NICE National Institute for Health and Care Excellence

Surveillance proposal consultation document

2018 surveillance of Pressure ulcers: prevention and management (NICE guideline CG179)

Proposed surveillance decision

We propose to not update the NICE guideline on pressure ulcers.

Section of the guideline	New evidence identified	Impact
Section 1.1 Prevention: adults		
Risk factors	Yes	No
Risk assessment tools	Yes	No
Repositioning	Yes	No
Massage	Yes	No
Nutrition	Yes	No
Pressure redistributing devices	Yes	No
Topical treatments	Yes	No
Dressings	Yes	No
Monitoring devices/processes	Yes	No
Heel protection	Yes	No
Wound care teams	Yes	No
Section 1.2 Prevention: neonates, infants, children and young people		
Heel protection	Yes	No

Risk assessment; Skin assessment; Repositioning; Skin massage; Nutritional supplements and hydration; Pressure redistributing devices; Barrier creams	No	No
Section 1.3 Prevention: all ages		
Care planning	Yes	No
Patient and carer information	Yes	No
Healthcare professional training and education	Yes	No
Section 1.4 Management: adults		
Ulcer measurement	Yes	No
Categorisation	No	No
Nutrition	Yes	No
Pressure redistributing devices	Yes	No
Negative pressure wound therapy	Yes	No
Hyperbaric oxygen therapy	Yes	No
Electrotherapy	Yes	No
Debridement	No	No
Ultrasound	Yes	No
Phototherapy	Yes	No
Systemic therapy	Yes	No
Topical treatments	Yes	No
Dressings	Yes	No
Repositioning	Yes	No
Reconstructive surgery	Yes	No
Grafts	Yes	No
Complementary and alternative medicine	Yes	No

Section 1.5 Management: neonates, infants, children and young people		
Ulcer measurement; Categorisation; Nutritional supplements and hydration; Pressure redistributing devices; Negative pressure wound therapy; Hyperbaric oxygen therapy and electrotherapy; Debridement; Systemic antibiotics and antiseptics; Topical antimicrobials and antiseptics; Dressings; Heel pressure ulcers	No	No
Areas currently out of scope		
Medical device-related pressure ulcers	Yes	No

Reasons for the proposal to not update the guideline

New evidence was found for most areas of the guideline focussing on adults (few studies were found specifically in children and young people), and was largely either consistent with current recommendations or insufficient to propose an update.

We therefore currently propose to not update the guideline.

However, some evidence suggesting there might be a need to update the guideline was found in 2 areas, but we do not currently plan to update for the reasons discussed below:

Medical device-related pressure ulcers

A gap in current guidance in this area was identified by the following placeholder statement from NICE quality standard QS89 Pressure ulcers: '[Quality statement 9: Prevention of medical device-related pressure ulcers]'. A placeholder statement is an area of care that has been prioritised by the Quality Standards Advisory Committee, but for which no source guidance is currently available. A placeholder statement indicates the need for evidence-based guidance to be developed in this area.

The new evidence from the surveillance review found that:

- there is a high rate of medical device-related pressure ulcers
- risk factors can be identified for medical device-related pressure ulcers
- the Braden QD Scale reliably predicts both immobility-related and device-related pressure ulcers in the paediatric acute care environment
- medical device-related pressure ulcers can be prevented.

However, only single studies for each of these different aspects of this new area were identified by the current surveillance review, and only 1 RCT examined prevention of

pressure ulcers. Therefore as part of the consultation, we have requested submission of any further evidence on medical device-related pressure ulcers. We will then consider any further evidence before making our final decision on whether to update the guideline.

Electrotherapy

The guideline states do not offer electrotherapy to adults to treat a pressure ulcer.

New evidence suggests there may be a benefit of electrotherapy in reducing ulcer area and improving wound healing time. As there is a Cochrane review protocol on Electrical stimulation for treating pressure ulcers, we will await completion of the full Cochrane review and we will consider any impact on the guideline when results are available.

For further details and a summary of all evidence identified in surveillance, see appendix A below.

Overview of 2018 surveillance methods

NICE's surveillance team checked whether recommendations in pressure ulcers (NICE guideline CG179) remain up to date.

The surveillance process consisted of:

- Feedback from topic experts via a questionnaire.
- A search for new or updated Cochrane reviews and national policy
- Examining related NICE guidance and quality standards and NIHR signals
- A search for ongoing research
- Literature searches to identify relevant evidence.
- Assessing the new evidence against current recommendations and deciding whether or not to update sections of the guideline, or the whole guideline.
- Consulting on the decision with stakeholders (this document)

For further details about the process and the possible update decisions that are available, see ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual.

See appendix A: summary of evidence from surveillance below for details of all evidence considered, with references.

Evidence considered in surveillance

Search and selection strategy

We searched for new evidence related to the whole guideline.

We found 123 studies in a search for randomised controlled trials and systematic reviews published between 28 August 2013 and 9 July 2018.

See appendix A: summary of evidence from surveillance below for details of all evidence considered, and references.

Selecting relevant studies

Although a filter for randomised controlled trials and systematic reviews was applied to the search, if studies of different types came through the search but were appropriate to address particular aspects of the guideline (such as risk assessment tools), they were included.

Ongoing research

We checked for relevant ongoing research; of the ongoing studies identified, 2 were assessed as having the potential to change recommendations; therefore we plan to check the publication status regularly, and evaluate the impact of the results on current recommendations as quickly as possible. These studies are:

- The number of heel pressure ulcers amongst patients on an orthopaedic ward who wear Prevalon boots or alternative heel protection over a 10 day period
- Text messages for pressure ulcer prevention in spinal cord injury

Intelligence gathered during surveillance

Views of topic experts

We sent questionnaires to 13 topic experts and received 5 responses. The topic experts either:

- participated in the guideline committee who developed the guideline
- were recruited to the NICE Centre for Guidelines Expert Advisers Panel to represent their specialty.

Topic experts raised a number of issues:

- Recommendations on nutrition have been published by the European Pressure Ulcer Advisory Panel (EPUAP) which gives more specific amounts of protein / energy intake, and a fortified diet should be considered in addition to nutritional supplements.

  - A cross-reference will be made to NICE guideline CG32 Nutrition support for adults, which makes specific recommendations on levels of protein and energy intake, and also focuses on 'Oral nutrition support' (which includes meal fortification, not just supplements).

- Greater consideration of costs of dressings by prescribers.
  - This issue was addressed by a comment from the guideline committee when the guideline was originally developed: 'The committee considered UK relevant unit costs, but noted that the major resource implications come from the frequency that each dressing requires changing. This is likely to be dependent on a range of factors, such as location of the ulcer, the amount of exudate, and patient acceptability. The frequency of dressing change can also have a substantial impact on quality of life. The committee therefore agreed that the dressing which was deemed more effective when taking these factors into account would be most likely to be cost-effective.'

- Mepilex dressings for prevention of pressure ulcers should be considered.
  - Evidence on Mepilex has been examined by the in-development NICE medical technologies guidance [GID-MT519] Mepilex Border Heel and Sacrum dressings for preventing pressure ulcers. The recommendation that was consulted on was: 'Mepilex Border Heel and Sacrum dressings show promise for preventing pressure ulcers in people who are considered to be at risk in acute care settings. However, there is currently insufficient evidence to support the case for routine adoption in the NHS.' The final guidance is expected to publish in December 2018, and will be linked to from the NICE Pathway on pressure ulcers

- Risk assessments should be carried out in all care homes (not just where residents are receiving NHS care), and in all patients in NHS settings (not just if they have a risk factor). And review of risk should be routine (not just after change in clinical status).
  - No evidence was found to support changes to the recommendations in this area. A NICE quick guide for social care on pressure ulcers is in development and is expected to publish within the business year.

- Adult safeguarding should be included, as pressure ulcers may be a sign of neglect.
  - An editorial amendment will be made to add a section on safeguarding adults to the introduction to NICE guideline CG179, alongside the section on safeguarding children. It will link to a document published by the Department of Health and Social Care from Jan 2018 'Safeguarding Adults Protocol: Pressure Ulcers and the interface with a Safeguarding Enquiry'

- Mattresses and seating technology need examining by surveillance.

  - Several new studies in this area were examined by the surveillance review but no impact on the guideline was found.

- The skin of older people is more prone to ulcers and the guidance needs to reflect this clearly.
  - 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 expected.
- Training of mainstream medical and nursing workforce is important as people may be poorly trained in this field.
  - This is likely to be an implementation issue as the guideline already recommends providing training to healthcare professionals on preventing a pressure ulcer. The comment will be passed to the implementation team.

Implementation of the guideline

Information from the NHS Digital Safety Thermometer found that the proportion of reported patients who had pressure ulcers declined from 6.8% in May 2012 to 4.4% in May 2017.

Other sources of information

We considered all other correspondence received since the guideline was published.

- An enquiry to NICE raised concerns about managing shear as part of an effective strategy for preventing and managing pressure ulcers, referring specifically to Parafricta products.
  - No evidence was found on shear by the current surveillance. NICE has published Parafricta Bootees and Undergarments to reduce skin breakdown in people with or at risk of pressure ulcers (2014) NICE Medical technologies guidance MTG20. The recommendations state that the technology has potential, but more evidence is needed to support the case for routine adoption in the NHS. NICE has deferred the review of MTG20 until 2020 pending results of an RCT commissioned specifically to address the research recommendation in MTG20. See the latest review decision of MTG20 for further information.

Views of stakeholders

We are consulting on this surveillance decision because we propose to update part of this guideline.

Equalities

No equalities issues were identified during the surveillance process.

Editorial amendments

During surveillance of the guideline we identified the following points in the guideline that should be amended.

- The introduction to CG179 has a section on safeguarding children. We will add the following section on safeguarding adults:

Safeguarding adults

The Department of Health and Social Care have issued a Safeguarding adults protocol: pressure ulcers and the interface with a safeguarding enquiry. It aims to help practitioners and managers across health and care organisations to provide caring and quick responses to people at risk of developing pressure ulcers.

It also offers a process for the clinical management of harm removal and reduction where ulcers occur, considering if an adult safeguarding response is necessary.

- A cross-referral to NICE guideline CG32 Nutrition support will be made from recommendation 1.4.5
- A cross-referral to NICE guideline NG51 Sepsis: recognition, diagnosis and early management will be made from recommendation 1.4.18
- A cross-referral to NICE guideline NG15 Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use will be made from recommendations 1.4.21, 1.4.22, 1.5.18 and 1.5.19
- 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.

Overall decision

After considering all evidence and other intelligence and the impact on current recommendations, we propose that no update is necessary.

Appendix A: Summary of evidence from surveillance

2018 surveillance of Pressure ulcers prevention and management (2014) NICE guideline CG179

Summary of evidence from surveillance

Studies identified in searches are summarised from the information presented in their abstracts.

Feedback from topic experts who advised us on the approach to this surveillance review, was considered alongside the evidence to reach a final decision on the need to update each section of the guideline.

1.1 Prevention: adults

Recommendations in this section of the guideline

Risk assessment

1.1.1 Be aware that all patients are potentially at risk of developing a pressure ulcer.

1.1.2 Carry out and document an assessment of pressure ulcer risk for adults:

- being admitted to secondary care or care homes in which NHS care is provided or
- receiving NHS care in other settings (such as primary and community care and emergency departments) if they have a risk factor, for example:
  - significantly limited mobility (for example, people with a spinal cord injury)
  - significant loss of sensation
  - a previous or current pressure ulcer
  - nutritional deficiency
  - the inability to reposition themselves
  - significant cognitive impairment.

1.1.3 Consider using a validated scale to support clinical judgement (for example, the Braden scale, the Waterlow score or the Norton risk-assessment scale) when assessing pressure ulcer risk.

1.1.4 Reassess pressure ulcer risk if there is a change in clinical status (for example, after surgery, on worsening of an underlying condition or with a change in mobility).

Skin assessment

1.1.5 Offer adults who have been assessed as being at high risk of developing a pressure ulcer a skin assessment by a trained healthcare professional (see recommendation 1.3.4). The assessment should take into account any pain or discomfort reported by the patient and the skin should be checked for:

- skin integrity in areas of pressure
- colour changes or discoloration[4]
- variations in heat, firmness and moisture (for example, because of incontinence, oedema, dry or inflamed skin).

1.1.6 Use finger palpation or diascopy to determine whether erythema or discolouration (identified by skin assessment) is blanchable.

1.1.7 Start appropriate preventative action (see recommendations 1.1.1–1.1.17) in adults who have non-blanching erythema and consider repeating the skin assessment at least every 2 hours until resolved.

Repositioning

1.1.8 Encourage adults who have been assessed as being at risk of developing a pressure ulcer to change their position frequently and at least every 6 hours. If they are unable to reposition themselves, offer help to do so, using appropriate equipment if needed. Document the frequency of repositioning required.

1.1.9 Encourage adults who have been assessed as being at high risk of developing a pressure ulcer to change their position frequently and at least every 4 hours. If they are unable to reposition themselves, offer help to do so, using appropriate equipment if needed. Document the frequency of repositioning required.

Skin massage

1.1.10 Do not offer skin massage or rubbing to adults to prevent a pressure ulcer.

Nutritional supplements and hydration

1.1.11 Do not offer nutritional supplements specifically to prevent a pressure ulcer in adults whose nutritional intake is adequate.

1.1.12 Do not offer subcutaneous or intravenous fluids specifically to prevent a pressure ulcer in adults whose hydration status is adequate.

Pressure redistributing devices

1.1.13 Use a high-specification foam mattress for adults who are:

- admitted to secondary care
- assessed as being at high risk of developing a pressure ulcer in primary and community care settings.

1.1.14 Consider a high-specification foam theatre mattress or an equivalent pressure redistributing surface for all adults who are undergoing surgery.

1.1.15 Discuss with adults at high risk of developing a heel pressure ulcer and, where appropriate, their family or carers, a strategy to offload heel pressure, as part of their individualised care plan.

1.1.16 Consider the seating needs of people at risk of developing a pressure ulcer who are sitting for prolonged periods.

1.1.17 Consider a high-specification foam or equivalent pressure redistributing cushion for adults who use a wheelchair or who sit for prolonged periods.

Barrier creams

1.1.18 Consider using a barrier preparation to prevent skin damage in adults who are at high risk of developing a moisture lesion or incontinence-associated dermatitis, as identified by skin assessment (such as those with incontinence, oedema, dry or inflamed skin).

[4] Healthcare professionals should be aware that non-blanchable erythema may present as colour changes or discolouration, particularly in darker skin tones or types.

Surveillance decision

This section of the guideline should not be updated.

Editorial amendments

The introduction to CG179 has a section on safeguarding children. We will add the following section on safeguarding adults:

Safeguarding adults

The Department of Health and Social Care have issued a Safeguarding adults protocol: pressure ulcers and the interface with a safeguarding enquiry. It aims to help practitioners and managers across health and care organisations to provide caring and quick responses to people at risk of developing pressure ulcers.

It also offers a process for the clinical management of harm removal and reduction where ulcers occur, considering if an adult safeguarding response is necessary.

Risk factors

2018 surveillance summary

Positioning (prone positioning, bed elevation, patient suspension)

A systematic review and meta-analysis (1) of 11 RCTs (n=2246) examined efficacy and safety of prone versus supine position during mechanical ventilation in acute respiratory distress syndrome. Prone positioning significantly reduced the primary endpoint of overall mortality, but was significantly associated with pressure ulcers and major airway problems.

A systematic review and meta-analysis (2) of 8 RCTs (n=2141) compared the efficacy and safety of prone and supine positioning in adult patients with acute respiratory distress syndrome. Mortality rates were significantly lower with prone than supine position, but heterogeneity of the studies was moderate and significant. Prone positioning was associated with a significantly increased incidence of pressure sores and endotracheal dislocation.

A sub-analysis of a multicentre RCT (3) (n=466) examined the impact of prone versus supine positioning on pressure ulcers in patients with severe acute respiratory distress syndrome. Pressure ulcers were assessed at randomisation, 7 days later, and on discharge from the intensive care unit. The primary end-point was the incidence (with reference to 1,000 days of invasive mechanical ventilation or 1,000 days of intensive care unit stay) of new patients with pressure ulcers at stage 2 or higher from randomisation to intensive care unit discharge. The incidence of new patients with pressure ulcers from randomisation to discharge did not differ significantly between prone and supine positioning with reference to 1,000 days of invasive mechanical ventilation, but was significantly higher in the prone than the supine group with reference to 1,000 days of intensive care unit stay. Covariates independently significantly associated with pressure ulcers were age over 60 years, female gender, and BMI of over 28.4 kg/m^2.

A Cochrane review (4) of 10 RCTS (n=878) examined semi-recumbent versus supine position for the prevention of ventilator-associated pneumonia in adults requiring mechanical ventilation. The authors judged all trials to be at high risk of bias. A semi-recumbent position (30 to 60 degrees) significantly reduced the risk of clinically suspected ventilator-associated pneumonia compared to a 0 to 10 degrees supine position (8 trials, n=759, GRADE: moderate quality evidence). There was no significant difference in pressure ulcers between the 2 positions (1 trial, n=221, GRADE: low quality evidence).

