no dressings. Results of Border trial cost-benefit analysis extrapolated to state populations and then combined national to population.	High-risk patients in public hospitals across Australia (10% subgroup of annual acute patients). Average PU costs derived from Intervention (N=161), Comparator (N=152), based on the Border Trial (therefore assume similar demographics to Santamaria, 2015[b] which was also published in 2013 under the same doi).	Cost of HAPU. Intervention cost per PU: AU$66.87 per patient Comparator cost per PU: AU$141.79 (average from trial) Marginal cost of intervention AU$33.32 per patient admission.	Significant reduction in incidence of HAPUs (P=0.001) Intervention: 3.1% HAPU incidence. Comparator: 13.1% HAPU incidence.	Estimate of overall national cost saving with intervention. $34,803.640.41 (55% reduction for the Australian healthcare system).

Kalowes P. et al. (2016) Five-layered soft silicone foam dressing to prevent pressure ulcers in the intensive care unit.	USA	RCT with cost data discussed. Standard care plus Mepilex® Border Sacrum versus standard care. Projection of the cost of prevention related to the estimated consumption of resources based on NPUAP prevention guidelines with financial investment. No 'bottom-up' analysis was conducted.	Medical/Surgical/Trauma ICU, Cardiac ICU. N=366 patients randomised to N=184 intervention versus N=182 comparator.	Cost of dressings estimate of £130,000 (excluding legal fees to defend against claims of HAPUs).	Incidence of HAPUs was significantly reduced from 0.% to 5.9% (P=0.01). 88% reduced risk of HAPU development.	Mean cost per patient lowered by $1,200-1,500 per day. Total organisational saving estimated to be $1m over two years.

Padula W.V. (2017) Effectiveness and value of prophylactic 5-layer foam sacral dressings to prevent hospital-acquired pressure injuries in acute care hospitals.	USA	Observational cohort study with cost data discussed. Standard care plus Mepilex® Border Sacrum vs. Standard care with no dressings. Retrospective observational cohort measuring recorded HAPI episodes, merged with dressing use.	Acute care settings. 18 years and over. Patients who were hospitalised for at least 5 days across 38 acute care hospitals with pressure injury as identified by Patient Safety Indicator PSI-03 (stage 3, 4 or unstageable PU not present on admission). Data from 2010-2015. N=618 cases.	Average cost of dressings used US$19,506 per quarter for 2586 units of dressings purchased per quarter ($7.54 per dressing). Spending on HAPUs recorded.	From 2010 to 2015, spending on PUs decreased from $120 to $43 per patients, while investment in sacral dressings increased from $2.60 to $20 per patient.	On average, a hospital using 1-2 dressings per patient experienced a 1.0 case reduction in PSI-03 per quarter. Given an average cost of PSI-03 PU treatment of US$50,000 to $150,000, the saving to hospitals could be from $200,000 to $600,000 p.a.

Johnstone and McGown (2016) **Innovations in the reduction of pressure ulceration and pain in critical care.**	Scotland	Single cohort product evaluation (cost study) over 3 months (N=75). Mean treatment of 9 days per patient.	Critical care units setting. Inclusion criteria: High-risk (Waterlow score >15), bariatric surgery, immobility, spinal cord injury (i.e. paralysis), liver failure, cardiac instability, diabetes, sedation, malnutrition, mechanical ventilation, age >65 years, surgical procedure >8 hours, heart disease, vasopressor medication >48 hours, peripheral vascular disease, past history of pressure ulcers, major trauma, traction, haemodynamically unstable.	Cost of PU treatment for patients with standard care calculated (£31.06, per day. Cost of intervention per patient (£1.50 per day based on £4.50 per dressing with changes every 3 days). Calculated based on a mean treatment of 9 days per patient.	Zero incidence of PUs in the 3 month period.	Potential cost saving of £29.56 per patient per day equating to £266.04 per patient admission avoiding a PU.
Lientz J. (2013) Dollars and sense: economic value in HAPU/sDTI prevention. [Poster]	USA	Single cohort observational study (cost study). N=56. 15 months. Duration of dressing use not stated.	Critical Care Units, ICU, CVICU patients meeting Brindle's inclusion criteria. CVOR patients with surgeries greater than or equal to 4 hours.	Cost per HAPU estimated at $43,180. Cost of dressings for the entire study population for 15 months $21,590.	Zero incidence of PUs. Incidence of 3 sDTI reported.	Cost of dressings would be more than covered by avoiding one HAPU.

Fimiani J. (2017) The evidence based prophylactic dressings reduces hospital-acquired press injuries by 68% and significantly lowers treatment costs. [Poster].	USA	'Upgraded Comparator': Allevyn® Life Sacrum (Smith and Nephew, Inc.). Intervention: Mepilex® Border Sacrum (two versions. Initial version implemented in September 2015, and improved adhesive version implemented in 2017.	'House-wide' implementation in Lancaster General Hospital over 22 months changing from Control to Intervention in September 2015.	Costs not stated.	Stage 3, 4, DTI and unstageable sacral and coccyx HAPI rates reduced by 68% in 22 months since September 2015. Reported 39 fewer HAPIs than would have resulted from the Control dressing. Additional result comparing the earlier variant of the comparator (Allevyn® Gentle Border Sacrum) showed a reduction in HAPIs from 73 to 48 within the period 2013-2015, prior to changing to the intervention dressing. Whilst not explicitly stated this means the reduction in HAPIs was from 48 to 9 for the intervention versus the 'Upgraded comparator.'	Estimated cost reduction of US$432,120 to $2,912,714 for the intervention dressing versus control dressing for 39 HAPIs avoided. Estimate based on Padula (2011) Improving the quality of pressure ulcer care with prevention. Stating cost of one PU prevention $7275.35 vs $10053.95.

8.2.2 Provide a complete quality assessment for each health economic study identified. A suggested format is shown in table C3.

The included papers are tabulated in tables C3 and following tables C3a etc.

Table C3 Quality assessment of health economic studies

Study name *Santamaria N. et al. (2015[b]*, also published 2013 electronically with same doi*) The cost-benefit of using soft silicone multi-layered foam dressings to prevent sacral and heel pressure ulcers in trauma and critically ill patients: a within-trial analysis of the Border Trial.*		
Study design Cost Consequences Analysis based on RCT results		
Study question	**Response (yes/no/not clear/N/A)**	**Comments**
1. Was the research question stated?	Yes	'cost-benefit' of using Mepilex® dressings on HAPU incidence
2. Was the economic importance of the research question stated?	Yes	States cost of treating PU from the literature in both UK and Australia.
3. Was/were the viewpoint(s) of the analysis clearly stated and justified?	Yes	Cost to Australian healthcare system.
4. Was a rationale reported for the choice of the alternative programmes or interventions compared?	Yes	Versus standard care.
5. Were the alternatives being compared clearly described?	Yes	Intervention is additive to standard pressure ulcer prevention modalities.
6. Was the form of economic evaluation stated?	Yes	Stated to be CBA but this would be described in UK as CCA since costs are compared to a primary outcome of HAPU incidence (but which is subsequently expressed as cost saving to the healthcare system).
7. Was the choice of form of economic evaluation justified in relation to the questions addressed?	Yes	The paper discusses justification of the analysis as additive to standard care.
8. Was/were the source(s) of effectiveness estimates used stated?	Yes	HAPU incidence (as used in the RCT)
9. Were details of the design and results of the effectiveness study given (if based on a single study)?	Yes	Based on RCT results.
10. Were details of the methods of synthesis or meta-analysis of estimates given (if based on an overview of a number of effectiveness studies)?	N/A	

11. Were the primary outcome measure(s) for the economic evaluation clearly stated?	Yes	HAPU incidence which is subsequently costed.
12. Were the methods used to value health states and other benefits stated?	Yes	Based on bed days incurred for patients who acquire a HAPU.
13. Were the details of the subjects from whom valuations were obtained given?	Yes	Through citation of the RCT paper which includes this information.
14. Were productivity changes (if included) reported separately?	N/A	
15. Was the relevance of productivity changes to the study question discussed?	N/A	
16. Were quantities of resources reported separately from their unit cost?	Yes	See Table 1.
17. Were the methods for the estimation of quantities and unit costs described?	Yes	See 'cost-benefit analysis section'
18. Were currency and price data recorded?	Yes	AU$ 2013
19. Were details of price adjustments for inflation or currency conversion given?	No	
20. Were details of any model used given?	Yes	
21. Was there a justification for the choice of model used and the key parameters on which it was based?	Yes	Based on the RCT.
22. Was the time horizon of cost and benefits stated?	Yes	Implicitly Acute Care in one year (2013) and stated to have been without follow-up after discharge.
23. Was the discount rate stated?	N/A	
24. Was the choice of rate justified?	N/A	
25. Was an explanation given if cost or benefits were not discounted?	No	Implicit.
26. Were the details of statistical test(s) and confidence intervals given for stochastic data?	N/A	

27. Was the approach to sensitivity analysis described?	Yes	Univariate and threshold
28. Was the choice of variables for sensitivity analysis justified?	No	But these are reasonable choices.
29. Were the ranges over which the parameters were varied stated?	Yes.	For threshold analysis only.
30. Were relevant alternatives compared? (That is, were appropriate comparisons made when conducting the incremental analysis?)	Yes.	Marginal intervention cost versus cost of HAPU treatment (averaged).
31. Was an incremental analysis reported?	No	
32. Were major outcomes presented in a disaggregated as well as aggregated form?	Yes	Table 6. Costs only.
33. Was the answer to the study question given?	Yes	The intervention led to cost savings
34. Did conclusions follow from the data reported?	Yes	
35. Were conclusions accompanied by the appropriate caveats?	Yes	E.g. discussion of follow-up which might result in further treatment costs (e.g. rehabilitation, societal costs); did not explicitly measure PU treatment durations; retrospective data used.
36. Were generalisability issues addressed?		Yes. States that results cannot be generalised to (non-critical care) in-patients.
Adapted from Drummond MF, Jefferson TO (1996) Guidelines for authors and peer reviewers of economic submissions to the BMJ. The BMJ Economic Evaluation Working Party. British Medical Journal 313 (7052): 275–83. Cited in Centre for Reviews and Dissemination (2008) Systematic reviews. CRD's guidance for undertaking reviews in health care. York: Centre for Reviews and Dissemination		

Table C3a Quality assessment of health economic studies

Study name *Santamaria N. et al. (2014) An estimate of the potential budget impact of using prophylactic dressings to prevent hospital-acquired PUs in Australia.*		
Study design Cost consequences extrapolated to national health care system perspective, based on RCT results		
Study question	**Response (yes/no/not clear/N/A)**	**Comments**
1. Was the research question stated?	Yes	Potential cost-saving to Australian healthcare system of PU prevention in the critical care acute setting.
2. Was the economic importance of the research question stated?	Yes	Gives an estimated total cost of treating PUs in Australia.
3. Was/were the viewpoint(s) of the analysis clearly stated and justified?	Yes	Yes. Cost to the public healthcare system.
4. Was a rationale reported for the choice of the alternative programmes or interventions compared?	Yes	Versus standard care.
5. Were the alternatives being compared clearly described?	Yes	Intervention is additive
6. Was the form of economic evaluation stated?	Yes	Stated to be CBA but this would be described in UK as CCA since costs are compared to a primary outcome of HAPU incidence (but which is subsequently expressed as cost saving to the healthcare system).
7. Was the choice of form of economic evaluation justified in relation to the questions addressed?	Yes	
8. Was/were the source(s) of effectiveness estimates used stated?	Yes	Based on cited RCT (same RCT as for Table C5).
9. Were details of the design and results of the effectiveness study given (if based on a single study)?	Yes	Based on RCT.

10. Were details of the methods of synthesis or meta-analysis of estimates given (if based on an overview of a number of effectiveness studies)?	N/A	
11. Were the primary outcome measure(s) for the economic evaluation clearly stated?	Yes	HAPU incidence from the RCT.
12. Were the methods used to value health states and other benefits stated?	Yes	Tables 2-4.
13. Were the details of the subjects from whom valuations were obtained given?	Yes	Implicit from reference to RCT where these details are available.
14. Were productivity changes (if included) reported separately?	N/A	
15. Was the relevance of productivity changes to the study question discussed?	N/A	
16. Were quantities of resources reported separately from their unit cost?	Yes	Frequencies of use are given in Table 2.
17. Were the methods for the estimation of quantities and unit costs described?	Yes	Table 2 notes.
18. Were currency and price data recorded?	Yes	AU$ and implicitly 2013 since this was the same as for the paper in C5
19. Were details of price adjustments for inflation or currency conversion given?	N/A	
20. Were details of any model used given?	Yes.	Methodology section.
21. Was there a justification for the choice of model used and the key parameters on which it was based?	Yes.	
22. Was the time horizon of cost and benefits stated?	N/A	Implicitly acute setting.
23. Was the discount rate stated?	N/A	
24. Was the choice of rate justified?	N/A	

25. Was an explanation given if cost or benefits were not discounted?	No	But implicit
26. Were the details of statistical test(s) and confidence intervals given for stochastic data?	N/A	
27. Was the approach to sensitivity analysis described?	No	There was no sensitivity analysis in this paper although this was described in the paper in C5 which this paper cites (2013 electronic version of Santamaria, 2015b).
28. Was the choice of variables for sensitivity analysis justified?	N/A	
29. Were the ranges over which the parameters were varied stated?	N/A	
30. Were relevant alternatives compared? (That is, were appropriate comparisons made when conducting the incremental analysis?)	N/A	
31. Was an incremental analysis reported?	N/A	
32. Were major outcomes presented in a disaggregated as well as aggregated form?	Yes	Table 4 breaks down input costs and treatment resources related to the primary outcome.
33. Was the answer to the study question given?	Yes	Intervention is cost saving
34. Did conclusions follow from the data reported?	Yes	
35. Were conclusions accompanied by the appropriate caveats?	Yes	Staff costs were excluded with justification. Lack direct of measurement of patient stay for PU treatment.
36. Were generalisability issues addressed?	Yes.	Limited to acute care in a public health care system setting.
Adapted from Drummond MF, Jefferson TO (1996) Guidelines for authors and peer reviewers of economic submissions to the BMJ. The BMJ Economic Evaluation Working Party. British Medical Journal 313 (7052): 275–83. Cited in Centre for Reviews and Dissemination (2008) Systematic reviews. CRD's guidance for undertaking reviews in health care. York: Centre for Reviews and Dissemination		

Table C3b Quality assessment of health economic studies

Study name *Kalowes P. et al. (2016) Five-layered soft silicone foam dressing to prevent pressure ulcers in the intensive care unit.*		
Study design. Cost study as part of RCT.		
Study question	**Response (yes/no/not clear/N/A)**	**Comments**
1. Was the research question stated?	Yes	Expressed in terms of HAPU reduction since this is an RCT report. No explicit HE question.
2. Was the economic importance of the research question stated?	Not clear	Expressed primarily in clinical terms but costs are computed.
3. Was/were the viewpoint(s) of the analysis clearly stated and justified?	Yes	'Research aim' section. Implicitly a health system viewpoint.
4. Was a rationale reported for the choice of the alternative programmes or interventions compared?	Yes	
5. Were the alternatives being compared clearly described?	Yes	
6. Was the form of economic evaluation stated?	No	Reports on aggregated costs during the RCT and cites cost of treatment for the consequences (PU ulcers)
7. Was the choice of form of economic evaluation justified in relation to the questions addressed?	Not clear	However, the need to calculate cost savings from PU prevention is implicit.
8. Was/were the source(s) of effectiveness estimates used stated?	Yes	RCT results.
9. Were details of the design and results of the effectiveness study given (if based on a single study)?	Yes	
10. Were details of the methods of synthesis or meta-analysis of estimates given (if based on an overview of a number of effectiveness studies)?	N/A	

11. Were the primary outcome measure(s) for the economic evaluation clearly stated?	Yes	Based on HAPU counts
12. Were the methods used to value health states and other benefits stated?	No	
13. Were the details of the subjects from whom valuations were obtained given?	Not clear	The annual health system cost for treating PUs was aggregated
14. Were productivity changes (if included) reported separately?	N/A	
15. Was the relevance of productivity changes to the study question discussed?	N/A	
16. Were quantities of resources reported separately from their unit cost?	No	The annual health system cost for treating PUs was aggregated
17. Were the methods for the estimation of quantities and unit costs described?	N/A	
18. Were currency and price data recorded?	No	
19. Were details of price adjustments for inflation or currency conversion given?	No	
20. Were details of any model used given?	No	
21. Was there a justification for the choice of model used and the key parameters on which it was based?	N/A	
22. Was the time horizon of cost and benefits stated?	No	However, an acute care setting implied.
23. Was the discount rate stated?	N/A	
24. Was the choice of rate justified?	N/A	
25. Was an explanation given if cost or benefits were not discounted?	N/A	
26. Were the details of statistical test(s) and confidence intervals given for stochastic data?	Yes	For clinical reporting of regression analysis

27. Was the approach to sensitivity analysis described?	N/A	No sensitivity analysis was conducted.
28. Was the choice of variables for sensitivity analysis justified?	N/A	
29. Were the ranges over which the parameters were varied stated?	N/A	
30. Were relevant alternatives compared? (That is, were appropriate comparisons made when conducting the incremental analysis?)	N/A	
31. Was an incremental analysis reported?	N/A	
32. Were major outcomes presented in a disaggregated as well as aggregated form?	No	
33. Was the answer to the study question given?	N/A	The paper was primarily clinically focussed and economics was not included in the study question as stated above.
34. Did conclusions follow from the data reported?	Not clear	The paper reports on total annual input costs on dressings and an estimated saving over 2 years since preventative dressings were introduced.
35. Were conclusions accompanied by the appropriate caveats?	Yes	The cost analysis of the paper was not 'bottom-up'. Single site. Consideration of bias due to non-blinding of the RCT.
36. Were generalisability issues addressed?	Yes	The study addresses the critical care context only and authors state it cannot be generalised to other patient populations.
Adapted from Drummond MF, Jefferson TO (1996) Guidelines for authors and peer reviewers of economic submissions to the BMJ. The BMJ Economic Evaluation Working Party. British Medical Journal 313 (7052): 275–83. Cited in Centre for Reviews and Dissemination (2008) Systematic reviews. CRD's guidance for undertaking reviews in health care. York: Centre for Reviews and Dissemination		

Table C3c Quality assessment of health economic studies

Study name *Padula W.V. (2017) Effectiveness and value of prophylactic 5-layer foam sacral dressings to prevent hospital-acquired pressure injuries in acute care hospitals.*		
Study design Observational cohort study with cost data discussed		
Study question	**Response (yes/no/not clear/N/A)**	**Comments**
1. Was the research question stated?	Yes	To study effectiveness and value of preventative dressings
2. Was the economic importance of the research question stated?	Yes	Introduction mentions overall cost of HAPIs in the United States, and annual number of patient deaths. Highlights the reduction in hospital payments (reimbursements) for treating HAPIs in Medicare and Medicaid services. Cites the daily cost of treating PU
3. Was/were the viewpoint(s) of the analysis clearly stated and justified?	Yes	The viewpoint is that of academic medical centres in Chicago, USA using Medicare payment rules and known case-mix.
4. Was a rationale reported for the choice of the alternative programmes or interventions compared?	Yes	
5. Were the alternatives being compared clearly described?	Not clear	The data is retrospective for hospitals pre- and post- use of preventative dressings where standard care is described as HAPI prevention programme (however hospitals that purchased no dressings were excluded from the analysis)
6. Was the form of economic evaluation stated?	Yes	Described as a Budget Impact Analysis and ROI calculation.
7. Was the choice of form of economic evaluation justified in relation to the questions addressed?	Yes	
8. Was/were the source(s) of effectiveness estimates used stated?	Yes	Effectiveness was measured in the cohort study at hospital level (episodes per 1000 patients).

9. Were details of the design and results of the effectiveness study given (if based on a single study)?	Yes	
10. Were details of the methods of synthesis or meta-analysis of estimates given (if based on an overview of a number of effectiveness studies)?	N/A	
11. Were the primary outcome measure(s) for the economic evaluation clearly stated?	Yes	Pressure injury rate as measured by Patient Safety Indicator PSI-03.
12. Were the methods used to value health states and other benefits stated?	Yes	An estimated cost of HAPI (PSI-03) was cited from the literature.
13. Were the details of the subjects from whom valuations were obtained given?	Not clear	Patient level data were not used but were stated to all be over 18 years
14. Were productivity changes (if included) reported separately?	N/A	
15. Was the relevance of productivity changes to the study question discussed?	N/A	
16. Were quantities of resources reported separately from their unit cost?	Yes	Table 1.
17. Were the methods for the estimation of quantities and unit costs described?	Yes	This included a cited cost of standard care for PU prevention and the total cost and number of units of dressings were presented.
18. Were currency and price data recorded?	Not clear	Could be implied from Table 1.
19. Were details of price adjustments for inflation or currency conversion given?	No	
20. Were details of any model used given?	Yes	Mixed-effects regression model in STATA software.
21. Was there a justification for the choice of model used and the key parameters on which it was based?	Yes	
22. Was the time horizon of cost and benefits stated?	Not clear	But the results of the analysis are given year by year and may be assumed to be the costs for those individual years.

23. Was the discount rate stated?	No	
24. Was the choice of rate justified?	N/A	
25. Was an explanation given if cost or benefits were not discounted?	No	
26. Were the details of statistical test(s) and confidence intervals given for stochastic data?	Yes	Negative Binomial Regression, Table 2.
27. Was the approach to sensitivity analysis described?	N/A	There was no sensitivity analysis presented, however the authors consider the marginal cost of the dressings stating this is within the willingness to pay (in addition to the standard HAPI prevention programme)
28. Was the choice of variables for sensitivity analysis justified?	N/A	
29. Were the ranges over which the parameters were varied stated?	N/A	
30. Were relevant alternatives compared? (That is, were appropriate comparisons made when conducting the incremental analysis?)	Yes	Table 2.
31. Was an incremental analysis reported?	No	
32. Were major outcomes presented in a disaggregated as well as aggregated form?	N/A	Cost study.
33. Was the answer to the study question given?	Yes	
34. Did conclusions follow from the data reported?	Yes	Although this depends on cited PU and standard HAPI prevention programme treatment costs.
35. Were conclusions accompanied by the appropriate caveats?	Yes.	Strengths and Limitations section.
36. Were generalisability issues addressed?	Yes	Discusses lack of generalisability to other dressings.
Adapted from Drummond MF, Jefferson TO (1996) Guidelines for authors and peer reviewers of economic submissions to the BMJ. The BMJ Economic Evaluation Working Party. British Medical Journal 313 (7052): 275–83. Cited in Centre for Reviews and Dissemination (2008) Systematic reviews. CRD's guidance for undertaking reviews in health care. York: Centre for Reviews and Dissemination		

Table C3d Quality assessment of health economic studies

Study name *Johnstone and McGown (2016) Innovations in the reduction of pressure ulceration and pain in critical care.*		
Study design Cost study		
Study question	**Response (yes/no/not clear/N/A)**	**Comments**
1. Was the research question stated?	Yes	See 'Aims of the evaluation'
2. Was the economic importance of the research question stated?	Yes	Implied in the aims.
3. Was/were the viewpoint(s) of the analysis clearly stated and justified?	Yes	Healthcare system critical care setting
4. Was a rationale reported for the choice of the alternative programmes or interventions compared?	N/A	The study does not have a true comparator but implicitly considers the potential cost of avoidance of PUs with the intervention.
5. Were the alternatives being compared clearly described?	No	The implicit comparator is non-use of dressings.
6. Was the form of economic evaluation stated?	Yes	Cost-benefit. However this is a cost study.
7. Was the choice of form of economic evaluation justified in relation to the questions addressed?	No	
8. Was/were the source(s) of effectiveness estimates used stated?	N/A	Cost study
9. Were details of the design and results of the effectiveness study given (if based on a single study)?	N/A	
10. Were details of the methods of synthesis or meta-analysis of estimates given (if based on an overview of a number of effectiveness studies)?	N/A	
11. Were the primary outcome measure(s) for the economic evaluation clearly stated?	Not clear	Implicitly PU incidence avoided by the intervention.
12. Were the methods used to value health states and other benefits stated?	N/A	Cost study

13. Were the details of the subjects from whom valuations were obtained given?	Yes	Box 1.
14. Were productivity changes (if included) reported separately?	N/A	
15. Was the relevance of productivity changes to the study question discussed?	N/A	
16. Were quantities of resources reported separately from their unit cost?	Yes	Note in Table 2.
17. Were the methods for the estimation of quantities and unit costs described?	Yes	Counted unit costs per patient.
18. Were currency and price data recorded?	No	
19. Were details of price adjustments for inflation or currency conversion given?	N/A	
20. Were details of any model used given?	No	
21. Was there a justification for the choice of model used and the key parameters on which it was based?	N/A	
22. Was the time horizon of cost and benefits stated?	Yes	3 months
23. Was the discount rate stated?	No	But implicitly not required in acute setting.
24. Was the choice of rate justified?	N/A	
25. Was an explanation given if cost or benefits were not discounted?	No	
26. Were the details of statistical test(s) and confidence intervals given for stochastic data?	N/A	
27. Was the approach to sensitivity analysis described?	No	
28. Was the choice of variables for sensitivity analysis justified?	N/A	

