Appendix B: Stakeholder consultation comments table

2018 surveillance of Pressure ulcers: prevention and management (2014)

Consultation dates: 28 September to 11 October 2018

Do you agree with the proposal not to update the guideline?			
Stakeholder	**Overall response**	**Comments**	**NICE response**
Frontier Medical Group	No	We strongly recommend you consider a new investigator initiated trial (IIT) performed at Ghent University (Prof. Beeckman) (https://clinicaltrials.gov/ct2/show/NCT03597750) reporting the difference in effectiveness of applying the concept of static air support surfaces versus alternating air support surfaces to prevent pressure ulcers in a high risk population. This trial was designed as a prospective, multicentre, randomised controlled clinical study. The research was done in 26 nursing homes in Belgium. We believe that this study gives good evidence to conclude that applying the concept of static air is significantly more effective compared to applying alternating air to prevent pressure ulcers in a high risk population. Repositioning is to be applied at all times. Over a follow- up period of 14 days, a significantly lower pressure ulcer Cat. II-IV incidence was found in the static air support surface group (n=8/154, 5.2%) compared to the alternating air group (n=18/154, 11.7%) (p=0.04). Besides, there was an impact on time to develop of pressure ulcers	Thank you for your comment. We will add this study to our database of ongoing research and examine the results and any potential impact on the guideline when published. Please also feel free to contact NICE with your published results when available.

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

		and cost at organisational level, both in favour of the static air group. Because of the particularly important evidence about effectiveness and important economic differences between the two concepts under study, we suggest you review the study and to re- consider revising the recommendations in the support surfaces section. The study is now being considered for publication in a peer-reviewed journal, but the research team at Ghent University (Belgium) will be pleased to share the results with the NICE review team.	
Pennine Care NHS Foundation Trust	No	We think the decision not to update hasn't taken into consideration the following report: NHS Improvement 2018. Pressure ulcers: revised definition and measurement. Available from https://improvement.nhs.uk/resources/pressure-ulcers-revised-definition-and-measurement-framework/ This document refers to terminology and states that the word category should be used. Currently CG179 refers to 'grade' in recommendation 1.4.15 and 1.4.24. The terms 'stage and grade' in recommendation 1.5.20	Thank you for your comment. We have examined the document from NHS Improvement that you refer to: Pressure ulcers: revised definition and measurement framework We will align the terminology in NICE guideline CG179 with that preferred by NHS Improvement. Namely we will change the term 'grade' to 'category' to in recommendations 1.4.15, 1.4.24 and 1.5.20. We will also add a cross-reference from NICE guideline CG179 to the NHS Improvement document in order that healthcare professionals are aware of the latest recommendations from the NHS to consistently define and measure pressure ulcers.
Tissue Viability Society	Yes	With regard to risk assessment tools – there is good evidence for PURPOSE T and I would ask that is added to the list of recommended tools.	Thank you for your comment. We included the study by Nixon et al. (2015) in the current surveillance review. We noted that the National Institute for Health

		Nixon et al 2015 Pressure UlceR Programme Of reSEarch (PURPOSE): using mixed methods (systematic reviews, prospective cohort, case study, consensus and psychometrics) to identify patient and organisational risk, develop a risk assessment tool and patient-reported outcome. Quality of Life and Health Utility measures. Programme grants for applied research Volume 3 issue 6 September 2015. Issn 2050-4322. Coleman et al 2018. Clinical evaluation of a new pressure ulcer risk assessment instrument, the Pressure Ulcer Risk Primary or Secondary Evaluation Tool (PURPOSE T). Journal of Advanced Nursing DOI: 10.1111/jan.13444 Vol 7 402-424	Research (NIHR) has analysed this study and concluded that further and ongoing evaluation of PURPOSE-T is needed. Other stakeholders responding to this consultation also agreed with this position. The study by Coleman et al. (2018) that you highlight also concluded that further study is needed to evaluate the impact of using the instrument on care processes and outcomes. Although the PURPOSE-T tool may have advantages over current assessment tools, we believe it is appropriate to await further evidence before considering it as a recommended tool.
Oxford University Hospitals NHS Foundation Trust	Yes	Reviewing the Surveillance document all aspects have been addressed or further recommendations are detailed.	Thank you for your comment.
City Health Care Partnership Community Interest Company	Yes	In relation to the Purpose T we agree that further evaluation is needed in relation to its reliability as well as the impact the tool has on decision-making and pressure ulcer incidence in practice. Locally we have explored the use of a validated tool across acute and primary care to ensure a seamless transition of patient care.	Thank you for your comment. We agree that further evaluation of the PURPOSE-T tool is needed. We have examined the document from NHS Improvement that you refer to: Pressure ulcers: revised definition and measurement framework We will align the terminology in NICE guideline CG179 with that preferred by NHS Improvement. Namely we will change the term 'grade' to 'category' in recommendations 1.4.15, 1.4.24 and 1.5.20.