An RCT (5) (n=120) examined the effect of head of bed elevation to 30 and 45 degrees versus routine bed position on the incidence of ventilator-associated pneumonia and risk of pressure ulcers in the intensive care unit. At the end of the third day of intervention, a significantly lower incidence of ventilator-associated pneumonia was seen in the elevation groups than control group, but mean pressure ulcer scores were no different between the groups.

An RCT (6) (n=200) examined a suspension positioning system used with elderly patients confined to bed with neurogenic faecal incontinence. Patients received routine care (individualised dietary modification, psychological support, health education, and social support for caregivers and family members) with or without the suspension positioning system. Rates of perianal faecal contamination, skin breakdown, incontinence associated dermatitis, pressure ulcer development, lower urinary tract infection, length of hospitalisation, costs of care and quality-of-life scores were all significantly better with the suspension system. No adverse events were observed.

Diabetes

A systematic review and meta-analysis (7) of 13 studies (n=2,367 patients and 12,053 controls) examined the association between pre-existing diabetes mellitus and pressure ulcers in patients following surgery. Incidence of pressure ulcers was significantly greater in patients with diabetes than those without diabetes. Estimates by type of surgery suggested similar results in cardiac surgery, general surgery, and major lower limb amputations, though there was no increased risk with hip surgery.

A systematic review and meta-analysis (8) of 16 observational studies (n=24,112) examined the impact of diabetes on risk of pressure ulcers in patients undergoing surgery. Patients with diabetes had a significantly higher risk of developing pressure ulcers. Results of subgroup analyses were consistent when stratified by surgery type, study design, research region, sample size, inclusion period, analysis method and study quality. There was evidence of publication bias among studies.

A systematic review and meta-analysis (9) of 8 studies (n=22,180) assessed the relationship between diabetes and pressure ulcer risk in patients with hip fractures. People with diabetes had a significantly higher risk of pressure ulcers than those without diabetes. No significant publication bias was found.

Incontinence-associated dermatitis

A systematic review and meta-analysis (10) of 58 studies examined incontinence-associated dermatitis and its most important causative factors (incontinence and moisture) as risk factors for pressure ulcer development. Meta-analysis showed a significant association of urinary incontinence and double incontinence with pressure ulcers.

Surgery

A systematic review and meta-analysis (11) (number of included studies not stated in the abstract) examined the relationship between length of surgery and pressure ulcer risk in cardiovascular surgery patients. The mean length of surgery was significantly higher in people with than without a pressure ulcer. The risk of pressure ulcers was significantly higher for a 60-minute increase in the length of surgery intervals, and higher still for a 600-minute increase. Modelling showed that risk of pressure ulcers increased almost linearly along with the length of surgery. The funnel plot showed no publication bias.

Dementia

A systematic review and meta-analysis (12) of 11 hospital administrative database studies (n=10,683,158) compared outcomes in elderly patients with and without dementia. One retrospective cohort study had outcomes of relevance, noting that patients with dementia had significantly higher rates of pressure ulcers.

Intelligence gathering

Skin of older people

A topic expert noted that the skin of older people is more prone to ulcers and the guidance needs to reflect this clearly.

Adult safeguarding

A topic expert raised concerns about adult safeguarding as pressure ulcers may be a sign of neglect. They provided a link to a document published by the Department of Health and Social Care from Jan 2018 'Safeguarding Adults Protocol: Pressure Ulcers and the interface with a Safeguarding Enquiry'

Impact statement

Positioning (prone positioning, bed elevation, patient suspension)

Evidence from 2 systematic reviews and an RCT suggests that prone positioning in adults with acute respiratory distress syndrome on a ventilator is associated with pressure ulcers. The guideline already recommends assessing pressure ulcer risk for adults if they have a risk factor (examples include significantly limited mobility, and the inability to reposition themselves), and goes on to recommend developing a care plan taking into account their mobility and ability to reposition themselves, and other comorbidities. The guideline already acknowledges the risks highlighted by the new evidence and no impact is expected.

A Cochrane review and an RCT found no difference in pressure ulcers between semi-recumbent and supine position during mechanical ventilation. The guideline already acknowledges risks in immobile patients, therefore no impact is expected.

An RCT found that a suspension positioning system for elderly patients with neurogenic faecal incontinence reduced pressure ulcers. The guideline did not examine any evidence for suspension systems and therefore no recommendations are made, however this was a single study and the authors stated that further studies are needed to examine the long-term effects of suspension systems. No impact on the guideline is currently expected.

New evidence is unlikely to change guideline recommendations.

Diabetes

Two systematic reviews found that risk of pressure ulcers in patients undergoing surgery was higher in people with diabetes. A further systematic review also found that diabetes increases pressure ulcer risk in patients with hip fracture. The guideline makes no recommendations specifically about diabetes and ulcer risk, however it does state that a high-specification foam theatre mattress or equivalent should be considered for all

adults who are undergoing surgery. The guideline also acknowledges risks in patients with limited mobility, and that a care plan for high-risk patients should take into account other comorbidities. The Waterlow score (1 of 3 tools the guideline recommends considering for assessing ulcer risk) includes diabetes as a risk factor. The risk factors highlighted by the new evidence are broadly covered by the guideline and no impact is expected.

New evidence is unlikely to change guideline recommendations.

Incontinence-associated dermatitis

A systematic review 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. No impact is expected.

New evidence is unlikely to change guideline recommendations.

Surgery

A systematic review found that length of surgery was a risk factor for pressure ulcers. The guideline states that a high-specification foam theatre mattress or equivalent should be considered for all adults who are undergoing surgery, therefore no impact is expected.

New evidence is unlikely to change guideline recommendations.

Dementia

A systematic review found that patients with dementia had higher rates of pressure ulcers. The guideline already recommends assessing pressure ulcer risk for adults if they have a risk factor (including significant cognitive impairment) and goes on to recommend developing a care plan taking into account other comorbidities. It also recommends taking into account individual needs when supplying information to people with degenerative conditions and cognitive impairment. Dementia as a risk factor is broadly covered by the guideline, and given that the evidence was from a single retrospective study, no impact is expected.

New evidence is unlikely to change guideline recommendations.

Adult safeguarding

To address topic expert concerns about adult safeguarding, we will make an editorial amendment to add a section on safeguarding adults to the introduction to NICE guideline CG179 alongside the section on safeguarding children. See ‘Editorial amendments’ at the start of this section for details.

New evidence is unlikely to change guideline recommendations.

Skin of older people

No evidence was found about this issue which was raised by a topic expert. 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.

New evidence is unlikely to change guideline recommendations.

Risk assessment tools

2018 surveillance summary

All tools

A Cochrane review (13) of 2 RCTS examined risk assessment tools for the prevention of pressure ulcers. One small, cluster RCT found no statistical difference in pressure ulcer incidence in patients who were assessed by nurses with the Braden risk assessment tool (n=74) compared with either: a) patients assessed by nurses who had receiving training and then used unstructured risk assessment (n=76); or b) patients assessed by nurses using unstructured risk assessment alone (n=106). The second study was a large single-blind RCT comparing the effect of risk assessment on pressure ulcer incidence using the Waterlow risk assessment tool (n=411), the Ramstadius risk screening tool (n=420) and no formal risk assessment (n=420). There was no significant difference in pressure ulcer incidence for: Waterlow versus no formal risk assessment; Ramstadius versus no formal risk assessment; or Waterlow versus Ramstadius.

A systematic review and meta-analysis (14) examined risk assessment scales and nurses' clinical judgment in predicting pressure ulcer development. The review identified 57 studies, including 31 that included a validation study, and also retrieved 4 studies testing clinical judgment as a risk prediction factor. Meta-analysis of 11 studies produced the following pooled predictive capacity indicators: Braden (relative risk=4.26); Norton (relative risk=3.69); Waterlow (relative risk=2.66); Cubbin-Jackson (relative risk=8.63); EMINA [mEntal state, Mobility, Incontinence, Nutrition, Activity] (relative risk=6.17); Pressure Sore Predictor Scale (relative risk=21.4); and clinical judgment (relative risk=1.89).

Braden scale

A systematic review and meta-analysis (15) of 8 studies (2 prospective cohorts, 6 cross-sectional studies; n=41,489 in total) evaluated the predictive validity of the Braden scale for pressure ulcer risk assessment in long-term care residents. The pooled sensitivity and specificity were 0.80 and 0.42 respectively, yielding a combined diagnostic odds ratios of 5.66. The area under the receiver operating characteristic curve was 0.7686, and the overall diagnostic accuracy (Q*) was 0.7090. Significant heterogeneity was noted among the included studies for sensitivity, specificity, and diagnostic odds ratios. Meta-regression analysis showed no heterogeneity among Braden scale cut-offs and pressure ulcer prevalence.

A systematic review and meta-analysis (16) of 11 datasets from 9 published studies (n=40,361 residents) examined predictive validity (ability to predict ulcers)

and concurrent validity (ability to detect pressure ulcers) of the Braden scale in long-term care. Pooled sensitivity, specificity, positive predictive value, and negative predictive values were 86%, 38%, 28%, and 93%, respectively. Specificity was poorer in concurrent samples as compared with predictive samples (38% versus 72%), while positive predictive value was low in both sample types (25% and 37%). Though random effects model results showed that the Braden scale had good overall predictive ability (relative risk=4.33), none of the concurrent samples were found to have 'optimal' sensitivity and specificity.

A systematic review and meta-analysis (17) of 21 prospective diagnostic studies (n=6,070) examined predictive validity of the Braden scale for pressure ulcer risk in hospitalised patients. Based on QUADAS-II, the authors stated the studies had high methodological quality. Pooled sensitivity was 0.72; pooled specificity was 0.81; and the summary receiver operating characteristic area under the curve was 0.84. Subanalysis confirmed that age and reference standards were the factors that affected the diagnostic accuracy of the Braden Scale.

A study (18) examined interrater reliability of the Braden scale and its subscales. Data were extracted from a previous retrospective, randomised, controlled trial involving adult patients with compromised mobility receiving care in a tertiary acute care hospital. One-way, intraclass correlation coefficients were calculated on item and total scores, and kappa statistics were used to determine reliability of categorising patients on their risk. Reliability was assessed on 64 patients, where nurses and research staff independently assessed enrolled participants at baseline and after 72 hours using the Braden Scale as it appeared on an electronic medical record. Interrater reliability for the total score was high (intraclass correlation coefficient=0.807). The friction and shear item had the lowest reliability (intraclass correlation coefficient=0.266). Reliability of categorising patients' level of risk had moderate agreement (kappa=0.408).

Pressure Ulcer Risk Scale (PURS)

A study (19) performed secondary data analysis of a combined dataset from 3 prospective cohort studies (n=1,418 people aged 70 or over) in 11 hospitals to validate the Pressure Ulcer Risk Scale (PURS) to screen for pressure ulcer outcomes. Trained nurses used the international Resident Assessment Instrument (interRAI) acute care assessment tool to collect data at admission and discharge. Adverse outcomes were documented on daily ward visits. The PURS was calculated from interRAI items, and its association with pressure ulcer outcomes was tested using the c-statistic (area under the receiver operator characteristic curve). Complete data were available for 1,371 (97%) participants, 85 of whom (6%) had a pressure ulcer at admission. Of the 1,286 without pressure ulcers at admission, 42 (3%) developed a new pressure ulcer during their hospital stay. The association between PURS and outcomes had a c-statistic (area under the receiver operator characteristic curve) of 0.81 for prevalence of pressure ulcers at

admission, and 0.70 for incidence of new pressure ulcers.

PURPOSE-T

An NIHR-funded study (20) developed and evaluated a new tool for assessing pressure ulcer risk, called PURPOSE-T. The tool, developed as part of a 5 year NIHR research programme, is used by following a manual and assesses 8 risk factors: mobility; skin; previous pressure ulcer; sensory perception; perfusion (blood flow); nutrition; moisture; and diabetes. Field testing by nurses showed very good agreement between tests and between assessors. This tool, drawing on new research, has many advantages over the various current assessment tools, which show numerous inconsistencies. PURPOSE-T is already being used by early adopter Trusts and could help to reduce the incidence of pressure ulcers.

Intelligence gathering

Risk assessment (population and setting)

A topic expert felt that risk assessments should be carried out in all (i.e. residential in addition to nursing) care homes not just those where residents are receiving NHS care. And that risk assessments should be carried out in all patients in NHS settings (i.e. screening) not just if they have a risk factor, as there are concerns people at risk could be missed. And that review of risk should be routine, not just after change in clinical status.

Impact statement

All tools

A Cochrane review of 2 RCTs (both of which were included when the NICE guideline was originally developed) found no effect of the Braden tool on pressure ulcer incidence (though the authors stated limitations of the study prevented firm conclusions), and no difference in pressure ulcer incidence after using either the Waterlow tool, the Ramstadius tool, or clinical judgement alone (from a high quality RCT). These conclusions were based on single studies.

A systematic review found that a number of tools (Braden, Norton, Waterlow, Cubbin-Jackson, EMINA, and Pressure Sore Predictor Scale) were able to predict the development of pressure ulcers, and that tools had a higher predictive capacity than clinical judgment alone.

The guideline recommends considering a validated scale to support clinical judgement (for example, the Braden scale, the Waterlow score or the Norton risk-assessment scale) when assessing pressure ulcer risk.

The studies in the Cochrane review were already examined by the guideline and are unlikely to affect it.

The other review demonstrated some evidence of the efficacy of tools other than those quoted by the guideline, but only relative risk was reported – other diagnostic outcomes such as sensitivity and specificity would be needed to confirm the utility of these tools. This review also found that assessment tools are more effective than clinical judgement

alone, which supports the current recommendation to consider a validated scale to support clinical judgement. During development of the guideline, the committee highlighted that the need to use a formal risk assessment tool was further supported by anecdotal evidence that healthcare professionals varied in their levels of skill and experience. Therefore, it was not possible to recommend the use of clinical judgement alone to identify whether an individual was at risk of developing a pressure ulcer.

New evidence is unlikely to change guideline recommendations.

Braden scale

Four studies looked specifically at the Braden scale for pressure ulcer risk: 2 systematic reviews found it had good sensitivity but low specificity in long-term care; 1 systematic review of high-quality studies found it had reasonable sensitivity and high specificity in hospital; and 1 study found that interrater reliability for the total score was high and reliability of categorising risk was moderate.

The guideline recommends considering the Braden scale when assessing pressure ulcer risk. The new evidence broadly lends support to the Braden scale, though 2 reviews found it had low specificity in long-term care (authors of 1 review suggested future studies could explore whether this is down to the choice of cutoff point and/or preventive strategies implemented by long-term care staff after the risk assessment).

New evidence is unlikely to change guideline recommendations.

Pressure Ulcer Risk Scale (PURS)

A single study found that the Pressure Ulcer Risk Scale had good ability to screen for pressure ulcer outcome in acute care. Further studies to reinforce these findings would be useful before considering an impact on the guideline.

New evidence is unlikely to change guideline recommendations.

PURPOSE-T

The NIHR study of the PURPOSE-T tool was subject to an NIHR Signal analysis, which stated that further and ongoing evaluation of PURPOSE-T is needed. Reliability of the tool across different patient populations needs to be assessed, as well as the impact the tool has on decision-making and pressure ulcer incidence in practice. No impact on the guideline is currently expected.

New evidence is unlikely to change guideline recommendations.

Risk assessment (population and setting)

No evidence was found related to the need to widen the settings and population of risk assessments as raised by topic experts. No impact on the guideline is currently expected. A NICE quick guide for social care on pressure ulcers is in development and is expected to publish within the business year.

New evidence is unlikely to change guideline recommendations.

Repositioning as prevention

2018 surveillance summary

A Cochrane review (21) of 3 RCTs and 1 economic study (n=502 participants in total from acute and long-term care settings) examined repositioning for pressure ulcer prevention in adults. Two trials of 30 versus 90 tilt positions using similar repositioning frequencies were pooled (n=252) and the risk ratio for developing a pressure ulcer showed no significant difference between groups. In the third RCT, participants were randomised between 2- and 3-hourly repositioning on standard hospital mattresses and 4- and 6-hourly repositioning on viscoelastic foam mattresses. The risk ratio for pressure ulcers (any category) showed no significant difference between 2- and 3-hourly repositioning on a standard mattress, nor between 4- and 6-hourly repositioning on viscoelastic foam. A cost-effectiveness analysis based on data derived from 1 of the included RCTs compared 3-hourly repositioning using the 30 tilt overnight with standard care consisting of 6-hourly repositioning using the 90 lateral rotation overnight. The only included cost was nursing time. The intervention was reported to be significantly cost saving compared with standard care.

