National Clinical Guideline Centre

Pressure ulcer prevention

The prevention and management of pressure ulcers in primary and secondary care

Clinical Guideline 179

Methods, evidence and recommendations

April 2014

Commissioned by the National Institute for Health and Care Excellence

Royal College of Physicians
The Royal College of Surgeons of England
Royal College of General Practitioners
Royal College of Nursing
NICE accredited
www.nice.org.uk/accreditation

Update information

Minor changes since publication

February 2019: After a surveillance review, links were added throughout to other NICE guidance that has been produced since this guideline was originally published. Some terms used in some recommendations were updated to reflect current practice. These changes can be seen in the short version of the guideline at http://www.nice.org.uk/guidance/cg179

Funding
National Institute for Health and Care Excellence 2014

Contents

Guideline Development Group members

Name	Role
Professor Gerard Stansby	Professor of Vascular Surgery and Honorary Consultant Surgeon, Newcastle upon Tyne Hospitals NHS Foundation Trust, Newcastle.
John Borthwick	Patient member.
Nigel Broad	Senior Charge Nurse, Powys Teaching Health Board, Swansea.
Richard Bull	Consultant Dermatologist, Barts Health NHS Trust, London.
Mark Collier	Lead Nurse/Consultant, Tissue Viability, United Lincolnshire Hospitals NHS Trust, Lincolnshire.
Elizabeth McGinnis	Nurse Consultant, Tissue Viability, Leeds Teaching Hospitals NHS Trust, Leeds.
Raquel Siganporia	Patient member.
Laura Stuart	Clinical Lead Occupational Therapist, Health and ageing unit, Kings College, London (until 2013) and Improvement fellow (frailty), UCLPartners, London (from 2013).
Carolyn Taylor	Specialist Dietitian, Spinal Injuries, Sheffield Teaching Hospital NHS Trust, Sheffield.
Pradeep Thumbikat	Consultant, Spinal Injuries, Sheffield Teaching Hospitals NHS Trust; Honorary Senior Lecturer, Sheffield University.
Chandi Vellodi	Consultant Physician, Acute Medicine and Medicine for the Elderly, Barnet and Chase Farm Hospitals NHS Trust, London.
Jane Willock	Clinical Nurse Specialist Paediatric Rheumatology, Children's Hospital for Wales, Cardiff, and Senior Lecturer in Children's Nursing, University of South Wales, Pontypridd.

Guideline development group co-optees

Name	Role
Davina Richardson	Physiotherapist, Imperial College Healthcare NHS Trust, London

National clinical guideline centre (NCGC) Staff

Name	Role
Elizabeth Avital	Associate director, NCGC
Lillian Cooper	CT2 Plastic Surgery, Royal Free Hospital, London
Katie Jones	Project manager, NCGC
Grace Marsden	Senior health economist, NCGC (from January 2012)
Paul Miller	Senior information scientist, NCGC
Julie Neilson	Senior research fellow, NCGC
Ebenezer Tetteh	Senior health economist, NCGC (until January 2012)
David Wonderling	Head of Health Economics, NCGC

Acknowledgements

The Guideline development group and project team would like to thank Serena Carville, Elisabetta Fenu, Karen Head, Sarah Hodgkinson, Clare Jones, Fatema Limbada, Zahra Naqvi, Jacoby Patterson, Mark Perry and Maggie Westby for all their help and support throughout the guideline.

The Guideline development group acknowledges the collaboration and work of the Belgian Healthcare Knowledge Centre (KCE) in development of this guideline. The group would like to thank Koen Van den Heede, Sabine Stordeur, Raf Mertens, Christian Léonard, Dimitri Beeckman, Catharina Mateï, Sabine van Houdt and Auréle van Lancker.

The Guideline development group would also like to formally acknowledge and thank the work of all individuals who participated in the Delphi consensus panel on pressure ulcers in neonates, infants, children and young people: Denis Anthony, Karen Armitage, Jaspreet Bansil, Rachael Bolland, Lisa Brown, Sue Burkin, Andrea Cockett, James Coulston, Caroline Dawn, Joanna Dixon, Louise Douglas, Julie Evans, Sally Farrer, Susan Flavin, Carley Gibbens, Evelyn Gilday, Anne-Marie Gillingham, Nikhil Gokhani, Andrew Graham, Lynne Grant, Jason Gray, Sylvie Hampton, Ceri Harris, Kerryanne Hatcher, Melanie Haughton, Karen Hill, Corrina Hulkes, Sara Hutchcox, Joanna Inglis-Lyons, Claire Jackson, Deb Jones, Hamish Laing, Ruth Lester, June Lindsay, Eva Madsen, Trish Mahon, Logan Manikam, Evelyn Mansoor, Jan Maxwell, Ruth May, Valerie McGurk, John McRobert, Jeanette Milne, Ofrah Muflahi, Alison Parnham, Gillian Parsons, Joan Pickersgill, Zoe Pooley, Jonathan Punt, Kumal Rajpaul, Mark Robinson, Angela Rodgers, Mike Samuels, Debby Sinclair, Jackie Stephen-Haynes, Kate Swailes, Norma Timoney, Julie Trudigan, Rachel von Graeventiz, Richard White, Rebecca Whitney, Elaine Wilkins, Nick Wilson Jones, Pam Taylor, Fania Pagnamenta, Rachel McConnell, James Callaghan, Caron Eyre, Lyn McIntyre and Louise Scannell.

We would also like to thank the following organisations for nominating individuals to join the Delphi panel: Central Manchester University Hospitals NHS Foundation Trust, Newcastle upon Tyne Hospitals NHS Foundation Trust, Birmingham Children's Hospital NHS Foundation Trust and Brighton and Sussex University NHS Trust.

1 Introduction

Pressure ulcers are serious and distressing adverse events that can represent a failure of care. We now understand that they are caused when an area of skin and the tissues below are damaged as a result of being placed under pressure sufficient to impair blood supply. The effects are related to both the magnitude and the duration of the pressure and in some circumstance they can occur very rapidly, such as over exposed bony prominences like the heels or sacrum. Typically they occur in a person confined to bed or chair by an illness and as a result they are also sometimes known as 'bedsores', or 'pressure sores'. Healthcare professionals now usually prefer the term pressure ulcer but the public still know, and frequently refer to them, by these other names.

There is also an overlap with ulcers caused mainly by moisture (moisture lesions) and those caused by shear stresses or friction rather than pressure alone, which can cause some confusion in classification. In reality, in many cases, pressure, shear, friction and moisture may all have contributed to varying degrees to the development of the ulcer. All pressure ulcers are serious but can range in severity from patches of discoloured skin which may recover through to deep open ulcers that expose the underlying bone or muscle. The latter type of pressure ulcers may be very difficult to treat. They often result in significant pain and distress, lead to other complications, increase mortality, extend stays in hospital and consume significant resources for the NHS. Pressure ulcers should be prevented whenever possible.

NICE has issued guidance relating to pressure ulcers previously. It issued clinical guideline 7 in 2003 "Pressure ulcer prevention: pressure ulcer risk assessment and prevention, including the use of pressure-relieving devices (beds, mattresses and overlays) for the prevention of pressure ulcers in primary and secondary care" and in 2005 clinical guideline 29 "Pressure ulcers: the management of pressure ulcers in primary and secondary care" was issued as a collaborative exercise between the Royal College of Nursing (RCN) and NICE. The current guideline updates and replaces these 2 previous guidelines.

How common are pressure ulcers? It is difficult to estimate their true incidence and prevalence due to variation in methods of classifying and reporting. Estimates from hospital-based studies vary widely according to definitions used, the population studied and the care setting. However, reported prevalence rates range from 4.7% to 32.1% for hospital populations and up to 22% in nursing-home populations. In 2007 Vanderwee et al surveyed 25 hospitals in 5 European countries to assess pressure ulcer prevalence.[212] The survey showed that the pressure ulcer prevalence (grade 1-4) was 18.1% and if grade 1 ulcers were excluded, it was 10.5%. [212] It was further shown that the sacrum and heels were the most affected locations and only 9.7% of the patients in need of prevention received fully adequate preventive care. [212]More recently, the NHS patient safety thermometer (a tool for measuring, monitoring and analysing patient harms) has recorded the number of pressure ulcers in the NHS by recording monthly prevalence. In May 2013 new pressure ulcers were reported in 1.29% of patients in all types of care in the National Patient Safety Thermometer dashboard.

For this guideline, consideration regarding the financial impact on the NHS of any recommendations was considered. It is clear that in regards to pressure ulcers there are significant potential savings to be made through prevention strategies, as they are costly once they have occurred. In 2004 the estimated annual cost of pressure ulcer care in the UK was between £1.4 billion and £2.1 billion a year, and the mean cost per patient of treatment for a grade 5 pressure ulcer was calculated to be £10,551 a year. It is therefore likely that current costs to the NHS are even higher. A more recent estimate was that the cost of treating a pressure ulcer varies from £1214 (grade 1) to £14,108 (grade 4).

It is important to stress that the guideline applies to all people under NHS care or where care is funded by the NHS. Unfortunatley, whilst there is much clinical expertise and good practice focussed on preventing and treating pressure ulcers, care is not universally to an optimal standard. It is

therefore hoped that this evidence based guidance will contribute to reducing pressure ulcers nationally through their local implementation throughout the NHS and improve the care of those where pressure ulcers do occur.

2 Development of the guideline

NICE clinical guidelines are recommendations for the care of individuals in specific clinical conditions or circumstances within the NHS, from prevention and self-care through primary and secondary care to more specialised services. We base our clinical guidelines on the best available research evidence, with the aim of improving the quality of health care. We use predetermined and systematic methods to identify and evaluate the evidence relating to specific review questions.

NICE clinical guidelines can:

- provide recommendations for the treatment and care of people by health professionals
- be used to develop standards to assess the clinical practice of individual health professionals
- be used in the education and training of health professionals
- help patients to make informed decisions
- improve communication between patient and health professional

While guidelines assist the practice of healthcare professionals, they do not replace their knowledge and skills.

We produce our guidelines using the following steps:

- Guideline topic is referred to NICE from the Department of Health
- Stakeholders register an interest in the guideline and are consulted throughout the development process.
- The scope is prepared by the National Clinical Guideline Centre (NCGC)
- The NCGC establishes a guideline development group
- A draft guideline is produced after the group assesses the available evidence and makes recommendations
- There is a consultation on the draft guideline.
- The final guideline is produced.

The NCGC and NICE produce a number of versions of this guideline:

- the full guideline contains all the recommendations, plus details of the methods used and the underpinning evidence
- the NICE guideline lists the recommendations
- the quick reference guide (QRG) presents recommendations in a suitable format for health professionals
- information for the public (‘understanding NICE guidance’ or UNG) is written using suitable language for people without specialist medical knowledge.

This version is the full version. The other versions can be downloaded from NICE at www.nice.org.uk.

2.1 Remit

NICE received the remit for this guideline from the Department of Health as part of the guideline review cycle. They commissioned the NCGC to produce the guideline. It was commissioned as an update of; 'Pressure ulcers', NICE clinical guideline 29 (2005), 'Pressure ulcer prevention', and NICE clinical guideline 7 (2003), available from www.nice.org.uk/guidance/CG29 and www.nice.org.uk/guidance/CG7.

The updated documents have been amalgamated into 1 guideline which will replace CG29 and CG7.

2.2 Who developed this guideline?

A multidisciplinary Guideline Development Group (GDG) comprising professional group members and consumer representatives of the main stakeholders developed this guideline (see section on Guideline Development Group Membership and acknowledgements).

The National Institute for Health and Clinical Excellence (NICE) funds the National Clinical Guideline Centre (NCGC) and thus supported the development of this guideline. The GDG was convened by the NCGC and chaired by Professor Gerard Stansby in accordance with guidance from the NICE.

The group met every 4-6 weeks during the development of the guideline. At the start of the guideline development process all GDG members declared interests including consultancies, fee-paid work, share-holdings, fellowships and support from the healthcare industry. At all subsequent GDG meetings, members declared arising conflicts of interest, which were also recorded (Appendix B).

Members were either required to withdraw completely or for part of the discussion if their declared interest made it appropriate. The details of declared interests and the actions taken are shown in Appendix B.

Staff from the NCGC provided methodological support and guidance for the development process. The team working on the guideline included a project manager, systematic reviewers, health economists and information scientists. They undertook systematic searches of the literature, appraised the evidence, conducted meta analysis and cost effectiveness analysis where appropriate and drafted the guideline in collaboration with the GDG.

2.3 What this guideline covers

This guideline covers the following populations:

- People of all ages, including all adults and children. Guideline developers paid specific attention to the needs of different subgroups, including different age groups.

This guideline covers the following healthcare settings:

- Primary care settings, including general practices, healthcare centres and polyclinics, community care settings where NHS care is provided or commissioned, including the persons' home and secondary care settings where NHS care is provided or commissioned.

The guideline developers noted that, although the guideline is commissioned for the NHS, people providing care in other settings, such as private settings, may find the recommendations relevant.

This guideline covers the following clinical issues:

- Risk assessment, including the use of risk assessment tools and scales and scales.
- Skin assessment.
- Prevention of pressure ulcers, including the use of barrier creams, the use of pressure relieving devices, skin massage and rubbing, positioning and repositioning, nutritional interventions and hydration strategies.
- Assessment and grading of pressure ulcers.
- Management of pressure ulcers, including debridement, the use of pressure relieving devices, nutritional interventions and hydration strategies, antimicrobials and antibiotics, dressings, management of heel pressure ulcers and other therapies, such as electrotherapy, negative pressure wound therapy and hyperbaric oxygen therapy.
- Patient/carer education and education and training for healthcare professionals.

For further details please refer to the scope in Appendix A and review questions in Chapter 3.1

2.4 What this guideline does not cover

This guideline does not cover:

- Prevention and management of ulceration caused by ischemia or neuropathy.
- Prevention and management of venous leg ulcers.
- Prevention and management of pressure ulcers caused by devices.
- Prevention and management of Kennedy terminal ulcers.

2.5 Relationships between the guideline and other NICE guidance

This guideline will update and replace:

- Pressure ulcers. NICE clinical guideline 29 (2005). Available from www.nice.org.uk/guidance/CG29
- Pressure ulcer prevention. NICE clinical guideline 7 (2003). Available from http://www.nice.org.uk/guidance/CG7
- Multiple sclerosis. NICE clinical guideline 8 (2003). Available from www.nice.org.uk/guidance/CG8 (recommendations on pressure ulcers only)

2.5.1 Related NICE Clinical Guidelines:

- End of Life Care for adults. NICE Quality Standard (2011). Available from http://www.nice.org.uk/guidance/qualitystandards/endoflifecare/home.jsp
- Diabetic foot problems. NICE clinical guideline 119 (2010). Available from www.nice.org.uk/guidance/CG119
- Surgical site infection. NICE clinical guideline 74 (2008). Available from www.nice.org.uk/guidance/CG74
- Obesity. NICE clinical guideline 43 (2006). Available from www.nice.org.uk/guidance/CG43
- Nutrition support in adults. NICE clinical guideline 32 (2006). Available from www.nice.org.uk/guidance/CG32
- Type 2 diabetes: prevention and management of foot problems. NICE clinical guideline 10 (2004). Available from www.nice.org.uk/guidance/CG10
- Infection: prevention and control of healthcare associated infections in primary and secondary care. NICE clinical guideline 139 (2012). Available from www.nice.org.uk/guidance/CG139
- Lower limb peripheral arterial disease: diagnosis and management. NICE clinical guideline 147 (2012). Available from www.nice.org.uk/guidance/CG147
- Urinary incontinence in neurological disease. NICE clinical guideline 148 (2012). Available from www.nice.org.uk/guidance/CG148
- Patient experience in adults NHS services. NICE clinical guideline 138 (2012). Available from www.nice.org.uk/guidance/CG138.

2.5.2 Related Medical Technology guidance:

- The MIST Therapy system for the promotion of wound healing. NICE medical technology guidance 5 (2011). Available from www.nice.org.uk/guidance/MTG5

3 Methods

This chapter sets out in detail the methods used to review the evidence and to generate the recommendations that are presented in subsequent chapters. This guidance was developed in accordance with the methods outlined in the NICE Guidelines Manual 2009.[142]

3.1 Developing the review questions and outcomes

Review questions were developed in a PICO framework (patient, intervention, comparison and outcome) for intervention reviews, using population, presence or absence of factors under investigation (for example, prognostic factors) and outcomes for prognostic reviews.

This use of a framework guided the literature searching process, critical appraisal and synthesis of evidence, and facilitated the development of recommendations by the Guideline Development Group (GDG). The review questions were drafted by the NCGC technical team and refined and validated by the GDG. The GDG chose approximately 7 outcomes identifying which outcomes were critical to their decision making and which were important. This distinction helped the GDG to make judgements about the importance of the different outcomes and their impact on decision making. For example, proportion of people with pressure ulcers healed will usually be considered a critical outcome and would be given greater weight when considering the clinical effectiveness of an intervention than an important outcome with less serious consequences. The GDG decide on the relative importance in the review protocol before seeing the review. The questions were based on the key clinical issues identified in the scope (Appendix A).

A total of 25 review questions were identified.

Full literature searches, critical appraisals and evidence reviews were completed for all the specified review questions.

Chapter	Type of review	Review question	Outcomes
PREVENTION			
1	Intervention	What is the clinical and cost effectiveness of risk assessment tools in the prevention of pressure ulcers?	**Critical outcomes** • Proportion of participants developing new pressure ulcers **Important outcomes** • Patient acceptability • Rate of development of pressure ulcers • Time to develop new pressure ulcer (time to event data) • Time in hospital or NHS care (continuous data) • Health-related quality of life (continuous data)
2	Prognostic	What is the predictive ability of risk assessment tools for pressure ulcer prevention?	**Outcomes:** • Patient outcomes: • Incidence of pressure ulcers (all grades and grade 2-4)– up to 1 week • Incidence of pressure ulcers (all grades and grade 2-4) – up to 3 months **Statistical measures:** • Sensitivity and specificity for a defined threshold • Area under the ROC curve (AUC) • Diagnostic odds ratio for a particular threshold
3	Intervention	What is the clinical and cost effectiveness of skin assessment methods in the prevention of pressure ulcers?	**Critical outcomes** • Proportion of participants developing new pressure ulcers (by categories of ulcer) **Important outcomes** • Rate of development of pressure ulcer • Time to develop new pressure ulcer • Time in hospital • Patient acceptability • Health-related quality of life
4	Prognostic	What is the predictive ability of skin assessment tools for pressure ulcer development?	**Outcomes** • Incidence of pressure ulcers (all grades and grade 2-4) – up to 1 week • Incidence of pressure ulcers (all grades and grade 2-4) – up to 3 months

			Statistical Measures • Adjusted odds ratio, preferably from multivariable analysis • Sensitivity • Specificity • Area under the ROC curve (AUC) (for skin temperature)
5	Intervention	How and at what frequency should repositioning be undertaken for the prevention of pressure ulcers?	**Critical outcomes** • Proportion of participants developing new pressure ulcers (dichotomous outcome)(describe different categories of ulcer) • Patient acceptability **Important outcomes** • Rate of development of pressure ulcers • Time to develop new pressure ulcer (time to event data) • Time in hospital or NHS care (continuous data) • Health-related quality of life (continuous data) (although unlikely to be sensitive enough to detect changes in pressure ulcer patients, therefore may have to be narratively summarised
6	Intervention	What is the clinical and cost effectiveness of skin massage and rubbing in the prevention of pressure ulcers?	**Critical outcomes** • Proportion of participants developing new pressure ulcers (dichotomous outcome) • Patient acceptability • Skin damage **Important outcomes** • Rate of development of pressure ulcers • Time to develop new pressure ulcer (time to event data) • Time in hospital or other healthcare settings (continuous data) • Health-related quality of life (continuous data)
7	Intervention	What are the most clinically and cost-effective nutritional interventions and hydration strategies for the prevention of pressure ulcers?	**Critical outcomes** • Proportion of participants developing new pressure ulcers • Patient acceptability **Important outcomes**

			• Rate of development of pressure ulcers • Time to develop new pressure ulcer (time to event data) • Time in hospital or NHS care (continuous data) • Health-related quality of life (continuous data)
8	Intervention	What are the most clinically and cost-effective pressure re-distributing devices for the prevention of pressure ulcers?	**Critical outcomes** • Proportion of participants developing new pressure ulcers • Patient acceptability **Important outcomes** • Rate of development of pressure ulcers • Time to develop new pressure ulcer (time to event data) • Time in hospital or NHS care (continuous data) • Health-related quality of life (continuous data)
9	Intervention	What is the clinical and cost effectiveness of pressure-redistributing devices for the prevention of heel pressure ulcers?	**Critical outcomes** • Proportion of participants developing new pressure ulcers • Patient acceptability **Important outcomes** • Rate of development of pressure ulcers • Time to develop new pressure ulcer (time to event data) • Time in hospital or NHS care (continuous data) • Health-related quality of life (continuous data)
10	Intervention	What are the most clinically and cost-effective topical barrier preparations for the prevention of pressure ulcers and moisture lesions?	**Critical outcomes** • Proportion of participants developing new pressure ulcers (dichotomous outcome) • Proportion of participants developing moisture lesions (incontinence associated dermatitis, perineal dermatitits) • Patient acceptability **Important outcomes** • Rate of development of pressure ulcers • Time to develop new pressure ulcer (time to event data) • Time in hospital or NHS care (continuous data)

			• Health-related quality of life (continuous data)
MANAGEMENT			
11	Diagnostic	What are the most reliable techniques/tools to measure the dimensions of a pressure ulcer?	**Critical outcomes:** • Reliability • Accuracy **Important outcomes:** • Impact linked to healing/delayed healing • Healing • Complications and pressure ulcers • Severity
12	Diagnostic	What is the best method of categorising different types of pressure ulcers?	**Critical outcomes** • Reliability - agreement • Accuracy **Important outcomes** • Time and ease of use of classification system
13	Intervention	What are the most clinically and cost-effective nutritional interventions and hydration strategies for the treatment of pressure ulcers?	**Critical outcomes** • Time to complete healing (time to event data) • Rate of complete healing (continuous data) • Rate in change of size of ulcer (absolute and relative) (continuous data) – reduction in size of ulcer and volume of ulcer. • Proportion of patients completely healed within trial period **Important outcomes** • Pain (wound-related) • Time in hospital (continuous data) • Patient acceptability of supplements – eg measured by compliance, tolerance, reports of unpalatability • Side effects (nausea, vomiting, diarrhoea) • Mortality (dichotomous) • Health-related quality of life (continuous data)
14	Intervention	What are the most clinically and cost	**Critical outcomes**

		effective pressure-redistributing devices for the management of pressure ulcers?	• Time to complete healing (time to event data) • Rate of complete healing (continuous data) • Rate in change of size of ulcer (absolute and relative) (continuous data) – reduction in size of ulcer and volume of ulcer. • Proportion of patients completely healed within trial period **Important outcomes** • Pain (wound-related) • Time in hospital or NHS care (continuous data) • Patient acceptability eg measured by compliance and tolerance • Side effects • Mortality (all cause) (dichotomous) • Health-related quality of life (continuous data)
15	Intervention	What is the clinical and cost effectiveness of negative pressure wound therapy for the treatment of pressure ulcers?	**Critical outcomes** • Time to complete healing (time to event data) • Rate of complete healing (continuous data) • Rate in change of size of ulcer (absolute and relative) (continuous data) – reduction in size of ulcer and volume of ulcer. • Proportion of patients completely healed within trial period **Important outcomes** • Pain (wound-related) • Time in hospital or NHS care (continuous data) • Patient acceptability eg measured by compliance and tolerance • Side effects (pain, problems with vacuum sealing, reaction of foam) • Mortality (all cause) (dichotomous) • Health-related quality of life (continuous data)
16	Intervention	What is the clinical and cost effectiveness of electrotherapy for the treatment of pressure ulcers?	**Critical outcomes** • Time to complete healing (time to event data) • Rate of complete healing (continuous data) • Rate in change of size of ulcer (absolute and relative) (continuous data) – reduction in size of ulcer and volume of ulcer.

			• Proportion of patients completely healed within trial period **Important outcomes** • Pain (wound-related) • Time in hospital or NHS care (continuous data) • Patient acceptability eg measured by compliance and tolerance • Side effects • Mortality (all cause) (dichotomous) • Health-related quality of life (continuous data)
17	Intervention	What is the clinical and cost-effectiveness of hyperbaric oxygen therapy for the treatment of pressure ulcers?	**Critical outcomes** • Time to complete healing (time to event data) • Rate of complete healing (continuous data) • Rate in change of size of ulcer (absolute and relative) (continuous data) – reduction in size of ulcer and volume of ulcer. • Proportion of patients completely healed within trial period **Important outcomes** • Pain (wound-related) • Time in hospital or NHS care (continuous data) • Patient acceptability eg measured by compliance and tolerance • Side effects • Mortality (all cause) (dichotomous) • Health-related quality of life (continuous data)
18	Intervention	What are the most clinically and cost effective methods of debridement of non-viable tissue for the treatment of pressure ulcers?	**Critical outcomes** • Time to complete healing (time to event data) • Rate of complete healing (continuous data) • Rate in change of size of ulcer (absolute and relative) (continuous data) – reduction in size of ulcer and volume of ulcer. • Proportion of patients completely healed within trial period **Important outcomes** • Pain (wound-related) • Time in hospital or NHS care (continuous data)

			• Patient acceptability eg measured by compliance and tolerance • Side effects (skin irritation skin, treatment related pain, bleeding, healthy tissue damage, health skin damage, rash, toxicity) • Mortality (all cause) (dichotomous) • Health-related quality of life (continuous data)
19	Intervention	What are the most clinically effective methods of maggot debridement of non-viable tissue for treatment of pressure ulcers?	**Critical outcomes** • Time to complete healing (time to event data) • Rate of complete healing (continuous data) • Rate in change of size of ulcer (absolute and relative) (continuous data) – reduction in size of ulcer and volume of ulcer. • Proportion of patients completely healed within trial period **Important outcomes** • Pain (wound-related) • Time in hospital or NHS care (continuous data) • Patient acceptability eg measured by compliance and tolerance • Side effects (skin irritation skin, treatment related pain, bleeding, healthy tissue damage, health skin damage, rash, toxicity) • Mortality (all cause) (dichotomous) • Health-related quality of life (continuous data)
20	Intervention	What are the most clinically and cost effective topical agents for the treatment of pressure ulcers?	**Critical outcomes** • Time to complete healing (time to event data) • Rate of complete healing (continuous data) • Rate in change of size of ulcer (absolute and relative) (continuous data) – reduction in size of ulcer and volume of ulcer. • Proportion of patients completely healed within trial period **Important outcomes** • Pain (wound-related) • Time in hospital or NHS care (continuous data) • Patient acceptability eg measured by compliance and tolerance • Side effects (irritation skin, rash, itching, allergic reaction, normal flora disruption, toxicity, treatment related pain)

			• Mortality (all cause) (dichotomous) • Health-related quality of life (continuous data)
21	Intervention	What are the most clinically and cost effective systemic agents for the treatment of pressure ulcers?	**Critical outcomes** • Time to complete healing (time to event data) • Rate of complete healing (continuous data) • Rate in change of size of ulcer (absolute and relative) (continuous data) – reduction in size of ulcer and volume of ulcer. • Proportion of patients completely healed within trial period **Important outcomes** • Pain (wound-related) • Time in hospital or NHS care (continuous data) • Patient acceptability eg measured by compliance and tolerance • Side effects (irritation skin, rash, itching, allergic reaction, normal flora disruption, toxicity, treatment related pain) • Mortality (all cause) (dichotomous) • Health-related quality of life (continuous data)
22	Intervention	What are the most clinically and cost effective dressings for the treatment of pressure ulcers?	**Critical outcomes** • Time to complete healing (time to event data) • Rate of complete healing (continuous data) • Rate in change of size of ulcer (absolute and relative) (continuous data) – reduction in size of ulcer and volume of ulcer. • Proportion of patients completely healed within trial period **Important outcomes** • Pain (wound-related) • Time in hospital or NHS care (continuous data) • Patient acceptability eg measured by compliance and tolerance • Side effects (infection, health skin damage, healthy tissue damage, maceration, treatment related pain, skin irritation, allergic reaction, itching, odor, bleeding, rash, toxicity) • Mortality (all cause) (dichotomous) • Health-related quality of life (continuous data)

23	Qualitative	What information is required for patients/carers to prevent the occurrence of pressure ulcers?	• Whichever outcomes were found in the studies.
24	Qualitative	What training and education is required for healthcare professionals to prevent the occurrence of pressure ulcers?	• Whichever outcomes were found in the studies.
	Intervention	What is the most clinically and cost-effective method for management of pressure ulcers of the heel?	**Critical outcomes** • Time to complete healing (time to event data) • Rate of complete healing (continuous data) • Rate in change of size of ulcer (absolute and relative) (continuous data) – reduction in size of ulcer and volume of ulcer. • Proportion of patients completely healed within trial period **Important outcomes** • Pain (wound-related) • Time in hospital or NHS care (continuous data) • Patient acceptability eg measured by compliance and tolerance • Side effects • Mortality (all cause) (dichotomous) • Health-related quality of life (continuous data)

3.2 Searching for evidence

3.2.1 Clinical literature search

The aim of the literature search was to identify all available, relevant published evidence in relation to the key clinical questions generated by the GDG. Systematic literature searches were undertaken to identify evidence within the published literature in order to answer the review questions as per The Guidelines Manual (2009). [143]Clinical databases were searched using relevant medical subject headings, free-text terms and study type filters where appropriate. Studies published in languages other than English were not reviewed. Where possible, searches were restricted to articles published in the English language. All searches were conducted on core databases, MEDLINE, Embase, Cinahl and The Cochrane Library. All searches were updated on 28th August 2013. No papers published after this date were considered.

Search strategies were checked by looking at reference lists of relevant key papers, checking search strategies in other systematic reviews and asking the GDG for known studies in a specific area. The questions, the study types applied, the databases searched and the years covered can be found in Appendix F.

During the scoping stage, a search was conducted for guidelines and reports on the websites listed below and on organisations relevant to the topic. Searching for grey literature or unpublished literature was not undertaken. All references sent by stakeholders were considered.

- Guidelines International Network database (www.g-i-n.net)
- National Guideline Clearing House (www.guideline.gov/)
- National Institute for Health and Care Excellence (NICE) (www.nice.org.uk)
- National Institutes of Health Consensus Development Program (consensus.nih.gov/)
- Health Information Resources, NHS Evidence (www.library.nhs.uk/)

The titles and abstracts of records retrieved by the searches were scanned for relevance to the GDG's review questions. Any potentially relevant publications were obtained in full text. These were assessed against the inclusion criteria and the reference lists were scanned for any articles not previously identified. Further references were also suggested by the GDG.

3.2.2 Health economic literature search

Systematic literature searches were also undertaken to identify health economic evidence within the published literature relevant to the review questions. The evidence was identified by conducting a broad search relating to the guideline population in the NHS economic evaluation database (NHS EED), the Health Economic Evaluations Database (HEED) and health technology assessment (HTA) databases with no date restrictions. Additionally, the search was run on MEDLINE and Embase, with a specific economic filter, to ensure recent publications that had not yet been indexed by these databases were identified. Studies published in languages other than English were not reviewed. Where possible, searches were restricted to articles published in the English language.

The search strategies for health economics are included in Appendix F. All searches were updated on 28th August 2013. No papers published after this date were considered.

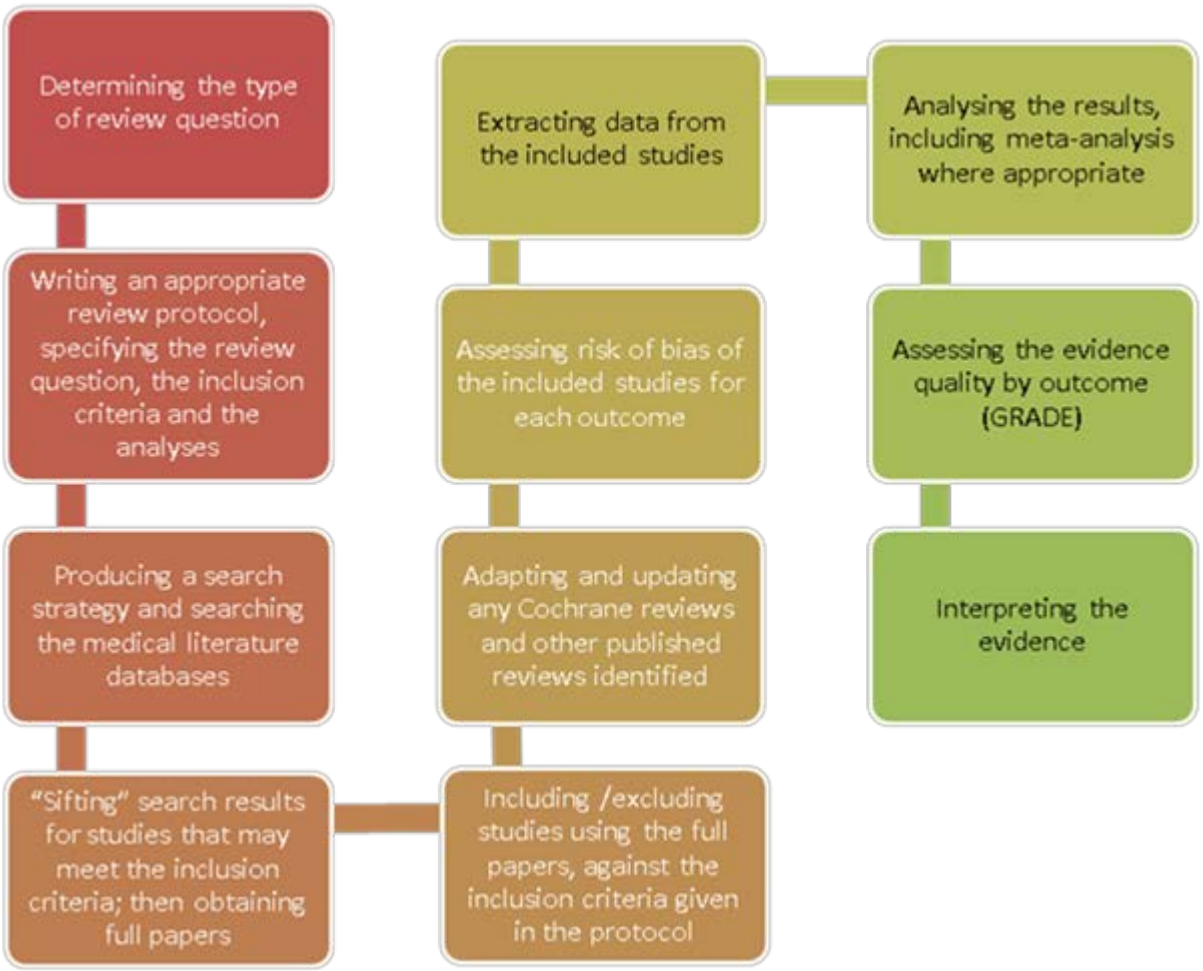
3.3 Evidence of effectiveness

The evidence was reviewed following the steps shown schematically in Figure 1:

- potentially relevant studies were identified for each review question from the relevant search results by reviewing titles and abstracts. Full papers were then obtained.
- full papers were reviewed against pre-specified inclusion/exclusion criteria to identify studies that addressed the review question in the appropriate population (review protocols are included in Appendix C).
- relevant studies were critically appraised using the appropriate checklists as specified in The Guidelines Manual. For prognostic studies, quality was assessed using the checklist for Prognostic studies (NICE Guidelines Manual, 2009). [143]
- key information was extracted on the study's methods and PICO factors and results were presented in evidence tables (Appendix G).
- summaries of the evidence were generated by outcome (included in the relevant chapter write-ups) and were presented in GDG meetings:
    - Randomised trials: meta-analysed, where appropriate and reported in GRADE profiles.
    - Prognostic studies (risk tools): data for risk assessment tools were summarised either as the Area Under the Receiver Operating Characteristics (ROC) Curve (AUC) or as coupled sensitivity and specificity pairs for particular thresholds. Meta-analysis was not conducted and the data were summarised across studies as the median with its 95% confidence interval, together with the range of values across studies; for sensitivity and specificity the median sensitivity was reported, with its corresponding specificity. These summaries were reported where possible in the GRADE profile format. Results were reported in tables in the text only for the 3 thresholds per risk assessment tool that maximised both sensitivity and specificity, with a preference for sensitivity.
    - Prognostic studies (risk factors): data for skin assessment methods were presented as the odds ratio or risk ratio, with their 95% confidence intervals (95%CI). Meta-analysis was not conducted and the data were summarised across studies as the median with its 95% confidence interval, together with the range of values across studies. These summaries were reported in the GRADE profile format, where possible

At least 20% of each of the above stages of the reviewing process was quality assured by the second reviewer to eliminate any potential of reviewer bias or error.

Figure 1: Step-by-step process of review of evidence in the guideline



The inclusion/exclusion of studies was based on the review protocols (Appendix C). The GDG were consulted about any uncertainty regarding inclusion/exclusion.

The guideline population was defined to be adults, children and young people with pressure ulcers. There was an overall lack of evidence for children and since recommendations for children were required across the guideline the GDG decided that a Delphi Consensus method would be most appropriate to develop these recommendations (see Chapter 4).

Randomised trials, non-randomised trials, and observational studies (including prognostic studies) were included in the evidence reviews as appropriate. Laboratory studies (in vivo or in vitro) were excluded.

Conference abstracts were not automatically excluded from the review. They were initially assessed against the inclusion criteria and then further processed only if no other full publication was available for that review question, in which case the authors of the selected abstracts would have been contacted for further information. Most reviews had full publications available and therefore no conference abstracts which were found through our searches were included. Conference abstracts in Cochrane reviews were included when they met the review inclusion criteria and authors were not contacted. Literature reviews, letters and editorials, non-English language publications and unpublished studies were excluded.

The review protocols are presented in Appendix C. Excluded studies (with their exclusion reasons) are listed in Appendix J and K.

Furthermore, the topical and dressings reviews included some of the same studies because dressings could be placed on top of the topical agent or the topical agent could be part of the dressing. There were also some studies included in the devices for prevention or treatment which were also included in the prevention or management of heel pressure ulcers as the studies presented data on the incidence or healing of heel pressure ulcers in addition to pressure ulcers overall.

For prevention studies we were looking at preventing any pressure ulcer. People who have pressure ulcers can get other pressure ulcers (and are often considered at higher risk as they already have pressure ulcer) therefore studies for prevention where participants already had pressure ulcers were included as well as those who did not.

Data synthesis for intervention reviews

Where possible, meta-analyses were conducted to combine the results of studies for each review question using Cochrane Review Manager (RevMan5) software. Where studies reported data which could not be analysed by meta-analysis a narrative summary is provided.

Fixed-effects (Mantel-Haenszel) techniques were used to calculate pooled risk ratios (relative risk) for binary outcomes. Where there were zero events in either arm of a trial we used Peto odds ratios. When 1 of the interventions has zero events, the computation of the meta-analysis risk ratio or its standard error becomes unstable (dividing by zero). The inverse variance methods including random effects models take this into account by adding 0.5 to the appropriate cell (and, to some extent, so do the Mantel Haenszel methods), but this tends to bias the effect estimate and/or the standard error. The best approach is the Peto fixed effects method for odds ratios (provided there is no substantial imbalance between treatment and control group sizes within studies, and treatment effects are not exceptionally large). The Peto OR method does not make this correction for zero events, but we note that the method only gives an approximation to the odds ratio.

For continuous outcomes, measures of central tendency (mean) and variation (standard deviation (SD)) were required for meta-analysis. Data for continuous outcomes were analysed using an inverse variance method for pooling mean differences, and where the studies had different scales, standardised mean differences were used. A generic inverse variance option in Review Manager was used if any studies reported solely the summary statistics and 95% confidence interval (or standard error) – this included any hazard ratios reported. However, in cases where standard deviations were not reported per intervention group, the standard error (SE) for the mean difference was calculated from other reported statistics - p-values or 95% confidence intervals (95% CI); meta-analysis was then undertaken for the mean difference and standard error using the generic inverse variance method in Cochrane Review Manager (RevMan5) software. Stratified analyses were predefined for some review questions at the protocol stage when the GDG identified that these strata are different in terms of biological and clinical characteristics and the interventions were expected to have a different effect on these groups of people. Statistical heterogeneity was assessed by visually examining the forest plots, and by considering the chi-squared test for significance at $p<0.1$ and the I-squared inconsistency statistic (with an I-squared value of more than 50% indicating considerable heterogeneity). Where considerable heterogeneity was present, we carried out subgroup analyses. Subgroup analyses were carried out, investigating the effect of subgroups pre-specified by the GDG. If the heterogeneity still remained, a random effects (DerSimonian and Laird) model was employed to provide a more conservative estimate of the effect.

For interpretation of the binary outcome results, differences in the absolute event rate were calculated using the GRADEpro software, for the median event rate across the control arms of the individual studies in the meta-analysis. The hazard ratio can be translated into an absolute difference in the proportion of patients who had an event at a particular time point, assuming proportional hazards. This is calculated using GRADEpro software. Absolute risk differences were presented in the GRADE profiles and in a clinical summary of findings tables, for discussion with the GDG.

3.3.1.1 Data synthesis for prognostic factor reviews

Prognostic data for risk assessment and skin assessment were analysed in 3 main ways:

Firstly, some studies were randomised trials that compared 2 assessment tools, and gave preventative treatment on the basis of the prognostic assessment. This was the ideal approach for prognostic studies and analysis was conducted as in the previous section.

Secondly, the skin assessment tools were analysed as prognostic factor data. Odds ratios (ORs) or risk ratios (RRs), with their 95% confidence intervals (95% CI) for the effect of the pre-specified prognostic factors were extracted from the papers. Studies of lower risk of bias were preferred, taking into account the analysis and the study design; in particular, prospective cohort studies that reported multivariable analyses for that outcome, which included key confounders as identified by the GDG at the protocol stage, and also took into account preventative treatment in the analysis. Where multivariable analyses were not reported, summary statistics were calculated from 2x2 tables derived from the raw data.

Thirdly, the predictive ability of risk assessment tools was analysed. Data were extracted in 2 ways: as the area under the ROC curve (with its 95% confidence interval), to take account of the multiple thresholds for these tools. Coupled forest plots of sensitivity and specificity with their 95% confidence intervals across studies (at various thresholds) were produced for each risk tool, using Cochrane Review Manager (RevMan5) software. In order to do that, 2 by 2 tables (the number of true positives, false positives, true negatives and false negatives) were either directly taken from the study if given or derived from raw data, or were calculated from the set of test accuracy statistics.

To allow comparison between tests, summary receiver operating characteristics (ROC) curves were generated for each prognostic test from the pairs of sensitivity and specificity calculated from the 2 x 2 tables. This was done only for the studies comparing more than 1 risk tool, and thresholds were selected that maximised both sensitivity and specificity. A ROC plot shows true positive rate (that is sensitivity) as a function of false positive rate (that is 1 – specificity). Data were entered into Review Manager 5 software and ROC curves were fitted using the Moses Littenburg approach.

Area under the ROC curve (AUC) data for each study was also plotted on a graph, for each prognostic test: the AUC describes the overall prognostic accuracy across the full range of thresholds. The GDG agreed on the following criteria for AUC: below 0.50 = worse than chance; 0.50-0.60 = very poor; 0.61-0.70 = poor; 0.71-0.80 = moderate; 0.81-0.92 = good; 0.91-1.00 = excellent or perfect test.

Preference was given to studies comparing more than 1 risk tool in the same participants.

Heterogeneity or inconsistency amongst studies was visually inspected in the forest plots. Heterogeneity in the area under the curve was investigated for the Braden scale in terms of preventative treatment, number of pressure ulcers (more than 100, 10-100 and less than 10), population (ICU versus general wards and long term care) and mean age (50-60 years, 60-70 years, 70-80 years).

3.3.1.2 Data synthesis for diagnostic reviews

Two reviews, measurement of pressure ulcers and categorisation of pressure ulcers, were diagnostic in nature. However the GDG agreed that there is not a gold standard for measurement or categorisation therefore a straight-forward diagnostic test accuracy review was not possible. A systematic review was found for measurement of pressure ulcers which was relevant for this question and was comprehensive enough to answer the review question. This systematic review used a modified version of the QUADAS tool, which was appropriate for this review. As the categorisation review was similar in nature to the measurement question it was thought appropriate to use the modified QUADAS tool for consistency of reviews.

3.3.1.3 Data synthesis for qualitative reviews

Two reviews, training and education of healthcare professionals and information required for patients (in regards to pressure ulcers), were qualitative in nature. This entailed searching and obtaining studies according to the protocol and extracting the details from each study. Themes were obtained from the studies and reported in the review with further details underpinning the themes.

3.3.1.4 Type of studies

For most intervention reviews in this guideline, parallel randomised trials (RCTs) were included because they are considered the most robust type of study design that could produce an unbiased estimate of the intervention effects.

For reviews of interventions where no randomised trials of pressure ulcers existed for pressure ulcers it was agreed by the GDG that we would not look at randomised trials of wounds. The GDG felt that wounds were significantly different in etiology from pressure ulcers and therefore thought it more appropriate to review a lower level of data on pressure ulcers. Therefore where there were no randomised trials, cohort studies were included.

3.3.1.5 Type of analysis

Estimates of effect from individual studies were based on the author reported data. As a preference available case analysis (ACA) was used and if this was not reported intention to treat analysis (ITT) with imputation) was then used.

The ACA method is preferred to an intention-to-treat with imputation analysis (ITT), in order to avoid making assumptions about the participants for whom outcome data were not available, and furthermore assuming that those with missing outcome data have the same event rate as those who continue. In addition, ITT analysis tends to bias the results towards no difference, and therefore the effect may be smaller than in reality.

3.3.1.6 Appraising the quality of evidence by outcome

The evidence for outcomes from the included RCTs and observational studies (when appropriate) was evaluated and presented using the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group (http://www.gradeworkinggroup.org/). The software (GRADEprofiler) developed by the GRADE working group was used to assess the evidence quality for each outcome, taking into account individual study quality factors and the meta-analysis results. Results were presented in GRADE profiles ('GRADE tables'), which consist of two adjacent sections: the "Clinical/Economic Study Characteristics" table includes details of the quality assessment while the "Clinical /Economic Summary of Findings" table includes pooled outcome data and an absolute measure of the intervention effect and the summary of quality of evidence for that outcome. In this table, the columns for intervention and control indicate summary measures and measures of dispersion (such as mean and standard deviation or median and range) for continuous outcomes and frequency of events (n/N: the sum across studies of the number of participants with events divided by sum of the number of completers) for binary outcomes.