		We are implementing the recommendations of the NHSI "Pressure ulcers: revised definition and measurement, summary and recommendations, June 2018" to develop and implement a consistent approach to assessment, diagnosis and treatments, guidelines and procedures (benchmark national and local / NHSE.).	We will also add a cross-reference from NICE guideline CG179 to the NHS Improvement document in order that healthcare professionals are aware of the latest recommendations from the NHS to consistently define and measure pressure ulcers.
3M UK Plc	Yes	• We strongly recommend to consider new evidence about the association between Moisture-Associated Skin Damage (MASD) (inflammation and/or skin erosion caused by prolonged exposure to various sources of moisture such as urine, stool, sweat, wound drainage, saliva, or mucus) and pressure ulcer development (including device related pressure ulcers). We also recommend reviewing the research reporting the effectiveness of various products and procedures for MASD prevention and treatment (and particularly skin damage caused by incontinence) published during the last five years. This research could have a significant impact on any best practice recommendations and guideline statements. Research published between 2013 and 2018 (so not considered in the 2014 NICE pressure ulcer guidelines) conclude to minimise skin exposure to urine and stool and to develop and implement a consistent regimen of skin care to protect the integrity of the skin barrier, including cleansing, moisturising and use of a skin protectant to minimise the risk of any MASD and associated pressure ulcer development in at-risk patients. Various primary research sources and a Cochrane systematic review in 2016 conclude the	Thank you for your comment. We note that you refer to new research published between 2013 and 2018. We conducted a formal evidence search for the current surveillance review from 28 August 2013 to 9 July 2018. Additionally we ask topic experts to send us any new evidence they are aware of that has published since the original guideline searches were conducted. We therefore believe that we have included the key studies from this time period. No evidence was identified for barrier films. Regarding the specific issue of moisture-associated skin damage that you raise. We identified a systematic review that found an association between incontinence and pressure ulcers. The guideline recommends that skin assessments for adults at high risk of pressure ulcer should check for variations in moisture (for example, because of incontinence) and therefore already acknowledges the risk noted in the new evidence. The guideline also recommends considering using a barrier preparation to prevent skin damage in adults who are at high risk of developing a moisture lesion or incontinence-associated dermatitis, and using barrier preparations to help prevent skin damage, such as moisture lesions, for neonates, infants, children and young people who are incontinent.

		implementation of these recommendations in clinical practice. If actions can be taken to address the corresponding incontinence, these should be considered while steps are taken to implement a skin care regimen to protect the skin from continued irritation. After the skin has been properly cleansed and moisturised, a skin barrier should be applied to protect the affected skin from further exposure. Any secondary infection of the affected area should be treated topically. In some cases, a containment or diversion device may be indicated. Research reporting the effectiveness of barrier films [defined as liquids containing a polymer (e.g. acrylate based) dissolved in a solvent, forming a transparent protective coating on the skin] and new elastomeric skin protectants (defined as a liquid containing cyanoacrylates and tetrapolymers dissolved in a solvent system) is emerging and should be considered as potential interventions with effective outcomes in MASD management and associated pressure ulcer prevention. Because of the evidence about the economic impact of MASD and associated pressure ulcer development, we strongly suggest to review the evidence since 2013 and to re- consider the decision not to revise the recommendations in the skin assessment/care section of the current guidelines.	We did not therefore believe there was any impact on the guideline.
The Whiteley Homes Trust	Yes	This guideline covers each area of pressure area management comprehensively.	Thank you for your comment.