An assessor-blinded multicentre RCT (22) across 27 long-term care facilities (n=942 residents; mean age 85.1 years) examined optimal frequency of repositioning on high-density foam mattresses for preventing pressure ulcers in at-risk residents. Participants were randomly allocated to 1 of 3 turning schedules (2-, 3-, or 4-hour intervals). The study continued for 3 weeks with weekly risk and skin assessment. Overall, no significant difference in pressure ulcer incidence (on the coccyx, sacrum, greater trochanter, or heels) was seen between the 2-, 3-, or 4- hour interval groups, nor between high-risk versus moderate-risk participants.

An open-label RCT (23) (n=329) compared repositioning every 2 or 4 hours for preventing pressure ulcers in patients on alternating pressure air mattresses in intensive care on mechanical ventilation for at least 24 hours. There was no significant difference between 2- and 4-hourly repositioning for the primary outcome of incidence of a pressure ulcer of at least grade II during intensive care stay. Nor were there any significant differences in unplanned extubation or endotracheal tube obstruction. However, 2-hourly repositioning was significantly associated with more device-related adverse events and a greater daily nursing workload for manual repositioning time per patient.

A multicentre RCT (24) (n=1,928) examined musical cues to remind staff in long-term care facilities to help residents move or reposition every 2 hours to reduce pressure ulcers. Four facilities

received intervention during months 1 to 12, four comparison facilities received intervention during months 7 to 12, and 2 pseudo-control facilities received no intervention. Alongside musical cues, the intervention comprised education for facility staff, and pamphlets on pressure ulcer prevention for visiting family. Musical cues were played daily over the intercom every 2 hours for the 12-hour daytime period. The primary outcome was frequency of new facility-acquired pressure ulcers divided by the total number of resident assessments conducted by the facility during the study period. Resident assessments are federally mandated for certified nursing homes, and are performed on admission and then annually, with additional assessments upon a significant change in status. The authors stated that the assessments have good reliability and validity as a record of resident health. During the study, there was a mandatory transition from version 2.0 to version 3.0 of the resident assessment system. The risk of a new pressure ulcer was not significantly lower in intervention facilities when version 2.0 of the resident assessments was used, but was significantly lower with version 3.0.

Intelligence gathering

No additional information was identified for this section.

Impact statement

The Cochrane authors stated that great uncertainty remains over repositioning frequency and position but it does not mean these interventions are ineffective since all comparisons were underpowered and at high risk of bias. All 4 studies in the Cochrane were included when the NICE guideline was originally developed.

Two RCTs found no benefit of turning every 2 hours (rather 3- or 4-hourly), and that more frequent turning increased adverse events and nursing workload. This lends support to the guideline recommendation of encouraging position changing at least every 4 hours in high-risk patients, and every 6 hours in at-risk patients.

Another RCT suggested that musical cues reminding staff in long-term care facilities to reposition residents may reduce pressure ulcers. However a change in protocol related to assessing residents part way through the trial introduced uncertainty to the findings and further evidence may be needed to confirm the results before any change to the guideline could be considered.

New evidence is unlikely to change guideline recommendations.

Massage

2018 surveillance summary

A Cochrane review (25) examined massage therapy for preventing pressure ulcers. It found no RCTs that met the inclusion criteria.

Intelligence gathering

No additional information was identified for this section.

Impact statement

A Cochrane review found no studies eligible for inclusion, therefore it was unable to examine whether massage therapy can prevent pressure ulcers. This does not affect the guideline which currently recommends not to offer skin massage or rubbing to adults to prevent a pressure ulcer.

New evidence is unlikely to change guideline recommendations.

Nutrition

2018 surveillance summary

A Cochrane review (26) of 23 RCTs (median=88 participants, range 9 to 4,023) examined nutritional interventions for preventing and treating pressure ulcers. Many trials were at high risk of bias. Eleven trials compared a combination of nutritional supplements, consisting of a minimum of energy and protein in different dosages, for preventing pressure ulcers. A meta-analysis of 8 trials (n=6,062) comparing mixed nutritional supplements with standard hospital diet found evidence suggesting a significant effect of supplementation on pressure ulcer development, though the authors deemed this outcome at unclear or high risk of bias and stated there was no clear evidence of effect.

Intelligence gathering

No additional information was identified for this section.

Impact statement

The Cochrane authors concluded there is currently no clear evidence of benefit of nutritional interventions for preventing pressure ulcers, which agrees with the guideline recommendation not to offer nutritional supplements to prevent a pressure ulcer if nutritional intake is adequate.

New evidence is unlikely to change guideline recommendations.

Pressure redistributing devices

2018 surveillance summary

A Cochrane review (27) of 59 RCTs (n=~18,000) examined support surfaces for preventing pressure ulcers. Foam alternatives to standard hospital foam mattresses significantly reduced the incidence of pressure ulcers in people at risk. The relative merits of alternating- and constant low-pressure devices were unclear. One high-quality trial suggested that alternating-pressure mattresses may be more cost effective than alternating-pressure overlays in a UK context. Pressure-relieving overlays on the operating table reduced postoperative pressure ulcer incidence, although 2 trials indicated that foam overlays caused adverse skin changes. Meta-analysis of 3 trials suggested a significant benefit of Australian standard medical sheepskins.

A systematic review and meta-analysis (28) of 7 RCTs and 3 quasi-RCTs (n=1,895 patients in total) examined pressure-redistribution surfaces versus standard (usually foam-based) hospital mattresses for prevention of surgery-related pressure ulcers. Pressure redistribution surfaces significantly decreased incidence of surgery-related pressure ulcers versus a standard mattress. Subgroup analysis showed pressure-redistribution surfaces used intra-operatively did not decrease the incidence of surgery-related pressure ulcers, but pressure ulcer incidence significantly decreased with postoperative use, as well as with intra-operative plus postoperative use. A funnel plot suggested minimal risk of publication bias.

A single-centre, crossover RCT (29) (n=41) in a nursing home examined a static air overlay mattress (without a pump) on top of a viscoelastic foam mattress, versus a viscoelastic foam mattress alone. Patients spent 6 months using 1 of the 2 mattress types, and then a second (crossover) period of 6 months using the alternative type. Patients were checked weekly and repositioned according to nursing home protocol if there was any sign of a pressure ulcer. The number of patients developing a category 2 or higher pressure ulcer was not significantly different between viscoelastic foam and static air mattress. For pressure ulcer healing (category 2 or higher), all pressure ulcers in the static air group healed, but in 2 out of 8 patients who developed a pressure ulcer on a foam mattress, ulcers showed no signs of healing (between-group significance not stated).

An RCT (30) (n=105) compared a viscoelastic foam support surface with standard viscoelastic foam for preventing pressure ulcers in the intensive care unit. In total, 43% of all patients developed a new pressure ulcer of stage 1 or worse. There was no significant difference in pressure ulcer incidence between the 2 types of foam.

An RCT (31) (n=110) compared a viscoelastic foam overlay with a standard hospital mattress for preventing pressure ulcers in acutely ill patients (19 years or older, a Braden Scale for Pressure Sore Risk score of 16 or less, on a neurology, oncology, or respiratory inpatient care unit). All patients received standard nursing care for prevention of pressure injury. Interface pressure was measured

over the sacral/coccygeal area with subjects in the supine position. Pressure ulcer incidence was significantly lower with the viscoelastic foam overlay than standard mattress.

An open-label, multicentre RCT (32) (n=76) compared an alternating pressure air mattress with a viscoelastic foam mattress for preventing pressure ulcers in patients in medium- and long-term stay facilities (aged 70 and over, moderate to high risk of developing ulcers, no pressure ulcers on enrolment, bedridden for at least 15 hours per day, reduced mobility, absent or minimal positioning capability, Braden score <14, nutritional status score >12, and Karnofsky score <40%). Preventive care was equivalent in both groups. Over 30-days, cumulative risk of pressure ulcers was significantly lower with alternating pressure air mattress than foam. The only risk factor significantly associated with increased risk of pressure ulcers was foam mattress. A secondary outcome of comfort and tolerance perceived by patients was high and similar in both groups.

A multicentre RCT (33) across 21 nursing homes (n=206) examined a microclimate-controlling skin interface multilayer support system for use on top of a viscoelastic foam mattress, versus a viscoelastic foam mattress alone. Participants had a Braden score <16, life expectancy >3 months, and no pressure ulcers during the previous 3 months. After 12 weeks, there was no significant difference between groups in the development of a category 2, 3, or 4 pressure ulcer.

An RCT (34) (n=120) compared an alternating inflatable head pad with a gel head pad in patients during open heart surgery. Occipital pressure ulcer and alopecia were significantly lower with the inflatable than with the gel head pad.

Intelligence gathering

A topic expert drew attention to the need for surveillance in the area of support surfaces.

Impact statement

The Cochrane authors concluded that people at high risk of pressure ulcers should use high-specification foam mattresses, and that organisations might consider pressure relief for high risk patients in the operating theatre, which agrees with the guideline to use high specification foam mattresses including for surgery. The Cochrane further found that the relative merits of constant low-pressure and alternating-pressure support surfaces were unclear – the guideline does not make recommendations about these types of surface and no impact is expected. The Cochrane also concluded that medical grade sheepskins were associated with a decrease in pressure ulcers – the same set of evidence was examined when the NICE guideline was originally developed and it concluded that high-specification foam was adequate as a minimum, and that sheepskin had comfort issues (irritation, too hot) so no impact is expected.

A systematic review concluded that postoperative pressure-redistribution surfaces can decrease pressure ulcers, agreeing with the guideline which recommends a high-specification foam mattress for adults admitted to secondary

care. The review also found that evidence for intraoperative pressure-redistribution surfaces is insufficient, contradicting the guideline which recommends intraoperative use of high-specification foam. However the review evidence all dated from 2006 or earlier and would have been available when the guideline was developed, and the recommendation is to 'consider' high-specification foam or equivalent for surgery, so the new evidence is unlikely to affect the guideline.

Individual RCTs found that:

- a static air overlay mattresses was better than foam mattresses alone
- a viscoelastic foam support surface was no better than standard viscoelastic foam
- a viscoelastic foam overlay was better than a standard hospital mattress
- alternating pressure air mattress was better than a viscoelastic foam mattress in elderly patients
- a microclimate-controlling skin interface multilayer support system is no better than viscoelastic foam mattress/cotton sheet
- an alternating inflatable head pad is better than a gel pad for preventing pressure ulcer during surgery.

These individual trials do 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 committee considered overlays as an alternative to high specification mattress. Although there was evidence of some benefit of overlays, high specification foam mattress was considered adequate as a minimum. Any further benefit of an overlay in addition to a high specification mattress was unclear – this evidence is unlikely to affect that conclusion.

New evidence is unlikely to change guideline recommendations.

Topical treatments

2018 surveillance summary

A Cochrane review (35) examined dressings and topical agents for preventing pressure ulcers in people at risk of developing a pressure ulcer (see the heading 'Dressings' later in this section for discussion of the evidence on dressings). Four RCTs and 1 cluster RCT (n=940) of unclear or high risk of bias compared a topical agent with a placebo. Meta-analysis showed no overall benefit of the topical agents. When the cluster randomised trial was omitted from the analysis, topical agents significantly reduced pressure ulcer incidence.

A multicentre, triple-blind, non-inferiority RCT (36) (n=831) compared topical extra virgin olive oil with hyperoxygenated fatty acids to prevent pressure ulcers in immobilised home-care patients at high risk of pressure ulcers. At 16-week follow up, in the per protocol analysis, none of the body areas evaluated (sacrum, right

and left heel, right and left trochanter) had risk differences for pressure ulcer incidence exceeding the 10% non-inferiority margin established. In the intention to treat analysis, the lower limit of the established confidence interval was never exceeded. Namely, extra-virgin olive oil was not inferior to hyperoxygenated fatty acids.

An RCT (37) (n=80) examined henna applied to the sacrum for preventing pressure ulcers in critical care units. Significantly fewer patients treated with henna than with usual care alone developed pressure ulcers.

Intelligence gathering

No additional information was identified for this section.

Impact statement

The Cochrane authors concluded there is insufficient evidence to support or refute topical agents applied over bony prominences to prevent pressure ulcers; the evidence all dated from 2008 or earlier and would have been available when the guideline was developed. It is unlikely to affect guideline recommendations to consider a barrier preparation to prevent skin damage.

Individual RCTs found that topical extra-virgin olive oil was not inferior to hyperoxygenated fatty acids, and henna was more effective than usual care, in preventing pressure ulcers. The guideline recommends considering a barrier preparation to prevent skin damage – the guideline committee decided there was insufficient evidence to recommend a specific preparation. The evidence of equivalence of olive oil and fatty acids does not add much to the limited evidence found in the original guideline on benefit of fatty acids over placebo, and no evidence was examined by the guideline on olive oil or henna, so further research confirming these effects would be helpful. The new evidence is unlikely to change the guideline.

New evidence is unlikely to change guideline recommendations.

Dressings

2018 surveillance summary

Silicone foam dressings

A systematic review and meta-analysis (38) of 25 RCTs, quasi-experimental and comparative studies examined pressure ulcer prevention strategies for adult patients in intensive care units. Meta-analysis showed a significant effect of silicone foam dressing (comparator not stated in the abstract) in reducing incidence of hospital-acquired pressure ulcers. Evidence of the effectiveness of nutrition, skin-care regimen, positioning and repositioning schedule, support surfaces, and the role of education was limited, which precluded strong conclusions.

An RCT (39) (n=461) compared silicone foam dressing plus standard care, fatty

acids oil spray plus standard care, and standard care alone, in preventing sacral pressure ulcers among high-risk patients. Development of pressure ulcers was not significantly different between groups. However, significant differences were found between the silicone foam dressing and standard care group, and between the fatty acids oil and standard care group, for patients with Braden score of 12 or less (i.e. higher risk).

An RCT (40) (n=366) examined 5-layered soft silicone foam dressing versus standard care to prevent pressure ulcers in the intensive care unit. The incidence rate of hospital-acquired pressure ulcers, and risk of ulcer development, was significantly less with foam dressing.

An RCT (41) (n=440) compared silicone multi-layered foam dressings (Mepilex) with usual care for preventing sacral and heel pressure ulcers in trauma and critically ill patients. There were significantly fewer patients with pressure ulcers, and fewer sacral, heel and overall pressure ulcers, with foam dressing.

Other dressings

A Cochrane review (35) examined dressings and topical agents for preventing pressure ulcers in people at risk of developing a pressure ulcer. Four RCTs (n=561) of high or unclear risk of bias, showed that dressings applied over bony prominences significantly reduced pressure ulcer incidence.

An RCT (42) (n=409, mean age 81 years) compared polyurethane with standard padded dressing for heel ulcer prevention in at-risk patients in a medium-stay hospital. No significant difference were seen for incidence of heel pressure ulcers between polyurethane and standard dressing.

An RCT (43) (n=359) examined a polyurethane foam multi-layer dressing in the sacral area versus standard care to prevent pressure ulcers in elderly patients with hip fractures. Significantly fewer pressure ulcers occurred with the polyurethane dressing than standard care, and average time to onset of ulcers was significantly later with polyurethane.

An RCT (44) (n=160) compared transparent polyurethane film with hydrocolloid dressings in preventing pressure ulcers in an intensive care unit, coronary care unit and medical clinic. The mean total number of dressing changes, and mean number of dressing changes in the sacral region, was significantly less with polyurethane film than hydrocolloid dressing. The most common reasons for changing dressings in both groups were moisture and shear (though shear was a significantly less common reason with film than with hydrocolloid). The incidence of pressure ulcers was significantly lower with film than hydrocolloid.

A cluster RCT (45) across 4 medical-surgical study units (n=462) compared disposable with reusable absorbent underpads for preventing hospital-acquired incontinence-associated dermatitis and pressure ulcers in incontinent adults. Hospital-acquired pressure ulcers were significantly lower in the disposable underpads group. Rates of hospital incontinence-associated dermatitis were not significantly different between the groups. Hospital length of

stay was also significantly lower in patients who used disposable underpads.

Intelligence gathering

A topic expert highlighted the NICE Medtech innovation briefing (MIB124) 'Mepilex Border dressings for preventing pressure ulcers'. This dressing has now been examined by an in-development NICE medical technologies guidance [GID-MT519] – see the impact statement on silicone foam dressings below for details.

Impact statement

Silicone foam dressings

A systematic review and 3 RCTS examined silicone foam dressings. This evidence has all been examined by the in-development NICE medical technologies guidance [GID-MT519] Mepilex Border Heel and Sacrum dressings for preventing pressure ulcers. The recommendation that was consulted on was: 'Mepilex Border Heel and Sacrum dressings show promise for preventing pressure ulcers in people who are considered to be at risk in acute care settings. However, there is currently insufficient evidence to support the case for routine adoption in the NHS.' The final guidance is expected to publish in December 2018, and will be linked to from the NICE Pathway on pressure ulcers.

New evidence is unlikely to change guideline recommendations.

Other dressings

The Cochrane authors noted that although pressure ulcers appeared to be reduced by preventive dressings, results were compromised by low quality trials at substantial risk of bias and clinical heterogeneity, and so deemed the results to be inconclusive.

Individual RCTs found that:

- polyurethane heel dressing was no better than a standard dressing
- polyurethane dressing was significantly better than standard care
- polyurethane film was better than hydrocolloid dressing
- disposable were better than reusable incontinence pads.