The evidence for each outcome was examined separately for the quality elements listed and each graded using the quality levels listed below. The main criteria considered in the rating of these elements are discussed below. Footnotes were used to describe reasons for grading a quality element as having serious or very serious problems. The ratings for each component were summed to obtain an overall assessment for each outcome.

1. A quality rating was assigned, based on the study design and the type of review. For intervention reviews, RCTs start HIGH and observational studies as LOW.
2. The rating was then downgraded for the specified criteria: risk of bias (study limitations), inconsistency, indirectness, imprecision and publication bias. These criteria are detailed below. Evidence from observational studies (that had not previously been downgraded) was upgraded if there was: a large magnitude of effect, dose-response gradient, and if all plausible confounding would reduce a demonstrated effect or suggest a spurious effect when results showed no effect. Each quality element considered to have "serious" or "very serious" risk of bias was rated at -1 or-2 points respectively.
3. The downgraded/upgraded marks were then summed and the overall quality rating was revised. For example, all RCTs started as HIGH and the overall quality became MODERATE, LOW or VERY LOW if 1, 2 or 3 points were deducted respectively.
4. The reasons used for downgrading were specified in the footnotes.

The details of criteria used for each of the main quality elements are discussed further in the following sections (see Chapter 3.3.1.7 to 3.3.1.12).

3.3.1.7 Risk of bias

Bias can be defined as anything that causes a consistent deviation from the truth. Bias can be perceived as a systematic error (for example, if a study were carried out several times there would be a consistently wrong answer, and the results would be inaccurate).

The risk of bias for a given study and outcome is associated with the risk of over or underestimation of true effect.

The risks of bias are listed in Table 1.

A study with a poor methodological design does not automatically imply high risk of bias; the risk of bias is considered individually for each outcome and it is assessed whether this poor design will impact on the estimation of the intervention effect.

Table 1: Risk of bias in randomised trials

Risk of bias	Explanation
Inadequate or unclear allocation concealment	Those enrolling patients are aware of the group to which the next enrolled patient will be allocated (major problem in “pseudo” or “quasi” randomised trials with allocation by day of week, birth date, chart number, etc.)
Lack of blinding	Patients, caregivers, those recording outcomes, those adjudicating outcomes, or data analysts are aware of the arm to which patients are assigned
Incomplete accounting of patients and outcome events	Missing data not accounted for and degree of ‘missingness’ is large enough to affect the results; participants not analysed in the groups to which they were assigned
Selective outcome reporting	Reporting of some outcomes and not others on the basis of the results
Other risks of bias	For example: • Stopping early for benefit observed in randomised trials, in particular in the absence of adequate stopping rules • Use of unvalidated patient-reported outcomes • Recruitment bias in cluster randomised trials

For prognostic factor studies, risk of bias was assessed using the checklist for Prognostic studies (NICE Guidelines Manual, 2009[143]). The quality rating was derived by assessing the risk of bias across 6

domains; selection bias, prognostic factor bias, attrition bias, outcome measurement bias, control for confounders and appropriate statistical analysis, with the last 4 domains being assessed per outcome. More details about the quality assessment for prognostic studies are shown below:

- The study sample represents the population of interest with regard to key characteristics – population at risk of pressure ulcers, source of sample and inclusion/ exclusion criteria adequately described,
- Loss to follow up is unrelated to key characteristics, sufficient to limit potential bias – reasons for loss to follow up adequately described.
- The prognostic factor of interest is adequately measured in study participants.
- The outcome of interest is adequately measured in study participants and not present at the start of the study
- Important potential confounders are appropriately accounted for and the ratio of events/covariate is acceptable (rule of thumb is more than ten).
- The statistical analysis is appropriate for the design of the study, limiting potential for the presentation of invalid results; multivariable analysis is preferred; account is taken of preventative treatment.

For prognostic tools, risk of bias was assessed taking into account the following domains: validation cohort (preferably external validation); prognostic factor bias; imputation of prognostic factor data or missing data; minimum of 100 events; analysis appropriate for a prognostic study (that is taking into account time); attrition bias.

- Tools are validated in a cohort dissimilar from the 1 in which the tool was derived, preferably with external validation
- Each factor comprising the prognostic tool is measured using an adequate method
- Missing data for each of the prognostic factors comprising the tool are taken into account adequately and imputation is done appropriately
- The outcome of interest is adequately measured in study participants and not present at the start of the study
- Loss to follow up is unrelated to key characteristics, sufficient to limit potential bias – reasons for loss to follow up adequately described.
- The statistical analysis is appropriate for the design of the study. The analysis takes into account time
- Account is taken of preventative treatment in the analysis: there is potential confounding in many studies because the patients were given preventative treatment when they were considered at risk (not necessarily as a result of the risk assessment). This meant that the number of true positive results was likely to be reduced artificially.

3.3.1.8 Inconsistency

Inconsistency refers to an unexplained heterogeneity of results. When estimates of the treatment effect across studies differ widely (that is, heterogeneity or variability in results), this suggests true differences in the underlying treatment effect.

Heterogeneity in a meta-analysis was examined and sensitivity and subgroup analyses performed as pre-specified in the protocols (Appendix C). Subgroup analysis is reported after the GRADE evidence profile in which heterogeneity is reported.

When heterogeneity existed (Chi square $p<0.1$ or I- squared inconsistency statistic of >50% or evidence from examining forest plots), but no plausible explanation could be found the quality of evidence was downgraded by 1 or two levels, depending on the extent of uncertainty in the evidence

contributed by the inconsistency in the results. In addition to the I-squared and Chi squared values, the decision for downgrading was also dependent on factors such as whether the intervention is associated with benefit in all other outcomes.

3.3.1.9 Indirectness

Directness relates to the extent to which the populations, intervention, comparisons and outcome measures are similar to those defined in the inclusion criteria for the reviews. Indirectness is important when these differences are expected to contribute to a difference in effect size.

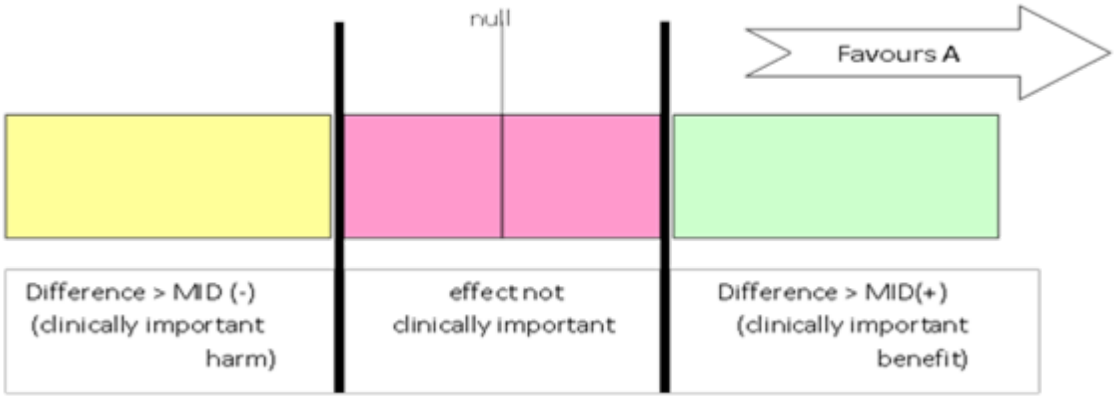
3.3.1.10 Imprecision

Imprecision in guidelines concerns whether the uncertainty (confidence interval) around the effect estimate means that we don't know whether there is a clinically important difference between interventions. Therefore, imprecision differs from the other aspects of evidence quality, in that it is not really concerned with whether the point estimate is accurate or correct (has internal or external validity) instead we are concerned with the uncertainty about what the point estimate is. This uncertainty is reflected in the width of the confidence interval.

The 95% confidence interval is defined as the range of values that contain the population value with 95% probability. The larger the trial, the smaller the confidence interval and the more certain we are in the effect estimate.

Imprecision in the evidence reviews was assessed by considering whether the width of the confidence interval of the effect estimate is relevant to decision making, considering each outcome in isolation. Figure 2 considers a positive outcome for the comparison of treatment A versus B. Three decision making zones can be identified, bounded by the thresholds for clinical importance (MID) for benefit and for harm (the MID for harm for a positive outcome means the threshold at which drug A is less effective than drug B and this difference is clinically important to patients (favours B).

Figure 2: Imprecision illustration



When the confidence interval of the effect estimate is wholly contained in 1 of the 3 zones (for example clinically important benefit), we are not uncertain about the size and direction of effect (whether there is a clinically important benefit or the effect is not clinically important or there is a clinically important harm), so there is no imprecision.

When a wide confidence interval lies partly in each of 2 zones, it is uncertain in which zone the true value of effect estimate lies, and therefore there is uncertainty over which decision to make (based on this outcome alone); the confidence interval is consistent with two decisions and so this is considered to be imprecise in the GRADE analysis and the evidence is downgraded by 1 ("serious imprecision").

If the confidence interval of the effect estimate crosses into 3 zones, this is considered to be very imprecise evidence because the confidence interval is consistent with 3 clinical decisions and there is a considerable lack of confidence in the results. The evidence is therefore downgraded by 2 in the GRADE analysis ("very serious imprecision").

Implicitly, assessing whether the confidence interval is in, or partially in, a clinically important zone, requires the GDG to estimate an MID or to say whether they would make different decisions for the 2 confidence limits.

The literature was searched for established MIDs for the selected outcomes in the evidence reviews, but no results were found. In addition, the GDG was asked whether they were aware of any acceptable MIDs in the clinical community of pressure ulcers but they confirmed the absence of research in the area. Finally, the GDG considered it clinically acceptable to use the GRADE default MID for dichotomous outcomes to assess imprecision: a 25% relative risk reduction or relative risk increase was used, which corresponds to a RR clinically important threshold of 0.75 or 1.25 respectively. For continuous outcomes the GRADE default of -0.50 or 0.50 multiplied by the standard deviation was used to gain a clinically important threshold. The standard deviation is obtained by using the median value for the baseline values of the intervention and control groups for a set of studies. If only 1 study was included, the standardised mean difference was calculated and a default MID of 0.50 was used. These default MIDs were used for all the outcomes in the interventions evidence reviews.

3.3.1.11 Publication bias

Downgrading for publication bias would only be carried out if the GDG were aware that there was serious publication bias for that particular outcome. Such downgrading was not carried out for this guideline.

3.3.1.12 Other risk of bias

There were particular issues in this guideline for outcomes time to healing, rate of reduction in size and volume of pressure ulcers and reduction in size and volume of pressure ulcers. It was noted that there were non-normal distributions for the change in size and that it would be advantageous to carry out log transformations. Where studies report simple means and standard deviations for the change or percentage change in size they are likely to be unreliable and therefore we have downgraded the evidence if simple means form the majority of the evidence.

3.3.1.13 Assessing clinical importance

The GDG assessed the evidence by outcome in order to determine if there was, or was potentially, a clinically important benefit, a clinically important harm or no clinically important difference between interventions. To facilitate this, the relative effect of estimates for binary outcomes were converted into absolute effects using GRADEpro software: the median control group risk across studies was used to calculate the absolute effect and its 95% confidence interval from the pooled risk ratio.

The assessment of benefit/harm/no benefit or harm was based on the point estimate of absolute effect for intervention studies which was standardized across the reviews. The GDG considered for most of the outcomes in the intervention reviews that if at least 100 participants per 1000 (10% cut off) achieved the outcome of interest (if positive) in the intervention group compared to the comparison group then this intervention would be considered beneficial. The same point estimate but in the opposite direction would apply if the outcome was negative. The cut off point for adverse events was lower and considered for each individual adverse and serious adverse event outcome. This assessment was carried out by the GDG for each outcome. The GDG used the assessment of

clinical importance for the outcomes alongside the evidence quality and the uncertainty in the effect estimates to make an overall judgement on the balance of benefit and harms of an intervention.

3.3.1.14 Evidence statements

Evidence statements are summary statements that are presented after the GRADE profiles, summarizing the key features of the clinical effectiveness evidence presented. The wording of the evidence statements reflects the certainty/uncertainty in the estimate of effect. The evidence statements are presented by outcome and encompass the following key features of the evidence:

- The number of studies and the number of participants for a particular outcome.
- An indication of the direction of clinical importance (if 1 treatment is beneficial or harmful compared to the other, or whether there is no difference between two tested treatments).
- A description of the overall quality of evidence (GRADE overall quality).

Specific wording was used to indicate whether there was serious imprecision or very serious imprecision. If there was serious imprecision the evidence statement used the words 'is potentially' and if there was very serious imprecision the evidence statement used the words 'there may be'. This is to show the level of uncertainty in the results and therefore in the clinical difference.

3.3.1.15 Other issues

It should be noted that various classification systems exist and were included in the studies. They differ not only by their descriptions of different pressure ulcers but also by terminology, typically grade or stage. Where data have been extracted from studies the original terminology (grade/stage) given in the study has been retained.

3.4 Evidence of cost effectiveness

The GDG is required to make decisions based on the best available evidence of both clinical and cost effectiveness. Guideline recommendations should be based on the expected costs of the different options in relation to their expected health benefits (that is, their 'cost effectiveness') rather than the total implementation cost.[143] Thus, if the evidence suggests that a strategy provides significant health benefits at an acceptable cost per patient treated, it should be recommended even if it would be expensive to implement across the whole population.

Evidence on cost effectiveness related to the key clinical issues being addressed in the guideline was sought. The health economist undertook:

- A systematic review of the published economic literature.
- New cost-effectiveness analysis in priority areas.

3.4.1 Literature review

The health economist:

- Identified potentially relevant studies for each review question from the economic search results by reviewing titles and abstracts – full papers were then obtained.
- Reviewed full papers against pre-specified inclusion and exclusion criteria to identify relevant studies (see below for details).
- Critically appraised relevant studies using the economic evaluations checklist as specified in The guidelines manual.[143]
- Extracted key information about the studies' methods and results into evidence tables (included in Appendix H).

- Generated summaries of the evidence in NICE economic evidence profiles (included in the relevant chapter for each review question) – see below for details.

3.4.1.1 Inclusion and exclusion

Full economic evaluations (studies comparing costs and health consequences of alternative courses of action: cost–utility, cost-effectiveness, cost–benefit and cost–consequence analyses) and comparative costing studies that addressed the review question in the relevant population were considered potentially includable as economic evidence.

Studies that only reported cost per hospital (not per patient), or only reported average cost effectiveness without disaggregated costs and effects, were excluded. Abstracts, posters, reviews, letters, editorials, comment articles, foreign language publications and unpublished studies were excluded.

Remaining studies were prioritised for inclusion based on their relative applicability to the development of this guideline and the study limitations. For example, if a high quality, directly applicable UK analysis was available, then other less relevant studies may not have been included. Where exclusions occurred on this basis, this is noted in the relevant section.

For more details about the assessment of applicability and methodological quality see the economic evaluation checklist (Appendix G of The guidelines manual,[143] and the health economics review protocol in Appendix C).

3.4.1.2 NICE economic evidence profiles

The NICE economic evidence profile has been used to summarise cost and cost-effectiveness estimates. The economic evidence profile shows an assessment of applicability and methodological quality for each economic evaluation, with footnotes indicating the reasons for the assessment. These assessments were made by the health economist using the economic evaluation checklist from The guidelines manual.[143]. It also shows incremental costs, incremental effects (for example, quality-adjusted life years [QALYs]) and the incremental cost-effectiveness ratio, as well as information about the assessment of uncertainty in the analysis. See Table 2 for more details.

If a non-UK study was included in the profile, the results were converted into pounds sterling using the appropriate purchasing power parity.[152]

Table 2: Content of NICE economic evidence profile

Item	Description
Study	First author name, reference, date of study publication and country perspective.
Applicability	An assessment of applicability of the study to the clinical guideline, the current NHS situation and NICE decision-making: Directly applicable – the study meets all applicability criteria, or fails to meet 1 or more applicability criteria but this is unlikely to change the conclusions about cost effectiveness. Partially applicable – the study fails to meet 1 or more applicability criteria, and this could change the conclusions about cost effectiveness. Not applicable – the study fails to meet 1 or more of the applicability criteria, and this is likely to change the conclusions about cost effectiveness. Such studies would usually be excluded from the review.
Limitations	An assessment of methodological quality of the study: Minor limitations – the study meets all quality criteria, or fails to meet 1 or more quality criteria, but this is unlikely to change the conclusions about cost effectiveness.

Item	Description
	Potentially serious limitations – the study fails to meet 1 or more quality criteria, and this could change the conclusions about cost effectiveness. Very serious limitations – the study fails to meet 1 or more quality criteria, and this is highly likely to change the conclusions about cost effectiveness. Such studies would usually be excluded from the review.
Other comments	Particular issues that should be considered when interpreting the study.
Incremental cost	The mean cost associated with 1 strategy minus the mean cost of a comparator strategy.
Incremental effects	The mean QALYs (or other selected measure of health outcome) associated with 1 strategy minus the mean QALYs of a comparator strategy.
Cost effectiveness	Incremental cost-effectiveness ratio (ICER): the incremental cost divided by the incremental effects.
Uncertainty	A summary of the extent of uncertainty about the ICER reflecting the results of deterministic or probabilistic sensitivity analyses, or stochastic analyses of trial data, as appropriate.

(a) Applicability and limitations were assessed using the economic evaluation checklist in Appendix G of The guidelines manual (2012)[143]

3.4.2 Undertaking new health economic analysis

As well as reviewing the published economic literature for each review question, as described above, new economic analysis was undertaken by the health economist in selected areas. Priority areas for new health economic analysis were agreed by the GDG after formation of the review questions and consideration of the available health economic evidence.

The GDG identified negative pressure wound therapy and repositioning as the highest priority areas for original economic modelling, as there was limited existing evidence and wide variation in current practice in both of these areas.

The following general principles were adhered to in developing the cost-effectiveness analysis:

- Methods were consistent with the NICE reference case.[140]
- The GDG was involved in the design of the models, selection of inputs and interpretation of the results.
- Model inputs were based on the systematic review of the clinical literature supplemented with other published data sources where possible.
- When published data was not available GDG expert opinion was used to populate the models.
- Model inputs and assumptions were reported fully and transparently.
- The results were subject to sensitivity analysis and limitations were discussed.
- The models were peer-reviewed by another health economist at the NCGC.

Full methods for the cost-effectiveness analysis for negative pressure wound therapy and repositioning are described in Appendix L.

3.4.3 Cost-effectiveness criteria

NICE's report 'Social value judgements: principles for the development of NICE guidance' sets out the principles that GDGs should consider when judging whether an intervention offers good value for money.[141] In general, an intervention was considered to be cost effective if either of the following criteria applied (given that the estimate was considered plausible):

a. The intervention dominated other relevant strategies (that is, it was both less costly in terms of resource use and more clinically effective compared with all the other relevant alternative strategies), or
b. The intervention cost less than £20,000 per QALY gained compared with the next best strategy.

If the GDG recommended an intervention that was estimated to cost more than £20,000 per QALY gained, or did not recommend 1 that was estimated to cost less than £20,000 per QALY gained, the reasons for this decision are discussed explicitly in the 'Recommendations and link to evidence' section of the relevant chapter, with reference to issues regarding the plausibility of the estimate or to the factors set out in 'Social value judgements: principles for the development of NICE guidance'.[141] When QALYs or life years gained are not used in the analysis, results are difficult to interpret unless 1 strategy dominates the others with respect to every relevant health outcome and cost.

3.4.4 In the absence of economic evidence

When no relevant published studies were found, and a new analysis was not prioritised, the GDG made a qualitative judgement about cost effectiveness by considering expected differences in resource use between options and relevant UK NHS unit costs alongside the results of the clinical review of effectiveness evidence.

3.5 Developing recommendations

Over the course of the guideline development process, the GDG was presented with:

- Evidence tables of the clinical and economic evidence reviewed from the literature. All evidence tables are in Appendix G and H.
- Summary of clinical (GRADE tables) and economic evidence and quality (as presented in individual chapters).
- Forest plots and ROC curves (Appendix I).
- A description of the methods and results of the cost-effectiveness analysis undertaken for the guideline (Appendix L).

Recommendations were drafted on the basis of the GDG's interpretation of the available evidence, taking into account the trade off between benefits, harms and costs of different courses of action. This was either done formally in an economic model, or informally. Firstly, the net benefit over harm was considered (clinical effectiveness), using the critical outcomes. When this was done informally, the GDG took into account the clinical benefits/harms when 1 intervention was compared with another. The assessment of net benefit was moderated by the importance placed on the outcomes (the GDG's values and preferences), and the confidence the GDG had in the evidence (evidence quality). Secondly, it was assessed whether the net benefit justified the costs.

When clinical and economic evidence was of poor quality, conflicting or absent, the GDG drafted recommendations based on their expert opinion. The considerations for making consensus based recommendations included the balance between potential harms and benefits, economic or other implications compared to the benefits, current practices, recommendations made in other relevant guidelines, patient preferences and equality issues. The consensus recommendations were done through discussions in the GDG. The GDG could also consider whether the uncertainty is sufficient to justify delaying making a recommendation to await further research, taking into account the potential harm of failing to make a clear recommendation. The wording of recommendations was agreed by the GDG and focused on the following factors:

- on the actions health professionals need to take

- include what readers need to know
- reflect the strength of the recommendation (for example the word “offer” was used for strong recommendations and “consider” for weak recommendations)
- emphasise the involvement of the patient (and/or their carers if needed) in decisions on treatment and care
- follow NICE’s standard advice on recommendations about drugs, waiting times and ineffective interventions.

The main considerations specific to each recommendation are outlined in the ‘Recommendations and link to evidence’ sections within each chapter.

3.5.1.1 Research recommendations

When areas were identified for which good evidence was lacking, the guideline development group considered making recommendations for future research. Decisions about inclusion were based on factors such as:

- the importance to patients
- national priorities
- potential impact on the NHS and future NICE guidance
- ethical and technical feasibility

3.5.1.2 Validation process

The guidance is subject to a 6 week public consultation and feedback as part of the quality assurance and peer review the document. All comments received from registered stakeholders are responded to in turn and posted on the NICE website when the pre-publication check of the full guideline occurs. Updating the guideline

3.5.1.3 Updating the guideline

A formal review of the need to update a guideline is usually undertaken by NICE after its publication. NICE will conduct a review to determine whether the evidence base has progressed significantly to alter the guideline recommendations and warrant an update.

3.5.1.4 Disclaimer

Healthcare providers need to use clinical judgement, knowledge and expertise when deciding whether it is appropriate to apply guidelines. The recommendations cited here are a guide and may not be appropriate for use in all situations. The decision to adopt any of the recommendations cited here must be made by the practitioners in light of individual patient circumstances, the wishes of the patient, clinical expertise and resources.

The National Clinical Guideline Centre disclaims any responsibility for damages arising out of the use or non-use of these guidelines and the literature used in support of these guidelines.

3.5.1.5 Funding

The National Clinical Guideline Centre was commissioned by the National Institute for Health and Care Excellence to undertake the work on this guideline.

4 Delphi consensus methods

It is recognised that in the area of pressure ulcer prevention and management there is often limited high quality evidence available. This is further exaggerated in the prevention and management of pressure ulcers in children (including neonates, infants, children and adolescents).

During development of the guideline, due to the scarcity of evidence identified, it was agreed by the GDG that this would be an area in which the use of formal consensus methods would be appropriate. A modified Delphi approach was chosen as this would provide a robust approach to allow the GDG to develop recommendations. Where there are any randomised trials or high quality cohort studies available these will be included in a review.

It is acknowledged that during development of the guideline, there are other areas or population subgroups where evidence of the required quality is not identified. In these cases lower levels of evidence was searched for, for example cohort studies, for the GDG to base their recommendations on. If no evidence was found, GDG consensus was used to form recommendations, in line with NICE methodology (see Chapter 3).

The methods for agreeing and developing the Delphi consensus statement are outlined below, a full report can be found in Appendix N.

4.1 Modified Delphi consensus methodology

Where a lack of published evidence was identified in the populations of neonates, infants, children and young people, the GDG chose to use a modified Delphi consensus methodology. The use of modified Delphi consensus methodology in guideline development is well established[143] and techniques have been used throughout the development of other NICE clinical guidelines.[138,139] The benefits of using Delphi consensus methods, as opposed to for example, informal consensus of the GDG, is that it allows for a wider range of knowledge and experience to be involved and that, as an anonymous technique, it prevents group members to conforming with the opinion of others.[136]

For each question, the NCGC conducted a search for published evidence (RCTs and cohort studies) relating to neonates, infants, children and young people, in line with the pre-defined protocols (see Appendix C). Where evidence was identified for neonates, infants, children and young people, reviews of the clinical and economic evidence were undertaken using the usual NICE processes and presented to the GDG who used this evidence as a basis to make further recommendations.

Only for 2 questions (repositioning and risk assessment) was any published evidence relating to these populations identified which met the inclusion criteria. For these studies, the evidence was considered by the GDG alongside the statements developed and included in the Delphi consensus survey and is included in the relevant Chapter.

The methods for developing the Delphi consensus were agreed with the GDG and NICE in advance of the process. The GDG agreed to conduct two consensus rounds and to recruit a minimum of 100 individuals to participate in the process. Although there is no consensus on the optimum number of rounds to include in the Delphi consensus survey, or the number of individuals to include in the panel,[74] the GDG chose to be pragmatic given the time and resources available. The GDG agreed the constitution of the panel in advance. Details on the agreed constitution can be found in Appendix N. Due to the spread of professionals included in the Delphi consensus panel, the GDG chose not to analyse any data identified by profession or specialty.

Delphi panel members were recruited via the GDG and registered stakeholder organisations. Letters asking for nominations were also sent to children's hospitals in England and Wales and GDG members were asked to identify 5-10 healthcare professionals to take part. Delphi panel members

were required to meet two criteria: to state that they had no conflict of interest and to complete a confidentiality agreement. 74 applications were received and 72 individuals subsequently recruited to the panel, with 2 applicants not meeting the pre-defined criteria. 71 responses were received to the final survey. A list of individuals who took part in the survey can be found in Appendix N.

The GDG worked in small groups to develop statements for inclusion in the survey. Statements for Round 1 of the survey were subsequently discussed and agreed amongst the whole GDG. A list of statements developed by the GDG for included in Round 1 can be found in Appendix N.

These statements were developed into a survey which was distributed to member of the NCGC as part of a pilot survey. Comments and responses on content and format from 14 members of staff were incorporated into the final survey.

The survey was then distributed to Delphi consensus panel members electronically, along with a glossary and definitions of the populations used within the survey (see Appendix N). Each statement was rated on a Likert scale of 1-9, where 1= 'strongly agree' and 9= 'strongly disagree'. The option of 'I do not have the expertise to answer this question was also included'. Each statement was accompanied by a free text box in which qualitative responses could be entered. Delphi panel members were given 4 weeks to respond to the survey, during that period, two reminders were sent to all panel members.

In order to ensure that the individual receiving the invite to respond and subsequently responding was the intended individual, each panel member was allocated a validation code, sent in a separate email, which would need to be entered into the survey for the results to be included in the final analysis.

As the importance of pre-defining a consensus level was outlined in the literature, (Keeney 2011) the GDG chose in advance to use a consensus agreement level of 75%.The GDG predefined that statements reaching 75% or greater agreement on ratings 1-3 or 7-9 would be accepted in the positive or negative and developed into recommendations by the GDG. Statements reaching less than 75% consensus in either pole would be amended by the GDG on the basis of text responses provided and entered into Round 2 of the Delphi consensus survey.

Those who had responded 'I do not have the expertise to answer this question' and those who had not completed the question were removed from the denominator when ascertaining whether consensus had been reached.

4.2 Round 1

72 individuals were recruited to the Delphi consensus panel and 71 individuals responded to the final survey. Of these, 8 individuals did not complete the survey. However, where answers were provided, they were included in the final analysis.

The GDG predefined that statements reaching 75% or greater agreement on ratings 1-3 or 7-9 would be accepted in the positive or negative and developed into recommendations by the GDG. Statements reaching less than 75% consensus in either pole would be amended by the GDG on the basis of text responses provided and entered into Round 2 of the Delphi consensus survey.

Those who had responded 'I do not have the expertise to answer this question' and those who had not completed the question were removed from the denominator when ascertaining whether consensus had been reached.

Appendix N contains data received for each statement. Appendix N also contains the analysis for each statement, to ascertain whether consensus was reached.

4.2.1 Qualitative analysis

Text responses (in the free text box) to questions which had reached consensus were considered by the GDG in developing the final recommendations. These qualitative responses were also used to inform the 'Linking evidence to recommendations' table for each recommendation. Themes for each can be found in Appendix N.

For statements which did not reach consensus level, free text responses were considered to inform the adaptation of the statement for Round 2 of the survey. Responses for statements that did not reach agreement can be found in Appendix N.

4.2.2 Accepted statements from Round 1

Details of the statements accepted in Round 1 can be found in Appendix N.

4.2.3 Developing recommendations from Round 1

Statements accepted in Round 1 of the Delphi consensus survey were used by the GDG in developing the corresponding recommendation and agreed by informal consensus of the GDG.

Each recommendation was included in the relevant chapter, with a 'Linking Evidence to Recommendations' section outlining how the recommendation was agreed and which statements were used to develop it.

4.2.4 Non-accepted statements from Round 1

Qualitative responses from the Delphi consensus panel for statements that were not accepted in Round 1 of the Delphi consensus survey were gathered and analysed and presented to the GDG. The GDG amended the statements on the basis of feedback gathered and discussion and these were included in Round 2 of the Delphi consensus survey. Qualitative responses received during Round 1 can be found in Appendix N. Amended statements included in Round 2 can be found in Appendix N.

4.3 Round 2

The GDG predefined that statements reaching 75% or greater agreement on ratings 1-3 or 7-9 would be accepted in the positive or negative and developed into recommendations by the GDG.

60 individuals of the 71 recruited to the Delphi consensus panel responded to Round 2 of the Delphi consensus survey.

4.3.1 Qualitative analysis

Text responses (in the free text box) to questions which had reached consensus were considered by the GDG in developing the final recommendations. These qualitative responses were also used to inform the 'Linking evidence to recommendations' table for each recommendation.

For statements which did not reach consensus level, free text responses were considered to inform GDG discussion.

4.3.2 Accepted statements from Round 2

Details of the statements accepted in Round 2 can be found in Appendix N.

4.3.3 Developing recommendations from Round 2

As in Round 1 of the survey, statements reaching 75% or greater agreement on ratings 1-3 or 7-9 were accepted in the positive or negative and developed into recommendations by the GDG, informed by qualitative responses gathered during the survey. Those who had responded 'I do not have the expertise to answer this question' and those who had not completed the question were removed from the denominator when ascertaining whether consensus had been reached.

4.3.4 Non-accepted statements from Round 2

Statements reaching less than 75% consensus in either pole were considered and discussed by the GDG and recommendations developed based upon informal consensus of the group or extrapolated from evidence in adult populations.

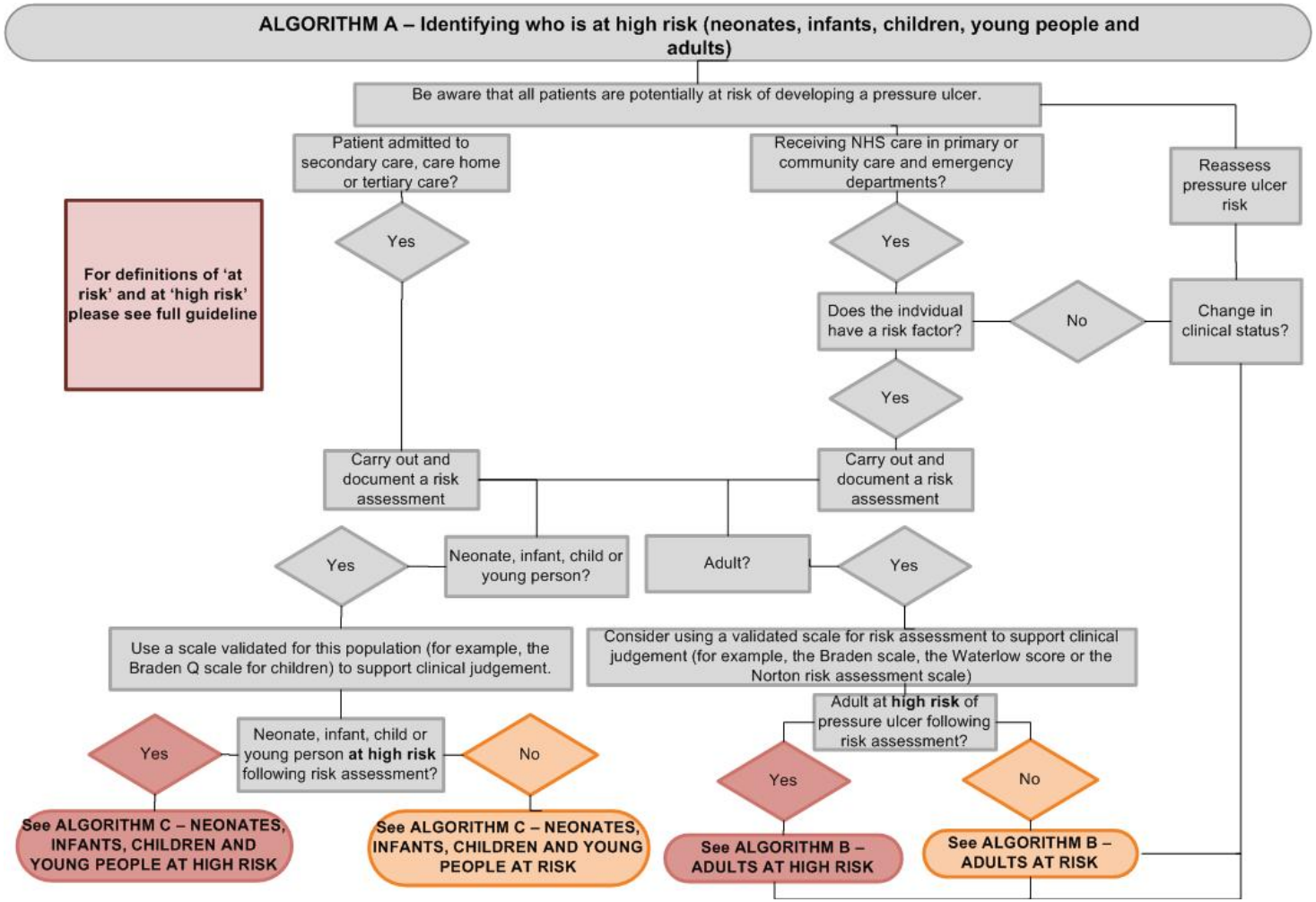
Appendix N contains data received for each statement. Appendix N also contains the analysis for each statement, to ascertain whether consensus was reached.

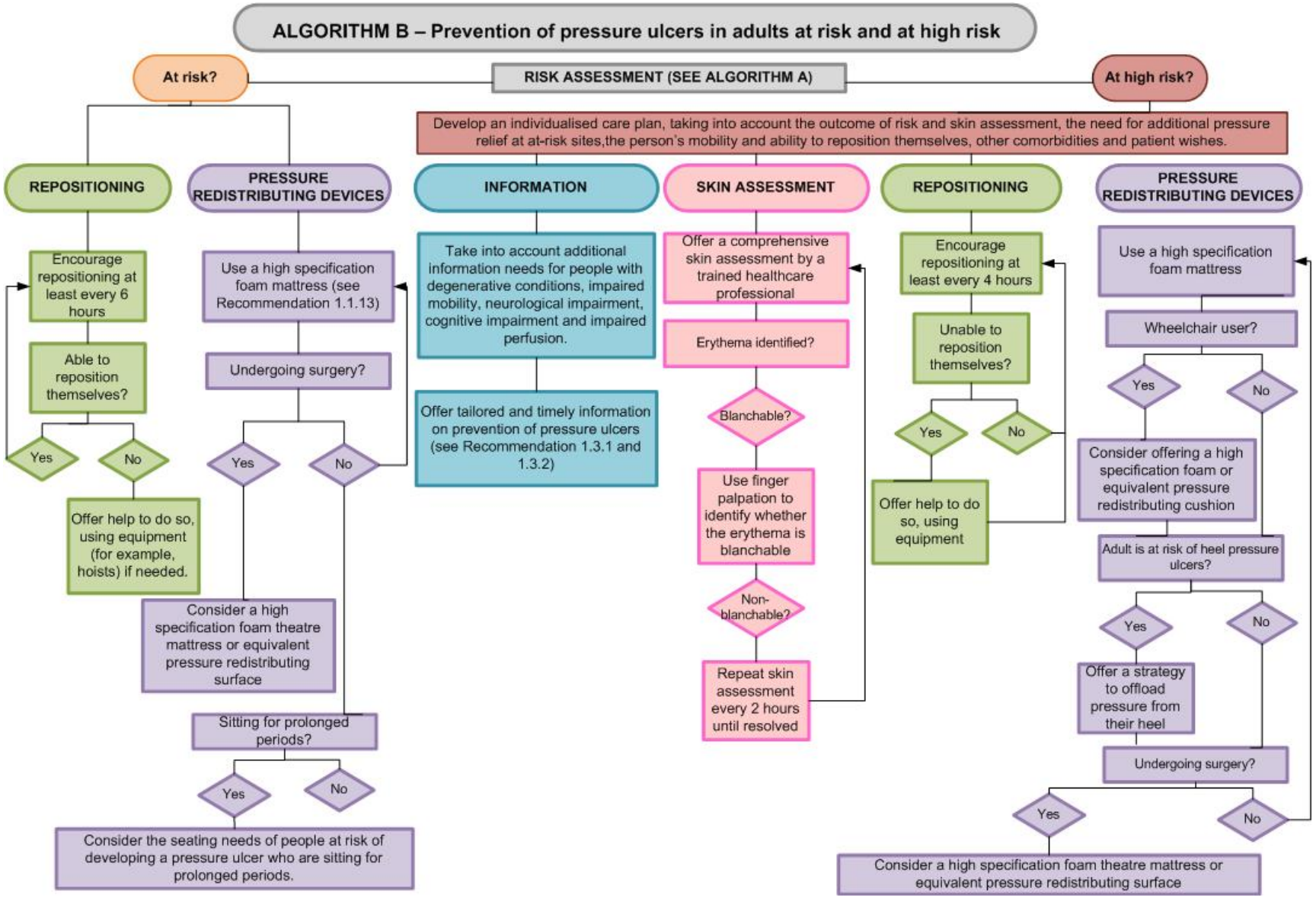
4.3.5 Economic considerations

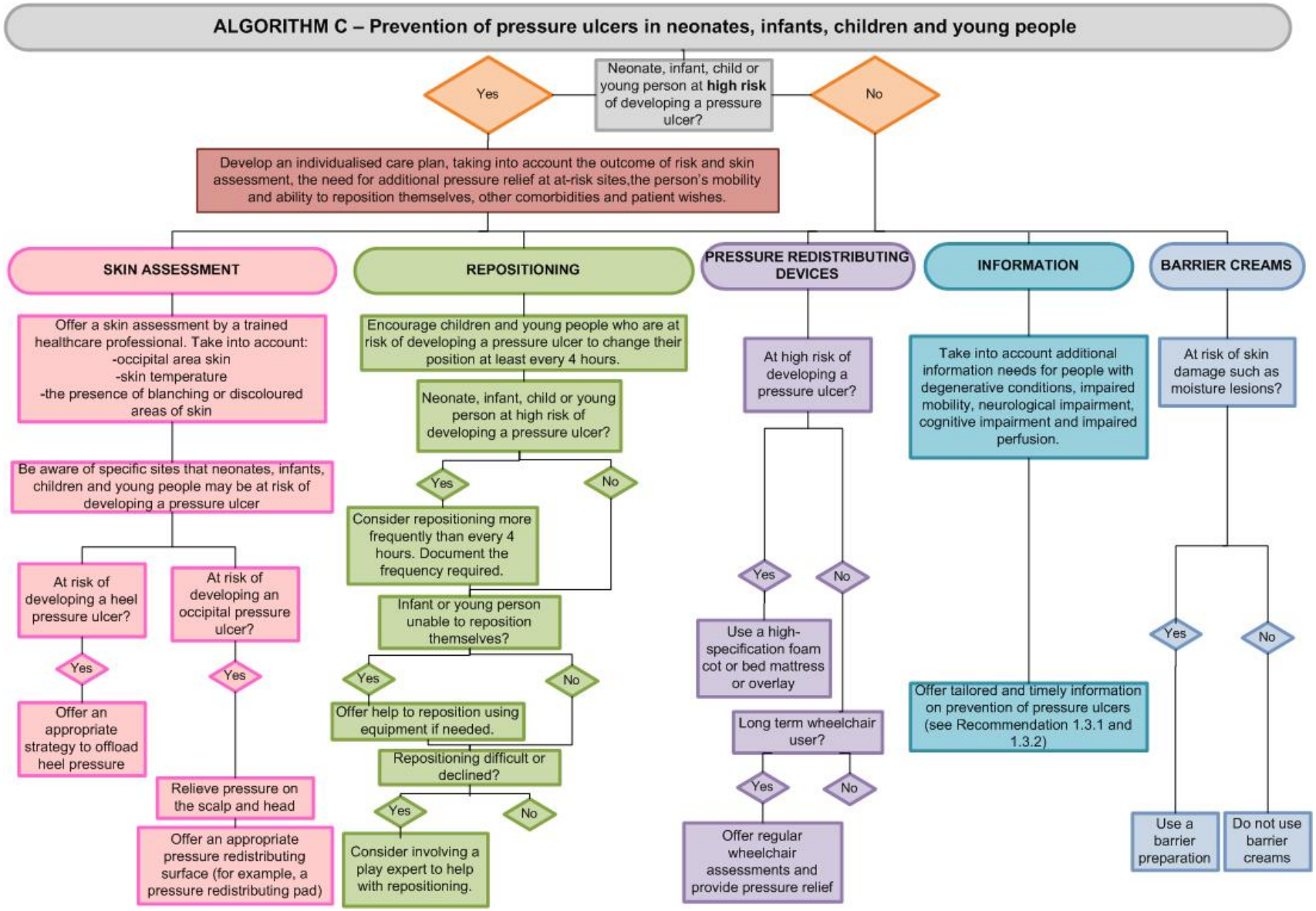
Economic evidence in neonates, infants, children and young people was not identified as part of the economic evidence review. The GDG did not feel that it was appropriate to include economic statements in the Delphi consensus and therefore chose to make a judgement as to the economic impact of Delphi consensus statements and the recommendations which they were used to develop. Unit costs of relevant interventions were presented where appropriate within each Chapter. A summary of the judgements made and the subsequent discussion of the GDG is included in the Linking Evidence to Recommendations section for each recommendation.

5 Guideline summary

5.1 Algorithms




ALGORITHM B – Prevention of pressure ulcers in adults at risk and at high risk
At risk?
RISK ASSESSMENT (SEE ALGORITHM A)
At high risk?
Develop an individualised care plan, taking into account the outcome of risk and skin assessment, the need for additional pressure relief at at-risk sites,the person's mobility and ability to reposition themselves, other comorbidities and patient wishes.
REPOSITIONING
PRESSURE REDISTRIBUTING DEVICES
INFORMATION
SKIN ASSESSMENT
REPOSITIONING
PRESSURE REDISTRIBUTING DEVICES
Encourage repositioning at least every 6 hours
Able to reposition themselves?
Yes
No
Offer help to do so, using equipment (for example, hoists) if needed.
Use a high specification foam mattress (see Recommendation 1.1.13)
Undergoing surgery?
Yes
No
Consider a high specification foam theatre mattress or equivalent pressure redistributing surface
Sitting for prolonged periods?
Yes
No
Consider the seating needs of people at risk of developing a pressure ulcer who are sitting for prolonged periods.
Take into account additional information needs for people with degenerative conditions, impaired mobility, neurological impairment, cognitive impairment and impaired perfusion.
Offer tailored and timely information on prevention of pressure ulcers (see Recommendation 1.3.1 and 1.3.2)
Offer a comprehensive skin assessment by a trained healthcare professional
Erythema identified?
Blanchable?
Use finger palpation to identify whether the erythema is blanchable
Non-blanchable?
Repeat skin assessment every 2 hours until resolved
Encourage repositioning at least every 4 hours
Unable to reposition themselves?
Yes
No
Offer help to do so, using equipment
Use a high specification foam mattress
Wheelchair user?
Yes
No
Consider offering a high specification foam or equivalent pressure redistributing cushion
Adult is at risk of heel pressure ulcers?
Yes
No
Offer a strategy to offload pressure from their heel
Undergoing surgery?
Yes
No
Consider a high specification foam theatre mattress or equivalent pressure redistributing surface


ALGORITHM C – Prevention of pressure ulcers in neonates, infants, children and young people
Neonate, infant, child or young person at high risk of developing a pressure ulcer?
Yes
No
Develop an individualised care plan, taking into account the outcome of risk and skin assessment, the need for additional pressure relief at at-risk sites,the person's mobility and ability to reposition themselves, other comorbidities and patient wishes.
SKIN ASSESSMENT
Offer a skin assessment by a trained healthcare professional. Take into account:
-occipital area skin
-skin temperature
-the presence of blanching or discoloured areas of skin
Be aware of specific sites that neonates, infants, children and young people may be at risk of developing a pressure ulcer
At risk of developing a heel pressure ulcer?
Yes
Offer an appropriate strategy to offload heel pressure
At risk of developing an occipital pressure ulcer?
Yes
Relieve pressure on the scalp and head
Offer an appropriate pressure redistributing surface (for example, a pressure redistributing pad)
REPOSITIONING
Encourage children and young people who are at risk of developing a pressure ulcer to change their position at least every 4 hours.
Neonate, infant, child or young person at high risk of developing a pressure ulcer?
Yes
No
Consider repositioning more frequently than every 4 hours. Document the frequency required.
Infant or young person unable to reposition themselves?
Yes
No
Offer help to reposition using equipment if needed.
Repositioning difficult or declined?
Yes
No
Consider involving a play expert to help with repositioning.
PRESSURE REDISTRIBUTING DEVICES
At high risk of developing a pressure ulcer?
Yes
No
Use a high-specification foam cot or bed mattress or overlay
Long term wheelchair user?
Yes
No
Offer regular wheelchair assessments and provide pressure relief
INFORMATION
Take into account additional information needs for people with degenerative conditions, impaired mobility, neurological impairment, cognitive impairment and impaired perfusion.
Offer tailored and timely information on prevention of pressure ulcers (see Recommendation 1.3.1 and 1.3.2)
BARRIER CREAMS
At risk of skin damage such as moisture lesions?
Yes
No
Use a barrier preparation
Do not use barrier creams

5.2 Key priorities for implementation

From the full set of recommendations, the GDG selected 10 key priorities for implementation. The criteria used for selecting these recommendations are listed in detail in The guidelines manual.[143] The reasons that each of these recommendations was chosen are shown in the table linking the evidence to the recommendation in the relevant chapter.