Willingsford Ltd.	No	Please see below.	Thank you for your comment. Please see our response to your comments in the next section.
Royal College of Paediatrics and Child Health		We have not received any responses for this consultation	Thank you for your comment.
Royal College of Nursing		Nurses caring for people with Pressure ulcers have reviewed the proposal and have no comments to submit at this stage.	Thank you for your comment.
Ideogeniq	Yes	Thank you for allowing Ideogeniq / Xodus Medical to comment. We agree that the guidance doesn't require any further updating. We would like to add that under the current recommendations Pressure redistributing devices 1.1.14 : consider a high – specification foam theatre mattress or an equivalent pressure redistributing surface for all adults who are undergoing surgery, should include children and young people. We would recommend to clarify the definition of a "high specification foam matrass" by providing specifications of a high specification foam matrass, which could include the following : • The rate of recovery is in the range of approximately 10-35 seconds for 100 percent recovery after deformation caused by placing an adult torso on an approximately one-inch thick layer of viscoelastic foam.	Thank you for your comment. The recommendations about high-specification foam mattresses for children and young people are less specific on settings than the recommendations in adults. Namely, high-specification foam is recommended for all children and young people who have been assessed as being at high risk of developing a pressure ulcer as part of their individualised care plan. This therefore covers using a high specification mattress in surgery. Regarding the definition of a high-specification foam mattress, the Guideline Committee works with evidence identified by the guideline developers, which consisted of a variety of different high-specification mattress types. The committee were therefore unable to be highly specific about the nature of mattresses and therefore used the term 'high-specification foam mattress' (which is also used by the NPUAP/EPUAP/PPPIA guideline) Regarding the Pink Pad product – this is a high specification foam mattress therefore is covered by the recommendations for high-specification foam mattresses in the guideline. We found no

		• The coefficient of static friction between the viscoelastic foam and the surface of a support table is greater than 0.2, or is in the range of approximately 0.2 or 0.5 to approximately 0.7 or 1.0. • The airflow in or through the viscoelastic foam is in the range of tenths of a cubic foot per minute to several cubic feet per minute • The thickness of the viscoelastic foam is in the range of from three-fourths of an inch to one inch, or to approximately one inch, or to one and a half inches, or to three inches or greater, which thickness is selected to minimize and/or prevent bottoming out on the operating table of one or more of the portions of the body • The tensile strength (at 25 percent deflection) of the viscoelastic foam is in the range of at least approximately 5 pounds per square inch (PSI) or approximately 8 PSI to approximately 12 PSI or approximately 15 PSI, or is in the range of approximately 10 PSI. • The tear strength (in a twenty inches per minute test) of the viscoelastic foam is in the range of approximately one to approximately two or three pounds of force per inch, or in the range of approximately 1.5 pounds of force per inch. • The nominal density of the viscoelastic foam is in a range of approximately 100 kilograms per cubic meter We would also like to bring to your attention a product called Pink Pad see link www.xodusmedical.com which has been on the market for 6 years, with more than 1 million	evidence in the current surveillance review specifically concerning this product.

		units sold worldwide. The pink Pad is designed to prevent pressure sores from happening in the operating theatre. This high specification foam mattress prevents patients from sliding and therefore reduces the risk of pressure sores and ulcers.	
British Association of Dermatologists		No comment	Thank you for your response.
British Healthcare Trades Association (BHTA)	No	There is reference throughout this guideline to using a 'high-specification mattress' (for example in 1.1.13) and in 1.4.10 the document refers to a 'standard specification foam mattress'. When this term was first used there was a contract NHS 'marble print' mattress, which may have been assumed was a standard foam mattress. The penultimate paragraph of page 29 refers to high-specification foam mattresses as being adequate. BHTA has been working on trying to define what a prescriber might look at as 'high specification' and as yet has not been able to agree on any definition or group of definitions. What is a 'high spec' for one patient is not 'high spec' for another. There is a guidance document 'What Lies Beneath' under development, which considers the equal importance of the support surface materials for skin health, with the materials below the surface. The term 'high-specification foam' is at best inadequate, and at worst, misleading. 'Pressure re-distributing surface' would overcome the focus on an undefined (and restrictive) 'specification'.	Thank you for your comment. The Guideline Committee works with evidence identified by the guideline developers, which consisted of a variety of different high-specification mattress types. The committee were therefore unable to be highly specific about the nature of mattresses and therefore used the term 'high-specification foam mattress' (which is also used by the NPUAP/EPUAP/PPPIA guideline)