The guideline did not include a review question on dressings to prevent pressure ulcers and therefore no recommendations are made in this area. The Cochrane review and the individual trials do not provide a clear steer for the benefit of any particular dressing and are unlikely to affect the guideline.

NICE Evidence summary medicines and prescribing briefing ESMPB2 'Chronic wounds: advanced wound dressings and antimicrobial dressings' includes a section on pressure ulcers. It discusses a meta-analysis by Huang et al. (2015) (35 RCTs or quasi-RCTs, n=5,401) on dressings for preventing pressure ulcers that was excluded from the current surveillance review for lack of data in the abstract. It found that compared with standard care alone, the risk of developing pressure ulcers was reduced in people who used hydrocolloid dressings, foam and film dressings. The quality of the evidence in the review was not graded, and the review authors noted that the included trials had many limitations. It is unlikely to affect the guideline.

New evidence is unlikely to change guideline recommendations.

Monitoring devices/processes

2018 surveillance summary

A systematic review and meta-analysis (46) of 9 non-randomised studies examined efficacy of monitoring devices to prevent pressure ulcers. The included studies evaluated monitoring devices that measured interface pressure, subdermal tissue stress, motion, and moisture. Most studies found a significant decrease in pressure ulcers. Two studies were eligible for meta-analysis, demonstrating that monitoring devices were associated with a reduced risk of developing pressure ulcers.

An RCT (47) (n=190) examined pressure mapping of the interface between the patient's body and the support surface to prevent pressure ulcers in hospital. Patients were eligible if they were aged over 50 years and expected to stay in the ward for at least 3 days. A continuous bedside pressure mapping system displayed the patient's pressure points in real-time showing pressure distribution at the body-mat interface. The system gave immediate feedback to staff about the patient's pressure points, facilitating preventive interventions related to repositioning. It was used from admittance to discharge from the ward (or 14 days at most). Both intervention and control groups received standard pressure ulcer prevention care. No significant difference in the prevalence and incidence of pressure ulcers was seen between intervention and control groups.

Intelligence gathering

No additional information was identified for this section.

Impact statement

A systematic review found that monitoring devices reduced pressure ulcers, however the included studies were not randomised and only 2 studies could be meta-analysed. An RCT found no benefit of a pressure mapping system on pressure ulcers. This evidence is unlikely to affect the guideline, which did not include a review question on monitoring devices and therefore no recommendations are made in this area.

New evidence is unlikely to change guideline recommendations.

Heel protection

2018 surveillance summary

A multicentre RCT (48) (n=183) examined the effect of early intervention during ambulance care with a heel suspension device boot among patients aged 70 or over. Significantly fewer patients developed heel pressure ulcers during their hospital stay.

An RCT (49) (n=54) examined a heel protector versus standard care (pillows) to prevent heel pressure injuries and plantar flexion contractures in high-risk neurotrauma, medical, and surgical intensive care units. Inclusion criteria were a minimum of 5 days of sedation related to care for a critical illness, immobility for 6 to 8 hours before study initiation, a Braden Scale for Pressure Sore Risk score 18 or less, and a mobility subscale score 2 or less. Significantly fewer patients treated with a heel protector developed pressure ulcer of the heels than controls.

Intelligence gathering

No additional information was identified for this section.

Impact statement

Two RCTs found that heel protection prevented pressure ulcers, which agrees with the guideline recommendation to discuss a strategy to offload heel pressure as part of the individualised care plan.

New evidence is unlikely to change guideline recommendations.

Wound care teams

2018 surveillance summary

A Cochrane review (50) examined wound-care teams for preventing and treating pressure ulcers. It found no RCTs that met the inclusion criteria.

Intelligence gathering

No additional information was identified for this section.

Impact statement

A Cochrane review of wound-care teams found no RCTs that met the inclusion criteria, therefore no conclusions could be made, and there is no impact on the guideline which does not make recommendations in this area.

New evidence is unlikely to change guideline recommendations.

1.2 Prevention: neonates, infants, children and young people

Recommendations in this section of the guideline

Risk assessment

1.2.1 Carry out and document an assessment of pressure ulcer risk for neonates, infants, children and young people:

- being admitted to secondary or tertiary care or
- receiving NHS care in other settings (such as primary and community care and emergency departments) if they have a risk factor, for example:
  - significantly limited mobility
  - significant loss of sensation
  - a previous or current pressure ulcer
  - nutritional deficiency
  - the inability to reposition themselves
  - significant cognitive impairment.

1.2.2 Use a scale validated for this population (for example, the Braden Q scale for children), to support clinical judgement.

Skin assessment

1.2.3 Offer neonates, infants, children and young people who are assessed as being at high risk of developing a pressure ulcer a skin assessment by a trained healthcare professional. Take into account:

- skin changes in the occipital area
- skin temperature
- the presence of blanching erythema or discoloured areas of skin.

1.2.4 Be aware of specific sites (for example, the occipital area) where neonates, infants, children and young people are at risk of developing a pressure ulcer.

Repositioning

1.2.5 Ensure that neonates and infants who are at risk of developing a pressure ulcer are repositioned at least every 4 hours.

1.2.6 Encourage children and young people who are at risk of developing a pressure ulcer to change their position at least every 4 hours. If they are unable to reposition themselves, offer help to do so, using appropriate equipment if needed.

1.2.7 Consider more frequent repositioning than every 4 hours for neonates and infants who have been assessed as being at high risk of developing a pressure ulcer. Document the frequency of repositioning required.

1.2.8 Encourage children and young people who have been assessed as being at high risk of developing a pressure ulcer to change their position more frequently than every 4 hours. If they are unable to reposition themselves, offer help to do so, using equipment if needed. Document the frequency of repositioning required.

1.2.9 Ensure that repositioning equipment is available to aid the repositioning of children and young people, if needed.

1.2.10 Ensure that healthcare professionals are trained in the use of repositioning equipment.

1.2.11 Ensure that patients, parents and carers understand the reasons for repositioning. If children and young people decline repositioning, document and discuss their reasons for declining.

1.2.12 Consider involving a play expert to encourage children who have difficulty with, or who have declined repositioning.

1.2.13 Relieve pressure on the scalp and head when repositioning neonates, infants, children and young people at risk of developing a pressure ulcer.

Skin massage

1.2.14 Do not offer skin massage or rubbing to neonates, infants, children and young people to prevent a pressure ulcer.

Nutritional supplements and hydration

1.2.15 Do not offer nutritional supplements specifically to prevent a pressure ulcer in neonates, infants, children and young people with adequate nutritional status for their developmental stage and clinical condition.

1.2.16 Do not offer subcutaneous or intravenous fluids specifically to prevent a pressure ulcer in neonates, infants, children and young people with adequate hydration status for their development stage and clinical condition.

Pressure redistributing devices

1.2.17 Use a high-specification foam cot mattress or overlay for all neonates and infants who have been assessed as being at high risk of developing a pressure ulcer as part of their individualised care plan.

1.2.18 Use a high-specification foam mattress or overlay 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.

1.2.19 Discuss with children and young people at high risk of developing a heel pressure ulcer and their parents and carers, where appropriate, a strategy to offload heel pressure as part of their individualised care plan.

1.2.20 Offer infants, children and young people who are long-term wheelchair users, regular wheelchair assessments and provide pressure relief or redistribution.

1.2.21 Offer neonates, infants, children and young people at risk of developing an occipital pressure ulcer an appropriate pressure redistributing surface (for example, a suitable pillow or pressure redistributing pad).

Barrier creams

1.2.22 Use barrier preparations to help prevent skin damage, such as moisture lesions, for neonates, infants, children and young people who are incontinent.

Surveillance decision

This section of the guideline should not be updated.

Editorial amendments

No editorial amendments are needed.

Heel protection

2018 surveillance summary

An RCT (51) (n=57) examined a splint with heel pressure offloaded in children with lower limb plaster casts. Children were randomised to either a custom-made splint positioned underneath the plaster after surgery, or maintaining the plaster position with cushions. The total number of pressure ulcers did not differ significantly between the groups.

Intelligence gathering

No additional information was identified for this section.

Impact statement

A splint with heel pressure offloaded in children with lower limb plaster cast did not reduce pressure ulcers, but is unlikely to affect the guideline which does not make specific recommendations about heel pressure offloading in children with plaster casts.

New evidence is unlikely to change guideline recommendations.

1.3 Prevention: all ages

Recommendations in this section of the guideline

Care planning

1.3.1 Develop and document an individualised care plan for neonates, infants, children, young people and adults who have been assessed as being at high risk of developing a pressure ulcer, taking into account:

- the outcome of risk and skin assessment
- the need for additional pressure relief at specific at-risk sites
- their mobility and ability to reposition themselves
- other comorbidities
- patient preference.

Patient and carer information

1.3.2 Offer timely, tailored information to people who have been assessed as being at high risk of developing a pressure ulcer, and their family or carers. The information should be delivered by a trained or experienced healthcare professional and include:

- the causes of a pressure ulcer
- the early signs of a pressure ulcer
- ways to prevent a pressure ulcer
- the implications of having a pressure ulcer (for example, for general health, treatment options and the risk of developing pressure ulcers in the future).

  Demonstrate techniques and equipment used to prevent a pressure ulcer.

1.3.3 Take into account individual needs when supplying information to people with:

- degenerative conditions
- impaired mobility
- neurological impairment
- cognitive impairment
- impaired tissue perfusion (for example, caused by peripheral arterial disease).

Healthcare professional training and education

1.3.4 Provide training to healthcare professionals on preventing a pressure ulcer, including:

- who is most likely to be at risk of developing a pressure ulcer
- how to identify pressure damage
- what steps to take to prevent new or further pressure damage

- who to contact for further information and for further action.

1.3.5 Provide further training to healthcare professionals who have contact with anyone who has been assessed as being at high risk of developing a pressure ulcer. Training should include:

- how to carry out a risk and skin assessment
- how to reposition
- information on pressure redistributing devices
- discussion of pressure ulcer prevention with patients and their carers
- details of sources of advice and support.

Surveillance decision

This section of the guideline should not be updated.

Editorial amendments

No editorial amendments are needed.

Care planning

2018 surveillance summary

Telecare

A single-blind, pilot RCT (52) (n=142) compared a community telehealth intervention with usual care for reducing pressure ulcers and depression and enhancing the use of appropriate health care in patients with multiple sclerosis or spinal cord injury using a wheelchair >6h per day. The intervention ('CareCall') comprised an automated, interactive voice response system combining patient education, cognitive behavioural interventions, screening and referrals, with alerts to a nurse telerehabilitation coordinator for direct non-emergent phone follow up. At 6 months, CareCall did not significantly reduce the number of pressure ulcers overall, but did significantly reduce pressure ulcers in women.

An RCT (53) (n=72) assessed the effect of telenursing on care provided by family members of patients with head trauma after discharge. Caregivers in both groups were provided with 1-hr face-to-face training session on patients' home care and educational booklets. Patients in the intervention group were followed up every week through phone calls by the telenurse for 12 weeks, who recorded the patient's status. Caregivers in the intervention group could call the telenurse at any time. The health status of the control group was followed up once by a phone call after 12 weeks. Risk of pressure ulcer did not differ significantly between groups.

A study (54) comprising an RCT (n=166), and a separate study wing involving a non-randomised standard care control group (n=66), examined a lifestyle intervention to reduce pressure ulcers in adults with spinal cord injury and a history of 1 or more pressure ulcers over the past 5 years. The Pressure Ulcer Prevention Program comprised a 12-month lifestyle-based treatment administered by healthcare professionals, via in-home visits and phone contacts. No significant difference between study groups was seen for blinded assessments of annualised pressure ulcer incidence rates at 12 and 24 months, based on: skin checks, quarterly phone interviews with participants, and review of medical charts and billing records.

A single-blind multicentre RCT (55) (n=143) across 6 centres compared telephone-based multicomponent interventions to improve skin care behaviours and prevent recurrence in veterans with spinal cord injury hospitalised for severe (stage III/IV) pressure ulcers. The intervention was telephone-based individual motivational interviewing counselling plus self-management skills group. The active control was telephone-based individual educational counselling plus group education (n=72). Skin behaviours had not changed significantly in either group at 3 and 6 months, and were not significantly different between the groups. Skin worsening, skin-related visits, and readmissions did not differ by study arm.

Clinical decision support system

A multicentre RCT (56) across 4 nursing homes (n=464 nursing home residents and 118 healthcare professionals) examined a 16-week multi-faceted tailored strategy to implement an electronic clinical decision support system for pressure ulcer prevention. The clinical decision support system included interactive education, reminders, monitoring, feedback and leadership. The control arm received a hard-copy of the pressure ulcer prevention protocol, supported by a 30 minute group lecture. For the primary outcome of adherence to guideline-based care recommendations (in terms of allocating adequate pressure ulcer prevention in residents at risk), patients in the intervention arm were significantly more likely to receive fully adequate pressure ulcer prevention when seated in a chair. No significant improvement was observed for pressure ulcer prevalence and knowledge of professionals. Attitude scores of healthcare professionals after the intervention were significantly higher in the experimental group.

Intelligence gathering

No additional information was identified for this section.

Impact statement

Telecare

Four RCTs of telecare found no benefit for pressure ulcers, and are unlikely to affect the guideline which recommends developing an individualised care plan for people at high risk of pressure ulcers, but does not make recommendations specifically on telecare.

New evidence is unlikely to change guideline recommendations.

Clinical decision support system

An RCT examining an electronic multi-faceted clinical decision support system did not reduce pressure ulcers, but is therefore unlikely to affect the guideline which recommends an individualised care plan for people at high risk of pressure ulcers, but does not make recommendations on the specific components of the system examined by the new evidence.

New evidence is unlikely to change guideline recommendations.

Patient and carer information

2018 surveillance summary

An assessor-blinded cluster RCT (57) across 8 tertiary referral hospitals (n=1,600 patients aged 18 or over) compared a pressure ulcer prevention care bundle with usual care in preventing hospital-acquired pressure ulcers among at risk patients. The guideline-based care bundle was multi-component with 3 messages for patients: keep moving; look after your skin; and eat a healthy diet. It included a DVD, brochure and poster. After adjusting for clustering and pre-specified covariates (age, pressure ulcer present at baseline, body mass index, reason for admission, residence and number of comorbidities on admission), the care bundle had no significant effect on new hospital-acquired pressure ulcers measured by daily skin inspection. No adverse events or harms were reported.

Intelligence gathering

No additional information was identified for this section.

Impact statement

A pressure ulcer prevention care bundle had no impact on pressure ulcers. The evidence is unlikely to affect the guideline which recommends offering general information to people at high risk of pressure ulcers including causes, early signs, prevention and implications of pressure ulcers, but which does not make recommendations on the specific components examined by the new evidence.

New evidence is unlikely to change guideline recommendations.

Healthcare professional training and education

2018 surveillance summary

A Cochrane review (58) of 5 RCTs examined education of healthcare professionals for preventing pressure ulcers. Healthcare settings, interventions and outcome measures differed across the studies, therefore due to study heterogeneity a narrative overview was done. The authors stated that the evidence left them uncertain about the following:

- whether there is a difference in health professionals' knowledge depending on whether they receive education or no education on pressure ulcer prevention (very low-certainty evidence from 1 study)
- whether there is a difference in pressure ulcer incidence with the following comparisons: training, monitoring and observation versus monitoring and observation; training, monitoring and observation versus observation alone; or monitoring and observation versus observation alone (very low-certainty evidence from 1 study)
- whether multilevel intervention versus attention control makes any difference to pressure ulcer incidence (insufficient data)
- whether education in different formats such as didactic education versus video-based education, or e-learning versus classroom education, makes any difference to health professionals' knowledge of pressure ulcer prevention (very low-certainty evidence from 2 studies).

None of the included studies explored change in health professionals' clinical behaviour. Only 1 study explored pressure ulcer severity and patient and carer reported outcomes. However, this study provided insufficient information to enable independent assessment of these outcomes within the review.

An RCT (59) (n=not stated) examined a self-learning e-learning tool (ePULab) for undergraduate nursing pressure ulcer training versus traditional on-campus teaching methods. Pre- and post-test questionnaires assessed the students' ability in pressure ulcer diagnosis and treatment. The e-learning tool produced significantly better learning acquisition results than those obtained by traditional lecture-style classes.

Intelligence gathering

A topic expert noted that training of mainstream medical and nursing workforce is important as people may be poorly trained in this field.

Impact statement

The Cochrane authors were uncertain whether educating healthcare professionals benefits pressure ulcers because the included studies were very low-certainty evidence. They stated that further information is needed to clarify the impact of education. The Cochrane review included only RCTs whereas the guideline included 7 high-quality qualitative studies. The guideline committee 'felt that all healthcare professionals would benefit

from receiving specific training in the prevention of pressure ulcers' and the Cochrane review is unlikely to impact the guideline which does currently recommend training.