29. Were the ranges over which the parameters were varied stated?	N/A	
30. Were relevant alternatives compared? (That is, were appropriate comparisons made when conducting the incremental analysis?)	N/A	
31. Was an incremental analysis reported?	N/A	
32. Were major outcomes presented in a disaggregated as well as aggregated form?	N/A	
33. Was the answer to the study question given?	Not clear	Cost effectiveness is not mentioned in conclusions but the discussion cites potential cost saving on avoiding a PU by use of the dressing (zero PUs reported in the study).
34. Did conclusions follow from the data reported?	Not clear	The analysis compares costs but as the study has no comparator the results is only a potential saving for avoiding PUs that may have occurred without the intervention and there is no Number Needed to Treat estimate.
35. Were conclusions accompanied by the appropriate caveats?	Yes	Small sample.
36. Were generalisability issues addressed?	No	
Adapted from Drummond MF, Jefferson TO (1996) Guidelines for authors and peer reviewers of economic submissions to the BMJ. The BMJ Economic Evaluation Working Party. British Medical Journal 313 (7052): 275–83. Cited in Centre for Reviews and Dissemination (2008) Systematic reviews. CRD's guidance for undertaking reviews in health care. York: Centre for Reviews and Dissemination		

Table C3e Quality assessment of health economic studies

Study name *Lientz J. (2013) Dollars and sense: economic value in HAPU/sDTI prevention. [Poster]*		
Study design Cost consequences study based on longitudinal audit data		
Study question	**Response (yes/no/not clear/N/A)**	**Comments**
1. Was the research question stated?	Yes	Economic value of prevention
2. Was the economic importance of the research question stated?	Yes	Cost of PU treatment stated.
3. Was/were the viewpoint(s) of the analysis clearly stated and justified?	Yes	Healthcare setting, ICU
4. Was a rationale reported for the choice of the alternative programmes or interventions compared?	N/A	Not comparative
5. Were the alternatives being compared clearly described?	N/A	However, intervention is described
6. Was the form of economic evaluation stated?	No	This could be described as a cost consequences study based on the potential savings from avoiding PUs
7. Was the choice of form of economic evaluation justified in relation to the questions addressed?	No	
8. Was/were the source(s) of effectiveness estimates used stated?	Yes	Table in poster of HAPU & sDTI counts in 2011/12 (over 7 quarters)
9. Were details of the design and results of the effectiveness study given (if based on a single study)?	Yes	
10. Were details of the methods of synthesis or meta-analysis of estimates given (if based on an overview of a number of effectiveness studies)?	N/A	

11. Were the primary outcome measure(s) for the economic evaluation clearly stated?	Yes	HAPU count
12. Were the methods used to value health states and other benefits stated?	Yes	Cited a cost of one PU treatment
13. Were the details of the subjects from whom valuations were obtained given?	Yes	In general terms, in the 'Participants' section of the poster.
14. Were productivity changes (if included) reported separately?	N/A	
15. Was the relevance of productivity changes to the study question discussed?	N/A	
16. Were quantities of resources reported separately from their unit cost?	No	
17. Were the methods for the estimation of quantities and unit costs described?	N/A	
18. Were currency and price data recorded?	No	
19. Were details of price adjustments for inflation or currency conversion given?	N/A	
20. Were details of any model used given?	No	
21. Was there a justification for the choice of model used and the key parameters on which it was based?	N/A	
22. Was the time horizon of cost and benefits stated?	Yes	15 month study followed up to 18 months (quarterly audit)
23. Was the discount rate stated?	No	
24. Was the choice of rate justified?	N/A	
25. Was an explanation given if cost or benefits were not discounted?	No	
26. Were the details of statistical test(s) and confidence intervals given for stochastic data?	N/A	

27. Was the approach to sensitivity analysis described?	N/A	No sensitivity analysis.
28. Was the choice of variables for sensitivity analysis justified?	N/A	
29. Were the ranges over which the parameters were varied stated?	N/A	
30. Were relevant alternatives compared? (That is, were appropriate comparisons made when conducting the incremental analysis?)	N/A	
31. Was an incremental analysis reported?	No	
32. Were major outcomes presented in a disaggregated as well as aggregated form?	No	Outcomes where presented at HAPU/sDTI counts for each quarter but not alongside the costs of intervention for each quarter. The cost saving results were presented separately as the total cost of intervention for all participants in the 15 month study alongside the cost of one HAPU.
33. Was the answer to the study question given?	Not clear	The result that the intervention is effective is implied rather than stated.
34. Did conclusions follow from the data reported?	Not clear	
35. Were conclusions accompanied by the appropriate caveats?	No	
36. Were generalisability issues addressed?	No	
Adapted from Drummond MF, Jefferson TO (1996) Guidelines for authors and peer reviewers of economic submissions to the BMJ. The BMJ Economic Evaluation Working Party. British Medical Journal 313 (7052): 275–83. Cited in Centre for Reviews and Dissemination (2008) Systematic reviews. CRD's guidance for undertaking reviews in health care. York: Centre for Reviews and Dissemination		

Table C3f Quality assessment of health economic studies

Study name *Fimiani J. (2017) The evidence based prophylactic dressings reduces hospital-acquired press injuries by 68% and significantly lowers treatment costs. [Poster].*		
Study design Consequences study (longitudinal audits of multiple products)		
Study question	**Response (yes/no/not clear/N/A)**	**Comments**
1. Was the research question stated?	Yes	
2. Was the economic importance of the research question stated?	Not clear	But implied by title.
3. Was/were the viewpoint(s) of the analysis clearly stated and justified?	Not clear	Implementation 'house-wide' in a hospital setting.
4. Was a rationale reported for the choice of the alternative programmes or interventions compared?	Yes	Further improving PU rates that had been observed with introduction of preventative dressings.
5. Were the alternatives being compared clearly described?	Yes	Different products were used across the duration of audit studies.
6. Was the form of economic evaluation stated?	Not clear	Presented as a 'product evaluation' – reports on consequences only, from changing the intervention product over time.
7. Was the choice of form of economic evaluation justified in relation to the questions addressed?	Yes	
8. Was/were the source(s) of effectiveness estimates used stated?	Yes	HAPI counts (recorded in each year).
9. Were details of the design and results of the effectiveness study given (if based on a single study)?	Yes	
10. Were details of the methods of synthesis or meta-analysis of estimates given (if based on an overview of a number of effectiveness studies)?	N/A	

11. Were the primary outcome measure(s) for the economic evaluation clearly stated?	Yes	HAPI counts
12. Were the methods used to value health states and other benefits stated?	Not clear	Cites literature on PU costs but does not give the values.
13. Were the details of the subjects from whom valuations were obtained given?	No	'House-wide' implementation in what is assumed, from the author affiliation, to be an acute hospital setting.
14. Were productivity changes (if included) reported separately?	N/A	
15. Was the relevance of productivity changes to the study question discussed?	N/A	
16. Were quantities of resources reported separately from their unit cost?	No	Cost of the intervention was not given
17. Were the methods for the estimation of quantities and unit costs described?	N/A	
18. Were currency and price data recorded?	No	
19. Were details of price adjustments for inflation or currency conversion given?	N/A	However cost savings used from the literature for PU prevention (in the conclusions) are in US$.
20. Were details of any model used given?	N/A	No model was presented.
21. Was there a justification for the choice of model used and the key parameters on which it was based?	N/A	
22. Was the time horizon of cost and benefits stated?	N/A	
23. Was the discount rate stated?	N/A	
24. Was the choice of rate justified?	N/A	
25. Was an explanation given if cost or benefits were not discounted?	N/A	
26. Were the details of statistical test(s) and confidence intervals given for stochastic data?	N/A	

27. Was the approach to sensitivity analysis described?	N/A	No sensitivity analysis
28. Was the choice of variables for sensitivity analysis justified?	N/A	
29. Were the ranges over which the parameters were varied stated?	N/A	
30. Were relevant alternatives compared? (That is, were appropriate comparisons made when conducting the incremental analysis?)	N/A	
31. Was an incremental analysis reported?	No	
32. Were major outcomes presented in a disaggregated as well as aggregated form?	N/A	
33. Was the answer to the study question given?	Yes	The HAPI incidence reduced over time.
34. Did conclusions follow from the data reported?	Yes	Yes, HAPI counts were presented from 2013-2017 showing a decline.
35. Were conclusions accompanied by the appropriate caveats?	No	
36. Were generalisability issues addressed?	No	
Adapted from Drummond MF, Jefferson TO (1996) Guidelines for authors and peer reviewers of economic submissions to the BMJ. The BMJ Economic Evaluation Working Party. British Medical Journal 313 (7052): 275–83. Cited in Centre for Reviews and Dissemination (2008) Systematic reviews. CRD's guidance for undertaking reviews in health care. York: Centre for Reviews and Dissemination		

9 De novo cost analysis

Section 9 requires the sponsor to provide information on the de novo cost analysis.

The de novo cost analysis developed should be relevant to the scope.

All costs resulting from or associated with the use of the technology should be estimated using processes relevant to the NHS and personal social services.

Note that NICE cites the price of the product used in the model in the Medical Technology guidance.

9.1 Description of the de novo cost analysis

9.1.1 Provide the rationale for undertaking further cost analysis in relation to the scope.

There is no existing cost analysis in the UK NHS setting except for a currency conversion of an Australian cost consequences study (Santamaria, 2015[b]) as presented in the NICE MIB. None of the published studies included a fully reported sensitivity analysis. However, due to the likelihood of transferability of trial results from Australia and the USA, it would be useful to conduct a *de novo* analysis with up to date UK data and a full sensitivity analysis.

Patients

9.1.2 What patient group(s) is (are) included in the cost analysis?

Patients at risk or at high risk of PUs in acute care settings.

Technology and comparator

9.1.3 Provide a justification if the comparator used in the cost analysis is different from the scope.

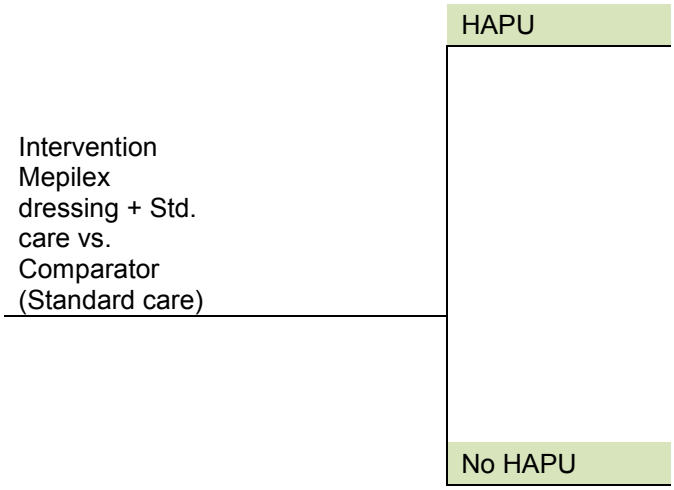
Although the scope for the clinical section has been expanded from the original NICE scope to include the ‘aged care setting’, the *de novo* analysis to

be presented is from the NHS acute care perspective only. This is the setting for the comparator in the relevant RCTs e.g. Santamaria, 2015[b] (see Section 7.6.1 **Table B9.4**) and there are no costing data available at the time of writing for associated trial in the aged care setting although this may be available in the future (Santamaria, 2018).

Model structure

9.1.4 Provide a diagram of the model structure you have chosen.

The model structure is a single level static decision tree with 2 outcomes as used in the completed NICE economic model template with outcomes of PU incidence in an acute critical care setting from Santamaria, 2015[b].



9.1.5 Justify the chosen structure in line with the clinical pathway of care identified in response to question 3.3.

Since the product is aimed at PU reduction (the primary outcome) and this is the focus of published analyses, the decision tree node on PU percentage is justified. All resource costs and patient QoL stem from the intervention cost outcome with the addition of intervention costs for applying dressings in an acute critical setting.

9.1.6 Provide a list of all assumptions in the cost model and a justification for each assumption.

Assumption	Justification
A cost consequences approach is chosen.	QoL gains will stem from the primary outcome of PU reduction in the acute setting. Input and resource costs/savings are readily available. PU incidence is the primary trial outcome for evidence used in the *de novo* analysis.
Time horizon is < 1 year.	Acute setting. Any PUs are expected to heal within this period.
PU rate reductions in the trial data from Australia and the USA are likely to be replicated in UK.	PU care guidelines are international and wound categories 1-4 are standardised.
PU rate reduction in the trial is likely to be achieved in a real world setting.	Nurses will be familiar with pressure ulcer protocols and products. The relevant trials were conducted in close to real-world settings.
Time resource for nurse application of dressing will be similar to the RCT.	As above
Costs of PU in UK are known	The model uses the latest and recently published (28 February 2018) modelling tool from NHS improvement including a table of average, best and worst case results.
Both sacral and heel outcomes are reflected in the model.	The RCT (Santamaria, 2015[b]) gives a full breakdown of PU rates for both anatomical areas. All patients in the

	intervention arm received a sacral dressing and dressings on both heels.
Results are comparable for variants of dressings in the RCT and products that are the subject of the submission.	The RCT (Santamaria, 2015[b]) used Mepilex® Heel (a 3 layer non-adhesive dressing requiring a tubular bandage to be used to secure it) whereas the current product is Mepilex® Border Heel which is a 5 layer self-adhesive dressing. The *de novo* analysis will use the pricing of Mepilex® Border Heel since this is more expensive that Mepilex® Border Heel plus Tubifast® bandage, but will also run the model with the older product data to test assumptions.
Agenda for change Banding costs in the NICE economic model template are appropriate for the model e.g. similar staff and consistent price base year.	Wound care nurses are typically band 6. From the publication date of the model template (last revision in 2016), Price base year will be assumed to be 2016-17 which is the same price base year for other data (except for product prices which are 2017-18).

9.1.7 Define what the model's health states are intended to capture.

The model intends to capture hospital acquired pressure ulcer (HAPU) states in an acute setting with an outcome of either no HAPU or HAPU (weighted average of PU severity categories from trial data).

9.1.8 Describe any key features of the cost model not previously reported. A suggested format is presented below.

Table C4 Key features of model not previously reported

Factor	Chosen values	Justification	Reference
Time horizon of model	<1	Acute setting.	Santamaria, 2015[b]
Discount of 3.5% for costs	0	Acute setting	Santamaria, 2015[b]
Perspective (NHS/PSS)	NHS	Hospital use in trial	Santamaria, 2015[b]
Cycle length	N/A		
NHS, National Health Service; PSS, Personal Social Services			

9.2 Clinical parameters and variables

9.2.1 Describe how the data from the clinical evidence were used in the cost analysis

The PU rates in both arms of the RCT (Santamaria, 2015[b]) of 13.1% for the comparator and 3.1% for the intervention were used directly. A convenient and plausible range for the intervention PU rate was chosen from 0% (no PUs) to 6.2% (double the trial rate) was chosen for the sensitivity analysis with the base case in the centre of the range. Comparator PU rate was assumed to be typical and not varied in addition to this. Cost-saving results from a difference in incidence rates. A threshold analysis was conducted to determine the minimum difference for cost saving.

9.2.2 Are costs and clinical outcomes extrapolated beyond the study follow-up period(s)? If so, what are the assumptions that underpin this extrapolation and how are they justified?

No. Since the intervention relates to Hospital Acquired PUs (HAPUs). If the outcome is PU this is treated as per standard practice in the acute setting, costs of which are assumed to be captured by the costings in NHS

Improvement modelling tool which are, in turn, related to PUs healing rates according to category. In the Discussion section of Santamaria (2015[b]) it is noted as a possible limitation of the model that patients who acquire PUs may not be fully healed and require additional treatment in the community at additional cost. However, if this were the case it would act to improve the cost saving from the intervention versus comparator.

9.2.3 Were intermediate outcome measures linked to final outcomes (for example, was a change in a surrogate outcome linked to a final clinical outcome)? If so, how was this relationship estimated, what sources of evidence were used and what other evidence is there to support it?

No.

9.2.4 Were adverse events such as those described in section 7.7 included in the cost analysis? If appropriate, provide a rationale for the calculation of the risk of each adverse event.

No. Additional adverse events other than wound healing issues related to PUs are unlikely.

9.2.5 Provide details of the process used when the sponsor's clinical advisers assessed the applicability of available or estimated clinical model parameter and inputs used in the analysis.

Direct consultation with the primary author of the Santamaria 2015[b] RCT cost study paper was available by email (all of the paper's authors were connected to Royal Melbourne Hospital, Australia). There were no stated conflicts of interest since the paper reporting on the RCT cost study, in acknowledging the sponsorship of Mölnlycke Healthcare, it was stated that the company was not involved with data collection or analysis or in the preparation of the manuscript. In addition, an independent health economics analyst was contracted via the Centre for

Healthcare Equipment And Technology Assessment based at Nottingham University Hospitals NHS trust. The analyst had access to

the relevant published literature via Mölnlycke Healthcare and was able to view the results of the literature search.

9.2.6 Summarise all the variables included in the cost analysis. Provide cross-references to other parts of the submission. A suggested format is provided in table C5 below.

Table C5 Summary of variables applied in the cost model

Variable	Value	Range or 95% CI (distribution)	Source
PU rate (intervention)	*3.1%*	*0-6.2%*	Base case direct obtained from Santamaria, 2015[b]. Range around base case is from no PUs to doubling of rate of PUs.
PU rate (comparator)	*13.1%*	*Assumed typical so kept constant in the model.*	Base case from Santamaria, 2015[b].
Number of PUs (intervention)	Total 7 in 161 patients Cat 1: 4 Cat 2: 3 Cat 3: 0 Cat 4: 0	*Not varied since PU rate is varied as above.*	Base case directly obtained from Santamaria, 2015[b], Table 3.
Number of PUs (comparator)	Total 27 in 152 patients. Cat 1: 23 Cat 2: 2 Cat 3: 0 Cat 4: 2	*Not varied (as per above reason)*	Base case directly obtained from Santamaria, 2015[b], Table 3
Number of changes per patient (for each anatomical region) during each spell of patient stay.	*2*	*1-3*	*Base case is derived from frequencies of use in RCT intervention population of 219 patients (Santamaria, 2015[b], Table 1) then rounded to integer values. i.e. 274/219 sacral dressing changes per patients rounded up to 2, 465/219 heel changes divided by 2 as there are 2 heels per patient, also rounded up to 2. The variable was varied equally around base case by 1 dressing change per anatomical region i.e. in analysis there are 6 changes in base case (2 sacral and 4 heel) with a 3-9 range per patient. Note: the base case of 2 can be seen to be an overestimate since the true values are closer to 1.*

Staff time for dressing changed (minutes)	*2*	*1-3*	*Base case of 2 minutes cited in RCT (Santamaria, 2015[b]). Varied equally around base case by 1 minute per dressing change.*
CI, confidence interval			

9.3 Resource identification, measurement and valuation

NHS costs

9.3.1 Describe how the clinical management of the condition is currently costed in the NHS in terms of reference costs and the payment by results (PbR) tariff.

HRGs are not used directly in the model since the recently updated NHS Improvement PU productivity tool (based on an uplift of the widely accepted Dealey et al. 2012 analysis of PU costs in the UK) is used instead.

PU costs are in the NHS tool as follows:

Resource cost	Value	Range or 95% CI (distribution)	Source
Cost of *PU treatment for each of the 4 categories. (Costs are used to compute a weighted average cost of PU treatment for both arms of the RCT).*	Cat 1: £1637 Cat 2: £6772 Cat 3: £11250 Cat 4: £16232	*£1326-1981* *£5485-8194* *£9112-13612* *£13148-19641*	NHS Pressure Ulcer Productivity Tool https://improvement.nhs.uk/resources/pressure-ulcers-productivity-calculator/ The tool, published 28/2/2018, is based on 2016/17 costs and uplifts the NHS quoted costs of PU treatment by Dealey et al. 2012 (which used 2009-10 tariffs). Average, Lower, and Upper costs are included in the tool which are shown in the range column. Note: the PU tool rounds its sum to the nearest £1000 but in the analysis the rounded values would have been only 0.5% of the unrounded sum (see Validation section for details).

From the productivity tool, using PU counts from Table C5, the average cost of PU treatment and range for the sensitivity analysis was computed directly in the NHS Productivity tool for the comparator (£3111 = £84,000 / 27, range £2481-£3741) and for the intervention (£3858 = £27,000 / 7 with proportional range used). In the NICE economic model tool, the intervention PU treatment cost value was input as using a x1.24 multiplier of the comparator value since it is not possible to enter the comparator intervention cost independently.

Although HRGs are used indirectly in the *de novo* analysis by means of the productivity tool, for completeness it can be seen that Costing of HAPUs is covered by several Tariffs which have previously been considered by Dealey et al. 2012 with some more recent changes. (Note also that HAPUs tariff will be in addition to the HRG of the primary diagnosis related to the patient's admission since a PU is acquired during the primary treatment episode).

Previous codes in Dealey 2012:

- Minor skin procedures category 1. HRG code JC07Z.
- Minor skin procedures category 2 without complications. HRG code JC06A.
- Infection of bones or joints without complications. HRG code HD25C.

Current codes from Annex A of NHS PbR reference costs:

Minor skin procedures > 13 years. HRG code JC43A. PbR tariff £509 (2017/18)

Intermediate skin procedures > 13 years. HRG code JC42A. PbR tariff £900 (2017/18)

Infection of bones or joints with CC (complications) score 0-1. HRG code HD25H. PbR tariff £1003 for a 5 day spell, £230 for subsequent days.

9.3.2 State the Office of Population, Censuses and Surveys Classification of Surgical Operations and Procedures (OPCS) codes for the operations, procedures and interventions relevant to the use of the technology for the clinical management of the condition.

PUs are coded according to ICD-10-CM code L89.X where X is according to anatomical region and severity. See:
http://www.icd10data.com/ICD10CM/Codes/L00-L99/L80-L99/L89-

Resource identification, measurement and valuation studies

9.3.3 Provide a systematic search of relevant resource data for the NHS in England. Include a search strategy and inclusion criteria, and consider published and unpublished studies.

Due to the existence of an NHS/NICE accepted source and the existence of the up to date NHS calculator which cites the best known source of UK resource data, a detailed search was not necessary for PU treatment costs. Likewise the resource data for nursing time is part of the NICE cost model template and technology cost from NHS Supply. All other data were sourced from the literature.

9.3.4 Provide details of the process used when clinical advisers assessed the applicability of the resources used in the model[1].

N/A

[1] Adapted from Pharmaceutical Benefits Advisory Committee (2008) Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (Version 4.3). Canberra: Pharmaceutical Benefits Advisory Committee.

Technology and comparators' costs

9.3.5 Provide the list price for the technology.

Resource cost	Value	Range or 95% CI (distribution)	Source
Unit cost of consumables, per dressing change (incl. VAT at 20%)	*Sacral: £5.33* *Heel: £8.65* *Prices inclusive of VAT (converted to excl. VAT in Table C6)*	*Range of pricing not used but the number of dressings used per patient was varied between 1-3 for Sacral and each Heel (2-6 in total for Heel)*	*Current prices from NHS Supply. Based on boxes of 10 of the medium size sacral dressing (product no. 782010) and of Heel (product no. 782710) costing £53.33 and £86.53 respectively. Quoted incl. VAT.* *Additional note: For comparison, in the RCT the Border Heel dressing used would be £34.11 incl. VAT per box of 5 if purchased 6 or more boxes (from NHS Supply product no. 288300) i.e. £6.82 per dressing incl. VAT. Item cost of a Tubifast® bandage used with each heel dressing heel was computed from Santamaria, 2015. Usage: 10 x 10m rolls for 465 changes of blue-line product with a price per roll of £5.64 = £56.4/465=£0.12 incl. VAT. Therefore the overall consumable cost for a single Mepilex® Heel dressing change would be £6.93 incl. VAT or £5.78 excl. VAT.*

9.3.6 If the list price is not used in the de novo cost model, provide the alternative price and a justification

The list prices of Mepilex® Border Heel and Mepilex® Border Sacrum are used.

9.3.7 Summarise the annual costs associated with the technology and the comparator technology (if applicable) applied in the cost model. A suggested format is provided in tables C6 and C7. Table C7 should only be completed when the most

relevant UK comparator for the cost analysis refers to another technology.

Table C6 Costs per treatment/patient associated with the technology in the cost model

Items	Value	Source
Price of the technology per treatment/patient	N/A	
Consumables (if applicable) Per treatment spell/patient	£45.28=((2*5.333)+(4*8.653)) incl. VAT @20% £37.73 excl. VAT	Base case computed from data in table C5 for 2 sacral dressing changes and 4 heel dressing changes
Maintenance cost	N/A	
Training cost	N/A	
Other costs Per treatment spell/patient	£72.80	Base case is 12 minutes of Band 6 nurse time for a total of 6 dressing changes, as computed by the NICE economic model template.
Total cost per treatment/patient	£110.53 excl. VAT	

Health-state costs

9.3.8 If the cost model presents health states, the costs related to each health state should be presented in table C8. The health states should refer to the states in section 9.1.7. Provide a rationale for the choice of values used in the cost model.

N/A

Adverse-event costs

9.3.9 Complete table C9 with details of the costs associated with each adverse event referred to in 9.2.4 included in the cost model. Include all adverse events and complication costs, both during and after longer-term use of the technology.

N/A

Miscellaneous costs

9.3.10 Describe any additional costs and cost savings that have not been covered anywhere else (for example, PSS costs, and patient and carer costs). If none, please state

None

9.3.11 Are there any other opportunities for resource savings or redirection of resources that it has not been possible to quantify?

No

9.4 Approach to sensitivity analysis

Section 9.4 requires the sponsor to carry out sensitivity analyses to explore uncertainty around the structural assumptions and parameters used in the analysis. All inputs used in the analysis will be estimated with a degree of imprecision. For technologies whose final price/acquisition cost has not been confirmed, sensitivity analysis should be conducted over a plausible range of prices.