Leeds Community Healthcare NHS Trust	No	I feel the definition should be linked to the EPUAP definition The EPUAP references need updating Is it possible to link heel ulcers to the diabetic foot, and lower limb PAD guidelines where relevant Could Purpose T be added as a validated risk assessment tool? The term 'confined' in the introduction implies an inability to move rather than reduced mobility, or choosing not to mobilise. Also awaiting publication of Pressure2 trial- unsure when this will be but certainly relevant.	Thank you for your comment. Regarding definitions, we have examined a document from NHS Improvement: Pressure ulcers: revised definition and measurement framework We will align the terminology in NICE guideline CG179 with that preferred by NHS Improvement. Namely we will change the term 'grade' to 'category' in recommendations 1.4.15, 1.4.24 and 1.5.20 We are proposing the following editorial amendment to the guideline to address the issue of outdated NPUAP-EPUAP references: 'CG179 recommendations 1.4.3 and 1.5.3 refer to the International NPUAP-EPUAP [2009] Pressure Ulcer Classification System. This has had 2 revisions since 2009 therefore the reference to a specific year will be deleted.' Regarding heel pressure ulcers. We will make editorial amends to add your additional suggestions for cross-references. We examined a study of PURPOSE-T by Nixon et al. (2015) in the current surveillance review. We noted that the National Institute for Health Research (NIHR) has analysed this study and concluded that further and ongoing evaluation of PURPOSE-T is needed. Other stakeholders responding to this consultation also agreed with this position. Although the PURPOSE-T tool may have advantages over current assessment tools, we believe it is appropriate to await further evidence before considering it as a recommended tool. Regarding the term 'confined'. This term is used in the first paragraph of the introduction to describe people in whom pressure ulcers typically occur. However the second paragraph goes on to note that all patients are potentially at risk of developing a pressure ulcer, but 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. Therefore the risk factors in the introduction are wider than patients 'confined' to bed or a chair and cover many different at-risk groups. Regarding the Pressure2 trial. We are aware of this study and it is logged on our database of ongoing research. We will examine the results and any potential impact on the guideline when published.

Are you aware of any further evidence on medical device-related pressure ulcers that we have not already considered in the current surveillance review? (Ideally evidence should be from the last 10 years).			
Stakeholder	**Overall response**	**Comments**	**NICE response**
Frontier Medical Group	No	No comments provided	Thank you for your answer.
Pennine Care NHS Foundation Trust	No	No comments provided	Thank you for your answer.
Tissue Viability Society	No	No comments provided	Thank you for your answer.
Oxford University Hospitals NHS Foundation Trust	No	No comments provided	Thank you for your answer.
City Health Care Partnership Community Interest Company	No	No comments provided	Thank you for your answer.
3M UK Plc	No	No comments provided	Thank you for your answer.

The Whiteley Homes Trust	No	No comments provided	Thank you for your answer.
Willingsford Ltd.	Yes	Acapsil is a novel first-in-class wound dressing based on micropore particle technology (MPPT). MPPT consists of small highly porous particles. The physical properties of these particles result in a system that by passive capillary evaporation removes exudate on the wound surface. This micro-pumping process in parallel removes the toxins and enzymes bacteria and fungi secrete into the wound to inhibit the immune cells and it creates holes in the biofilm that bacteria and fungi secrete as a shield against the immune cells. The result is that MPPT disrupts the weaponry of bacteria and fungi, whereby the immune cells regain their ability to selectively remove bacteria and fungi and becomes able to create the balance the immune system seeks in the microbiome, i.e. the ecosystem of bacteria, fungi, viruses and mites that live on our external surfaces and form part of our protection against the outside environment. It is unbalances in this microbiome that interfere with healing and is expressed as infection. Newer data have shown that the skin has its own dedicated immune system, which demonstrates the importance of this barrier for protecting the integrity of the body (1). The micro-pumping effects of MPPT automatically stop when the excess exudate has been removed and the particles will retain a certain moisture levels, thus preventing over-drying of the wound surface.	Thank you for your comment. Regarding the items of evidence you have supplied: 1. Abdallah (2017) This is a non-systematic review of aetiology and is not relevant to include in the surveillance review. 2. Bilyayeva (2017) The types of ulcers included in this study are not specifically relevant to NICE guideline CG179. 3. Ryan (2017) This included only a single pressure ulcer, and also no numerical data was reported in the abstract. It is therefore not suitable to include in the surveillance review. YouTube video reference: This included only a single pressure ulcer and videos are not a suitable evidence type for inclusion in a surveillance review. 4. Lovgren (2018) Posters are not a suitable evidence type for inclusion in a surveillance review. 5. Walker (2017) This Cochrane review was included and examined in the current surveillance review. It was deemed not to impact the guideline. See Appendix A Evidence summary for our statement about the review. 6. Westby (2017) This Cochrane review was included and examined in the current surveillance review. It was deemed not to impact the guideline. See Appendix A Evidence summary for our statement about the review. 7. Leaper (2015) This is a non-systematic review and is not relevant to include in the surveillance review.