An RCT showed benefits of e-learning for pressure ulcer training but only on knowledge – effect on pressure ulcer prevention would be useful before any impact on the guideline is considered.

The topic expert comment that people may be poorly trained in this field is likely to be an implementation issue as the guideline recommends providing training to healthcare professionals on preventing a pressure ulcer. The comment will be passed to the implementation team.

New evidence is unlikely to change guideline recommendations.

1.4 Management: adults

Recommendations in this section of the guideline

Ulcer measurement

1.4.1 Document the surface area of all pressure ulcers in adults. If possible, use a validated measurement technique (for example, transparency tracing or a photograph).

1.4.2 Document an estimate of the depth of all pressure ulcers and the presence of undermining, but do not routinely measure the volume of a pressure ulcer.

Categorisation

1.4.3 Categorise each pressure ulcer in adults using a validated classification tool (such as the International NPUAP-EPUAP [2009] Pressure Ulcer Classification System). Use this to guide ongoing preventative strategies and management. Repeat and document each time the ulcer is assessed.

Nutritional supplements and hydration

1.4.4 Offer adults with a pressure ulcer a nutritional assessment by a dietitian or other healthcare professional with the necessary skills and competencies.

1.4.5 Offer nutritional supplements to adults with a pressure ulcer who have a nutritional deficiency.

1.4.6 Provide information and advice to adults with a pressure ulcer and, where appropriate, their family or carers, on how to follow a balanced diet to maintain an adequate nutritional status, taking into account energy, protein and micronutrient requirements.

1.4.7 Do not offer nutritional supplements to treat a pressure ulcer in adults whose nutritional intake is adequate.

1.4.8 Do not offer subcutaneous or intravenous fluids to treat a pressure ulcer in adults whose hydration status is adequate.

Pressure redistributing devices

1.4.9 Use high-specification foam mattresses for adults with a pressure ulcer. If this is not sufficient to redistribute pressure, consider the use of a dynamic support surface.

1.4.10 Do not use standard-specification foam mattresses for adults with a pressure ulcer.

1.4.11 Consider the seating needs of adults who have a pressure ulcer who are sitting for prolonged periods.

1.4.12 Consider a high-specification foam or equivalent pressure redistributing cushion for adults who use a wheelchair or sit for prolonged periods and who have a pressure ulcer.

Negative pressure wound therapy

1.4.13 Do not routinely offer adults negative pressure wound therapy to treat a pressure ulcer, unless it is necessary to reduce the number of dressing changes (for example, in a wound with a large amount of exudate).

Hyperbaric oxygen therapy and electrotherapy

1.4.14 Do not offer the following to adults to treat a pressure ulcer:

- electrotherapy
- hyperbaric oxygen therapy.

Debridement

1.4.15 Assess the need to debride a pressure ulcer in adults, taking into consideration:

- the amount of necrotic tissue
- the grade, size and extent of the pressure ulcer
- patient tolerance
- any comorbidities.

1.4.16 Offer debridement to adults if identified as needed in the assessment:

- use autolytic debridement, using an appropriate dressing to support it
- consider using sharp debridement if autolytic debridement is likely to take longer and prolong healing time.

1.4.17 Do not routinely offer adults with a pressure ulcer:

- larval (maggot) therapy
- enzymatic debridement.

  Consider larval therapy if debridement is needed but sharp debridement is contraindicated or if there is associated vascular insufficiency.

Systemic antibiotics and antiseptics

1.4.18 After a skin assessment, offer systemic antibiotics to adults with a pressure ulcer if there are any of the following:

- clinical evidence of systemic sepsis
- spreading cellulitis
- underlying osteomyelitis.

1.4.19 Discuss with a local hospital microbiology department which antibiotic to offer adults with infection to ensure that the chosen systemic antibiotic is effective against local strains of infection.

1.4.20 Do not offer systemic antibiotics specifically to heal a pressure ulcer in adults.

1.4.21 Do not offer systemic antibiotics to adults based only on positive wound cultures without clinical evidence of infection.

Topical antimicrobials and antiseptics

1.4.22 Do not routinely use topical antiseptics or antimicrobials to treat a pressure ulcer in adults.

Dressings

1.4.23 Discuss with adults with a pressure ulcer and, if appropriate, their family or carers, what type of dressing should be used, taking into account:

- pain and tolerance
- position of the ulcer
- amount of exudate
- frequency of dressing change.

1.4.24 Consider using a dressing for adults that promotes a warm, moist wound healing environment to treat grade 2, 3 and 4 pressure ulcers.

1.4.25 Do not offer gauze dressings to treat a pressure ulcer in adults.

Heel pressure ulcers

1.4.26 Discuss with adults with a heel pressure ulcer and, if appropriate, their family or carers, a strategy to offload heel pressure as part of their individualised care plan.

Surveillance decision

This section of the guideline should not be updated.

Editorial amendments

A cross referral to NICE guideline CG32 Nutrition support for adults will be made from recommendation 1.4.5.

A cross-referral to NICE guideline NG51 Sepsis: recognition, diagnosis and early management will be made from recommendation 1.4.18

A cross-referral to NICE guideline NG15 Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use will be made from recommendations 1.4.21 and 1.4.22

Recommendation 1.4.3 refers 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.

Ulcer measurement

2018 surveillance summary

A multicentre study (60) examined reliability and validity of the revised Photographic Wound Assessment Tool (revPWAT) on digital images taken of various types of chronic wounds. A total of 206 photographs of 68 individuals (32 of whom had pressure ulcers) with 95 chronic wounds of various aetiologies were reviewed. An initial wound assessment using the revPWAT was performed at the bedside, and 3 digital photographs were taken: 2 photographs within 72 hours when no change had occurred, and a third photograph 3.5 to 6 weeks later. The revPWAT scores derived from photographs assessed by the same rater on different occasions and by different raters showed moderate to excellent intrarater intraclass correlation coefficients (ICC=0.52 to 0.93), as well as test-retest (ICC=0.86 to 0.90) and interrater (ICC=0.71) reliability. There was excellent agreement between bedside assessments and assessments using photographs (ICC=0.89).

Intelligence gathering

No additional information was identified for this section.

Impact statement

The study authors concluded that revPWAT is a valid and reliable tool to assess chronic wounds of various aetiologies where digital images are viewed. Further assessment of the tool specifically in pressure ulcers would be useful before any impact on the guideline, which does not currently recommend this tool, is considered.

New evidence is unlikely to change guideline recommendations.

Nutrition

2018 surveillance summary

A Cochrane review (26) of 23 RCTs (median=88 participants, range 9 to 4023) examined nutritional interventions for preventing and treating pressure ulcers. Many trials were at high risk of bias. Fourteen trials evaluated nutritional supplements for healing existing pressure ulcers: 7 trials examined mixed supplements, 3 the effects of proteins, 2 examined zinc, and 2 ascorbic acid. The included trials were heterogeneous and meta-analysis was not appropriate. There was no clear evidence of an improvement in pressure ulcer healing from the nutritional supplements evaluated in any of these individual studies.

A systematic review and meta-analysis (61) examined disease-specific nutritional support for pressure ulcer healing. Of the 9 RCTs identified, 3 studies (n=273) could be included in the meta-analysis. The 2 smallest studies in the meta-analysis were included in the Cochrane review (26) above; this more recent meta-analysis added a larger study (62) of n=200. Compared with control, formulas enriched with arginine, zinc and antioxidants resulted in significantly higher reduction in ulcer area and a higher proportion of participants having a 40% or greater reduction in pressure ulcer size at 8 weeks. No significant effect was seen for complete healing at 8 weeks and the percentage of change in the area at 4 weeks.

An RCT (63) (n=24, of whom 10 had pressure ulcers or chronic surgical wounds) compared a specialised oral nutrition supplement enriched with arginine, vitamin C and zinc compared to a standard supplement for healing chronic wounds. Patients were randomised to a specialised or standard supplement for 4 weeks, then best wound and nutrition care for an additional 4 weeks. There was a significant improvement in wound-healing in patients receiving the standard versus the specialised supplement, although there was no effect on nutritional status, dietary intake, quality of life and patient satisfaction.

An RCT (64) (n=23) compared a specialised amino acid mixture (beta-hydroxy beta-methylbutyrate, arginine and glutamine) with standard oral nutritional supplements for inpatients with stage II, III or IV pressure ulcers in an acute care hospital. Ulcer area did not decrease significantly in the short term for either group. Amino acid supplementation significantly increased the proportion of viable tissues within 2 weeks, and significantly improved Pressure Ulcer Scale for Healing scores within 1 week.

A multicentre RCT (65) (n=175, mean age 86 years) across 7 nursing homes examined an oral nutritional supplement for weight loss and anorexia in malnourished adults. All participants received the standard nursing home diet, and intervention group participants also received daily high-protein and high-energy cookies for 6 weeks with texture adapted to edentulous patients. Average weight increased significantly in the intervention group versus control. Weight gain persisted significantly for 1 and 3 months after the end of the intervention,

with significant diarrhoea reduction. There was also a significant positive impact on reduction of pressure ulcer episodes.

A double-blind RCT (66) (n=not stated) compared collagen hydrolysate with placebo for treating stage II or III pressure ulcers. End point was a comparison between groups of levels of Pressure Ulcer Scale for Healing (PUSH) score, Pressure Score Status Tool (PSST) score and decubitus area score 16 weeks after ingestion. Pressure Ulcer Scale for Healing score and Pressure Score Status Tool score decreased significantly more with collagen hydrolysate. Pressure ulcer area score was also reduced significantly with collagen hydrolysate than the level in the placebo group. Though there was no significant difference in blood albumin level of the subjects between the 2 groups, an intra-group significant difference in the level was observed in the collagen hydrolysate group.

Intelligence gathering

Two topic experts raised issues about nutrition. They noted that further recommendations on nutrition have been published by European Pressure Ulcer Advisory Panel (EPUAP) which gives more specific amounts of protein / energy intake. They also noted that a fortified diet should be considered in addition to nutritional supplements.

Impact statement

The Cochrane authors concluded there is currently no clear evidence of a benefit associated with nutritional interventions for treating pressure ulcers. This agrees with the guideline (which had examined most studies included in the Cochrane) not to offer nutritional supplements to treat a pressure ulcer in adults whose nutritional intake is adequate.

A systematic review found that formulas enriched with arginine, zinc and antioxidants may improve pressure ulcer healing. However 2 further RCTs (not included in the review meta-analysis) found no benefit of an oral nutrition supplement enriched with arginine, vitamin C and zinc, or of a specialised amino acid mixture (beta-hydroxy beta-methylbutyrate, arginine and glutamine). This mixed evidence is unlikely to affect the guideline which makes no recommendations about specialised supplements.

An RCT found that daily high-protein and high-energy cookies in malnourished adults reduced pressure ulcers, agreeing with the guideline to offer nutritional supplements to adults with a pressure ulcer who have a nutritional deficiency.

A single RCT found that collagen hydrolysate intake had a beneficial effect on pressure ulcers. The guideline examined some limited evidence and found no benefit of collagen hydrolysate. The evidence on this intervention is currently mixed and is unlikely to affect the guideline which does not recommend this supplement.

The comments by the topic experts will be addressed by linking NICE guideline CG179 to NICE guideline CG32 Nutrition support for adults, which makes specific recommendations on levels of protein and energy intake, and also focuses on ‘Oral nutrition support’ (rather than just

supplements) – which includes any of the following methods to improve nutritional intake: fortified food with protein, carbohydrate and/or fat, plus minerals and vitamins; snacks; oral nutritional supplements; altered meal patterns; the provision of dietary advice.

New evidence is unlikely to change guideline recommendations.

Pressure redistributing devices

2018 surveillance summary

A Cochrane review (67) examined pressure-relieving devices for treating heel pressure ulcers. In the original Cochrane review, only 1 RCT (n=141) comparing 2 mattresses met inclusion criteria but losses to follow up were too great to permit reliable conclusions. No further relevant studies were found during this updated review.

A Cochrane review (68) examined bed rest for pressure ulcer healing in wheelchair users. No RCTs were identified that met the inclusion criteria.

Intelligence gathering

No additional information was identified for this section.

Impact statement

A Cochrane review of pressure-relieving devices for heel pressure ulcers found 1 small study at moderate to high risk of bias which provided no evidence to inform practice, and therefore does not affect the guideline which recommends discussing with adults with a heel pressure ulcer a strategy to offload heel pressure as part of their individualised care plan.

A Cochrane review of bed rest for pressure ulcer healing in wheelchair users found no studies, and therefore does not affect the guideline.

New evidence is unlikely to change guideline recommendations.

Negative pressure wound therapy

2018 surveillance summary

A Cochrane review (69) of 4 RCTS (n=149) examined negative pressure wound therapy for treating pressure ulcers. The studies compared negative pressure with: dressings (2 studies), a series of gel treatments (1 study), and 'moist wound healing' (1 study). Three of the 4 included studies were deemed to be at a high risk of bias and all evidence was deemed to be of very low quality. Only 1 study reported usable primary outcome data (complete

wound healing) among 12 participants and there were very few events (only 1 participant healed in the study). There was little other useful data available from the included studies on positive outcomes such as wound healing or negative outcomes such as adverse events.

An RCT (70) (n=60) compared a novel negative pressure wound therapy device with standard pressure ulcer wound dressing in traumatic patients with paraplegia and sacral pressure ulcers of stage 3 and 4. Ulcer length and width reduced significantly more with negative pressure than standard care at week 9. At weeks 1, 2 and 3, ulcer depth was significantly higher with negative pressure, whereas at week 9 a significant reduction was observed. Exudates were significantly lower with negative pressure at weeks 4 and 9. Conversion of slough into red granulation tissue was significantly higher with negative pressure. Discharge became significantly lower with negative pressure at week 2 and no discharge was observed after week 6.

An RCT (71) (n=20) examined negative-pressure wound therapy with and without a poly-N-acetyl glucosamine nanofiber membrane at the wound interface. Safety was also assessed in patients treated with antiplatelet drugs. Compared with negative pressure therapy without the membrane, use of the membrane significantly promoted wound healing due to an improved contraction of the wound margins without a change in wound epithelisation. In 6 patients treated with antiplatelet drugs, no increased wound bleeding was observed in patients treated by negative pressure and the membrane.

Intelligence gathering

No additional information was identified for this section.

Impact statement

The Cochrane authors concluded there is currently no rigorous RCT evidence for negative pressure wound therapy in treating pressure ulcers, and high uncertainty remains. This agrees with the guideline which states do not routinely offer adults negative pressure wound therapy.

Two small RCTs examined a novel device, and a poly-N-acetyl glucosamine nanofiber membrane, for negative pressure wound therapy, which both found evidence of benefit for pressure ulcers. However, further evidence confirming these effects would be useful before any impact on the guideline is considered.

New evidence is unlikely to change guideline recommendations.

Hyperbaric oxygen therapy

2018 surveillance summary

A Cochrane review (72) examined hyperbaric oxygen therapy for chronic wounds. Ten trials enrolled people with a diabetic foot ulcer (which is covered by NICE guideline NG19 Diabetic foot problems). One trial considered venous ulcers (which is out of scope of NICE guideline CG179 Pressure ulcers). One trial enrolled patients with diabetic ulcers as well as venous ulcers. No trials were identified that considered arterial and pressure ulcers.

Intelligence gathering

No additional information was identified for this section.

Impact statement

The Cochrane review found no evidence for hyperbaric oxygen therapy in pressure ulcers, and therefore does not impact the guideline which states do not offer hyperbaric oxygen therapy to treat a pressure ulcer.

New evidence is unlikely to change guideline recommendations.

Electromagnetic and electrotherapy

2018 surveillance summary

Electromagnetic therapy

A Cochrane review (73) of 2 RCTs (n=60) examined electromagnetic therapy for treating pressure ulcers. This updated review identified no new trials beyond the 2 originally included. Both trials were at unclear risk of bias and compared the use of electromagnetic therapy with sham, although 1 of the trials included a third arm in which only standard therapy was applied. Neither study found a significant difference in complete healing with electromagnetic therapy versus control, though 1 trial found that wound surface area was significantly reduced with electromagnetic therapy versus control.

Electrotherapy

A systematic review and meta-analysis (74) of 15 RCTs examined electrostimulation for pressure ulcer healing. A meta-analysis of 5 studies found that adding unidirectional electrostimulation to standard wound care over 4 weeks of treatment led to a significantly greater reduction in percentage ulcer area than in the control group.

A systematic review and meta-analysis (75) of 15 studies examined electrostimulation for the treatment of pressure ulcers in patients with spinal cord injury. A meta-analysis of 5 studies demonstrated that electrostimulation significantly decreased the ulcer size compared to standard wound care or sham. Another meta-analysis of 4 studies showed that electrostimulation significantly increased the likelihood of

wound healing versus standard wound care or sham.