- 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 settings 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 [1.1.2]

- 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[a]
  - variations in heat, firmness and moisture (for example, because of incontinence, oedema, dry or inflamed skin).[1.1.5]

- 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.[1.3.1]

- 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.[1.1.8]

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

- 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.[1.1.13]

- 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 (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. [1.2.1]

- 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.[1.3.4]

- Provide further training to healthcare professionals who have contact with anyone who is 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.[1.3.5]

- Discuss with adults with heel pressure ulcers and if appropriate, their carers, a strategy to offload heel pressure as part of their individualised care plan.[1.4.26]

5.3 Full list of recommendations

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

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- significant loss of sensation

- a previous or current pressure ulcer

- nutritional deficiency

- the inability to reposition themselves

- significant cognitive impairment.

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.

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).

5. 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
- patient mobility and ability to reposition themselves
- other comorbidities
- patient preference.

6. 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 (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.

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

8. 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

- variations in heat, firmness and moisture (for example, because of incontinence, oedema, dry or inflamed skin).

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

10. 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.

11. 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.

12. 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.

13. 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.

14. 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.

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

16. 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 where needed.

17. 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.

18. 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.

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

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

21. 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.

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

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

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

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

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

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

28. 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.

29. 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.

30. 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

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

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

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

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

35. 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.

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

37. 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).

38. 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.

39. 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.

40. 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).

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

42. Offer timely, tailored information to people who have been assessed as being at high risk of developing a pressure ulcer, and their 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.

43. 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).

44. 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.

45. 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.

5.4 Key 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?

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?

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

4. 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?

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

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?

6 Pressure ulcer prevention

6.1 Introduction

For an individual to suffer harm which could be prevented as a result of their care is clearly unacceptable and something to be avoided. Pressure ulcers are often an example of such avoidable harm occurring and their prevention is now a priority for the NHS.

It has been accepted for many years that pressure ulcers are often preventable. Unfortunately there is significant variation in the consistency of approach to pressure ulcer prevention, and to the treatment and care of established pressure ulcers across the NHS in both secondary and primary care. There is, therefore, a need for guidance to rationalise the approaches used for prevention, of pressure ulcers, and to ensure practice is based on the best available evidence. Every patient has the right to expect safe care as described by domain 5 of the NHS outcome Framework 2013/2014 and this includes prevention of avoidable pressure ulcers.

One of the potential problems is that all adults are potentially at risk of pressure ulcers - in certain circumstances anyone can develop one. However they are significantly more likely to occur in people who are seriously ill, neurologically compromised, have impaired mobility, impaired nutrition, poor posture or use equipment such as seating or beds that do not provide appropriate pressure redistribution. A significant number of pressure ulcers, therefore, arise during care for other disorders and people with limited mobility who live in residential or nursing care facilities are at increased risk of developing pressure ulcers. Because of this strategies for their prevention and treatment need to be applicable across a wide range of settings including both community and secondary care. This may require significant organisational and individual change and commitment to deliver preventative strategies effectively at a local level.

Another myth is that pressure ulceration is only a problem of older people. As mentioned above anyone can potentially develop a pressure ulcer at any time and neonates, children and young people can also be at risk. Neonates have particularly vulnerable skin and high rates of pressure ulceration can occur in neonatal intensive care for example. So in addition to developing recommendations for adults, we have carried out an expert Delphi process for prevention in neonates, infants, children and young people.

Regarding prevention we have looked at methods for risk assessment and who should be risk assessed for pressure ulceration. Several structured risk assessment scales have been developed for pressure ulcer risk and many are routinely used within the NHS. However, it is unclear if these scales are better than expert clinical assessment alone and whether their use can help prevent pressure ulceration. Prevention of ulceration caused by ischemia or neuropathy, moisture, friction and shear, venous leg ulcers, pressure ulcers caused by devices and Kennedy terminal ulcers have not been specifically included. However, in clinical practice these factors may also need to be considered.

It is hoped that this guideline will result in a reduction in the numbers of people developing pressure ulceration in the NHS. However, it will only be the start. Pressure ulcer prevention requires constant vigilance – even a brief lapse can result in a pressure ulcer which could take weeks or months to heal. Preventing pressure ulcers effectively will usually require a system approach that requires fundamental organisational change. That may be difficult, requiring multiple modifications to ways of working at all levels of an organisation. Some people may persist with the view that pressure ulcers are inevitable. However, that view is outdated and many organisations have already managed to very significantly reduce their pressure ulcer rates by some relatively simple interventions hinged around awareness and staff attitudes. It is hoped that this guideline will help others follow their lead successfully.

6.1.1 Adults 'at risk' and at 'high risk' of developing a pressure ulcer

For the purposes of this guideline, people receiving care from, or commissioned by, the NHS are considered to be either:

- 'at -risk': people who are, after formal assessment using clinical judgement or a risk assessment tool, considered to be at risk of developing a pressure ulcer.
- 'at high risk' of developing a pressure ulcer: people at high risk usually have multiple risk factors (for example, significantly limited mobility, risk of nutritional deficiency, an inability to reposition themselves, a neurological condition or significant cognitive impairment[b]) identified during risk assessment with or without a validated scale. Adults with a history of pressure ulcers or a current pressure ulcer are also considered to be at high risk.

The GDG noted that there were a number of methods of formally assessing an individual's level of risk (see Chapter 7). In addition to the use of clinical judgement, there were several risk assessment scales available but only limited evidence to suggest which method of risk assessment was a more accurate predictor of subsequent risk than clinical judgement. Additionally, the GDG noted that different tools have different thresholds for identifying those at risk and at high or very high risk, which healthcare professionals often amend for their own use.

As a result, the GDG did not consider that it was possible to develop recommendations based upon the categories outlined in a particular risk assessment scale and the group chose to develop the above two categories to help distinguish between those people at risk of developing a pressure ulcer and those with additional individual factors which may result in them having an high risk of developing a pressure ulcer.

Although it was outside the remit of the guideline to review the evidence and identify risk factors for pressure ulcer development, the GDG highlighted that there were likely to be a number of factors which might mean that an adult is considered to be at significant risk of developing a pressure ulcer. These may include, but are not limited to, a lack of activity and mobility (including people undergoing surgery and in the immediate post operative period), poor perfusion and skin status (for example, the presence of redness, blanching, erythema or dryness).[34](Coleman et al 2013)

6.1.2 Neonates, infants, children and young people 'at risk' and 'at highd risk' of developing a pressure ulcer

For the purposes of this guideline, neonates, infants, children and young people receiving care from, or commissioned by, the NHS are considered to be either at:

- 'at-risk': neonates, infants, children or young people who are, after formal assessment using clinical judgement or a risk assessment tool, considered to be risk of developing a pressure ulcer. Healthcare professionals should consider each neonate, infant, child or young person for their individual risk factors and formally assess whether they are at risk (see Chapter 7).
- 'at high risk' of developing a pressure ulcer: neonates, infants, children and young people at high risk usually have multiple risk factors (for example, significantly limited mobility, risk of nutritional deficiency, an inability to reposition themselves, a neurological condition or significant cognitive impairment[b]) identified during risk assessment with or without a validated scale. Those with a history of pressure ulcers or a current pressure ulcer are also considered to be at high risk.

The GDG noted that neonates, infants, children and young people were likely to have different risk factors to adults and that these should be considered when assessing the risk of these populations.

[b] Please note that examples given are not exhaustive.

6.1.3 Extrapolating adults recommendations to neonates, infants, children and young people

For ease of use, the guideline and its recommendations have been divided into two sections, part 1 (prevention) and part 2 (management). Part 1 and part 2 both contain recommendations for adults and neonates, infants, children and young people, using methods outlined in Chapter 3 and 4, respectively.

It is acknowledged that there are differences in the recommendations for adults and those for neonates, infants, children and young people. However, due to the significant differences in the means and sites by which younger populations may develop pressure ulcers, the GDG chose to use the results of the Delphi consensus to develop the recommendations, rather than extrapolating from evidence in adult populations.

However, the GDG acknowledge that some of those recommendations developed for adults may be applicable to neonates, infants, children and young people and that healthcare professionals may wish to consider the principles of these recommendations when treating these populations.

In each 'Linking evidence to Recommendations' section, recommendations for adults can be found in yellow boxes and recommendations for neonates, infants, children and young people in pink boxes. Recommendations which are applicable for all ages can be found in blue boxes.

6.1.4 Pressure ulcers caused by devices

The GDG wished to highlight that the prevention and management of pressure ulcers caused by devices is outside the scope of the current guideline (see Appendix A).

6.1.5 Accounting for individuals' comfort and preferences

Throughout the guideline, when developing recommendations for the prevention and management of pressure ulcers, the GDG have taken consideration of the individuals' concurrent needs for sleep, pain relief, meal times and rehabilitation. The GDG felt that it was important to highlight that a balance needs to be achieved between all of these factors for each individual who is at risk of or who has developed a pressure ulcer.

7 Risk assessment

7.1 Introduction

Risk assessment aims to identify people who are susceptible to pressure ulcer development in order to target appropriate preventative interventions. Both risk assessment scales and clinical judgement are widely described as methods being used in day-to-day practice to identify who is at risk of developing a pressure ulcer.

Risk assessment tools are combinations of individual risk factors, and are used to assess the risk of tissue damage due to pressure or shear forces. Most existing risk assessment tools are scales which assign numerical values to various factors (for example, mobility, nutrition, level of continence), with a total score produced from the sum of these values (Papanikolaou et al. 2003).[157] The resulting score is used as an indicator for pressure ulcer risk (Kottner & Dassen 2010).[108] Risk assessment scales are used to stratify patients likely to develop pressure ulcers into categories reflecting their degree of risk (such as low risk, medium risk, high risk) (Griffiths & Jull 2010),[81] Recommendations for action can be given on the basis of the assigned risk category.

Risk assessment scales are assessed on their ability to predict pressure ulcer development, however preventative interventions are usually initiated as soon as a risk has been identified (Papanikolaou et al. 2003) and in some cases pressure ulcer development is prevented. Therefore, validating pressure ulcer risk assessment scales by comparing obtained scores with the occurrence of pressure ulcers is problematic, because pressure ulcer risk assessment scales determine pressure ulcer risk but they are not diagnostic tests predicting who will and who will not develop pressure ulcers (Anthony et al. 2008, Kottner & Dassen 2010).[4,108]

The GDG were interested in how to guide health care professionals in their decision making about the most appropriate method of risk assessment to detect individuals at risk for pressure ulcers, in order to inform prevention and identify if risk assessment tools have benefits over clinical judgement alone. This chapter therefore has two parts:

- part 1; focusing on the clinical and cost effectiveness of risk assessment tools as part of a complex intervention for pressure ulcer prevention.
- part 2; focusing on the prognostic ability of risk assessment scales and clinical judgement in predicting pressure ulcer risk

7.1.1 Part 1: What is the clinical and cost effectiveness of risk assessment tools in the prevention of pressure ulcers?

For full details see review protocol in Appendix A.

7.1.2 Clinical evidence (adults)

A Cochrane review by Moore and Cowan (2010)[134] was identified and used as reference for this review. The Cochrane review was an update of a previous version conducted in 2008. This original review reported no randomised trials (RCTs), but the authors' update search revealed 1 new RCT.[169] The Cochrane review was further updated for the guideline and searches identified an additional RCT.[221]

Therefore, 2 RCTs were included in this review.[169,221] Evidence from these are summarised in the clinical GRADE evidence profile below (Table 3). See also the study selection flow chart in Appendix D, forest plots in Appendix I, study evidence tables in Appendix G and exclusion list in Appendix J.

Both studies included people with a pressure ulcer at the start of the study and people considered to be at higher risk (according to the risk assessment methods) received preventative treatment (see Chapter 7.1.2.1).

The Saleh 2009 study was a cluster RCT which stated that there were significant baseline differences between groups in terms of referral for pressure ulcer care, medical diagnoses and the use of creams and vitamins. Nine wards were randomised, with very different people across groups; only those at high risk were included. The study also conducted a logistic regression analysis with covariates of: intervention group, Braden score, age, referral to the wound care team and use of protective mattresses; all were significant except for the intervention group. The Cochrane Review suggested that there may be some additional confounding in this study that is an individual's clinical judgement is likely to be influenced by prior knowledge of risk assessment tools. The Cochrane Review also suggested that there are too many methodological issues (for example, the use of preventative strategies) with the study to draw firm conclusions from it.

For the Webster 2011 study, people were randomised and the appropriate risk assessment tool was placed in their medical record for use by the ward nurse. It was noted that this resulted in a risk of contamination, for example clinical judgement being affected by the more formal instrument used for the previous person. This study conducted logistic regression analyses to investigate risk factors for pressure ulcers, but included the treatment group as 1 of the covariates, thereby giving adjusted odds ratios.

7.1.2.1 Summary of included studies

Study	Population	Intervention/comparison	Outcomes
Saleh 2009[169]	Hospitalised people with a pressure ulcer or Braden scale of less than 18 (30-33% pressure ulcers pre-training and high risk group)- Group 1: male medical, isolation, male orthopaedic and spinal surgery wards Group 2: rehabilitation, renal and neurosurgery wards Group 3: female medical, oncology and VIP medical-surgical wards.	(1) Training in wound management and in the use of the Braden scale plus application of the Braden scale. (2) Training (wound management and Braden) only; no implementation of Braden. (3) Training in wound management (Clinical judgement group). For all groups, various treatments were given: protective mattresses, creams and skin barriers, vitamin supplements and nutritional formulae, referral to the wound care team and patient turning every 2, 3-4 or 6 hours. Reasons for treatment decisions not stated.	• Incidence of people with pressure ulcers
Webster 2011[221]	Hospitalised people older than 18 years with or without a pressure ulcer.	(1) Waterlow scale (2) Ramstadius scale (3) Clinical judgement For all groups, various treatments were given: special mattresses, documentation of an explicit pressure care plan, referral to the specialist skin integrity nurse or referral to a dietician.	• Incidence of people with pressure ulcers

Table 3: Clinical evidence profile: training in wound management, training in using the Braden scale plus application of the Braden scale versus training inwound management plus clinical judgement

Quality assessment							No of people with pressure ulcers		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Braden	Clinical judgement	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers - all grades[169]												
1	Cluster randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	16/74 (21.6%)	16/106 (15.1%)	RR 1.43 (0.77 to 2.68)	65 more per 1000 (from 35 fewer to 254 more)	Very low	Critical

(a) Sequence generation, and blinding not reported; unclear allocation concealment; difference at baseline for medical diagnoses, pressure ulcer prevention practices, use of barrier creams and use of vitamin supplements, proportion at severe risk of a pressure ulcer; no intention-to-treat analysis; account of cluster randomization not stated.

(b) Confidence interval crossed 1 MID.

Table 4: Clinical evidence profile: application of the Braden scale versus no application (all nurses received training in wound management and the use of the Braden scale)

Quality assessment							No of people with pressure ulcers		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Braden	No Braden	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcer - all grades[169]												
1	Cluster randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	16/74 (21.6%)	17/76 (22.4%)	RR 0.97 (0.53 to 1.77)	7 fewer per 1000 (from 105 fewer to 172 more)	Very low	Critical

(a) Sequence generation and blinding not reported; unclear allocation concealment; difference at baseline for medical diagnoses, pressure ulcer prevention practices, use of barrier creams and use of vitamin supplements; no intention-to-treat analysis; account of cluster randomization not stated.

(b) Confidence interval crossed both MIDs.

Table 5: Clinical evidence profile: Braden training only (no implementation) versus clinical judgement (all nurses had wound management training)

Quality assessment							No of people with pressure ulcers		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Braden training	Clinical judgement	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcer - all grades[169]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	17/76 (22.4%)	16/106 (15.1%)	RR 1.48 (0.8 to 2.74)	72 more per 1000 (from 30 fewer to 263 more)	Very low	Critical

(a) Sequence generation and blinding not reported; inadequate allocation concealment (ward allocation); difference at baseline for medical diagnoses, pressure ulcer prevention practices, use of barrier creams and use of vitamin supplements; no intention-to-treat analysis; account of cluster randomization not stated.

(b) Confidence interval crossed 1 MID.

Table 6: Clinical evidence profile: Waterlow scale versus clinical judgement

Quality assessment							No of people with pressure ulcers		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Waterlow	Clinical judgement	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcer - all grades[221]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	31/411 (7.5%)	28/410 (6.8%)	RR 1.10 (0.68 to 1.81) Multivariable analysis: OR 1.06 (95%CI 0.59 to 1.91)	7 more per 1000 (from 22 fewer to 55 more)	Very low	Critical
Incidence of pressure ulcer – grade 2[221]												

Quality assessment							No of people with pressure ulcers		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Waterlow	Clinical judgement	Relative (95% CI)	Absolute		
1	Randomised trials	Serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	10/411 (2.4%)	8/410 (2%)	RR 1.25 (0.5 to 3.13)	5 more per 1000 (from 10 fewer to 42 more)	Very low	Critical

(a) Health care professional not blinded and may be influenced by learning from other instruments (that is contamination).
(b) Confidence interval crossed both MIDs.

Table 7: Clinical evidence profile: Ramstadius scale versus clinical judgement

Quality assessment							No of people with pressure ulcers		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Ramstadius	Clinical judgement	Relative (95% CI)	Absolute		
Incidence of pressure ulcer - all grades[221]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	22/410 (5.4%)	28/410 (6.8%)	RR 0.79 (0.46 to 1.35) Multivariable analysis: OR 0.60 (95%CI 0.31 to 1.13)	14 fewer per 1000 (from 37 fewer to 24 more)	Very low	Critical
Incidence of pressure ulcer – grade 2[221]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	4/410 (1%)	8/410 (2%)	Pressure ulRR 0.50 (0.15 to 1.65)	10 fewer per 1000 (from 17 fewer to 13 more)	Very low	Critical

(a) Health care professional not blinded and may be influenced by learning from other instruments (that is contamination).
(b) Confidence interval crossed both MIDs.

Table 8: Clinical evidence profile: Waterlow scale versus Ramstadius scale

Quality assessment							No of people with pressure ulcers		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Waterlow	Ramstadius	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcer - all grades[221]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	31/411 (7.5%)	22/410 (5.4%)	RR 1.41 (0.83 to 2.39)	22 more per 1000 (from 9 fewer to 75 more)	Low	Critical
Incidence of pressure ulcer – grade 2[221]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	10/411 (2.4%)	4/410 (1%)	RR 2.49 (0.79 to 7.89)	15 more per 1000 (from 2 fewer to 67 more)	Low	Critical

(a) Health care professional not blinded and may be influenced by learning from other instruments (that is contamination).
(b) Confidence interval crossed 1 MID.

7.1.3 Economic evidence (adults)

No relevant economic evidence was identified.

7.1.4 Clinical evidence (neonates, infants, children and young people)

No RCTs or cohort studies were identified. Recommendations were developed using a modified Delphi consensus technique. Further details can be found in Chapter 4 and Appendix N.

7.1.5 Economic evidence (neonates, infants, children and young people)

No relevant economic evidence was identified.

7.1.6 Evidence statements

7.1.6.1 Clinical (adults)

- One study (n=180) suggested that wound management training plus clinical judgement (with subsequent preventative treatment) may be more clinically effective at reducing pressure ulcer incidence (all grades) compared to wound management training and training in the use of the Braden scale, with or without application of the Braden scale (and preventative treatment). However, the level of confounding makes this evidence unreliable (Very low quality).
- One study (n=180) suggested there may be no clinically important difference between people in wards that applied the Braden scale following training in its use and in wound management, versus people whose nurses only received the training in wound management and training in the use of the Braden scale (all grades of pressure ulcer), but the level of confounding makes this evidence unreliable (Very low quality).
- One study (n= 821) showed there may be no clinically important difference in pressure ulcer incidence (all grades and also for stage 2 pressure ulcers alone) between people assessed by nurses who used the Waterlow scale compared to clinical judgement with subsequent treatment (Very low quality).
- One study (n=820) showed that the Ramstadius scale (with subsequent preventative treatment) may be more clinically effective at reducing pressure ulcer incidence (all grades and grade 2 alone) compared to clinical judgement (Very low quality).
- One study (n=821) showed that the Ramstadius scale may be more clinically effective at reducing pressure ulcer incidence (all grades and grade 2 alone) compared to the Waterlow scale (Low quality).

7.1.6.2 Economic (adults)

No evidence was identified.

7.1.1 Clinical (neonates, infants, children and young people)

No evidence was identified.

7.1.2 Economic (neonates, infants, children and young people)

No evidence was identified.

7.1.3 Part 2: review question: What is the predictive ability of risk assessment tools for pressure ulcer prevention?

For full details see review protocol in Appendix C.

7.1.4 Clinical evidence (adults)

A systematic review by Pancorbo-Hidalgo et al. (2006)[155] was identified and updated. This resulted in an additional 16 studies, with 1 further study retrieved through screening of reference lists.

The systematic review by Pancorbo-Hidalgo (2006)[155] was used as a reference for this review. The review by Pancorbo-Hidalgo et al. (2006)[155] included 32 studies, of which 5 were excluded because they did not meet the inclusion criteria for this review. One was excluded because it was a retrospective cohort study.[16] and another study was removed because it was written in Spanish.[67] Three other studies were excluded because they included people who had a pressure ulcer at the start of the study.[25,84,85] Twenty seven studies from the Pancorbo-Hidalgo review were therefore included in the final review. Sensitivity and specificity of each scale and cut-off score were re-calculated using the raw data as presented in the individual studies and some adjustments were made to the Pancorbo-Hidalgo review.[155]

In total 44 prospective studies were included in the review.[5,11,26,36,116,119,122,151,154,162,183,187,197,3,17,18,18,19,29,32,49,59,63,73,86,89,89,97,97,105,105,111,111,118,156,158,170,177,182,182,184,194,196,205,211,219,222,222] Evidence from these are summarised in the clinical GRADE evidence profile below (Table 13). See also the study selection flow chart in Appendix D, forest plots in Appendix I, study evidence tables in Appendix G and exclusion list in Appendix J. A table comprising information on the 5 most commonly used risk assessment tools (Braden scale, Norton scale, Waterlow scale, Cubbin-Jackson scale and Braden-Q scale) is provided in Appendix O.

A variety of scales were reviewed: Waterlow (10 studies), Braden (27), modified Braden (3), Norton (11), Cubbin Jackson (2), Northern Hospital Pressure Ulcer Prevention Plan (1), Song and Choi (1), Fragmment (1), Douglas (1), Anderson (1), Gosnell, Risk Assessment Pressure Sore scale (1), Suriadi and Sanada (1), Knoll (1). Two studies also reported the predictive ability of clinical judgement. Data on all these scales are reported in the appendices. Seven studies compared more than 1 scale, but only 2 had more than 100 events (and so are at lower risk of bias): Schoonhoven 2002[177] compared the Waterlow, Braden and Norton scales, and Perneger 2002[158] compared the Braden and Norton scales and a scale of their own (Fragmment). The evidence for these 2 studies is reported in the text and the evidence for the other 5 studies can be found in Appendix O.

Four studies reported the predictive ability of different scales for all grades of pressure ulcer development. The remaining 3 studies (Hatanaka 2008, Ramundo 1995, Weststrate 1998) were restricted to grade II and above.[89,162,222]

Limitations

An important limitation of this prognostic review is confounding due to preventative treatment in the included studies, which means that the sensitivity and specificity (and area under the curve) measures are likely to be inaccurate. In addition, the studies varied according to the type of preventative measures used and who initiated treatment, which is explicitly addressed below:

- One study stated it did not give preventative treatment (de Souza 2010) or implied these were not given(Suriadi 2006).[197];[49]
- Twelve did not report any preventative treatment (Anthony 2003, Barnes 1993, Braden 1994, Compton 2008, Lewicki 2000, Lindgren 2002, Lyder 1999, Ongoma 2006, Page 2011, Ramundo 1995, Serpa 2009, Smith 1989).[5,11,26,36,116,119,122,151,154,162,183,187]

- Five gave preventative treatment to fewer than 50% of participants (Andersen 1982, Edwards 1995, Perneger 2002, Schoonhoven 2002, Towey 1988).[3,59,158,177,205]
- Four gave preventative treatment to more than 50% of participants (Bergstrom 1987b, Goodridge 1998 (assumed), Halfens 2000, Salvadalena 1992).[18,73,86,170]
- Six gave preventative treatment to all participants (Hatanaka 2008, Jalali 2005, Kim 2009, Langemo 1991, Seongsook 2004, Weststrate 1998)[89,97,105,111,182,222]
- Twelve were vague about the extent of preventative treatment or only implied it was used. (Bergstrom 1987a, Bergstrom 1987b, Bergstrom 1998, Capobianco 1996, Chan 2009, Feuchtinger 2007, Lincoln 1986, Pang 1998, Serpa 2011, Suriadi 2008, Stotts 1988, VandenBosch 1996) [17-19,29,32,63,118,156,184,194,196,211]
- One study stated that it gave preventative treatment to participants at risk on the risk assessment scale (Wai-Han 1997).[219]

In addition, the types of preventative measures varied across the studies: some described preventative measures as 'nursing interventions' or 'normal practice' (Bergstrom 1987a, Bergstrom 1987b, Chan 2009, Langemo 1991 Serpa 2011, Stotts 1988); others employed special mattresses or turning regimens (Goodridge 1998, Halfens 2000; Hatanaka 2008, Jalali 2005, Kim 2009, Kwong 2005, Pang 1998, Perneger 2002, Salvadalena 1992, Schoonhoven 2002, Seongsook 2004, Weststrate 1998) whilst some stated that preventative treatment was given but there were no details (Bergstrom 1998, Lincoln 1986,Towey 1988, VandenBosch 1996).

Generally, it was the responsibility of the nurses to decide the need for preventative interventions. In some studies the nures were blinded to the risk assessment scale results (Chan 2009, Goodridge 1998, Lincoln 1986, Perneger 2002), and in other studies the preventative treatment was not related to the risk assessment score (Capobianco 1996, Schoonhoven 2002).

In terms of determining the usefulness of the risk assessment scales, preventative treatment is a confounding factor, and this was taken into account when considering heterogeneity.

Two of the studies explicitly investigated this counfounding by undertaking multivariable analysis

- Goodridge et al 1998 conducted a multivariable logistic regression analysis including the Braden score and the number of preventative treatments as covariates. The Braden score was a predictor only when the number of treatments was omitted from the analysis.
- Perneger et al 2002 found from multivariable Cox proportional hazards regression analysis that the predictive ability of their Fragmment risk assessment score was significantly reduced ($p<0.001$) in the presence of prevention strategies (HR 1.3 (95%CI 1.2 to 1.5) per 1 point difference in score) compared with that in the absence of a prevention strategy(HR 1.7 (95%CI 1.6 to 1.9)).

Other quality aspects are shown in Appendix O. In general, the studies were considered to be at high (Andersen 1982, Bergstrom 1998, Braden 1994, Capobianco 1996, Curley 2003, Feuchtinger 2007, Schoonhoven 2002) or very high risk of bias for the other quality aspects. The absence of a description of enrolment, of time points when participants dropped out (discharge, death, transfer, pressure ulcer development) from the study, of an imputation technique, a poor description of the definition and measurement of predictive test, and an event rate lower than 100 were the most important methodological flaws.

Three studies had more than 100 events (Anthony 2003, Perneger 2002 and Schoonhoven 2002), Eight studies had fewer than 10 events (Bergstrom 1987a, Kwong 2005, Lincoln 1986, Page 2011, Ramundo 1995, Serpa 2009, Serpa 2011, Wai-Han 1995) and were considered to be at very high risk of bias or were flawed.

Heterogeneity was considered informally for the area under the curve (AUC) for the Braden scale in terms of preventative treatment, number of pressure ulcers (more than 100, 10-100 and less than 10), population (intensive care unit versus general wards and long term care) and mean age (50-60 years, 60-70 years, 70-80 years). There was no clear explanation for the heterogeneity, although the Braden scale appeared to be more effective in an intensive care unit than in the general population.

Summary of included studies

Study	Risk tool and Outcome	Population and preventative treatment	Length of follow-up	No. of patients	No. of events
Andersen 1982[3]	• Andersen scale • Pressure ulcer development (all grades, but no details)	People in an acute observation ward Preventative treatment in some participants (7 had water mattresses, 7 air mattresses and 21 ordinary mattresses)	Maximum 3 months	3,398	43 (1%)
Anthony 2003[5]	• Waterlow scale • Pressure ulcer development	Hospitalised people; mean age 63 years with pressure ulcers and 41.8 years without Preventative treatment not mentioned (database study)	Not reported (median days in hospital two days for pressure ulcer free participants versus 22 days for pressure ulcer participants)	45,735	203 (0.4%)
Barnes 1993[11]	• Braden scale • Pressure ulcer development	People in a nursing home; mean age 68.4 years. No preventative measures reported, though 'standard nursing care' mentioned.	Maximum 2weeks	361	22 (6%)
Bergstrom 1987a (1) and (2)[18,19]	• Braden scale • Pressure ulcer development (all grades)	(1) People undergoing medical or surgical treatment; mean (SD) age: 57.2 (16.8) years (2) People undergoing medical or surgical treatment (unit with higher acuity levels and longer expected length of stay than group 1); mean (SD) age: 50.5 (24) years Preventative measures given described as 'nursing therapies' – no details provided. The same nurse applied the Braden scale and assessed the skin.	(1) Maximum 6 weeks (2) Maximum 12 weeks	(1) 99 (2) 100	(1) 7 (7%) (2) 9 (9%)
Bergstrom 1987b[19]	• Braden scale • Pressure ulcer development	People in intensive care; mean age 58.5 (SD 14.5) years Preventative treatment given to people as decided by nurses (unclear rationale): egg crate	Maximum 2 weeks	60	24 (40%)

Study	Risk tool and Outcome	Population and preventative treatment	Length of follow-up	No. of patients	No. of events
		mattresses (38/60), turning every 2 hours (16/60) plus other therapies			
Bergstrom 1998[17]	• Braden scale • Pressure ulcer development	(1) People in a tertiary care hospital (2) People in a Veteran Medical Centre (3) People in a skilled nursing facility Mean age: 63 years (SD 16) Preventative treatment given but reported in a separate paper (not available).	48-72 hours and maximum 11 days	(1) 306 (2) 282 (3) 255	(1) 26 (8%) (2) 21 (7%) (3) 61 (24%)
Braden 1994[26]	• Braden scale • Pressure ulcer development	People in a skilled nursing facility; mean age 75.9 (SD 9.5) years. Apparently no preventative therapies.	Maximum4weeks	102	28 (27%)
Capobianco 1996[29]	• Braden scale • Pressure ulcer development	People undergoing medical or surgical treatment; mean age 66.9 (SD 19.3) years. Preventative therapies given but not related to Braden score; few details, but foam overlays were given as an example.	Maximum 2 weeks	50	14 (28%)
Chan 2009[32]	• Braden scale • Modified Braden scale • Pressure ulcer development	Orthopaedic participants; mean age 79.4 (SD 10.9) years. Preventative measures applied 'as normal practice' by nurses blinded to Braden score.	Maximum 9 days	197	18 (9%)
Compton 2008[36]	• Waterlow scale • Pressure ulcer grade 2 and above development	People in intensive care; median age 66 years (IQR 56. 75.25). Preventative therapies not mentioned	Maximum 13 days	698	121 (17%)
de Souza 2010[49]	• Braden scale • Pressure ulcer development	People in a long-term care facility; aged 60 years and older; mean age 76.6 (SD 9.2) years. Appropriate procedures for prevention were not implemented because not part of the routine protocol in the institutions concerned, with the exception of changing position and minimisation of skin exposure to moisture.	Three months	233	44 (19%)

Study	Risk tool and Outcome	Population and preventative treatment	Length of follow-up	No. of patients	No. of events
Edwards 1995[59]	• Waterlow scale • Pressure ulcer development	People receiving home care; 2/31 received preventative aids and 1 received a ripple mattress.	Eight weeks	31	2 (6%)
Feuchtinger 2007[63]	• Braden scale • Modified Norton scale • 4-factor model • Pressure ulcer development	People in intensive care (people who have undergone cardiac surgery); mean age 62 years (SD 12.1). Preventative treatment implied, but not stated	Maximum 4days	53	26 (49%)
Goodridge 1998[73]	• Braden scale • Pressure ulcer development	People from the medical and geriatric unit of a tertiary care hospital and long-term care facility; aged 65 years and older; mean age 78.6 (SD 8.5) years. Preventative treatment given by nurses blinded to Braden score (for example, turning, mattresses, barrier creams, nutrition), but rationale not stated. Mean number of prevention strategies: 3.3 for those not at risk and 6.4 for those with Braden of less than19. The number of prevention strategies correlated with the Braden score, and both were used in regression analysis.	Maximum 3months	330	32 (10%)
Halfens 2000[86]	• Braden scale • Extended Braden scale • Pressure ulcer development and/or use of preventative measures	People undergoing surgical, neurological, orthopaedic and internal medicine treatment; mean age 60.9 (SD 18.3) years. Preventative treatment given to 177/320 participants – not dependent on Braden score – mainly anti-decubitus mattress, mobilisation and/or position change. Also includes stepwise regression analysis.	Not reported	320	186 (58%)
Hatanaka 2008[89]	• Braden scale (Regression analysis by subscore of	Bedridden people in hospital with a respiratory disorder; mean age 71.6 (SD 11.3) years.	Maximum 79 days	149	38

Study	Risk tool and Outcome	Population and preventative treatment	Length of follow-up	No. of patients	No. of events
	Braden) • • Pressure ulcer development (> grade 1 of 5)	All participants were given a standard pressure relieving mattress.			(26%)
Jalali 2005[97]	• Braden scale • Norton scale • Waterlow scale • Gosnell scale • Pressure ulcer development (all grades)	People undergoing neurological, intensive care, orthopaedic and medical care; mean age 60 years (range 21 to 89). All participants received 'routine nursing care' plus turning regimen to complement 'multidisciplinary activities'. None received air mattresses or other pressure relieving or pressure reducing equipment (because not used in Iran).	Maximum 14 days	230	74 (32%)
Kim 2009[105]	• Braden scale • Cubbin-Jackson scale • Song and Choi scale • Pressure ulcer development	People in surgical intensive care; mean age 58.1 (SD 1.2) years. All participants received preventative measures: position changed every 2 hours; dried, cleaned and friction/shear managed.	Maximum 90 days	219	40 (18%)
Kwong 2005[109]	• Braden scale • Modified Braden scale • Norton scale • Pressure ulcer development (all grades)	People in acute care; mean age 54.1 (SD 16.9) years. Preventative measures assigned on the basis of nurses clinical judgment to all participants (turning every 2 hours, material to reduce pressure, keeping skin dry and clean, positioning, use of draw sheet for lifting participants, massage of pressure points.	Maximum 21 days	429	9 (2%)
Langemo 1991 (1),(2)[111]	• Braden scale • Pressure ulcer development (all grades)	(1) People in hospital; mean age: with pressure ulcers 62 (SD 14.9) years: without pressure ulcers 61 (6.6) years. (2) People in a long-term care facility; mean	(1) Maximum 16 days (2) Maximum 31 days	74	11 (15%)

Study	Risk tool and Outcome	Population and preventative treatment	Length of follow-up	No. of patients	No. of events
		age: with pressure ulcers 82 (SD 13.8) years: without pressure ulcers 84 (8.6) years. Care was "per normal unit/agency routine".		25	7 (28%)
Lewicki 2000[116]	• Braden scale • Pressure ulcer development (all grades)	People undergoing elective cardiac surgery ; mean age 62 years (SD 11.6). Preventative measures not mentioned.	Five days	337	7 (2%)
Lincoln 1986[118]	• Norton scale • Pressure ulcer development (all grades – 1 to 5)	People undergoing medical or surgical care aged 65 years and older; mean age 72.2 years (SD 15.8). Preventative measures instituted by other staff who did not know Norton scores (no details).	Maximum 26 days	36	5 (14%)
Lindgren 2002[119]	• Risk Assessment Pressure Sore scale (RAPS) • Pressure ulcer development	People in acute care; mean age 69.3 (SD 14.4) years. Preventative measures not mentioned.	Maximum 12 weeks	488	54 (11%)
Lothian 1989[120]	• Pressure Sore Prediction Score (PSPS) • PU development	People undergoing orthopaedic treatment.	Maximum 3weeks	1244	53 (4%)
Lyder 1999[122]	• Braden scale • Pressure ulcer development	People from a tertiary hospital; black and Latino or Hispanic older people; mean age 72 (SD 8.3) years. Research nurses assessing skin were blinded to Braden scores. Preventative measures not mentioned.	Not reported	177	24 (14%)
Ongoma 2005[151]	• Sunderland Pressure Sore Risk Calculator (modified Cubbin-Jackson scale) • Modified Norton scale • Pressure ulcer development	People in intensive care (trauma) on total bed rest; age 18 to 65 years. Preventative measures not mentioned.	Three weeks	66	25 (38%)
Page 2011[154]	• The Northern Hospital	People in acute care; 65% over 65 years.	Not reported	165	7 (4%)

Study	Risk tool and Outcome	Population and preventative treatment	Length of follow-up	No. of patients	No. of events
	Pressure Ulcer Prevention Plan (TNH-PUPP) • Pressure ulcer development	Preventative measures not mentioned.			
Pang 1998[156]	• Braden scale • Norton scale • Waterlow scale • Pressure ulcer development	People undergoing medical and orthopaedic treatment. Chinese participants; age range 45 to 92 years; 84% 65 years and older. Nursing interventions applied by ward staff (including positioning, using pillows, using sheepskin pads, clean sheets and pull taut, water mattress, air mattress, range of motion exercises, massage).	Maximum 14 days	106	21 (20%)
Perneger 2002[158]	• Braden scale • Norton scale • Fragmment scale • Pressure ulcer development (all stages) • Multivariable Cox regression	People undergoing internal medicine, abdominal surgery, orthopaedic, neurosurgery, intensive care, and dermatological treatment. 288/1190 (24%) participants received preventative interventions (regular change of position, or special pillow, mattress or bed). Interventions implemented by nursing team independent of Braden/Norton scales. Hazard Ratio reported in presence and absence of prevention interventions.	Maximum 3weeks	1190	170 (14%)
Ramundo 1995[162]	• Braden scale • Pressure ulcer grade 2 development	People receiving home care (convenience sample); age not stated. No mention of preventative measures.	Maximum 4weeks	48	7 (15%)
Salvadalena 1992[170]	• Braden scale • Clinical judgement • Pressure ulcer development	People receiving acute medical care; mean age 72 (SD 13 years). About half the participants had preventative measures: 17 participants received 2 inch overlays, 4 had alternating pressure mattresses and 5 had static air mattresses; 17 had turning	Maximum 6months	99	20 (20%)

Study	Risk tool and Outcome	Population and preventative treatment	Length of follow-up	No. of patients	No. of events
		schedules and multiple strategies were provided to 13 participants. Blinding of skin assessment and Braden assessment nurses.			
Schoonhoven 2002[177]	• Braden scale • Norton scale • Waterlow scale • Pressure ulcer development	People receiving surgical, internal care, neurological, and geriatric care; mean age 60.1 (SD 16.7) years. 57/1229 (5%) participants received preventative treatment (pressure reducing mattresses or beds, and regular repositioning) – some were in low risk group, but split reported by patient weeks and not participants. Treatment appeared to be independent of risk assessment.	Maximum 12 weeks	1229	135 (11%)
Seongsook 2004[182]	• Braden scale • Cubbin-Jackson scale • Douglas scale • Pressure ulcer development	People in intensive care (internal, surgical and neurological); mean age 62 years. All participants received preventative measures: water mattresses, massages, changed position every 2 hours.	Study duration of 1 year	112	35 (31%)
Serpa 2009[183]	• Waterlow scale • Pressure ulcer development	Hospitalised people; a Braden score of less than 19 or a Waterlow score of over 15 (that is, a selected group of people); mean age 71.1 (SD 15.5) years. Preventative measures not mentioned.	Maximum 6 days	98	7 (7%)
Serpa 2011[184]	• Braden scale • Pressure ulcer development	People in intensive care; a Braden score of less than 19 (that is, a selected group of people); mean age 60.9 (SD 16.5). Preventative measures were the 'responsibility of the institution'.	Maximum 6 days	72	8 (11%)
Smith 1989[187]	• Norton scale	People in hospital; age not stated. Preventative measures not mentioned.	Not reported	101	30 (30%)

Study	Risk tool and Outcome	Population and preventative treatment	Length of follow-up	No. of patients	No. of events
	• Waterlow scale • Pressure ulcer development	Acknowledged help from Judy Waterlow.			
Stotts 1988[194]	• Norton scale • Pressure ulcer development	People undergoing cardiovascular surgery and neurosurgery; 117 participants over 65 years and 270 under 65 years. Preventative measures not mentioned (apart from 'routine nursing care').	Maximum 3weeks	387	67 (17%)
Suriadi 2006[197]	• Braden scale • Pressure ulcer development	People in intensive care, who were bedfast or could not walk; mean age for participants with a pressure ulcer was 50.9 (SD 17.0) years and without a pressure ulcerwas 47.5 (SD 17.6) Study implies that preventative measures were not used.	Maximum 22 days	105	35 (33%)
Suriadi 2008[196]	• Suriadi and Sanada scale (SS) • Pressure ulcer development	People in intensive care; age 55.2 (SD 18.4) in unit 1 and 42.6 (SD 18.8) years in unit 2. Appeared to be validation in the derivation cohort. Participants received 'standard equipment mattresses'.	Not reported	253	47 (19%)
Towey 1988[205]	• Knoll scale • Pressure ulcer development	People in a long-term care facility; aged 65 years and older, mean age 81.3 years (range 65 to 97). 1 out of 3 units 'vigorously' treated any participant with a score above10 with preventative measures (unspecified). 2 out of 3 units were controls.	Fourteen and 38 days	60	28 (47%)
VandenBosch 1996[211]	• Braden scale • Clinical judgement • Pressure ulcer	People in general and intensive care and people undergoing rehabilitation in hospitlal; mean age with a pressure ulcer 67.0 (SD 13.8), without a pressure ulcer 62.4 (SD 16.4) years.	Maximum 2 weeks	103	29 (28%)

Study	Risk tool and Outcome	Population and preventative treatment	Length of follow-up	No. of patients	No. of events
	development	Nurses assessing skin and pressure ulcers blinded to Braden scores. Study states that 'prevention strategies already in place' but no details.			
Wai-Han 1997[219]	• Norton scale • Waterlow scale • Pressure ulcer development	Geriatric people in hospital; aged 70 years and older; mean age women 82.6 years, mean age men 77.5 years. People at risk on the Norton score were given 'usual' preventative treatment.	Four weeks	185	8 (4%)
Weststrate 1998[222]	• Waterlow scale • Pressure ulcer grade 2 and above development • Cox regression analysis (univariate)	People in surgical intensive care, mean age 58.8 years (range 9 to 96). Nursing staff carried out preventative treatments (turning every 3 hours onto 1 side, nursing for at least 1 hour continuously on alternate sides, mobilising the participant) appeared to be for all people where possible. People were excluded from the study if they used a special mattress on admission.	Maximum of 183 days	594	47 (8%)

7.1.4.1 Evidence summary for area under the receiver operating characteristics (ROC) curve for the major scales

Table 9: Clinical evidence profile: scales for predicting the incidence of pressure ulcers (all grades): area under the ROC curve

No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	No. patients No. events (total and range)	AUC*: median study with its 95%CI and range of point estimates	Quality
Braden scale									
9 (all)	Cohort studies	Very serious[a]	Very serious inconsistency[b]	No serious indirectness	No serious imprecision[c]	Likely confounding by preventative treatment	n=3496 \72-1229 events=523 (8-170)	74% (95%CI 70 to 78) – Perneger 2002 range 55 – 88%	Very low
5 (general population)	Cohort studies	Very serious [a]	Serious inconsistency[b]	No serious indirectness	Serious imprecision[c]	Likely confounding by preventative treatment	n=2998 (149-1229) events=405 (38-170)	68% (51 to 79) – Hatanaka 2007 range 55– 81	Very low
4 (ICU)	Cohort studies	Very serious[a]	Serious inconsistency[b]	No serious indirectness	Serious imprecision[c]	May be confounding by preventative treatment	n=498 (72-219) events=118 (8-40)	79% (95%CI 70 to 89) – Suriadi 2006 range 71– 88)	Very low
Norton scale									
2 (general population)	Cohort studies	Serious[a]	Serious inconsistency[b]	No serious indirectness	Serious imprecision[c]	Likely confounding by preventative treatment	n=1190 and 1229 events=135 and 170	56% (95%CI 51 to 61) – Schoonhoven 2002 and 74 (95%CI 70 to 78) – Perneger 2002	Very low
Waterlow scale									
4 (all)	Cohort studies	Very serious [a]	Serious inconsistency[d]	No serious indirectness	No serious imprecision[c]	Majority of evidence did not mention preventative treatment	n=47,760 (98-45,735) events=466 (7-203)	59 (95%CI 54 to 65);- Compton 2008; range 54 – 90	Very low
Cubbin Jackson scale									
2 (ICU)	Cohort studies	Very serious[a]	No serious inconsistency	No serious indirectness	Serious imprecision[e]	Likely confounding by preventative treatment	n=112 and 219 events=35 and 40	83% (no CI) and 90 (no CI reported)	Very low

** AUC 90.0-100.0: perfect discrimination; 80.0-89.0: good discrimination; 70.0-79.0: fair discrimination; 60.0-69.0: poor discrimination;50.0-59.0: fail to discriminate*

(a) The majority of studies were at very high risk of bias.

(b) Consistent with more than 1 decision (very serious if more than 2 decisions, serious if 2 decisions); unexplained by subgroup analysis.

(c) Judged on confidence interval around the median study; serious means consistent with 2 decisions, very serious means consistent with 3 decisions.
(d) Inconsistency was caused by an outlier (a very large study).
(e) Confidence intervals estimated from size of study – likely to be consistent with more than 1 decision.

7.1.4.2 Summary of the evidence comparing 3 main scales (Braden, Waterlow, Norton) and clinical judgement for all populations and all stages

The table summarises the evidence for all studies, reporting the summary statistic with its 95% confidence interval of the median study, and also reporting the range across studies. Sensitivity and specificity pairs were reported for the 3 thresholds that maximised both sensitivity and specificity with a preference for sensitivity. The results for the threshold with the highest sensitivity and its corresponding specificity are highlighted in Table 10.

"Clinical judgement" was defined to be:

- Salvadalena 1992: prediction of the staff nurse assigned to the participant for the day. More than 50% of the participants received mattresses.
- VandeBosch 1996: prediction of the staff nurse assigned to the participant for the day. Prevention strategies were reported to be in place but no details were given.