		MPPT has no antimicrobial effects, but it has repeatedly been seen to remove wound infections and facilitate the healing of difficult wounds – including wounds that did not respond to standard antimicrobials, NPWT, honey and absorbent dressings. As MPPT lacks antimicrobial effects, its use will not lead to the generation of resistance and its effects will not be limited by resistance. A review of MPPT, its mode-of-action and its use in wound healing has been accepted for publication in the US journal WOUNDS and is scheduled to appear in their November issue: "Sams-Dodd J, Sams-Dodd F (2018) Time to abandon antimicrobial approaches in wound healing – a paradigm shift. WOUNDS, in press." (This has now published) MPPT has been evaluated in a comparative clinical study with 266 patients covering a range of wound types (2). The study found that the use of MPPT resulted in an infection-free and healing wound 60% quicker compared to a topical antibiotic (gentamicin) and an antiseptic (iodine) and that MPPT on average reduced the number of hospitalisation days by 31%. The reduction in hospitalisation days by MPPT compared to gentamicin was 41% for acute wounds (includes dehisced surgical wounds, abscesses and carbuncles), 31% for diabetic foot ulcers and 19% for venous leg ulcers.	8. Zhai (2007) This is outside the search window of the current surveillance review, There is also no data in the abstract and it included some animal studies. It is not relevant to include in the surveillance review. 9. Park (2016) This is an animal study and is not relevant to include in the surveillance review. 10. Jørgensen (2017) This is an animal study and is not relevant to include in the surveillance review. Sams-Dodd (2018) This is a non-systematic review, and the evidence on pressure ulcers is from single case studies (including an animal). It is therefore not relevant to include in the surveillance review. Regarding your comment that it would seem relevant in a revised guideline to mention these newly reported limitations regarding moist wound care. The current surveillance review identified 2 RCTs showing benefit of moist dressings, which agrees with the guideline recommendation to consider using a dressing that promotes a warm, moist wound healing environment to treat grade 2, 3 and 4 pressure ulcers.

		A clinical audit was performed at Bristol University Hospital, covering 9 acute dehisced surgical wounds and 1 category 4 pressure ulcer (3). MPPT was able to induce a clean healing wound in 3-5 days. All wounds reached closure. Standard-of-care at the hospital is 1 week with UrgoClean followed by 2 or more weeks with NPWT to reach the same state of healing as was achieved by 3-5 days with MPPT. Health economic calculations indicate that MPPT resulted in savings of 67% to reach the healing wound state, when compared to the 1 week with UrgoClean and 2 weeks with NPWT. With respect to the category 4 pressure ulcer, several treatment approaches had already been tried but without success before the use of MPPT. MPPT was used in community care on a 9-week-old deep pressure ulcer with two sinuses and undermining. Hydrogel, Manuka honey and Flaminal Forte had been tried and failed. MPPT was after 3 applications able to advance the ulcer towards healing. Estimated savings were 89%. A short video is available on youtube: https://www.youtube.com/channel/UCdY3srLHCM9sKGvzd8LT31w. MPPT has been used on additional acute and chronic pressure ulcers in the UK and comparable effects have been reported.	