Analysis of a representative range of plausible scenarios should be presented and each alternative analysis should present separate results.

9.4.1 Has the uncertainty around structural assumptions been investigated? State the types of sensitivity analysis that have been carried out in the cost analysis.

One-way (univariate) sensitivity analysis was conducted on variables from C5, included in the NICE economic modelling template. We can note that the NICE template presents uncertainty in two ways. First, as a table of Base case, Best case and Worst case based on variation of decision tree probabilities. In this case, this results from varying the PU ulcer rate from 0-6.2% (base case 3.1%) whilst keeping the comparator ulcer rate constant (13.1%). Second, results are presented as a conventional one-way analysis on selected variables shown as a Tornado diagram and in tables. Variables may be selected for detailed analysis where ranges have been specified.

9.4.2 Was a deterministic and/or probabilistic sensitivity analysis undertaken? If not, why not? How were variables varied and what was the rationale for this? If relevant, the distributions and their sources should be clearly stated.

Yes. A deterministic sensitivity analysis was run in the NICE economic model template for the static decision tree.

9.4.3 Complete table C10.1, C10.2 and/or C10.3 as appropriate to summarise the variables used in the sensitivity analysis.

Table C10.1 Variables used in one-way scenario-based deterministic

sensitivity analysis

Variable	Base-case value	Range of values
Average weighted cost of PU treatment in comparator (also used in intervention with a multiplier of 1.24 based on computation of trial outcomes data as explained in section 9.3.1)	£3111.11	£2,481-£3,741
Cost of intervention per patient (based on number of dressings used)	£37.73	£18.87-£56.60
PU rate of intervention from RCT (PU rate of comparator held constant)	3.1%	0-6.2%

9.4.4 If any parameters or variables listed in section 9.2.6 were omitted from the sensitivity analysis, provide the rationale.

Variable	Base-case value	Range of values
Operational (staffing) cost of intervention per patient (based on Band 6 nurse time)	£72.80	£36.40-£109.20

A range was included in the input data but appears not to be processed in the NICE economic template sensitivity analysis results so we are not able to report on the result from the tool directly. However, the sensitivity of the model to the combined consumables and operational cost (£110.53 base case) will be considered in section 9.5.11 (Miscellaneous results).

As discussed earlier, comparator HAPU incidence rate was kept constant.

9.5 Results of de novo cost analysis

Section 9.5 requires the sponsor to report the de novo cost analysis results. These should include the following:

- costs
- disaggregated results such as costs associated with treatment, costs associated with adverse events, and costs associated with follow-up/subsequent treatment
- a tabulation of the mean cost results
- results of the sensitivity analysis.

Base-case analysis

9.5.1 Report the total costs associated with use of the technology and the comparator(s) in the base-case analysis. A suggested format is presented in table C11.

Table C11 Base-case results

Consumables + staff costs	Total per patient cost (£)
Technology (Mepilex® Border)	110.53
Comparator 1 (Standard care)	0

9.5.2 Report the total difference in costs between the technology and comparator(s).

The total is the sum of the average per patient resource cost of treating PUs (27 in comparator arm of RCT, 7 in intervention arm) and the intervention costs. The totals were computed by the NICE economic model template (rounding anomaly corrected in the difference).

PU treatment costs (base case)	Total per patient cost (£)
Technology (Mepilex® Border)	230.12
Comparator 1 (Standard care)	407.56
Difference	-177.44 (-177.43 in template)

9.5.3 Provide details of the costs for the technology and its comparator by category of cost. A suggested format is presented in table C12.

Table C12 Summary of costs by category of cost per patient

Item	Cost *intervention (Mepilex® Border heel and sacral dressings)*	Cost *comparator (Standard care)*	Increment	Absolute increment	% absolute increment
Technology cost (dressings)	*37.73*	*0*	*37.73*	*37.73*	*9.47%*
Mean total treatment cost (PU treatment)	*119.59*	*407.56*	*-287.96*	*287.96*	*72.26%*
Administration cost (staffing cost)	*72.80*	*0*	*72.80*	*72.80*	*18.27%*
Total	*230.12*	*407.56*	*-177.44*	*398.49*	*100%*
Adapted from Pharmaceutical Benefits Advisory Committee (2008) Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (Version 4.3). Canberra: Pharmaceutical Benefits Advisory Committee					

9.5.4 If appropriate, provide details of the costs for the technology and its comparator by health state. A suggested format is presented in table C13.

N/A

9.5.5 If appropriate, provide details of the costs for the technology and its comparator by adverse event. A suggested format is provided in table C14. Sensitivity analysis results

N/A

9.5.6 Present results of deterministic one-way sensitivity analysis of the variables described in table C10.1.

Results from NICE economics tool sensitivity analysis were as follows (irrelevant rows removed). First the results are displayed for the variation in HAPU incidence for the intervention (base case 3.1%, worst case 6.2%, best case 0%).

Base case

	Intervention	Standard Care	Incremental
Net capital cost	£0.00	£0.00	£0.00
Consumables	£37.73	£0.00	£37.73
Maintenance cost	£0.00	£0.00	£0.00
Training cost	£0.00	£0.00	£0.00
Other device and staffing costs	£72.80	£0.00	£72.80
Average PU treatment cost	£119.59	£407.56	-£287.96
Total NHS cost - Year 1	**£230**	**£408**	**-£177.43**
Total PSS cost - Year 1	**£0**	**£0**	**£0**
Total long term NHS costs	**£0**	**£0**	**£0**
Total long term PSS costs	**£0**	**£0**	**£0**
Total cost per patient	**£230.12**	**£407.56**	**-£177.43**
Total cost per use	**£230.12**	**£407.56**	**-£177.43**

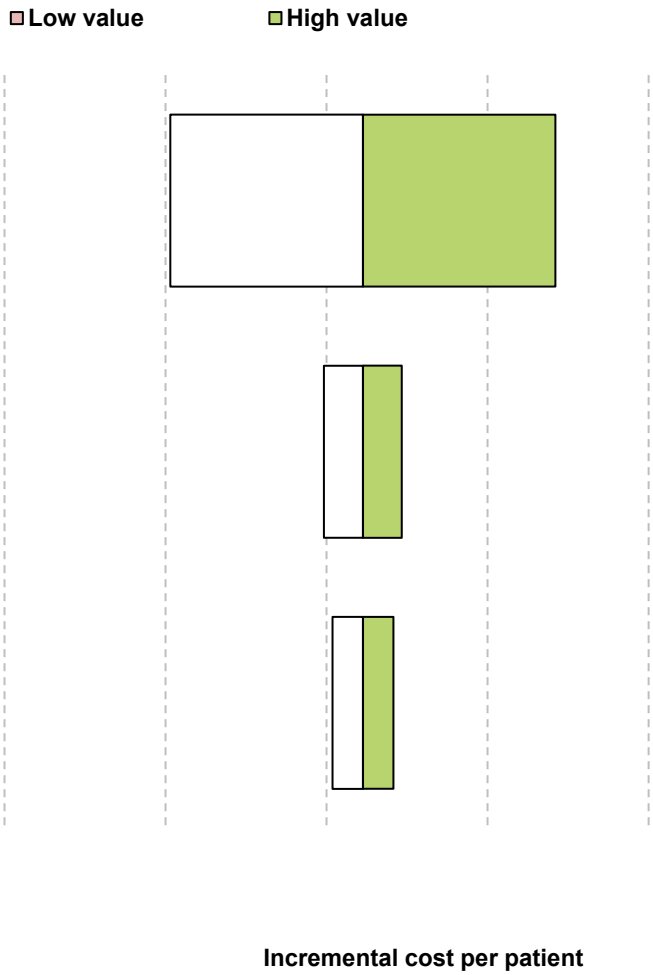
Worst case

	Intervention	Standard Care	Incremental
Net capital cost	£0.00	£0.00	£0.00
Consumables	£37.73	£0.00	£37.73
Maintenance cost	£0.00	£0.00	£0.00
Training cost	£0.00	£0.00	£0.00
Other device and staffing costs	£72.80	£0.00	£72.80
Average PU treatment cost	£239.18	£407.56	-£168.37
Total NHS cost - Year 1	**£350**	**£408**	**-£57.84**
Total PSS cost - Year 1	**£0**	**£0**	**£0**
Total long term NHS costs	**£0**	**£0**	**£0**
Total long term PSS costs	**£0**	**£0**	**£0**
Total cost per patient	**£349.71**	**£407.56**	**-£57.84**
Total cost per use	**£349.71**	**£407.56**	**-£57.84**

Best case

	Intervention	Standard Care	Incremental
Net capital cost	£0.00	£0.00	£0.00
Consumables	£37.73	£0.00	£37.73
Maintenance cost	£0.00	£0.00	£0.00
Training cost	£0.00	£0.00	£0.00
Other device and staffing costs	£72.80	£0.00	£72.80
Average PU treatment cost	£0.00	£407.56	-£407.56
Total NHS cost - Year 1	**£111**	**£408**	**-£297.03**
Total PSS cost - Year 1	**£0**	**£0**	**£0.00**
Total long term NHS costs	**£0**	**£0**	**£0.00**
Total long term PSS costs	**£0**	**£0**	**£0.00**
Total cost per patient	**£110.53**	**£407.56**	**-£297.03**
Total cost per use	**£110.53**	**£407.56**	**-£297.03**

Second, the results for all key variables are presented as a tornado diagram.



9.5.7 Present results of deterministic multi-way scenario sensitivity analysis described in table C10.2.

N/A

9.5.8 Present results of the probabilistic sensitivity analysis described in table C10.3.

N/A

9.5.9 What were the main findings of each of the sensitivity analyses?

For the variation of Hospital Acquired PU incidence from 0-6.2% around a base case of 3.1% the cost saving per patient from the NICE template is -

£177.43 in the base case, -£57.84 in the worst case and -£297.03 in the best case.

9.5.10 What are the key drivers of the cost results?

The key driver is the relative incidence of HAPU in the acute setting which is much reduced for the intervention.

Miscellaneous results

9.5.11 Describe any additional results that have not been specifically requested in this template. If none, please state.

A threshold analysis was carried out on the HAPU incidence. The result was seen to become cost incurring if the HAPU incidence in the intervention arm exceeded 7.7% which is almost 2½ times the base case of 3.1% and outside of the range of the sensitivity analysis undertaken here (0%-6.2%).

The threshold of combined cost of consumables (where cost is dependent on the number of dressing changes) and operational (staff) cost was also examined since these are not independent. Since the base case saving is -£177.43 and the combined base case cost of the intervention is £110.53, it can be seen that the model would be cost incurring if the number of dressings used per patient were 2.6 times higher than in the base case (with the additional nurse time to apply them included). This is outside of the ranges used in the univariate deterministic sensitivity which examined the possibility of a 50% increase (and also a 50 % decrease) in either cost. In terms of number of dressings this would mean 5-6 full dressing changes per patient (including the initial dressing on admission) during the patient ICU stay (i.e. nearly every day) to reach the threshold, whereas the trial data shows this was actually between 1 and 2 (once every 3 days).

Similarly, an increase to reach the cost saving threshold of either cost of consumables (5.7 times as expensive) or the amount of nurse time taken (3.4 times as long per change) considered independently of each other are also well outside of plausible ranges. Since the threshold analysis is averaged over all patients there is therefore no concern about the effect of occasional

wastage of consumables or for some patients requiring longer for their dressing changes in the overall model.

The results were also checked with additional data. Firstly the model was run again with the Mepilex® Heel and Tubifast® pricings instead of Mepilex® Border Heel as these were the heel products actually used in the RCT of Santamaria 2015[b]. Due to the less expensive 3 layer heel product (see prices in section 9.3.5) and the unit cost of the bandage being very small, it was seen that the cost saving would be improved to -£186.96. The model was also run with the trial data of Kalowes (2016) which used the Mepilex® Border Sacrum dressing only and the saving was found to be -£205.96 (see 9.16.7 for more discussion of this result). The additional modelling adds confidence in the finding from the *de novo* analysis and appears to show that the most conservative cost saving case has been submitted by the selection of the Santamaria 2015[b] RCT which is the one trial that uses both Sacral and Heel dressings (albeit using Mepilex® Heel instead of Mepilex® Border Heel).

9.6 Subgroup analysis

For many technologies, the capacity to benefit from treatment will differ for patients with differing characteristics. Sponsors are required to complete section 9.6 in accordance with the subgroups identified in the scope and for any additional subgroups considered relevant.

Types of subgroups that are not considered relevant are those based solely on the following factors.

- Subgroups based solely on differential treatment costs for individuals according to their social characteristics.
- Subgroups specified in relation to the costs of providing treatment in different geographical locations within the UK (for example, if the costs of facilities available for providing the technology vary according to location).

9.6.1 Specify whether analysis of subgroups was undertaken and how these subgroups were identified. Cross-reference the response to the decision problem in table A1 and sections 3.2 and 7.4.4.

No.

9.6.2 Define the characteristics of patients in the subgroup(s).

N/A

9.6.3 Describe how the subgroups were included in the cost analysis.

N/A

9.6.4 What were the results of the subgroup analysis/analyses, if conducted? The results should be presented in a table similar to that in section 9.5.1 (base-case analysis).

N/A

9.6.5 Were any subgroups not included in the submission? If so, which ones, and why were they not considered?

N/A

9.7 Validation

9.7.1 Describe the methods used to validate and cross-validate (for example with external evidence sources) and quality-assure the model. Provide references to the results produced and cross-reference to evidence identified in the clinical and resources sections.

The operational cost data embedded in the NICE HE tool (which included Agenda for Change Banding calculations was assumed to be for 2016-7 and

this was checked since these were closest to figures found independently and were consistent with the version date of the template), checked by the independent analyst.

The new NHS productivity tool for PUs is based on the work of Dealey et al. (the main UK source of PU cost data as cited in NICE CG179 Costing Tool), uplifted to 2016/7 prices. Since the tool rounds its total summation of costs for a set of PUs to the nearest £1000, the base costs in the tool were discovered by finding the overall cost of 1000 cases of each PU category. Unit costs per PU were seen to be £1637, £6772, £11250 and £16232 as already presented in section 9.3.1. A check was also made to see that by presenting its results as rounded figures, the NHS productivity tool overestimates the sum of unrounded costs from the categories of each arm of the Santamaria 2015[b] trial by only 0.4-0.5% (£26,864 versus £27,000 for the intervention and £83,659 versus £84,000 for the comparator). Therefore it can be considered that the use of the NHS tool with its presentation of unrounded values is fair and justified, especially as it could be used by Trusts to estimate their own PU costs which could also be used to judge the value of other interventions for PU prevention.

9.8 Interpretation of economic evidence

9.8.1 Are the results from this cost analysis consistent with the published economic literature? If not, why do the results from this evaluation differ, and why should the results in the submission be given more credence than those in the published literature?

There was no existing analysis in the UK setting so this was a *de novo* analysis based on the RCT of Santamaria (2015) but with UK prices for consumables (sacral and heel dressings and tubular bandages), operational cost (Band 6 nurse time) and PU ulcer treatment. The price of the 3 layer Mepilex® Heel (plus tubular bandage) in the RCT was replaced with the higher price of the 5 layer and self-adhesive Mepilex® Border Heel dressing, since it

is the Border products which are the subject of the submission. This is similar to the approach taken in the NICE MIB.

In the NICE MIB, a potential per patient saving was computed from the same RCT cost study using the marginal cost of the intervention converted from A$ in the paper to £UK versus the 'downstream' cost savings of PU avoidance quoted in the trial. These savings were found to be A$36.61 (£21.56) marginal cost per patient of the dressings and A$70.82 (£41.71) saving on PU treatment compared with A$144.56 (£85.14) for the downstream saving.

However it can readily be seen that the marginal cost of the technology is an underestimate in the UK context due to cost of 3 dressings per patient with 2 changes of dressings in the base case which is just over twice the marginal dressing cost presented in the MIB, and with the addition of operational costs of £72.80 per patient for nurse time costed in for applying the dressing changes. Furthermore, the PU treatment costs per acute episode stated in the Australian RCT are much less that in the UK acute setting. It is seen that savings from avoidance of PUs is larger in our analysis compared to the RCT since the average cost per patient £230.12 intervention versus £407.56 comparator) compares more favourably to standard care than that estimated in the MIB (£41.71 intervention versus £85.14 using exchange rate conversion from $A, with pricing/conversion dated September 2017 in MIB) i.e. an overall saving of £177.44 in our *de novo* analysis compared with £43.43 in the MIB which is just over 4 times as much.

Although the saving is 4 times as much as found in an exchange rate conversion from Santamaria (2015), it can be seen that our *de novo* analysis properly includes the most up to date UK costs available for technology, operational (nursing staff) cost (from the NICE template) and PU treatment estimates (from a newly updated NHS Improvement PU productivity tool which uses the same data source as the NICE CG179 costing statement i.e. Dealey et al., uplifted to 2016/17 in the tool). It can further be noted that the Discussion section of Santamaria (2015[b]) stated that costs of PU treatment

are likely to be ‘significantly underestimated’ in the RCT according to the authors.

Finally, we can note that one of the published economic studies cited did not include nurse time. If this time resource of 2 minutes per dressing was similarly considered part of routine operation i.e. not costed explicitly, the cost saving of the submission would be further improved.

9.8.2 Is the cost analysis relevant to all groups of patients and NHS settings in England that could potentially use the technology as identified in the scope?

The scope includes patients in the community setting which is a subject of a more recent trial (Santamaria, 2018) but a cost analysis on this is not yet published and we therefore focus on the acute setting and NHS costs only rather than NHS+PSS costs for this submission.

Paediatric patients were not considered as a subgroup. However they would likely use smaller dressings on average and PU costs would be increased (since HRGs are higher), so the saving would be increased with a similar incidence of PUs (although the reduction in HAPU incidence for the intervention is unknown in this subgroup).

9.8.3 What are the main strengths and weaknesses of the analysis? How might these affect the interpretation of the results?

The strength of the analysis is that it derives from an RCT and uses the most up to date UK prices from NHS Supply and used all other data that is consistent with both the NHS PU productivity tool and the NICE economic model template (i.e. 2016-17). A weakness is that the analysis is based on an analysis of an RCT that was conducted in the Australian setting, was single site and was not blinded, and standard care was not very well defined. However, the treatment of PUs in the acute setting is well standardised internationally.

The heel product used in the Santamaria 2015[b] RCT was Mepilex® Heel which has since been superceded by Mepilex® Border Heel. The higher price of Mepilex® Border Heel was used to determine the UK consumable costs but its use could also have produced different results in the RCT. However, the expectation is for improved performance of the 5 layered construction versus 3 layers in the older product (also requiring tubular bandage). The *de novo* analysis with Mepilex® Border Heel pricing without the modelling of potential improved outcomes is therefore a conservative model.

The cost analysis is limited by it being based on the one trial where both dressings were used. However, a further study by the same authors of patients admitted to Emergency Department and transferred to ICU, which included 150 additional prospective patients with 152 from the Border trial RCT (heel only), resulted in no HAPUs in the Mepilex® Border Heel arm and 9.2% in the standard care arm which is a similar relative HAPU incidence reduction to this *de novo* analysis (where the reduction was 10% from 13.1% to 3.1%), also noting intervention costs would have been lower for dressing heels only.

Furthermore, in the included USA study (Kalowes, 2016) where only the sacral product was used, the HAPU incidence rate (here denoted HAPI, Hospital Acquired Pressure Injury) was found to be reduced from 5.9% to 0.7%. Based in this case on an average of 3 changes per patient (due to an average ICU stay of 7-8 days, with changes assumed to be every 3 days as is typical and including the dressing applied on admission) and assuming unstageable ulcers and deep tissue injuries costed at the cheapest rate (i.e. £2000, as per Stage I, in order to maximally disadvantage the intervention), further analysis again using the NICE economic model template showed that the intervention is cost saving with an average of -£205.96 per patient (£63.73 for intervention versus £269.69 for the comparator), in the context of critically ill patients admitted to ICU from the Emergency Room (A&E).

We have noted the results may not transfer well to a paediatric population especially due to uncertainty in HAPU incidences as there are no trial data to

show clinical improvement with this subgroup, however the pricing of the consumables is decreased and HRG cost of PU treatment is likely to be increased which could theoretically contribute to an improved result for the intervention.

Similarly, the case for community deployment is uncertain due to lack of RCT data.

9.8.4 What further analyses could be undertaken to enhance the robustness/completeness of the results?

A trial could be conducted in a UK setting but it is probably unnecessary due to likely good transferability of clinical practice. However, if a trial were to be conducted, it could include a quality of life measure which would support an incremental (Cost per QALY) analysis. This said, the QoL effect of avoiding HAPUs is likely to outweigh any other consideration for critical care patients.

References

Aloweni, F., Lim, M.L., Chua, T.L., Tan, S.B., Lian, S.B., Ang, S.Y. A randomised controlled trial to evaluate the incremental effectiveness of a prophylactic dressing and fatty acids oil in the prevention of pressure injuries. Wound Practice and Research 2017;25(1):24-34.

Australian Wound Management Association. Clinical practice guidelines for the prevention and management of pressure ulcers. West Leederville, WA: Cambridge Publishing, 2001.

Baker, G. Nursing driving excellence: preventing pressure ulcers in the high-risk population. Poster presentation at the Symposium on Advanced Wound Care Fall, Las Vegas, Nevada, United States of America, 2014.

Bateman S.D., Roberts, S. Moisture lesions and associated pressure ulcers - getting the dressing regime right. Wounds UK 2013;9(2):97-102

Black, J., Brindle, C.T., Homaker, J.S. Differential diagnosis of suspected deep tissue injury. International Wound Journal 2015; doi: 10.1111/iwj.12471.

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

Black, J.M., Kalowes, P. Medical device-related pressure ulcers. Chronic Wound Care Management and Research 2016;3:91-99.

Brindle, C.T. Outliers to the Braden Scale: identifying high-risk ICU patients and the results of prophylactic dressing use. World Council of Enterostomal Therapists Journal 2010; 30 (1): 11-18.

Brindle, C.T., Creehan, S., Beavers, S. Deep tissue injury "imposters": resolution without evolution. Poster presentation at 43rd Wound Ostomy and Continence Nurse Annual Conference, New Orleans, Louisiana, United States of America, 2011.

Brindle, C.T., Wegelin, J.A. Prophylactic dressing application to reduce pressure ulcer formation in cardiac surgery patients. Journal of Wound Ostomy & Continence Nursing 2012; 39(2):133-142.

Byars, M., Raxter, K., Reed-Chism, R. How to prevent pressure ulcers on a kinetic therapy support surface. Poster presentation at the Joint Conference of the Wound Ostomy and Continence Nurses Society and the World Council of Enterostomal Therapists, New Orleans, Louisiana, United States of America, 2011.

Call, E., Pedersen, B., Bill, B., Black, J., Alves, P., Brindle, C.T., Dealey, C., Santamaria, N,, Clark, M. Enhancing pressure ulcer prevention using wound dressings: what are the modes of action? International Wound Journal 2015;12(4):408-413.

Call, E., Pedersen, J., Bill, B., Oberg, C., Ferguson, Pell, M. Microclimate impact of prophylactic dressings used in vitro body analog method. Wounds 2013;25(4):94-103.

Cano, A., Smits, D., Corvino, P. Efficacy of the prohylactic use of silicone foam dressing for the prevention of pressure ulcers in patients: an observational study in a 24 bed cardiovascular and cardiac intensive care unit. Journal of Wound, Ostomy and Continence Nursing 2011;38(3S):S73.

Castelino, I., Mercer, D., Forrest Calland, J. Reducing peri-operative pressure ulcers in thoracic, cardiovascular, and spinal surgery patients: achieving zero incidence is possible! Poster presentation at the Symposium on Advanced Wound Care (Spring), Atlanta, Georgia, 2012.

Chaiken, N. Reduction of sacral pressure ulcers in the intensive care unit using a silicone border foam dressing. Journal of Wound Ostomy & Continence Nursing 2012;39(2):143-145.

Clark, M., Black, J., Alves, P., Brindle, C., Call, E., Dealey, C., Santamaria, N. Systematic review of the use of prophylactic dressings in the prevention of pressure ulcers. International Wound Journal 2014;11(5):460-471.

Cooper, D.N., Jones, S.L., Currie, L.A. In our unit. Against all odds: preventing pressure ulcers in high-risk cardiac surgery patients. Critical Care Nurse 2015;35(5):76-82.

Cornish, L. The use of prophylactic dressings in the prevention of pressure ulcers: a literature review. British Journal of Community Nursing 2017;2(22 Supplement 6):S26-S32.

Cubit, K., McNally, B. Lopez, V. 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 2013;10:579-584.

Daukste, M. Mepilex Border Sacrum dressing use for pressure ulcers prevention in period of open heart surgery and in intensive care unit. Poster presentation at the European Pressure Ulcer Advisory Panel meeting, Stockholm, Sweden, 2014.

de Wert, L.A., Schoonhoven, L., Stegen, J.H.C.H., Piatkowski, A.A., van der Hulst, R.R., Poeze, M., Bouvy, N.D. Improving the effect of shear on skin viaiblity with wound dressings. Journal of the Mechanical Behavior of Biomedical Materials 2016 http://dx.doi.org/10.1016/j.jmbbm.2016.03.006.

Donovan, R., Schindler, P., Weinberger, J., Dollars, collaboration, and pressure injury prevention (PIP): saving upwards of a million by achieving zero. Poster presentation at Wound Ostomy and Continence Nurses Society and Canadian Association for Enterostomal Therapy, Montreal, Canada, 2016.