In addition, the GDG noted that prognostic studies are prone to publication bias with large studies being likely to be the most reliable. Therefore, the values for the 2 largest studies are provided in Table 10. Reference should be made to the forest plots in order to visually assess the variability amongst studies.

Table 10: Summary of the evidence comparing 3 main scales (Braden, Waterlow, Norton) and clinical judgement for all populations and all stages

	Braden	Waterlow	Norton	Clinical judgement
AUC	74% (70 to 78); range 55 – 88 (9 studies) Very low **Largest studies** Perneger 2002 (n=1190): 74% (70 to 78) and Schoonhoven 2002 (n=1229): 55% (49 to 60)	59% (95%CI 54 to 65); range 54–90 (4 studies) Very low **Largest studies:** Anthony 2003 (n=3,398): 90% (88 to 92) and Schoonhoven 2002 (n=1229): 61% (56 to 66)	56% (51 to 61) and 74% (70 to 78) (2 studies) Very low **Largest studies:** Perneger 2002 (n=1190) and Schoonhoven 2002 (n=1229) as above	Not applicable
Follow up less than 1 week				
Median sensitivity at each threshold	**17 or less**: Bergstrom 1998 59% (No CI); R: 50-62% (4 studies) **18 or less**: Bergstrom 1998 75% (No CI); R: 60-88% (4 studies) **19 or less:** Bergstrom 1998 86.5% (No CI); R: 67-100% (4 studies)	**17 or more** (indirect - high risk - population): Serpa 2009 71% (29 to 96) (1 study, pressure ulcers=7) **20 or more** (indirect - high risk - population): Serpa 2009 85.7% (42 to 100) (1 study)	Not reported	Not reported
Corresponding specificity at each threshold	**17 or less** 80% (no CI); R: 76-85% (4 studies) **18 or less** 68% (no CI); R: 68-81% (4 studies) **19 or less** 62.5% (No CI); R: 40-73% (4 studies)	**17 or more** (indirect - high risk - population) 67% (56 to 77) (1 study, pressure ulcers = 7) **20 or more** (indirect - high risk - population) 41.0% (30 to 51) (1 study, pressure ulcers = 7)	Not reported	Not reported
Follow up more than 1 week				
Median sensitivity at each threshold	**18 or less**: Bergstrom 1998 80% (68 to 89); R: 46-100% (10 studies) Largest study: Goodridge 1998	**10 or more:** Wai Han 1997 87.5% (47 to 100); R: 82-90% (3 studies) Largest study: Anthony 2003	**14 or less** (highly heterogeneous) Stotts 1998: 16% (8 to 27) and 75% (35 to 97); R: 0-89 (4 studies)	Yes/no (ICU population) Salvadalena 1992 & VandenBosch 1996

	Braden	Waterlow	Norton	Clinical judgement
	(n=330) 50% (32 to 68) **19 or less**: Capobianco 1996 86% (57 to 98); R: 46-100% (5 studies) Largest study: Bergstrom 1998 (1) (n=306) 46% (27 to 67) **20 or less**: Braden 1994 93.2% (76 to 99); R: 65-100% (5 studies) Largest study: Bergstrom 1998 (1) (n=306) 65% (44 to 83)	(n=45,735) 82% (76 to 87) **15 or more: Anthony 2003** 48.8% (42 to 56); (1 study) Largest study: Anthony 2003 (n=45,735) as above **16 or more: Pang 1998 & Smith 1989** 95% (76 to 100) and 73% (54 to 88) (2 studies) Largest study: Pang 1998 (n=106), but Smith 1989 (n=101)	Largest study: Kwong 2005 (n=429) 89% (52 to 100) **15 or less: Schoonhoven 2002** 45.9% (37 to 55) (1 study) Largest study: Schoonhoven 2002 (n=1229) **16 or less: Pang 1998 & Smith 1989** 60% (41 to 77) and 81% (58 to 95) (2 studies) Largest study: Pang 1998 (n=106), but Smith 1989 (n=101)	50% (27 to 73) and 52% (33 to 71) (2 studies) Largest study: VandenBosch 1996 (n=102), but Salvadalena 1992 (n=99)
Corresponding specificity at each threshold	**18 or less** 73% (66 to 79); R: 14-100% (10 studies) Largest study: Goodridge 1998 (n=330) 52% (47 to 58) **19 or less** 78% (61 to 90); R: 43-78% (5 studies) Largest study: Bergstrom 1998 (1) (n=306) 69% (63 to 74) **20 or less** 43% (32 to 55); R: 32-67% (5 studies) Largest study: Bergstrom 1998 (1) (n=306) 55% (49 to 61)	**10 or more** 28% (22 to 35); R: 22-85% (3 studies) Largest study: Anthony 2003 (n=45,735) 85% (85 to 85) **15 or more** 94% (94 to 95); (1 study) Largest study: Anthony 2003 (n=45,735) as above **16 or more** 44% (33 to 55) and 38% (27 to 50) (2 studies) Largest study: Pang 1998 (n=106), but Smith 1989 (n=101)	**14 or less** 94% (91 to 97); and 67% (59 to 74)R: 61-94 (4 studies) Largest study: Kwong 2005 (n=429) 61% (56 to 66) **15 or less** 60.3% (57 to 63) (1 study) Largest study: Schoonhoven 2002 (n=1229) as above **16 or less** 31% (21 to 43) and 59% (48 to 69) (2 studies) Largest study: Pang 1998 (n=106), but Smith 1989 (n=101)	Yes/no (ICU population) 80% (69 to 88) and 59% (47 to 70) Largest study: VandenBosch 1996 (n=102), but Salvadalena 1992 (n=99)

7.1.4.3 Within-study comparisons

Two studies (Perneger 2002, Schoonhoven 2002) compared 2 or more of the 3 major tools reporting the AUC . Five studies compared 2 or more of the 3 major tools or clinical judgement in the same participants and gave sufficient information to calculate sensitivities and specificities (Pang 1998, Salvadalena 1992, Schoonhoven 2002, VandenBosch 1996, Waihan 1997).[156,170,177,211,219] The next table summarises the results for studies comparing different tools in the same study, using standard thresholds (see also Appendix O); the data are also shown in the forest plot and the ROC curve in Appendix O.

Table 11: Within study comparisons

	Braden	Waterlow	Norton	Clinical judgement
Area under the ROC curve				
Perneger 2002[158] (n=1190, events 170)	74% (95%CI 70 to 78)	Not studied	74% (95%CI 70 to 78)	Not applicable
Schoonhoven 2002 [176](n=1229, events 135)	55% (95%CI 49 to 60)	61% (95%CI 56 to 66)	56% (95%CI 51 to 61)	Not applicable
Sensitivity and specificity for standard thresholds (unless otherwise stated)				
Jalali 2005[97] (n=230, events 74)	18 or less Sensitivity 53% (95%CI 41 to 64) Specificity 62% (95%CI 51 to 73)	16 or less assumed Sensitivity 64% (95%CI 52 to 74) Specificity 83% (95%CI 76 to 88)	16 or less Sensitivity 49% (95%CI 57 to 61) Specificity 100% (95%CI 98 to 100)	
Pang 1998[156] (n=106, events 21)	18 or less Sensitivity 90% (95%CI 70 to 99) Specificity 62% (95%CI 51 to 73)	16 or less Sensitivity 95% (95%CI 76 to 100) Specificity 44% (95%CI 33 to 55)	16 or less Sensitivity 81% (95%CI 58 to 95) Specificity 59% (95%CI 48 to 69)	Not studied
Salvadelena 1992[170] (n=99, events 20)	17 or less Sensitivity 60% (95%CI 36 to 81) Specificity 54% (95%CI 43 to 66)	Not studied	Not studied	Yes/no Sensitivity 50% (95%CI 27 to 73) Specificity 80% (95%CI 69 to 88)
Schoonhoven 2002 [175] (n=1229, events 135)	18 or less Sensitivity 44% (95%CI 35 to 53) Specificity 68% (95%CI 65 to	10 or less Sensitivity 90% (95%CI 83 to 94) Specificity 22% (95%CI 20 to 25)	15 or less Sensitivity 46% (95%CI 37 to 55) Specificity 60% (95%CI 57 to 63)	Not studied

	Braden	Waterlow	Norton	Clinical judgement
	70)			
VandenBosch 1996[211] (n=103, events 29)	17 or less Sensitivity 59% (95%CI 39 to 76) Specificity 59% (95%CI 47 to 71)	Not studied	Not studied	Yes/no Sensitivity 52% (95%CI 33 to 71) Specificity 59% (95%CI 47 to 70)

7.1.5 Economic evidence (adults)

Published literature

No relevant economic evaluations of risk assessment were identified.

Five studies[124,153,202,225,226] were identified in which risk assessment was involved as part of a more complex prevention strategy, yet these studies were not considered useful in informing the cost effectiveness of risk assessment.

7.1.6 Clinical evidence (neonates, infants, children and young people)

One prospective cohort study was included in the review.[45] Evidence from this study is summarised in the clinical GRADE evidence profile below (Table 15). See also the study selection flow chart in Appendix C, forest plots in Appendix I, study evidence tables in Appendix G and exclusion list in Appendix J.

Table 12: Summary of studies included in the review

Study	Intervention	Population	Outcomes	Length of study
Curley 2003[44]	Braden Q score and skin assessment.	Children from 3 paediatric intensive care units.	Incidence of pressure ulcers.	Two weeks then once a week until discharge from paediatric intensive care unit.

Table 13: Clinical evidence profile: Braden Q scale

No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	AUC (confidence interval)	Acceptability of values*	Quality
Braden Q score- 16 or less cut-off – people in paediatric intensive care unit[45]								
1	Prospective cohort study	Serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	0.83 (0.76 to 0.91) Cut-off ≥16	Good discrimination	Low

** 90.0-100.0: perfect discrimination; 80.0-89.0: good discrimination; 70.0-79.0: fair discrimination; 60.0-69.0: poor discrimination;50.0-59.0: fail to discriminate*
(a) Study had high risks of bias (see quality table).
(b) Low events rates (less than 100).

7.1.6.1 Predictive ability

Table 14: Braden Q scale

Study	Cut-off score*	Sensitivity**	Specificity**
Follow-up less than 1 week – all stages – people in paediatric ICU			
Curley (2003)[45]	≤15	75.6	67.8
Curley (2003)[45]	≤16	88.4	58.1
Curley (2003)[45]	≤17	91.9	44.1

** The reported thresholds are these with the highest values for sensitivity and specificity*
*** Percentage*

7.1.7 Economic evidence (neonates, infants, children and young people)

No relevant economic evaluations of risk assessment were identified.

7.1.8 Evidence statements

7.1.8.1 Clinical (adults)

7.1.8.1.1 Braden scale

- Nine studies in 3500 people with 523 pressure ulcers, across all populations, had a median AUC value of 74.0% (range 55.0 to 88.0%) for the Braden scale, indicating a fair discriminating power, but much inconsistency.
- In a subgroup analysis, 5 studies in 3000 people with 405 pressure ulcers, across all populations, had a median AUC of 68.0% (range 55.0 to 81.0%), indicating a poor discriminating power and inconsistency. Four studies in the remaining 500 participants with 118 pressure ulcers, who were in intensive care, had a median AUC of 79.0% (range 71.0 to 88.0%), indicating a fair discriminating power (all evidence was of very low quality).
- Two studies (1 of the studies consisted of 3 independent samples) (across all populations) showed a median sensitivity of 59.0% (range 50-62.0%) and a corresponding specificity of 80% (range 76-85%) for the Braden scale based on a cut-off score 17 or less and a follow-up period of less than 1 week (low quality).
- Two studies (1 of the studies consisted of 3 independent samples) (across all populations) showed a median sensitivity of 75% (range 60-88%) and a corresponding specificity of 68% (range 68-81%) for the Braden scale based on a cut-off score of 18 or less and a follow-up period of less than 1 week (low quality).
- Two studies (1 of the studies consisted of 3 independent samples) (across all populations) showed a median sensitivity of 86.5% (range 67-100%) and a corresponding specificity of 62.5% (range 40-73%) for the Braden scale based on a cut-off score of 19 or less and a follow-up period point of less than 1 week (low quality).
- One study (ICU population) showed a sensitivity of 87.5% and a specificity of 64.1% for the Braden scale based on a cut-off score of 12 or less and a follow-up period point of 48 hours (very low quality).
- One study (ICU population) showed a sensitivity of 75.0% and a specificity of 82.1% for the Braden scale based on a cut-off score of 13 or less and a follow-up period point of less than 1 week (very low quality).
- One study (ICU population) showed a sensitivity of 76.9% and a specificity of 29.6% for the Braden scale based on a cut-off score of 16 or less and a follow-up period point of less than 1 week (low quality).
- Ten studies (some studies had multiple samples) (across all populations) showed a median sensitivity of 79.5 (range 46.2-100.0) and a corresponding specificity of 73.6% (range 14.0-100.0) for the Braden scale based on a cut-off score of 18 or less and a follow-up period point of more than 1 week (very low quality).
- Five studies (some studies had multiple samples) (across all populations) showed a median sensitivity of 86.3% (range 46-100.0%) and a corresponding specificity of 78% (range 42.9-77.8%) for the Braden scale based on a cut-off score of 19 or less and a follow-up period point for more than 1 week (low quality)
- Five studies (some studies had multiple samples) (across all populations) showed a median sensitivity of 93.2% (range 65-100.0%) and a corresponding specificity of 43% (range 31.6-66.7%)

for the Braden scale based on a cut-off score of 20 or less and a follow-up period point of more than 1 week (low quality).

- One study (across all populations) showed a sensitivity of 42.9% and a specificity of 63.4% for the Braden scale (grade 2 and above pressure ulcers) based on a cut-off score of 17 or less, a follow-up period point of more than 1 week (low quality).
- One study (across all populations) showed a sensitivity of 100.0% and a specificity of 34.1% for the Braden scale (pressure ulcers of grade 2 and above) based on a cut-off score of 18 or less, a follow-up period point of more than 1 week (low quality).
- One study (across all populations) showed a sensitivity of 100.0 and a specificity of 22.0 for the Braden scale (pressure ulcers of grade 2 and above) based on a cut-off score of 19 or less, a follow-up period point of more than 1 week (low quality).

7.1.8.1.2 Norton scale

- Two studies in 1190 and 1229 participants, with 135 and 170 pressure ulcers respectively, across all populations had AUCs of 56.0% and 74.0% for the Norton scale, indicating poor and fair discriminating power (very low quality).
- Four studies (across all populations) showed a median sensitivity of 45.7% (range 0.0-88.9) and a corresponding specificity of 80.6% (range 61.0-94.4) for the Norton scale based on a cut-off score of 14 or less and a follow-up period point of more than 1 week (very low quality).
- One study (across all populations) showed a sensitivity of 45.9% and a specificity of 60.3% for the Norton scale based on a cut-off score of 15 or less, a follow-up period point of more than 1 week (low quality).
- Two studies (across all populations) showed a mean sensitivity of 70.5% (range 60.0-81.0) and a corresponding specificity of 44.9% (range 31.0-58.8) for the Norton scale based on a cut-off score of 16 or less and a follow-up period point of more than 1 week (very low quality).

7.1.8.1.3 Waterlow scale

- Four studies in 47,760 participants with 466 pressure ulcers, across all populations, had a median AUC of 60.0% (range 54.0 to 90.0%) for the Waterlow scale, indicating a poor discriminating power.
  In a subgroup analysis, 3 of these studies in 47,000 participants with 345 pressure ulcers, in a general population, had a median AUC of 61.0% (range 54.0 to 90.0%), indicating a poor discriminating power. One study in 700 people with 121 pressure ulcers, in an intensive care population, had an AUC of 59.0%) indicating that the scale fails to discriminate (very low).
- One study (across all populations) showed a sensitivity of 71.4% and a specificity of 67.0% for the Waterlow scale based on a cut-off score of 17 or more, a follow-up period of 48 hours (very low quality).
- One study (across all populations) showed a sensitivity of 85.7% and a specificity of 41% for the Waterlow scale based on a cut-off score of 20 or more, a follow-up period of less than 1 week (very low quality).
- Three studies (across all populations) showed a median sensitivity of 87.5% (range 82.3-89.6%) and a corresponding specificity of 28.2% (range 22.4-85.2%) for the Waterlow scale based on a cut-off score of 10 or more and a follow-up period point 1 week or more (low quality)
- One study (across all populations) showed a sensitivity of 48.8% and a specificity of 94.4% for the Waterlow scale based on a cut-off score of 15 or more, a follow-up period of less than 1 week (;ow quality). Two studies (across all populations) showed a mean sensitivity of 84.3% (range 73.3-95.2%) and a corresponding specificity of 40.8% (range 38.0-43.5%) for the Waterlow scale based on a cut-off score of 16 or more and a follow-up period point 1 week or more (very low quality).

- One study (across all populations) showed a sensitivity of 80.9% and a specificity of 28.5% for the Waterlow scale (pressure ulcers of grade 2 and above) based on a cut-off score of 15 or less, a follow-up period point 1 week or more (low quality).

7.1.8.1.4 Cubbin-Jackson scale

- Two studies in 112 and 219 people with 35 and 40 pressure ulcers respectively, had a mean AUC of 87.0% (range 83.0 to 90.0%) for the Cubbin-Jackson scale (ICU population) indicating a good discriminating power (very low quality).
- One study (ICU population) showed a sensitivity of 88.6% and a specificity of 61.0% for the Cubbin-Jackson scale based on a cut-off score of 24 or less and a follow-up period point 1 week or more (low quality).
- One study (ICU population) showed a sensitivity of 95.0% and a specificity of 81.6% for the Cubbin-Jackson scale based on a cut-off score of 28 or less and a follow-up period point 1 week or more (low quality).

7.1.8.1.5 Clinical judgement

- Two small studies in 103 and 99 people with 29 and 20 pressure ulcers respectively, across all populations showed a mean sensitivity of 50.9% (range 50.0-51.7%) and a corresponding mean specificity of 68.9% (range 58.1-79.7%) for clinical judgement based on a follow-up period point 1 week or more (low quality).

7.1.8.1.6 Braden scale versus Norton scale versus Waterlow scale

- One study examined the Braden, Norton and Waterlow scales in the same sample of 1229 people with 135 pressure ulcers, in the general population. The scales had a similar discriminating power (AUC 55.0% versus 56.0% versus 61.0%) (very low quality).

7.1.8.1.7 Braden scale versus Norton scale versus Fragmment scale

- One study examined the Braden, Norton and Fragmment scale in the same sample of 1190 people with 170 pressure ulcers in the general population. The scales had a similar discriminating power (AUC 74.0% versus 74.0% versus 79.0%) (very low quality).

7.1.8.1.8 Braden scale versus Cubbin-Jackson scale versus Douglas scale

- One small study examined the Braden, Cubbin-Jackson and Douglas scale in the same sample of 112 people with 35 pressure ulcers in an ICU population. The Cubbin-Jackson scale may have had a higher discriminating power compared to the Braden and Douglas scales (AUC 83% versus 71% versus 79%) (very low quality).

7.1.8.1.9 Braden scale versus Cubbin-Jackson scale versus Song and Choi scale

- One study examined the Braden, Cubbin-Jackson and Song and Choi scale in the same sample of 219 people with 40 pressure ulcers in an ICU population. The discriminating power was similar in all scales (AUC 88 versus 91 versus 89%) (very low quality).

7.1.8.1.10 Braden scale versus modified Braden scale

- One study examined the Braden and modified Braden scale in the same sample of 197 people with 18 pressure ulcers, in a general population. The discriminating power of the 2 scales were similar (AUC 73 and 68%) (very low quality).

7.1.8.2 Economic (adults)

- No relevant economic evaluations were identified.

7.1.8.3 Clinical (neonates, infants, children and young people)

7.1.8.3.1 Braden-Q scale

- One study showed an AUC of 83.0% for the Braden-Q scale (paediatric ICU) indicating a good discriminating power (low quality).
- One study (paediatric ICU population) showed a sensitivity of 75.6% and a specificity of 67.8% for the Braden-Q scale based on a cut-off score of 15 or less and a follow-up period point 1 week or more (low quality).
- One study (paediatric ICU population) showed a sensitivity of 88.4% and a specificity of 58.1% for the Braden-Q scale based on a cut-off score of 16 or less and a follow-up period point 1 week or more (low quality).
- One study (paediatric ICU population) showed a sensitivity of 91.9% and a specificity of 44.1% for the Braden-Q scale based on a cut-off score of 17 or less and a follow-up period point 1 week or more (low quality).

7.1.8.4 Economic (neonates, infants, children and young people)

- No relevant economic evaluations were identified.

7.2 Recommendations and link to evidence

7.2.1 Adults

Recommendations	**1. Be aware that all patients are potentially at risk of developing a pressure ulcer.** **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- significant loss of sensation** **- a previous or current pressure ulcer** **- nutritional deficiency** **- the inability to reposition themselves** **- significant cognitive impairment.** **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.**
Relative values of different outcomes	The GDG's preferred approach was to look at the impact on pressure ulcer incidence, of applying a risk tool plus targeted preventative treatment. Additionally, the GDG was interested in the area under the Receiver Operator Characteristics (ROC) curve (AUC) as a means of comparing the predictive ability of the various tests, alongside sensitivity and specificity measures at optimum thresholds; for the latter, the GDG focused on optimising sensitivity. The GDG noted that there was much heterogeneity amongst studies and therefore placed importance on within-study comparisons. Only 2 patient outcomes were considered; pressure ulcer incidence and the incidence of pressure ulcers grade 2 and above.
Trade off between clinical benefits and harms	The GDG discussed the evidence relating to the use of risk assessment tools in the prevention of pressure ulcers. The GDG felt that there were potential benefits of using a risk assessment tool to identify an individual's risk of developing a pressure ulcer, and then using the results of risk assessment to ensure that targeted preventative treatment was provided. For example, the results of a risk assessment may help to inform the frequency or position of repositioning or whether a pressure redistributing device is to be used. The GDG were not confident in the direct RCT evidence comparing the Braden scale plus preventative treatment versus clinical judgement plus prevention. The quality of evidence according to GRADE rating was very low and potentially flawed in 1 study, and there was a risk of contamination in another. The evidence in the latter suggested that there was no clinically important difference between clinical judgement versus either the Waterlow scale or the Ramstadius scale. In Part 2 of the review, there was much variability across studies in the predictive ability of each tool, and there was probable confounding by the use of preventative

	treatments. The main tools of Braden, Waterlow and Norton gave only moderate areas under the curve, and low to moderate sensitivities at standard thresholds. However, there was much heterogeneity. The GDG took into consideration the ROC curve analysis at standard thresholds. This suggested that there was little difference between the 3 main tools and, tentatively indicated that all were better tests than clinical judgement (although there were only 2 studies reporting clinical judgement). However, there was much heterogeneity. The GDG highlighted that the need to use a formal risk assessment tool was further supported by anecdotal evidence that healthcare professions 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. Furthermore, the GDG thought that the formal process of using a risk assessment tool would ensure that pressure ulcer risk was documented and acknowledged as a significant issue. In addition, the process of undertaking pressure ulcer risk assessment was regarded as a positive patient contact point, and thus providing an opportunity to address other concerns that the individual may have. The GDG felt that all people are considered to be potentially at risk of developing a pressure ulcer. Therefore all healthcare professionals need to be aware of this potential risk. All patients in secondary care, or care homes where NHS care is provided, should receive a risk assessment on admission. The GDG developed a subsequent recommendation to encapsulate all other situations, including those who receive on-going care in other NHS care settings such as primary care, community care or emergency departments. The GDG felt that in these settings, individuals who have a risk factor should be considered for a risk assessment, as there were individuals within these settings who may not be considered potentially at risk of developing a pressure ulcer. The GDG emphasised that this also includes individuals who are waiting to receive care, for example in an outpatient department may also be at risk. This led the GDG to outline the examples of clinical risk factors which should lead to a risk assessment being carried out. It is by no means intended that this list is exhaustive and healthcare professionals should exercise clinical judgement at all times in identifying relevant risk factors. The GDG then considered whether to recommend a tool in preference to another. They noted that the evidence from the head-to-head comparisons within individual studies showed that there was not much difference between existing tools. Therefore, although the GDG felt that healthcare professionals should use a validated risk assessment tool, they did not feel that there was strong enough evidence to recommend the use of a specific risk assessment tool, and consequently provided 3 commonly used tools as examples; the Braden scale, the Waterlow score and the Norton risk- assessment scale.
Economic considerations	No economic evidence was identified. The GDG acknowledged that there is a resource implication of carrying out risk assessments, associated with the impact on staff time. However, risk assessment is current best practice and as such the GDG do not anticipate a substantial impact on resource use. Furthermore, it is anticipated that initial cost outlays associated with risk assessment will be offset by the ability to use remaining resources more efficiently, targeting more intensive prevention strategies towards those identified as being at risk. For example, as noted above, the results of a risk assessment are used to help inform the frequency or position of repositioning, or whether a particular pressure redistributing device is to be put in place. The GDG agreed the benefits of risk assessment are such that risk assessment most likely leads to cost

	savings, due to a reduction in pressure ulcer incidence and the resultant decrease in treatment costs.
Quality of evidence	The quality of the evidence was generally very low according to the GRADE criteria. In Part 1, the GDG noted the lack of baseline comparability for preventative treatment in the Saleh study, and were also aware of contamination issues in the Webster study, such that nursing staff could have improved their clinical judgement by learning from the risk tool. In Part 2, the quality of the evidence was again very low, with confounding by preventative treatment occurring in a number of studies, with inconsistency across studies in the preventative treatment given. The effect of giving preventative treatment was likely to have an impact on the statistical measures, and this was not taken into account in the authors' analyses, with two exceptions. In the prognostic review, there was considerable heterogeneity that could not be explained.
Other considerations	The GDG noted that the prognostic evidence suggested a possible need for training in the use of the risk assessment tools and most studies trained the assessors in the use of risk assessment tools. It was noted that assessment was sometimes done by the researchers.

Recommendations	**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).**
Relative values of different outcomes	The GDG considered the proportion of participants developing new pressure ulcers to be the critical outcome for decision making. Patient acceptability, rate of development of new pressure ulcers, time to develop new pressure ulcers, time in hospital and health related quality of life were considered important outcomes.
Trade off between clinical benefits and harms	This recommendation was developed using informal consensus of the GDG after reviewing the evidence for assessment of risk. The GDG acknowledged that risk status was not a constant and was likely to change during the course of care. As such, they wished to emphasise the need to provide a reassessment of pressure ulcer risk following any change in clinical status. The GDG highlighted that a change in status can occur at various times including; following surgery, worsening of an underlying condition or a change in mobility.
Economic considerations	See economic considerations for recommendations 1 and 2. It is important to note that risk status is not constant and must be assessed after any change in status to ensure the efficient use of resources through the application of appropriate preventative strategies.
Quality of evidence	No evidence was identified and informal consensus of the GDG was used to develop this recommendation.
Other considerations	There were no other considerations.

7.2.2 All ages

Recommendations	**5. 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**

	• **patient mobility and ability to reposition themselves** • **other comorbidities** • **patient preference.**
Relative values of different outcomes	The recommendation was based upon informal consensus of the GDG.
Trade off between clinical benefits and harms	The recommendation was based upon informal consensus of the GDG.
Economic considerations	The recommendation was based upon informal consensus of the GDG. The GDG acknowledged that there was a small resource implication associated with this recommendation, as it would take approximately 5-10 minutes of nursing time. The GDG agreed that this initial cost outlay would be offset by a reduction in pressure ulcers, leading to improvements in health related quality of life and substantial cost savings (the cost of a pressure ulcer has recently been estimated at £5672 per case).[50] Development of an individualised care plan is considered current best practice and is therefore unlikely to have significant resource implications.
Quality of evidence	The recommendation was based upon informal consensus of the GDG.
Other considerations	During the discussion of the recommendation the GDG noted that the care plan should be reviewed if the individual has a change in clinical status, for example, where their condition deteriorates. The care plan should also be shared with the individual and their carer as well as any other relevant healthcare professionals.

7.2.3 Neonates, infants, children and young people

Recommendations	**6. 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 (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.** **7. Use a scale validated for this population (for example, the Braden Q scale for children) to support clinical judgement.**
Relative values of different outcomes	The GDG's preferred approach was to look at the impact on pressure ulcer incidence, of using a risk assessment tool plus targeted preventative treatment. This would be the most direct evidence. Additionally, the GDG was interested in the area under the Receiver Operator Characteristics (ROC) curve (AUC) as a means of comparing the predictive ability of

	the various tests, alongside sensitivity and specificity measures at optimum thresholds; in the latter, the GDG's focus was on optimising sensitivity. Only 2 patient outcomes were considered; pressure ulcer incidence and the incidence of pressure ulcers of grade 2 and above.
Trade-off between clinical benefits and harms	One cohort study, which used the Braden Q scale and was conducted in an intensive care unit, was identified for risk assessment of neonates, infants and children (21 days to 8 years).The Braden-Q scale showed good discriminating power and high sensitivity for cut-off scores of less than 15, 16 or 17. The specificity was lower and reduced as the cut-off score increased. No other RCTs or cohort studies were identified for risk assessment of neonates, infants, children and young people therefore the GDG used the Delphi method as further evidence to develop the recommendation. The GDG developed a statement for inclusion in the Delphi consensus survey; 'Healthcare professionals should use a validated risk assessment tool, appropriate for age and setting, for the prevention of pressure ulcers in neonates, infants, children and young people'. The statement was agreed in Round 1 of the Delphi consensus survey. Further detail on the Delphi consensus survey can be found in Appendix N. Round 1 of the Delphi consensus survey also included a statement that 'Healthcare professionals should consider using a non-validated risk assessment or scoring tool to promote the awareness of risk factors in the prevention of pressure ulcers in neonates, infants, children and young people'. This statement was not accepted during Round 1 of the survey, with qualitative responses highlighting that the use of non-validated tools was inappropriate given the availability of validated ones. The GDG discussed these results and agreed with comments received, therefore the statement was removed for Round 2 of the survey. The GDG considered the accepted statement and the qualitative responses received in developing the subsequent recommendation. The GDG agreed that the likely benefit of conducting an assessment of risk in these populations outweighed any possible harms in terms of falsely identifying an individual as being of high risk and providing unnecessary preventative treatment. The GDG also recognised that recommending the use of a formal risk assessment tool would help to minimise the differences in the experience of clinical staff using judgement to identify those at high risk. However, qualitative responses gathered by the Delphi consensus survey suggested that it was important to highlight the need to use clinical judgement in combination with any risk assessment tool. The GDG agreed that this was important and this was reflected in the recommendation developed. The GDG discussed the availability of risk assessment tools specifically designed for a population of neonates, infants, children and young people. Some Delphi consensus panel members stressed there was a lack of validated tools available for use in these populations, whilst others identified the Glamorgan scale as an available tool to risk assess individuals in this group. The GDG discussed whether a specific risk assessment tool should be recommended and agreed that, it was not possible to recommend a specific tool and that further risk assessment tools in this population may be available in the future. The GDG did however agree with qualitative responses gathered during Round 1 of the Delphi consensus survey that it was important that any risk assessment tool used should be validated.

	Following discussion of the responses from the Delphi consensus, the GDG expressed concern that neonates, infants, children and young people were also at risk of developing a pressure ulcer in a range of settings where NHS care is provided. The GDG therefore identified that a recommendation was needed to encapsulate the settings in which a risk assessment should be conducted. The GDG felt that this shold be in line with the recommendations developed for adults and that all neonates, infants, children and young people being admitted to secondary and tertiary care should receive a risk assessment. The GDG also felt that those receiving care in other situations, including those who receive on-going care in other NHS care settings such as primary care, community care or emergency departments. The GDG felt that in these settings, neonates, infants, children and young people who have a risk factor should be considered for a risk assessment, as there were individuals within these settings who may not be considered potentially at risk of developing a pressure ulcer. The GDG emphasised that neonates, infants, children and young people who are waiting to receive care, for example in an outpatient department may also be at risk. This led the GDG to outline the examples of clinical risk factors which should lead to a risk assessment being carried out. It is by no means intended that this list is exhaustive and healthcare professionals should exercise clinical judgement at all times in identifying relevant risk factors.
Economic considerations	The GDG acknowledged that there is a resource implication associated with carrying out risk assessments, associated with the impact on staff time. However, risk assessment is current best practice and as such the GDG do not anticipate a great impact on resource use. Furthermore, it is anticipated that small initial cost outlays associated with risk assessment are offset by the ability to use remaining resources more efficiently, targeting more intensive prevention strategies towards those deemed to be at risk. For example, the results of a risk assessment can be used to help to inform the frequency or position of repositioning, or whether a particular pressure redistributing device is needed. The GDG agreed the benefits of risk assessment are such that risk assessment most likely leads to cost savings, due to a reduction in pressure ulcer incidence and the resultant decrease in treatment costs.
Quality of evidence	One cohort study was identified for neonates, infants and children in an intensive care unit. This study had some limitations and no other studies were identified for neonates, infants, children or young people. Formal consensus using a modified Delphi was therefore used to develop the recommendation. One statement was included in Round 1 of the survey which was used to inform the recommendation; ‘Healthcare professionals should use a validated risk assessment tool, appropriate for age and setting, for the prevention of pressure ulcers in neonates, infants, children and young people’ which reached 91% agreement. Further details can be found in Appendix N.
Other considerations	There were no further considerations.

8 Skin assessment

8.1 Introduction

The skin has many important functions; including protection from harmful substances and microbes, prevention of loss of body water, and temperature control. It is therefore essential to maintain the health and integrity of the skin. Healthy adults are usually able to assess and care for their own skin, however, at extremes of age and during periods of illness skin assessment and care may need to be carried out by carers or healthcare professionals. If skin assessment is to be undertaken, the individual should be informed of the reasons and procedures so that they can consent and participate where able. Skin assessment requires moving the individual in order to examine the skin and therefore healthcare providers should use appropriate moving and handling techniques and equipment to prevent harm to themselves or the individual. It is also important that skin assessment is carried out in the right environment where there is good (preferably natural) lighting to observe the colour and texture of the skin and where a person's privacy, dignity and warmth can be respected (see NICE clinical guideline 138 'Patient experience').

The assessment for potential tissue damage includes an observation of the skin for changes in colour compared with the surrounding skin or in comparison to the skin on the contralateral side of the body. It should be noted that in some cases deep tissue injury can occur before any changes on the surface of the skin are discernible; grade 3 and 4 pressure ulcers may therefore develop without prior superficial skin damage.

8.2 Review question: What is the clinical and cost effectiveness of skin assessment methods in the prevention of pressure ulcers?

For full details see review protocol in Appendix C.

This review focuses on the clinical effectiveness of skin assessment as part of a larger number of interventions for pressure ulcer prevention. The prognostic ability of skin assessment tools is reported separately.

8.2.1 Clinical evidence (adults)

One randomised trial by Vanderwee (2007) was included in this review.[215] Evidence from this study is summarised in the clinical GRADE evidence profile below (Table 15). See also the study selection flow chart in Appendix D, forest plots in Appendix I, study evidence tables in Appendix G and exclusion list in Appendix J.

8.2.1.1 Summary of included studies

Study	Intervention/comparison	Population	Outcomes	Comments
Vanderwee 2007[215]	• Daily skin assessment with transparent disk. Preventative measures were started only when non-blanchable erythema (NBE) appeared and were discontinued when NBE disappeared. • Braden score and daily skin assessment with transparent disk. Preventative measures were started if the Braden score was less than 17 at initial assessment or after 3 days or if NBE appeared. • People assessed to be at high risk received preventative measures according to the same pressure redistribution protocol. • Participants were randomised to either the Polyethylene–urethane Mattress (PUM) or to the Alternating pressure air mattress (APAM). On the former mattress, participants were turned every 4 hours, following Defloor et al. 2005. On the latter mattress, no standardised position changes were carried out. • People not assessed to be at high risk received standard measures as normally used in the ward they were on.	People with an expected hospitalisation of at least 3 days admitted between May 2000 and March 2002 in 14 surgery, internal medicine and geriatric wards of 6 Belgian hospitals.	• Incidence of pressure ulcers (grade 2-4) per 1000 days (95% CI) • Time (days) to development of pressure ulcers (grade 2-4) • Resource use: number of participants receiving preventative measures.	The study was carried out between May 2000 and March 2002. Each nursing unit took part in the study for the duration of 5 months.

Table 15: Clinical evidence profile: skin assessment with transparent disk plus targeted preventative measures versus Braden scale then skin assessment with transparent disk plus targeted preventative measures

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Skin assessment	Braden + skin assessment	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers (grade 2-4)[215]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	Serious imprecision[b]	None	56/826 (6.8%)	53/791 (6.7%)	RR 1.01 (0.7 to 1.45)	1 more per 1000 (from 20 fewer to 30 more)	Low	Critical
Time to event (pressure ulcer) (days from start of prevention)[215]												
1	Randomised trial	Very serious[a,c]	No serious inconsistency	No serious indirectness	Not possible to assess	None	Median (range) 4 (2-5)	8 (4-16)	--	Log rank test 6.67, df 1, p 0.01	Low	Important
Number of participants receiving preventative measures[215]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	No serious imprecision	None	128/826 (15.5%)	251/791 (31.7%)	RR 0.49 (0.40 to 0.59)	162 fewer per 1000 (from 130 fewer to 190 fewer)	Moderate	Additional
Number of participants with false negative results[215]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	No serious imprecision	None	30/826	10/791	RR 2.87 (1.41 to 5.84)	24 more per 1000 (from 5 more to 61 more)	Moderate	Additional

(a) No blinding was reported by the authors and there was only partial concealment of allocation sequence.

(b) The confidence interval crosses both MIDs for risk ratio, but not for absolute risk reduction.

(c) There were incomplete data (outcome reporting bias).

The study also allowed calculation of the sensitivity and specificity: the details informing the 2 x 2 table are given in the evidence table and the forest plot is given in Appendix O. Sensitivity and specificity results are as follows:

- Group 1 (NBE plus targeted preventative treatment): sensitivity 46% (95%CI 33 to 60); specificity 87% (95%CI 84 to 89)
- Group 2 (Braden then NBE plus targeted preventative treatment): sensitivity 81% (95%CI 68 to 91); specificity 72% (95%CI 68 to 75).

In this context, sensitivity and specificity are likely to be confounded by preventative treatment – it is unclear if a high value of sensitivity can be attributed to the relative lack of success of the preventative treatment or the success of the risk assessment method. Therefore the false negative rate for the 2 test-and-treat interventions was considered and this is reported in the GRADE table above.

The evidence showed that, of the 251 assessed to be at-risk in the control group (Braden then NBE), 219 people were identified on the basis of having a Braden score less than 17and 32 of 572 (6%) people with a Braden score above 17 were identified using skin assessment. The study does not compare using the Braden score head-to-head with skin assessment.

8.2.2 Economic evidence (adults)

Published literature

No relevant economic evaluations of skin assessment techniques were identified.

One economic evaluation[13] was identified which included use of skin assessment as part of a more complex skin care protocol, but this was not considered useful in informing the cost effectiveness of skin assessment.

8.2.3 Clinical evidence (neonates, infants, children and young people)

No RCTs or cohort studies were identified. Recommendations were developed using a modified Delphi consensus technique. Further details can be found in Appendix N.

8.2.4 Economic evidence (neonates, infants, children and young people)

No relevant economic evidence was identified.

8.2.5 Evidence statements

8.2.5.1 Clinical (adults)

- One study (n=1,617) showed that there is no clinically important difference in the incidence of pressure ulcers (grade 2-4) between skin assessment of non-blanchable erythema with transparent disk (NBE) plus targeted preventative measures versus the Braden scale then skin assessment with transparent disk plus targeted preventative measures (low quality).
- One study (n=1,617) showed that time to development of pressure ulcers (grade 2-4) was significantly shorter for skin assessment with transparent disk (NBE) than for skin assessment with transparent disk combined with the Braden scale (control) (low quality).
- One study (n=1,617) showed that there were many fewer preventative treatments initiated in the participants assessed with skin assessment compared with the Braden scale then skin assessment. However, there were slightly more participants missed using the NBE approach compared with

the combined approach who later had pressure ulcers; overall the proportion of missed participants was low (4% and 1%) (moderate quality)

8.2.5.2 Economic (adults)

- No relevant economic evaluations were identified.

8.2.5.3 Clinical (neonates, infants, children and young people)

- No evidence was identified.

8.2.5.4 Economic (neonates, infants, children and young people)

- No relevant economic evaluations were identified.

8.3 Review question: What is the predictive ability of skin assessment tools for pressure ulcer development?

For full details see review protocol in Appendix C.

8.4 Part 2

The second approach is applied in this review, but there are confounding factors in the prognostic review due to preventative treatment.

8.4.1 Clinical evidence (adults)

Five studies were included in the review.[36,107,144,146,213]Odds ratios for the predictive effect of different skin assessment factors on pressure ulcer incidence are reported, with emphasis on those calculated from multivariable regression analyses. Sensitivity and specificity were calculated using the raw data as presented in the individual studies. The evidence is summarised in the clinical GRADE evidence profile below (Table 3). See also the study selection flow chart in Appendix D, forest plots in Appendix O, study evidence tables and the quality assessment table in Appendix G and O, and the exclusion list in Appendix J. Evidence was also considered from a further study (Compton 2008),[36] that also conducted multivariable analysis of different skin assessment features, but by nurse assessment rather than using skin assessment tools.

If preventative measures are used as a consequence of skin assessment findings, the probability that an individual will develop a pressure ulcer at the start of the study will not remain constant through the study. The use of effective targeted prevention will alter the assessment of predictive ability. The results should therefore be considered with caution where preventative treatment was given, but not taken into account in the analysis. The studies varied according to their use of preventative measures:

- Two did not report any preventative treatment (Compton 2008, Newman 1981).[36,144]
- One gave preventative treatment to all participants (Nixon 2007).[146]
- One gave preventative treatment to people at high risk following skin assessment (Vanderwee 2007).[213]
- One was unclear about the numbers receiving preventative treatment and whether this was dependent on skin assessment (Konishi 2008).[107]

None of the studies took preventative treatment into account in the results.

Summary of included studies

Study	Population	Skin assessment tool	Outcomes
Konishi 2008	People in hospital	Presence of blanchable erythema assessed by finger test.	• Occurrence of pressure ulcer development according to the National Pressure Ulcer Advisory Panel classification. Length of follow up not reported. Incidence 8 (3%) pressure ulcers (all grades) and grade 4 (2%) grade 2-4.
Newman 1981	People in hospital	Thermography: presence of thermal anomaly (an area of the skin at least 1°C warmer than the surrounding skin).	• Development of skin breakdown in the buttock region within 10 days of admission was reported by the nursing staff and photographed. Redness alone, however marked or persistent, was not categorized as a pressure sore. Follow up not reported. Incidence of pressure ulcers: 6 (7%).
Nixon 2006	People who have had surgery	Presence of blanchable or non-blanchable erythema, method not stated, assumed finger.	• Occurrence pressure ulcer development (grade 2-4) according the classification scale adapted from international classification scales (AHCPR (Agency for Health Care Policy and Research) 1992; EPUAP, 1999). Follow up not reported. Incidence of pressure ulcers: 15 (15%)
Vanderwee 2007	People in surgical, internal medicine and geriatric wards of 6 Belgian hospitals	Daily skin assessment with transparent disk, with and without Braden scale risk assessment.	• Incidence of pressure ulcers: 56 (7%). • Follow up 5 months.
Compton 2008	People in ICU	Subjective nursing skin assessment on admission.	• Occurrence of pressure ulcers development (grade 2-4) according to the European Pressure Ulcer Advisory Panel classification system in the course of ICU treatment. Length of follow up not reported. Incidence of pressure ulcers: 121 (17%).

Table 16: Clinical evidence profile: skin assessment tools for prediction of pressure ulcers

Blanchable erythema by finger test

The Nixon 2006 study assessed blanchable erythema for the worst grade observed on any ulcer site (and some people in the study had non-blanchable erythema), but the Konishi 2008 study only assessed blanchable erythema sites.

Quality assessment							No of patients with outcome		Effect		Quality
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**Predictor**	**Lack of predictor**	**Relative (95% CI)**	**Absolute (95%CI)**	
Predictor: blanchable erythema by finger test. outcome: pressure ulcer (all grades) development (follow-up not stated)[107]											
1	Prospective cohort	Very serious[a]	No serious inconsistency	No serious indirectness	Serious imprecision[b]	Prevention treatment unclear	Blanchable erythema: 6/62	No erythema: 2/187	OR (unadjusted): 9.9 (1.94 to 50.49)	81 more per 1000 (from 9 more to 328 more) Non-predictor risk 1% (0 to 4)	Very low
1	Prospective cohort	Very serious[a]	No serious inconsistency	No serious indirectness	Serious imprecision[b]		Blanchable erythema: 6/62	No erythema: 2/187	--	Sensitivity: 75% (35 to 97) Specificity: 77% (71 to 82)	Very low
Predictor: blanchable erythema by the finger test. outcome: pressure ulcer (grade 2-4) development (follow-up not stated)[107,146]											
2	Prospective cohort	Very serious[a]	Serious inconsistency[c]	No serious indirectness	No serious imprecision	None	Blanchable erythema 3/62 and 3/58	No erythema 1/187 and 1/7	OR (unadjusted): 9.4 (0.94 to 94.58) and 0.33 (0.03 to 3.27)	77 more per 1000 (from 1 fewer to 479 more) and 89 fewer per 1000 (from 135 fewer to 207 more) Non-predictor risk: 1% (0 to 3) and 14% (0 to 58%)	Very low
2	Prospective cohort	Very serious[a]	No serious inconsistency for sensitivity	No serious indirectness	Very serious imprecision[d]	Based on sensitivity likely confounded	Blanchable erythema 3/62 and	No erythema 1/187 and 1/7	--	Sensitivity: 75% (19 to 99): same for both Specificity: 76% (70 to	Very low

Quality assessment							No of patients with outcome		Effect		Quality
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Predictor	Lack of predictor	Relative (95% CI)	Absolute (95%CI)	
						by preventive treatment	3/58			81) and 10% (4 to 20)	

(a) No multivariable analysis was conducted, the same nurses conducted skin assessment and pressure ulcer assessment. There were fewer than 10 pressure ulcers.
(b) The confidence interval was consistent with more than 1 decision.
(c) The point estimates were consistent with different decisions.
(d) The confidence interval for sensitivity consistent with more than 1 decision.