		MPPT has also demonstrated positive effects in other wound types, e.g. a pilonidal sinus, which was not responding to anything; acute and chronic venous leg ulcers; a 3-year-old diabetic foot ulcer; and a 35-year-old radiation induced abscess. Lovgren et al. (2018) presented a poster on MPPT in 3 cases of stable, inactive pyoderma gangrenosum ulcers at the British Association for Dermatology meeting in Edinburgh July 3-5 (4). In all 3 cases, once daily application of MPPT for 5 consecutive days led to a change in the ulcer such that they continued to improve even after 2-3 months after application. In one case, it was possible to reduce the dose of immunosuppressant. For case stories, please see: www.acapsil.com/en-gb/ MPPT has not been associated with any wound irritation or allergy. It has been used directly on exposed tendon and bone and for prolonged periods of time. In summary, MPPT has demonstrated the ability to advance the healing of wounds and ulcers, including acute and chronic pressure ulcers. It does not rely on any antimicrobial actions and it will consequently not contribute to the generation of AMR. The current guideline on pressure ulcers advise healthcare professionals to consider using moist wound healing principles in the treatment of category 2-4 pressure ulcers. However, two very recent Cochrane publications (5,6) did	

		not find evidence of efficacy in the treatment of pressure ulcers using this approach. Furthermore, Leaper et al. (7) in a review of chronic ulcers stated: “Infection is the likeliest single cause of delayed healing in healing of chronic open wounds by secondary intention”. This statement will extend to pressure ulcers and newer evidence has shown that moist conditions are likely to exacerbate an infection (8,9,10). The use of moist wound healing in wounds, where there is any risk of an underlying infection – which will be the case if the wound is not healing normally – is therefore likely to exacerbate the condition. The existing 2014 guideline recommends healthcare professionals to consider the use of moist wound care for the treatment of category 2, 3 and 4 pressure ulcers. However, as reviewed above, newer studies from 2016-2017 have reported limited effects of moist wound care in pressure ulcers and that moist wound care is associated with a risk of exacerbating any existing infection - which is likely to be present if the ulcer is not healing, as concluded by Leaper et al. (2015). In light of this new knowledge, it would seem relevant in a revised guideline to mention these newly reported limitations regarding moist wound care and in parallel to mention the existence of MPPT as a novel approach that in a large clinical study and in a clinical audit has demonstrated positive effects on wound healing and that has been able to support the healing of acute and chronic pressure ulcers.	

		Efforts to obtain additional data on pressure ulcers are ongoing, but will necessarily take time. However, given the paucity of positive data in this field, it seems relevant to mention MPPT as it has been able to support the healing of ulcers that had not responded to other approaches. MPPT has not been associated with any adverse events and when considering that moist wound care has not been shown to be effective against infected to critically colonised wounds and that an open pressure ulcer exposes the patient to an increased risk of cellulitis, septicaemia and osteomyelitis, it must from a risk-based perspective be valid to try MPPT rather than to continue with an approach known to have limited efficacy and which may worsen an infection. Based on these risk considerations, it would be appropriate to mention MPPT in the new guideline. 1. Abdallah F, Mijouin L, Pichon C. Skin Immune Landscape: Inside and Outside the Organism. Mediators Inflamm. 2017;2017:5095293. doi: 10.1155/2017/5095293. Epub 2017 Oct 18. 2. Bilyayeva, O.O; Neshta, V.V., Golub, A.A; Sams-Dodd, F. Comparative Clinical Study of the Wound Healing Effects of a Novel Micropore Particle Technology: Effects on Wounds, Venous Leg Ulcers, and Diabetic Foot Ulcers. Wounds. 2017 Aug;29(8):1-9. Epub 2017 May 25.	

		3. Ryan E. The use of a micropore particle technology in the treatment of acute wounds. J Wound Care. 2017 Jul 2;26(7):404-413. doi: 10.12968/jowc.2017.26.7.404. 4. Lovgren M-L, Wernham A, James M, Martin-Clavijo A (2018) Pyoderma gangrenosum ulcers treated with novel micropore particle technology. Br.J.Dermatol. 179 (Suppl. 1):BI22, p. 152. 5. Walker RM, Gillespie BM, Thalib L, Higgins NS, Whitty JA. Foam dressings for treating pressure ulcers. Cochrane Database Syst Rev. 2017 Oct 12;10:CD011332. doi: 10.1002/14651858.CD011332.pub2. 6. Westby MJ, Dumville JC, Soares MO, Stubbs N, Norman G. Dressings and topical agents for treating pressure ulcers. Cochrane Database Syst Rev. 2017 Jun 22;6:CD011947. doi: 10.1002/14651858.CD011947.pub2. 7. Leaper D, Assadian O, Edmiston CE. Approach to chronic wound infections. Br J Dermatol. 2015 Aug;173(2):351-8. doi: 10.1111/bjd.13677. Epub 2015 Mar 15. 8. Zhai H and Maibach JI (2007) Effect of Occlusion and Semi-occlusion on Experimental Skin Wound Healing: A Reevaluation. WOUNDS 19(10) https://www.woundsresearch.com/article/7894	