Dykes, P.J. The effect of adhesive dressing edges on cutaneous irritancy and skin barrier function. Journal of Wound Care. 2007;16(3):97-100.

Dykes, P.J. Heggie, R. The link between the peel force of adhesive dressings and subjective discomfort in volunteer subjects. Journal of Wound Care 2003;12(7): 260-262.

Dykes, P.J., Heggie, R., Hill, S.A. Effects of adhesive dressings on the stratum corneum of the skin. Journal of Wound Care 2001;10(2):7-10.

Edwards, M.B., Lynch, J.H. Head over heels for prevention: use of a silicone bordered foam heel dressing in the prevention of pressure ulcers. Poster presentation at the Symposium on Advanced Wound Care Fall, Las Vegas, Nevada, United States of America, 2014.

Fimiani, J. The evidence-based prophylactic dressing reduced hospital-acquired pressure injuries by 68% and significantly lowers treatment costs. Poster presentation at National Pressure Ulcer Advisory Panel Annual Meeting, Las Vegas, Nevada, United States of America, 2018.

Gefen, A., Santamaria, N. Comment on ‘Effectiveness of a multi-layer foam dressing in preventing sacral pressure ulcers for the early acute care of patients with a traumatic spinal cord injury: comparison with the use of a gel mattress’ International Wound Journal 2017;14(5):882-884.

Gentry, T., Wright, A. The 'Sacral Heart' Dressing Study: use of an absorbent self-adherent soft silicone sacral foam dressing across acute care settings. Poster presentation at the Joint Conference of the Wound Ostomy and Continence Nurses Society and the World Council of Enterostomal Therapists, Phoenix, Arizona, United States of America, 2010.

Gimenez, J.G. Preventing hospital acquired pressure ulcers in high risk surgical patients at NGHA Al Ahsa. Oral presentation at the 6th Abu Dhabi Wound Care Conference, Abu Dhabi, United Arab Emirates, 2015.

Haggard, C., Tiamson, L., Mathews, L., Blair, J. Preventing pressure ulcers in the prone perioperative patient. Poster presentation at the 46th Annual Conference of the Wound Ostomy and Continence Nurses' Association, Nashville, Tennessee, United States of America, 2014.

Haisley, V., Potter, K., Wallace, J., George, R., Betsill, K. An ounce of prevention: the use of an absorbent soft silicone self-adherent bordered foam heel dressing to decrease the incidence of hospital-acquired heel pressure

ulcers in an acute care setting. Poster presentation at Wound Ostomy and Continence Nurses' Society conference, San Antonio, Texas, United States of America, 2015.

Huang, L., Woo, K.Y., Liu, L-B., Wen, R-J., Hu, A-L., Shi, C-G. Dressings for preventing pressure ulcers: a meta-analysis. Advances in Skin and Wound Care 2015;28(6):267-273.

Jin,H.E [redacted]

Johnstone, A., McGown, K. Innovations in the reduction of pressure ulceration and pain in critical care. Wounds UK 2013;9(3):76-80.

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

Kalowes, P., Messina, V., Paige, R. Reducing medical device related pressure ulceres. An interprofessional approach using data & innovation to improve adult & pediatric outcomes. Poster presentation at the Symposium on Advanced Wound Care Fall, Las Vegas, Nevada, United States of America, 2014.

Kaufman, L.M. When small stomas are a big deal: the use of a soft silicone pouching system on the neonatal ostomate complicated by a peristomal wound. Poster presentation at the 40th Annual Conference of the Wound Ostomy and Continence Nurses Society, Orlando, Florida, United States of America, 2008.

Kiely, C. Cultural transformation in pressure ulcer prevention and care. Journal of Wound Ostomy and Continence Nursing 2012; 39 (4): 443-446.

Kimsey, D., Flannigan, C., Quill, J. A formal process for reducing the risk of perioperative pressure injury. Poster presentation at Association of

periOperative Registered Nurses Global Surgical Conference & Expo, Boston, Massachusetts, United States of America, 2017.

Koerner, S. Does the use of an absorbent soft silicone self-adherent bordered foam improve quality of care by decreasing incidence of hospital acquired pressure ulcers? Abstract No. 5315. Scientific and clinical abstracts from the 43rd Annual Wound, Ostomy and Continence Nurses Conference, New Orleans, Louisiana, June 4-8, 2011. Journal of Wound Ostomy and Continence Nursing 2011;38(3 Supplement):S70-S75.

Lancon, O. Finite element analysis studying the effect of the prevention dressings MBS and ALS on protecting soft tissues from high stresses and deformation. Alten AB, Gothenburg, Sweden, 2016 [unpublished].

Lancon, O. Finite element analysis studying the effect of the prevention dressings MBS and APFS on protecting soft tissues from high stresses and deformation. Alten AB, Gothenburg, Sweden, 2016[a] [unpublished].

Levy, A., Gefen, A. Assessment of the biomechanical effects of prophylactic sacral dressings on tissue loads: a computational modelling analysis. Ostomy Wound Management 2017;63(10):48-55.

Levy A, Frank MB, Gefen A. The biomechanical efficacy of dressings in preventing heel ulcers. J Tissue Viability. 2015;24(1):1-11.

Lientz, J. Dollars and sense: economic value in HAPU/sDTI prevention. Poster presentation at National Pressure Ulcer Advisory Panel Biennial Conference, Houston, Texas, United States of America, 2013.

Melzack R. The McGill Pain Questionnaire: Major properties and scoring methods. Pain. 1975;1:277-299.

Miller, S.K., Sharma, N., Aberegg, L.C., Blasiole, K.N., Fulton, J.A. Analysis of the pressure distribution qualities of a silicone border foam dressing. Journal of Wound Ostomy and Continence Nursing 2015;42(4):346-351.

Mölnlycke Health Care. Post Marketing Surveillance Report. 2016

Moore, Z., Thorpe, E. Dressings for pressure ulcer prevention Made Easy. Wounds UK 2015; http://www.wounds-uk.com/pdf/content_11557.pdf.

Moore ZEH, Webster J. Dressings and topical agents for preventing pressure ulcers. Cochrane Database of Systematic Reviews 2013, Issue 8. Art. No.: CD009362.

Muldoon, C., Grossman, N., Lawrence, P. Initial use absorbent soft silicone self-adherent bordered foam dressing reduces sacral pressure ulcers in the cariobascular ICU. Poster presentation at the Joint Conference of the Wound Ostomy and Continence Nurses Society and the World Council of Enterostomal Therapists, Phoenix, Arizona, United States of America, 2010.

National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline. Haesler, E. (Ed). Cambridge Media, Perth, Australia, 2014.

National Pressure Ulcer Advisory Panel. NPUAP Pressure Injury Stages. January 2007.

NICE Pathways. Preventing pressure ulcers in adults. Last updated: 30 November 2017.

NICE Pathways. Preventing pressure ulcers in neonates, infants, children and young people. Last updated: 30 November 2017.

NICE. Pressure ulcers: prevention and management. Clinical guideline CG179, 2014.

NICE. Costing statement: Pressure ulcers. Implementing the NICE guideline on pressure ulcers (CG179), April 2014.

NICE. Putting NICE guidance into practice. Algorithm for risk assessment, prevention and management in adults. Implementing the NICE guideline on pressure ulcers CG179, 2014[a].

Oomens, C.W.I., Zenhorst, W., Broek, M., Hemmes, B., Poeze, M., Brink, P.R., Bader, D.L. A numerical study to analyse the risk for pressure ulcer development on a spine board. Clinical Biomechanics 2013;28(7):736-742

Ordona, R.B., Kirkland-Walsh, H. Fixed it! Protecting against device related pressure ulcers. Poster presentation at Wound Ostomy and Continence Nurses Society and Canadian Association for Enterostomal Therapy, Montreal, Canada, 2016.

Padula, W.V. Effectiveness and value of prophylactic 5-layer foam sacral dressings to prevent hospital-acquired pressure injuries in acute care hospitals. An observational cohort study Journal of Wound Ostomy and Continence Nursing 2017;44(5):1-6 [Epub ahead of print].

Park, K.H. The effect of a silicone border foam dressing for prevention of pressure ulcers and incontinence associated dermatitis in intensive care unit patients. Journal of Wound Ostomy and Continence Nurses 2014;41(5):424-429.

Qiuli, B., Qiongyu, J. [Observation on effect of Mepilex on the prevention and treatment of pressure sores]. Chinese Journal of Medical Nursing 2010. (Published in Chinese).

Ranganathan, P., Pramesh, C.S., Aggarwal, R. Common pitfalls in statistical analysis: Intention-to-treat versus per-protocol analysis. Perspect Clin Res. 2016; 7(3): 144–146.

Richard-Denis A, Thompson C, Mac-Thiong J-M. Effectiveness of a multi-layer foam dressing in preventing sacral pressure ulcers for the early acute care of patients with a traumatic spinal cord injury: comparison with the use of a gel mattress. Int Wound J 2017; doi: 10.1111/iwj.12710

Richard-Denis, A. Thompson, C., Mac-Thiong, J-M. Reply to: Effectiveness of a multi-layer foam dressing in preventing sacral pressure ulcers in the early acute care of patients with a traumatic spinal cord injury: comparison with the

use of a gel mattress by Gefen and Santamaria. International Wound Journal 2017;14(5):885.

Santamaria, N. A randomised controlled trial of the clinical effectiveness of multi-layer silicone foam dressings for the prevention of pressure injuries in high-risk aged care residents: The Border III Trial. 2018,.

Santamaria, N., Gerdtz, M., Sage, S., McCann, J., Freeman, A., Vassiliou, T., De Vincentis, S., Ng, A.W., Manias, E., Liu, W., Knott, J. A randomised controlled trial of the effectiveness of soft silicone multi-layered foam dressings in the prevention of sacral and heel pressure ulcers in trauma and critically ill patients: the border trial. International Wound Journal 2015;12(3):302-308.

Santamaria, N., Gerdtz, M., Liu, W., Rakis, S., Sage, S., Ng, A.W., Tudor, H., McCann, J., Vassiliou, T., Morrow, F., Smith, K., Knott, J., Liew, D. Clinical effectivness of a silicone foam dressing for the prevention of heel pressure ulcers in critically ill patients: Border II Trial. Journal of Wound Care 2015[a];24(8):340-345.

Santamaria, N., Gerdtz, M., Sage, S., McCann, J., Freeman, A., Vassiliou, T., De Vincentis, S., Ng, A.W., Manias, E., Liu, W., Knott, J., Liew, D. The cost-benefit of using soft silicone multi-layered foam dressings to prevent sacral and heel pressure ulcers in trauma and critically ill patients: a within-trial analysis of the Border Trial. International Wound Journal 2015[b];12(3):344-350.

Santamaria, N., Santamaria, H. An estimate of the potential budget impact of using prophylactic dressings to prevent hospital-acquired PUs in Australia. Journal of Wound Care 2014;23(11):583-589.

Sibbald, R.G., Krasner, D.L., Woo, K.Y. Pressure ulcer staging revisited: superficial skin changes and Deep Pressure Ulcer Framework. Advances in Skin and Wound Care 2011;24(12):571-580.

Spencer, A., Gazzani, P., Thompson, D.A. Dressings: An emerging source of acrylate contact allergy. British Journal of Dermatology, suppl. 2016. Supplement 1 (175):177.

Sullivan, R. A two-year retrospective review of suspected deep tissue injury evolution in adult acute care patients. Ostomy Wound Management 2013;59(9):30-39.

Sullivan, R. Use of a soft silicone foam dressing to change the trajectory of destruction associated with suspected deep tissue pressure ulcers. MedSurg Nursing 2015;24(4):237-267.

Tamburino, J., McGrath, M., Cooper, M., McLeod, B., Binns, M. A quality improvement initiative focusing on high risk left ventricular device patients; a combination of people, process, and technology. Poster presentation at the 46th Annual Conference of the Wound Ostomy and Continence Nurses' Society, Nashville, Tennessee, United States of America, 2014.

Tariq, G. Pressure ulcer prevalence and prevention in Sheikh Khalifa Medical City, Abu Dhabii. Wounds Middle East 2014;1(2):8-14.

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.

Thorpe, E. Prophylactic use of dressings for pressure ulcer prevention. British Journal of Nursing 2016;25(12):S6-S12.

Thul, J., Valero, E. Sacral pressure ulcer prevention in trauma patients. Poster presentation at Wound Ostomy and Continence Nurses' Society conference, San Antonio, Texas, United States of America, 2015.

Walsh, N.S., Blanck, A.W., Smith, L., Cross, M., Andersson, L., Polito, C. Use of a sacral silicone border foam dressing as one component of a pressure ulcer prevention program in an intensive care unit setting. Journal of Wound Ostomy & Continence Nursing 2012;39(2):146-149.

Waring, M., Bielfeldt, S., Mätzold, K., Wilhelm, K.P., Butcher, M. An evaluation of the skin stripping of wound dressing adhesives. Journal of Wound Care 2011;20(9):412-422.

World Union of Wound Healing Societies (WUWHS) Role of dressings in pressure ulcer prevention. Wounds International, 2016.

Whitlock, J. SSKIN bundle: preventing pressure damage across the health-care community. British Journal of Community Nursing 2013; Supplement S32:S34-S39

Yoshimura, M., Ohura, N., Tanaka, J., Ichimura, S., Kasuya, Y., Hotta, O., Kagaya, Y., Sekiyama, T., Tannba, M., Suzuki, N. Soft silicone foam dressing is more effective than polyurethane film dressing for preventing intraoperatively acquired pressure ulcers in spinal surgery patients: the Border Operating room Spinal Surgery (BOSS) trial in Japan. International Wound Journal 2016; Dec 7. doi: 10.1111/iwj.12696. [Epub ahead of print].

10 Appendices

10.1 Appendix 1: Search strategy for clinical evidence (section 7.1.1)

The following information should be provided:

10.1.1 The specific databases searched and the service provider used (for example, Dialog, DataStar, OVID, Silver Platter), including at least:

- **Medline**
- **Embase**
- **Medline (R) In-Process**
- **The Cochrane Library.**

The service provider Dialog Proquest was used to search the following databases:

- Medline
- Embase

10.1.2 The date on which the search was conducted.

5th January, 2018.

10.1.3 The date span of the search.

There were no date restrictions and MEDLINE and EMBASE were searched up until 5th January, 2018.

10.1.4 The complete search strategies used, including all the search terms: textwords (free text), subject index headings (for example, MeSH) and the relationship between the search terms (for example, Boolean).

MEDLINE and EMBASE search strategies used:

Set#	Searched for	Databases	Results

S9	S7 AND S8 AND prevent*	Embase®	118°
S8	mepilex OR (foam dressing)	Embase®	1740
S7	((bed sore* or bedsore*)) OR (pressure (ulcer* or sore* or injury)) OR (decubitus (ulcer* or sore* or injury))	Embase®	130425
S6	S1 AND S2 AND prevent*	Embase®, MEDLINE®	85°
S5	mepilex OR (foam dressing)	Embase®	1719°
S4	((bed sore* or bedsore*)) OR (pressure (ulcer* or sore* or injury)) OR (decubitus (ulcer* or sore* or injury))	Embase®	130425*
S3	S1 AND S2 AND prevent*	MEDLINE®	85°
S2	mepilex OR (foam dressing)	MEDLINE®	774°
S1	((bed sore* or bedsore*)) OR (pressure (ulcer* or sore* or injury)) OR (decubitus (ulcer* or sore* or injury))	MEDLINE®	80074*

* Duplicates are removed from the search, but included in the result count. ° Duplicates are removed from the search and from the result count.

10.1.5 Details of any additional searches, such as searches of company or professional organisation databases (include a description of each database).

Search of company Excel database of all known published or presented papers assessing Mepilex® Border dressings.

10.1.6 The inclusion and exclusion criteria.

Inclusion criteria	
Population	People at risk of developing pressure ulcers but with no signs of established pressure damage (<category 1 pressure ulcers, as defined by NPUAP et al. [2014] or equivalent validated scale).
Interventions	Use of any Mepilex® Border dressing to assist pressure ulcer prevention as an adjunct to standard pressure ulcer prevention procedures.
Outcomes	• Incidence of developing pressure ulcers • Incidence of skin breakdown at the heel and sacrum • Level of patient satisfaction • Length of hospital stay • Patient compliance with pressure ulcer prevention strategies • Level of pain and discomfort and impact on quality of life • Patients ability to self-reposition in bed • Complications avoided from pressure ulcer prevention e.g. infection, abscess, septicaemia, bone infections, meningitis • Ease of use of product
Study design	Systematic reviews, randomised, non-randomised, cohort, case studies, observational and qualitative studies.
Language restrictions	No language restrictions.
Search dates	The databases (MEDLINE and EMBASE) were searched from inception to the date of the search.
Exclusion criteria	
Population	People at risk of developing pressure ulcers but who already have established pressure damage (≥category 1 pressure ulcers, as defined by NPUAP et al. [2014] or equivalent validated scale).
Interventions	Any intervention that was not a Mepilex® Border dressing being used as part of a pressure ulcer prevention programme.
Outcomes	Any outcomes that were unrelated to pressure ulcer prevention (e.g. pressure ulcer healing, the prevention and treatment of other chronic and acute wounds).
Study design	Studies not using Mepilex® Border dressings to augment pressure ulcer prevention, testimonials, non-systematic reviews containing no primary data, editorials, in vitro, healthy volunteer studies.
Language restrictions	None

Search dates	Studies published before the introduction of Mepilex® dressings (2001). Any studies published after 4th January 2018, any studies not indexed in MEDLINE or EMBASE on 4th January, 2018.

10.1.7 The data abstraction strategy.

Relevant papers were identified from the search titles and the full papers were reviewed for relevance to the decision problem. All papers were reviewed and reasons were provided for any papers that were excluded from assessment in the submission.

Data from RCT's and observational studies was abstracted in line with the methodology, appraisal, and outcomes tables presented in the submission template. Data from systematic reviews was abstracted in a summarised table assessing the methodology, and appraisal of the reviews. The outcomes of these reviews used the same outcomes provided in the submission template.

10.2 Appendix 2: Search strategy for adverse events (section 7.7.1)

The following information should be provided.

10.2.1 The specific databases searched and the service provider used (for example, Dialog, DataStar, OVID, Silver Platter), including at least:

- **Medline**
- **Embase**
- **Medline (R) In-Process**
- **The Cochrane Library.**

The service provider Dialog Proquest was used to search the following databases:

- Medline
- Embase

10.2.2 The date on which the search was conducted.

15th January, 2018.

10.2.3 The date span of the search.

There were no date restrictions and MEDLINE and EMBASE were searched up until 15th January, 2018.

10.2.4 The complete search strategies used, including all the search terms: textwords (free text), subject index headings (for example, MeSH) and the relationship between the search terms (for example, Boolean).

MEDLINE and Embase search strategies used:

Set#	Searched for	Databases	Results
S1	adverse (event or effect or reaction) AND (mepilex or (soft silicone foam dressing)	MEDLINE	20°
S2	adverse (event or effect or reaction) AND (mepilex or (soft silicone foam dressing)	Embase	45°

° Duplicates are removed from the search and from the result count.

10.2.5 Details of any additional searches (for example, searches of company databases [include a description of each database]).

Search of company Excel database of all known published or presented papers assessing Mepilex® Border dressings.

10.2.6 The inclusion and exclusion criteria.

Population	People at risk of developing pressure ulcers but with no signs of established pressure damage (<category 1 pressure ulcers, as defined by NPUAP et al. [2014] or equivalent assessment).
Interventions	Use of any Mepilex® Border dressing to assist pressure ulcer prevention as an adjunct to standard pressure ulcer prevention procedures.
Outcomes	• Incidence of skin breakdown at the heel and sacrum • Length of hospital stay • Level of pain and discomfort and impact on quality of life • Device related adverse events
Study design	Systematic reviews, randomised, non-randomised, cohort, case studies, observational and qualitative studies.
Language restrictions	No language restrictions.
Search dates	The databases (MEDLINE and EMBASE) were searched from inception to the date of the search.
Exclusion criteria	
Population	People at risk of developing pressure ulcers but who already have established pressure damage (≥category 1 pressure ulcers, as defined by NPUAP et al. [2014] or equivalent validated scale).
Interventions	Any intervention that was not a Mepilex® Border dressing being used as part of a pressure ulcer prevention programme.
Outcomes	Any outcomes that were unrelated to pressure ulcer prevention (e.g. pressure ulcer healing, the prevention and treatment of other chronic and acute wounds).
Study design	Studies not using Mepilex® Border dressings to augment pressure ulcer prevention, testimonials, non-systematic reviews containing no primary data, editorials, in vitro studies.
Language restrictions	None
Search dates	Studies published before the introduction of Mepilex® dressings (2001). Any studies published after 4th January 2018, any studies not indexed in MEDLINE or EMBASE on 4th January, 2018.

10.2.7 The data abstraction strategy.

Relevant papers were identified from the search titles and the full papers were reviewed for relevance to the decision problem. Five papers were reviewed and reasons were provided for why they were excluded from assessment in the submission.

10.3 Appendix 3: Search strategy for economic evidence (section 8.1.1)

The following information should be provided.

10.3.1 The specific databases searched and the service provider used (for example, Dialog, DataStar, OVID, Silver Platter), including at least:

- Medline
- Embase
- Medline (R) In-Process
- EconLIT
- NHS EED.

The same search strategy was used as for the clinical section, but with inclusion in the tabulation to include studies with economic outcomes. As for the main search, economics papers were included in the tabulation if they referred to at least one Mepilex® Border product (Sacrum Border or Heel Border). EconLIT was not searched as this is a proprietary database that the analysts did not have access to.

10.3.2 The date on which the search was conducted.

For the main search, as for 10.10.4, 15th January, 2018. A search on NHS EED was conducted on 25th March 2018, noting the NHS EED has been closed and archived since 31st March 2015.

10.3.3 The date span of the search.

As for 10.10.5. There were no date restrictions and MEDLINE and EMBASE were searched up until 15th January, 2018. NHS EED was searched up to its end date of 31st March 2015.

10.3.4 The complete search strategies used, including all the search terms: textwords (free text), subject index headings

(for example, MeSH) and the relationship between the search terms (for example, Boolean).

As for the clinical search. For NHS EED the database was searched on the title terms (pressure AND ulcer) which only resulted in 5 irrelevant papers.

10.3.5 Details of any additional searches (for example, searches of company databases [include a description of each database]).

N/A.

10.4 Appendix 4: Resource identification, measurement and valuation (section 9.3.2)

The following information should be provided.

10.4.1 The specific databases searched and the service provider used (for example, Dialog, DataStar, OVID, Silver Platter), including at least:

- Medline
- Embase
- Medline (R) In-Process
- NHS EED
- EconLIT.

Resource information was obtained directly from known relevant public sources in the UK and so no additional search was conducted. These sources included, NHS web based sources including NHS Supply, NHS Improvement, PSSRU health and care unit costs annual reports, and NICE.

10.4.2 The date on which the search was conducted.

Public sources were all accessed during March 2018.

10.4.3 The date span of the search.

N/A

10.4.4 The complete search strategies used, including all the search terms: textwords (free text), subject index headings (for example, MeSH) and the relationship between the search terms (for example, Boolean).

N/A

10.4.5 Details of any additional searches (for example, searches of company databases [include a description of each database]).

N/A

The inclusion and exclusion criteria.

N/A

10.4.6 The data abstraction strategy.

N/A

11 Related procedures for evidence submission

11.1 Cost models

An electronic executable version of the cost model should be submitted to NICE with the full submission.

NICE accepts executable cost models using standard software – that is, Excel, TreeAge Pro, R or WinBUGs. If you plan to submit a model in a non-standard package, NICE should be informed in advance. NICE, in association with the External Assessment Centre, will investigate whether the requested software is acceptable, and establish if you need to provide NICE and the External Assessment Centre with temporary licences for the non-standard software for the duration of the assessment. NICE reserves the right to reject cost models in non-standard software. A fully executable electronic copy of the model must be submitted to NICE with full access to the programming code. Care should be taken to ensure that the submitted versions of the model programme and the written content of the evidence submission match.

NICE may distribute the executable version of the cost model to a consultee if they request it. If a request is received, NICE will release the model as long as it does not contain information that was designated confidential by the model owner, or the confidential material can be redacted by the model owner without producing severe limitations on the functionality of the model. The consultee will be advised that the model is protected by intellectual property rights, and can be used only for the purposes of commenting on the model's reliability and informing comments on the medical technology consultation document.

Sponsors must ensure that all relevant material pertinent to the decision problem has been disclosed to NICE at the time of submission. NICE may request additional information not submitted in the original submission of evidence. Any other information will be accepted at NICE's discretion.

When making a full submission, sponsors should check that:

- an electronic copy of the submission has been given to NICE with all confidential information highlighted and underlined
- a copy of the instructions for use, regulatory documentation and quality systems certificate have been submitted
- an executable electronic copy of the cost model has been submitted
- the checklist of confidential information provided by NICE has been completed and submitted.

- A PDF version of all studies (or other appropriate format for unpublished data, for example, a structured abstract) included in the submission have been submitted

11.2 Disclosure of information

To ensure that the assessment process is as transparent as possible, NICE considers it highly desirable that evidence pivotal to the Medical Technologies Advisory Committee's decisions should be publicly available at the point of issuing the medical technology consultation document and medical technology guidance.

Under exceptional circumstances, unpublished evidence is accepted under agreement of confidentiality. Such evidence includes 'commercial in confidence' information and data that are awaiting publication ('academic in confidence').