Table 17: Non-blanchable erythema by finger test or transparent disc

Quality assessment							No of patients		Effect		Quality
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Predictor	Lack of predictor	Relative (95% CI)	Absolute	
Predictor: non-blanchable erythema by finger test[146] and by transparent disc[213]:outcome: pressure ulcer (all grades) development (follow-up not stated)											
2	Prospective cohort	Very serious [a,b]	No serious inconsistency	No serious indirectness	No serious imprecision	Likely confounded by preventive treatment	(1) Grade ≥1b 11/32 (2) non-blanchable 26/128	Grade 1a and 0: 4/65 (2) 30/698	OR (multivariable) 7.02 (1.67 to 29.51) and OR (unadjusted) 5.68 (3.23 to 9.99)	249 more per 1000 (from 36 more to 593 more) and 151 more per 1000 (from 79 more to 254 more) Non-predictor risk: 6% (2 to 15) and 4% (3 to 6)	Very low
2	Prospective cohort	Very serious [a,b]	Serious inconsistency[d]	No serious indirectness	Serious imprecision[c]	Based on sensitivity Likely confounded by preventive treatment	(1) Grade ≥1b 11/32 (2) non-blanchable 26/128	Grade 1a and 0: 4/65 (2) 30/698	--	Sensitivity: 73% (45 to 92) and 46% (33 to 60) Specificity: 74% (64 to 83) and 87% (84 to 89)	Very low
Predictor: Braden score then non-blanchable erythema by transparent disc. Outcome pressure ulcer (grade 2-4) development (follow-up not stated) Vanderwee 2007											

Quality assessment							No of patients		Effect		Quality
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Predictor	Lack of predictor	Relative (95% CI)	Absolute	
1	Prospective cohort	Very serious[b]	No serious inconsistency	No serious indirectness	No serious imprecision	Likely confounded by preventive treatment	43/251	10/540	OR (unadjusted): 10.96 (5.41 to 22.21)	163 more per 1000 (from 79 more to 254 more) Non-predictor risk: 2% (1 to 3)	Very low
1	Prospective cohort	Serious[b]	No serious inconsistency	No serious indirectness	No serious imprecision	Based on sensitivity Likely confounded by preventive treatment	43/251	10/540	--	Sensitivity: 81% (68 to 91) Specificity: 72% (68 to 75)	Very low

(a) The study used an unrepresentative or selected population, same nurses conducted skin assessment and pressure ulcer assessment. Ratio of events/covariates low (=2).
(b) The same nurses measured skin assessment and pressure ulcers; not multivariable analysis.
(c) The confidence interval for sensitivity consistent with more than 1 decision.
(d) Inconsistency in sensitivity.

Table 18: Thermography

Quality assessment							No of patients		Effect		Quality
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Predictor	Lack of predictor	Relative (95% CI)	Absolute	
Predictor: thermography (presence of thermal anomaly – an area of skin at least 1°C warmer than the surrounding skin):outcome: pressure ulcer (grade 2-4) development (follow-up not stated)[144]											
1	Prospective cohort	Very serious[a]	No serious inconsistency	No serious indirectness	Serious imprecision[b]	None	6/28	0/63	OR (unadjusted): 36.7 (1.41 to 952.24)	210 more per 1000 (from 60 more to 370 more Non-predictor risk: 0% (0 to 6)	Very low
1	Prospective cohort	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious imprecision[b]	Based on sensitivity	6/28	0/63	--	Sensitivity: 100% (54 to 100)	Very low

Quality assessment							No of patients		Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Predictor	Lack of predictor	Relative (95% CI)	Absolute	Quality
										Specificity: 74% (63 to 83)	

(a) The study used an unrepresentative/selected population, pressure ulcer assessment details not reported, not multivariable analysis
(b) The confidence interval consistent with more than 1 decision

8.4.2 Economic evidence (adults)

No relevant economic evaluations were identified.

8.4.3 Clinical evidence (neonates, infants, children and young people)

No RCTs or cohort studies were identified. Recommendations were developed using a modified Delphi consensus technique. Further details can be found in Appendix N.

8.4.4 Economic evidence (neonates, infants, children and young people)

No relevant economic evaluations were identified.

8.4.5 Evidence statements

8.4.5.1 Clinical (adults)

- One study in 249 people in hospital with 8 pressure ulcers, gave an (unadjusted) odds ratio of 9.9 (95%CI 1.9 to 50.5) for the predictor blanchable erythema assessed by the finger test for all grades of pressure ulcer according to the European Pressure Ulcer Advisory Panel classification system. The sensitivity and specificity were 75% (95%CI 35 to 97) and 77% (95%CI 71 to 82) (very low quality).
- Two studies in 314 people with 8 pressure ulcers (grade 2-4) showed gross heterogeneity in the unadjusted odds ratios and in the specificity for the predictor blanchable erythema by the finger test; the sensitivity was 75% (19 to 99) for each study. (very low quality).
- One study in 97 surgical inpatients with 15 pressure ulcers, showed, in multivariable analysis, that the subjective nursing assessment of non-blanchable erythema was a significant predictor of pressure ulcers (grade 2-4) according to the European Pressure Ulcer Advisory Panel classification system (OR 7.02 (95%CI 1.67 to 29.5)). The sensitivity was 73% (95%CI 45 to 92) and the specificity was 74% (95%CI 64 to 83) (very low quality). A second large study in 826 people in hospital with 56 pressure ulcers, gave an unadjusted odds ratio of 5.68 (95%CI 3.23 to 9.99) and a sensitivity of 46% (95%CI 33 to 60) and a specificity of 87% (95%CI 84 to 89); the results of both studies were possibly confounded by preventative treatment. (very low quality).
- One study in 91 people in hospital with 6 pressure ulcers, who were not given preventative treatment, gave an unadjusted odds ratio of 36.7 (95%CI 1.41 to 952.2), a sensitivity of 100% (95%CI 54 to 100), and a specificity of 74% (95%CI 63 to 83) for thermography (presence of thermal anomaly – an area of the skin at least 1°C warmer than the surrounding skin) as a predictor for the development of pressure ulcers grade 2-4. (very low quality).

8.4.5.2 Economic (adults)

- No relevant economic evaluations were identified.

8.4.5.3 Clinical (neonates, infants, children and young people)

- No evidence was identified.

8.4.5.4 Economic (neonates, infants, children and young people)

- No relevant economic evaluations were identified.

8.5 Recommendations and link to evidence

8.5.1 Adults

Recommendations	8. **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[c]** • **variations in heat, firmness and moisture (for example, because of incontinence, oedema, dry or inflamed skin).**
Relative values of different outcomes	The GDG was interested in any predictors for pressure ulcer development and their identification through clinical assessment by a healthcare professional. Evidence from multivariable analysis of risk was considered the most important.
Trade-off between clinical benefits and harms	The evidence from the prognostic review on skin assessment suggested the components of skin assessment (for example, measuring skin temperature and assessing for the presence of non-blanchable erythema) may predict the development of pressure ulcers. This evidence was supported by the RCT evidence on clinical effectiveness; skin assessment plus targeted preventative treatment. The GDG felt that people who are at an increased risk of pressure ulcers following a risk assessment (see recommendation 1-3) would benefit from an assessment of the skin to identify the presence of the components above. Therefore, the GDG developed a recommendation to highlight this. The assessment will contribute to the development of an individualised care plan to prevent pressure ulcers (see recommendation 5). The GDG did not feel that everyone would benefit significantly from clinical assessment of the skin and that this should be limited to those who have been identified as high risk following a risk assessment. The GDG also took into consideration the evidence from 1 small study (Compton 2008) about the predictive ability of skin assessment factors, and drew on their experience of skin prognostic factors. The evidence was not reviewed fully as this question was concerned only with skin assessment tools rather than skin assessment features. However, the GDG highlighted that the specific factors that might form part of a clinical assessment included the presence of erythema, discolouration (particularly in those with darker skin), warmth, oedema or induration, that is, features that could be identified by simple direct observation and palpation of the at risk skin.
Economic considerations	No economic evidence was identified. The GDG acknowledged that there is a resource implication associated with carrying out skin assessments, as it would take approximately 5 minutes of nurse time (at a cost of approximately £3[47]). However, skin assessment is used to predict the development of pressure ulcers, and therefore is a potentially useful preventative tool. The cost of a pressure ulcer has recently been estimated at £5,672 per case,[50] and thus the small resource use associated with skin assessment is highly likely to be offset by costs savings as more pressure ulcers are prevented. Furthermore, skin assessment is considered to be current best practice, and as such this

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

	recommendation is unlikely to lead to substantial increases in resource requirements. The GDG agreed that the use of skin assessment is highly likely to be cost-neutral, or even cost-saving, and will improve health related quality of life.
Quality of evidence	The evidence in the prognostic studies was of very low quality according to GRADE. For the Compton 2008 study, there were very few pressure ulcers, and multivariable analysis was conducted, but there were too few events per covariate for reliability. The results were confounded, in some studies (but not Compton 2008), by the use of preventative treatments, which were not taken into account in the analysis. The evidence in the RCT was rated as low quality.
Other considerations	There were no other considerations.

Recommendations	**9. Use finger palpation or diascopy to determine whether erythema or discolouration (identified by skin assessment) is blanchable.** **10. 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.**
Relative values of different outcomes	The GDG placed the most importance on the randomised evidence for skin assessment in conjunction with targeted preventative treatment and its impact on patient outcomes. They also considered the predictive ability of skin assessment in discriminating patients at risk, particularly taking into account absolute risk differences from multivariable analyses.
Trade off between clinical benefits and harms	Evidence from 1 RCT compared the combination of risk assessment using the Braden scale (with a cut-off of 17) plus NBE versus NBE testing alone. People at high risk according to each of these 2 methods were given preventative treatment. There was no clinically important difference between interventions in terms of the incidence of pressure ulcers. However, there was a large difference in the number of preventative treatments given, with more treatments being given to the combined assessment approach than to NBE alone. The sensitivity was larger for the NBE plus Braden scale intervention than the NBE alone. The absolute risk of pressure ulcer development in people defined by each strategy to be at low risk was larger for NBE alone, but the GDG did not consider this to be an important difference. The study reported that 6% of people with normal scores on the Braden scale were identified as at risk using NBE. The evidence from Part 1 of the review suggested that NBE was an independent predictor of pressure ulcers; there was also some limited evidence on the use of thermography to predict pressure ulcer development, although the evidence included few events. Although no evidence was identified comparing risk assessment versus skin assessment and therefore, it was not possible to ascertain the value of skin assessment in addition to risk assessment, the GDG felt that the assessment of skin was important for reasons of patient care. The GDG felt that, where erythema or discoloration of the skin was identified, evidence supported the use of diascopy to determine whether the erythema was blanchable or non-blanchable, in addition to a formal risk assessment (see recommendation 1). However, the GDG noted that there were some situations in which transparent plastic discs were not available or where the use of these tools posed a specific infection risk. As such, the GDG highlighted that the use of finger palpation to identify whether erythema was blanching or non-blanching would be appropriate and preferable to any delay in obtaining specific tools. The GDG used informal consensus to agree that this reassessment should take place

	at least every 2 hours, until this has been resolved.
Economic considerations	No economic evidence was identified. Once erythema or discoloration has developed, it is vital to determine whether it is blanchable or non- blanchable, as non- blanchable erythema is indicative of pressure damage. The primary concern here is to prevent any pressure damage from worsening, and therefore the use of finger palpation or diascopy is considered essential. The GDG did not anticipate that using finger palpation or diascopy would substantially increase resource use over that required for the clinical skin assessment. The GDG agreed that where non-blanchable erythema is identified, regular skin assessments are required in order to prevent pressure ulcers developing through application of appropriate preventative strategies. The prevention of pressure ulcers at this stage would lead to improvements in quality of life and substantial cost savings.
Quality of evidence	The evidence in the RCT was rated as low quality. The evidence in the prognostic studies was of very low quality: there were very few pressure ulcers, multivariable analysis was not always conducted and the results were confounded, in some studies, by the use of preventative treatments, which were not taken into account in the analysis.
Other considerations	The GDG felt that it was important to highlight that people who had non-blanchable erythema would also be more likely to develop a pressure ulcer on that site, as well as other sites. Therefore, the GDG felt that people who have been identified as having non-blanchable erythema should be offered preventative treatment and reassessed on a regular basis to identify any changes in skin condition. The GDG noted that following reassessment, the individualised care plan (including the use of preventative measures) should be adapted to account for any change in risk status.

8.5.2 Neonates, infants, children and young people

Recommendations	**11. 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.**
Relative values of different outcomes	The GDG was interested in any predictors for pressure ulcer development and their identification through clinical assessment by a healthcare professional. Evidence from multivariable analysis of risk was considered the most important.
Trade-off between clinical benefits and harms	The GDG used 3 statements from the Delphi consensus survey to inform the recommendation. The statements were 'Healthcare professionals should measure skin temperature for the assessment of skin in neonates, infants, children and young people considered to be at risk of developing pressure ulcers', 'Healthcare professionals should use diascopy for the assessment of skin in neonates, infants, children and young people considered to be at risk of developing pressure ulcers' and 'Health professionals should inspect the occipital area skin when carrying out skin inspection in neonates, infants, children and young people at risk of developing pressure ulcers'. Further detail on the Delphi consensus survey can be found in Appendix N.

	Two statements (on skin temperature and diascopy) were included in Round 1 of the survey but were not accepted by the Delphi consensus panel at the necessary level of agreement. For the statement on diascopy, comments from the panel during Round 1 suggested some lack of understanding relating to the term 'diascopy'. Other comments highlighted a possible infection risk of using plastic discs to carry out diascopy. The GDG discussed the statement for inclusion in Round 2 and agreed that the term diascopy should be removed to ensure that people are clear that the purpose of the assessment is to identify the presence of non-blanchable erythema and that the method of identifying this may vary between individuals. The GDG also agreed with comments from the Delphi consensus panel that any assessment of blanching should be carried out as part of a wider comprehensive skin assessment and the statement was amended further to recognise this. For the statement on skin temperature, comments from the Delphi consensus panel suggested that an assessment of skin temperature as part of a general assessment may be helpful but formal measurement was not necessary. A statement on comprehensive skin assessment was therefore developed for inclusion in Round 2, highlighting the need to account for both blanching and skin temperature as part of the assessment. During Round 2 of the Delphi consensus survey, the GDG identified from qualitative comments gathered in response to some statements, that there were specific sites in which neonates, infants, children and young people were at significant risk of developing a pressure ulcer, most importantly, the occipital region. The group felt that it was important to include statements relating to this in Round 2 of the survey and importantly, to develop a statement highlighting the need to inspect this area in the at risk population. The statement 'Health professionals should inspect the occipital area skin when carrying out skin inspection in neonates, infants, children and young people at risk of developing pressure ulcers' was therefore developed by the GDG and included in Round 2, where it reached an agreement of 96%. The GDG discussed the accepted statements on skin temperature, assessment of blanching, and the statement developed to address the increased incidence of occipital pressure ulcers. They identified that assessment of these factors was likely to be beneficial as part of a wider skin assessment to predict pressure ulcer development and was likely to result in a decrease in the incidence of pressure ulcers. The group therefore agreed to develop a recommendation on skin assessment, as it was likely that any benefits of conducting a skin assessment in those at risk of developing a pressure ulcer outweighed any potential harms in terms of falsely predicting pressure ulcer development, and therefore providing unnecessary preventative treatment.
Economic considerations	The GDG discussed the resource implications of carrying out skin assessments; this would likely take approximately 5 minutes of nurse time (at a cost of approximately £3[47]). Skin assessment is used to predict the development of pressure ulcers, and therefore is an extremely useful preventative tool. The small resource use associated with skin assessment is highly likely to be offset by costs savings as more pressure ulcers are prevented. The GDG agreed that the use of skin assessment is highly likely to be cost-neutral, or even cost-saving, and will improve health related quality of life.
Quality of evidence	No RCTs or cohort studies were identified for neonates, infants, children or young people. Formal consensus using a modified Delphi was therefore used to develop the recommendation.

	To inform the recommendation, the GDG used 3 statements. Two statements were amended after failing to reach the pre-agreed consensus level in Round 1 and were amended and included in Round 2 of the Delphi consensus survey as a single statement which reached a 95% agreement level. One statement was included in Round 2 as a response to the qualitative responses gathered in Round 1 of the survey and reached a 96% agreement. Further details can be found in Appendix N.
Other considerations	There were no further considerations.

Recommendations	**12. 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.**
Relative values of different outcomes	The GDG was interested in any predictors for pressure ulcer development and their identification through clinical assessment by a healthcare professional. Evidence from multivariable analysis of risk was considered to be the most important.
Trade-off between clinical benefits and harms	The GDG used 1 statement from the Delphi consensus survey to inform the recommendation. The statement was 'Healthcare professionals should take into account the specific sites at risk of developing pressure ulcers in neonates, infants, children and young people, when undertaking and documenting a skin assessment'. The statement was accepted by the Delphi consensus panel. Further detail on the Delphi consensus survey can be found in Appendix N. The GDG discussed the statement and agreed that a recommendation should be developed to ensure that healthcare professionals are aware of specific sites that may be at risk of developing a pressure ulcers in neonates, infants, children and young people, as they differed from other populations (for example, adults). Specific sites highlighted by the panel as being at risk sites in the younger populations included the occiput, sacrum, back, hands and elbows. Other panel members highlighted that the use of body maps and medical photography could help to document the results of skin assessment. The GDG felt that there were likely to be benefits in ensuring that healthcare professionals were aware of areas that may be at risk in neonates, infants, children and young people in that a raised awareness may lead to a reduction in the incidence of pressure ulcers. The GDG could not identify any possible harms in raising awareness of these sites.
Economic considerations	No economic considerations.
Quality of evidence	No RCTs or cohort studies were identified for neonates, infants, children or young people. Formal consensus using a modified Delphi was therefore used to develop the recommendation. To inform the recommendation, the GDG used 1 statement which was included in Round 1 of the Delphi consensus survey and reached 96% consensus agreement. Further details can be found in Appendix N.
Other considerations	There were no further considerations.

9 Repositioning

9.1 Introduction

It is widely recognised that immobility and lack of sensation are significant risk factors affecting both the development and healing of pressure ulcers. Repositioning, that is a change in the individual's position whether by themselves or assisted (with or without the use of equipment) is an accepted method of pressure ulcer prevention. The aims of repositioning are to reduce or relieve the pressure on the area at risk, maintain muscle mass and general tissue integrity and ensure adequate blood supply to the at risk area. Despite frequent repositioning for people at risk of pressure ulcers being accepted best practice, there is a lack of published evidence in this area. Other guidelines and reviews have relied on consensus opinion of best practice.

This review focuses on identifying the most appropriate position for people who are at risk of developing a pressure ulcer, in order to reduce or relieve the pressure and prevent the development of a pressure ulcer. The review also aims to identify the optimum frequency at which people should be repositioned.

9.2 Review question: How and at what frequency should repositioning be undertaken for the prevention of pressure ulcers?

For full details see review protocol in Appendix C.

9.2.1 Clinical evidence (adults)

Six studies were included in the review.[51 135 186 210 215 228]Evidence from these are summarised in the clinical GRADE evidence profile below (Table 19). See also the study selection flow chart in Appendix D, forest plots in Appendix I, study evidence tables in Appendix G and exclusion list in Appendix J.

For the purposes of the review, searches were conducted for RCT assessing effectiveness of repositioning for the prevention of pressure ulcers in people of all ages in any setting. Six RCTs (3 cluster RCTs [51 135 215] and 3 parallel RCTs [186 210 228]) were identified.

The population varied from populations of older adults to individualsin intensive care units, all were assessed in different inpatient hospital settings. Four trials included older adults with a mean age of 80 years, 1 trial included acute inpatients with a mean age of 70 years. One trial included people admitted to an intensive care unit with a mean age of 63.9 years.[210]

Studies looked at different repositioning techniques applied at different time intervals. For the purpose of this review, the trials have been grouped and analysed in 4 different comparisons:

- Repositioning (frequent turning with or without the use of a pressure reducing mattress) versus no repositioning (standard care without turning).[51]
- Different frequencies of repositioning. [51 186 215]
- Different positions for repositioning – 30° tilt position versus 90° lateral and supine position [135 228] and semi recumbent position (a 45° position of the head and back) versus standard care (supine position). [210]

Trials reported the incidence of pressure ulcer (proportion of participants developing pressure ulcers (grade 1- 4) with 3 trials [135 215 228] giving a narrative report on 'time to pressure ulcer development' and tolerability. A narrative summary was included for studies where the outcome reported was not appropriate for GRADE. Included studies had varying time periods (ranging from 1 night to 5 weeks). Cluster RCTs have been analysed separately.

Summary of studies included in the review

Study	Intervention/comparator	Population	Outcomes	Study length
Defloor 2005 [51]	Participants either received a 2-hourly or a 3-hourly turning scheme on a standard institutional mattress or a 4-hourly or 6-hourly turning scheme on a pressure reducing mattress. The turning schemes consisted of alternating a semi-recumbent position with a lateral position. Standard care involving preventive nursing care based on clinical judgement of the nurses. Preventive measures used were water mattresses, alternating mattresses, sheepskins and gel cushions. Preventive care did not include turning.	People in a geriatric nursing home. Mean age: 84.4 (SD 8.33) years, The mean Braden score was 13.2 (SD 2.36) and the mean Norton score was 10.0 (SD 1.96). Participants were considered to be at risk of developing pressure ulcers.	• Proportion of people developing pressure ulcers.	4 weeks.
Moore 2011 [135]	Repositioning by using the 30° tilt (left side, back, right side, back) every 3 hours during the night. Repositioning every 6 hours at night, using 90° lateral rotation. Both groups were nursed during the day according to planned care. Pressure redistribution devises in current use on the bed and on the chair was continued. Participants positions were altered every 2-3 hours.	People from 12 long-term care of the older person hospital settings. Seventy-nine percent were women. Eighty-seven per cent were chair-fast and 77% had very limited activity. Participants were at risk of developing pressure ulcers (using the Braden pressure ulcer risk assessment scale).	• Proportion of people developing pressure ulcers (grade 1 – 4). • Time to pressure ulcer development.	4 weeks
Smith 1990 [186]	Small shift in body (adjusting the position of a limb or body part by placing a small rolled towel to designated areas). Shifts were completed in less than 1 minute. Sites for placement of rolled towel were under each arm, shoulder, hip, and leg. Both groups received normal, routine care and were turned every 2 hours.	Elderly adults. Participants ranged in age from 65 years to 91 years with a mean age of 80.55. Fourteen participants were women and five were men.	• Proportion of people developing pressure ulcers (grade 2 and higher).	2 weeks

Study	Intervention/comparator	Population	Outcomes	Study length
Vanderwee 2007 [215]	Four hours in a semi-recumbent 30° position and 2 hours in a lateral position 30°. Repositioning was the same as above but with equal time intervals of 4 hours in lateral 30° as in semi-recumbent 30° position. Participants in both groups were lying on a visco-elastic foam overlay mattress.	People in a geriatric nursing home. Mean age: 84.4 (SD 8.33) years, The mean Braden score was 13.2 (SD 2.36) and the mean Norton score was 10.0 (SD 1.96).	• Proportion of people developing pressure ulcers (grade 2 and higher). • Time to developing pressure ulcer.	5 weeks
Van Nieuwenhoven 2006 [210]	Semi recumbent position. Aim was to achieve 45° position of the head and back. The 45° position was not achieved for 85% of the study time, and these participants more frequently changed position than supine positioned participants. Standard care (supine position).	221 adults admitted to 4 ICUs in 3 university hospitals in the Netherlands. 112 randomised to semi recumbent positioning and 109 to supine positioning. Mean age of 63.9 years	• Proportion of people developing ulcer (grade 1-4).	7 days
Young 2004 [228]	30° tilt position during the night. 90° side-lying position during the night.	Acute inpatient in a district general hospital. Mean age of 70.3 years. Participants were at risk of developing pressure ulcers (indicated by a Waterlow risk assessment score above 10).	• Proportion of people developing pressure ulcers (grade 1: non-blanching erythema). • Patient tolerability.	One night

Table 19: Clinical evidence profile: repositioning (frequent turning or the use of pressure reducing mattress) versus no repositioning (standard care without turning).

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Repositioning	No repositioning	Relative (95% CI)	Absolute		
Incidence of pressure ulcers (all grades of pressure ulcers) - 2-hourly turning scheme on a standard institutional mattress (follow-up 4 weeks)[52]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	No serious	None	39/63 (61.9%)	322/511 (63%)	RR 0.98 (0.8 to 1.21)	13 fewer per 1000 (from 126 fewer to 132 more)	Low	Critical
							-	63%		13 fewer per 1000 (from 126 fewer to 132 more)		
Incidence of pressure ulcers (all grades of pressure ulcers) - 3-hourly turning scheme on a standard institutional mattress (follow-up 4 weeks) [52]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	40/58 (69%)	322/511 (63%)	RR 1.09 (0.91 to 1.32)	57 more per 1000 (from 57 fewer to 202 more)	Very low	Critical
							-	63%		57 more per 1000 (from 57 fewer to 202 more)		
Incidence of pressure ulcers (all grades of pressure ulcers) - 4-hourly turning plus a pressure reducing mattress (follow-up 4 weeks) [52]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	30/66 (45.5%)	322/511 (63%)	RR 0.72 (0.55 to 0.95)	176 fewer per 1000 (from 32 fewer to 284 fewer)	Very low	Critical

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Repositioning	No repositioning	Relative (95% CI)	Absolute		
							-	63%		176 fewer per 1000 (from 32 fewer to 283 fewer)		
Incidence of pressure ulcers (all grades of pressure ulcers) - 6-hourly turning plus a pressure reducing mattress (follow-up 4 weeks) [52]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	No serious	None	39/63 (61.9%)	322/511 (63%)	RR 0.98 (0.8 to 1.21)	13 fewer per 1000 (from 126 fewer to 132 more)	Low	Critical
							-	63%		13 fewer per 1000 (from 126 fewer to 132 more)		
Incidence of pressure ulcers (grade 2 and higher) - 2-hourly turning scheme on a standard institutional mattress (follow-up 4 weeks) [52]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[c]	None	9/63 (14.3%)	102/511 (20%)	RR 0.72 (0.38 to 1.34)	56 fewer per 1000 (from 124 fewer to 68 more)	Very low	Critical
							-	20%		56 fewer per 1000 (from 124 fewer to 68 more)		
Incidence of pressure ulcers (grade 2 and higher) - 3-hourly turning scheme on a standard institutional mattress (follow-up 4 weeks) [52]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[c]	None	14/58 (24.1%)	102/511 (20%)	RR 1.21 (0.74 to	42 more per 1000	Very low	Critical

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Repositioning	No repositioning	Relative (95% CI)	Absolute		
									1.97)	(from 52 fewer to 194 more)		
							-	20%		42 more per 1000 (from 52 fewer to 194 more)		
Incidence of pressure ulcers (grade 2 and higher) - 4-hourly turning plus pressure reducing mattress (follow-up 4 weeks) [52]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	No serious	None	2/66 (3%)	102/511 (20%)	RR 0.15 (0.04 to 0.6)	170 fewer per 1000 (from 80 fewer to 192 fewer)	Low	Critical
							-	20%		170 fewer per 1000 (from 80 fewer to 192 fewer)		
Incidence of pressure ulcers (grade 2 and higher) - 6-hourly turning plus a pressure reducing mattress (follow-up 4 weeks) [52]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[c]	None	10/63 (15.9%)	102/511 (20%)	RR 0.8 (0.44 to 1.44)	40 fewer per 1000 (from 112 fewer to 88 more)	Very low	Critical
							-	20%		40 fewer per 1000 (from 112 fewer to 88 more)		

Quality assessment							No of patients		Effect			Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Repositioning	No repositioning	Relative (95% CI)	Absolute	Quality	
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcer												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) Incomplete data for 3 participants though authors claim that analysis including these individuals did not change the result, unclear allocation concealment,the mattress used was not the same for the experimental group.

(b) The confidence interval crossed 1 MID point (0.75 to 1.25 for dichotomous outcomes).

(c) The confidence interval crossed both MID points (0.75 to 1.25 for dichotomous outcomes).

Table 20: Clinical evidence profile: different frequencies of repositioning: 2 hourly turning on a standard institutional mattress versus 3 hourly turning on a standard institutional mattress.

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	2-h turning	3-h turning	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers (all grades of pressure ulcers) - 2-hourly turning on a standard institutional mattress versus 3-hourly turning on a standard institutional mattress (follow-up 4 weeks) [52]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	39/63 (61.9%)	40/58 (69%)	RR 0.9 (0.69 to 1.16)	69 fewer per 1000 (from 214 fewer to 110 more)	Very low	Critical
							-	69%		69 fewer per 1000 (from 214 fewer to 110 more)		
Incidence of pressure ulcers (grade 2 and above pressure ulcers) - 2-hourly turning on a standard institutional mattress versus 3-hourly turning on a standard institutional mattress (follow-up 4 weeks) [52]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[c]	None	9/63 (14.3%)	14/58 (24.1%)	RR 0.59 (0.28 to 1.26)	99 fewer per 1000 (from 174 fewer to 63 more)	Very low	Critical
							-	24.1%		99 fewer per 1000 (from 174 fewer to 63 more)		
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcer												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital												

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	2-h turning	3-h turning	Relative (95% CI)	Absolute	Quality	Importance
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There were incomplete data for 3 participants though the authors report that analysis including these individuals did not change the result. There was unclear allocation concealment, and the mattress used was not the same for both groups.

(b) The confidence interval crossed 1 MID point.

(c) The confidence interval crosses both ends of MID point (0.75 to 1.25 for dichotomous outcomes).

Table 21: Clinical evidence profile: different frequencies of repositioning: 2 hourly turning on a standard institutional mattress versus 4 hourly turning plus pressure reducing mattress

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	2-h turning	4-h turning+ pressure reducing mattress	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers (all grades of pressure ulcers) - 2-hourly turning on a standard institutional mattress versus 4-hourly turning plus a pressure reducing mattress (follow-up 4 weeks) [52]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	39/63 (61.9%)	30/66 (45.5%)	RR 1.36 (0.98 to 1.89)	164 more per 1000 (from 9 fewer to 405 more)	Very low	Critical
							-	45.5%		164 more per 1000 (from 9 fewer to 405 more)		
Incidence of pressure ulcers (grade 2 and above pressure ulcers) - 2-hourly turning on a standard institutional mattress versus 4-hourly turning plus a pressure reducing mattress (follow-up 4 weeks) [52]												

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**2-h turning**	**4-h turning+ pressure reducing mattress**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	9/63 (14.3%)	2/66 (3%)	RR 4.71 (1.06 to 20.98)	112 more per 1000 (from 2 more to 605 more)	Very low	Critical
							-	3%		111 more per 1000 (from 2 more to 599 more)		
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcer												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There were incomplete data for 3 participants though the authors report that analysis including these individuals did not change the result. There was unclear allocation concealment, and the mattress used was not the same for both groups.

(b) The confidence interval crosses 1 end of MID point (0.75 to 1.25 for dichotomous outcomes).

Table 22: Clinical evidence profile: different frequencies of repositioning: 2 hourly turning on a standard institutional mattress versus 6 hourly turning plus pressure reducing mattress

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	2-h turning	6-h turning+ pressure reducing mattress	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers (all grades of pressure ulcers) - 2-hourly turning on a standard institutional mattress versus 6-hourly turning plus a pressure reducing mattress (follow-up 4 weeks) [52]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	39/63 (61.9%)	39/63 (61.9%)	RR 1 (0.76 to 1.32)	0 fewer per 1000 (from 149 fewer to 198 more)	Very low	Critical
							-	61.9%		0 fewer per 1000 (from 149 fewer to 198 more)		
Incidence of pressure ulcers (grade 2 and above pressure ulcers) - 2-hourly turning on a standard institutional mattress versus 6-hourly turning plus pressure reducing mattress (follow-up 4 weeks) [52]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[c]	None	9/63 (14.3%)	10/63 (15.9%)	RR 0.9 (0.39 to 2.06)	16 fewer per 1000 (from 97 fewer to 168 more)	Very low	Critical
							-			16 fewer per 1000 (from 97 fewer to 168 more)		
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcers												

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	2-h turning	6-h turning+ pressure reducing mattress	Relative (95% CI)	Absolute	Quality	Importance
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There was incomplete data for 3 participants though the authors report that analysis including these individuals did not change the result. There was unclear allocation concealment and the mattress used was not the same for both groups.
(b) The confidence interval crossed 1 MID point.
(c) The confidence interval crosses both ends of MID point (0.75 to 1.25 for dichotomous outcomes).

Table 23: Clinical evidence profile: different frequencies of repositioning: 3 hourly turning on a standard institutional mattress versus 4 hourly turning plus pressure reducing mattress

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	3-h turning	4-h turning+ pressure reducing mattress	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers (all grades of pressure ulcers) - 3-hourly turning on a standard institutional mattress versus 4-hourly turning plusa pressure reducing mattress (follow-up 4 weeks) [52]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	40/58 (69%)	30/66 (45.5%)	RR 1.52 (1.11 to 2.08)	236 more per 1000 (from 50 more to 491 more)	Very low	Critical

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**3-h turning**	**4-h turning+ pressure reducing mattress**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
							-	45.5%		237 more per 1000 (from 50 more to 491 more)		
Incidence of pressure ulcers (grade 2 and above pressure ulcers) - 3-hourly turning on a standard institutional mattress versus 4-hourly turning plus a pressure reducing mattress (follow-up 4 weeks) [52]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[c]	None	14/58 (24.1%)	2/66 (3%)	RR 7.97 (1.89 to 33.59)	211 more per 1000 (from 27 more to 988 more)	Very low	Critical
							-	3%		209 more per 1000 (from 27 more to 978 more)		
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There was incomplete data for 3 participants though authors report that analysis including these individuals did not change the result. There was unclear allocation concealment and the mattress used was not the same for both groups.
(b) The confidence interval crosses 1 MID point.
(c) The confidence interval crosses both ends of MID point (0.75 to 1.25 for dichotomous outcomes).

Table 24: Clinical evidence profile: different frequencies of repositioning: 3 hourly turning on a standard institutional mattress versus 6 hourly turning plus pressure reducing mattress

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**3-h turning**	**6-h turning+ pressure reducing mattress**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
Incidence of pressure ulcers (all grades of pressure ulcers) - 3-hourly turning on a standard institutional mattress versus 6-hourly turning plus a pressure reducing mattress (follow-up 4 weeks) [52]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	40/58 (69%)	39/63 (61.9%)	RR 1.1 (0.86 to 1.44)	68 more per 1000 (from 87 fewer to 272 more)	Very low	Critical
								61.9%		68 more per 1000 (from 87 fewer to 272 more)		
Incidence of pressure ulcers (grade 2 and above pressure ulcers) - 3-hourly turning on a standard institutional mattress versus 6-hourly turning plus a pressure reducing mattress (follow-up 4 weeks) [52]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[c]	None	14/58 (24.1%)	10/63 (15.9%)	RR 1.52 (0.73 to 3.15)	83 more per 1000 (from 43 fewer to 342 more)	Very low	Critical
							-	15.9%		83 more per 1000 (from 43		

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	3-h turning	6-h turning+ pressure reducing mattress	Relative (95% CI)	Absolute	Quality	Importance
										fewer to 342 more)		
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcer												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There were incomplete data for 3 participants though the authors report that analysis including these individuals did not change the result. There was unclear allocation concealment and the mattress used was not the same for both groups
(b) The confidence interval crosses one MID point (0.75 to 1.25 for dichotomous outcomes).
(c) The confidence interval crossed both MID points (0.75 to 1.25 for dichotomous outcomes).

Table 25: Clinical evidence profile: different frequencies of repositioning: 4 hourly turning plus pressure reducing mattress versus 6 hourly turning plus pressure reducing mattress

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	4-h turning+ pressure reducing mattress	6-h turning+ pressure reducing mattress	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers (all grades of pressure ulcer) - 4-hourly versus 6-hourly turning plus a pressure reducing mattress (follow-up 4 weeks)[51]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	30/66 (45.5%)	39/63 (61.9%)	RR 0.73 (0.53 to 1.02)	167 fewer per 1000 (from 291 fewer to 12 more)	Very low	Critical
							-	61.9%		167 fewer per 1000 (from 291 fewer to 12 more)		
Incidence of pressure ulcers (grade 2 and above pressure ulcers) - 4-hourly versus 6-hourly turning plus a pressure reducing mattress (follow-up 4 weeks) [51]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	2/66 (3%)	10/63 (15.9%)	RR 0.19 (0.04 to 0.84	129 fewer per 1000 (from 25 fewer to 153 fewer)	Very low	Critical
							-	15.9%		129 fewer per 1000 (from 25 fewer to 153 fewer)		
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	4-h turning+ pressure reducing mattress	6-h turning+ pressure reducing mattress	Relative (95% CI)	Absolute	Quality	Importance
Time to develop new pressure ulcer												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There were incomplete data for 3 participants though the authors report that analysis including these individuals did not change the result. There was unclear allocation concealment.
(b) The confidence interval crosses 1 MID point (0.75 to 1.25 for dichotomous outcomes)

Table 26: Clinical evidence profile: different frequencies of repositioning: turning 2 hourly in a lateral and 4 hourly in a supine position versus repositioning 4 hourly

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	2-h in a lateral and 4-h in a supine position	4-hrly turning	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers (grade 2 and higher) - turning with unequal time intervals (follow-up 5 weeks)[215]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	20/122 (16.4%)	24/113 (21.2%)	RR 0.77 (0.45 to 1.32)	49 fewer per 1000 (from 117 fewer to 68 more)	Very low	Critical
								21.2%		49 fewer per 1000 (from		

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**2-h in a lateral and 4-h in a supine position**	**4-hrly turning**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
										117 fewer to 68 more)		
Time to develop new pressure ulcer – turning with unequal time intervals												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	No serious	Very serious[c]	-	-	Log-rank test 1.18, d.f = 0.1, p=0.28	-	Low	Important
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) Blinding, intention to treat analysis and allocation concealment not reported by the authors. The sample size was lower than the desired (calculated) needed.
(b) The confidence interval crosses both ends of MID point (0.75 to 1.25 for dichotomous outcomes).
(c) No data was given for each arm but log-rank data was presented. No statistical difference was found using Kaplan-Meier survival analysis.

Table 27: Clinical evidence profile: different frequencies of repositioning: unscheduled small shifts in body position versus 2-hourly turning

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**Unscheduled small shifts**	**2-hrly turning**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
Incidence of pressure ulcers (grade 2 and higher) - unscheduled (small) shifts in body positions (follow-up 2 weeks)[186]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	1/9 (11.1%)	1/10 (10%)	RR 1.11 (0.08 to 15.28)	11 more per 1000 (from 92 fewer to 1000 more)	Very low	Critical
							-	10%		11 more per 1000 (from 92 fewer to 1000 more)		
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcer												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) Blinding, intention to treat analysis and allocation concealment not reported by the authors. The sample size was lower than the desired (calculated) needed, high rate of drop outs (difference between control and experimental greater than 10%).

(b) The confidence interval crosses both ends of MID point (0.75 to 1.25 for dichotomous outcomes)

Table 28: Clinical evidence profile: different positions for repositioning – 30° tilt position versus 90° lateral and supine position (control)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**30° tilt position**	**90° lateral and supine position**	**Relative (95% CI)**	**Absolute**		
Incidence of pressure ulcers (grade –1 - 4) - 30 degree tilt 3 hourly-(cluster) (follow-up 4 weeks)[135]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	3/99 (3%)	13/114 (11.4%)	RR 0.27 (0.08 to 0.91)	83 fewer per 1000 (from 10 fewer to 105 fewer)	Very low	Critical
							-	11.4%		83 fewer per 1000 (from 10 fewer to 105 fewer)		
Incidence of pressure ulcers (grade 1: non-blanching erythema) - 30 degree tilt -(follow-up 1 night)[228]												
1	Randomised trial	Serious[c]	No serious inconsistency	No serious indirectness	Very serious[d]	None	3/23 (13%)	2/23 (8.7%)	RR 1.5 (0.28 to 8.16)	43 more per 1000 (from 63 fewer to 623 more)	Very low	Critical
							-	8.7%		43 more per 1000 (from 63 fewer to 623 more)		
Time to develop new pressure ulcer – mean days												
1	Randomised trial	Serious[c]	No serious inconsistency	No serious indirectness	Very serious[e]	None	26 days (range 3 days)	17 days (range 24 days)	-	MD 9 days	Very low	Important
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	30° tilt position	90° lateral and supine position	Relative (95% CI)	Absolute		
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) Blinding was not reported by the authors, the sample size was lower than the desired (calculated) power needed.
(b) The confidence interval crossed 1 MID point (0.75 to 1.25 for dichotomous outcomes)
(c) There was a small sample size
(d) The confidence interval crosses both ends of MID (0.75 to 1.25 for dichotomous outcomes).
(e) No standard deviations were given. No log-rank values were given.

Table 29: Clinical evidence profile: different positions for repositioning – semi recumbent position (45° position of the head and back) versus standard care (supine position)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Semi recumbent position (45 degree position of the head and back)	Supine position	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers (grade 1 - 4) - semi recumbent position (45° position of the head and back) (follow-up 7 days)[210]												

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**Semi recumbent position (45 degree position of the head and back)**	**Supine position**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
1	Randomised trial	No serious risk of bias	No serious inconsistency	No serious indirectness	Very serious[a]	None	31/112 (27.7%)	30/109 (27.5%)	RR 1.01 (0.66 to 1.54)	3 more per 1000 (from 94 fewer to 149 more)	Low	Critical
							-	27.5%		3 more per 1000 (from 93 fewer to 148 more)		
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcer												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) The confidence interval crossed both ends of MID points (0.75 to 1.25 for dichotomous outcomes).

9.2.1.1 Comparison between kinetic beds and conventional beds

Table 30: Clinical evidence profile: kinetic treatment table versus standard care for pressure ulcer prevention

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**Kinetic treatment table**	**Standard care**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
Incidence of pressure ulcers[69,195]												
2	Randomised trials	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	9/70 (12.9%)	10/81 (12.3%)	RR 1.23 (0.57 to 2.65)	28 more per 1000 (from 53 fewer to 204 more)	Very low	Critical
Time in hospital (days)[195]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	None	Very serious[c]	6.7 days	11.6 days	-	-	Very low	Important
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcer												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There was unclear allocation concealment and blinding reported (Gentilello 1988, Summer 1989) and unclear addressing of incomplete outcome data (Gentilello 1988). It was unclear if the groups were similar at baseline (Summer 1989).

(b) The confidence interval crossed both MIDs.

(c) There was not enough data for analysis in Revman.

(d) Participants in Summer (1989) randomised only obtunded or unconscious people (although this was not the initial intention) and Gentillello (1988) included people immobilised from head injury, spinal injuries or traction. Most participants would not be able to reposition themselves so the 2 studies were meta-analysed together.

9.2.1.2 RCT Narrative summary

The following study is summarised as a narrative because the outcomes were not appropriate for GRADE due to incomplete outcome reporting:

One study [228] examining the effects of the 30° tilt position (experimental arm) in reducing the incidence of non-blanching erythema (grade 1 pressure ulcer)compared to the use of 90° lateral and supine position (control arm) reported that 5(22%) out of 23 participants in the experimental arm were unable to tolerate the intervention. No data was provided for the individuals in the control arm.

9.2.2 Economic evidence (adults)

Published literature

One economic evaluation was identified with a relevant comparison and has been included in this review.[133] This is summarised in the economic evidence profile below (Table 31) and the economic evidence table in Appendix H.

Ten studies were found which included repositioning as part of more complex prevention strategies. [13,121,124,153,181,190,202,225-227] These studies were not included as they evaluated the cost-effectiveness of these more complex prevention strategies as a whole, and did not provide information on the cost-effectiveness of repositioning alone.

See also the economic article selection flow diagram in Appendix D.

Table 31: Economic evidence profile: Repositioning schedules

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effects	Cost effectiveness	Uncertainty
Moore 2013[133] (Ireland)	Partially applicable[a]	Minor limitations[b]	A within trial analysis comparing repositioning using a 30° tilt (left side, back, right side, back) every 3 hours during the night to repositioning every 6 hours at night using 90° lateral rotation.	-£39	-0.08 pressures ulcers per person	Repositioning using a 30° tilt every 3 hours during the night dominates repositioning every 6 hours at night using 90° lateral rotation.	No analysis of uncertainty reported.
NCGC model	Directly applicable[c]	Minor limitations[d]	A probabilistic cost-utility analysis comparing 4 hours in a semi-Fowler 30° position and 2 hours in a lateral position 30° to 4 hours spent in the semi-Fowler 30° position, and 4 hours in lateral 30° position. All peoplehad non-blanchable erythema.	£541	0.00029 QALYs	ICER = £1,854,070 per QALY gained	Probabilistic analysis revealed only a 3.2% probability that 4 and 2 hour repositioning is cost-effective at the £20,000 per QALY threshold. The conclusions were robust to a wide range of deterministic analyses.

(a) Perspective of Irish healthcare payer; health outcomes not reported in QALYs; 2009 cost inputs

(b) Short time horizon (especially considering the long term care population), the cost of treating pressure ulcers is not fully accounted for (although this is unlikely to change the results), all resource estimates and effectiveness estimates obtained from within 1 trial. No analysis of uncertainty.

(c) Perspective of UK NHS; health outcomes reported as QALYs; 2013 stud

(d) The analysis was based on single trial, although this represents the best available clinical evidence. Short time horizon; no consideration of long term quality of life impact of pressure ulcer post healing.

New cost-effectiveness analysis

Repositioning was identified by the GDG as a priority area for new economic analysis. An overview of the methods and results of the analysis are presented here, with full details reported in Appendix L. The analysis is also summarised in the economic evidence profile above (Table 31).

The model was based on a key randomised trial identified in the systematic review of clinical literature.[215] This approach was taken because none of the studies identified in the clinical review had common comparators, and the majority had different populations and different follow up times, thus the interventions could not be reliably compared across the trials.

Costs were considered from a UK NHS and personal social services perspective and health outcomes expressed as quality adjusted life years (QALYs) in accordance with the NICE reference case.[140] The time horizon of the model was duration of the trial, or until healing of pressure ulcer. Discounting was not undertaken due to the short time horizon.

Overview of analysis

The population and interventions were dictated by the trial and are summarised below; full details are provided in the evidence table in Appendix L.

Population: Residents of Belgian elder care nursing homes who had non-blanchable erythema in a pressure area. The mean age was 84 years.

Intervention 1: Four hours in a semi-Fowler 30° position and 4 hours in a lateral position 30°. The semi-Fowler position consisted of a 30° elevation of the head end and the foot end of the bed. In a lateral position, the position, the individual was rotated 30°, with their back supported with an ordinary pillow.

Intervention 2: Repositioning was the same as above but with 4 hours spent in the semi-Fowler 30° position, and 2 hours in lateral 30° position.

Individuals in the model received intervention 1 or intervention 2. The key clinical outcome was the incidence of pressure ulcers. The proportion of people developing pressure ulcers in each trial arm determined the magnitude of the incremental QALYs. The costs were calculated based on the cost of the repositioning strategies themselves, plus the cost of treating the number of pressure ulcers which developed. Where possible, the model was built probabilistically to take account of the uncertainty around input parameter point estimates. Deterministic sensitivities analyses were also undertaken (for full details see Appendix L).