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		9. Park E, Long SA, Seth AK, Geringer M, Xu W, Chavez-Munoz C, Leung K, Hong SJ, Galiano RD, Mustoe TA. The use of desiccation to treat Staphylococcus aureus biofilm-infected wounds. Wound Repair Regen. 2016 Mar;24(2):394-401. doi: 10.1111/wrr.12379. Epub 2015 Dec 10. 10. Jørgensen E, Bay L, Bjarnsholt T, Bundgaard L, Sørensen MA, Jacobsen S. The occurrence of biofilm in an equine experimental wound model of healing by secondary intention. Vet Microbiol. 2017 May;204:90-95. doi: 10.1016/j.vetmic.2017.03.011. Epub 2017 Mar 9.	
Royal College of Paediatrics and Child Health	Not answered	No comments provided	Thank you for your response.
Royal College of Nursing	Not answered	No comments provided	Thank you for your response.
Ideogeniq	Yes	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4845766/	Thank you for your comment. The article you provide a link to is a guideline. Surveillance reviews do not consider guidelines.
British Association of Dermatologists	Not answered	No comments provided	Thank you for your response.

British Healthcare Trades Association (BHTA)	See comments	The NICE guidance is derived from the evidence of expensive RCTs. Currently MHRA guidance around MDR requirements for CE marking for 'clinical' evidence allows for the use of standard-based testing etc. The NICE guidelines would be better informed if it were to broaden its basis for evidence.	Thank you for your comment. The MHRA has a different remit to NICE and CE marking requires a different approach to guidelines. NICE recognises a hierarchy of evidence and uses the most appropriate evidence in differing circumstances. RCTs are the gold standard for effectiveness, but other study types may be used to answer review questions about, for example, diagnostic tests. Where RCTs weren't available to answer review questions where they had been deemed the most suitable evidence type, the guideline allowed other study types such as cohort studies.
Leeds Community Healthcare NHS Trust	No	No comments provided	Thank you for your answer.

Do you have any comments on areas excluded from the scope of the guideline?

Stakeholder	Overall response	Comments	NICE response
Frontier Medical Group	No	No comments provided	Thank you for your answer.
Pennine Care NHS Foundation Trust	No	No comments provided	Thank you for your answer.
Tissue Viability Society	Yes	NHSI has published recommendations for measuring and reporting PU that includes medical device related and moisture associated skin damage, Has this guidance been reviewed?	Thank you for your comment. We have examined the document from NHS Improvement that you refer to: Pressure ulcers: revised definition and measurement framework

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		Heel pressure ulcers- no mention of potential link to NICE guidelines on Diabetic foot or Lower limb PAD.	We will align the terminology in NICE guideline CG179 with that preferred by NHS Improvement. Namely we will change the term 'grade' to 'category' in recommendations 1.4.15, 1.4.24 and 1.5.20. We will also add a cross-reference from NICE guideline CG179 to the NHS Improvement document in order that healthcare professionals are aware of the latest recommendations from the NHS to consistently define and measure pressure ulcers. Regarding heel pressure ulcers. We will make editorial amends to add your additional suggestions for cross-references.
Oxford University Hospitals NHS Foundation Trust	No	No comments provided	Thank you for your answer.
City Health Care Partnership Community Interest Company	No	No comments provided	Thank you for your answer.
3M UK Plc	No	No comments provided	Thank you for your answer.
The Whiteley Homes Trust	Yes	Management in Adults is covered but that age group is wide ranging. We were wondering if frail older people 80+ should be a separate category since the aging process increases surveillance of skin integrity in this group.	Thank you for your comment. No evidence was found about this issue by the current surveillance review. The Waterlow score (1 of 3 tools the guideline recommends considering for assessing ulcer risk) includes items for age, and skin type (e.g. tissue paper - thin/fragile). No impact on the guideline is currently expected.
Willingsford Ltd.	No	No comments provided	Thank you for your answer.