A systematic review and meta-analysis (76) of 6 RCTs and 2 non-RCTs (n=517) examined electrostimulation for pressure ulcer healing in people with spinal cord injuries. Studies compared electrostimulation with standard wound care and/or sham. Of the included studies, 2 were rated good quality, 2 were poor quality, and 4 were moderate. Evidence showed electrostimulation significantly increased the rate of pressure ulcer healing (7 studies, 559 ulcers), and a significantly higher proportion of ulcers healed (2 studies, 226 ulcers). Pulsed current electrostimulation significantly increased the healing rate (6 studies, 509 ulcers) whereas constant current had no significant effect on healing rate (2 studies, 200 ulcers). In addition, wounds with electrodes overlaying the wound bed seemed to heal ulcers faster than wounds with electrodes placed on intact skin around the ulcer (significance not reported in the abstract).

A multicentre double-blind RCT (77) (n=49) in 2 nursing and care centres examined cathodal high-voltage monophasic pulsed current electrostimulation versus sham for treating stage II and III pressure ulcers in patients not respond to previous treatment for at least 4 weeks. There was a significantly greater decrease in percentage wound surface area after 1 week and after 6 weeks of electrostimulation versus control.

A single-blind RCT (78) (n=77) examined high-voltage pulsed electrical stimulation and high-frequency ultrasound for patients (age range 60–95 years) with category II, III and IV pressure ulcers. Patients were randomised to 1 of 3 groups: standard wound care alone, or standard care plus either electrical stimulation or ultrasound. After 6 weeks, percentage reduction in surface area of pressure ulcers was significantly greater with ultrasound and electrical stimulation than standard care alone. The electrical stimulation group also had a significantly greater proportion of pressure ulcers that decreased in area by at least 50% or closed than with standard care. The ultrasound and electrical stimulation groups were not statistically significant different regarding treatment results. Clinical side effects were not recorded.

A multicentre RCT (79) (n=63) in 3 nursing and care centres compared cathodal with cathodal-anodal high-voltage monophasic pulsed current electrostimulation for treating stage II to IV pressure ulcers. Patients were randomised to cathodal, cathodal-anodal, or placebo electrostimulation. For the primary outcome, wound surface area at 6 weeks significantly decreased with both cathodal and cathodal-anodal electrostimulation; these reductions were significantly greater than with placebo. Treatment results with cathodal and cathodal-anodal groups were not significantly different.

A double-blind RCT (80) (n=61) examined anodal and cathodal high-voltage monophasic pulsed current electrostimulation for stage 2 to 4 pressure ulcers in people with neurological injuries. Patients were randomised to anodal, cathodal, or placebo electrostimulation for a maximum of

8 weeks. Periwound skin blood flow at week 2 was significantly higher with anodal and cathodal than placebo electrostimulation. Week 4 differences were not significant. Wound percentage area reduction at week 8 was significantly greater with anodal and cathodal than placebo electrostimulation. In both electrostimulation groups, periwound skin blood flow at week 4 and percent wound surface area reductions between weeks 4 and 8 were positively correlated, but only the anodal correlation was significant.

Intelligence gathering

No additional information was identified for this section.

Impact statement

Electromagnetic therapy

The guideline makes no recommendations on electromagnetic therapy, and no review questions in the guideline specifically looked for evidence on it.

The 2015 Cochrane review authors concluded there was no strong evidence of benefit of electromagnetic therapy to treat pressure ulcers. However, they stated the possibility of a beneficial or harmful effect could not be ruled out because there were only 2 included trials, both with methodological limitations and small numbers of participants. The evidence is currently unlikely to impact the guideline.

New evidence is unlikely to change guideline recommendations.

Electrotherapy

The guideline states do not offer electrotherapy to adults to treat a pressure ulcer.

Three systematic reviews found that electrotherapy reduced ulcer area, and increased the rate and likelihood of wound healing. Pulsed current appeared to be more effective than constant current.

Four individual RCTs published after the 3 systematic reviews found that pulsed electrotherapy reduced ulcer surface area versus sham stimulation.

Overall, the new evidence suggests there may be a benefit of electrotherapy. There is a Cochrane review protocol on Electrical stimulation for treating pressure ulcers. We will await completion of the full Cochrane review and we will consider any impact on the guideline when results are available.

New evidence is unlikely to change guideline recommendations.

Ultrasound

2018 surveillance summary

A multicentre RCT (81) (n=42) across 4 nursing and care centres examined high-frequency ultrasound versus standard care for stage II and stage III pressure ulcers in older patients (age range 71–95 years) with wounds that did not respond to previous treatment for at least 4 weeks. After 6 weeks of treatment, the following

significant benefits were seen with ultrasound: greater decrease in wound surface area; greater Gilman's parameter (average distance advanced by wound margin over time); greater mean weekly change of wound surface area (but only for stage II pressure ulcers); and more stage II pressure ulcers that decreased by at least 50%. No significant difference between groups was seen for number of stage II pressure ulcers closed, number of stage III pressure ulcers that decreased by at least 50%, and number of stage III pressure ulcers closed.

A single-blind RCT (78) (n=77) examined high-voltage pulsed electrical stimulation and high-frequency ultrasound for patients (age range 60–95 years) with category II, III and IV pressure ulcers. Patients were randomised to 1 of 3 groups: standard wound care alone, or standard care plus either electrical stimulation or ultrasound. After 6 weeks, percentage reduction in surface area of pressure ulcers was significantly greater with ultrasound and electrical stimulation than standard care alone. The electrical stimulation group also had a significantly greater proportion of pressure ulcers that decreased in area by at least 50% or closed than with standard care. The ultrasound and electrical stimulation groups were not statistically significant different regarding treatment results. Clinical side effects were not recorded.

Intelligence gathering

No additional information was identified for this section.

Impact statement

The guideline makes no recommendations on ultrasound, and no review questions in the guideline specifically looked for evidence on it.

Although 2 RCTs found that high-frequency ultrasound therapy offers benefits for pressure ulcer healing, they were in heterogeneous populations with small numbers exposed to the intervention, therefore further evidence would be useful before considering any impact on the guideline.

New evidence is unlikely to change guideline recommendations.

Phototherapy

2018 surveillance summary

A Cochrane review (82) of 7 RCTs (n=403) examined phototherapy for treating pressure ulcers. All the trials were assessed as being at unclear risk of bias. Trials compared the use of phototherapy with standard care only (6 trials) or sham phototherapy (1 trial). One trial included a third arm in which another type of phototherapy was applied. Overall, there was insufficient evidence to determine the relative effects of phototherapy for healing pressure ulcers. Time to complete healing was reported in 3 studies. Two studies showed the ultraviolet treated group had a significantly shorter mean time to complete healing than the control

group. One study reported that the laser group had a longer mean time to complete healing than the control group but the authors stated this result should be interpreted with caution, as these were small studies and the findings may have been due to chance. Three studies reported proportions of ulcers healed with a variety of results. One study reported a different outcome measure, and the other 2 studies had different treatment durations. These variations did not allow pooling of the studies or drawing any conclusions as to whether phototherapy is effective. Adverse effects were reported in only 2 studies that compared phototherapy with control; the risk ratio for adverse events was imprecise. Among 5 studies reporting the rate of change in ulcer area, 3 studies found no significant difference between the 2 groups. Pooling was not undertaken because of differences in outcome measures reported. The results were based on data from trials with unclear risk of bias for which generation of the randomisation sequence, concealment allocation and blinding of outcome assessors were unclear. No studies reported on quality of life, length of hospital stay, pain or cost.

A double-blind RCT (83) (n=43 patients with 58 stage 2 to 4 pressure ulcers) examined ultraviolet-C versus placebo irradiation of pressure ulcers in people with spinal cord injury. Ulcers were stratified by location to buttock or lower extremity. Overall healing did not differ significantly between groups. In subgroup analysis, percentage ulcer area relative to baseline for stage 2 buttock ulcers was significantly smaller in the group receiving ultraviolet-C than placebo at weeks 3, 5, and 7. Groups were similar in percentage area relative to baseline for stage 2 lower extremity ulcers. There were no group differences in the percentage area relative to baseline and the mean percentage area change between consecutive weeks for stage 3 to 4 ulcers. Groups were similar for all other secondary outcomes (surface appearance, weeks to closure, impact on quality of life and wound status post-intervention).

An RCT (84) (n=42) examined photodynamic antimicrobial therapy for infected pressure ulcers. In both groups, fu fang huang bai liquid (a traditional Chinese medicine) was applied to the ulcer, but in the intervention group the ulcer was then irradiated by semiconductor laser 30 minutes later. The rates of bacterial culture, rates of change of wound inflammation, healing rate at days 7 and 14, and expression of epidermal growth factor on wound granulation tissue were all significantly in favour of photodynamic therapy.

Intelligence gathering

No additional information was identified for this section.

Impact statement

The guideline makes no recommendations on ultrasound, and no review questions in the guideline specifically looked for evidence on it.

The Cochrane review concluded there was uncertainty about effects of phototherapy in treating pressure ulcers. The quality of evidence was very low due to the unclear risk of bias and small number of trials.

The RCT of ultraviolet-C (excluded from the Cochrane review because it reported outcomes based on ulcers not participants, contravening the review protocol) found benefits only in a sub-analysis of stage 2 buttock ulcers – all other outcomes did not show an effect.

The second RCT found that photodynamic antimicrobial therapy benefited healing rate of infected pressure ulcers.

Overall, the evidence does not suggest a clear benefit of phototherapy and is unlikely to impact the guideline. Further evidence confirming the positive findings for photodynamic antimicrobial therapy would be useful before considering any impact on the guideline.

New evidence is unlikely to change guideline recommendations.

Systemic therapy

2018 surveillance summary

A Cochrane review (85) examined anabolic steroids for treating pressure ulcers. The review identified 1 RCT (86) with 212 participants, all with spinal cord injury and open, stage III and IV pressure ulcers. It compared oxandrolone (20 mg/day orally) with placebo. There was very low-certainty evidence on the relative effect of oxandrolone on complete ulcer healing at the end of a 24-week treatment period, with a 95% confidence interval spanning both benefit and harm. There was low-certainty evidence suggesting a significant risk of non-serious adverse events with oxandrolone compared with placebo. There was very low-certainty evidence on the risk of serious adverse events with oxandrolone compared with placebo, with a 95% confidence interval spanning both benefit and harm. None of the 5 serious adverse events in the oxandrolone group were classed as treatment-related. Secondary outcomes (pain, length of hospital stay, change in wound size or wound surface area, incidence of different type of infection, cost of treatment and quality of life) were not reported in the included trial. The trial stopped early when the interim analysis showed that oxandrolone had no benefit over placebo.

Intelligence gathering

No additional information was identified for this section.

Impact statement

A Cochrane review found no high quality evidence to support the use of anabolic steroids in treating pressure ulcers. The guideline did not search for evidence on systemic steroids. 'The committee highlighted that there are some systemic agents such as steroids which are detrimental to the healing of pressure ulcers.' The evidence is unlikely to affect the guideline which makes no recommendations on systemic steroids.

New evidence is unlikely to change guideline recommendations.

Topical treatments

2018 surveillance summary

All topicals

A Cochrane network meta-analysis (87) identified 51 RCTs (n=2,947) examining dressings and topical agents for treating pressure ulcers. Network meta-analysis was carried out for the sole outcome of probability of complete healing. The relative effectiveness of any 2 treatments were modelled as a function of each treatment relative to the reference treatment (saline gauze). The network included 21 different interventions (13 dressings, 6 topical agents and 2 supplementary linking interventions) and was informed by 39 studies (n=2,127, of whom 783 had completely healed wounds). The network was judged to be sparse (few participants, few events, and most studies were small or very small) and therefore highly imprecise. Most studies informing the network were at high risk of bias. The authors judged most evidence to be of low or very low certainty, and had no confidence in the findings regarding the rank order of interventions in the review (very low-certainty evidence). In the abstract, the authors reported only those results which were not considered to be very low certainty. From the results reported, the authors stated they were not clear whether the following regimens increased the probability of pressure ulcer healing compared with saline gauze: protease-modulating dressings (moderate-certainty evidence, low risk of bias); collagenase ointment, foam dressings, basic wound contact dressings, and polyvinylpyrrolidone plus zinc (low-certainty evidence).

Antibiotics and antiseptics

A Cochrane review (88) of 12 RCTs (n=576) examined antibiotics and antiseptics for pressure ulcers. The studies assessed the following antimicrobial topical agents (none looked at systemic antibiotics): povidone iodine, cadexomer iodine, gentian violet, lysozyme, silver dressings, honey, pine resin, polyhexanide, silver sulfadiazine, and nitrofurazone with ethoxy-diaminoacridine. Comparators included a range of other dressings and ointments without antimicrobial properties and alternative antimicrobials. Each comparison had only 1 trial, participant numbers were low and follow-up times short. Six trials reported the primary outcome of wound healing. All except 1 compared an antiseptic with a non-antimicrobial comparator. There was some moderate and low quality evidence that significantly fewer ulcers may heal in the short term when treated with povidone iodine compared with non-antimicrobial alternatives (protease-modulating dressings and hydrogel), and low quality evidence of no clear difference between povidone iodine and a third non-antimicrobial treatment (hydrocolloid). There was low quality evidence that pine resin salve may heal significantly more pressure ulcers than hydrocolloid. There was very low quality evidence of no clear difference between cadexomer iodine and

standard care, and between honey and a combined antiseptic/antibiotic treatment. Six trials reported adverse events. Four reported no adverse events; there was very low quality evidence from 1 showing no clear evidence of a difference between cadexomer iodine and standard care; in 1 trial it was not clear whether data were appropriately reported.

Phenytoin

A Cochrane review (89) of 3 RCTs (n=148) examined topical phenytoin for treating pressure ulcers. The included studies compared 3 treatments with topical phenytoin: hydrocolloid dressings, triple antibiotic ointment and simple dressings. All participants had grade I or II ulcers. Two RCTs had a high risk of bias and the other was at unclear risk of bias. One study (n=56) found that hydrocolloid dressings may significantly improve ulcer healing compared to phenytoin (low quality evidence). From 1 study (n=55) the authors were uncertain whether topical phenytoin improved ulcer healing compared to simple dressings, with a 95% confidence interval spanning both increased healing and reduced healing (very low quality evidence). No outcomes of interest were reported in a study comparing topical phenytoin with triple antibiotic ointment. No adverse drug reactions or interactions were detected in any of the 3 RCTs. Minimal pain was reported in all groups in 1 trial comparing topical phenytoin with hydrocolloid dressings and triple antibiotic ointment.

Honey

A Cochrane review (90) of 26 RCTs (n=3,011) examined honey as a topical treatment for wounds. From 1 trial in pressure ulcers (n=40), honey healed pressure ulcers significantly more quickly than saline soaks (very low quality evidence).

Platelet-rich plasma/growth factor

A Cochrane review (91) of 10 RCTs (n=442) examined autologous platelet-rich plasma for treating chronic wounds. Pressure ulcers were within scope of the review but no studies were found in this population.

An RCT (92) (n=100 patients with 124 pressure ulcers) examined platelet-rich growth factor (PRGF; from the patients' own peripheral blood) and hyaluronic acid for treating stage 2 and 3 pressure ulcers. Patients were randomised to standard care (n=25 pressure ulcers), or to treatment with one (n=34 pressure ulcers) or two (n=25 pressure ulcers) doses of PRGF or two doses of PRGF plus hyaluronic acid (n=40 pressure ulcers). At 36 days, a significant reduction in ulcer area was seen in all treatment groups. The greatest mean reduction of 80% was seen with PRGF plus hyaluronic acid. Complete wound healing was observed in 32% of pressure ulcers treated with 2 doses of PRGF and in 38% of those treated with 2 doses of PRGF plus hyaluronic acid. There were no signs of infection in any pressure ulcers during the 36-day follow-up period. The degree of wound healing was inversely correlated with the consumption of drugs such as statins and with the peripheral blood platelet levels of patients at baseline.

Sucralfate

A double-blind RCT (93) (n=40) examined daily topical sucralfate gel versus placebo in hospitalised patients with stage II pressure ulcers. Both interventions reduced the average Pressure Ulcer Scale for Healing score, but there was no significant between-group difference in average score reduction, or average healing time. One in each group discontinued the trial because of exacerbation of the ulcer.

Propylbetaine-polihexanide

A single-blind RCT (94) (n=289) examined a surfactant (propylbetaine-polihexanide) wound cleansing solution versus normal saline for wound bed preparation in pressure ulcers or vascular leg ulcers. There were significant differences in favour of the surfactant solution after 28 days for scores on the Bates-Jensen wound assessment tool (total score, inflammatory items score, and wound size reduction score), and granulation tissue improvement. Pain did not differ significantly between the groups.

Atorvastatin

An RCT (95) (n=104) compared once a day topical atorvastatin (1%) ointment with placebo for treating pressure ulcers in critically ill patients with stage I or II pressure ulcers. Mean stage of pressure ulcers significantly decreased, and mean surface areas of ulcers declined significantly, with atorvastatin versus placebo on day 7 and day 14 of treatment.

Sildenafil

An RCT (96) (n=122) compared daily topical sildenafil (10%) ointment with placebo for treating pressure ulcers. Decreases in grade of pressure ulcers were significantly higher with sildenafil versus placebo at days 7 and 14 of intervention. In addition, surface areas of ulcers were significantly reduced with sildenafil versus placebo at day 14.