Model inputs

Model inputs were based on clinical evidence identified in the systematic review undertaken for the guideline, supplemented by additional data sources as required. Model inputs were validated with clinical members of the GDG. A summary of the model inputs used in the base-case analyses is provided in

Table 32. Full details about sources, calculations and rationale for selection can be found in Appendix L.

Table 32: Overview of parameters and parameter distributions used in the model

Parameter description	Point estimate	Probability distribution	Distribution parameters	Source
Cost of pressure ulcer	£5,672	Deterministic sensitivity analysis only		Dealey et al[50]
Utility loss from pressure ulcer	0.026	Normal	μ = 0.026, σ = 0.008	Soares et al[189]
Probability of developing pressure ulcer				
Intervention 1	0.16	Beta	α = 24, β = 89	Vanderwee et al[215]
Intervention 2	0.21	Beta	α = 20, β = 102	Vanderwee et al[215]
Nurse time required per position change (minutes)				
Intervention 1	10	Deterministic sensitivity analysis only		GDG assumption
Intervention 2	10	Deterministic sensitivity analysis only		GDG assumption
Cost per position change				
Intervention 1	£11.67	Deterministic sensitivity analysis only		Based on cost of nurse time.[46]
Intervention 2	£11.67	Deterministic sensitivity analysis only		
Position changes per day				
Intervention 1	6	Set by intervention – not varied		Vanderwee et al[215]
Intervention 2	8	Set by intervention – not varied		Vanderwee et al[215]

Aspects of preventative care other than staff time for repositioning, for example nutritional strategies or pressure redistributing devices, were not included in the analysis. These were assumed to be constant between the groups, and would therefore not impact the incremental analysis.

Computations

The model was constructed in Microsoft Excel.

Let U_{PU} represent the utility loss associated with a pressure ulcer, and T_{PU} represent the time spent with a pressure ulcer. $PUs\ avoided$ is the incremental number of pressure ulcers between the two trial arms. Then, incremental QALYs were calculated as follows:

$$Incremental\ QALYs = PUs\ avoided\ \times U_{PU}\ \times T_{PU}$$

For costs, let $staff_i$ represent the total cost of staff time for intervention i (i=1,2), $nurse\ cost$ is the cost of nurse time per minute, and $minutes_i$ is the number of minutes required per day to implement intervention i. $days$ is the number of days in the time horizon. Then:

$$Staff_i\ = nurse\ cost \times\ minutes_i \times days$$

Now let p_i represent the probability of developing a pressure ulcer when receiving intervention i, and let $cost_{PU}$ represent the cost of a pressure ulcer. Then total cost for strategy i is computed as follows:

$$Total\ Cost_i\ = Staff_i\ + (p_i \times cost_{PU})$$

Sensitivity analyses

Sensitivity analyses were undertaken to explore the effect of different parameter inputs and assumptions on the results of the model. Analyses included varying the staff time required for

repositioning, using clinical support workers instead of nurses to reposition people, and varying the cost of a pressure ulcer. Full details of all sensitivity analyses can be found in Appendix L

Results

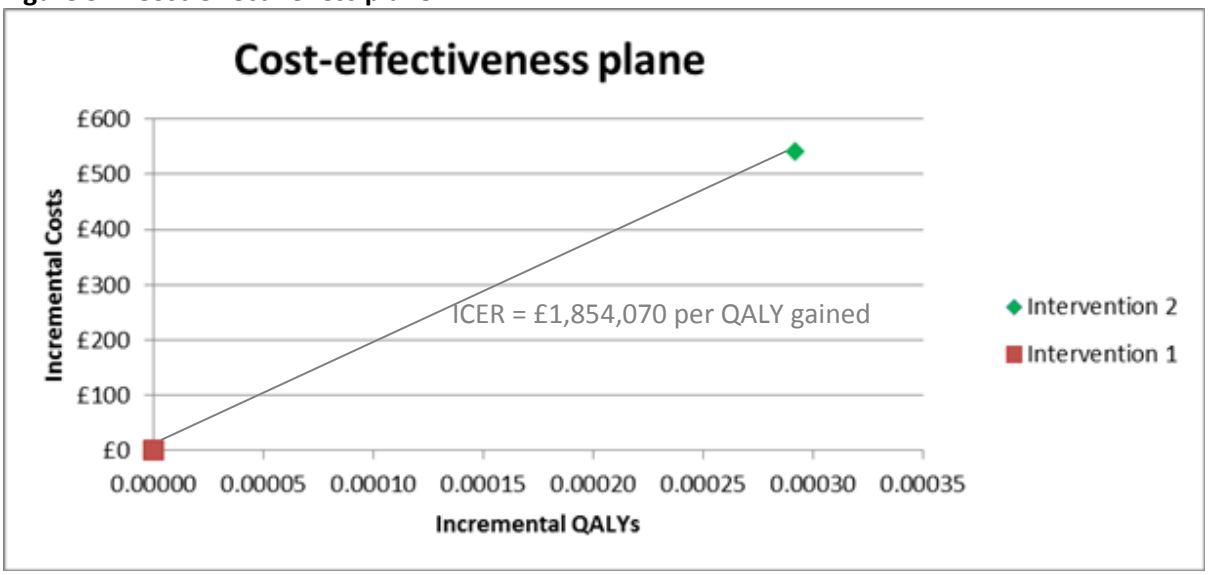
Table 33 shows the results of the probabilistic base case analysis. Intervention 2 is more costly than intervention 1, and also leads to a greater health benefit. However, the incremental QALY gains are small, and as such, intervention 2 has not been found to be cost-effective at the £20,000 per QALY gained threshold. These results are shown graphically in Table 33. Probabilistic sensitivity analysis revealed that intervention 2 has a probability of being cost-effective of just 3.2%, when compared to intervention 1.

Table 33: Base case results (probabilistic)

Intervention	Total cost	Incremental cost	Pressure ulcers avoided	Incremental QALYs	ICER
Intervention 1	£3,656				
Intervention 2	£4,197	£541	0.049	0.000292	£1,854,070

Note: all results are mean (per patient) results

Figure 3: Cost-effectiveness plane



Overall, sensitivity analyses demonstrated that the results of this analysis were largely robust to changes in key assumptions, costs, and frequency of dressing change. See Appendix L for details.

Discussion

This analysis found that 2 and 4 hourly repositioning is not cost-effective compared to 4 hourly repositioning in elderly people in a nursing home with non-blanchable erythema. This conclusion was robust to a range of sensitivity analyses, demonstrating that although uncertainty surrounds model inputs, variation within reasonable ranges does not change the results.

The results above are based on 1 trial, comparing just 2 possible repositioning strategies. Based on this, we cannot conclude that intervention 1 compared to all possible alternatives, but rather that it is cost-effective compared to intervention 2. Ideally, clinical evidence would have allowed a full comparison of all feasible strategies against each other; however this was not possible in this case.

This economic evaluation considered different interventions to those included in the analysis presented by Moore and colleagues,[133] and therefore the results of the 2 studies cannot be compared directly. See Appendix L for full discussion.

9.2.3 Clinical evidence (children and young people)

One study was included in this review. [64]Evidence from this study is summarised in the clinical GRADE evidence profile below (Table 34). See also the study selection flow chart in Appendix D, forest plots in Appendix I, study evidence tables in Appendix G and exclusion list in Appendix G.

The study identified was a parallel randomised trial including infants and children and looked at different positions for repositioning prone or semi-recumbent versus control supine positioning.

Summary of studies included in the review

Study	Intervention/comparison	Population	Outcomes	Study length
Fineman 2006 [64]	Prone positioning: a 2 hourly cyclic rotation from full prone to right lateral/prone to full prone to left lateral/prone and then to full prone. Supine positioning. All participants were maintained on standard hospital beds. Individually sized head, chest, pelvic, distal femoral and lower limb cushions were created using pressure-relieving material.	One hundred and two children with acute lung injury.	• Proportion of people that developed stage 2 or greater pressure ulcers.	28-days

Table 34: Clinical evidence profile: critically ill infants and children: different positions for repositioning – prone positioning versus control supine positioning (control)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Prone positioning	Supine positioning	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers (grade 2 and higher) – prone positioning (2 hour cyclic rotation) (follow-up 28 days)[64]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	10/51 (19.6%)	8/51 (15.7%)	RR 1.25 (0.54 to 2.91)	39 more per 1000 (from 72 fewer to 300 more)	Very low	Critical
							-	15.7%		39 more per 1000 (from 72 fewer to 300 more)		
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) The authors did not report blinding of any kind.
(b) The confidence interval crosses both ends of MID (0.75 to 1.25 for dichotomous outcomes)

9.2.4 Economic evidence (children and young people)

Published literature

No relevant economic evaluations were identified.

New cost-effectiveness analysis

The results of the new cost-effectiveness analysis presented above were not intended to be generalisable to people under the age of 18.

Economic considerations

In the absence of economic evidence for this review question, the GDG considered relevant UK NHS unit costs. These were considered alongside clinical evidence obtained from the Delphi consensus panel to inform qualitative judgement about cost-effectiveness.

The ease of repositioning depends on the weight of the child and how stable they are. Small, light children can be repositioned by a nurse or carer in a couple of minutes. Heavier, immobile children, or those in an unstable condition, may require 2 nurses or healthcare support workers for up to 10 minutes (costing an estimated £7.00-11.60[47]). Repositioning equipment may also be required.

The GDG estimated that patient hoists cost £500 - £1,500, but noted that cheaper equipment is also available, such as repositioning sheets (or slide sheets). Example repositioning sheets include the Disposaglide tubular patient specific slide sheet 100cm x 120cm, which costs £80.04 for 10 disposable sheets, and the Laundraglide tubular washable slide sheet 100cm x 120cm, which costs £57.77 for 5 reusable sheets.

Play experts can also be used to encourage children to move around. The GDG expected most play experts to be NHS Band 4, thus 1 hour of play expert time could be estimated to cost £26 (calculated based on annual costs of Band 4 healthcare professionals, including for example, overheads and capital costs, divided by the annual hours worked by a hospital nurse [1,573][47]).

9.2.4.1 Clinical (adults)

9.2.4.1.1 Repositioning compared to no repositioning

- One study (n= 574) showed there is no clinical difference between frequent turning (2 hourly) compared to standard care for reducing the incidence of pressure ulcers (all grades), the direction of effect favoured 2 hour turning (very low quality).
- One study (n=569) showed there is no clinical difference between frequent turning (3 hourly) and standard care for reducing the incidence of pressure ulcers (all grades), the direction of the effect favoured the standard hospital mattress (very low quality).
- One study (n= 577) showed a pressure reducing mattress in combination with less frequent turning (4 hourly) was more clinically effective than standard care for the incidence of pressure ulcers (all grades)(very low quality).
- One study (n=578) showed there is no clinical difference between a pressure-reducing mattress in combination with less frequent turning (6 hourly) and standard care for the incidence of pressure ulcers (all grades), the direction of the effect favoured the pressure-reducing mattress and less frequent turning (low quality).
- One study (n=574) showed there is no clinical difference between frequent turning (2 hourly) and standard care for the incidence of pressure ulcers (grade 2 and above) (very low quality).

- One study (n= 574) showed there is no clinical difference between frequent turning (3 hourly) and standard care for the incidence of pressure ulcers (grade 2 and above) (very low quality).
- One study (n=569) showed that the use of a pressure reducing mattress in combination with less frequent turning (4 hourly) is clinically effective at reducing the incidence of pressure ulcers (grade 2 and above) compared to standard care (low quality).
- One study (n=577) showed there is no clinical difference between a pressure reducing mattress in combination with less frequent turning (6 hourly) and standard for the incidence of pressure ulcers (grade 2 and above) (very low quality).
- No evidence was found for the following outcomes:
  - Acceptability of treatment
  - Rate of development of pressure ulcers
  - Time to development of pressure ulcers
  - Time in hospital or NHS care
  - Health-related quality of life

9.2.4.1.2 Different frequencies of repositioning

- One study (n=121) showed there is potentially a clinical benefit of frequent turning (2 hourly) when compared to frequent turning (3 hourly) for the incidence of pressure ulcer (all grades)(very low quality).
- One study (n=121) showed there may be a clinical benefit of frequent turning (2 hourly) when compared to frequent turning (3 hourly) for the incidence of pressure ulcer (grade 2 and above)(very low quality).
- One study (n= 129) showed there is potentially a clinical benefit of a pressure reducing mattress in combination with less frequent turning (4 hourly) when compared to frequent turning (2 hourly) for the incidence of pressure ulcers (all grades) (very low quality).
- One study (n= 129) showed there is potentially a clinical benefit of a pressure reducing mattress in combination with less frequent turning (4 hourly) when compared to frequent turning (2 hourly) for the incidence of pressure ulcers (grade 2 and above) (very low quality).
- One study (n= 126) showed there is no clinical difference between frequent turning (2 hourly) compared to a pressure reducing mattress in combination with less frequent turning (6 hourly) for reducing the incidence of pressure ulcers, but the direction of the estimate of effect could favour either intervention (all grades) (low quality).
- One study (n= 126) showed there may be no clinical difference between frequent turning (2 hourly) compared to a pressure reducing mattress in combination with less frequent turning (6 hourly) for reducing the incidence of pressure ulcers, but the direction of the estimate of effect could favour either intervention (grade2 and above) (very low quality).
- One study (n=124) showed that less frequent turning (4 hourly) was more clinically effective when compared to a pressure reducing mattress in combination with frequent turning (3 hourly) for reducing the incidence of pressure ulcers (all grades) (very low quality).
- One study (n=124) showed that less frequent turning (4 hourly) may be more clinically effective when compared to a pressure reducing mattress in combination with frequent turning (3 hourly) for reducing the incidence of pressure ulcers (grade 2 and above) (low quality).
- One study (n= 121) showed there is potentially a clinical benefit of less frequent turning (6 hourly) compared to a pressure reducing mattress in combination with frequent turning (3 hourly) for reducing the incidence of pressure ulcer (all grades) (very low quality).
- One study (n= 121) showed there may be a clinical benefit of less frequent turning (6 hourly) compared to a pressure reducing mattress in combination with frequent turning (3 hourly) for reducing the incidence of pressure ulcer (grade 2 and above) (very low quality).

- One study (n=129) showed there is potentially a clinical benefit of a pressure reducing mattress in combination with more frequent turning (4 hourly) compared to a pressure reducing mattress in combination with less frequent turning (6 hourly) for reducing the incidence of pressure ulcers (all grades) (very low quality).
- One study (n=129) showed there is potentially a clinical benefit of a pressure reducing mattress in combination with more frequent turning (4 hourly) compared to a pressure reducing mattress in combination with less frequent turning (6 hourly) for reducing the incidence of pressure ulcers (grade 2 and above) (very low quality).
- One study (n= 235) showed there may be no clinical difference between repositioning with unequal time interval (2 hours in a lateral position and 4 hours in a supine position) compared to repositioning with equal time interval (4 hourly) for reducing the incidence of pressure ulcers (grade 2 and above) but the direction of the estimate of effect could favour either intervention (very low quality).
- One study (n= 235) reported that there may be no difference between repositioning on a pressure reducing mattress alternately for 2 hours in a lateral position and 4 hours in a supine position compared with repositioning every 4 hours for the time to develop a pressure ulcer. The clinical importance and imprecision is unknown (very low quality).
- One study (n=19) showed there may be no clinical difference between repositioning with unequal time intervals (small unscheduled shifts) compared to repositioning with equal time intervals (2 hourly) at 2 weeks follow up for the incidence of pressure ulcers (grade 2 and above), but the direction of the estimate of effect could favour either intervention (very low quality).
- No evidence was found for the following outcomes:
  - Acceptability of treatment
  - Rate of development of pressure ulcers
  - Time to development of pressure ulcers
  - Time in hospital or NHS care
  - Health-related quality of life

9.2.4.1.3 Different positions for repositioning

- One study (n= 213) showed that repositioning using the 30° tilt (3 hourly at night) is potentially more clinically effective at reducing pressure ulcers (grade 1-4) when compared to the 90° lateral position (6 hourly at night) (very low quality).
- One study (n=46) showed that the 90° lateral position (at night) may be more clinically effective at reducing the incidence of pressure ulcers (grade l: non-blanching erythema) when compared to the 30° tilt over 1 night (very low quality).
- One study (n=46) reported a mean time to pressure ulcer development of 26 days (range 3 days) for the 30° tilt group and 17 days (range 24 days) with the a 90° lateral rotation. The clinical importance and imprecision is unknown (very low quality).
- One study (n= 221) showed there may be no clinical difference between the semi recumbent positioning (45° position of the head and back) when compared to supine positioning (standard care) for reducing the incidence of pressure ulcers (grade 1-4), but the direction of the estimate of effect could favour either intervention (low quality).
- No evidence was found for the following outcomes:
  - Acceptability of treatment
  - Rate of development of pressure ulcers
  - Time to development of pressure ulcers
  - Time in hospital or NHS care
  - Health-related quality of life

9.2.4.1.4 Turning tables

- Two studies (n=151) showed there may be no clinical difference between a kinetic treatment table and standard care for reducing the incidence of pressure ulcers (all grades), but the direction of the estimate of effect could favour either intervention (very low quality).
- One study (n=86) reported evidence for a kinetic treatment table and standard care for the time in hospital. The number of days in hospital was reported. The clinical importance and imprecision is unknown.
- No evidence was found for the following outcomes:
  - Acceptability of treatment
  - Rate of development of pressure ulcers
  - Time to development of pressure ulcers
  - Time in hospital or NHS care
  - Health-related quality of life

9.2.4.2 Economic (adults)

- One cost-effectiveness analysis found that repositioning using a 30° tilt every 3 hours during the night dominates repositioning every 6 hours at night using 90° lateral rotation in people in long term care. This analysis was assessed as partially applicable with minor limitations.
- One cost-utility analysis found that repositioning every 4 and 2 hours (alternatively) was not cost-effective compared to repositioning every 4 hours (ICER = £1,854,070) in people in long term care with non-blanchable erythema. This analysis was assessed as directly applicable with minor limitations.

9.2.4.3 Clinical (neonates, infants, children and young people)

9.2.4.3.1 Critically ill infants and children: different positions for repositions (prone positioning) versus control (supine positioning)

Proportion of people developing pressure ulcers

- One study (n=102) showed supine positioning (2 hour cyclic rotation) may be more clinically effective at reducing pressure ulcers (grade 2 and above) when compared to prone positioning (very low quality).

9.2.4.4 Economic (neonates, infants, children and young people)

- No relevant economic evaluations were identified.

9.3 Recommendations and link to evidence

9.3.1 Adults

Recommendations	13. **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.** 14. **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.**
Relative values of different outcomes	The GDG identified that the proportion of people developing new pressure ulcers and patient acceptability were the most critical outcomes to inform decision making, given that the primary goal of pressure ulcer prevention was to limit the number of new pressure ulcers. Acceptability was identified as being critical from the perspective of the patient, as it was noted that frequency of repositioning could have a significant impact upon quality of life. Rate of development of new pressure ulcers, time to develop new pressure ulcers, time in hospital or NHS care and health related quality of life were considered important outcomes to inform decision making.
Trade-off between clinical benefits and harms	The GDG considered that relieving pressure by repositioning people at risk of pressure ulcers is fundamental to the prevention of pressure ulcers and is current best practice. The GDG therefore used the evidence identified to ascertain the optimal repositioning strategy (including frequency and position) to prevent pressure ulcers. The evidence for frequency of repositioning came from 1 study. There was a clinical benefit of 4 hour turning (the intervention included a pressure-reducing mattress) compared to standard care for reduction in incidence of grade 2 and above pressure ulcers, and for all grades of pressure ulcers. When comparing the differing turning schemes for reducing the incidence of pressure ulcers there was a clinical benefit for 2 hour turning compared to 3 hour for grade 2 pressure ulcers. There was a clinical benefit of 4 compared to 2 hours (all grades, grade 2 and above) but no clinical benefit of 6 hours compared to 2 hours (all grades, grade 2 and above), and 4 and 6 hours compared to 3 hours (all grades, grade 2 and above) but this was confounded by the fact that the 4 and 6 hour intervention had a pressure-reducing mattress. For grade 1 pressure ulcers and grade 2 and above, 4 hour turning plus a pressure-reducing mattress was more clinically beneficial for reducing grade 1 pressure ulcers than 6 hour turning plus a pressure-reducing mattress. Three studies looked at the differing positions and frequency of positioning. There was no clinical difference between 2 hours lateral and 4 hours supine positioning compared to repositioning at 4 hours, prone compared to supine positioning or small unscheduled shifts in position in comparison to 2 hour turning. There was a clinical benefit of 30 degree tilt (3 hourly at night) compared to 90 degree tilt (6 hourly at night) for grade 1 to 4 ulcers. There was no difference between 45 degree position of head and back compared to supine position for grade 1 to 4. No differences were found in time to develop a pressure ulcer. Another study found no clinical difference between a kinetic treatment table (which turns people) compared to a standard bed

	for incidence of pressure ulcers and time in hospital. No data was identified on patient acceptability. The GDG wished to highlight patient acceptability was likely to be impacted by frequent repositioning, particularly during the night time. The GDG also felt that many people who are at risk of developing a pressure ulcer are likely to be unable to tolerate lying in 1 position for a signigifcant period of time and in these situations, healthcare professionals should discuss tolerability and preferences with the person at risk. The evidence identified suggested that a lower frequency of repositioning (4 hour hour) was beneficial yet this was confounded by the use of a pressure redistributing mattress. However, the GDG considered that people at risk would be provided with a high specification mattress (in line with recommendation 29). The results were inconclusive for other frequencies of repositioning however the GDG felt that any patients who have the chance of developing a pressure ulcer should be turned at least every 6 hours. The evidence was extrapolated for patients in hospital populations to those in the community as the outcome of reducing pressure ulcer development should be the same and that the benefits of repositioning was important enough to be extended to this population. The GDG acknowledged that there were challenges in doing this in the community but that the impact of avoiding a pressure ulcer was likely to have a large impact on quality of life. Care packages should allow for this frequency of repositioning. The GDG emphasised that where a person is able to reposition themselves, they should be encouraged to do so, as this was likely to be more acceptable to the individual and require fewer resources. However, it was acknowledged that there are situations in which people would not be able to reposition themselves and in these scenarios, healthcare professionals should reposition individuals manually. No evidence was identified on the use of repositioning equipment (for example, hoists or slide sheets) however the GDG felt that the use of this equipment may be essential in repositioning some individuals (for example people who are obese) and therefore the recommendation highlighted the possible use of such devices. The GDG highlighted that where equipment was used for the repositioning of people at risk or high risk of developing a pressure ulcer, appropriate equipment should be used, in discussion with the individual.
Economic considerations	An original economic model was developed based on the best available clinical evidence. The primary clinical outcome included in the model was the development of a pressure ulcer, the probability of which varied according to each repositioning schedule. The probability data was taken from 1 key RCT identified in the clinical review.[215] Costs were calculated from an NHS and social services perspective, and the impact on quality of life was included for the proportion of individuals who developed a pressure ulcer. 4 hours in a semi-Fowler 30° position (the individual lies on their back with upper body high by 30°) and 4 hours in a lateral position 30°, was found to be cost-effective compared to 4 hours in a semi-Fowler 30° position and 2 hours in a lateral position 30° (ICER = £1,864,070). The population was people at high risk, and the majority were lying on pressure reducing devices (as per recommendation 29). The model was robust to the majority of sensitivity analyses surrounding key assumptions and data used to inform the model. However, the model did reveal that if the cost of treating a pressure ulcer is £11,584 (compared to £5,672 in the base case), repositioning every 3 hours during the night would be cost-effective compared to repositioning every 6 hours. The GDG did not think that this was an unrealistic scenario, as people at high risk are likely to develop more severe pressure ulcers

	which take a long time to heal and could feasibly cost this much to treat. No additional economic evidence was identified. The GDG felt that the evidence was not strong enough to pinpoint an exact time interval at which individuals should be repositioned, as the benefits, and therefore the economic impact, varied greatly between individuals. The GDG considered the evidence presented, and agreed that it would most likely be cost effective to reposition adults at the frequencies identified in the recommendation above. The GDG noted that the resource implications may be higher in a community setting, but agreed that the benefits were likely to be such that repositioning at the specified intervals was still likely to be cost-effective. In many situations repositioning would be undertaken during contact with a health care professional for other reasons and the additional resources required for repositioning would be small. Also note that it was assumed in the model that all adults required 2 members of staff to change their position, whereas many adults are able to reposition themselves, and in such cases the economic impact will be greatly reduced.
Quality of evidence	The evidence was graded as low to very low.The evidence either had serious or very serious imprecision and the studies had risk of bias. Studies used different repositioning regimens and some of them used repositioning in combination with different pressure redistributing devices. There were differences between studies in the use of risk assessment tools for identifying people who were at high risk. Some studies used standard care which did not include repositioning. The GDG did not consider this to be representative of the standard care provided within the NHS. The majority of evidence was based in different settings for example, ICU, nursing homes, geriatric wards. Older studies may have used adjunctive pressure redistributing devices of a different standard to those used in current practice. GDG consensus was used to develop the recommendation on repositioning those assessed to be at risk at least every 6 hours, as they thought this necessary as a minimum preventional strategy.
Other considerations	The GDG felt that it was important to consider an individuals' preference when offering repositioning, particularly when this takes place during the night-time. The GDG highlighted that the needs and preferences of each individual should be considered by the healthcare professional, emphasising that it is important that every person at risk understands the benefits of being repositioned. The GDG also highlighted that less frequent repositioning may impact upon an individual's comfort and tolerability and that this should also be considered when identifying the optimum frequency of repositioning. For example, some people who are at risk of developing a pressure ulcer are likely to be unable to tolerate lying in 1 position for a significant period of time and in these situations, healthcare professionals should discuss tolerability with the person at risk. The GDG referred to anecdotal evidence which suggested that there were often difficulties in obtaining access to repositioning equipment and therefore delays in accomplishing repositioning of an individual at risk may occur as a result. The GDG thus amended the recommendation to highlight that repositioning equipment should be made readily available and that healthcare professionals should ensure that the timing of access to equipment is considered when planning a prevention

	strategy.

9.3.2 Neonates, infants, children and young people

Recommendations	**15. Ensure that neonates and infants who are at risk of developing a pressure ulcer are repositioned at least every 4 hours.** **16. 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 where needed.** **17. 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.** **18. 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.**
Relative values of different outcomes	The GDG identified that the proportion of people developing new pressure ulcers and patient acceptability were the most critical outcomes to inform decision making, given that the primary goal of pressure ulcer prevention was to limit the number of new pressure ulcers. Acceptability was identified as being critical from the perspective of the patient, as it was noted that this could have a significant impact upon quality of life. Rate of development of new pressure ulcers, time to develop new pressure ulcers, time in hospital or NHS care and health related quality of life were considered important outcomes to inform decision making.
Trade-off between clinical benefits and harms	One RCT was identified, which included critically ill infants and children. Only 1 relevant outcome was included; incidence of pressure ulcers (grade 2 and above), which showed no clinical benefit for the prone position compared to the supine position. There were no studies identified for neonates, infants, children or young people which considered the frequency of repositioning therefore formal consensus using a modified Delphi was used to develop the recommendation.. The GDG used 1 statement from the Delphi consensus survey to inform the recommendation. The statement was 'Healthcare professionals should ensure that neonates, infants, children and young people at high risk of developing a pressure ulcer are repositioned at least every 4 hours'. The statement was accepted by the Delphi consensus panel. Further detail on the Delphi consensus survey can be found in Appendix N. The GDG discussed the statement and agreed that a recommendation should be developed. Qualitative comments gathered from the Delphi consensus panel suggested that there are situations in which there may be benefits from more frequent repositioning, particularly for people considered to be at high risk of developing a pressure ulcer. Additionally, the GDG felt that it was likely that benefits in pressure ulcer prevention gained by the adult population and identified in the evidence was likely to be applicable to the paediatric population. Additional comments from the panel also highlighted that there may be some cases in which the benefits of frequent repositioning are outweighed by the harms. For example, for some children

	the clinical condition may prevent frequent repositioning and in these cases, alternative strategies for achieving pressure reduction should be considered. The group also noted that there are some situations in which less frequent repositioning may be considered for example, those nearing the end of life for which repositioning is carried out for comfort. Given the potential benefits in the prevention of pressure ulcers, the GDG decided to amend the final recommendation to reflect these benefits, to favour repositioning every 4 hours. In addition, qualitative comments from the GDG highlighted the importance of ensuring that the frequency of repositioning is tailored to the needs of the individual. The panel and the GDG felt that some individuals at high risk of developing a pressure ulcer, including for example, children with a spinal cord injury or with neurological disease, may require more frequent repositioning and that this should be considered on an individual basis. The GDG therefore developed a recommendation to reflect the need for more frequent repositioning in high risk populations. Qualitative comments from the Delphi panel also identified that there was a need to ensure that processes were in place to ensure that healthcare professionals caring for a neonate, infant, child or young person were aware of the need for more frequent repositioning. Panel members suggested that this process may involve documenting an individualised care pathway, including the process for repositioning or a pathway outlining the times repositioning was required. The GDG did not feel that it was possible to recommend a specific method for documenting the need for increased repositioning because of the variety of examples suggested and the lack of evidence identified,. However, the group agreed that as the benefits of doing so were likely to outweigh harms in terms of the additional resource required, the need to document increased frequency of repositioning should be recommended.
Economic considerations	There are some costs associated with repositioning. Small children can be repositioned by nurses or carers in a few minutes, whereas heavier, immobile children may need 2 nurses or health care support workers for up to 10 minutes, at an estimated cost of £7-£12. The GDG noted that repositioning is crucial for pressure redistribution, and its benefit is supported by evidence from the Delphi consensus panel. The GDG considered the economic implications and concluded that repositioning will improve the quality of life of those with pressure ulcers, as well as reduce future treatment costs by preventing pressure ulcers. The improvement in quality of life and reduction in future treatment costs were considered likely to outweigh the costs.
Quality of evidence	One RCT was identified for critically ill infants and children. The study had only 1 relevant outcome, which was graded according to GRADE criteria, very low due to serious risk of bias and very serious imprecision. No RCTs or cohort studies were identified for neonates, infants, children or young people for frequency of repositioning. Formal consensus using a modified Delphi was therefore used to develop the recommendation. To inform the recommendation, the GDG used 1 statement which was included in Round 1 of the Delphi consensus survey and reached 77% consensus agreement. Further details can be found in Appendix N.
Other considerations	Qualitative comments from the Delphi consensus panel highlighted the importance of ensuring that any special considerations relating to settings in which a child may require repositioning were considered for example, in school. Other comments identified that many neonates and infants were likely to be

Recommendations	**19. Ensure that repositioning equipment is available to aid the repositioning of children and young people, where needed.** **20. Ensure that healthcare professionals are trained in the use of repositioning equipment.**
	repositioned frequently through their standard care, for example, when they are picked up and held or their nappy is changed.
Relative values of different outcomes	The GDG identified that the proportion of people developing new pressure ulcers and patient acceptability were the most critical outcomes to inform decision making, given that the primary goal of pressure ulcer prevention was to limit the number of new pressure ulcers. Acceptability was identified as being critical from the perspective of the patient, as it was noted that this may have a significant impact upon quality of life. Rate of development of new pressure ulcers, time to develop new pressure ulcers, time in hospital or NHS care and health related quality of life were considered important outcomes to inform decision making.
Trade-off between clinical benefits and harms	One RCT was identified, which included critically ill infants and children. Only 1 relevant outcome was included; incidence of pressure ulcers (grade 2 and above), which showed no clinical benefit for the prone position compared to the supine position. There were no studies identified for neonates, infants, children or young people regarding repositioning equipment therefore formal consensus using a modified Delphi was used to develop the recommendation. The GDG used 1 statement from the Delphi consensus survey to inform the recommendation; 'Healthcare professionals should ensure that repositioning equipment is made available to aid repositioning of young people, where clinically indicated'. The statement was accepted by the Delphi consensus panel in Round 1 of the Delphi consensus survey. Further detail on the Delphi consensus survey can be found in Appendix N. The GDG discussed the statement and agreed that a recommendation should be developed. Qualitative responses gathered from the Delphi consensus panel reported that there were often difficulties in obtaining access to repositioning equipment, despite benefits to both the individual and the healthcare professional. The GDG acknowledged that not all individuals within the paediatric population would require the use of repositioning equipment. However it was clear that the possible benefits gained from preventing pressure ulcers by facilitating repositioning were likely to be high and as such, outweigh any possible harm. Hence the GDG developed a recommendation to highlight that this equipment should be readily available for use by healthcare professionals in repositioning children and young people. Qualitative responses also highlighted the need to ensure that healthcare professionals were trained in the use of this equipment, so that it is used safely. The GDG agreed that this was important and developed a recommendation to reflect this need.
Economic considerations	There are some costs associated with repositioning equipment and associated training. Hoists are available in the majority of hospitals and are estimated to cost around £500-£1,500. Repositioning sheets can also be used in some cases, and can be obtained at a much lower cost of £12 for a reusable sheet (based on £57.77 for 5

	Laundraglidesheets), or £8 for a disposable sheet (based on £80.04 for 10 Disposaglide sheets). The GDG has considered the economic implications of the use of repositioning equipment, and concluded that these interventions will improve the safety and quality of life of the individual who needs to be repositioned. In addition, upfront costs will be mitigated through reductions in future treatment costs. The improvement in quality of life and reduction in future costs were considered likely to outweigh the costs. Qualitative responses also highlighted the need to ensure that healthcare professionals were trained in the use of this equipment, so that it is used safely. The GDG agreed that this was important and developed a recommendation to reflect this need.
Quality of evidence	One RCT was identified for critically ill infants and children. The study had only 1 relevant outcome, which was graded very low due to serious risk of bias and very serious imprecision. No RCTs or cohort studies were identified for neonates, infants, children or young people for repositioning equipment. Formal consensus using a modified Delphi was therefore used to develop the recommendation. To inform the recommendation, the GDG used 1 statement which was included in Round 1 of the Delphi consensus survey and reached 95% consensus agreement. Further details can be found in Appendix N.
Other considerations	There were no other considerations.

Recommendations	**21. 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.**
Relative values of different outcomes	The GDG identified that the proportion of people developing new pressure ulcers and patient acceptability were the most critical outcomes to inform decision making, given that the primary goal of pressure ulcer prevention was to limit the number of new ulcers. Acceptability was identified as being critical from the perspective of the patient, as it was noted that this could have a significant impact upon quality of life. Rate of development of new pressure ulcers, time to develop new pressure ulcers, time in hospital or NHS care and health related quality of life were considered important outcomes to inform decision making.
Trade-off between clinical benefits and harms	One RCT was identified, which included critically ill infants and children. Only 1 relevant outcome was included which was incidence of pressure ulcers (grade 2 and above), which showed no clinical benefit for the prone position compared to the supine position. There were no studies identified for neonates, infants, children or young people for reasons for repositioning therefore the GDG used formal consensus using a modified Delphi to develop the recommendation. The GDG used 1 statement from the Delphi consensus survey to inform the recommendation. The statement was 'In children and young people, who refuse repositioning, healthcare professionals should ensure that patients and carers understand the reasons for repositioning'. The statement was accepted by the Delphi consensus panel. Further detail on the Delphi consensus survey can be found in Appendix N. The GDG discussed the statement and agreed that a recommendation should be

	developed. Qualitative responses from the Delphi consensus panel discussed methods of ensuring that the need for repositioning is well understood by children and their parents or carers. Specifically, comments identified that pictures can be beneficial in providing information, particularly for individuals in whom English is not their first language. The GDG did not feel that it was possible to recommend a method by which the reasons for repositioning should be explained as the needs of each individual should be considered by the healthcare professional in identifying the best approach. The GDG did not identify any possible harms in ensuring that the reasons for repositioning were explained, particularly as it was felt that this was part of obtaining informed consent. However, the GDG felt that an increase in understanding was likely to result in the prevention of a greater number of pressure ulcers, due to the associated increase in the rates of repositioning. A recommendation was therefore developed to highlight the need to ensure that the reasons for repositioning were well understood. A number of comments from the panel also identified that the use of the word 'decline' was more appropriate than 'refuse'. Other comments identified that parents and carers may decline repositioning on behalf of their child and therefore, the recommendation should also include these individuals. The recommendation was suitably amended to incorporate these changes.
Economic considerations	No economic considerations.
Quality of evidence	One RCT was identified for critically ill infants and children. The study had only1 relevant outcome, which was graded very low due to serious risk of bias and very serious imprecision. No RCTs or cohort studies were identified for neonates, infants, children or young people for understanding the reasons for repositioning. Formal consensus using a modified Delphi was therefore used to develop the recommendation. To inform the recommendation, the GDG used 1 statement which was included in Round 1 of the Delphi consensus survey and reached 100% consensus agreement. Further details can be found in Appendix N.
Other considerations	Panel members identified that where children, parents or carers decline repositioning, the reasons for repositioning should be clearly documented in the child's notes.

Recommendations	**22. Consider involving a play expert to encourage children who have difficulty with, or who have declined repositioning.**
Relative values of different outcomes	The GDG identified that the proportion of people developing new pressure ulcers and patient acceptability were the most critical outcomes to inform decision making, given that the primary goal of pressure ulcer prevention was to limit the number of new ulcers. Acceptability was identified as being critical from the perspective of the patient, as it was noted that this could have a significant impact upon quality of life. Rate of development of new pressure ulcers, time to develop new pressure ulcers, time in hospital or NHS care and health related quality of life were considered important outcomes to inform decision making.

Trade-off between clinical benefits and harms	One RCT was identified, which included critically ill infants and children. Only 1 relevant outcome was included which was incidence of pressure ulcers (grade 2 and above), which showed no clinical benefit for the prone position compared to the supine position. There were no studies identified for neonates, infants, children or young people for the use of a play expert to encourage repositioning therefore the GDG used formal consensus using a modified Delphi to develop the recommendation. The GDG used 1 statement from the Delphi consensus survey to inform the recommendation. The statement was 'Healthcare professionals should consider the use of play experts to encourage repositioning in children who have difficulty with compliance.' The statement was accepted by the Delphi consensus panel. Further detail on the Delphi consensus survey can be found in Appendix N. The GDG discussed the statement and agreed that a recommendation should be developed. Qualitative comments received from members of the Delphi consensus panel focused on methods which the play expert may use to encourage repositioning. The GDG agreed that the use of play specialists to increase compliance with repositioning was likely to result in benefits in the prevention of pressure ulcers from an increase in rates of repositioning. The group felt that these benefits were likely to outweigh any harms in terms of resources and developed a recommendation to suggest that the use of a play expert should be considered.
Economic considerations	There are costs associated with the use of a play expert. The estimated cost per hour for a band 4-5 play expert is £26 (typical salary band identified by GDG members). The GDG considered these costs likely to be offset by the benefits of the intervention in terms of improvement in the person's quality of life and reductions in future treatment costs through the prevention of pressure ulcers.
Quality of evidence	One RCT was identified for critically ill infants and children. The study had only 1 relevant outcome, which was graded very low due to serious risk of bias and very serious imprecision. No RCTs or cohort studies were identified for neonates, infants, children or young people for use of a play expert to encourage repositioning. Formal consensus using a modified Delphi was therefore used to develop the recommendation. To inform the recommendation, the GDG used 1 statement which was included in Round 1 of the Delphi consensus survey and reached 97% consensus agreement. Further details can be found in Appendix N.
Other considerations	There are no other considerations.

Recommendations	**23. Relieve pressure on the scalp and head when repositioning neonates, infants, children and young people at risk of developing a pressure ulcer.**
Relative values of different outcomes	The GDG identified that the proportion of people developing new pressure ulcers and patient acceptability were the most critical outcomes to inform decision making, given that the primary goal of pressure ulcer prevention was to limit the number of new ulcers. Acceptability was identified as being critical from the perspective of the patient, as it was noted that this could have a significant impact upon quality of life. Rate of development of new pressure ulcers, time to develop new pressure ulcers, time in hospital or NHS care and health related quality of life were considered important outcomes to inform decision making.
Trade-off between clinical benefits and harms	One RCT was identified, which included critically ill infants and children. Only 1 relevant outcome was included which was incidence of pressure ulcers (grade 2 and above), which showed no clinical benefit for the prone position compared to the supine position. There were no studies identified for neonates, infants, children or young people for the relieving of scalp and head pressure when repositioning therefore the GDG used formal consensus using a modified Delphi to develop the recommendation. The GDG used 1 statement from the Delphi consensus survey to inform the recommendation. The statement was 'Repositioning neonates, infants, children and young people at risk of developing pressure ulcers should include ensuring that pressure on areas of the scalp of the head is also relieved.' The statement was included in Round 2 of the Delphi consensus survey after being identified as a relevant area for inclusion in qualitative comments gathered during Round 1. The statement was accepted by the Delphi consensus panel. Further detail on the Delphi consensus survey can be found in Appendix N. The GDG discussed the statement and agreed that a recommendation should be developed. The GDG felt that the benefits of recommending pressure redistribution were likely to be substantial in the subsequent prevention of pressure ulcer development and that the scalp and head were areas that neonates, infants, children and young people were likely to be at risk of developing pressure ulcers. The GDG could not identify any likely harms of relieving pressure in these areas and therefore a recommendation was developed to ensure that pressure redistribution in these areas was achieved to prevent the development of pressure ulcers.
Economic considerations	No additional economic considerations further to those discussed for repositioning.
Quality of evidence	One RCT was identified for critically ill infants and children. The study had only 1 relevant outcome, which was graded very low due to serious risk of bias and very serious imprecision. No RCTs or cohort studies were identified for neonates, infants, children or young people for the relieving of head and scalp pressure when repositioning. Formal consensus using a modified Delphi was therefore used to develop the recommendation. To inform the recommendation, the GDG used 1 statement which was included in Round 2 of the Delphi consensus survey and reached 96% consensus agreement. Further details can be found in Appendix N.
Other considerations	Qualitative comments from the Delphi consensus panel identified that there were

	other at risk areas which should be considered when repositioning this population for example, the scalp, and that any repositioning regimen should take into account and inspect all areas which may be at risk of developing a pressure ulcer. Recommendations on the provision of pressure redistributing devices for the prevention of occipital pressure ulcers in neonates, infants, children and young people can be found in Chapter 10.

10 Skin massage

10.1 Introduction

Skin massage has traditionally been used to prevent the development of pressure ulcers, on the assumption that massage increases local blood flow to tissue which have been subject to pressure. Gentle massage is often facilitated using a cream to reduce friction on the skin. Despite this, any benefit in the use of skin massage for the prevention of pressure ulcers is uncertain, and there is some suggestion that the benefits which may be seen are a result of the individual being repositioned and pressure on the at-risk site being relived. However, there is also the possibility of massage causing harm - massage or rubbing of vulnerable skin may exert shear stresses which may themselves potentially cause damage. In addition, it is also possible that the use of a cream or emollient as part of the massage regimen may increase epidermal hydration and prevent dermal stripping and the subsequent exposure of fragile dermal tissue. However, the effectiveness of skin massage as a means of pressure ulcer prevention is questionable as is rubbing (massage with some pressure). In view of the uncertainty of the benefits and the potential risks of too much pressure, the GDG was interested in identifying the effectiveness of skin massage or rubbing in preventing pressure ulcers.

10.2 Review question: What is the clinical and cost effectiveness of skin massage and rubbing in the prevention of pressure ulcers?

For full details see review protocol in Appendix C.

10.2.1 Clinical evidence (adults)

One study was included in the review.[57] Evidence from this study is summarised in the clinical GRADE evidence profile below (Table 36). See also the study selection flow chart in Appendix D, forest plots in Appendix I, study evidence tables in Appendix G and exclusion list in Appendix J.

Summary of included studies

Table 35: Summary of studies included in the review

Study	Intervention/comparison	Population	Outcomes	Comments
Duimel-Peeters 2007[57]	Massage with petroleum jelly versus massage with dimethyl sulfoxide (DMSO) cream versus no massage.	Residents of 8 Dutch nursing homes.	• Incidence of pressure ulcers.	4 weeks of treatment followed by a wash-out period of 2 weeks and another 4 weeks of treatment.

Table 36: Clinical evidence profile: massage with petroleum jelly plus position change versus position change only

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Massage with petroleumjelly + position change	Position change	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers (follow-up 4 weeks; assessed with the 4 grade system of the EPUAP using a transparent disk)[57]												
1	Randomised trial	Very serious [a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	13/31 (41.9%)	7/18 (38.9%)	RR 1.08 (0.53 to 2.20)	31 more per 1000 (from 183 fewer to 467 more)	Very low	Critical
							-	38.9%		31 more per 1000 (from 183 fewer to 467 more)		
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Skin damage												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcer												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) No details of allocation concealment were provided by the authors.It was not clear whether the outcome assessors were blinded

(b) The confidence interval crossed both MID points.

Table 37: Clinical evidence profile: massage with DMSO cream plus position change versus position change only

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Massage with DMSO cream + position change	Position change	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers(follow-up 4 weeks; assessed with the 4-grade system of the EPUAP using a transparent disk) [57]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	18/29 (62.1%)	7/18 (38.9%)	RR 1.6 (0.84 to 3.04)	233 more per 1000 (from 62 fewer to 793 more)	Very low	Critical
							-	38.9%		233 more per 1000 (from 62 fewer to 794 more)		
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Skin damage												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcer												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) No details of allocation concealment were provided by the authors. It was not clear whether the outcome assessors were blinded.
(b) The confidence interval crossed one MID point.

Table 38: Clinical evidence profile: massage with DMSO cream plus position change versus massage with petroleum jelly plus position change

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Massage with DMSO cream + position change	Massage with petroleum jelly + Position change	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers(follow-up 4 weeks; assessed with the 4-grade system of the EPUAP using a transparent disk) [57]												
1	Randomised trial	Very serious [a]	No serious inconsistency	Serious indirectness [b]	Serious[c]	None	18/29 (62.1%)	13/31 (41.9%)	RR 1.48 (0.90 to 2.45)	201 more per 1000 (from 42 fewer to 608 more)	Very low	Critical
							-	41.9%		201 more per 1000 (from 42 fewer to 608 more)		
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Skin damage												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcer												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) No details of allocation concealment were provided by the authors. It was not clear whether the outcome assessors were blinded.
(b) The protocol did not state different types of cream for massage.
(c) The confidence interval crossed 1 MID point.

10.2.2 Economic evidence (adults)

Published literature

No relevant economic evaluations of skin massage or rubbing for the prevention of pressure ulcers were identified.