Royal College of Paediatrics and Child Health	Not answered	No comments provided	Thank you for your response.
Royal College of Nursing	Not answered	No comments provided	Thank you for your response.
Ideogeniq	No	No comments provided	Thank you for your answer.
British Association of Dermatologists	Not answered	No comments provided	Thank you for your response.
British Healthcare Trades Association (BHTA)	No	The primary causes of skin integrity are often secondary to pressure, such as friction, shear, and microclimate. The interrelationship of these elements, particularly where the support surface cover comes into play, should be covered in this guidance. Proper maintenance of pressure redistributing support surfaces is not currently addressed within the guideline. The MHRA highlighted the need for correct care, cleaning and inspection in its alert MDA/2010/002, and BHTA addressed this issue in its publication 'Protect, Rinse and Dry' (http://www.bhta.net/sites/default/files/Protect%2C%20Rinse%2C%20Dry%20v2.pdf)	Thank you for your comment. No specific evidence on managing friction and shear was found by the current surveillance. We found a single RCT in which a microclimate-controlling skin interface multilayer support system was no better than viscoelastic foam mattress/cotton sheet. The surveillance review conclusion on pressure redistributing devices was that the evidence did not provide a clear steer for the benefit of any particular support surface beyond the guideline recommendation of a high-specification foam mattress. The guideline does include some recommendations related to moisture, friction and shear. For example recommendation 1.1.5 states a skin assessment by a trained healthcare professional should check the skin for variations in heat, firmness and moisture, and there are subsequent recommendations about using a barrier preparation to prevent skin damage in people at high risk of developing a moisture lesion.

			Additionally, recommendation 1.1.3 refers to the use of validated scales to support clinical judgement (for example, the Braden scale, the Waterlow score or the Norton risk-assessment scale) when assessing pressure ulcer risk. These scales variously include items related to moisture, friction and shear. The full guideline acknowledges (p.12) that 'There is also an overlap with ulcers caused mainly by moisture (moisture lesions) and those caused by shear stresses or friction rather than pressure alone [...] In reality, in many cases, pressure, shear, friction and moisture may all have contributed to varying degrees to the development of the ulcer.' Therefore the guideline committee were mindful of these issues during development of the guideline. Additionally, NICE has published the following medical technologies guidance related to shear and friction in pressure ulcers: Parafricta Bootees and Undergarments to reduce skin breakdown in people with or at risk of pressure ulcers. Regarding proper maintenance of pressure redistributing support surfaces. This is considered to be standard practice, and it is the responsibility of healthcare professionals to ensure that any equipment is fit for its purpose – including keeping abreast of safety alerts relevant to any equipment.
Leeds Community Healthcare NHS Trust	No	No comments provided	Thank you for your answer.

Do you have any comments on equalities issues?			
Stakeholder	**Overall response**	**Comments**	**NICE response**
Frontier Medical Group	No	No comments provided	Thank you for your answer.
Pennine Care NHS Foundation Trust	No	No comments provided	Thank you for your answer.
Tissue Viability Society	No	No comments provided	Thank you for your answer.
Oxford University Hospitals NHS Foundation Trust	No	No comments provided	Thank you for your answer.
City Health Care Partnership Community Interest Company	No	No comments provided	Thank you for your answer.
3M UK Plc	No	No comments provided	Thank you for your answer.
The Whiteley Homes Trust	No	No comments provided	Thank you for your answer.
Willingsford Ltd.	No	No comments provided	Thank you for your answer.

Royal College of Paediatrics and Child Health	Not answered	No comments provided	Thank you for your response.
Royal College of Nursing	Not answered	No comments provided	Thank you for your response.
Ideogeniq	No	No comments provided	Thank you for your answer.
British Association of Dermatologists	Not answered	No comments provided	Thank you for your response.
British Healthcare Trades Association (BHTA)	No	No comments provided	Thank you for your answer.
Leeds Community Healthcare NHS Trust	No	No comments provided	Thank you for your answer.