When data are 'commercial in confidence' or 'academic in confidence', it is the sponsor's responsibility to highlight such data clearly, and to provide reasons why they are confidential and the timescale within which they will remain confidential. The checklist of confidential information should be completed: if it is not provided, NICE will assume that there is no confidential information in the submission. It is the responsibility of the manufacturer or sponsor to ensure that the confidential information checklist is kept up to date.

It is the responsibility of the sponsor to ensure that any confidential information in their evidence submission is clearly underlined and highlighted correctly. NICE is assured that information marked ‘academic in confidence’ can be presented and discussed during the public part of the Medical Technologies Advisory Committee meeting. NICE is confident that such public presentation does not affect the subsequent publication of the information, which is the prerequisite allowing for the marking of information as ‘academic in confidence’.

Please therefore underline all confidential information, and highlight information that is submitted under ‘commercial in confidence’ in blue and information submitted under ‘academic in confidence’ in yellow.

NICE will ask sponsors to reconsider restrictions on the release of data if there appears to be no obvious reason for the restrictions, or if such restrictions would make it difficult or impossible for NICE to show the evidential basis for its guidance. Information that has been put into the public domain, anywhere in the world, cannot be marked as confidential.

Confidential information submitted will be made available for review by the External Assessment Centre and the Medical Technologies Advisory Committee. NICE will at all times seek to protect the confidentiality of the information submitted, but nothing will restrict the disclosure of information by NICE that is required by law (including in particular, but without limitation, the Freedom of Information Act 2000).

The Freedom of Information Act 2000, which came into force on 1 January 2005, enables any person to obtain information from public authorities such as NICE. The Act obliges NICE to respond to requests about the recorded information it holds, and it gives people a right of access to that information. This obligation extends to submissions made to NICE. Information that is designated as ‘commercial in confidence’ may be exempt under the Act. On receipt of a request for information, the NICE secretariat will make every effort to contact the designated company representative to confirm the status of any

information previously deemed ‘commercial in confidence’ before making any decision on disclosure.

11.3 Equality

NICE is committed to promoting equality and eliminating unlawful discrimination, including paying particular attention to groups protected by equalities legislation. The scoping process is designed to identify groups who are relevant to the evaluation of the technology, and to reflect the diversity of the population. NICE consults on whether there are any issues relevant to equalities within the scope of the evaluation, or if there is information that could be included in the evidence presented to the Medical Technologies Advisory Committee to enable them to take account of equalities issues when developing guidance.

Evidence submitters are asked to consider whether the chosen decision problem could be impacted by NICE’s responsibility in this respect, including when considering subgroups and access to recommendations that use a clinical or biological criterion.

For further information, please see the NICE website (www.nice.org.uk/aboutnice/howwework/NICEEqualityScheme.jsp).

NICE National Institute for Health and Care Excellence

National Institute for Health and Care Excellence

Centre for Health Technology Evaluation

Pro-forma Response

External Assessment Centre Report factual check

Mepilex Border Heel and Sacrum dressings for preventing pressure ulcers

Please find enclosed the assessment report prepared for this assessment by the External Assessment Centre (EAC).

You are asked to check the assessment report from Newcastle upon Tyne Hospitals (NUTH) and York Health Economics Consortium (YHEC) External Assessment Centre (EAC), to ensure there are no factual inaccuracies contained within it. If you do identify any factual inaccuracies you must inform NICE by 12pm, **25 May 2018** using the below proforma comments table. All your comments on factual inaccuracies will receive a response from the EAC and when appropriate, will be amended in the EAC report. This table, including EAC responses will be presented to the Medical Technologies Advisory Committee and will subsequently be published on the NICE website with the Assessment report.

21 May 2018

NICE National Institute for Health and Care Excellence

Issue 1

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Section 2.1.1, page 11, paragraph 1, line 1 "The dressings are made up of 5 layers, the first of which…."	Addition of text (as shown underlined below) "The dressings are made up of 5 layers (referred to as Deep Defense Technology), the first of which…"	In the same way that the EAC uses the proprietary name 'Safetac' with reference to the silicone layer of the dressing, we think it would be beneficial to also mention the proprietary name of the five-layer structure of the dressing, i.e. 'Deep Defense Technology', in this section.	Thank you for your comment. No change to the report has been made as the current statement is not factually inaccurate.

Issue 2

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Section 2.1.1, page 11, paragraph 1, lines 6-11 "The Safetac technology, contained in the layer closest to the skin is designed to mould to the skin without sticking to the moist wound, enabling the dressing to be easily peeled back and reapplied enabling multiple inspections of the skin site without needing to fully replace the dressing (Section 2.1, Submission). The silicone layer is also designed to not adhere to the surface of a wound and, therefore, allows the dressing to be removed without causing pain or trauma…"	Addition of text (as shown underlined below) "The Safetac technology, contained in the layer closest to the skin is designed to mould to the skin without sticking aggressively, enabling the dressing to be easily peeled back and reapplied allowing multiple inspections of the skin site without needing to fully replace the dressing (Section 2.1, Submission). The gentle but effective fixation of the silicone layer allows the dressing to be removed without causing pain or trauma…"	While we fully agree with the EAC that Safetac technology prevents Mepilex Border dressings from sticking to moist wounds and avoiding trauma on dressing removal, the evaluation it refers to specifically relates to the use of the dressings on intact skin to prevent pressure ulcers. We feel that the proposed amendments make the text more relevant to the scope of the evaluation.	Thank you for your comment. No change to the report has been made as the current statement is not factually inaccurate.

Issue 3

NICE National Institute for Health and Care Excellence

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response

Section 2.1.1, page 11, paragraph 2, lines 4-7 "The scope issued by NICE (NICE scope, Section 1.1) specifies the technology under consideration to be Mepilex Border Heel and Sacrum dressings. Therefore, the EAC deemed the 3-layer Mepilex dressings to be outside the scope of this evaluation."	Amendment of text (as shown underlined below) "The scope issued by NICE (NICE scope, Section 1.1) specifies the technology under consideration to be Mepilex Border Heel and Sacrum dressings. <u>Although the EAC recognised the differences in structure between Mepilex Heel dressings (3-layer) and the Mepilex Border dressings (5-layer), it was felt that the differences are small enough to warrant the inclusion of clinical and economic data pertaining to the former in this evaluation</u>."	The principle differences between Mepilex Heel and Mepilex Border Heel dressings are discussed in section 7.4.3 of the sponsor evidence submission. The text highlights that, based on the results of studies into the ability of different dressing designs to prevent tissue deformation and published international clinical consensus, the self-adherent 5-layer Mepilex Border is the dressing of choice. Furthermore, the 3-layer Mepilex Heel dressing requires some form of retention device (bandage or adhesive tape) to keep it in place. However, there are similarities between the 3-layer and 5-layer dressings, e.g. they both incorporate a silicone (Safetac) contact layer. As highlighted in the EAC report, the number of reported studies specifically relating to Mepilex Border Heel is relatively low so we firmly believe that including clinical and economic data pertaining to Mepilex Heel would be relevant to the assessment of the performance and safety of the technology under evaluation, particularly in relation to the prevention of heel pressure ulcers.	Thank you for your comment. In the early part of our assessment we discussed the inclusion of the 3-layer Mepilex Dressing with NICE. We judged that given that the 3-layer version of the dressing is not a predecessor of the existing dressing, but rather is separate dressing it is outside the scope of the current assessment. As no comparative studies reporting on the relative efficacy of the two devices are available, the likely direction of bias of including evidence relating to the 3-layer dressing is unknown. Evidence on the 5-layer Mepilex Border dressing is presented in line with the notified technology and published scope. No change to the report has been made.

		We also note that one of the key sources of clinical and economic data cited in the NICE Medtech Innovation Briefing (MIB124) *Mepilex Border dressings for preventing pressure ulcers* is a randomised controlled trial that included Mepilex Heel (in conjunction with Mepilex Border Sacrum) as the intervention. From the perspective of consistency, we feel that the same data should be considered by the EAC as being relevant to the evaluation.	

Issue 4

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Section 2.1.2, page 13, paragraph 1 "The Mepilex Border dressings aim to address only the moisture, friction and shear risk factors."	Addition of text (as shown underlined below) "The Mepilex Border dressings aim to address only the moisture, friction, <u>shear and pressure</u> risk factors,"	In addition to moisture, friction and shear, Mepilex Border dressings are designed to address pressure. This is outlined in section 2.2 of the sponsor evidence submission We feel that it is important to highlight that Mepilex Border dressings can influence all four of the key extrinsic risk factors in pressure ulcer development.	Thank you for flagging this omission. The wording within Section 2.1.2 has been amended.

NICE National Institute for Health and Care Excellence

Issue 5

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Table 2.3, page 19, row 2 (Population) "The company expanded the scope to include patients in an aged care setting…. …Within this report, the EAC has considered the population included within the scope only."	To delete "Within this report, the EAC has considered the population included within the scope only	Irrespective of whether patients are in acute care or aged care settings, the aetiology and risk factors in pressure ulcer development are broadly the same, as are the preventive strategies. We believe that data generated from clinical studies, irrespective of the patient population and setting, are relevant to the assessment of the performance and safety of Mepilex Border dressings. We would, therefore, request that the EAC re-considers its decision to exclude such data from the report	Thank you for your comment. In the early part of our assessment we discussed the inclusion of evidence outside of the acute care setting with NICE. We judged that the selection criteria used should be aligned with the scope and therefore did not look for or include evidence within the acute care setting. Whilst evidence outside of this setting may be informative in estimating the treatment effect of Mepilex Border dressings, its generalisability to decision problem is unclear. No change to the report has been made.

NICE National Institute for Health and Care Excellence

Issue 6

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Section 3.2, page 24, paragraph 2, bullet point 3 Appendix B, page 163, row 2 "The interventions is not specifically referred to as a Mepilex or Mepilex Border dressing anywhere in the publication. Therefore, the EAC would have excluded this study as there is insufficient information reported about the intervention."	Reversal of decision to exclude Bateman & Roberts 2013	The article actually includes a picture of the intervention (i.e. a Mepilex Border Sacrum dressing so we would like the EAC to consider including this study in the review. We can obtain written confirmation from the authors that Mepilex Border Sacrum was used in the study, if required.	Thank you for providing clarification information around this study. Even though this study uses Mepilex Border dressings, it is a single arm study not reporting safety data. Therefore, we would not have included the study in any case. However, we note that the study should be included using the company's criteria. The report has been updated for this.

NICE National Institute for Health and Care Excellence

Issue 7

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Section 3.2, page 24, paragraph 2, bullet point 3 Appendix B, page 163, row 4 "The EAC would have excluded this study due to insufficient information reported about the intervention….the intervention is never formally referred to as Mepilex or Mepilex Border…"	Reversal of decision to exclude Gentry & Wright 2010	The poster actually includes a picture of the intervention (i.e. a Mepilex Border Sacrum dressing) so we would like the EAC to consider including this study in the review. We can obtain written confirmation from the authors that Mepilex Border Sacrum was used in the study, if required.	Thank you for providing clarification information around this study. Even though this study uses Mepilex Border dressings, it is a single arm study not reporting safety data. Therefore, we would not have included the study in any case. However, we note that the study should be included using the company's criteria. The report has been updated for this.

NICE National Institute for Health and Care Excellence

Issue 8

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Section 3.3, page 27, paragraph 1, bullet point 1 ¨Santamaria 2018 comprised of an unpublished report obtained from the company and a recently published paper (Santamaria et al. 2015b)"	Amendment of text (as shown underlined below) "¨Santamaria 2018 comprised of an unpublished report obtained from the company and a recently published paper (Santamaria et al. 2018)" The list of references also needs to be updated as the study report has now been published, i.e.'(unpublished)' needs to be removed and replaced with '2018 DOI: 10.1111/iwj.12891'.	The citation in the EAC report refers to the wrong report.	Thank you for flagging this error, the citation has been updated.

NICE National Institute for Health and Care Excellence

Issue 9

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Table 3.3, pages 31-33, Comments column, *Comparative studies – randomised controlled trials* rows 1-3 "Study matches scope ….and provides limited non-UK comparative data	Amendment of text (as shown underlined below) "Study matches scope …. and provides non-UK comparative data" . We would like the EAC to consider replacing 'limited' with 'substantial' for the 'Aloweni 2017', 'Kalowes 2016' and 'Santamaria 2015a'	We agree with the EAC in stating that the 'Walker 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 the other hand, we believe that the larger sample sizes and the detailed reporting of the methodologies (e.g. the inclusion of details of power calculations) of the other three RCTs warrants the proposed amendment	Thank you for your comment. Given that the studies do not report all (or most) of the outcomes within the scope, we judged that the evidence that they provide is limited. Therefore, no update has been made to the report.

Issue 10

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Section 3.6.2, page 62, paragraph 1 (beginning) "In 2 of the RCTs (Aloweni et al. 2017, Kalowes et al. 2016), a lower number of patients developing pressure ulcers was observed in the Mepilex Border Sacrum group. However the difference was not statistically significant."	Amendment of text (as shown underlined below) "In 2 of the RCTs (Aloweni et al. 2017, Kalowes et al. 2016), a lower number of patients developing pressure ulcers was observed in the Mepilex Border Sacrum group, <u>with a statistically significant difference observed in 1 of the studies (Kalowes et al.2016)</u>."	While the EAC report is correct in stating that the difference was not significant in the case of the Aloweni et. 2017 study, a statistical difference was observed in favour of Mepilex Border Sacrum in the Kalowes et al. 2016 study. In Table 1 of the Kalowes et al. 2016 study report, the number of patients who had pressure ulcers develop in the intervention and control groups was 1 and 7, respectively (p=0.01).	Thank you for your comment. We have added this into the text and updated the table accordingly.

Issue 11

NICE National Institute for Health and Care Excellence

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response

Section 3.6.2, page 62, paragraph 1 (end) "The proportion of patients who received Mepilex Border Sacrum, however, was not reported."	Deletion of "The proportion of patients who received Mepilex Border Sacrum, however, was not reported."	In the Santamaria et al 2015a report, it is stated that all patients in the intervention group received Mepilex Border Sacrum dressings.	Thank you for your comment and highlighting this error. We acknowledge that the number of patients receiving the dressing is reported. However, the number of patients who have a sacral pressure ulcer is not reported. We have updated the text to read: The number of patients who developed pressure ulcers at the sacrum, however, was not reported. Only the number of pressure ulcers is reported. We have contacted the authors to ask them how many *patients* developed pressure ulcers at the sacrum in each arm of the study, but to date have received no response. We checked all previous systematic reviews included within the company submission to see if the data are reported and found the following: Black (2014) = published before Santamaria et al 2015a Clark (2014) = published before Santamaria et al 2015a Cornish (2017) = does not include Santamaria et al 2015a Huang (2015) = SR conducted before Santamaria et al 2015a published Moore and Webster (2013) = published before Santamaria et al 2015a

			NPUAP et al. (2014) = published before Santamaria et al 2015a Tayyib and Coyer (2016) = don't report data on a per patient basis We have included a second meta-analysis whereby the data from Santamaria, 2015a are included with the assumption that number of pressure ulcers is equal to the number of patients with pressure ulcers. A scenario analysis for the model has also been included. The limitations of this assumption are reported.

NICE National Institute for Health and Care Excellence

Issue 12

NICE National Institute for Health and Care Excellence

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response

Section 3.8, page 70, paragraph 2 "The EAC has pooled the results of 3 included RCTs (Aloweni et al. 2017, Kalowes et al. 2016, Walker et al. 2017) in relation to pressure ulcer incidence." Section 4.2.5, page 84, paragraph 3 "Rather than use 1 trial, the EAC pooled the results of the 3 included RCTs in relation to sacrum pressure ulcer incidence which gave a relative risk estimate of 0.51 [CI 0.22 to 1.18], as described in Section 3.8, which was used in the EAC base case"	Amendment of text (as shown underlined below) "The EAC has pooled the results of 4 included RCTs (Aloweni et al. 2017, Kalowes et al. 2016, Santamaria et al. 2015a, Santamaria et al. 2018) in relation to pressure ulcer incidence." "Rather than use 1 trial, the EAC pooled the results of the 4 included RCTs in relation to sacrum pressure ulcer incidence which gave a relative risk estimate of 0.51 [CI 0.22 to 1.18], as described in Section 3.8, which was used in the EAC base case"	We would like to acknowledge the excellent work of the EAC in searching for relevant studies (e.g. identification of the Walker et al. 2007 RCT) and for undertaking the meta-analysis outline in section 3.8 of the report. We would, however, like to query a few things: 1. As discussed in Issue 9 above, the Walker et al. 2017 study was undertaken to determine the feasibility and effect size to inform a larger RCT and involved a sample size that was reported to be too small to determine an effect of the intervention. On this basis, we question the appropriateness of including the data from this particular study in the meta-analysis. 2. Conversely, due to the large sample size of the Santamaria et al. 2015a study and the fact that data from this RCT have been referred to in NICE Medtech Innovation Briefing (MIB124) *Mepilex Border dressings for preventing pressure ulcers*, previously published systematic reviews and meta-analyses, we question the decision of the EAC to exclude the Mepilex Border Sacrum-specific data from this particular study in the meta-analysis.	Thank you very much for this comment. We have responded to reach point in turn. 1. Because the Walker 2017 trial is small in comparison to the other trials, it is given a lower weight within the meta-analysis. There is no reason to exclude this trial. 2. In the Santamaria trial, the key issue is that they report the number of sacral pressure ulcers that developed but not the number of patients that developed on. We know from other trials of Mepilex Border that patients can develop more than one pressure ulcer. We have contacted the authors for clarity on this point but have not yet heard back from them. We have included a sensitivity analysis including this study. Results are statistically in favour of Mepilex based on fixed effects model but the difference is not significant based on the random effects model. 3. Please see our response to issue 5 on this.

		3. For reasons stated in Issue 5, we would like the EAC to consider using data from the Santamaria et al. 2018 RCT (aged care setting) in the meta-analysis.	

Issue 13

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Table 4.2, page 72, row 3 '(Kalowes et al. 2016) USA' 'The EAC excluded the study as it was not a health economic study" Section 4.1, pages 75-76 (Overview and critique of the company's critical appraisal for each study)	Addition of text at the end of the section headed 'Overview and critique of the company's critical appraisal for each study' "Although the EAC determined that the study reported by Kalowes et al. 2016 was not technically an economic study, the company appropriately referred to in the sponsor evidence submission as a useful source of data for the economic model and does at least present an estimate for cost saving	While we agree with the EAC that the study reported by Kalowes et al. 2016 was not technically an economic study, modelling data from this study were included as additional material in the sponsor evidence submission and also used by the EAC in its reappraisal of our model with different data.	Thank you for this comment. Whilst we appreciate that Kalowes et al. 2016 contains relevant data for use in economic model, we would not include it within a cost-effectiveness review for the reasons stated. Therefore, no factual inaccuracy is reported and no update to the report made.

Issue 14

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Table 4.2, page 74, row 4 '(Padula 2017) USA' "The EAC excluded this study on the basis of no comparator	Reversal of decision to exclude Padula 2017	The study report (Padula, 2017) highlights that the hospital-level cohort was divided into periods when Mepilex Border Sacrum dressings were purchased (intervention) or were not purchased for use at the participating hospitals (control) and the average rates of pressure ulcers pre- and post-dressing purchased were compared. The study involved data from approximately 1.3 million patients in acute care settings, albeit in the United States of America but arguably similar enough to acute care facilities in the United Kingdom to warrant being considered for inclusion in the report.	Thank you for your comment. Whilst the authors did make a comparison between Mepilex border dressings and standard care, this was not a head-to-head comparison, but used retrospective data and a regression analysis to form a comparison and therefore did not meet our selection criteria. We have updated Table 4.2 so that this rationale is made clearer.

Issue 15

NICE National Institute for Health and Care Excellence

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response

Section 4.2.5, pages 81-84, paragraph 2 - paragraph 11, line 10 "The key clinical parameter….which was used in the EAC base case	Replacement of paragraphs 2-11, line 10 with the following: "The key clinical parameter in the model is the incidence of pressure ulcer with standard care and with standard care plus Mepilex Border dressings. For both the standard care and the Mepilex Border dressing arms, the company used pressure ulcer incidence reported in 1 RCT (Santamaria et al. 2015a) The company justified the choice of the Santamaria 2015 RCT as this is the only RCT examining both sacrum and heel dressings with an economic analysis, although the heel dressing is not a Mepilex Border dressing but the 3-layer Mepilex dressing combined with Tubifast for attachment to the foot."	The EAC report states "The pressure ulcer incidence with Mepilex Border dressings in the company model was taken from Santamaria 2015 (Santamaria et al. 2015a). There was no justification provided in the company submission as to why this particular RCT was chosen." We accept this was not made explicit earlier on, but we feel this was subsequently covered by the later consideration of the other included studies (additional modelling using data from the Kalowes 2016 study which referred to Mepilex Border Sacrum only). This additional modelling is acknowledged in section 4.2.8 of the EAC report. In section 9.5.11 of the sponsor evidence submission, it states "The additional modelling adds confidence in the finding from the *de novo* analysis and appears to show that the most conservative cost saving case has been submitted by the selection of the Santamaria 2015[b] RCT which is the one trial that used both sacral and heel dressings (albeit using Mepilex Heel instead of Mepilex Border Heel)."	Thank you for this comment. We have removed the text stating that "There was no justification provided in the company submission as to why this particular RCT was chosen." Given that this is explained later in your submission as you report.

		It is noteworthy that the Santamaria 2015[b] RCT is the main data source for the economics component of the NICE Medtech Innovation Briefing (MIB124) *Mepilex Border dressings for preventing pressure ulcers*,	

Issue 16

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Table 4.2, page 92, colum 4, rows 3-4 Cost of pressure ulcer treatment – standard care £4,823 Cost of pressure ulcer treatment – Mepilex Border dressings £4,823	Dependent on outcome of enquiry	We would like to see an explanation as to why these two costs are the same.	Thank you for your comment. The justification for this is provided under Table 4.5. This limitation of our analysis is also explored within sensitivity analysis. No update to the report has been made.

Issue 17

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Section 5.2, page 107, paragraph 6 "A further limitation of the analysis is that it was not possible to ascertain how the use of Mepilex Border dressings impacted on the stage of pressure ulcer, due to the low incidence of pressure ulcers in the trials." .	Addition of text onto the end of the sentence highlighted to the left "…trials, although Santamaria 2015 and Kalowes 2016 report on stages in both arms of their respective RCTs."	Some of the RCTs do break-down results by stage in each arm We appreciate that it may be more difficult to include effect on stages in the different arms of the RCTs once pooled in the manner used by the EAC. However we chose to model different RCTs separately and so it was deemed possible in the sponsor evidence submission.	Thank you for your comment. To avoid repetition we have added a link here to the relevant clinical section, Table 3.8. Ideally, data would be available reporting robust information on the stage of pressure ulcer by prevention method. However, this would require a very large trial (in order to be sufficiently powered for pressure ulcer incidence). If these data were available, we could have pooled the information and weighted our pressure ulcer costs accordingly.

Issue 18

NICE National Institute for Health and Care Excellence

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response

Section 4.2.6, pages 87-88 'Dressing changes' "…a conservative value of 4 dressings per patient for the sacrum was used in the model base case." "…a slightly lower value of 3 dressings per heel was used in the base case (6 dressings in total per patient)."	Reduction in the number of dressings used per patient in the model base case	We would like to express our appreciation for the excellent work undertaken by the EAC in relation to determining the most appropriate number of dressings used per patient. We are, however, that the figures proposed by the EAC are a little on the high side. Using the mean LoS 4.8 days), the number of sacrum dressings (4) and heel dressings (2x3) per patient proposed by the EAC, this would equate to dressing changes being undertaken every 1.2 (sacrum) to 1.6 (heel). This appears somewhat at odds with the following statement which appears earlier in section 4.2.6 of the report: "Clinical experts surveyed by the EAC suggested that the dressing should be changed every 3 days, ore more often if soiled or dislodged." Following on from this, we revisited the clinical study reports that were cited in the sponsor evidence submission and recorded details of the reported dressing wear time / dressing change frequencies in a file (Mepilex Border and Mepilex Heel dressings for pressure ulcer prevention – reported wear times). The reported wear times range from 2-7 days, with 3 being the most common. Many include provisos	Thank you for your comment. We have based the number of dressing changes on the only UK evidence reporting on this outcome (Johnstone and McGown 2013b). This study reports an average length of stay of 9 days. We appreciate that the number of dressing changes used would be high considering a length of stay of 4.8 days, this is discussed in Section 4.2.6 under dressing changes. We agree that there is much uncertainty around this value and will likely be dependent on the type of patients using the dressing. Therefore, sensitivity analyses around these values have been conducted. We have now explicitly reported the estimate cost savings with 2 and 4 Mepilex Border Sacrum and Heel dressings, respectively under sensitivity analysis.

		suggesting the need for more frequent changes if dressings become soiled or detached. However, the extremely low level of complaints highlighted in the post-market surveillance data supplied with the sponsor evidence submission strongly suggest that problems such as detachment are very rare occurrences. On this basis, we believe that, over a period of 4.8 days, the number of sacrum and heel dressings used per patient are more likely to be in the region of 2 and 4 respectively.	