Insulin

An RCT (97) (n=50 patients with 50 ulcers) compared a topical insulin dressing with normal saline gauze (twice daily for 7 days) for treating grade 2 or 3 pressure ulcers in an acute care facility. By day 7, mean wound area and Mean Pressure Ulcer Scale for Healing scores had significantly decreased with insulin but not with saline. No significant decrease in blood glucose level before and after topical insulin application was observed.

Tetrachlorodecaoxide

A double-blind RCT (98) (n=150, of whom 10 had pressure ulcers) compared tetrachlorodecaoxide with super-oxidised solution in wound healing. Patients were observed for 8 weeks. At the end of week 2 and week 4, a significant change from baseline in wound tissue type was seen in the 2 groups. Other comparisons (wound area, scoring of wound exudation, and pain) were not significant. No study-related adverse events were observed.

Nitric oxide

An RCT (99) (n=58) compared nitric oxide releasing cream with placebo for healing pressure ulcers. No significant difference between the 2 groups was found for individual scores on the Pressure Ulcer Scale for Healing for ulcer size, amount of exudates, or tissue type. However mean

total score (healing) on the scale between the 2 groups was significant.

Complementary and alternative medicine

An RCT (100) (n=72) compared 'moist exposed burn ointment' (comprising sesame oil, beta-sitosterol, berberine, and other Chinese herbal ingredients) with placebo for treating pressure ulcers. After 2 months of treatment, the mean change from baseline was significantly greater with the burn ointment for wound surface area, Pressure Ulcer Scale for Healing score, and visual analog scale score. From a questionnaire about pressure ulcer status, ulcers were 'completely healed' in significantly more patients with the burn ointment. No major adverse effects were found in the 2 groups.

An RCT (101) (n=75 men) compared 'mummy' (also known as 'shilajit'; a mineral substance) with saline for treating pressure ulcers in patients with cerebrospinal injury in an intensive care unit. Both groups showed reduction in the average ulcer surface area, exudate amount, and tissue score. After 28 days, the intervention group showed significantly more 'acceptable signs of healing' (not defined in the abstract) than control group.

A double-blind RCT (102) (n=60 patients with chronic wounds, 41 of whom had pressure ulcer) compared an aloe vera/olive oil combination cream with phenytoin cream for treating chronic wounds. After 30 days of treatment, significant improvements in wound size, depth, and edges; necrotic tissue type and amount; exudate type and amount; colour of wound surroundings; and peripheral tissue oedema score were observed with aloe vera/olive oil. The total wound healing score showed significant improvement in both groups, although aloe vera/olive oil was significantly more effective. Likewise, although both treatments reduced the initial pain visual analogue scale score, the efficacy of aloe vera/olive oil was significantly greater.

Intelligence gathering

A topic expert noted that costs are high especially in the community, and low cost local and topical treatments should be encouraged by education and cost-awareness of staff.

Impact statement

All topicals

The Cochrane network meta-analysis was sparse and the evidence of low or very low certainty (due mainly to risk of bias and imprecision). Consequently the authors were unable to determine which dressings or topical agents were the most likely to heal pressure ulcers, and it was generally unclear whether the treatments examined were more effective than saline gauze. This agrees with the conclusion of the guideline committee, who felt that there was no convincing evidence to support a recommendation to suggest the use of 1 topical agent over another or against placebo, and hence the guideline states do not routinely use topical antiseptics or antimicrobials to treat a pressure ulcer in adults.

The comment about costs from the topic expert is addressed by a comment by the guideline committee: 'The committee felt that there was no convincing clinical

evidence for the use of topical agents, and noted that use of such topical agents will have resource implications. Therefore, based on current evidence, the use of topical agents is considered unlikely to be cost-effective.' The new evidence is unlikely to change this position.

New evidence is unlikely to change guideline recommendations.

Antibiotics and antiseptics

The Cochrane authors concluded that the relative effects of topical antimicrobial treatments are not clear. Where differences in wound healing were found, these sometimes favoured the comparator treatment without antimicrobial properties. The trials were small, clinically heterogenous, generally of short duration, and at high or unclear risk of bias. The quality of the evidence ranged from moderate to very low; evidence on all comparisons was subject to some limitations. The evidence is unlikely to affect the guideline which states do not routinely use topical antiseptics or antimicrobials to treat a pressure ulcer in adults.

New evidence is unlikely to change guideline recommendations.

Phenytoin

The Cochrane authors concluded it is uncertain whether topical phenytoin improved ulcer healing. The evidence is unlikely to affect the guideline which does not make recommendations on phenytoin.

New evidence is unlikely to change guideline recommendations.

Honey

The Cochrane review found a single small trial showing honey healed pressure ulcers more quickly than saline soaks. The guideline found 1 study showing that honey is more clinically effective than ethoxy-diaminoacridine plus nitrofuazone, but it was not sufficient to make any recommendations on honey. Further evidence confirming the effects of honey would be useful before any impact on the guideline is considered.

New evidence is unlikely to change guideline recommendations.

Platelet-rich plasma/growth factor

The Cochrane review found no studies of platelet-rich plasma for treating pressure ulcers.

A single RCT found benefits of platelet-rich growth factor for pressure ulcers but it was not clear how much benefit there was over standard care. The evidence is unlikely to affect the guideline which makes no recommendations on growth factors, particularly given the guideline committee noted they are very expensive.

New evidence is unlikely to change guideline recommendations.

Sucralfate

An RCT found that sucralfate does not improve healing of pressure ulcers, and no impact on the guideline is expected which makes no recommendations on sucralfate.

New evidence is unlikely to change guideline recommendations.

Propylbetaine-polihexanide

An RCT found benefits of propylbetaine-polihexanide for healing pressure ulcers. The guideline did not examine any evidence for this treatment and so does not make any recommendations on it. Further evidence confirming findings would be useful before considering any impact on the guideline.

New evidence is unlikely to change guideline recommendations.

Atorvastatin

An RCT found that atorvastatin accelerated healing of pressure ulcers. The guideline did not examine any evidence for this treatment and so does not make any recommendations on it. Further evidence confirming findings would be useful before considering any impact on the guideline.

New evidence is unlikely to change guideline recommendations.

Sildenafil

An RCT found benefits of sildenafil for healing pressure ulcers. The guideline did not examine any evidence for this treatment and so does not make any recommendations on it. Further evidence confirming findings would be useful before considering any impact on the guideline.

New evidence is unlikely to change guideline recommendations.

Insulin

An RCT found insulin was safe and effective in reducing pressure ulcer size. The guideline found no benefit of insulin from a small study with few relevant outcomes, and so does not make any recommendations on it. Further evidence confirming findings would be useful to establish an effect before considering any impact on the guideline.

New evidence is unlikely to change guideline recommendations.

Tetrachlorodecaoxide

An RCT found similar efficacy of tetrachlorodecaoxide and super-oxidised solution for ulcer healing. The guideline did not examine any evidence for these treatments and so does not make any recommendations on them. Further evidence confirming findings would be useful before considering any impact on the guideline.

New evidence is unlikely to change guideline recommendations.

Nitric oxide

An RCT found that nitric oxide can benefit pressure ulcer healing. The guideline did not examine any evidence for this treatment and so does not make any recommendations on them. Further evidence confirming findings would be useful before considering any impact on the guideline.

New evidence is unlikely to change guideline recommendations.

Complementary and alternative medicine

Two RCTs found benefits of 'moist exposed burn ointment' (comprising sesame oil, beta-sitosterol, berberine, and other Chinese herbal ingredients) and 'mummy' (also known as 'shilajit'; a mineral substance) for healing pressure ulcers. The guideline did not examine any evidence for these treatments and so does not make any recommendations on them. Further evidence confirming findings would be useful before considering any impact on the guideline.

An RCT found benefits of an aloe vera/olive oil combination cream for healing pressure ulcers. The guideline committee found no clinically important benefit for isotonic saline solution compared with aloe vera and so did not make any recommendations on aloe. Further evidence confirming findings would be useful before considering any impact on the guideline.

New evidence is unlikely to change guideline recommendations.

Dressings

2018 surveillance summary

All dressings

A Cochrane network meta-analysis (87) identified 51 RCTs (n=2,947) examining dressings and topical agents for treating pressure ulcers. Network meta-analysis was carried out for the sole outcome of probability of complete healing. The relative effectiveness of any 2 treatments were modelled as a function of each treatment relative to the reference treatment (saline gauze). The network included 21 different interventions (13 dressings, 6 topical agents and 2 supplementary linking interventions) and was informed by 39 studies (n=2,127, of whom 783 had completely healed wounds). The network was judged to be sparse (few participants, few events, and most studies were small or very small) and therefore highly imprecise. Most studies informing the network were at high risk of bias. The authors judged most evidence to be of low or very low certainty, and had no confidence in the findings regarding the rank order of interventions in the review (very low-certainty evidence). In the abstract, the authors reported only those results which were not considered to be very low certainty. From the results reported, the authors stated they were not clear whether the following regimens increased the probability of pressure ulcer healing compared with saline gauze: protease-modulating dressings (moderate-certainty evidence, low risk of bias); collagenase ointment, foam dressings, basic wound contact dressings, and polyvinylpyrrolidone plus zinc (low-certainty evidence).

Hydrogel

A Cochrane review (103) of 11 RCTs (n=523) examined hydrogel dressings for treating pressure ulcers. Ten studies had 2 arms and one had 3 arms. Hydrogel dressing was compared with: a basic

wound contact dressing (3 studies); a hydrocolloid dressing (3 studies); another hydrogel dressing (3 studies); a foam dressing (1 study); a dextranomer paste dressing (1 study); and topical collagenase (1 study). Limited data were available for analyses and no meta-analyses were done. Where data were available there was no evidence of a difference between hydrogel and alternative treatments in terms of complete wound healing or adverse events. One small study reported that hydrogel was, on average, less costly than hydrocolloid dressings, but this estimate was imprecise and its methodology was not clear. All included studies were small, had short follow-up times and were at unclear risk of bias.

Alginate

A Cochrane review (104) of 6 RCTs (n=336) examined alginate dressings for treating pressure ulcers. The included studies compared alginate dressings with 6 other interventions that included: hydrocolloid dressings, silver containing alginate dressings, and radiant heat therapy. Each of the 6 comparisons included just 1 study and these had limited participant numbers and short follow-up times. No meta-analyses were done. All the evidence was of low or very low quality. Where data were available there was no evidence of a difference between alginate dressings and alternative treatments in terms of complete wound healing or adverse events.

A randomised cost-effectiveness analysis (105) (n=20) was included in the above Cochrane review. It compared alginate silver dressing with silver zinc sulfadiazine cream for treating grade III or IV sacral or trochanteric pressure ulcers. After 8 weeks, the 2 groups showed no significant difference in the reduction of PUSH (Pressure Ulcer Scale for Healing) score, wound size, or volume of exudate. The tissue type score was significantly lower in the alginate group. The cost of treatment was significantly lower in the alginate group.

Foam

A Cochrane review (106) of 9 RCTs (n=483) examined foam dressings for treating pressure ulcers in adults (aged 59 years or older) with an existing pressure ulcer of stage II or above. The authors reported the following evidence that was deemed very low certainty, and therefore left them uncertain about the following outcomes:

- From 1 trial (n=38) lasting 8-weeks: Whether a silicone foam dressing versus another (hydropolymer) foam dressing affected incidence of healed pressure ulcers or adverse events.
- From 4 trials (n=230) lasting 8 weeks or less: Whether foam dressing versus hydrocolloid dressing affected healing, adverse events, reduction in ulcer size, patient satisfaction/acceptability, pain and cost effectiveness.
- From 1 trial (n=34) lasting 8 weeks: Whether foam dressing versus hydrogel dressing affected the probability of healing, time to complete healing, adverse events, or reduction in ulcer size.
- From 3 trials (n=181) ranging from 8 to 24 weeks in length: Whether foam dressing versus basic wound contact

dressing affected the probability of healing, time to complete healing, adverse events, reduction in ulcer size, patient satisfaction/acceptability, pain and cost effectiveness.

None of the included trials reported quality of life or pressure ulcer recurrence. The authors stated they had very little confidence in the estimate of effect of included studies.

Hydrocolloid

A systematic review and meta-analysis (107) of 9 studies examined hydrocolloid dressings versus other dressings for pressure ulcers in adults. Of the included studies, 4 were meta-analysed. There was no significant difference between hydrocolloid dressing and either foam dressing or polyurethane dressing.

A systematic review and meta-analysis (108) of 7 RCTs (n=329) compared hydrocolloid dressing with saline gauze for treating pressure ulcer. Meta-analysis of the 7 trials indicated a significant benefit of hydrocolloid dressing for complete ulcer healing over saline gauze. The significance remained when the meta-analysis was re-run to remove 1 study that did not report number of ulcers healed, and to remove 1 study of 6-month duration (the rest were 8-12 week duration). No publication bias was found.

Plastic wrap

An open-label RCT (109) (n=142) across 10 hospital wards and 2 care facilities examined plastic wrap (typically used for food) as a dressing material versus standard treatment for stage III and IV pressure ulcers in the inflammatory phase. For the primary outcome, at 4, 8, and 12 weeks, mean ulcer surface area reduced significantly more with plastic wrap than standard treatment. At 4, 8, and 12 weeks the median reduction in Pressure Sore Status Tool score from baseline was significantly greater with plastic wrap than standard treatment. The incidence of adverse events was comparable between the groups.

Chitosan

A multicentre RCT (110) (n=90) across 3 medical centres examined a chitosan wound dressing versus traditional vaseline gauze for unhealed chronic wounds including pressure ulcers, vascular ulcers, diabetic foot ulcers, and wounds with minor infections, or at risk of infection. After 4 weeks, the primary end point of wound area reduction was significantly greater with chitosan than control. Pain level and wound depth was also lower with chitosan (significance not stated in the abstract). The level of exudate fell and the dressing could be removed integrally in both the chitosan and control groups. No adverse events were reported in either group.

Moist wound healing dressing

An RCT (111) (n=95) examined cost and clinical effectiveness of moist wound healing dressings versus gauze in home care patients with stage III and IV pressure ulcers. The average healing time, and dressing change frequency per patient, was significantly less with moist wound healing dressings than gauze. Use of moist dressings had a lower total treatment cost than gauze (significance not reported in the abstract).

An RCT (112) (n=50) examined gelatin sponge combined with a moist wound-healing intervention versus standard care in treating stage 3 pressure ulcers. Gelatin sponge had significant benefits over standard care for the following outcomes: improvement rate (not defined in the abstract), Braden score, pressure ulcer area, frequency and time of dressing change, and average cost of hospitalisation.

Intelligence gathering

Two experts raised issues about costs: the role of foam dressing is a direct cost pressure and there is a need to ensure it is based on a sound evidence base; and that costs are high especially in the community, and low-cost local and topical treatments should be encouraged by education and cost-awareness of staff.

Impact statement

All dressings

The Cochrane network meta-analysis was sparse and the evidence of low or very low certainty (due mainly to risk of bias and imprecision). Consequently the authors were unable to determine which dressings or topical agents were the most likely to heal pressure ulcers, and it was generally unclear whether the treatments examined were more effective than saline gauze. This agrees with the guideline committee, who did not feel that the evidence allowed for a recommendation to be made about the use of a specific type of dressing. This was due to the lack and quality of evidence, as well as the importance of considering the function of the dressing and specific patient factors. The guideline therefore recommends discussing what type of dressing should be used, taking into account: pain and tolerance; position of the ulcer; amount of exudate; and frequency of dressing change.

The comment about costs from the topic experts is addressed by a comment by the guideline committee: 'The committee considered UK relevant unit costs, but noted that the major resource implications come from the frequency that each dressing requires changing. This is likely to be dependent on a range of factors, such as location of the ulcer, the amount of exudate, and patient acceptability. The frequency of dressing change can also have a substantial impact on quality of life. The committee therefore agreed that the dressing which was deemed more effective when taking these factors into account would be most likely to be cost-effective.'

Additionally, a NICE key therapeutic topic (KTT14) 'Wound care products' discusses costs associated with prescribing dressings (The document summarises the evidence-base on wound care products. It is a key therapeutic topic which has been identified to support medicines optimisation. It is not formal NICE guidance.)

New evidence is unlikely to change guideline recommendations.

Hydrogel

The Cochrane review concluded it was not clear if hydrogel dressings are more or less effective than other treatments in healing pressure ulcers or if different hydrogels have different effects. There is no impact

on the guideline which does not recommend any specific dressings.

New evidence is unlikely to change guideline recommendations.

Alginate

The Cochrane review concluded that the relative effects of alginate dressings compared with alternative treatments are unclear. An RCT found no difference between alginate silver dressing and silver zinc sulfadiazine cream. There is no impact on the guideline which does not recommend any specific dressings.

New evidence is unlikely to change guideline recommendations.