One study was found which included massage as part of a more complex prevention strategy.[124] This study was not included as it evaluated the cost-effectiveness of the complex prevention strategies as a whole, and did not provide information on the cost-effectiveness of massage alone.

10.2.3 Clinical evidence (neonates, infants, children and young people)

No RCTs or cohort studies were identified. Recommendations were developed using a modified Delphi consensus technique. Further details can be found in Appendix N.

10.2.4 Economic evidence (neonates, infants, children and young people)

No relevant economic evidence was identified.

10.2.5 Evidence statements

10.2.5.1 Clinical (adults)

10.2.5.1.1 Massage with petroleum jelly plus position change versus position change only for the prevention of pressure ulcers

- One cross-over study (n= 79) showed there may be no clinical difference between the group that received massage with petroleum jelly plus position change compared to the group that only received position change for reducing the incidence of pressure ulcers (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rate of development of pressure ulcers
  - Time to develop new pressure ulcer
  - Time in hospital or NHS care
  - Health-related quality of life

10.2.5.1.2 Massage with DMSO cream plus position change versus position change only for the prevention of pressure ulcers

- One cross-over study (n= 79) showed there is potentially a clinical harm for massage with DMSO cream plus position change compared to the group that only received position change for reducing the incidence of pressure ulcers (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rate of development of pressure ulcers
  - Time to develop new pressure ulcer
  - Time in hospital or NHS care
  - Health-related quality of life

10.2.5.1.3 Massage with DMSO cream plus position change versus massage with petroleum jelly plus position change for the prevention of pressure ulcers

- One cross-over study (n= 79) showed massage with petroleum jelly plus position change is potentially more effective for reducing the incidence of pressure ulcers compared to massage with DMSO cream plus position change (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rate of development of pressure ulcers
  - Time to develop new pressure ulcer
  - Time in hospital or NHS care
  - Health-related quality of life

10.2.5.2 Economic (adults)

No evidence was identified.

10.2.5.3 Clinical (neonates, infants, children and young people)

No evidence was identified.

10.2.5.4 Economic (neonates, infants, children and young people)

No evidence was identified.

10.3 Recommendations and link to evidence

10.3.1 Adults

Recommendations	24. Do not offer skin massage or rubbing to adults to prevent a pressure ulcer.
Relative values of different outcomes	The proportion of participants developing new pressure ulcers was considered by the GDG to be the most important outcome, with patient acceptability and skin damage also considered critical outcomes for decision making. The GDG also considered the rate of development of new pressure ulcers, time to develop new pressure ulcer, time in hospital or NHS care and health related quality of life to be important outcomes. Data was only identified on the incidence of new pressure ulcers developed. No data was identified relating to patient acceptability or skin damage.
Trade off between clinical benefits and harms	One study was found which focused on massage for the prevention of pressure ulcers. However, the study was of limited applicability as both the intervention and control arms included massage with different topical preparations. The GDG noted that there were no benefits reported concerning the use of skin massage or rubbing, with or without preparations, for the prevention of pressure ulcers. There was some evidence of potential harm as there was a higher incidence of pressure ulcers in the massage or rubbing (with DMSO cream) in addition to position change group when compared to the position-change only group, or the petroleum jelly and position-change group. There were study limitations and wide

	confidence intervals. The GDG highlighted that in addition, skin at risk of developing pressure ulcers was likely to be fragile and as such, provision of skin massage or rubbing could potentially result in skin damage. A recommendation was therefore developed to emphasise that skin massage and rubbing should not be used for the prevention of pressure ulcers.
Economic considerations	No economic studies were identified. The GDG felt that the use of skin massage would lead to an increase in costs associated with staff time and the use of any skin preparations used. Additionally, the GDG noted that the increased incidence in pressure ulcers found in the clinical evidence review could lead to a reduction in quality of life, and an increase in pressure ulcer related treatment costs. Skin massage is therefore not considered to be either clinically or cost-effective.
Quality of evidence	Overall, the quality of the evidence identified was very low and only 1 study was identified that met the inclusion criteria, which was of limited applicability. The only outcome reported was 'incidence of new pressure ulcers developed', which was graded as very low quality.
Other considerations	The GDG agreed that it was important to highlight that the use of skin massage and rubbing may be detrimental to existing pressure ulcers. They also agreed that skin massage and rubbing may damage already fragile skin. Whilst acknowledging that skin massage and rubbing may increase patient contact and increase the opportunity and frequency of repositioning, the GDG do not support the use of skin massage or rubbing for the prevention of pressure ulcers. The GDG did highlight the importance of maintaining frequent contact with all patients and ensuring that all patients are repositioned in line with recommendations in chapter 9. Where emollients and topical skin preparations are applied for other purposes (for example, for dermatological and infection purposes), applications of these products should be continued. These products should be applied in line with manufacturer's instruction.

10.3.2 Neonates, infants, children and young people

Recommendations	**25. Do not offer skin massage or rubbing to neonates, infants, children and young people to prevent a pressure ulcer.**
Relative values of different outcomes	The proportion of participants developing new pressure ulcers was considered by the GDG to be the most important outcome, with patient acceptability and skin damage also considered critical outcomes for decision making. The GDG also considered the rate of development of new pressure ulcers, time to develop new pressure ulcers, time in hospital or NHS care and health related quality of life to be important outcomes. Data was only identified on the incidence of new pressure ulcers developed. No data was identified relating to patient acceptability or skin damage.
Trade-off between clinical benefits and harms	The GDG used 1 statement from the Delphi consensus survey to inform the recommendation. The statement was 'Healthcare professionals should not offer skin massage to neonates, infants, children and young people, for the prevention of pressure ulcers'. Further detail on the Delphi consensus survey can be found in

	Appendix N. The statement was not accepted by the Delphi consensus panel in Round 1 of the survey. Qualitative responses gathered from the Delphi panel during Round 1 suggested that panel members agreed that the use of skin massage was unlikely to be beneficial in the prevention of pressure ulcers. Specific comments were gathered in relation to neonates and infants, in whom the panel felt there was an increased risk of skin breakdown resulting from the use of skin massage. Panel members believed that populations undergoing end of life care, were likely to benefit from the use of skin massage. The GDG considered these comments in amending the statement for inclusion in Round 2 of the survey. It was acknowledged that the majority of comments gathered supported the message that skin massage was not useful as a pressure ulcer prevention strategy and that there were possible harms in populations of neonates, infants, children and young people who are at risk of developing pressure ulcers, namely in compromising integrity of the skin. However, some comments from members of the panel suggested that massage may be beneficial for purposes other than pressure ulcer prevention and the GDG therefore agreed that the statement would be clarified to emphasise that the use of skin massage of the area at risk, for the prevention of pressure ulcers was not recommended. The statement 'Healthcare professionals should not offer skin massage for the area at risk specifically for the prevention of pressure ulcers in neonates, infants, children and young people' was therefore developed for inclusion in Round 2 of the survey. The statement was not accepted by the Delphi consensus panel in Round 2 of the survey. However, qualitative responses gathered from the panel generally agreed with the statement that skin massage should not be used as a means of preventing pressure ulcers but continued ('I agree with this statement as it reinforces the importance of not offering skin massage -many practitioners believe this helps prevent pressure ulcers') and some comments continued to reinforce the benefits of massage for other purposes, for example, in children in end-of-life care. The GDG therefore felt that, in line with the recommendation developed for adults, skin massage should not be recommended for the prevention of pressure ulcers. Although the GDG acknowledged that skin massage may have benefits for other conditions and purposes outside the remit of the current guideline (for example, in end of life care), that there were unlikely to be benefits specifically in the prevention of pressure ulcers and that the potential harm to skin integrity may result in the development of additional pressure ulcers.
Economic considerations	The GDG felt that the use of skin massage would most likely lead to an increase in costs associated with staff time and any skin preparations used. As the GDG agreed that there were unlikely to be benefits of skin massage specifically in the prevention of pressure ulcers, and that there is potential harm, skin massage is not considered to be either clinically or cost-effective.
Quality of evidence	No RCTs or cohort studies were identified for neonates, infants, children or young people. Formal consensus using a modified Delphi was therefore used to develop the recommendation. To inform the recommendation, the GDG used 1 statement which was included in Round 1 of the Delphi consensus survey and reached 51% consensus agreement. The statement was therefore amended for inclusion in Round 2 of the Delphi consensus survey where it reached 70% consensus. Further details can be found in Appendix N.

Other considerations	There were no other considerations.

11 Nutritional supplements and hydration strategies

11.1 Introduction

Adequate hydration and nutritional intakes of, energy, protein, carbohydrate and micronutrients (vitamins and minerals) are all associated with skin integrity and the prevention of tissue breakdown. It is commonly considered that the development of pressure ulcers can be associated with an inadequate nutritional intake. Those who are underweight, immobile, overweight or obese are also considered as being at increased risk of developing pressure ulcers due to increased pressure reducing oxygen flow to the affected areas. It could therefore be hypothesised that achieving an ideal nutritional state would reduce the risk of developing pressure ulcers. In addition identification of those at risk of malnutrition would help in identifying those at risk of pressure ulcers. The use of validated nutritional screening tools is recommended by NICE clinical guideline 32 'Nutrition support for adults'. Once identified as being at risk of malnutrition appropriate treatment to improve nutritional state is required. The GDG considered whether the meeting of general requirements to improve nutritional state would be adequate in preventing pressure ulcer development or whether there were any additional requirements that would further prevent the development of pressure ulcers. Nutritional intervention to improve nutritional state is a lengthy process, starting with a focus on food first and moving to prescribable nutritional supplements when not successful. Prescribable nutritional supplements are sometimes considered a more reliable source of nutrients although palatability can also affect compliance. Whilst these supplements are often used in hospitals, in the community cost for the length of time required for an improvement in nutritional status can become an inhibitive factor.

The GDG was interested in considering whether there was any specific evidence of nutritional or hydration interventions that would help prevent the development of pressure ulcers. They considered studies that reviewed both malnourished and well-nourished populations.

In order to review possible nutritional treatments in preventing pressure ulcers, the GDG included all studies that examined an additional nutritional element above a standard diet. The GDG also searched for any studies that investigated hydration levels and its role in preventing the development of pressure ulcers.

11.2 Review question: What are the most clinically and cost-effective nutritional interventions for the prevention of pressure ulcers?

For full details see review protocol in Appendix C.

11.2.1 Clinical evidence (adults)

There were no limitations on sample size and only direct studies relating to pressure ulcers and nutrition or hydration were included. No indirect interventions, comparisons or outcomes were considered. Only randomised trials were included. Abstracts were not included unless there were no randomised trial full papers for the comparison. No studies were found for hydration strategies to prevent the occurrence of pressure ulcers.

A Cochrane Review by Langer (2003)[112] was found and reported 4 studies which are included in this review. The Cochrane Review did not meta-analyse the studies as the population, interventions and outcomes differed. For the purposes of this review, the results have been separated and meta-analysed. Initially, the GDG considered that it was possible to meta-analyse the studies to gain a greater confidence in the evidence and then report on heterogeneity of studies where this existed. Therefore, the Cochrane review was updated with 4 additional studies identified through searches,

Dennis (2005)[55], Craig (1998)[43], Theilla (2007)[201] and Oloffson (2007)[150]. Dennis (2005)[55], Craig (1998)[43] and Oloffson (2007)[150] did not focus on the development of pressure ulcers, but rather pressure ulcers were an event or complication that occurred during these trials.

In total, 5 RCTs comparing participants who received nutritional supplementation in addition to their standard diet (which was the hospital standard diet) to those who received only the standard hospital diet (Bourdel-Marchasson 2000, Houwing 2003,Hartgrink 1998, Delmi 1990 and Dennis 2005) were identified. These studies all included older people in hospital. Houwing (2003) and Hartgrink (1998) included people with a hip fracture, Delmi (1990) included people with fractured neck of femur, Bourdel-Marchasson (2000) included people who were critically ill and Dennis (2005) included people who have had a stroke. The study by Dennis (2005) was not aimed at the prevention of pressure ulcers but the incidence of pressure ulcers was included as a complication. Hartgrink (1998) gave participants a supplement of energy and protein by nasogastric tube compared to the standard hospital diet (Hartgrink 1998). The follow-up period for studies period ranged from 2 weeks to 6 months. The supplements included various compositions of protein, carbohydrate, vitamins and minerals.

One study (Craig 1998) included people with type 2 diabetes. They gave the participants a disease-specific (reduced-carbohydrate and modified fat) formula compared to the standard high carbohydrate formula. Participants were followed up for 3 months. Another study (Theilla 2007) gave people suffering from lung injury a macronutrient diet plus lipids and vitamins compared to a macronutrient diet alone. These people were followed up for 7 days. In 1 RCT (Oloffson 2007) with people who had a femoral neck fracture(where pressure ulcers was a complication), participants were given protein-enriched meals compared to normal postoperative care and were followed up for 4 months. Many of the studies did not specify whether people were malnourished. In the studies where this was specified the majority tended to be malnourished. In the studies where it was not stated there was often the assumption that the population was likely to be malnourished due to being older adults in hospital for fractures such as of the hip.

Studies were meta-analysed together, where they looked at nutritional supplements in addition to standard hospital diet (which mainly included energy and protein) versus the standard hospital diet (Bourdel-Marchasson 2000, Houwing 2003, Hartgrink 198, Delmi 1990 and Dennis 2005). Another meta-analysis of the studies of nutritional supplements included a study (Oloffson, 2007)[150] with a protein diet compared to the standard hospital diet since all of the interventions had a high proportion of protein.

Some of the studies gave the results separately by grade of pressure ulcer that occurred as well as all grades of ulcers that occurred. Therefore the results were split to show data for all pressure ulcers and for those with grade 2-4 ulcers (with details of the classification system of grading).

Summary of included studies

Study	Study design	Population	Interventions/comparison	Outcomes	Follow-up period (weeks)
Houwing 2003[91]	RCT Double blind	Older people with hip fracture	Standard diet with additional oral supplementation (high protein enriched with arginine zinc and antioxidants) versus standard diet with a placebo.	• Incidence of pressure ulcers; time to first day of pressure ulcer; mortality.	28 days
Bourdel-Marchasson 2000[24]	RCT Unblinded	Critically ill older people	Standard diet with additional oral supplementation (protein, fat, carbohydrate and minerals and vitamins) versus standard diet.	• Incidence of pressure ulcers	15 days.
Hartgrink 1998[88]	RCT Unblinded	Older people with hip fracture	Standard diet with tube feeding (energy, protein, Nutricia) versus standard diet	• Incidence of pressure ulcers	2 weeks
Delmi 1990[53]	RCT Unblinded	Older people with fractured neck of the femur	Standard diet with additional oral nutrition supplements (protein, carbohydrate, lipid, calcium, vitamin A, vitamin D, vitamins E, B1, B2, B6, B12, C, nicotinamide, folate, calcium pantothenate, biotin, and minerals) versus standard diet	• Incidence of pressure ulcers	Assessed at 14, 21 and 28 days and followed up at 6 months

Study	Study design	Population	Interventions/comparison	Outcomes	Follow-up period (weeks)
Craig 1998[43]	RCT double-blinded pilot study	Long term care residents with type 2 diabetes.	Disease-specific (reduced-carbohydrate, modified-fat) formula versus standard high-carbohydrate formula.	• Incidence of pressure ulcers	3 months
Theilla 2007[201]	RCT Unblinded	People who are critically ill, mechanically ventilated and suffering from acute lung injury	Macronutrient diet plus lipids (elcosapentanoic acid, gamma-linolenic acid, vitamins A, C and E) versus macronutrient diet read to feed (high fat, low carbohydrate, enteral formula)	• Incidence of pressure ulcers	7 days
Olofsson 2007[150]	RCT	Femoral neck fracture patients	Protein-enriched meals versus normal postoperative care	• Incidence of pressure ulcers; time in hospital	4 months follow-up
Dennis 2005[55]	Multicentre RCT	Elderly adults who have had a stroke and are in hospital	Normal hospital diet plus oral supplements versus normal hospital diet.	• Incidence of pressure ulcers; length of stay in hospital	6 months follow-up

Table 39: Clinical evidence profile: protein, fat, carbohydrate, minerals and vitamins supplement (twice daily 200kcal, protein 30%, fat 20%, carbohydrate 50%, zinc 1.8mg, vitamin C 15mg) and standard diet versus standard diet (participants not specified as malnourished but thought to be at higher risk as critically ill older population)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Nutritional supplement plus standard hospital diet	Standard hospital diet	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers –critically ill older adults[24]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious imprecision[b]	None[c]	118/295 (40%)	181/377 (48%)	RR 0.83 (0.7 to 0.99)	82 fewer per 1000 (from 5 fewer to 144 fewer)	Very low	Critical
								48%		82 fewer per 1000 (from 5 fewer to 144 fewer)		
Acceptability of supplements – compliance – critically ill older adults[24]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	N/A	None[d]	See footnote d	N/A	N/A	N/A	N/A	Critical
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) No details of sequence generation or allocation concealment were reported by the authors.
(b) The confidence interval crossed both MID points.
(c) Approximately 70% of participants consumed the supplement for a week or more. 75% of the participants consumed 75% or more of their daily dose.

Table 40: Clinical evidence profile: protein, carbohydrate, lipid, calcium, vitamin A, vitamin D, vitamins E, B1, B2, B6, B12, C, nicotinamide, folate, calcium pantothenate, biotin, and minerals supplement (250ml supplement energy 254kcal, protein 20.4g, carbohydrate 29.5g, lipid 5.8g, calcium 525mg, vitamin A 750 IU, vitamin Ds 25 IU) and standard hospital diet versus standard hospital diet (most participants nutritionally deficient)

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**Nutritional supplement plus standard hospital diet**	**Standard hospital diet**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
Incidence of pressure ulcers (at 6 months) – older adults with fractured neck of the femur[53]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None[f]	0/25[d] (0%)	2/27[d] (7.4%)	Peto OR 0.14 (0.01 to 2.31)	70 fewer per 1000 (from 190 fewer to 40 more)	Very low	Critical
Acceptability of treatment – compliance – older adults with fractured neck of the femur[53]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	N/A	None[f]	See footnote[e]	N/A	N/A	N/A	N/A	Critical
Time in hospital – older adults with fractured neck of the femur[53]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[c]	None[f]	Median 24 days (range 13-157) n=27	Median 40 days (range 10-259) n=32	p=0.09	-	Very low	Important
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to development f pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Nutritional supplement plus standard hospital diet	Standard hospital diet	Relative (95% CI)	Absolute	Quality	Importance
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) No details of sequence generation, allocation concealment or blinding were reported by the authors. There was a high drop-out rate. There were baseline differences in plasmas levels, which were lower in non-supplemented participants.
(b) The confidence interval crossed both MID points.
(c) No standard deviations given.
(d) This is the number at 6 months follow-up.
(e) The supplement was said to be well-tolerated and completely ingested and no side-effects were observed.
(f) A dietary survey of 50 daily measurements of foot intake showed energy intake was only 1100kcal (SD 300) per day - protein 34g (11) per day, calcium 400mg (250) per day. The supplement increased the intake of energy by 23%, protein 62%, calcium 130%. The supplements did not reduce the voluntary oral intake.

Table 41: Clinical evidence profile: nutritional supplement (360mL at 6.27kJml and 62.5gl in protein) plus standard hospital diet versus standard hospital diet (majority were undernourished)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Nutritional supplement plus standard hospital diet	Standard hospital diet	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers – older adults who have had a stroke[55]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	15/2016 (0.7%)	26/2007 (1.3%)	RR 0.57 (0.31 to 1.08)	6 fewer per 1000 (from 9 fewer to 1 more)	Very low	Critical
							-	1.3%		6 fewer per 1000 (from 9		

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Nutritional supplement plus standard hospital diet	Standard hospital diet	Relative (95% CI)	Absolute	Quality	Importance
										fewer to 1 more)		
Acceptability of supplements (compliance)– older adults who have had a stroke [55]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	N/A	N/A	See footnote[c]	N/A	N/A	N/A	N/A	Critical
Length of time in hospital (days) – older adults who have had a stroke [55]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	34.0 (48.0) n=2016	32.0 (46.0) n=2007	-	MD 2.00 higher (0.91 lower to 4.91 higher)	Low	Critical
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) The aim of the study was not to look at pressure ulcers and there were no details of pressure ulcers reported at start of the trial.The authors did nto conduct blinding to the treatment allocation. There was a higher drop-out rate than the event rate. The trial was stopped before the authors reached their target as no funding was available to continue beyond 2004 and to ensure the trial was closed in an orderly manner.

(b) The confidence interval crossed 1 MID point.

(c) Crude compliance rate of 79 (4%) did not receive any supplement. 48 of those who were supposed to only receive the normal diet had some supplements, crude compliance of 98%.

Table 42: Clinical evidence profile: tube fed energy, protein (1 litre Nutrion Steriflo Energy-plus - energy 1500kcal/l, protein 60 g/l) and standard diet versus standard diet (participants not specified as malnourished but assumed to be a higher risk as a population of older adults with hip fracture)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Nutritional supplement plus standard hospital diet	Standard hospital diet	Relative (95% CI)	Absolute	Quality	Importance
Incidence of grade 2-4 pressure ulcers (stage 0=normal skin, 1=persistent erythema of the skin, stage 2=blister formation, stage 3=superficial (sub)cutaneous necrosis, stage 4=subcutaneous necrosis, according to the Dutch consensus meeting for the prevention of pressure ulcers) – older adults who have a fractured hip[88]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	25/48 (52.1%)	30/53 (56.6%)	RR 0.92 (0.64 to 1.32)	45 fewer per 1000 (from 204 fewer to 181 more)	Very low	Critical
							-	56.6%		45 fewer per 1000 (from 204 fewer to 181 more)		
Incidence of all pressure ulcers – older adults who have a fractured hip[88]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[c]	None	30/48 (62.5%)	37/53 (69.8%)	RR 0.90 (0.68 to 1.19)	70 fewer per 1000 (from 223 fewer to 133 more)	Very low	Critical
							-	69.8%		70 fewer per 1000 (from 223 fewer to 133 more)		
Acceptability of supplement												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Nutritional supplement plus standard hospital diet	Standard hospital diet	Relative (95% CI)	Absolute	Quality	Importance
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) No details of sequence generation were provided. Allocation concealment and no blinding were reported by the authors. There was a high drop-out in both groups. Very few participants remained tube fed at 2 weeks (16/70). Blinding was not done as it was thought unethical to discomfort the control group with a nasogastric tube.

(b) The confidence interval crossed both MID points.

(c) The confidence interval crossed 1 MID point.

Table 43: Clinical evidence profile: disease-specific (reduced-carbohydrate, modified-fat) formula (1000kcal, 41.8g protein,93.7g carbohydrate, 55.7g fat) versus standard (high-carbohydrate) formula (1060kcal, 44.4g protein, 151.7g carbohydrate, 35.9g fat) (participants not specified as malnourished but assumed to be at higher risk as older adults in long-term care)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Disease-specific (reduced-carbohydrate, modified-fat) formula	Standard (high-carbohydrate) formula	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers – older adults with type 2 diabetes[43]												
1	Randomised trial	Very serious [a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	7/17 (41.2%)	8/15 (53.3%)	RR 0.77 (0.37 to 1.62)	123 fewer per 1000 (from 336 fewer to 331 more)	Very low	Critical

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**Disease-specific (reduced-carbohydrate, modified-fat) formula**	**Standard (high-carbohydrate) formula**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
							-	53.3%		123 fewer per 1000 (from 336 fewer to 330 more)		
Adverse events – older adults with type 2 diabetes[43]												
1	Randomised trial	Very serious [a]	No serious inconsistency	No serious indirectness	N/A	N/A	See footnote[c]	N/A	N/A	N/A	N/A	Critical
Acceptability of supplements												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) The study aim was not to look at pressure ulcers, it was only an event experienced during the study. No details of sequence generation or allocation concealment were provided by the authors.

(b) The confidence interval crossed both MID points.

(c) There were no statistically significant differences for number of adverse events reported.

(d) Disease-specific formula was 1000kca

Table 44: Clinical evidence profile: macronutrient diet plus lipids (elcosapentanoic acid, gamma-linolenic acid, vitamins A, C and E) versus macronutrient diet ready to feed (high fat, low carbohydrate, enteral) formula[c] (participants not specified as malnourished)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Macronutrient diet plus lipids, gamma-linolenic acid, vitamins A,C and E	Macronutrient diet ready to feed, high fat, low carbohydrate, enteral formula	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers – critically ill adultswho weremechanically ventilated with acute lung injury[201]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None[d]	8/46 (17.4%)	10/49 (20.4%)	RR 0.85 (0.37 to 1.97)	31 fewer per 1000 (from 129 fewer to 198 more)	Very low	Critical
							-	20.4%		31 fewer per 1000 (from 129 fewer to 198 more)		
Incidence of grade 2-4 pressure ulcers - critically ill adultswho weremechanically ventilated with acute lung injury [201]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None[d]	4/49 (8.2%)	6/49 (12.2%)	RR 0.71 (0.21 to 2.36)	36 fewer per 1000 (from 97 fewer to 167 more)	Very low	Critical
							-	12.2%				
Acceptability of supplements												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Macronutrient diet plus lipids, gamma-linolenic acid, vitamins A,C and E	Macronutrient diet ready to feed, high fat, low carbohydrate, enteral formula	Relative (95% CI)	Absolute	Quality	Importance
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) No details of sequence generation or allocation concealment were provided by the authors. No blinding was reported. The BMI was higher in the intervention group at baseline.
(b) The confidence interval crossed both MID points.
(c) Formulas contained: EPA+GLA – 62.5g/L protein, 105.5g/L carbohydrate, 93.7g/L lipids, 317IU/L vitamin E, 844mg/L vitamin C, 5.0 B-carotene (mg/L), 316g/L Taurine, 181mg/L L-carnitine; the control group – 62.6g/L protein; 105.7g/L carbohydrate; 92.1g/L lipids, 85IU/L vitamin E, 317mg/L vitamin C, 160mg/L taurine, 160mg/L L-carnitine. The lipids in EPA+GLA had 31.8% canola oil, 25% MCT, 20% fish oil, 3.2% soy lecithin the control group had 55.8% canola oil, 20% MCT, 14% corn oil, 7% high oleic safflower oil and 3.2% soy lecithin.
(d) Nutritional intake at baseline for EPA+GLA was 1053+/-351kcal/day (49%) and 1624+/-512 (69%) at day 7; the nutritional intake at baseline for the control diet was 1055+/-378kcal/day (57%), and 1420+/-437kcal/day (71%) at 7 days.

Table 45: Clinical evidence profile: protein-enriched meals[d] versus normal postoperative care (large proportion of participants were malnourished)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Protein-enriched meals	Normal postoperative care	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers – older adults with femoral neck fracture [150]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	7/83 (8.4%)	14/74 (18.9%)	RR 0.45 (0.19 to 1.04)	104 fewer per 1000 (from 153 fewer to 8 more)	Very low	Critical
							-	18.9%		104 fewer		

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Protein-enriched meals	Normal postoperative care	Relative (95% CI)	Absolute	Quality	Importance
										per 1000 (from 153 fewer to 8 more)		
Time in hospital (days) (Better indicated by lower values) – older adults with femoral neck fracture [150]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	Serious imprecision[c]	None	27.4 (14.9) days n=83	39.8 (41.9) days n=74	-	MD 12.4 lower (22.47 to 2.33 lower)	Low	Important
Acceptability of supplements												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) Participants were randomised to different wards. No blinding was reported by the authors. There was a higher drop-out rate than the event rate.

(b) The confidence interval crossed 1 MID point.

(c) There were a limited number of events.

(d) The intervention group had a nutritional journal for the first 4 days whilst the participants nutritional deficiencies were established. Protein-enriched meals were calculated at approximately 30 calories per kilo body weight to supply the extra energy requirement for the first four postoperative days or longer if required. At lunch an appetiser was served with the protein-enriched meals and a dessert at dinner. If the participants were malnourished on admission the nurses found out when or why they lost their appetite to see if the participants needed even more energy/calories. If the individual had problems in these areas a dietitian was consulted. The participants in the intervention group also received 2 nutritional protein drinks 2x200ml daily while hospitalised. Additional nutritional and protein drinks were served after every meal for participants who needed extra calories. The environment was also optimised to facilitate the intake of nutrition eg no unnecessary noise. The control group had conventional postoperative care routines.

Table 46: Clinical evidence profile: oral supplements plus standard hospital diet versus standard hospital diet (mixed population)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Nutritional supplement	Standard hospital diet	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers[24,53,55,88,91]												
5	Randomised trials	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	185/2435 (7.6%)	269/2516 (10.7%)	RR 0.82 (0.71 to 0.95)	19 fewer per 1000 (from 5 fewer to 31 fewer)	Very low	Critical
							-	48%		86 fewer per 1000 (from 24 fewer to 139 fewer)		
Acceptability of supplements												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) The authors provided unclear details of sequence generation and allocation concealment. The majority of studies had a lack of blinding. Some trials had high level of missing data in both groups.

(b) The confidence interval crossed 1 MID point.

The results were pooled for all studies that included an oral supplement compared to normal hospital diet, as the main constituents of the supplement were protein and energy.

Table 47: Clinical evidence profile: nutritional supplementation (supplements or diet containing protein and energy) plus standard hospital diet versus standard hospital diet (mixed population)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Nutritional supplements /diet	Standard hospital diet	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers[24,53,55,88,91,150]												
6	Randomised trials	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	192/2518 (7.6%)	283/2590 (10.9%)	RR 0.8 (0.69 to 0.92)	22 fewer per 1000 (from 9 fewer to 34 fewer)	Very low	Critical
							-	33.5%		67 fewer per 1000 (from 27 fewer to 104 fewer)		

(a) There were unclear details of sequence generation and allocation concealment reported. The majority of studies had a lack of blinding. Some trials had high level of missing data in both groups.

(b) The confidence interval crossed 1 MID point.

The results were pooled for all studies that included nutritional supplementation compared to a normal hospital diet, as the main constituents of the supplement were protein and energy. This included a study of nutritional supplements which were given by tube feeding

11.2.2 Economic evidence (adults)

Published literature

Two studies were included with the relevant comparison.[159,168] These are summarised in the economic evidence profile below (Table 48). See also the study selection flow chart in Appendix D and study evidence tables in Appendix H.

Two studies were selectively excluded[10,13] – these are summarised in Appendix K, with reasons for exclusion given.

From Table 39 it is clear that both of the included studies found that the nutritional interventions improved clinical outcomes. However, Rypkema and colleagues found that the intervention reduced costs, and Pham and colleagues found that the nutritional intervention increased costs. This is because in the study reported by Rypkema, the reduction in pressure ulcers led to a reduction in nursing days, antibiotics and diagnostics for nosocomial infections, yet in the Pham study the reduction in pressure ulcer incidence was not sufficient for the reduction in treatment costs to outweigh the initial cost of the intervention. Note that the effectiveness evidence in the Pham paper was obtained from a meta-analysis of four RCTs, yet the equivalent evidence in the Rypkema paper was obtained from a single prospective controlled study. A further notable difference is that the 2 studies approach correction of nutritional deficiency differently: Pham and colleagues report daily provision of nutritional supplementation in the intervention group, whereas Rypkema and colleagues explain that the use of nutritional supplementation was actually higher in the control group, as those in the intervention group were more likely to receive protein, energy-enriched meals and drinks prepared by the hospital kitchen. Additional kitchen staff time has been accounted for in the cost analysis, but it is not clear whether the additional food items have been accounted for. In the latter study the use of pressure ulcer prevention mattresses was higher in the intervention group than in the control group, thus the difference in costs and effects may not be solely attributable to the nutritional intervention.

A weakness to the analysis presented by Pham and colleagues, is that the increase in quality of life due to the intervention is only associated with the prevention of pressure ulcers. Therefore when averaged over all patients, the increase in QALYs is just 0.00008. However, in reality, the benefits of correcting nutritional deficiency extend far beyond the prevention of pressure ulcers, and would lead to a much greater increase in quality of life than is captured by this analysis. Therefore the results bias away from the nutritional intervention. In order for the nutritional intervention to be considered cost effective at the £20,000 per QALY threshold, the intervention would need to produce a QALY gain of 0.0241

Table 48: Economic evidence profile: Nutritional supplementation versus standard care

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effects	Cost effectiveness	Uncertainty
Pham 2011[159] (Canada)	Partially applicable[a]	Potentially serious limitations[b]	A decision analytic model that uses a markov model of 1 week cycle length and considers patients of both high and low risk. Daily oral nutritional supplements (for exampledaily drinks of 237ml, 2kcal/ml) to high-risk residents with recent weight loss is compared to a standard hospital diet in elderly hospital patients.	£482	0.00008 QALYs	£5,160,924 per QALY gained	Including excess mortality attributable to pressure ulcers and including supply costs only reduced the ICER yet the intervention was still not deemed cost-effective. At a willingness to pay of $50,000 (£32,978) per additional QALY, there is a 1% chance that this intervention is cost—effective.
Rypkema 2004[168] (The Netherlands)	Partially applicable[c]	Potentially serious limitations[d]	A within study analysis (prospective controlled study) with analysis of individual level data. An intervention in which all patients admitted to a geriatric ward were screened for malnutrition, dysphagia and dehydration and treated accordingly, was compared to standard care.	-£285	Pressure ulcer incidence: -0.04	The intervention dominated standard care, with lower costs and reduction in incidence of pressure ulcers.	Length of stay was tested in sensitivity analysis, using the lower and upper confidence interval values. The incremental cost was found to vary between -£1,177 and £607 per patient.

(a) Study based in Canadian health care setting

(b) Utility data is not calculated from EQ-5D or SF-36 data. Baseline health estimates and progression of pressure ulcers through the various stages are estimated from RAI-MDS instead of obtained via a systematic procedure.

(c) Study based in The Netherlands, quality of life not considered.

(d) Effectiveness and resource use estimates based solely on this prospective study, nutritional supplementation not described in detail. Uncertainty is not thoroughly explored. Control and intervention arms were carried out in separate locations, and preventative efforts (other than just the nutritional protocol) differed. For example the use of pressure ulcer prevention mattresses was higher in the intervention group. Differences in costs and effects may not be completely due to the nutritional intervention.

Unit costs

Unit costs of common nutritional supplements are provided below to aid consideration of cost effectiveness. These costs represent costs per day of supplements used in the prevention of pressure ulcers. These are the list prices, and the GDG acknowledged that the actual price paid is often much lower than those stated in the table below. The specific supplements included are illustrative only, and should not be interpreted as GDG recommendations.

Table 49: Unit cost estimates per day for nutritional supplements in a community setting

Item	Cost	Notes
Vitamin C (200mg)	£0.14	£1.31 per packet of 28 tablets. 3 tablets per day.
High protein supplements[a] (200ml)	£3.70	Fortisip extra. £1.85 per 200ml bottle. 2 bottles given per day.

(a) Such supplements also contain further beneficial ingredients such as Zinc and Arginine

Source: BNF62[100], dosage based on discussion with GDG member

Total costs depend on the duration that nutritional supplementation is provided, and will vary greatly amongst patients. Monthly costs of vitamin C and protein supplementation would be £4.34 and £114.70 respectively.

11.2.3 Clinical evidence (neonates, infants, children and young people)

No RCTs or cohort studies were identified. Recommendations were developed using a modified Delphi consensus technique. Further details can be found in Appendix N.

11.2.4 Economic evidence (neonates, infants, children and young people)

No economic evidence was identified.

11.2.5 Evidence statements

11.2.5.1 Clinical (adults)

11.2.5.1.1 A supplement containing protein, fat, carbohydrates, minerals and vitamins versus standard diet

- One study (n=672) showed there is potentially no clinical difference between a supplement containing protein, fat, carbohydrates, minerals and vitamins and standard diet for reducing the incidence of pressure ulcers, but the direction of effect favoured the supplement (very low quality).
- One study (n=672) reported compliance of 60% for the first week and 99% for the 2nd week for the supplements group. The clinical importance and imprecision is unknown.
- No evidence was found for the following outcomes:
  - Rate of development of pressure ulcers
  - Time to development of pressure ulcers
  - Time in hospital or NHS care
  - Health-related quality of life

11.2.5.1.2 A supplement containing high amounts of protein, arginine, zinc and antioxidants versus a standard diet

- One study (n=103) showed there may be no clinical difference between a supplement containing high amounts of protein, arginine, zinc and antioxidants and a standard diet for reducing the

incidence of pressure ulcers (all grades), but the direction of the estimate of effect could favour the supplement (very low quality).

- One study (n=103) showed there may be no clinical difference between a supplement containing high amounts of protein, arginine, zinc and antioxidants and a standard diet for reducing the incidence of pressure ulcers (grade 2 and above), but the direction of the estimate of effect could favour the supplement (very low quality).
- One study (n=103) reported compliance of 70% for a supplement containing high amounts of protein, arginine, zinc and antioxidants. The clinical importance and imprecision is unknown.
- No evidence was found for the following outcomes:
  - Rate of development of pressure ulcers
  - Time to development of pressure ulcers
  - Time in hospital or NHS care
  - Health-related quality of life

11.2.5.1.3 A supplement containing protein, carbohydrate, lipid, calcium, vitamin A, vitamin D, vitamins E, B1, B2, B6, B12, C, nicotinamide, folate, calcium, pantothenate, biotin, and minerals versus a standard diet

- One study (n=52) showed there may be no clinical difference between a supplement containing protein, carbohydrate, lipid, calcium, vitamin A, vitamin D, vitamins E, B1, B2, B6, B12, C, nicotinamide, folate, calcium, pantothenate, biotin, and minerals and standard diet for reducing the incidence of pressure ulcers, but the direction of the estimate of effect could favour the supplement (very low quality).
- One study (n=52) reported a supplement containing protein, carbohydrate, lipid, calcium, vitamin A, vitamin D, vitamins E, B1, B2, B6, B12, C, nicotinamide, folate, calcium pantothenate, biotin, and minerals was said to be well-tolerated and completely ingested and no side-effects were observed. The clinical importance is unknown (very high quality).
- One study (n=52) reported medians for a supplement containing protein, carbohydrate, lipid, calcium, vitamin A, vitamin D, vitamins E, B1, B2, B6, B12, C, nicotinamide, folate, calcium pantothenate, biotin, and minerals and the standard diet for time in hospital. The median for the supplement was 24 days (range 13-157) and 40 days (range 10-259) for the standard diet. No estimate of effect or precision could be derived.
- No evidence was found for the following outcomes:
  - Rate of development of pressure ulcers
  - Time to development of pressure ulcers
  - Health-related quality of life

11.2.5.1.4 A nutritional supplement (360mL at 6.27kJmL and 62.5gL in protein) versus a standard hospital diet

- One study (n=4023) showed there is potentially no clinical difference between a nutritional supplement (360mL at 6.27kJmL and 62.5gL in protein) and standard hospital diet for reducing the incidence of pressure ulcers, but the direction of the estimate favoured the supplement (low quality).
- One study (n=4023) reported evidence between nutritional supplement (360mL at 6.27kJmL and 62.5gL in protein) and standard hospital diet. There was a crude compliance rate of 96% for the normal diet group, where 48 people who were supposed to receive the normal diet received some supplements. The supplement group had a crude compliance rate of 98%. The clinical importance and imprecision is unknown.
- One study (n=4023) showed there is potentially no clinical difference between a nutritional supplement (360mL at 6.27kJmL and 62.5gL in protein) and standard hospital diet for length of time in hospital, but the direction of effect favoured the standard hospital diet (low quality).
- No evidence was found for the following outcomes:

- Rate of development of pressure ulcers
- Time to development of pressure ulcers
- Health-related quality of life

11.2.5.1.5 A supplement of tube fed energy and protein versus standard diet

• One study (n= 101) showed there is potentiallly no clinical difference between a supplement of tube fed energy and protein and standard diet for reducing the incidence of pressure ulcers (grade 2 and above), but the direction of effect could favour the supplement (very low quality).

• One study (n= 101) showed there may be no clinical difference between a supplement of tube fed energy and protein and standard diet for reducing the incidence of pressure ulcers (all grades), but the direction of effect could favour the supplement (very low quality).

- No evidence was found for the following outcomes:
  - Rate of development of pressure ulcers
  - Time to development of pressure ulcers
  - Time in hospital or NHS care
  - Health-related quality of life

11.2.5.1.6 A disease-specific supplement (reduced-carbohydrate, modified-fat formula) and a standard high-carbohydrate formula

• One study (n=32) showed there may be no clinical difference between a disease-specific supplement (reduced-carbohydrate, modified-fat formula) and a standard high-carbohydrate formula for reducing the incidence of pressure ulcers, but the direction of effect could favour the supplement (very low quality).

• One study (n=32) reported no differences for number of adverse events reported. The clinical importance and imprecision is unknown.

- No evidence was found for the following outcomes:
  - Acceptability of treatment
  - Rate of development of pressure ulcers
  - Time to development of pressure ulcers
  - Time in hospital or NHS care
  - Health-related quality of life

11.2.5.1.7 A macronutrient diet plus lipids (eicosapentanoic acid, gamma-linolenic acid, vitamins A, C and E) versus a macronutrient diet (high fat, low carbohydrate, enteral formula)

• One study (n=96) showed there may be no clinical difference between a macronutrient diet plus lipids (eicosapentanoic acid, gamma-linolenic acid, vitamins A, C and E) and a macronutrient diet (high fat, low carbohydrate, enteral formula) in mechanically ventilated critically ill adults for reducing the incidence of pressure ulcers (all grades), but the direction of effect could favour the supplement (very low quality).

• One study (n=98) showed there may be no clinical difference between a macronutrient diet plus lipids (eicosapentanoic acid, gamma-linolenic acid, vitamins A, C and E) and a macronutrient diet (high fat, low carbohydrate, enteral formula) in mechanically ventilated critically ill adults for reducing the incidence of pressure ulcers (grade 2 and above), but the direction of effect could favour the supplement (very low quality).

- No evidence was found for the following outcomes:
  - Acceptability of treatment
  - Rate of development of pressure ulcers
  - Time to development of pressure ulcers

- Time in hospital or NHS care
- Health-related quality of life

11.2.5.1.8 A protein-enriched meal versus normal postoperative care

- One study (n=157) showed a protein-enriched meal is potentially more clinically effective at reducing the incidence of pressure ulcers when compared to normal postoperative care (very low quality).
- One study (n=157) showed there is potentially no clinical difference between a protein-enriched meal and normal postoperative care for time in hospital, the direction of effect favoured the protein-enriched meal (low quality).
- No evidence was found for the following outcomes:
  - Acceptability of treatment
  - Rate of development of pressure ulcers
  - Time to development of pressure ulcers
  - Health-related quality of life

11.2.5.1.9 Oral supplements versus normal hospital diet

- Five studies pooled (n=4951) showed there is potentially no clinical difference between oral supplements and normal hospital diet for reducing the incidence of pressure ulcers, the direction of effect favoured the oral supplements (very low quality).

11.2.5.1.10 Nutritional supplementation versus normal hospital diet

- Six studies pooled (n=5108) showed there is potentially no clinical difference between nutritional supplementation and normal hospital diet for reducing the incidence of pressure ulcers, the direction of effect favoured the oral supplements (very low quality).

11.2.5.2 Economic (adults)

- One cost-utility analysis found that a strategy of providing daily oral nutritional supplements to high risk residents with recent weight loss was not cost effective (ICER: £5,160,924) compared to standard care. This study was assessed as partially applicable with potentially serious limitations.
- One cost-consequence analysis found that an intervention in which people were screened for malnutrition, dysphagia and dehydration on admission, and treated accordingly, dominated standard care (lower costs and lower incidence of pressure ulcers). This study was assessed as partially applicable with potentially serious limitations.

11.2.5.3 Clinical (neonates, infants, children and young people)

No evidence was identified.

11.2.5.4 Economic (neonates, infants, children and young people)

No evidence was identified.

11.3 Recommendations and link to evidence

11.3.1 Adults

Recommendations	**26. Do not offer nutritional supplements specifically to prevent a pressure ulcer in adults whose nutritional intake is adequate.**
Relative values of different outcomes	The GDG identified that the proportion of people developing new pressure ulcers and patient acceptability were the most critical outcomes to inform decision making, given that the primary goal of pressure ulcer prevention was to limit the number of new ulcers. Acceptability was identified as being critical from the perspective of the patient, as it was noted that this could have a significant impact upon quality of life. Rate of development of new pressure ulcers, time to develop new pressure ulcers, time in hospital or NHS care and health related quality of life were considered important outcomes to inform decision making.
Trade off between clinical benefits and harms	The evidence identified was mainly in people whose nutritional status was not adequate and therefore was of limited applicability to people with adequate nutritional status. Each study used different supplementation and results varied. The results of 1 study were contradictory showing that there was a clinical benefit of nutritional supplements in people with a hip fracture for pressure ulcers grade 2 and above, but no difference for all grades of pressure ulcer (including grade 1), whereas another study of people with hip fracture who were tube-fed showed there was no difference. Another 3 studies in people with fractured neck of femur and older people who had had a stroke showed no clinical benefit of supplementation. One study of older people with type 2 diabetes in long-term care showed a clinical benefit for the reduced incidence of pressure ulcers for a reduced-carbohydrate, modified-fat formula compared to a standard high-carbohydrate formula. There was no clinical difference for a macronutrient diet plus lipids compared to a macronutrient ready to feed diet in critically ill, mechanically ventilated people with acute lung injury. Protein enriched meals had a clinical benefit in reducing the incidence of pressure ulcers for older people with femoral neck fractures compared to normal post-operative care. Two studies showed a lower time in hospital for people who received supplementation, whereas 1 found an increased time in hospital for people who received supplementation. The evidence included a variety of components in the supplements, thus it is not possible to isolate which specific component provided benefit. Overall, there was an unclear clinical benefit of nutritional supplementation for the prevention of pressure ulcers in populations which included people who had inadequate nutritional status. As such, the GDG felt that for the prevention of pressure ulcers, it was unlikely that it was beneficial to provide specific nutritional supplementation to people with adequate nutrition and were unable to develop a recommendation in support of providing nutritional supplementation for this population. However, it was acknowledged that in clinical practice, it is likely that people at risk of developing pressure ulcers may also be at risk of having an inadequate nutritional status (for example older people) and it is important that any nutritional deficiency is corrected in these populations.
Economic considerations	The economic evidence focused on people who were malnourished. One cost-utility analysis found that daily nutritional supplements were not cost effective in people with recent weight loss (at a threshold of £20,000 per QALY) for the prevention of pressure ulcers. However, the GDG noted that correction of nutritional deficiency has benefits which extend far beyond prevention of pressure ulcers, and such health benefits were not captured in the analysis. The GDG felt strongly that had such health benefits been included in the analysis, correction of nutritional deficiency

	would have been found cost-effective. Another economic analysis found that a nutritional intervention was cost saving, although the GDG noted the limited applicability and limitations of both of these studies. The GDG decided that there was limited additional benefit to providing extra nutritional supplementation where nutritional status was adequate, and that it would not be cost-effective to do so.
Quality of evidence	The GRADE rating of the evidence for the effectiveness of nutritional interventions on the prevention of pressure ulcers was low to very low quality. This was mainly due to serious or very serious imprecision and risk of bias in the studies. In all cases, the population focused on a population of older adults. It was not possible to conduct a meta-analysis of the randomised trials included in the review due to heterogeneity in the components of the supplements used, the population and the outcomes considered.
Other considerations	The GDG considered that this recommendation relates to the provision of adequate nutrition and that this should be provided in line with the NICE clinical guideline 138 'Patient Experience' and NICE clinical guideline 32'Nutrition support in adults'.