NICE National Institute for Health and Care Excellence

Expert adviser collated comments table

MT366 Mepilex Border Heel and Sacrum dressings for preventing pressure ulcers

Expert #1	**Ms Carol Johnson, Clinical Matron – Tissue Viability, County Durham and Darlington NHS Foundation Trust**
Expert #2	**Ms Samantha Holloway, Senior Lecturer, Cardiff University School of Medicine**
Expert #3	**Ms Deborah Gleeson, Lead Nurse Tissue Viability, St Helens and knowsley NHS trust**
Expert #4	**Ms Fiona Downie, Nurse Consultant Tissue Viability, Royal Papworth Hospital Foundation Trust**
Expert #5	**Ms Gillian Maclean, Staff Nurse, NHS Lothian**
Expert #6	**Ms Lisa Robson, Tissue Viability Nurse, Royal Liverpool and Broadgreen NHS Trust Hospitals**

#	Question	Expert responses	
1	*Please describe your level of experience with the technology, for example:* – *Are you familiar with the technology?* – *Have you used it?* – *Are you currently using it?* – *Have you been involved in any research or development on this technology?* – *Do you know how widely used this technology is in the NHS?*	Expert #1:	I am fully aware of the technology and have undertaken a localised study to ascertain its effectiveness as an adjacent prevention strategies, we currently have it within our local fractured neck of femur pathway for all pateints identified as having a spinal or epidural anaesthesia with application from admission time until 72 hours post operatively or until full sensory and motor sensation is returned and mobilisation occurs. We have had no incidences of PU development within these patients since the introduction of the prevention strategy I have not been involved in any research or development of the product our work within CDDFT was based on the Australia & USA work I have used the technology within wound care for a number of years and now with Pu prevention for the last 2 years

		Expert #2:	I have used this dressing in my clinical work previously. As a member of the International Skin Tear Advisory Panel it is one the dressings that was referred to in a generic manner as part of the new management guidelines - http://www.woundsinternational.com/made-easys/view/istap-best-practice-recommendations-for-the-prevention-and-management-of-skin-tears-in-aged-skin It is one of the dressings of choice for patients attending our out-patient clinic as well as in-patients with suitable wounds
		Expert #3:	Yes, have used it and use on patients with fragile skin. Not involved in any research. Aware this product is on a number of formularies in the northwest
		Expert #4:	I have used the product in a very small trial on critically unwell patients on ITU. I have had no further involvement in this product other than this small trial.
		Expert #5:	Yes Only occasionally We have just placed an order for the product and we will try it out, I have the company rep coming in to the unit to discuss product. As a trust we do not widely use it, it is not on our formulary.
		Expert #6:	We are familiar with the technology and use it daily throughout the organisation. We have not been involved with any formal research or development of this product. I do no think it is used everywhere as expensive
2	*Has the technology been superseded or replaced?*	Expert #1:	Not aware of any
		Expert #2:	Whilst there are other foams that offer a silicone wound contact layer to reduce the risk of damaging the wound bed, Mepilex border sacrum has some strong evidence to support the claim that it can reduce the risk of pressure damage prophylactically. This evidence is lacking for other foams.

		Expert #3:	No on formulary for its fluid handling capacity
		Expert #4:	Other foam dressings are used on heels as a pressure ulcer (PU) prevention aid, but I am not aware of any evidence behind other products used in this way.
		Expert #5:	We have previously discussed using it in the past, it has not been replaced by anything else.
		Expert #6:	We have tried alternatives for wound management but non clinically as good. We have not tried any others for pressure ulcer prevention.
3	*How innovative is this technology, compared to the current standard of care? Is it a minor variation or a novel concept/design?*	Expert #1:	In my opinion it is a novel concept/design as a prevention tool. I have used this for where there is a sensory & motor deficit with the patient. The technology is much better received by patients and is better than current technology for patient compliance
		Expert #2:	Its' innovation is in its' simplicity. Nurses are very familiar with the use of Foam dressings to manage wounds. The novel aspect lies in promoting the use of the dressing in a prophylactic manner for high risk patients. However it's imperative that Nurses understand that the use of the dressing needs to be part of the 'bundle of care' for pressure ulcer prevention which should include regular re-positioning and assessment.
		Expert #3:	No difference to any other foam dressing on the market not used to prevent pressure but as with any dressing acts a barrier for moisture, friction and shearing
		Expert #4:	It is a minor variation on products such as silicone pads/heel shapes used for PU prevention.
		Expert #5:	We currently do not use any specific dressings to prevent pressure damage. If this dressing is shown to prevent pressure damage, then we would use it on specific at risk patients but not on all patients
		Expert #6:	This is our current standard
4	*Are you aware of any other competing or alternative technologies available to the NHS which*	Expert #1:	None Known

	have a similar function/mode of action to the notified technology? *If so, how do these products differ from the technology described in the briefing?*	Expert #2:	There is a body of evidence (1998 – to date) examining the role of different dressings in pressure ulcer prevention i.e, hydrocolloids, films and foams. The challenge of drawing firm conclusions for any product is that the dressing is only one element of a strategy to prevent pressure ulcers (as discussed above), hence it is always difficult to definitively state that dressing A is better than dressing B. The strengths of the Mepilex border is the evidence relating to the reduced risk of skin irritation.
		Expert #3:	Parafricta heel products work and stay in place. This technology is designed to reduce friction and shearing were by foam dressings help as a by-product of its fluid handling role by basically proving a membrane between vulnerable skin and external forces
		Expert #4:	Silicone pads/heel shapes used for PU prevention, i.e. Aderma or Kerrapro They differ in that they do not adhere to the patient's skin, so less likely to stay where they are placed to aid PU prevention. In addition, anecdotally, when using silicone pads/heel shapes clinically we see quite a lot of moisture build up between the product and the patient's skin, which is not good from a maceration/skin integrity perspective. In the small trial of Mepilex border we did not see this happen.
		Expert #5:	Yes. One product is an application of a film that dries and prevents moisture/shearing. There are other similar dressings, but I don't know the differing technologies.
		Expert #6:	Not aware of any 5 layers, other similar products, most companies have a silicone foam dressing
5	*What do you consider to be the potential benefits to patients from using this technology?*	Expert #1:	Prevents friction damage we utilise this within patients who have a defined sensory deficit due to spinal/epidural anaesthesia. Prevents heel blisters occurring
		Expert #2:	If a patient experiences pressure damage / ulceration this can have a significant impact on their recovery in terms of pain / discomfort which can lead to increased hospital stay. There is also an increased risk of infection in the presence of an open wound. Therefore preventative strategies are key to reducing the risk of pressure ulcers. The use of a technology with a strong evidence base as part of a bundled approach to care.
		Expert #3:	Costly other cheaper products on market

		Expert #4:	It may be an extra aid in the potential prevention of PUs in the high risk patient.
		Expert #5:	Prevention of pressure damage
		Expert #6:	Prevention of some pressure ulcers and associated complications
6	*Are there any groups of people who would particularly benefit from this technology?*	Expert #1:	Those who have a sensory deficit due to spinal/epidural anaesthesia, those who have had spinal blocks. We are also looking at testing this within palliative care areas in see if it prevents terminal pressure ulceration and also within elderly people services for those with cognitive impairments.
		Expert #2:	The majority of the existing evidence related to patients within an intensive care, accident and emergency and cardiac surgery. However these are not the only groups of individuals at risk therefore it would seem to be appropriate to use this technology for any patient at risk.
		Expert #3:	High risk patients for heel ulcers
		Expert #4:	Unstable critically unwell patients in an ITU/HDU setting where the patient is too unwell or unstable to be repositioned.
		Expert #5:	Patients who are log rolls for spinal damage and are predominantly lying on their backs. They are not nursed on air mattresses andbe nursed from sise to side. Obese patients
		Expert #6:	At risk patient in care
7	*Does this technology have the potential to change the current pathway or clinical outcomes? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?*	Expert #1:	As the technology in our areas has prevented heel blistering it has significantly improved the outcomes for those patients, and has prevented complications of surgery, on track rehabilitation times and uneventful post surgical receovery from the pressure ulcer perspective.
		Expert #2:	Based on more recent evidence the data suggests that positive clinical outcomes can be achieved in terms of a reduced incidence of pressure ulcers however the technology cannot be used in isolation of other preventative strategies. It follows that if

			pressure ulcers can be prevented this will help to reduce the risk of an increased hospital stay due to the development of a pressure ulcer.
		Expert #3:	No not evidenced the nhs has used film dressings on heels for years
		Expert #4:	No it would be used as an adjunct to current PU prevention pathways. There would be a need for very large trials to demonstrate an effect on outcomes, i.e. reduced PU numbers.
		Expert #5:	Yes if the technology is successfully proven to prevent pressure damage
		Expert #6:	It is an improvement if pressure ulcers are prevented as ultimately they can lead to pain, infection and death
8	*What do you consider to be the potential benefits to the health or care system from using this technology?*	Expert #1:	A cheaper, non invasive pressure ulcer prevention strategy that can be available immediately which prevents pressure ulcer formation
		Expert #2:	Reduction in pressure ulcer incidence.
		Expert #3:	Addition prevention strategy
		Expert #4:	As above: there would be a need for very large trials to demonstrate an effect on outcomes, i.e. reduced PU numbers.
		Expert #5:	Reduce length of stay in hospital Less nursing time required to care for patient
		Expert #6:	Prevention the costs in terms of human suffering and financial costs
9	*Considering the care pathway as a whole, including initial capital and possible future costs avoided, is*	Expert #1:	If used in conjunction with current care pathways this technology is cheaper than other equipment provision

	the technology likely to cost more or less than current standard care, or about the same?	Expert #2:	In the short term the cost would be higher if the technology was recommended for all at risk patients, however the cost of treating a patient with a pressure ulcer is higher, out with the costs to the patients in terms of pain and discomfort, increased hospital stay and also psychological consequences of developing pressure damage.
		Expert #3:	more
		Expert #4:	If used routinely as prevention it would always be an adjunct so would increase cost. However, if PU numbers were proven to be reduced with its use then a cost saving and quality improvement for the patient could potentially be made. As yet this is not proven, so the use of the technology would increase costs.
		Expert #5:	Cost less if pressure damage is avoided
		Expert #6:	This is our current standard
10	*What do you consider to be the resource impact from adopting this technology?* *Could it, for example, change the number or type of staff needed, the need for other equipment, or effect a shift in the care setting such as from inpatient to outpatient, or secondary to primary care?*	Expert #1:	Within our area having adopted the technology the PU hospital acquired data has been at Zero since the implementation of the technology as a prevention component. As such there has been a substantial reduction in nursing time to undertake dressings, etc , much improved quality of recovery for patients, etc. Uncomplicated recovery from the surgery, full mobility as expected rather than heel blistering and delayed mobility
		Expert #2:	The technology is unlikely to reduce the number of staff needed to care for patients as they will still require re-positioning. However the use of the dressing could have an impact on nurses time as having to perform dressing changes for a patient with a pressure ulcer is time consuming, whereas the use of this foam dressing could reduce the number of dressing changes as it can stay in place for a longer period in the absence of active ulceration. The incidence of pressure ulcers in the community is largely an unknown entity, in combination with more patients being cared for in their own home, the use of this dressing in a prophylactic manner could help to reduce the incidence of pressure damage and as a consequence reduce the likelihood of individuals having to be admitted to hospital. So there could be huge cost savings for in-patient care, however

			there would be a requirement for the technology to be used as standard practice for those deemed to be at risk, hence the cost would need to be funded by primary care.
		Expert #3:	Significant costs per patient
		Expert #4:	No effect.
		Expert #5:	Reduce number of staff needed to give pressure area care and dressing changes if a pressure sore is avoided. Could potentially reduce use of equipment i.e. dressing device (VAC). Reduced length of stay in hospital and care in the community
		Expert #6:	None extra for us, but could have implications to organisations who adopt
11	*Are any changes to facilities or infrastructure, or any specific training needed in order to use the technology?*	Expert #1:	We implemented this within our fracture pathway and provided training on the application of the dressing as it was new to the units in question
		Expert #2:	It would be relatively simple to integrate the use of the technology into existing bundles of care / care pathways which would require additional training. For example integrating the recommendation to use the technology as part of the SSKIN bundle approach: https://improvement.nhs.uk/resources/Using-SSKIN-to-manage-and-prevent-pressure-damage/ . I would see the use of this technology as an ideal opportunity to train carers / relatives to use the product, particularly in a community setting.
		Expert #3:	no
		Expert #4:	No.
		Expert #5:	Some training would be beneficial for the nursing staff who will participate in the dressing changes. Theory behind the technology and advice on how often to change dressings and step down.

		Expert #6:	Not to my organisation
12	*Are you aware of any safety concerns or regulatory issues surrounding this technology?*	Expert #1:	None Known
		Expert #2:	None - although contraindications include anyone who may have a sensitivity to any of the components of the dressing.
		Expert #3:	no
		Expert #4:	No.
		Expert #5:	No
		Expert #6:	I am not aware of any
13	*Please add any further comments on your particular experiences or knowledge of the technology, or experiences within your organisation.*	Expert #1:	None
		Expert #2:	Blank
		Expert #3:	This dressing is no different to others on the market and has no pressure reducing qualities, dressings have been used in the nhs to reduce friction and shear for 10 years
		Expert #4:	See all the above.
		Expert #5:	We have issues with dressings getting faecally soiled, many of our patients are incontinent and dressings need to be changed frequently.

		Expert #6:	Blank
14	*Approximately how many people each year would be eligible for intervention with this technology, either as an estimated number, or a proportion of the target population?*	Expert #1:	Unknown in the wider NHS, within our organisation currently being received by approx. 200-300 patients per year, depending on our findings within the adjacent areas this number may be suitable would lead to a higher population being suitable for intervention
		Expert #2:	Estimates suggest that approximately 700, 000 individuals experience a pressure ulcer annually with many more being at risk. A large proportion of patients in hospital are likely to be at risk of pressure damage at some point in their in-patient journey however existing methods for identifying those to be at risk cannot accurately predict who will develop a pressure ulcer, therefore strategies to reduce the risk are paramount. The use of this technology as part of a bundled approach could help to reduce the risk.
		Expert #3:	In our trust we use parafricta so none Potentially huge for community
		Expert #4:	If used routinely with our unstable ITU patients, i.e. unable to reposition, it could potentially be a 1000 plus patients/year.
		Expert #5:	10% of our admissions to critical care, 2600 were admitted last year.
		Expert #6:	Blank
15	*Would this technology replace or be an addition to the current standard of care?*	Expert #1:	In some instances it could replace, but may also be used in addition to current care
		Expert #2:	In addition to standard care which is currently repositioning and regular assessment
		Expert #3:	Not in our trust No research to support amending current standards of care

		Expert #4:	Addition.
		Expert #5:	It would be an addition
		Expert #6:	This is our current standard
16	*Are there any issues with the usability or practical aspects of the technology?*	Expert #1:	We have not found any issues
		Expert #2:	In my opinion there are limited issues, it's a simple dressing to use and does not require any expertise. It could be something that untrained carers / relatives could be instructed to use.
		Expert #3:	Dressings by their nature are designed for vulnerable skin and shear off
		Expert #4:	No.
		Expert #5:	We would need to ensure there was adequate training to reduce misuse and large costs.
		Expert #6:	Blank
17	*Are you aware of any issues which would prevent (or have prevented) this technology being adopted in your organisation or across the wider NHS?*	Expert #1:	We haven't found any issues in the adoption of this technology
		Expert #2:	Cost is likely to be the main issue, however the short term product related costs needs to be considered in terms of the likely long term benefits in relation to cost savings from reduced incidence of pressure damage
		Expert #3:	Cost and lack or robust research to support

		Expert #4:	Potentially cost.
		Expert #5:	Cost, not on the joint Lothian formulary and has to be ordered in as a non-stock item
		Expert #6:	It is already in place
18	*Are you aware of any further evidence for the technology that is not included in this briefing?*	Expert #1:	Not at present
		Expert #2:	None
		Expert #3:	no
		Expert #4:	No.
		Expert #5:	No
		Expert #6:	no
19	*Are you aware of any further ongoing research or locally collected data (e.g. audit) on this technology?* *Please indicate if you would be able/willing to share this data with NICE. Any information you provide will be considered in confidence within the NICE process and will not be shared or published.*	Expert #1:	We have audit data within our local area on the trial we undertook and will have further data upon completion of the ongoing developments within CDDFT
		Expert #2:	None
		Expert #3:	no

		Expert #4:	Our own local small trial in a specific group of patients in ITU. Yes, we would be willing to share our data.
		Expert #5:	No not presently, I believe there has previously been an evaluation of this product a few years ago.
		Expert #6:	no
20	*Is there any research that you feel would be needed to address uncertainties in the evidence base?*	Expert #1:	No
		Expert #2:	There needs to be a strong case to support the idea that the use of this technology can reduce the incidence of pressure damage, however this is difficult as the use of a prophylactic dressing cannot be viewed in isolation of the other preventative measures needed as part of an overall strategy. Stronger evidence to support the claim that *the "Proprietary Deep Defense Technology* protects against the extrinsic forces - pressure, shear and friction; and manages micro-climate"* would be useful.
		Expert #3:	In house experimental testing at laboratory level to examine if difference to pressure, friction and shearing gradients alongside other dressings
		Expert #4:	Yes large scale studies across lots of different specialities, using existing PU incidence figures to compare to. PU incidence figures are robustly kept in most NHS organisations in both primary and secondary care settings.
		Expert #5:	Should it be used for all sedated critically ill patients, or only patients who meet a set criteria
		Expert #6:	Perhaps further trials of other silicone dressings
21	*How useful would NICE guidance on this particular technology be to you or other NHS colleagues?*	Expert #1:	Very useful in my opinion
		Expert #2:	Particularly useful as it would provide a strong argument for investment to help prevention.

		Expert #3:	Not very useful
		Expert #4:	Fairly useful, but I am aware that there is a need for further evidence to be collected on this technology.
		Expert #5:	Very useful, if it works.
		Expert #6:	We may be able to justify a cheaper alternative in terms of financial cost if it is a comparable technology

National Institute for Health and Care Excellence

External Assessment Centre correspondence

Mepilex Border dressings

The purpose of this table is to show where the External Assessment Centre relied in their assessment of the topic on information or evidence not included in the sponsors' original submission. This is normally where the External Assessment Centre:

a) become aware of additional relevant evidence not submitted by the sponsor
b) need to check "real world" assumptions with NICE's expert advisers, or
c) need to ask the sponsor for additional information or data not included in the original submission, or
d) need to correspond with an organisation or individual outside of NICE

These events are recorded in the table to ensure that all information relevant to the assessment of the topic is made available to MTAC. The table is presented to MTAC in the Assessment Report Overview, and is made available at public consultation.

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	Thirteen initial questions to Mölnlycke Health Care, submitted by EAC on 26/03/18 for discussion at company introductory teleconference 28/03/18, hosted by NICE. **The full list of questions was as follows:**	Written responses from the company were received on 28/03/18 [Appendix 1]. An updated PRISMA flow diagram (figure A2) was also received [Appendix 2]. These responses were discussed further, and clarified where necessary, during the teleconference. Written and verbal responses were summarised in this log by the EAC (below). Italicised text indicates notes made by the EAC based on verbal discussion during the teleconference and confirmed with the company on 04/04/18.	
7.2	1. Can you confirm the total number of included and excluded studies at each stage of the selection process?	We assume that this question refers to Figure A1: PRISMA flow diagram of included and excluded published studies in the sponsor evidence submission, as errors were noted upon review. Figure A2 has been re-submitted (along with this document) with corrected figures. *EAC addition – the discrepancy in numbers between the new and revised PRISMA diagrams are the removal of the 2 unpublished studies from the number of studies included in the qualitative synthesis.*	Noted with thanks

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
7.2	2. Can you provide more detail on how the study selection was conducted? a. Were there two independent reviewers involved? b. How were any conflicts resolved?	a) The studies were identified by one reviewer and were then independently assessed by a second reviewer in order to ascertain that they met the predefined inclusion/exclusion criteria. b) Any discrepancies were resolved by the second reviewer.	Noted with thanks
7	3. Can you provide more detail on how you performed the data extraction? a. Was this performed by one reviewer or two independent reviewers?	One reviewer extracted the data with a second reviewer independently checking the data extraction form for accuracy and completeness.	Noted with thanks
7.5	4. Can you provide more detail on how studies were critically appraised? a. Were there two independent reviewers involved?	a) Two independent reviewers were involved in the critical appraisal process so that bias and error were minimised at all stages of the review process.	Noted with thanks

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	b. How were any conflicts resolved?	b) Any conflicts of interest were discussed early in the process and, if required, steps were taken to ensure that these did not impact on the review process.	
2	5. When were Mepilex® Border Heel dressing and Mepilex® Border Sacrum dressings first developed (understood to be 2001 based upon search strategies)?	Mepilex® Border Heel and Mepilex® Border Sacrum were launched in 2013 and 2007, respectively.	Noted with thanks
2	6. Have there been any previous versions of the dressings? If so, a. When were they replaced? b. What are the differences between these and the current versions? c. Do any clinical studies use previous versions of the technologies?	a) In October 2017, new versions of these dressings were launched. b) The enhanced designs of the new versions include new handling tabs and thicker borders, to facilitate easy inspection and patient checking. The shapes of the dressings have been refined to facilitate better coverage of the high-risk areas (heels and sacrum). The new version of Mepilex Border Sacrum features an improved gluteal seal for maximum protection. However, the key five-layer construction of the dressings remains the same.	Noted with thanks

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
		EAC addition – the latest versions of the dressings (launched October 2017) are designed to improve ease of use, but are not expected to have an impact on the efficacy of the device in preventing pressure ulcers. c) All studies reported in the sponsor evidence submission involved the use of the pre-October 2017 versions of Mepilex® Border Heel and Mepilex® Border Sacrum. However, as the new versions of the dressing are designed in exactly the way as the pre-October 2017 versions (i.e. with the five-layer construction), then the findings of the studies are relevant to both current and previous versions.	
2	7. Are the Mepilex® Border Heel dressing and Mepilex® Border Sacrum dressings listed on NHS supply chain? If so, please could you provide us with the relevant product codes?	The dressings are listed on the NHS supply chain. The relevant numbers are as follows: Product — NPC — Pieces / box — Unit price Mepilex Border Sacrum 15 x 15 cm — ELA577 — 5 — £3.06	Noted with thanks

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
		Mepilex Border Sacrum 16 x 20 cm ELA1020 10 £4.44 Mepilex Border Sacrum 22 x 25 cm ELA1021 10 £7.26 Mepilex Border Heel 22 x 23 cm ELA1091 10 £7.21	
2	8. We note that the Mepilex® Border Heel dressing employs a different design (less complex 3-layer, non-adherent, dressing). Please could you summarise the principle differences in design between the two technologies and any resulting clinical differences?	The principle differences between Mepilex® Heel dressings and Mepilex® Border Heel dressings are discussed in section 7.4.3 of the sponsor evidence submission. "The Mepilex® and Mepilex® Heel dressings are 3-layered dressings which utilise the same Safetac® technology used in the Mepilex® Border dressings. Mepilex® Border is the dressing of choice as it is based on the five-layer design that has been reported to be key to the prevention of tissue deformation (Call et al. 2015, Miller et al. 2015, De Wert et al. 2016, Call et al. 2013) and is recommended in the consensus recommendations by Black et al. (2014), whereas Mepilex® Heel has a less complex three-layer structure. Mepilex® Border dressings are also self-	Noted with thanks

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
		adherent, whereas Mepilex® dressings require some form of retention device (bandage or adhesive tape) to keep them in place." *EAC addition – in summary, Mepilex **Border** dressings have 5 layers and are self-adhesive. Mepilex dressings have 3 layers and require attachment using a second device (e.g. tape or retention bandage). No head-to-head clinical studies between Mepilex Border and Mepilex dressings have been conducted. From pre-clinical work it is expected that the 5 layer Mepilex Border design is more effective in preventing pressure ulcers.*	
2	9. Which conferences would you consider relevant for the publication of data on Mepilex® Border Heel dressing and Mepilex® Border Sacrum dressings?	There are numerous national and international wound care conferences / congresses and specific pressure ulcer conferences / congresses at which data have been presented on the safety and effectiveness of Mepilex® Border Heel or Mepilex® Border Sacrum dressings. For example: Abu Dhabi Wound Care Annual Conference Association of periOperative Registered Nurses Global Surgical Annual Conference & Expo	Noted with thanks

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
		European Pressure Ulcer Advisory Panel Annual Meeting* National Pressure Ulcer Advisory Panel Biennial Conference, Symposium on Advanced Wound Care Biannual (Spring / Fall) Event*^ Wound Ostomy and Continence Nurse Annual Conference^ *EAC addition – information on Mepilex/Mepilex border dressings are known to have been published at each of the conferences above. Many other wound conferences exist. All data on Mepilex/Mepilex Border published at any of the above conferences should be included within Molnlycke's internal database. Those conferences noted with a * have a greater global audience, whilst those noted with a ^ have had a higher volume of Mepilex/Mepilex Border data presented at them.*	
3.7	10. We understand from Section 3.7 that Mepilex® Border Heel dressing and Mepilex® Border Sacrum dressings are	The recommended use of the dressing is summarised in section 3.5 of the sponsor evidence submission and conforms with the algorithm from the WUWHS	Noted with thanks

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	anticipated to be used in addition to existing measures. Please could you describe the additional activities required to incorporate the dressings into standard care (e.g. applying/replacing the dressing, checking the site under the dressing).	consensus recommendations (2016) in guiding clinicians on how to use the dressing. These recommendations suggest assessing the skin underneath the dressing at least daily and the dressing should continue to be used until the risk of pressure ulcer development has reduced significantly. The dressing should be applied and changed in line with the product's instructions for use (IFU). The IFU for the products state that the dressing may be left in place for several days 'depending on the condition of the…surrounding skin, or as indicated by accepted clinical practice'. Data on application of the dressing and duration of use varies according to specific pressure ulcer prevention protocols, as detailed in the sponsor evidence submission. *EAC addition – when used within ICU and theatre pathways, the application and removal of dressings as well as the skin inspection would typically be conducted by a nurse (of varying level, but typically mid-level).*	