Foam

The Cochrane review concluded it is uncertain whether foam dressings are more effective, more acceptable, or more cost effective than alternative dressings, and it was difficult to make comparisons due to lack of data. There is no impact on the guideline which does not recommend any specific dressings.

New evidence is unlikely to change guideline recommendations.

Hydrocolloid

One systematic review concluded evidence is not sufficient to decide whether hydrocolloid dressings are superior to other dressings. Another systematic review suggested hydrocolloid dressing increased the likelihood of complete healing compared with saline gauze. All evidence included in the 2 reviews was examined by the guideline, and is therefore unlikely to affect the guideline which does not recommend any specific dressings.

New evidence is unlikely to change guideline recommendations.

Plastic wrap

An RCT found that plastic wrap dressing was effective in managing pressure ulcers. The guideline did not examine any evidence for this treatment and so does not make any recommendations on it. Further evidence confirming findings would be useful before considering any impact on the guideline, which does not recommend any specific dressings.

New evidence is unlikely to change guideline recommendations.

Chitosan

An RCT found that chitosan dressing was of benefit in healing chronic wounds including pressure ulcers. The guideline did not examine any evidence for this treatment and so does not make any recommendations on it. Further evidence confirming findings would be useful before considering any impact on the guideline, which does not recommend any specific dressings.

New evidence is unlikely to change guideline recommendations.

Moist wound healing dressing

Two RCTs found that moist wound healing dressing was of benefit in healing stage III and IV pressure ulcers, and gelatin sponge

combined with a moist wound-healing intervention may significantly improve stage III pressure ulcers. The evidence agrees with the guideline to consider using a dressing that promotes a warm, moist wound healing environment to treat grade 2, 3 and 4 pressure ulcers.

New evidence is unlikely to change guideline recommendations.

Repositioning

2018 surveillance summary

A Cochrane review (113) examined repositioning for treating pressure ulcers. No RCTs were identified that met the inclusion criteria.

Intelligence gathering

No additional information was identified for this section.

Impact statement

The Cochrane review did not identify any studies on repositioning for treating existing pressure ulcers. It is unlikely to affect the guideline which did not examine any evidence for this treatment and so does not make any recommendations on it.

New evidence is unlikely to change guideline recommendations.

Reconstructive surgery

2018 surveillance summary

A Cochrane review (114) examined reconstructive surgery for treating pressure ulcers. No RCTs were identified that met the review eligibility criteria nor any registered studies investigating the role of reconstructive surgery in the management of pressure ulcers.

Intelligence gathering

No additional information was identified for this section.

Impact statement

The Cochrane review did not identify any studies on reconstructive surgery for treating pressure ulcers. It is unlikely to affect the guideline which did not examine any evidence for this treatment and so does not make any recommendations on it.

New evidence is unlikely to change guideline recommendations.

Grafts

2018 surveillance summary

An RCT (115) (n=24 patients with 24 pressure ulcers, mean age 44 years) examined allografting with cryopreserved human amniotic membrane versus routine pressure ulcer care in treating stage 2 and 3 pressure ulcers. Complete pressure ulcer healing (which occurred only in the amnion group), and partial healing, were significantly higher in the amnion group. Healing time was not significantly different between groups. No major complication was recorded with amniotic graft.

Intelligence gathering

No additional information was identified for this section.

Impact statement

An RCT found that amniotic membrane is effective for healing pressure ulcers. The guideline did not examine any evidence for this treatment and so does not make any recommendations on it. Further evidence confirming findings would be useful before considering any impact on the guideline.

New evidence is unlikely to change guideline recommendations.

Complementary and alternative medicine

2018 surveillance summary

A systematic review and meta-analysis (116) of 14 RCTs (n=618) examined resina draconis as a topical treatment for pressure ulcers. The meta-analysis showed that resina draconis was significantly associated with a higher healing rate for pressure ulcers. Adverse reactions were not reported.

A systematic review and meta-analysis (117) of 10 RCTs (n=893) examined traditional Chinese medicine (Chinese herbal medicine ointment, acupuncture and moxibustion) for pressure ulcers. All included RCTs examined Chinese herbal medicine ointment. Meta-analysis showed beneficial effects of Chinese herbal medicine ointment for pressure ulcer compared with other treatments on the total effective rate, curative ratio, and inefficiency rate. A funnel plot indicated that there was publication bias in this study.

An RCT (118) (n=34) examined acupuncture for grade IV pressure ulcer. Patients in the control group were treated with conventional nursing, ultrasound and ultraviolet therapy; additionally, 'encircling needling' acupuncture was applied in the intervention group. After treatment, pressure ulcer area, 24-hour volume of exudates and wound-bed tissue type were significantly more greatly reduced in the acupuncture group. The total clinical efficacy rate (undefined in the abstract) was significantly greater with acupuncture.

An RCT (119) (n=35) examined a traditional Chinese herbal formula (gypsum fibrosum, hydrargyrum oxydatum crudum, red orpiment and borneol) versus arnebia

root oil for pressure ulcers in paraplegic patients. After 28 days of treatment, wound healing rate and non-response rate were significantly better with the novel Chinese herbal formula.

Intelligence gathering

No additional information was identified for this section.

Impact statement

The authors of the 2 systematic reviews stated that although the Chinese herbal medicines appear to be of benefit for pressure ulcers, limitations of the included studies meant that findings should be replicated in more high quality studies. The evidence is therefore unlikely to impact the guideline which did not examine any evidence for these treatments and so does not make any recommendations on them.

Two individual RCTs found that acupuncture and a Chinese herbal medicine appear to be of benefit for pressure ulcers. The guideline did not examine any evidence for these treatments and so does not make any recommendations on them. Further evidence confirming findings would be useful before considering any impact on the guideline.

New evidence is unlikely to change guideline recommendations.

1.5 Management: neonates, infants, children and young people

Recommendations in this section of the guideline

Ulcer measurement

1.5.1 Document the surface area of all pressure ulcers in neonates, infants, children and young people, preferably using a validated measurement technique (for example, transparency tracing or a photograph).

1.5.2 Document an estimate of the depth of a pressure ulcer and the presence of undermining, but do not routinely measure the volume of a pressure ulcer in neonates, infants, children and young people.

Categorisation

1.5.3 Categorise each pressure ulcer in neonates, infants, children and young people at onset using a validated classification tool (such as the International NPUAP-EPUAP [2009]) Pressure Ulcer Classification System) to guide ongoing preventative and management options. Repeat and document each time the ulcer is assessed.

Nutritional supplements and hydration

1.5.4 Offer an age-related nutritional assessment to neonates, infants, children and young people with a pressure ulcer. This should be performed by a paediatric

dietitian or other healthcare professional with the necessary skills and competencies.

1.5.5 Discuss with a paediatric dietitian (or other healthcare professional with the necessary skills and competencies) whether to offer nutritional supplements specifically to treat a pressure ulcer in neonates, infants, children and young people whose nutritional intake is adequate.

1.5.6 Offer advice on a diet that provides adequate nutrition for growth and healing in neonates, infants, children and young people with a pressure ulcer.

1.5.7 Discuss with a paediatric dietitian whether to offer nutritional supplements to correct nutritional deficiency in neonates, infants, children and young people with a pressure ulcer.

1.5.8 Assess fluid balance in neonates, infants, children and young people with a pressure ulcer.

1.5.9 Ensure there is adequate hydration for age, growth and healing in neonates, infants, children and young people. If there is any doubt, seek further medical advice.

Pressure redistributing devices

1.5.10 Consider using specialist support surfaces (including dynamic support surfaces where appropriate) for neonates, infants, children and young people with a pressure ulcer, taking into account their current pressure ulcer risk and mobility.

1.5.11 Use a high-specification cot or bed mattress or overlay for all neonates, infants, children and young people with a pressure ulcer.

1.5.12 If pressure on the affected area cannot be adequately relieved by other means (such as repositioning), consider a dynamic support surface, appropriate to the size and weight of the child or young person with a pressure ulcer, if this can be tolerated.

1.5.13 Tailor the support surface to the location and cause of the pressure ulcer for neonates, infants, children and young people.

Negative pressure wound therapy

1.5.14 Do not routinely use negative pressure wound therapy to treat a pressure ulcer in neonates, infants, children and young people.

Hyperbaric oxygen therapy and electrotherapy

1.5.15 Do not use the following to treat a pressure ulcer in neonates, infants, children and young people:

- electrotherapy
- hyperbaric oxygen therapy.

Debridement

1.5.16 Consider autolytic debridement with appropriate dressings for dead tissue in neonates, infants, children and young people. Consider sharp and surgical debridement by trained staff if autolytic debridement is unsuccessful.

Systemic antibiotics and antiseptics

1.5.17 Consider systemic antibiotics for neonates, infants, children and young people with a pressure ulcer with clinical evidence of local or systemic infection.

1.5.18 Discuss with a local hospital microbiology department which antibiotic to offer neonates, infants, children and young people with infection to ensure that the chosen systemic antibiotic is effective against local strains of bacteria.

Topical antimicrobials and antiseptics

1.5.19 Do not routinely use topical antiseptics or antimicrobials to treat a pressure ulcer in neonates, infants, children and young people.

Dressings

1.5.20 Consider using a dressing that promotes a warm, moist healing environment to treat grade 2, 3 and 4 pressure ulcers in neonates, infants, children and young people.

1.5.21 Consider using topical antimicrobial dressings to treat a pressure ulcer where clinically indicated in neonates, infants, children and young people, for example, where there is spreading cellulitis.

1.5.22 Do not use iodine dressings to treat a pressure ulcer in neonates.

1.5.23 Do not offer gauze dressings to treat a pressure ulcer in neonates, infants, children and young people.

Heel pressure ulcers

1.5.24 Discuss with the parents or carers of neonates and infants and with children and young people (and their parents or carers if appropriate), a strategy to offload heel pressure as part of their individualised care plan to manage their heel pressure ulcer, taking into account differences in size, mobility, pain and tolerance.

Surveillance decision

No new information was identified at any surveillance review.

Editorial amendments

A cross-referral to NICE guideline NG15 Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use will be made from recommendations 1.5.18 and 1.5.19

Recommendation 1.5.3 refers 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.

2018 surveillance summary

No relevant evidence was identified.

Intelligence gathering

No additional information was identified for this section.

Areas not currently covered in the guideline

In surveillance, evidence was identified for areas not covered by the guideline. This new evidence has been considered for possible addition as a new section of the guideline.

Medical device-related pressure ulcers

NICE quality standard QS89 Pressure ulcers has the following placeholder statement: 'Quality statement 9: Prevention of medical device-related pressure ulcers'. A placeholder statement is an area of care that has been prioritised by the Quality Standards Advisory Committee, but for which no source guidance is currently available. A placeholder statement indicates the need for evidence-based guidance to be developed in this area.

The prevention and management of pressure ulcers caused by medical devices is currently outside the scope of NICE guideline CG179.

Surveillance decision

This new question should not be added.

Medical device-related pressure ulcers

2018 surveillance summary

A multicentre prospective study (120) (n=175) across 5 adult intensive care units aimed to determine the rate and characteristics of, and risk factors for, the development of hospital-acquired medical device-related pressure ulcers. The previously established point prevalence of hospital-acquired pressure ulcers in these intensive care units was 15%. Patients were evaluated in the first 24 hours after admission and observed 6 times thereafter in intervals of 48 hours. Twenty seven patients (15%) developed non-medical device-related pressure ulcers and 70 patients (40%) developed medical device-related pressure ulcers. Medical device-related ulcers occurred most frequently (45%) in patients with an endotracheal tube. The most frequent type (43%) was Stage II. The highest rates of medical device-related ulcers were observed among internal medicine intensive care units patients, patients who also had a non-medical device-related ulcer, patients in the high Braden risk score group, or patients who received enteral feeding.

An observational study (121) (n=1,519) measured incidence and risk factors of pressure ulcers related to continuous electroencephalogram (EEG) electrodes in acutely hospitalised patients over a 22-month period. Pressure ulcers related to continuous EEG occurred in 118 (8%) patients. Most consisted of hyperaemia only without skin breakdown. A major predictor was monitoring duration, with 3-, 5-, and 10-day risks of 16%, 32%, and 60%, respectively. Risk factors significantly associated with ulcers included older age, care in an intensive care, lack of a head wrap, use of vasopressors, enteral feeding, and fever. Elderly patients (71 to 80 years) were at significantly higher risk, even after accounting for monitoring time and other pertinent variables in multivariate analysis.

A multicentre prospective cohort study (122) across 8 centres (n=625) examined the Braden QD Scale for predicting pressure ulcer risk in hospitalised patients (preterm to 21 years of age) on bedrest for at least 24 hours with a medical device in place. The intention of the QD scale was to predict both immobility-related and medical device-related pressure ulcer risk. The authors stated that the Braden QD Scale performed well in predicting immobility-related and medical device-related pressure ulcers, with an area under the curve of 0.78. At a cutoff score of 13, the area under the curve was 0.72, providing a sensitivity of 0.86, specificity of 0.59, positive predictive value of 0.15, negative predictive value of 0.98, and a positive likelihood ratio of 2.09.

An RCT (123) (n=152) assessed 4 strategies to prevent facial pressure ulcers related to non-invasive mechanical ventilation with oro-nasal masks in critically ill hospitalised patients with acute respiratory failure. The incidence of facial pressure ulcers was significantly lower in the group receiving a solution of hyperoxygenated fatty acids to protect the skin when compared with 2 of the other therapeutic strategies: adhesive thin dressing, and adhesive foam dressing. There was no significant difference between the fatty acids group and the group in which the mask was applied directly on the patient's skin.

Intelligence gathering

No topic expert feedback was relevant to this section.

Impact statement

The new evidence found:

- a high rate of medical device-related pressure ulcers
- risk factors can be identified for medical device-related pressure ulcers
- the Braden QD Scale reliably predicts both immobility-related and device-related pressure ulcers in the paediatric acute care environment
- medical device-related pressure ulcers can be prevented.

NICE quality standard QS89 Pressure ulcers has the following placeholder statement: '[Quality statement 9: Prevention of medical device-related pressure ulcers]'. A placeholder statement is an area of care that has been prioritised by the Quality Standards Advisory Committee, but for which no source guidance is currently available. A

placeholder statement indicates the need for evidence-based guidance to be developed in this area.

Given that only single studies on several different aspects of this new area were identified by the current surveillance review, and of those only a single RCT examined prevention of pressure ulcers, further evidence would be useful to guide the decision whether to update. There is therefore currently no impact on the guideline.

However, questions about the existence of further evidence in this area have been asked of stakeholders as part of the consultation. We will consider any further evidence before making our final decision on whether to update the guideline.

Note: The 2014 guidance (p.30) from the National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance does make recommendations on medical device related pressure ulcers (though mostly based on indirect evidence, with 1 recommendation based on direct evidence from clinical series).

New evidence is unlikely to change guideline recommendations.

Research recommendations

1. What is the effect of enzymatic debridement of non-viable tissue compared with sharp debridement on the rate of healing of pressure ulcers in adults?

Summary of findings

No new evidence relevant to the research recommendation was found and no ongoing studies were identified.

Surveillance decision

This research recommendation will be considered again at the next surveillance point.

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2. Does negative pressure wound therapy (with appropriate dressing) improve the healing of pressure ulcers, compared with the use of dressing alone in adults with pressure ulcers?

Summary of findings

The new evidence shows that there is currently no rigorous RCT evidence for negative pressure wound therapy in treating pressure ulcers, and high uncertainty remains.

Surveillance decision

This research recommendation will be considered again at the next surveillance point.

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3. Which pressure ulcer tools are most effective for predicting pressure ulcer risk in children?

Summary of findings

The new evidence shows that the Braden QD Scale reliably predicts both immobility-related and device-related pressure ulcers in the paediatric acute care environment. However only children with a medical device in place were included in the study, and no evidence on any other assessment tools in children were identified.

Surveillance decision

This research recommendation will be considered again at the next surveillance point.

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4. Do pressure redistributing devices reduce the development of pressure ulcers for those who are at risk of developing a pressure ulcer?

Summary of findings

The new evidence suggests benefits of pressure redistributing devices but provides no clear steer beyond the current recommendation for a high-specification foam mattress.

Surveillance decision

This research recommendation will be considered again at the next surveillance point.

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5. When repositioning a person who is at risk of developing a pressure ulcer, what is the most effective position – and optimum frequency of repositioning – to prevent a pressure ulcer developing?

Summary of findings

The new evidence included a Cochrane review which expressed uncertainty over repositioning frequency and position. Two RCTs found no benefit of turning every 2 hours (rather 3- or 4-hourly), and that more frequent turning increased adverse events and nursing workload.

Surveillance decision

This research recommendation will be considered again at the next surveillance point.

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6. In neonates, infants, children, young people and adults who have adequate nutritional status and who have a pressure ulcer, does providing further nutritional supplements improve healing of the pressure ulcer?

Summary of findings

The new evidence included a Cochrane review that found no benefit of nutritional interventions for treating pressure ulcers. Other evidence for specialised supplements was mixed.

Surveillance decision

This research recommendation will be considered again at the next surveillance point.

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