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
3	11. How long can Mepilex® Border Heel dressing and Mepilex® Border Sacrum dressings be applied for before they require replacing?	The IFU for the products state that the dressing may be left in place for several days 'depending on the condition of the…surrounding skin, or as indicated by accepted clinical practice'. Data on duration of dressing use varies according to specific pressure ulcer prevention protocols, as detailed in the evidence submission.	Noted with thanks
3	12. Please describe any training required to use Mepilex® Border Heel dressing and Mepilex® Border Sacrum dressings including: a. Who provides the training b. How long the training takes c. Which clinical staff would be trained (within the UK NHS) d. How many staff would be trained per hospital e. The cost of the training is and who pays for it f. Any ongoing training	a) Training is provided by the Molnlycke Clinical Support Manager and the local Account Manager. There is also the option of additional support from the Molnlycke Pressure Ulcer Prevention Specialist, if required. b) Training takes up to a maximum of one hour, dependent on the size of the group. This is established over a set timeframe to maximise attendance of staff, including night staff. The following topics are covered: application of the dressings, utilisation of local guidance on the identification of those patients deemed at risk of pressure injury, and the current SSKIN (pressure-redistributing Support surface, regular Skin inspection, Keep moving	Noted with thanks

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
		[repositioning], management of Incontinence / moisture and optimised Nutrition) bundle. c) All clinical staff within intensive care units and focus wards receive the training. During the training, a 'champion' to act as a point of contact when Molnlycke personnel are not in attendance is identified. d) The goal is to train 85% of clinical staff in those areas where the use of the dressings is implemented. e) The training is provided free by Molnlycke as part of the implementation process. f) The Molnlycke Clinical Support Manager and local Account Manager ensure regular diarised contact and training for new members of the clinical staff.	
	13. Lastly, could we ask some advance questions on what to expect from the economic model? a. What software will it be written on?	a) The model will be based on the NICE economic model template. b) The comparator in the model will be standard care only (prophylactic dressings in the intervention are additive).	Noted with thanks

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	b. Which comparators will be included within the model (e.g. standard care only)? c. Will it incorporate sensitivity analysis?	c) The model will incorporate sensitivity analysis. Deterministic sensitivity analysis will be run on all of the data ranges. Results will be presented as the Base case, Best and Worst case tables as computed by the tool (varying HAPU incidence associated with the intervention), and the tornado diagram from the tool will display the sensitivity results from all the other data ranges. Additional threshold analysis will be conducted on HAPU incidence to find the cost-saving/cost incurring threshold.	
	On 16/04/18 EAC submitted a further question to Phil Davies of Mölnlycke Health Care: As we continue with our assessment of Mepilex border we had a further question that we wondered if you could help with. We are looking for the abstracts from the "Symposium on Advanced Wound Care Biannual (Spring / Fall) Event" and have thus far been unable to locate them. I don't anticipate that you will have all of these precedings, but we thought it worth asking in	**Response received from Phil Davies on 17/04/18:** I've searched the relevant websites but, unfortunately, have not located any electronic depository of oral / poster presentation abstracts relating to the Fall 2017, Fall 2016, Fall 2015 and Spring 2015 conferences; neither do I have printed abstract books for any of the conferences. I'm so sorry that I can't fulfil your request on this occasion. Before I forget, I'd just like to draw your attention to the fact that the full results of one of the unpublished clinical studies cited in the sponsor submission of	Noted with thanks. EAC cites published article for Santamaria study in assessment report (file received from company shown in Appendix 3)

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	case. If possible we need full abstracts (for both oral and poster presentations) for the following: **Spring 2018** (will be held in April 25–29 2018, but all accepted oral/poster details for abstracts have been finalised and a list of abstract titles are available online, so possible you may have full abstract details) **Fall 2017** **Fall 2016** **Fall 2015** **Spring 2015** The abstracts need to be in some kind of searchable format (e.g. a PDF we can conduct Ctrl-F term searches across).	evidence have now been published (see attached file). The unpublished report is cited in the submission of evidence as: Santamaria, N. A randomised controlled trial of the clinical effectiveness of multi-layer silicone foam dressings for the prevention of pressure injuries in high-risk aged care residents: The Border III Trial. 2018, unpublished. The citation for the published results article is: Santamaria, N., Gerdtz, M., Kapp, S., Wilson, L., Gefen, A. A randomised controlled trial of the clinical effectiveness of multi-layer silicone foam dressings for the prevention of pressure injuries in high-risk aged care residents: The Border III Trial. International Wound Journal 2018 DOI: 10.1111/iwj.12891. I can confirm that the information about this particular study no longer needs to be considered as academic in confidence. If new research relating to Mepilex Border dressings, presented or published subsequent to the completion of the sponsor submission of evidence, becomes	

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
		available, do you want me to alert you to it, as I have done for the attached research article?	
	On 05/04/18, a query was submitted to the Symposium on Advanced Wound Care (abstractsubmissions@naccme.com) regarding access to conference abstracts 2015-18: I am interested in viewing the full abstracts (oral and poster) for the SAWC Spring and Fall events from 2015 to 2018, and wonder if you could help me please? If this is not an appropriate contact address, please could you guide me to the right one? I have seen documents which list abstract titles for Spring 2018 and Fall 2017 at the following Abstract Information webpages (http://www.sawc.net/fall/poster-information; http://www.sawc.net/spring/abstract-information) - but am interested in viewing the full abstracts for these and past events. I believe the full abstracts for SAWC events are made available in the Conference	**Response received 05/04/18:** Thank you for submitting in the below inquiry. For the Spring and Fall events, we do not have access to full abstracts are unable to send them to you or direct you to them online. Abstract materials are only distributed onsite.	Noted with thanks

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	Abstract Book, but am unable to find these online. Please could you tell me: 1. Are the full abstracts (for oral and poster presentations) from 2015 - 2018 available to be viewed online anywhere (e.g. as PDFs, journal supplements, searchable database)? 2. If not, would it be possible to be sent the PDFs giving the full abstracts for all Spring / Fall events from 2015 to date (e.g. the Conference Abstract Books)? 3. If full abstracts for 2015 - 2018 are not available online, and cannot be sent, please could you confirm this is the case. Many thanks for your help - it is much appreciated.		

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	On 11/04/18, a list of 9 questions was sent by the EAC to 8 Expert Advisors named by NICE for this project: See Appendix X.	**Responses received by EAC were collated into a single documented response: See Appendix 4.** 11/04/18 - Response received from Elaine Thorpe confirming that she would respond to the questions by 20/04/18 11/04/18 – Responses received from Lisa Robson and Samantha Holloway 13/04/18 – Responses received from Michael Clark and Fiona Dowie 19/04/18 – Responses received from Gillian MacLean and Elaine Thorpe 20/04/18 – Responses received from Debbie Gleeson	Responses noted with thanks. To inform EAC report
	On 13/04/18, a further question was sent to Fiona Dowie regarding her answers to the above questions:	**Response received 17/04/18:** The only National reporting mechanisms are Safety Thermometer, which is a point prevalence audit. It	EAC consulted NHS Safety Thermometer for baseline rates of

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	With regard to this question on risk of pressure ulcers (Are you aware of any sources reporting on the baseline risk of pressure ulcers (in at risk/high risk patients) within the NHS acute care setting?) what we are wondering is if you know of any publications reporting on the proportion of patients getting pressure ulcers within the NHS? For instance, I think the "stop the pressure" campaign may report this type of information. It's not a problem if you're not aware of anything, we just want to ensure that we're not missing anything obvious.	isn't a very accurate tool for many reasons but mainly because if the patient is in the organisation for a long period of time they end up on the ST audit every month so effectively counting the PU twice. In addition it doesn't collect avoidability status. The DATIX system is used by a lot of NHS Trusts and this is a more accurate incident count, but I'm not aware that any overall NHS figures come out from this.	pressure ulcers, noting the limitations highlighted by the expert
	On 20/04/18, a further question was sent to Debbie Gleeson regarding her answers to the above questions: Could I check that with respect to your answer to question 7, you use Mepilex dressings for patients who have a pressure injury, rather than to prevent potential pressure injuries?	**Response received 20/04/18:** We 3m foam for some areas, ie ankles, knees and elbows as a preventive method, mepilex not on our current formulary was on previous formulary.	Noted with thanks
	On 23/04/18, EAC contacted Jennie Hall (Programme Director - National Stop the	**Response received 25/04/18:**	EAC responded 26/04/18 thanking

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	Pressure programme, NHS Improvement; jennie.hall1@nhs.net) regarding incidence of pressure ulcers in the UK: I am emailing regarding the 'stop the pressure' campaign and its associated research. We are trying to find the prevalence or incidence of pressure ulcers in the UK NHS in patients who are considered at risk or at high risk of developing a pressure ulcer. Ideally we would like to find these rates specific to the heel or sacrum and broken down by category or stage of pressure ulcer. From the report published on the campaign it looks as though a lot of this data is being collected and we wondered whether you would be able to share this with us?	I am the Programme Director for NSTPP so it is really helpful to know that you are involved with work with NICE. Are you in a position to share any more detail about the work? One of the key challenges that we have regarding pressure ulcers is that there is not a consistent approach in the definition or measurement for Pressure Ulcers. This position raises a raft of challenges as you can imagine not least really understanding the size of the improvement challenge we need to deliver. We have been undertaking work for a number of months with a range of colleagues from different backgrounds to develop a recommended way forward to reduce variation in practice. This work is concluding shortly in terms of the design phase but there will then be an implementation period likely through to March 2019 to ensure a sustainable way forward. We do not current national collect incidence data, there is a monthly point prevalence tool (PST) but this does not risk stratify patients or indicate location., it is not a national database either as a number of Trusts do not collect the data. In addition	Jennie Hall for her response and giving some background to the project

<table>
<tr><th>Submission Document Section/Sub-section number</th><th>Question / Request
Please indicate who was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.</th><th>Response
Attach additional documents provided in response as Appendices and reference in relevant cells below.</th><th>Action / Impact / Other comments</th></tr>
<tr><td></td><td></td><td>there is incident data but the high level NLRS would not have the level of detail you are seeking.

I am sorry I am not in a position to send links to the data you are seeking but I hope that this background as to why is helpful.</td><td></td></tr>
<tr><td></td><td>On 04/05/18, EAC contacted Emily Fitzsimmons of Mölnlycke Health Care with a query:

As part of our assessment of the economic model, we were wondering if you would be able to provide information around the relative sales of your dressing sizes. We don't need to know the sales figures, just an approximation of the proportion of sales by dressing size (i.e. completion of the second column in the table below):

<table><tr><th>Dressing</th><th>Approximate percentage of overall sales (by dressing type)</th></tr><tr><td colspan="2">Mepilex Border Sacrum</td></tr><tr><td>15x15cm</td><td></td></tr><tr><td>18x18cm</td><td></td></tr></table></td><td>Response received 08/05/18:

<table><tr><th>Dressing</th><th>Approximate percentage of overall sales (by dressing type)</th></tr><tr><td colspan="2">Mepilex Border Sacrum</td></tr><tr><td>15x15cm</td><td>31%</td></tr><tr><td>18x18cm</td><td>47%</td></tr><tr><td>22x25cm</td><td>22%</td></tr><tr><td>Total Mepilex Border Sacrum</td><td>100%*</td></tr><tr><td colspan="2">Mepilex Border Heel</td></tr><tr><td>22x23cm</td><td>4%</td></tr><tr><td>18x24cm</td><td>96%</td></tr><tr><td>Total Mepilex Border Heel</td><td>100%</td></tr></table>* The approximate sales for the 3 sizes of Mepilex Border Sacrum should sum to 100%.</td><td>Received with thanks. Responses used to inform EAC report</td></tr>
</table>

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	22x25cm | Total Mepilex Border Sacrum | 100%* ***Mepilex Border Heel*** 22x23cm | 18x24cm | Total Mepilex Border Heel | 100% * The approximate sales for the 3 sizes of Mepilex Border Sacrum should sum to 100%.		
	On 08/05/18, EAC contacted Emily Fitzsimmons of Mölnlycke Health Care with a further query regarding the table above: Thank you for getting back to me so quickly. Jude and I have just been looking at the information and wanted to double check that the sales for the heel dressings are the correct way around? We note that you only report the 22x23cm sized dressing in your submission and therefore wondered if this was because the majority of sales (96%) are for this size (rather than the 4% in your email)? Apologies if these are correct in your	**Response received 08/05/18:** The 22x23 is a new shape of the Heel dressing which now allows the malleolus to be covered. However as this is new to the market and both versions are still available in primary care, we haven't seen a large transition across to the new size as of yet.	Noted with thanks

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	previous email, we just thought it worth double checking.		
	On 25/05/18, EAC contacted Professor Nick Santamaria: Dear Prof Santamaria, We are currently working with NICE as part of their Medical Technologies Evaluation Programme to evaluate Mepilex Border Sacrum and Heel dressings for preventing pressure ulcers (PUs). We have a clarification question concerning your 2015 study (the Border trial) that we hope you can help us with. In Table 2 of your publication, the results for PU development are broken down by the number of cases (i.e. number of affected patients) and the specific number of PUs that developed amongst patients at the sacral and/or heel site. According to this table, there were 2 sacral PUs which developed amongst patients in the intervention group and 8 sacral	**No response received**	

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	PUs that developed in patients in the control. Our question is the following: **Is the reported number of PUs that developed at the sacrum (amongst the affected patients) equivalent to the proportion of patients that developed PUs at the sacrum?** (i.e. were there 2 patients in the intervention group and 8 patients in the control that developed PUs at the sacrum, or, is it possible that one or more patients developed more multiple sacral PUs?). We would appreciate your response to this as soon as possible. Thank you in advance. Best wishes, Michelle		

Questions for company

Questions on submission

1. Can you confirm the total number of included and excluded studies at each stage of the selection process?

   We assume that this question refers to Figure A2: PRISMA flow diagram of included and excluded published studies in the sponsor evidence submission, as errors were noted upon review. Figure A2 has been re-submitted (along with this document) with corrected figures.

EAC addition – the discrepancy in numbers between the new and revised PRISMA diagrams are the removal of the 2 unpublished studies from the number of studies included in the qualitative synthesis.

2. Can you provide more detail on how the study selection was conducted?
   a. Were there two independent reviewers involved?

      The studies were identified by one reviewer and were then independently assessed by a second reviewer in order to ascertain that they met the predefined inclusion/exclusion criteria.

   b. How were any conflicts resolved?

      Any discrepancies were resolved by the second reviewer.

3. Can you provide more detail on how you performed the data extraction?
   a. Was this performed by one reviewer or two independent reviewers?

      One reviewer extracted the data with a second reviewer independently checking the data extraction form for accuracy and completeness.

4. Can you provide more detail on how studies were critically appraised?
   a. Were there two independent reviewers involved?

      Two independent reviewers were involved in the critical appraisal process so that bias and error were minimised at all stages of the review process.

   b. How were any conflicts resolved?

      Any conflicts of interest were discussed early in the process and, if required, steps were taken to ensure that these did not impact on the review process.

Device

5. When were Mepilex® Border Heel dressing and Mepilex® Border Sacrum dressings first developed (understood to be 2001 based upon search strategies)?

   Mepilex® Border Heel and Mepilex® Border Sacrum were launched in 2013 and 2007, respectively.

6. Have there been any previous versions of the dressings? If so,
   a. When were they replaced?

      In October 2017, new versions of these dressings were launched.

   b. What are the differences between these and the current versions?

      The enhanced designs of the new versions include new handling tabs and thicker borders, to facilitate easy inspection and patient checking. The shapes of the dressings have been refined to facilitate better coverage of the high-risk areas (heels and sacrum). The new version of Mepilex Border Sacrum features an improved gluteal seal for maximum protection. However, the key five-layer construction of the dressings remains the same.

EAC addition – the latest versions of the dressings (launched October 2017) are designed to improve ease of use, but are not expected to have an impact on the efficacy of the device in preventing pressure ulcers.

   c. Do any clinical studies use previous versions of the technologies?

      All studies reported in the sponsor evidence submission involved the use of the pre-October 2017 versions of Mepilex® Border Heel and Mepilex® Border Sacrum. However, as the new versions of the dressing are designed in exactly the way as the pre-October 2017 versions (i.e. with the five-layer construction), then the findings of the studies are relevant to both current and previous versions.

7. Are the Mepilex® Border Heel dressing and Mepilex® Border Sacrum dressings listed on NHS supply chain? If so, please could you provide us with the relevant product codes?

   The dressings are listed on the NHS supply chain. The relevant numbers are as follows:

Product	NPC	Pieces / box	Unit price
Mepilex Border Sacrum 15 x 15 cm	ELA577	5	£3.06
Mepilex Border Sacrum 16 x 20 cm	ELA1020	10	£4.44
Mepilex Border Sacrum 22 x 25 cm	ELA1021	10	£7.26

Mepilex Border Heel 22 x 23 cm ELA1091 10 £7.21

8. We note that the Mepilex® Border Heel dressing employs a different design (less complex 3-layer, non-adherent, dressing). Please could you summarise the principle differences in design between the two technologies and any resulting clinical differences?

The principle differences between Mepilex® Heel dressings and Mepilex® Border Heel dressings are discussed in section 7.4.3 of the sponsor evidence submission.

"The Mepilex® and Mepilex® Heel dressings are 3-layered dressings which utilise the same Safetac® technology used in the Mepilex® Border dressings. Mepilex® Border is the dressing of choice as it is based on the five-layer design that has been reported to be key to the prevention of tissue deformation (Call et al. 2015, Miller et al. 2015, De Wert et al. 2016, Call et al. 2013) and is recommended in the consensus recommendations by Black et al. (2014), whereas Mepilex® Heel has a less complex three-layer structure. Mepilex® Border dressings are also self-adherent, whereas Mepilex® dressings require some form of retention device (bandage or adhesive tape) to keep them in place."

*EAC addition – in summary, Mepilex **Border** dressings have 5 layers and are self-adhesive. Mepilex dressings have 3 layers and require attachment using a second device (e.g. tape or retention bandage). No head-to-head clinical studies between Mepilex Border and Mepilex dressings have been conducted. From pre-clinical work it is expected that the 5 layer Mepilex Border design is more effective in preventing pressure ulcers.*

9. Which conferences would you consider relevant for the publication of data on Mepilex® Border Heel dressing and Mepilex® Border Sacrum dressings?

There are numerous national and international wound care conferences / congresses and specific pressure ulcer conferences / congresses at which data have been presented on the safety and effectiveness of Mepilex® Border Heel or Mepilex® Border Sacrum dressings. For example:

- Abu Dhabi Wound Care Annual Conference
- Association of periOperative Registered Nurses Global Surgical Annual Conference & Expo
- European Pressure Ulcer Advisory Panel Annual Meeting*
- National Pressure Ulcer Advisory Panel Biennial Conference,
- Symposium on Advanced Wound Care Biannual (Spring / Fall) Event*^
- Wound Ostomy and Continence Nurse Annual Conference^

*EAC addition – information on Mepilex/Mepilex border dressings are known to have been published at each of the conferences above. Many other wound conferences exist. All data on Mepilex/Mepilex Border published at any of the above conferences should be included within Molnlycke's internal database. Those conferences noted with a * have a greater global audience,*

whilst those noted with a ^ have had a higher volume of Mepilex/Mepilex Border data presented at them.

Care pathway

10. We understand from Section 3.7 that Mepilex® Border Heel dressing and Mepilex® Border Sacrum dressings are anticipated to be used in addition to existing measures. Please could you describe the additional activities required to incorporate the dressings into standard care (e.g. applying/replacing the dressing, checking the site under the dressing).

    The recommended use of the dressing is summarised in section 3.5 of the sponsor evidence submission and conforms with the algorithm from the WUWHS consensus recommendations (2016) in guiding clinicians on how to use the dressing. These recommendations suggest assessing the skin underneath the dressing at least daily and the dressing should continue to be used until the risk of pressure ulcer development has reduced significantly. The dressing should be applied and changed in line with the product's instructions for use (IFU). The IFU for the products state that the dressing may be left in place for several days 'depending on the condition of the…surrounding skin, or as indicated by accepted clinical practice'. Data on application of the dressing and duration of use varies according to specific pressure ulcer prevention protocols, as detailed in the sponsor evidence submission.

EAC addition – when used within ICU and theatre pathways, the application and removal of dressings as well as the skin inspection would typically be conducted by a nurse (of varying level, but typically mid-level).

11. How long can Mepilex® Border Heel dressing and Mepilex® Border Sacrum dressings be applied for before they require replacing?

    The IFU for the products state that the dressing may be left in place for several days 'depending on the condition of the…surrounding skin, or as indicated by accepted clinical practice'. Data on duration of dressing use varies according to specific pressure ulcer prevention protocols, as detailed in the evidence submission.

Training

12. Please describe any training required to use Mepilex® Border Heel dressing and Mepilex® Border Sacrum dressings including:
    a. Who provides the training

    Training is provided by the Molnlycke Clinical Support Manager and the local Account Manager. There is also the option of additional support from the Molnlycke Pressure Ulcer Prevention Specialist, if required.

b. How long the training takes

Training takes up to a maximum of one hour, dependent on the size of the group. This is established over a set timeframe to maximise attendance of staff, including night staff. The following topics are covered: application of the dressings, utilisation of local guidance on the identification of those patients deemed at risk of pressure injury, and the current SSKIN (pressure-redistributing Support surface, regular Skin inspection, Keep moving [repositioning], management of Incontinence / moisture and optimised Nutrition) bundle.

c. Which clinical staff would be trained (within the UK NHS)

All clinical staff within intensive care units and focus wards receive the training. During the training, a 'champion' to act as a point of contact when Molnlycke personnel are not in attendance is identified.

d. How many staff would be trained per hospital

The goal is to train 85% of clinical staff in those areas where the use of the dressings is implemented.

e. The cost of the training is and who pays for it

The training is provided free by Molnlycke as part of the implementation process.

f. Any ongoing training

The Molnlycke Clinical Support Manager and local Account Manager ensure regular diarised contact and training for new members of the clinical staff.

Economic model

13. Lastly, could we ask some advance questions on what to expect from the economic model?

a. What software will it be written on?

The model will be based on the NICE economic model template.

b. Which comparators will be included within the model (e.g. standard care only)?

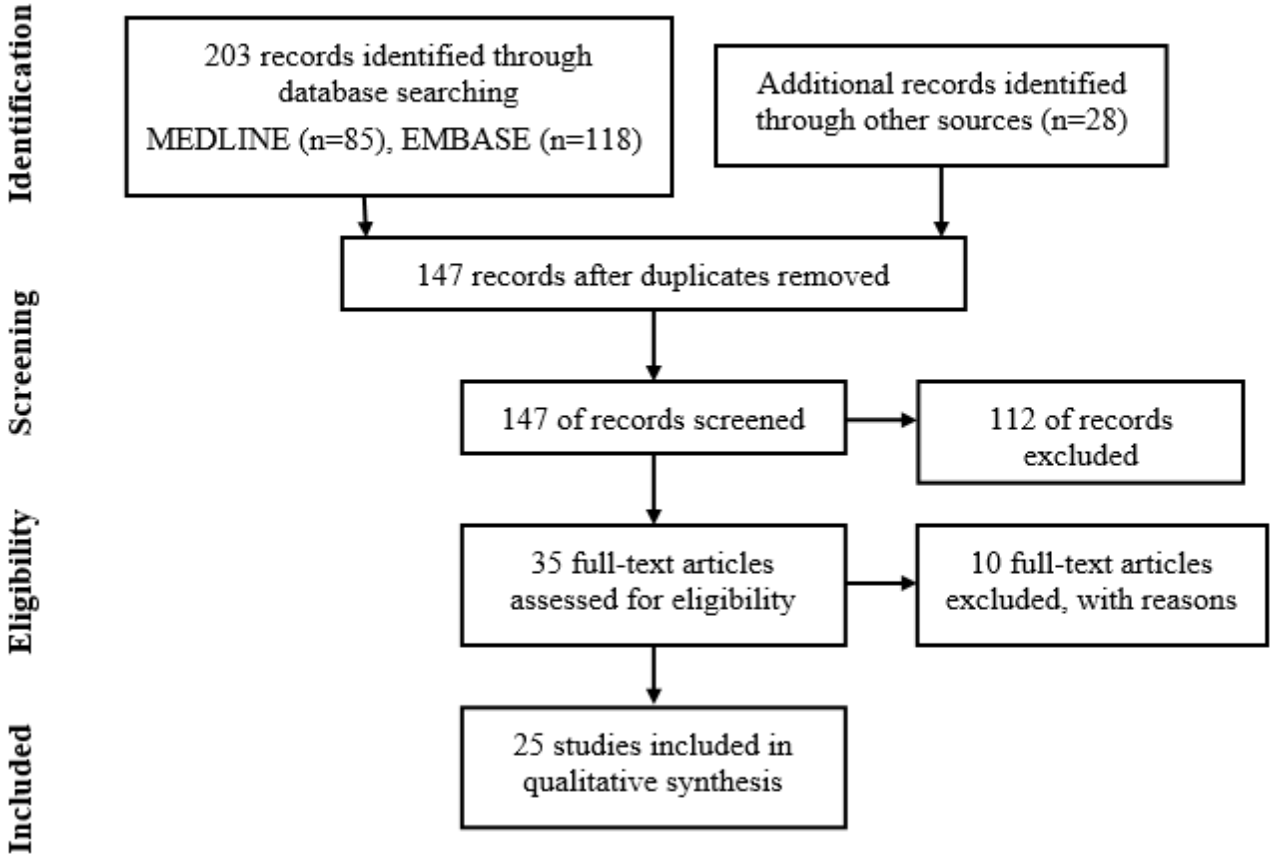
The comparator in the model will be standard care only (prophylactic dressings in the intervention are additive).

c. Will it incorporate sensitivity analysis?

The model will incorporate sensitivity analysis. Deterministic sensitivity analysis will be run on all of the data ranges. Results will be presented as the Base case, Best and Worst case tables as computed by the tool (varying HAPU incidence

associated with the intervention), and the tornado diagram from the tool will display the sensitivity results from all the other data ranges. Additional threshold analysis will be conducted on HAPU incidence to find the cost-saving/cost incurring threshold.

Figure A2: PRISMA flow diagram of included and excluded published studies



Appendix 3 -
Santamaria 2018.pdf

Appendix 4

Question 1. Within the scope issued by NICE, standard care (i.e. pressure ulcer prevention without Mepilex border dressings) is described of comprising the following items. Please could you state which of these elements you use and how frequently? For example, “Skin assessment conducted - once per day in all patients”.

- 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

Lisa Robson **Royal Liverpool and Broadgreen Hospitals**	-Risk assessments. We use a modified waterlow risk assessment for all inpatients. In general the risk assessment is calculated within 6 hours of admission, on clinical change in patients condition or at least weekly. However, in the critical care areas, HDU, ITU etc it is calculated daily. -Skin assessments. This is used in addition to the waterlow however, it is a requirement of our guidelines that a registered health professional inspects the skin of at risk patients at least twice daily. -Repositioning. This is determined on an individual basis however, in general at risk patients are at least 4 hourly and high risk patients are 2 hourly. -all patients admitted to the trust are at least nursed on a high specification foam mattress, however we have alternating cell pressure relieving mattresses and low air loss mattresses for use, some of these are used immediately on admission for some high risk groups. We use high specification foam and alternating cell cushions for chairs. - we do not use any other dressings to prevent pressure ulcers, however we do use other equipment such as parafricta bootees, foam troughs and heelpro offloading devices. - all patients are given a patient information leaflet on admission along with ongoing verbal education regarding management and prevention of pressure ulcers. - we use derma s, Metainium ointment and proshield skin protectants.
Samantha Holloway **Cardiff University School of Medicine**	As I am not in clinical practice anymore I do not feel able to answer this set of questions, but I could ask some of the Clinical Nurse Specialists for Wales to respond if you wish some input on this.
Prof Michael Clark	I am not a clinician but each of the above elements of pressure ulcer prevention should be conducted at regular intervals with the exception of use of dressings to prevent pressure ulcers which is not at present, a routine aspect of prevention.

Fiona Downie - Nurse Consultant Tissue Viability Royal Papworth Hospital NHS Foundation Trust	· Risk assessment with a validated scale (on admission and if high risk daily thereafter, if mod to low x 3/week – Braden score) · Skin assessment (should be carried out daily as per our Trust's SSKIN bundle, but this doesn't always happen in practice) · Frequent repositioning (at least 6 hourly in people considered to be at risk and 4 hourly in people considered to be at high risk) (high/mod risk we advocate 2-4 hourly repositioning, low risk patients are often self-caring so we advocate 4-6 hourly moving around by the patient) · Pressure redistribution using devices such as high specification foam mattress or pressure redistributing cushions. (both used depending, the level of equipment used is based on the clinical assessment of the patient and their current skin integrity) · Other dressings or skin applications to prevent pressure ulcers (rarely use dressings as preventative aids for PUs, but occasionally use them, especially in ITU and respiratory patients, generally around intubation and oxygen use plus CPAP masks) · Information (use patient information sheets for patients with capacity and conscious) · Barrier cream (we use emollients as both prevention and management)
Gillian MacLean, NHS Lothian, Scotland	• Risk assessment with a validated scale: The Waterlow Score is carried out daily on each patient in our critical care. • Skin assessment: Carried out 3-4hrly when pressure area care is performed. (SSKIN/PPURA care bundles can be documented). • Repositioning is carried out routinely during the day at set times, usually3-4 times per shift (6-8 times in 24hrs). If a patient required more frequent repositioning this would happen. • All patients in critical care are nursed on air mattresses/cushions unless their condition doesn't allow for it (spinal patients and proned patients would be care for on foam mattresses). • We don't routinely use dressings on all high risk patients to prevent pressure ulcers, if we think there is high risk/friable skin/evidence of skin deterioration, we may order sacral and heel dressings in especially for that patient. We might apply a dressing over a bony prominence, but there is no set dressing of choice. The decisions made could vary between nurses, depending on preference and experience. We do apply barrier creams and sprays to patients who are incontinent of loose stool, but this is only usually applied once there is evidence of skin deterioration. We do not apply prophylactic moisture/barrier creams, but this will be changing soon and all patients admitted to critical care will have twice daily barrier cream applied.
Elaine Thorpe, UCL NHS Foundation Trust	Assessment should be performed within 1 hour of admission, with regular re-assessments, particularly when new risk factors become apparent and/or the patient's condition deteriorates. There are many standardised risk assessment tools available (e.g., the Waterlow, Braden, or Norton Scales). However, these tools mostly incorporate generic risk factors rather than those specific to critical care. Furthermore, there is no good evidence that use of standardised risk assessment tools affects PU incidence; establishing a culture of active PU prevention with a system of regular assessments using nurses' clinical judgement is more effective on critical care. A validated Quality Improvement tool – SSKIN bundle permits nurses to use professional clinical judgement by encouraging a preventative mindset. S: Skin inspection S: Surface K: keep Moving I: Incontinence N: Nutrition · Skin assessment Skin assessments are carried out top to toe within 1 hour of admission and at least once per shift. Inspection of patient's pressure areas should also take place between staff as part of nursing handovers. If there is a change – a 2 person or even 3 person should agree the change and what category the deterioration is. · Frequent repositioning (at least 6 hourly in people considered to be at risk and 4 hourly in people considered to be at high risk)

	Critically ill patients should be proactively turned 2-3 hourly, placed on alternate sides to avoid the supine position and minimise pressure on 'at risk' areas. If there is skin injury, turn frequency should be increased to a 2 hourly schedule or occasionally more frequent. Similarly, patients admitted following prolonged surgery should be positioned off the sacrum as soon as possible and have high turn frequency even though no obvious damage can be seen. Turn frequency may be decreased when the patient's risk factors reduce or his or her skin is shown empirically to be resilient. A 30-degree tilt position has been recommended as standard practice but increasing this to 60-90 degrees should be feasible and enables the sacrum/coccyx to be completely free from contact with any surface · Pressure redistribution using devices such as high specification foam mattress or pressure redistributing cushions. Patients with multiple risk factors should be prophylactically placed on a high specification (not standard foam) mattress on admission, noting that this alone is not enough to prevent skin injury; the mattress is part of the prevention strategy alongside regular repositioning. Care must be taken with patients sitting out in a chair; the need for a pressure redistributing cushion should be assessed and the time sitting out restricted to 30 minutes on the first few occasions, with the sacrum in particular checked for any potential damage. Other dressings or skin applications to prevent pressure ulcers The risk of shear/friction damage to the skin can be minimised by using aids such as sliding sheets placed under the patient prior to moving, or inflatable lateral transfer systems (Hoverslide). These also reduce the effort in moving patients. Prophylactic dressings over at-risk skin areas can be beneficial; these work by redistributing shear forces, redistributing pressure, reducing friction and maintaining an optimal microclimate (see below for more comments). · Information Pressure ulcer prevention is part of holistic care for any patient but even more so in high risk areas like critical care. Patient and relative involvement of preventing pressure ulcers by means of explanation is critical. · Barrier cream Moisture - in the form of urine, faeces or perspiration – increases the risk of skin injury can lead to superficial injury to the epidermis and/or dermis and is also a risk factor in PU development. This type of damage is commonly referred to as a 'moisture lesion' or as 'incontinence associated dermatitis'. Barrier creams protect the skin from excessive moisture and should be applied as soon as a patient develops incontinence to prevent damage occurring. If moisture damage is severe and other interventions have failed a bowel management system should be considered to prevent faeces causing further damage and to allow skin healing.
Debbie Gleeson, St Helens and Knowsley Teaching Hospitals	· Risk assessment with a validated scale every patient on admission and once weekly, upon condition change pre and post-operative · Skin assessment daily · Frequent repositioning (at least 6 hourly in people considered to be at risk and 4 hourly in people considered to be at high risk) 2hourly · Pressure redistribution using devices such as high specification foam mattress or pressure redistributing cushions. For all patients · Other dressings or skin applications to prevent pressure ulcers Barrier products, foam dressings for at risk areas ie elbows and parafricta booties for heels · Information leaflet on admission · Barrier cream regular applications patient specific times

Question 2. The NICE scope describes the patient population as those at risk or at high risk of pressure ulcers in acute care settings. Which patients populations would you consider falling into the at risk/high risk category (e.g. patients in ICU)?

Lisa Robson Royal Liverpool and Broadgreen Hospitals	AT RISK- All patients admitted to hospital are at risk, clinical judgment is used to compliment the risk assessment tool. We have had patients score as low risk, who then go on to develop pressure ulcers for a variety of reasons. HIGH RISK- High risk includes the following although the reason for admission to the acute trust may not be the primary risk, Bedbound, immobile, diabetic patients, peripheral vascular disease, impaired sensation, dementia, non-concordance, neurological conditions, parkinsonism, tremors, agitated, leg spasm's, leg oedema, some orthopaedic patients, critically unwell patients, patients nursed in areas outside their specialist condition, previous history of ulceration, emaciated patients, terminally ill, bariatric. We tend to specify conditions rather than specific clinical groups of patients as patients nursed in the specialist areas rarely develop pressure ulcers, e.g fractured hip patients don't develop heel ulcers when nursed in orthopaedic as there is a well-established management and operational procedure in place, however, if these patients are nursed outside of orthopaedic area, e.g care of elderly we have seen heel ulcers develop due to delay in implementing guidance.
Samantha Holloway Cardiff University School of Medicine	At risk individuals may be those with: • Reduced mobility / Immobility • Sensory impairment • Acute illness • Decreased level of Consciousness • Extremes of age • Previous history of pressure damage • Vascular disease • Severe chronic or terminal illness / end of life • Malnutrition
Prof Michael Clark	Patients at high risk of developing pressure ulcers are found throughout the NHS with no specific population being at greatest risk
Fiona Downie - Nurse Consultant Tissue Viability Royal Papworth Hospital NHS Foundation Trust	(I work in acute Adult care my at risk group is ITU patients/long theatre times/respiratory patients/emaciated and the very elderly with lots of co-morbidities/heart failure patients – poor perfusion and fluid overload)
Gillian MacLean, NHS Lothian, Scotland	The patient population that I consider to fall into the risk/high risk category are patients with poor mobility/bed bound, critically ill patients and suffering incontinence/moisture.
Elaine Thorpe, UCL NHS Foundation Trust	Critically unwell patients who have multiple risk factors as well as 'general' risk factors, these include: • Catecholamine/vasopressor therapy • Long theatre times/periods of immobility due to instability • Multi-organ failure • Long length of stay on critical care Patients who have low BMI and have bony prominences are at a very high risk of shear/friction injury. Delirious/Agitated patients are also high risk of shear and friction injury.
Debbie Gleeson, St Helens and Knowsley Teaching Hospitals	Itu, Fractured neck of femur, stroke, Parkinson's, dementia, low and high BMI, post-operative, over 80 years, incontinent, those with history of pressure ulcers and those with existing damage, moisture lesions

Question 3. We are aware of the following clinical guidelines in this area: NICE clinical guideline 179, NICE guideline 19, NPUAP guideline, Black 2015, WUWHS Consensus Document. Are you aware of any further key guidelines not included on this list? If so, which ones?

Lisa Robson Royal Liverpool and Broadgreen Hospitals	Yes- National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers: Quick Reference Guide. Emily Haesler (Ed.). Cambridge Media: Perth, Australia; 2014
Samantha Holloway Cardiff University School of Medicine	http://rnao.ca/bpg/guidelines/risk-assessment-and-prevention-pressure-ulcers http://www.woundsaustralia.com.au/publications/#pipm
Prof Michael Clark	No other relevant guidance
Fiona Downie - Nurse Consultant Tissue Viability Royal Papworth Hospital NHS Foundation Trust	(In the UK we follow the EPUAP 2014 guidelines which was developed in collaboration with NPUAP)
Gillian MacLean, NHS Lothian, Scotland	Most guidelines are adapted from the ones listed. There are guides available from Health Improvement Scotland and from the Pressure and Management of Pressure Ulcers Standards. But most are adaptations of NPUAP/EPUAP.
Elaine Thorpe, UCL NHS Foundation Trust	No
Debbie Gleeson, St Helens and Knowsley Teaching Hospitals	No

Question 4. Are you aware of any other widely used assessments/scales other than NPUAP for categorizing/staging pressure ulcer? If so:
• How do they equate to the NPUAP (i.e. are there any important differences between them in assignment of categories, in particular for category I and II)?
• Is the NPUAP the standard assessment method used across the UK?

Lisa Robson Royal Liverpool and Broadgreen Hospitals	We use guidelines adapted from NPUAP/EPUAP 2009, with the Northwest Network of tissue viability nurses to grade/ categorise pressure ulcers. This enables us to recognise potential deep tissue damage. This is used throughout the Northwest of England and I am sure that other UK areas employ similar methods
Samantha Holloway Cardiff University School of Medicine	Clinical practice in Wales is to use the 2014 NPUAP/EPUAP/PPPIA classification system
Prof Michael Clark	The classification within the International Guidelines (NPUAP, EPUAP, PPPIA) is the most widely used in the UK although some sites limit to categories I to IV omitting suspected deep tissue injury and unstageable wounds

Fiona Downie - Nurse Consultant Tissue Viability Royal Papworth Hospital NHS Foundation Trust	Are you aware of any other widely used assessments/scales other than NPUAP for categorizing/staging pressure ulcer? If so: · How do they equate to the NPUAP (i.e. are there any important differences between them in assignment of categories, in particular for category I and II)? See below · Is the NPUAP the standard assessment method used across the UK? (No we use in the UK an adapted EPUAP PU category tool. NHSI have a National project at present looking at English usage PU definitions)
Gillian MacLean, NHS Lothian, Scotland	THE EPUAP is an adaptation of the NPUAP early warning signs and the NPUAP seems to be the standard assessment method used nationally.
Elaine Thorpe, UCL NHS Foundation Trust	No. To my knowledge this is the only standard assessment method used in the UK
Debbie Gleeson, St Helens and Knowsley Teaching Hospitals	· How do they equate to the NPUAP (i.e. are there any important differences between them in assignment of categories, in particular for category I and II)?yes we use northwest tissue viability forums amended version · Is the NPUAP the standard assessment method used across the UK? With adaptions in most areas

Question 5. We would like to understand more about the relationship between blisters and pressure ulcers:
• Can blisters, particularly on heels, develop into pressure ulcers if left untreated?
• Are blisters indicative of a high risk of pressure ulcer development?
• Are patients susceptible to pressure ulcers likely to suffer blisters beforehand?

Lisa Robson Royal Liverpool and Broadgreen Hospitals	It is my opinion that the majority of heel ulcers are caused by friction/ shear rather than direct pressure but can be a combination and one factor will exacerbate the primary aetiology. So some blisters on heels are pressure ulcers see EPUAP guidance.
Samantha Holloway Cardiff University School of Medicine	A blister on the heel is classified as a Category / Stage 2 PU
Prof Michael Clark	There is no evidence that blisters will progress into pressure ulcers and blisters are not indicative of high risk of developing pressure ulcers (think of the effect of new shoes where a blister might develop in a healthy individual not at risk of pressure damage). Patients susceptible to pressure ulcers are not likely to develop blisters before pressure damage.
Fiona Downie - Nurse Consultant Tissue Viability Royal Papworth Hospital NHS Foundation Trust	· Can blisters, particularly on heels, develop into pressure ulcers if left untreated? (It isn't about blisters developing into PUs in areas over a bony prominence, if there is a blister over a heel area this will be as a result of shear and pressure combination. The area will be non-blanching.) · Are blisters indicative of a high risk of pressure ulcer development? (No not on their own, but if over a bony prominence as above this will be a PU if non-blanching. Remember a blister, especially on the heel, can be a superficial grade 2 or a deep tissue injury depending on the appearance of the blister, so blisters on bony prominences are complex things.) · Are patients susceptible to pressure ulcers likely to suffer blisters beforehand? (see above)
Gillian MacLean, NHS Lothian, Scotland	Blisters are graded as category 2 pressure ulcers, blisters occur due to damage of underlying soft tissue from pressure and/or shear, therefore if there is a blister developing this is an early and could further deteriorate.
Elaine Thorpe, UCL NHS Foundation Trust	Blisters are pressure ulcers – Category 2 – (see below for definition). If a blister is present and left untreated/ pressure not relieved/cause not removed then further deterioration to Category 3 or greater could occur.

	Category/Stage II: Partial thickness skin loss involving the dermis, presenting clinically as a shallow blister or an open ulcer with a pink/red wound bed. Yes – once identified pressure injury has already occurred. No - Not all pressure ulcers will present as a blister from the outset.
Debbie Gleeson, St Helens and Knowsley Teaching Hospitals	· Can blisters, particularly on heels, develop into pressure ulcers if left untreated? yes · Are blisters indicative of a high risk of pressure ulcer development? yes friction · Are patients susceptible to pressure ulcers likely to suffer blisters beforehand? Only if the cause is friction and shear related

Question 6. Are you aware of any sources reporting on the baseline risk of pressure ulcers (in at risk/high risk patients) within the NHS acute care setting?

Lisa Robson Royal Liverpool and Broadgreen Hospitals	No
Samantha Holloway Cardiff University School of Medicine	See: http://nhs.stopthepressure.co.uk/ https://www.england.nhs.uk/wp-content/uploads/2016/02/pu-summit-feb16.pdf http://www.nes.scot.nhs.uk/media/3660858/pressure_ulcers_scenario_july_2016.pdf http://www.wales.nhs.uk/sitesplus/888/news/39390
Prof Michael Clark	We reported in BMJ Open last year upon the risk status of all hospital in-patients in Wales (http://bmjopen.bmj.com/content/7/8/e015616). 2044/6957 patients were considered to be at the highest risk of developing pressure ulcers.
Fiona Downie - Nurse Consultant Tissue Viability Royal Papworth Hospital NHS Foundation Trust	The only National reporting mechanisms are Safety Thermometer, which is a point prevalence audit. It isn't a very accurate tool for many reasons but mainly because if the patient is in the organisation for a long period of time they end up on the ST audit every month so effectively counting the PU twice. In addition it doesn't collect avoidability status. The DATIX system is used by a lot of NHS Trusts and this is a more accurate incident count, but I'm not aware that any overall NHS figures come out from this.
Gillian MacLean, NHS Lothian, Scotland	There are several risk assessment tools and care bundles used to try and predict risk and prevent pressure ulcer development, pressure ulcer care forms part of the Scottish Patient Safety programme and is one of the harms of the SPS indicators, there is also the NHS Scotland Pressure Ulcer Safety Cross reporting tool. NHSLothian use a system called MIDAS and this pulls data together from several reporting sources.
Elaine Thorpe, UCL NHS Foundation Trust	No but a large multicentre Study is taking place across Europe on the 15th May 2018 which will be a good indication of actual incidence and data on critically ill patients – the first to my knowledge – see link below. DecubICUs study webpage https://www.esicm.org/research/trials/trials-group-2/decubicus/
Debbie Gleeson, St Helens and Knowsley Teaching Hospitals	Safety thermometer

Question 7. Is it typical for Mepilex border dressing to be applied to multiple sites on a patients (e.g. the sacrum and both heels)?

Lisa Robson Royal Liverpool and Broadgreen Hospitals	Yes
Samantha Holloway Cardiff University School of Medicine	As I am not in clinical practice anymore I do not feel able to answer this set of questions, but I could ask some of the Clinical Nurse Specialists for Wales to respond if you wish some input on this.
Prof Michael Clark	Where used the dressing may be applied to sacrum and heels
Fiona Downie - Nurse Consultant Tissue Viability Royal Papworth Hospital NHS Foundation Trust	(We have only trialled it on patient heels in a very specific group of ITU patients)
Gillian MacLean, NHS Lothian, Scotland	We currently do not use mepilex border dressings, but it would not be uncommon to apply pressure relieving dressings to heels, the sacrum and/or bony/friable areas deemed at risk or with signs of pressure damage/skin deterioration. We would order pressure relieving dressing in for patient specific use.
Elaine Thorpe, UCL NHS Foundation Trust	I can mostly comment on the use of Mepilex Border Dressing to be used on sacrum in all our Critical Care Patients. However on low BMI agitated patients it is applied to elbows, hips and heels.
Debbie Gleeson, St Helens and Knowsley Teaching Hospitals	No foams used no one has any specific pressure relieving characteristics. We 3m foam for some areas, ie ankles, knees and elbows as a preventive method, mepilex not on our current formulary was on previous formulary.

Question 8. Checking skin under Mepilex border dressing:
• How frequently is the skin checked?
• How long does this check take?
• What grade of nurse would typically undertake the check?

Lisa Robson Royal Liverpool and Broadgreen Hospitals	If mepilex border dressings are in use for management or prevention of pressure ulcers they are inspected and replaced daily. The length of time varies on what is beneath the dressing and how many dressings are in use. It is our policy that registered nurse band 5 or above would check beneath dressings, however, some band 4s are also competent.
Samantha Holloway Cardiff University School of Medicine	As I am not in clinical practice anymore I do not feel able to answer this set of questions, but I could ask some of the Clinical Nurse Specialists for Wales to respond if you wish some input on this.
Prof Michael Clark	It is recommended that checking the skin is undertaken daily, the check should take only a few minutes. I have no information upon which grade of nurse would undertake this practice.
Fiona Downie - Nurse Consultant Tissue Viability Royal Papworth Hospital NHS Foundation Trust	Checking skin under Mepilex border dressing: (For us this would be as above with regard to site and patient group and: · How frequently is the skin checked? (At each reposition change) · How long does this check take? (approximately a minute max) · What grade of nurse would typically undertake the check? (band 5 and above)
Gillian MacLean, NHS Lothian, Scotland	I am aware that Mepilex border dressings can be repositioned and they re-stick, we would only take down the dressings we use if it was soiled or wrinkled up. We would leave in position for 5-7 days if intact (most dressings on the sacrum are soiled and changed daily, therefore skin would be checked frequently). Frequency of checks is

	down to individual nurse's knowledge and understanding of the dressing. A skin check would be done during pressure area care, which takes place 3-4 hourly and would probably only add a minute or so on to the task. It could be any grade of qualified nurse that would undertake the checks in our clinical area.
Elaine Thorpe, UCL NHS Foundation Trust	At least once per shift and then reapplied. If there is damage occurring checking the condition of the skin will be performed more frequently as 3 – 4 hourly. It takes seconds to pull back the condition of the sacrum (or other) and reapply. There is no increase in workload for nurses All nursing staff are trained to do this so it can be from Band 5 – 8 but we also involve nursing assistants and student nurses too.
Debbie Gleeson, St Helens and Knowsley Teaching Hospitals	· How frequently is the skin checked? As per care plan individual to patient · How long does this check take? seconds · What grade of nurse would typically undertake the check? all grades primarily care assistants

Question 9. Changing the dressing:
• How frequently is the dressing changed?
• How long does changing the dressing take?
• What grade of nurse would typically change the dressing?

Lisa Robson Royal Liverpool and Broadgreen Hospitals	See above
Samantha Holloway Cardiff University School of Medicine	As I am not in clinical practice anymore I do not feel able to answer this set of questions, but I could ask some of the Clinical Nurse Specialists for Wales to respond if you wish some input on this.
Prof Michael Clark	It is recommended that the dressing be changed every 3-4 days.
Fiona Downie - Nurse Consultant Tissue Viability Royal Papworth Hospital NHS Foundation Trust	(For us this would be as above with regard to site and patient group and: · How frequently is the dressing changed? (if it deteriorates in its condition or is at its recommended wear time) · How long does changing the dressing take? (a few minutes max if it is on intact skin) · What grade of nurse would typically change the dressing? (band 5 and above)
Gillian MacLean, NHS Lothian, Scotland	Most dressings can be left on for 5-7 days if they remain clean and intact, if soiled we change them as frequently as is needed. If we use heel pressure relieving dressings, skin can be viewed anytime as not secured to skin and this would be done during pressure area care or at least once per shift. A dressing change only takes a few minutes, any grade of nurse could change the dressing or a care support worker could also apply it under a qualified nurses supervision.
Elaine Thorpe, UCL NHS Foundation Trust	The dressing can stay in place up to 3 days and so is changed prn. When used for prophylaxis the dressing change will take only a few seconds. It is usually changed when the patient is being turned (position change). All nursing staff are trained to do this so it can be from Band 5 – 8 but we also involve nursing assistants and student nurses too.
Debbie Gleeson, St Helens and Knowsley Teaching Hospitals	· How frequently is the dressing changed? When becomes loose or displaced · How long does changing the dressing take? minutes · What grade of nurse would typically change the dressing? All grades