Recommendations	**27. Do not offer subcutaneous or intravenous fluids specifically to prevent a pressure ulcer in adults whose hydration status is adequate.**
Relative values of different outcomes	The GDG identified that, the proportion of people developing new pressure ulcers and patient acceptability were the most critical outcomes to inform decision making, given that the primary goal of pressure ulcer prevention was to limit the number of new ulcers. Acceptability was identified as being critical from the perspective of the patient, as it was noted that this could have a significant impact upon quality of life. Rate of development of new pressure ulcers, time to develop new pressure ulcers, time in hospital or NHS care and health related quality of life were considered important outcomes to inform decision making.
Trade off between clinical benefits and harms	No data was identified on the effectiveness of hydration strategies for the prevention of pressure ulcers. The GDG did not consider that there would be any benefit for the prevention of pressure ulcers for providing additional subcutaneous or intravenous fluids, where hydration status is adequate. Furthermore, the group felt that there were potential harms associated with providing hydration beyond that needed to achieve adequate hydration status. A recommendation was therefore developed using informal consensus of the GDG.
Economic considerations	No economic evidence on the cost effectiveness of hydration strategies in the prevention of pressure ulcers was identified.
Quality of evidence	No data was identified on the effectiveness of hydration strategies in the prevention of pressure ulcers. The GDG acknowledged that the nutritional interventions employed may affect hydration, as well as nutritional status. The recommendation was therefore based upon informal consensus of the GDG.
Other considerations	The GDG agreed that it was important that people were provided with adequate hydration, regardless of the effectiveness in preventing pressure ulcers. Recommendations on the provision of intravenous fluids for adults will be found in NICE clinical guideline 'Intravenous fluids therapy in adults' (currently in development) and NICE clinical guideline 138 'Patient experience in adult NHS services'.

11.3.2 Neonates, infants, children and young people

Recommendations	28. 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.
Relative values of different outcomes	The GDG identified that the proportion of people developing new pressure ulcers and patient acceptability were the most critical outcomes to inform decision making, given that the primary goal of pressure ulcer prevention was to limit the number of new ulcers. Acceptability was identified as being critical from the perspective of the patient, as it was noted that this could have a significant impact upon quality of life. Rate of development of new pressure ulcers, time to develop new pressure ulcers, time in hospital or NHS care and health related quality of life were considered important outcomes to inform decision making.
Trade-off between clinical benefits and harms	The GDG used 1 statement from the Delphi consensus survey to inform the recommendation. The statement was 'Healthcare professionals should not offer nutritional supplementation to neonates, infants, children or young people at risk of developing pressure ulcers, where nutritional intake is adequate for developmental age and comorbidities.' Further detail on the Delphi consensus survey can be found in Appendix N. The statement was not accepted by the Delphi consensus panel and was therefore amended by the GDG for inclusion in Round 2 of the survey. Qualitative comments gathered from Round 1 focused on the need to ensure that neonates, infants, children and young people at risk of developing a pressure ulcer are treated on an individual basis, with care tailored to the child. Comments suggested that there were some situations in which the panel felt that it would be appropriate to provide nutritional supplementation for the prevention of pressure ulcers. However, comments identified that this should only be considered after consultation with a paediatric dietitian or dietitian with experience of working with these age groups. The GDG considered the qualitative feedback and felt that the statement should be clarified to emphasise that nutritional supplementation should not be given specifically for the prevention of pressure ulcer in neonates, infants, children and young people who have been identified as having adequate nutritional status following assessment. The GDG therefore amended the statement to 'Following nutritional assessment, if nutritional status is adequate, taking into account developmental age and comorbidities, healthcare professionals should not give further supplementation specifically for the prevention of pressure ulcers in neonates, infants, children and young people' for inclusion in Round 2. The statement was included in Round 2 of the survey and was accepted by the Delphi consensus panel. Qualitative responses from the panel generally felt that the statement was improved however, a minority of individuals still felt that there might be situations in which nutritional supplementation would be beneficial in the prevention of pressure ulcers. The GDG considered all the responses and developed a recommendation to reflect the statement, that nutritional supplementation should not be given for the prevention of pressure ulcers. The GDG highlighted that this was in line with the recommendation developed for adults and that, there were no identified benefits in the prevention of pressure ulcers for a population with adequate nutritional status. The GDG acknowledged that individuals with nutritional deficiencies should always have these deficiencies corrected and therefore the recommendation was worded to

	account for individuals whose nutritional status may not be appropriate for their developmental age or their clinical condition.
Economic considerations	The GDG felt there was limited additional benefit to providing extra nutritional supplementation where nutritional status was adequate, and agreed that it would not be cost effective to do so.
Quality of evidence	No RCTs or cohort studies were identified for neonates, infants, children or young people. Formal consensus using a modified Delphi was therefore used to develop the recommendation. To inform the recommendation, the GDG used 1 statement which was included in Round 1 of the Delphi consensus survey and reached 45% consensus agreement. The statement was therefore amended and included in Round 2 of the consensus, where it reached 77% agreement. Further details can be found in Appendix N.
Other considerations	There were no other considerations.

Recommendations	**29. 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.**
Relative values of different outcomes	The GDG identified that the proportion of people developing new pressure ulcers and patient acceptability were the most critical outcomes to inform decision making, given that the primary goal of pressure ulcer prevention was to limit the number of new ulcers. Acceptability was identified as being critical from the perspective of the patient, as it was noted that this could have a significant impact upon quality of life. Rate of development of new pressure ulcers, time to develop new pressure ulcers, time in hospital or NHS care and health related quality of life were considered important outcomes to inform decision making.
Trade-off between clinical benefits and harms	The GDG used 1 statement from the Delphi consensus survey to inform the recommendation. The statement was 'Healthcare professionals should not offer hydrational supplementation to neonates, infants, children or young people at risk of developing pressure ulcers, where hydrational intake is adequate for developmental age and associated fluid losses.' Further detail on the Delphi consensus survey can be found in Appendix N. The statement was not accepted by the Delphi consensus panel and was therefore amended by the GDG for inclusion in Round 2 of the survey. Qualitative comments gathered via Round 1 suggested that any decision as to whether the use of further hydration was needed should be made after an assessment. The GDG discussed the comments and amended the statement for inclusion in Round 2 of the survey. The GDG felt that, ensuring necessary hydration was important for all children and young people but the use of further hydration specifically for the prevention of pressure ulcers was inappropriate and potentially harmful. As such, the GDG wished to clarify in Round 2 that hydrational supplementation was not appropriate for the prevention of pressure ulcers if, after assessment, a child is deemed to have an appropriate hydrational status for their developmental age, accounting for any comorbidities. The statement for Round 2 was therefore amended to 'Following assessment of hydration, if hydrational status is adequate, taking into account developmental age and comorbidities, healthcare professionals should not give further supplementation specifically for the prevention of pressure ulcers in neonates, infants, children and

	young people.' The statement was included in Round 2 of the survey and was accepted by the Delphi consensus panel. Qualitative responses from the panel generally felt that the inclusion of the term 'healthcare professional' within the statement was inappropriate, as this may include individuals involved in the prescription of fluids. Other comments also highlighted the lack of evidence to support the provision of additional hydration for the prevention of pressure ulcers and emphasised the potential harms in increasing fluid intake. The GDG therefore developed a recommendation to reflect the statement, that additional hydration (in the form of subcutaneous or intravenous fluids) should not be given for the prevention of pressure ulcers. The GDG highlighted that this was in line with the recommendation developed for adults and that, there were no identified benefits in the prevention of pressure ulcers for a population with adequate nutritional status. The GDG acknowledged that individuals with a reduced hydrational status should always have these deficiencies corrected and therefore the recommendation was worded to account for individuals whose hydrational status may not be appropriate for their developmental age or their clinical condition.
Economic considerations	The GDG felt it would not benefit the individual to provide additional fluids where hydration status was adequate, and agreed that to do so would not be cost effective.
Quality of evidence	No RCTs or cohort studies were identified for neonates, infants, children or young people. Formal consensus using a modified Delphi was therefore used to develop the recommendation. To inform the recommendation, the GDG used 1 statement which was included in Round 1 of the Delphi consensus survey and reached 52% consensus agreement. The statement was therefore amended and included in round 2 of the survey where it reached 75% agreement. Further details can be found in Appendix N.
Other considerations	Recommendations on the use intravenous fluids in children and young people can be found in the NICE guideline on intravenous fluids therapy for children, due for publication in 2015.

12 Pressure redistributing devices

Pressure relieving and redistributing devices are widely accepted methods of trying to prevent the development of pressure ulcers for people considered as being at risk. The devices used include different types of mattresses, overlays, cushions and seating. These devices work by reducing or redistributing pressure, friction or shearing forces.

Selection of a device may depend on factors such as mobility of the individual, the results of skin assessment, the level of and site at risk, weight, staff availability and skill plus the general health and condition of the individual. It is also important that any device is able to be cleaned and decontaminated effectively. It is accepted that these devices should be used in conjunction with other preventative strategies such as repositioning.

Specific devices are available for certain at risk sites, for example, the heel. Pressure redistributing devices for heels are considered in Chapter 13.

The GDG were therefore interested in identifying whether the use of pressure redistributing devices, including both static and dynamic surfaces, are effective in the prevention of pressure ulcers.

12.1 Review question: What are the most clinically and cost-effective pressure re-distributing devices for the prevention of pressure ulcers?

For full details see review protocol in Appendix C.

12.1.1 Clinical evidence (adults)

A Cochrane review by McInnes et al (2011)[127] was identified from the search and was adapted for this review. The Cochrane review was quality assured and, as it was of very high quality and matched the majority of the protocol (see Appendix C), the information was used to populate this review for the summary of studies, forest plots and for the quality assessment of studies (see Appendix G-I). Fifty-three studies were included in the Cochrane review. Three studies were removed but used in the review on the use of pressure redistributing devices for the prevention of heel pressure ulcers[28,71,207] as they included devices which are specific to only heel ulcers (see Chapter 13). One study[60] was at high risk of bias and did not report outcomes clearly and was excluded (from our review and the Cochrane review). One other study (Economides, 1995)[58] was excluded as it looked at wound breakdown rather than incidence of pressure ulcers. Two other studies (Gentilello, 1988[69] and Summer, 1989[195]) were excluded from this review as they were more relevant to the repositioning review (see Chapter 9). Eight other studies[27,30,54,82,125,163,209,217] which were not included in the Cochrane review, were identified and included in this review (see Appendix G).

In total, 54 studies were included in this review [3,6,15,31,33,35,38-40,42,48,61,62,70,72,76,77,83,87,90,94,101,103,104,113,114,117,126,130,148,14927,30,54,68,82,125,161,163-165,172,174,180,185,192,198-200,209,214,217,218,223]. Evidence from these studies is summarised in the clinical GRADE evidence profiles below.

See also the study selection flow chart in Appendix D, forest plots in Appendix I, study evidence tables in Appendix G and exclusion list in Appendix J.

In the studies, various types of devices were used to redistribute pressure to prevent pressure ulcers. The Cochrane review categorised them as low-tech (non-powered) constant low pressure support surfaces, high-tech support surfaces and other support surfaces. The types of devices included are listed below;

- 'Low-tech' continuous low pressure (CLP) support surfaces:
  - Standard foam mattresses.
  - Alternative foam mattresses/overlays: conformable and aim to redistribute pressure over a larger contact area.
  - Gel-filled mattresses/overlays: conformable and aim to redistribute pressure over a larger contact area.
  - Fibre-filled mattresses/overlays: conformable and aim to redistribute pressure over a larger contact area.
  - Air-filled mattresses/overlays: conformable and aim to redistribute pressure over a larger contact area.
  - Water-filled mattresses/overlays: conformable and aim to redistribute pressure over a larger contact area.
  - Bead-filled mattresses/overlays: conformable and aim to redistribute pressure over a larger contact area.
  - Sheepskins
- 'High-tech' support surfaces:
  - Alternating-pressure mattresses/overlays: air-filled sacs that inflate and deflate sequentially to relieve pressure at different anatomical sites for short periods; these may incorporate a pressure sensor
  - Air-fluidised beds: warmed air circulates through fine ceramic beads covered by a permeable sheet; allowing support over a larger contact area (CLP)
  - Low-air-loss beds: support provided by a series of air sacs through which warmed air passes (CLP)
- Other support surfaces:
  - Turning beds/frames: aides manual repositioning of the patient, or by motor driven turning and tilting.
  - Operating table overlays: conformable and aim to redistribute pressure over a larger contact area. .
  - Wheelchair cushions: either conforming cushions that reduce contact pressures by increasing surface area in contact, or mechanical cushions which alternate pressure.
  - Limb protectors: pads and cushions of different forms to protect bony prominences.

The Cochrane review considered all studies, regardless of whether grade 1 pressure ulcers were described separately, although the authors state that studies comparing the incidence of pressure ulcers of grade 2 or greater are more likely to be reliable. For the purposes of the current review, the GDG therefore chose to include pressure ulcers of grade 2 and above were.

Although the included studies used a range of grading systems, those which reported pressure ulcers of grade 2 and above separately, used the EPUAP or NPUAP classification system (see Table 50). For studies that did not use the EPUAP/NPUAP and reported grade of ulcer separately, the distinction was usually a break in the skin or blister.

The Cochrane review reported that methods of measuring secondary outcomes such as comfort, durability, reliability and acceptability were not well developed. Where data were presented details were provided, but this was not incorporated into the analysis. As some of these outcomes were considered by the GDG to be critical for decision making, for the purposes of this review these outcomes have been included in the GRADE evidence tables (see Table 52).

The Cochrane review meta-analysed studies where there was more than 1 trial for an outcome which compared similar devices. The results were pooled using a fixed effect model, but if heterogeneity (I^2 = 50% or above and the p value was less than 0.10) was found, a random-effects model was used. The review states that it was assumed that the risk ratio remained constant for different lengths of follow-up and so results were pooled if participants were followed-up for different lengths of time.

No studies were found for standard or pressure-relieving chairs, tilt-in-space wheelchairs, postural support or limb protectors.

Table 50: Glossary of terms (NPUAP 2007)[20]

Term	Definition
Physical concepts related to support surfaces	
Static	Not active or moving; stationary. However with regards to support surfaces the description has now changed to mean 'non-powered'.
Dynamic	Relating to energy or to objects in motion. However with regards to support surfaces the description has now changed to mean 'powered'.
Friction (frictional force)	The resistance to motion in a parallel direction relative to the common boundary of 2 surfaces.
Coefficient of friction	A measurement of the amount of friction existing between 2 surfaces.
Envelopment	The ability of a support surface to conform, so to fit or mold around irregularities in the body.
Fatigue	The reduced capacity of a surface or its components to perform as specified. This change may be the result of intended or unintended use and/or prolonged exposure to chemical, thermal, or physical forces.
Force	A push-pull vector with magnitude (quantity) and direction (pressure, shear) that is capable of maintaining or altering the position of a body.
Immersion	Depth of penetration (sinking) into a support surface.
Life expectancy	The defined period of time during which a product is able to effectively fulfil its designated purpose.
Mechanical load	Force distribution acting on a surface.
Pressure	The force per unit area exerted perpendicular to the plane of interest.
Pressure redistribution	The ability of a support surface to distribute load over the contact areas of the human body. This term replaces prior terminology of pressure reduction and pressure relief surfaces
Pressure reduction	This term is no longer used to describe classes of support surfaces. The term is pressure redistribution; see above.
Pressure relief	This term is no longer used to describe classes of support surfaces. The term is pressure redistribution; see above
Shear (shear stress)	The force per unit area exerted parallel to the plane of interest.
Shear strain	Distortion or deformation of tissue as a result of shear stress.
Components of support surfaces	
Air	A low density fluid with minimal resistance to flow.
Cell/bladder	A means of encapsulating a support medium.
Viscoelastic foam	A type of porous polymer material that conforms in proportion to the applied weight. The air exists and enters the foam cells slowly which allows the material to respond slower than a standard elastic foam (memory foam).
Elastic foam	A type of porous polymer material that conforms in proportion to the applied weight. Air enters and exits the foam cells more rapidly, due to greater density (non memory).
Closed cell foam	A non-permeable structure in which there is a barrier between cells, preventing gases or liquids from passing through the foam.
Open cell foam	A permeable structure in which there is no barrier between cells and gases or liquids can pass through the foam.

Gel	A semisolid system consisting of a network of solid aggregates, colloidal dispersions or polymers which may exhibit elastic properties (can range from a hard gel to a soft gel).
Pad	A cushion-like mass of soft material used for comfort, protection or positioning.
Viscous fluid	A fluid with a relatively high resistance to flow of the fluid.
Elastomer	Any material that can be repeatedly stretched to at least twice its original length; upon release the stretch will return to approximately its original length.
Solid	A substance that does not flow perceptibly under stress. Under ordinary conditions retains its size and shape.
Water	A moderate density fluid with moderate resistance to flow.
Features of support surfaces	
Air fluidised	A feature of a support surface that provides pressure redistribution via a fluid-like medium created by forcing air through beads as characterised by immersion and envelopment.
Alternating pressure	A feature of a support surface that provides pressure redistribution via cyclic changes in loading and unloading as characterised by frequency, duration , amplitude, and rate of change parameters.
Lateral rotation	A feature of a support surface that provides rotation about a longitudinal axis as characterised by degree of patient turn, duration and frequency.
Low air loss	A feature of a support surface that provides a flow of air to assist in managing the heat and humidity (microclimate) of the skin.
Zone	A segment with a single pressure redistribution capability.
Multi-zoned surface	A surface in which different segments can have different pressure redistribution capabilities.
Categories of support surfaces	
Reactive support surface	A powered and non-powered support surface with the capability to change its load distribution properties only in response to applied load.
Active support surface	A powered support surface, with the capability to change its load distribution properties, with or without applied load.
Integrated bed system	A bed frame and support surface that are combined into a single unit whereby the surface is unable to function separately.
Non-powered	Any support surface not requiring or using external sources of energy for operation (Energy = D/C or A/C).
Powered	Any support surface requiring or using external sources of energy to operate (Energy = D/C or A/C).
Overlay	An additional support surface designed to be placed directly on top of an existing surface.
Mattress	A support surface designed to be placed directly on the existing bed frame.

Summary of included studies

Table 51: Summary of included studies

Study	Intervention/comparator	Population	Outcomes	Study length
Andersen 1982[3]	Standard hospital mattress versus alternating air mattress versus water-filled mattress (air mattress for camping filled with water).	Peoplein acute setting at high risk of pressure ulcer development (Anderson scale) and without pressure ulcers.	• Incidence of pressure ulcers (all grades).	10-day follow-up
Aronovitch 1999[6]	Alternating pressure system intra and postoperatively (MICROPULSE) versus conventional management (gel pad (ACTION PAD) or standard pad in operating room and a replacement mattress (PRESSURE GUARD II) postoperatively).	People undergoing elective surgery under general anaesthetic.	• Occurrence of pressure ulcer within 7 days of surgery (all grades).	7-day follow-up
Bennett 1998[15]	Low air loss hydrotherapy (Permeable fast drying filter sheet over low-air-loss cushions (circulating air)(clensicair) versus standard care (standard bed or foam, air, alternating-pressure mattresses, skin care not standardised).	People in acute and long-term care incontinent of urine or faeces with pressure ulcers grade 2 or below.	• Number of people who developed pressure ulcers (grade 2-4); number of people with non-blanchable erythema (grade 1).	60-day follow-up
Brienza 2010[27]	Skin protection cushion (SPC) versus segmented foam cushion (SFC) The skin protection cushion was a commercially available cushion with an incontinence cover. Cushions were selected from 3 which were designed to improve tissue tolerance by reducing peak pressures near bony prominences, accommodating orthopaedic deformities through immersion, enveloping small irregularities at the seating interface	Elderly, nursing home population who used wheelchairs as primary means of seating and mobility and were at-risk for developing pressure ulcers.	• Incidence of pressure ulcers (different areas of the body) (all grades).	6 months

Study	Intervention/comparator	Population	Outcomes	Study length
	without causing height pressure gradients, and dissipating heat and moisture. Solid seat inserts were provided. The segmented foam cushion was a cross-cut, 7.6cm thick, segmented foam cushion with fitted incontinence cover and solid seat insert.			
Cassino 2013[30]	Three-dimensional overlay (AIARTEX), made of 3-D macro-porous material, 9mm thick, made completely of polyester and weighing 800grams, consisting of 2 parallel layers, 1 on top of the other, linked by transverse monofilaments versus dry viscoelastic polyurethane polymer overlay (AKTON) 15.9mm thick, made of vulcanised rubber with a strong memory for shape, weighing 35kg	People in long term care.	• Incidence of pressure ulcers (all grades)	12 weeks
Cavicchioli 2007[31]	High-tech (HILL-ROM, DUO 2) mattress on alternating low-pressure setting versus high-tech (HILL-ROM DUO 2), mattress on continuous low-pressure setting.	People in acute and long-term care deemed at risk of pressure ulceration (Braden score of less than 17 activity or mobility sub-scales less than 3).	• Number of people with incidence of pressure ulcer (grade 1 and 2).	2-week follow-up
Cobb 1997[33]	Low air loss bed (KINAIR) versus static air mattress overlay (EHOB WAFFLE).	People in hospital and intensive care units considered high risk on Braden score.	• Number of participants with incidence pressure ulcer (grade 1 and 2)	40-day follow-up
Collier 1996[35]	Comparison of 8 foam mattresses: new standard hospital mattress versus pressure redistributing foam mattresses (CLINIFLOAT, OMNIFOAM, SOFTFORM, STM5, THERAREST, TRANSFOAM, VAPOURLUX).	People on a general medical ward, no further details.	• Incidence of pressure ulcers (all grades)	Not clear but assessed weekly

Study	Intervention/comparator	Population	Outcomes	Study length
Conine 1990[39]	Alternating-pressure overlay versus silicore overlay over standard hospital mattress (spring or foam) All participants received usual care including 2-3 hourly turning; daily bed baths; weekly bath or shower; use of heel, ankle and other protectors.	People with chronic neurological diseases.	• Incidence of pressure ulcers (all grades)	3-month follow-up
Conine 1993[38]	Slab cushion bevelled at base to prevent seat sling versus contoured foam cushion with a posterior cut out in the area of ischial tuberosities and an anterior ischial bar.	People in extended care at high risk of pressure ulcers.	• Incidence of pressure ulcers (all grades)	3-month follow-up
Conine 1994[40]	Gelcushion with foam base (JAY) versus foam cushion.	Elderly adults in an extended care hospital deemed at high risk of pressure ulcers	• Incidence of pressure ulcers (all grades)	3-month follow-up
Cooper 1998[42]	Dry flotation mattress (ROHO) versus dry flotation mattress (SOFFLEX).	People in a mixed emergency orthopaedic trauma ward with Waterlow risk scores of 15 or above.	• Incidence of pressure ulcers (grade 2 and above)	7-day follow-up
Daechsel 1985[48]	Alternating-pressure mattress versus silicore overlay.	People with neurological conditions in a long-term care hospital at high risk.	• Incidence of pressure ulcers (all grades)	3-month follow-up
Demarre 2012[54]	Alternating low pressure air mattress with multi-stage inflation and deflation of the air cells (CLINACTIV, HILL-ROM) versus standard Alternating low pressure air mattress with single stage, steep inflation and deflation of air cells (HILL-ROM).	People In hospital. The wards were neurology, rehabilitation, cardiology, dermatology, pneumology oncology and chronic care or a combination of different types of medical conditions.	• Incidence of pressure ulcers (all grades and grade 2 ulcer or greater); withdrawal due to discomfort; time to develop new pressure ulcers	14 days

Study	Intervention/comparator	Population	Outcomes	Study length
Exton-Smith 1982[61]	Alternating-pressure mattress with 2 layers of air cells (PEGASUS AIRWAVE SYSTEM) versus alternating-pressure large cell ripple mattress	Geriatric adults, with fractured neck of femur and long-stay patients without pressure ulcers of grade 2 or greater, Norton score less than 14.	• Incidence of pressure ulcers (grade 2 or above)	2-week follow-up
Feuchtinger 2006[62]	Operating table with water-filled warming mattress and a 4-cm thermo active viscoelastic foam overlay versus standard operating room table configuration (operating room table with water-filled warming mattress)	People scheduled for cardiac surgery with extracorporeal circulation, not required to be free of pressure ulcers.	• Number of participants with incidence of pressure ulcers (all grades and grade 2 and above)	5-day follow-up
Gebhardt 1996[68]	Alternating-pressure air mattresses (shallow small cell overlays, medium depth large cell overlays, deep mattresses and deep pulsating low air loss bed) versus constant low-pressure supports (fibre overlays, foam mattresses/overlays, static air overlays, gel overlay, water overlay, bead overlay, low air loss mattresses, static air overlay, low-air-loss beds and air-fluidised bead beds)	People in ICU with a Norton score less than 13 with no pressure ulcers.	• Support provided; incidence of pressure ulcers (all grades and grade 2 and above); cost	unclear
Geyer 2001[70]	Pressure-reducing wheelchair cushions (a commercial cushion, chosen by nurse based on the individual, from a group of cushions designed specifically to improve tissue tolerance in sitting by providing more surface area and/or reducing peak pressure near the ischial tuberosities, sacrum and coccygeal areas. A fitted incontinence cover was also included versus standard 3-inch convoluted foam (EGGRATE) cushion	Elderly adults in nursing homes; wheelchair users with Braden score of 18 or less.	• Number of participants with incidence of pressure ulcer (all grades)	12-month follow-up

Study	Intervention/comparator	Population	Outcomes	Study length
Goldstone 1982[72]	Bead bed system (BEAUFORT)(includes bead-filled mattress on A&E trolley; bead-filled operating table overlay; bead-filled sacral cushion for operating table; bead-filled boots to protect heels on operating table	People over 60 years with femur fracture.	• Incidence of pressure ulcer (all grades)	Follow-up not clear
Gray 1994[77]	Pressure redistributing foam mattress (SOFTFOAM) versus standard 130mm NHS foam mattress.	People with orthopaedic trauma, vascular and medical oncology units without breaks in the skin.	• Incidence of pressure ulcers (grade 2 or greater)	10-day follow-up
Gray 1998[76]	Pressure redistributing foam mattress (TRANSFOAM) versus pressure redistributing foam mattress (TRANSFOAMWAVE).	People in hospital admitted for bed-rest or surgery with intact skin, no terminal illness.	• Incidence of pressure ulcers (all grades)	10-day follow-up
Grisell 2008[82]	A neoprene air filled bladder (dry flotation) device (ROHO) versus a disposable polyurethane foam prone head positioner (OSI) versus a prone view protective helmet system with a disposable polyurethane foam head positioner).	People undergoing elective surgery – thoracic, lumbar or thora-columbar spinal surgery that required prone positioning.	• Incidence of pressure ulcers (all grades and grade 2 and above)	No details
Gunningberg 2000[83]	10cm visco-elastic foam mattress (TEMPUR-PEDIC) on arrival in A&E, and visco-elastic foam overlay on standard ward mattress versus standard A&E trolley mattress (5cm) and ward mattress (10cm foam).	People admitted with a suspected hip fracture via an A&E department; over 65 years; who did not have pressure ulcers.	• Incidence of pressure ulcer (grade 2 to 4); mean comfort rating	Follow-up until discharge or 14 days postoperatively
Hampton 1997[87]	Alternating-pressure mattress (CAIRWAVE SYSTEM) versus alternating pressure mattress (AIRWAVE SYSTEM).	People with average age 77 years; number of people at high-very high risk.	• Incidence of pressure ulcers (grade 2 and above)	20 days maximum follow-up
Hofman 1994[90]	Cubed foam mattress (COMFORTEX DECUBE) versus standard hospital foam	People with a femoral-neck fracture and risk	• Incidence of pressure ulcers	2-week follow-up

Study	Intervention/comparator	Population	Outcomes	Study length
	mattress (standard polypropylene SG40)	score over 8 (Dutch consensus scale).	(grade 2 and above)	
Inman 1993[94]	Low-air-loss air-suspension beds (KINAIR) versus standard Intensive care unit bed (people rotated every 2 hours)	People over 17 years with APACHE II score over 15.	• Incidence of pressure ulcers (ulcers per person and people with ulcers) (grade 2 and above)	Average 17 days follow-up
Jolley 2004[101]	Australian medical sheepskin mattress overlay (leather-backed with a dense uniform 25 mm wool pile versus usual care determined by staff (repositioning and any other pressure redistributing device or prevention strategy with/without low-tech constant pressure relieving devices	People at low to moderate risk of developing a pressure ulcer; aged over 18 years.	• Number of participants with incidence of pressure ulcer (all grades)	Unclear follow-up period; average 7 days.
Kemp 1993[103]	Convoluted foam overlay (either 3 inch overlay with density of 1.42lb per cubic foot (acute settings) or a 4 inch overlay with unknown density (long-term settings)) versus solid foam overlay (4 inches solid sculptured overlay with density to 1.33lb per cubic foot)	People aged over 65 years, inpatients with Braden Score of 16 or less from general medicine, acute geriatric medicine and long term care. Free from pressure ulcers.	• Incidence of pressure ulcers (all grades)	1-month follow-up
Keogh 2001[104]	Profiling bed with a pressure reducing foam mattress/cushion versus. Flat-based bed with a pressure relieving/redistributing mattress/cushion.	People from 2 surgical and 2 medical wards; aged over 18 years; Waterlow score of 15-25; tissue damage no greater than grade 1	• Incidence of pressure ulcers (all grades); healing of existing grade 1 ulcers	5-10 days follow-up
Laurent 1998[113]	Standard mattress in ICU; standard mattress postoperatively versus alternating pressure mattress (NIMBUS) in ICU; standard mattress postoperatively versus standard mattress in ICU; Constant low pressure mattress (TEMPUR) postoperatively versus alternating pressure mattress (NIMBUS) in ICU;	Adults over 15 years of age, admitted for major cardiovascular surgery	• Incidence of pressure ulcers (grade 2 and above)	unclear

Study	Intervention/comparator	Population	Outcomes	Study length
	constant low pressure mattress (TEMPUR) postoperatively.			
Lazzara 1991[114]	Air-filled (SOFCARE) overlay versus gel mattress.	People in a nursing home at risk of pressure ulcers (Norton score over15)	• Incidence of pressure ulcers (all grades and grade 2 and above)	6-month follow-up
Lim 1988[117]	Foam slab cushion (2.5cm medium density foam glued to 5cm firm chipped foam) versus contoured foam cushion (same foam as above; cut into a customised shape to relieve pressure on ischial tuberosities).	Residents of an extended care facility; aged at least 60; free of pressure ulcers but at high risk of developing 1 (Norton score of less than 4); using a wheelchair for at least 4 hours per day; without progressive disease or confined to bed	• Incidence of pressure ulcers (all grades)	5-month follow-up
Malbrain 2010[125]	Reactive dry floatation mattress overlay (ROHO) versus the active alternating pressure mattress (NIMBUS 3).	People in ICU at high risk of pressure ulcers (Norton score of less than 8) and requiring mechanical ventilation for at least 5 days with intact skin or with Pus on admission.	• Incidence of pressure ulcers (all grades and grade 2 and above)	No details but mean study duration reported for patients was 15 (s.d 14) in the NIMBUS group and 12.2 (s.d 5.5) in the ROHO group
McGowan 2000[126]	Standard hospital mattress, sheet and an Australian Medical Sheepskin overlay; sheepskin heel and elbow protectors as required versus standard hospital mattress, sheet with or without other low tech constant pressure devices as required.	Orthopaedic patients aged 60 years and over; low or moderate risk (Braden scale)	• Incidence of pressure ulcers (all grades of)	Discharge from hospital, transfer to a rehabilitation ward.
Mistiaen 2009; Mistiaen 2010[132]	Australian medical sheepskin versus usual care. Co-interventions: usual intervention for	People from an aged care facility (predominantly rehabilitation department) and	• Incidence of pressure ulcers (all grades)	30-day follow-up

Study	Intervention/comparator	Population	Outcomes	Study length
	prevention of pressure ulcers in study settings.	rehabilitation centre. Grade 1 pressure ulcers included in sample		
Nixon 1998[148]	Dry visco-elastic polymer pad on operating table versus standard operating theatre table mattress plus aheel support (GAMGEE).	People 55 years and over; admitted for elective major general, gynaecological or vascular surgery in supine or lithotomy position and free of preoperative pressure damage greater than grade 1.	• Incidence of pressure ulcers (all grades)	8-day follow-up
Nixon 2006[149]	Alternating-pressure overlay (alternating cell height minimum 8.5cm, max 12.25 cm) versus alternating-pressure mattress (alternating cell height min 19.6cms, max 29.4cms).	People in acute or elective hospital aged 55 years or over with limited Braden activity and mobility score (1 or 2) .	• Incidence of pressure ulcers (grade 2 and above)	30-day follow-up and a further 30-day follow-up
Price 1999[161]	Low-pressure inflatable mattress (REPOSE SYSTEM) and cushion in polyurethane material) versus dynamic flotation Nimbus II plus alternating-pressure cushion for a chair (ALPHA TRANSCELL): all other care standard best practice, including regular repositioning.	People with fractured neck of femur and Medley score of over 25 (very high risk) aged over 60 years.	• Incidence of pressure ulcers (grade 2 and above)	14-day follow-up
Ricci 2013[163]	3-D mattress overlay (AIARTEX) (a macro-porous 3-D material (9mm thick)) made in polyester flame retardant versusvisco-elastic mattress overlay (AKTON)(15.9mm thick). Made of vulcanised cross-linked rubber material which keeps its shape.	People in a long-term unit at moderate or high risk of pressure ulcer development (according to Braden scale).	• Incidence of pressure ulcers (all grades)	4 weeks
Russell 2000[165]	Multi-cell pulsating dynamic mattress system (MICROPULSE SYSTEM)in the operating room and postoperatively versus	People over 18 years; undergoing scheduled cardiothoracic surgery	• Incidence and severity of pressure ulcers (all grades)	7-day follow-up

Study	Intervention/comparator	Population	Outcomes	Study length
	Conventional care (gel pad (ACTION PAD) in operating room, standard mattress (HILL_ROM CENTRA with 6 inch foam overlay or HILL-ROM CENTRA with 4 inch foam overlay) postoperatively).	under general anaesthetic; surgery of at least 4 hours duration; free of pressure ulcers.		
Russell 2003[166]	Visco-polymer energy absorbing foam mattress (CONFOR-MED 3 inch layer viscoelastic foam and a 3 inch layer of standard polyurethane foam))/cushion combination versus standard mattress/cushion combination (KING'S FUND, LINKNURSE, SOFTFOAM, TRANSFOAM, KING'S FUND MATTRESS with a SPENCO or PROPAD mattress overlay).	People in elderly acute, orthopaedic and rehabilitation wards; over 65 years; Waterlow score of 15-20.	• Development of non-blanching erythema	Median 8-14 (experimental) and 9-17 (control)
Sanada 2003[172]	Double-layer cell overlay (TRICELL) - 2 layers consisting of 24 narrow cylinder air cells, 10cm) versus single-layer air cell overlay (AIR DOCTOR single layer consisting of 20 round air cells, 7.5cm) versus standard hospital mattress (PARACARE 8.5cm polyester).	People in an acute care unit; Braden score of 16 or less; bed bound; free of pressure ulcers.	• Incidence of pressure ulcers (all grades of pressure ulcer and grade 2 and above)	Follow-up duration not reported
Santy 1994[174]	Pressure redistributing mattresses (CLINIFLOAT, OMNIFOAM, THERAREST, TRANSFOAM, VAPERM) versus NHS contract surface – standard foam (REYLON 150mm).	People aged over 55 years with hip fracture, with or without pressure ulcers.	• Incidence of pressure ulcers (all grades).	14-day follow-up
Schultz 1999[179]	Experimental mattress overlay in operating room made of foam with a 25% indentation load deflection of 30lb and density of 1.3 cubic feet versus usual care (padding as required, including gel pads, foam mattresses, ring cushions).	People admitted for surgery; aged over 18 years; admitted with intact skin.	• Incidence of pressure ulcers (all grades)	6-day follow-up

Study	Intervention/comparator	Population	Outcomes	Study length
Sideranko 1992[185]	Alternating air mattress (LAPIDUS AIRFLOAT SYSTEM 1.5 inch thick) versus static air mattress (GAY MARSOFCARE, 4-inch thick) versus Water mattress (LOTUSs PXM 3666,4 inch thick).	Adults in surgical ICU ; without existing skin breakdown	• Incidence of pressure ulcers (all grades)	Mean 9.4 days follow-up
Stapleton 1986[192]	Large cell ripple bed pad (TALLEY) versus polyether foam pad 2 feet x 2 feet x 3 inch thickness versus silicore bed pad (SPENCO).	Female elderly adults with fractured neck of femur; without existing pressure ulcers; Norton score 14 or less.	• Incidence of pressure ulcers (all grades and grade 2 and above)	Duration of follow-up unclear
Takala 1996[198]	Constant low pressure mattress (CARITAL OPTIMA) (21 double air bags on a base) versus standard hospital foam mattress (10cm thick foam density 35kg/m3).	People admitted to ICU with non-trauma conditions.	• Incidence of pressure ulcers (all grades)	14-day follow-up
Taylor 1999[199]	Alternating-pressure mattress with pressure redistributing cushion (PEGASUS TRINOVA) versus alternative alternating-pressure system (unnamed) with pressure redistributing cushion.	People in hospital aged 16 or over; intact skin, requiring a pressure-relieving support.	• Incidence of pressure ulcers (all grades)	Discharge from hospital or death
Theaker 2005[200]	Alternating pressure mattress (KCI THERAPULSE) versus alternating pressure mattress(HILL-ROM DUO).	People in ICU at high risk.	• Number of participants with incidence of pressure ulcers (all grades)	2 weeks follow-up after discharge from ICU
Vanderwee 2005[214]	Alternating pressure air mattress (ALPHA-X-CELL) versus visco-elastic foam mattress (TEMPUR).	People in surgical, internal medicine or geriatric hospital; at risk of developing pressure ulcer (Braden score of less than 17)	• Incidence of pressure ulcers (all grades)	unclear
Van Leen 2011[209]	Combination of a standard 15cm cold foam mattress with a static air overlay versus a standard 15cm cold foam mattress.	People in a nursing home.	• Incidence of pressure ulcers (grade 2 and above)	6 months follow-up

Study	Intervention/comparator	Population	Outcomes	Study length
Vermette 2012[217]	Air-inflated static overlay (RIK and THERAKAIR) versus microfluid static overlay or a low-air-loss dynamic mattress with pulsation for people at moderate to very high risk.	People on a medical, surgical, active geriatric, or an intensive care unit ward of an acute care hospital. Considered to be at moderate to high risk (Braden score of 14 or less)	• Incidence of pressure ulcers (all grades); comfort	2 weeks follow-up
Vyhlidal 1997[218]	Foam mattress overlay (IRIS 3000, 4-inch thick 1.8lb density with dimpled surface) versus foam mattress replacement (MAXIFLOAT).	People newly admitted to a skilled nursing facility; free of pressure ulcers but at risk (Braden score of less than 18).	• Incidence of pressure ulcers (all grades)	10-21 day follow-up
Whitney 1984[223]	Alternating-pressure mattress (134 3-inch diameter air cells, 3 minute cycle) versus. convoluted foam pad (eggcrate) People in both groups were turned every 2 hours.	People on medical – surgical units; relatively little skin breakdown; aged 19-91 years.	• Changes in skin conditions (all grades)	8-day follow-up

12.1.2 'Low-tech' constant low-pressure (CLP) supports

The Cochrane review compared standard foam hospital mattresses with other low specification ('low-tech'), constant low-pressure (CLP) supports. Sheepskin, static air-filled supports; water-filled supports; contoured or textured foam supports; gel-filled supports; bead-filled supports; fibre-filled supports, and alternative foam mattresses or overlays were considered to be low-tech CLP. However it is noted that there is not an international definition of what a standard foam mattress is. In addition the definition can change over time, within countries, and even within hospitals. If a description of the standard mattress was given it was included in the review, which is outlined in Table 51. The Cochrane review assumes that standard mattresses are likely to vary less within countries than between countries, and undertook subgroup analysis by country, although this intention was not pre-specified.

12.1.2.1 Standard foam hospital mattress compared with other "low-tech" CLP

Table 52: Clinical evidence profile: constant low-pressure supports (CLP) versus standard foam mattresses (SFM) for pressure ulcer prevention

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Constant low-pressure supports (CLP)	Standard foam mattresses (SFM)	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers - cubed foam mattress (COMFORTEX DECUBE) versus standard hospital mattress (standard polypropylene SG40) – grade 2-4 pressure ulcers (Dutch consensus[j])[90]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	4/17 (23.5%)	13/19 (68.4%)	RR 0.34 (0.14 to 0.85)	452 fewer per 1000 (from 103 fewer to 588 fewer)	Very low	Critical
							-	68.4%		451 fewer per 1000 (from 103 fewer to 588 fewer)		
Incidence of pressure ulcers - softfoam mattress versus standard 130mm NHS foam mattress – grade 2-4 pressure ulcers (no details of grading system)[77]												
1	Randomised trial	Very serious[d]	No serious inconsistency	No serious indirectness	No serious imprecision	None	6/90 (6.7%)	27/80 (33.8%)	RR 0.2 (0.09 to 0.45)	270 fewer per 1000 (from 186 fewer to 307 fewer)	Low	Critical
							-	33.8%		270 fewer per 1000 (from 186 fewer to 308 fewer)		
Incidence of pressure ulcers - cubed foam mattress (COMFORTEX DECUBE) versus standard hospital mattress (standard polypropylene SG40) – all grades of pressure ulcers (Dutch												

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**Constant low-pressure supports (CLP)**	**Standard foam mattresses (SFM)**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
consensus[j])[90]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	6/17 (35.3%)	14/19 (73.7%)	RR 0.48 (0.24 to 0.96)	383 fewer per 1000 (from 29 fewer to 560 fewer)	Very low	Critical
							-	73.7%		383 fewer per 1000 (from 29 fewer to 560 fewer)		
Incidence of pressure ulcers - bead-filled mattress (BEAUFORT) versus standard hospital mattress – all grades of pressure ulcers[72]												
1	Randomised trial	Very serious[c]	No serious inconsistency	No serious indirectness	Serious[b]	None	5/32 (15.6%)	21/43 (48.8%)	RR 0.32 (0.14 to 0.76)	332 fewer per 1000 (from 117 fewer to 420 fewer)	Very low	Critical
							-	48.8%		332 fewer per 1000 (from 117 fewer to 420 fewer)		
Incidence of pressure ulcers - water-filled mattress versus standard hospital mattress – all grades of pressure ulcers[k3]												
1	Randomised trial	Very serious[e]	No serious inconsistency	No serious indirectness	Serious[b]	None	7/155 (4.5%)	21/161 (13%)	RR 0.35 (0.15 to 0.79)	85 fewer per 1000 (from 27 fewer to 111 fewer)	Very low	Critical

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**Constant low-pressure supports (CLP)**	**Standard foam mattresses (SFM)**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
							-	13%		84 fewer per 1000 (from 27 fewer to 110 fewer)		
Incidence of pressure ulcers - alternative foam pressure-reducing mattresses (CLINIFLOAT, OMNIFOAM, SOFTFORM, STM5, THERAREST, TRANSFOAM, VAPOURLUX) versus standard hospital mattress – all grades of pressure ulcers (RCN and NPUAP grading system)[l35]; Santy (1994)[174]												
2	Randomised trials	Very serious[f]	No serious inconsistency	No serious indirectness	No serious imprecision	None	42/571 (7.4%)	17/73 (23.3%)	Not pooled as Collier (1996) had 0 events but 0.36 (0.22 to 0.59) for Santy (1994)	149 fewer per 1000 (from 95 fewer to 182 fewer)	Low	Critical
							-	13.3%		85 fewer per 1000 (from 55 fewer to 104 fewer)		
Incidence of pressure ulcers – high specification foam mattress/cushion - visco-polymer energy absorbing foam mattress (CONFORM-ED) versus standard mattress or cushion(KING's FUND, LINKNURSE, SOFTFOAM, TRANSFOAM, KING'S FUND MATTRESS with a SPENCO or PROPAD mattress overlay – all grades of pressure ulcers (Torrance scale)[m167]												
1	Randomised trial	Very serious[g]	No serious inconsistency	No serious indirectness	Serious[b]	None	48/562 (8.5%)	66/604 (10.9%)	RR 0.78 (0.55 to 1.11)	24 fewer per 1000 (from 49 fewer to 12 more)	Very low	Critical
							-	10.9%		24 fewer per 1000 (from 49		

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Constant low-pressure supports (CLP)	Standard foam mattresses (SFM)	Relative (95% CI)	Absolute	Quality	Importance
										fewer to 12 more)		
Comfort scores – very uncomfortable – pressure-reducing foam mattress (SOFTFOAM) versus standard 130mm NHS foam mattress[77]												
1	Randomised trial	Very serious[d]	No serious inconsistency	No serious indirectness	No serious imprecision	None	0/90 (0%)	0/80 (0%)	Not pooled	Not pooled	Low	Critical
Comfort scores - uncomfortable – pressure-reducing foam mattress (SOFTFOAM) versus standard 130mm NHS foam mattress[77]												
1	Randomised trial	Very serious[d]	No serious inconsistency	No serious indirectness	Very serious imprecision[i]	None	0/90 (0%)	2/80 (2.5%)	OR 0.12 (0.01 to 1.91)	22 fewer per 1000 (from 25 fewer to 22 more)	Very low	Critical
							-	2.5%		22 fewer per 1000 (from 25 fewer to 22 more)		
Comfort scores – adequate – pressure-reducing foam mattress (SOFTFOAM) versus standard 130mm NHS foam mattress[77]												
1	Randomised trial	Very serious[d]	No serious inconsistency	No serious indirectness	No serious imprecision	None	6/90 (6.7%)	44/80 (55%)	RR 0.12 (0.05 to 0.27)	484 fewer per 1000 (from 402 fewer to 523 fewer)	Low	Critical
							--	55%		484 fewer per 1000 (from 402 fewer to 523 fewer)		
Comfort scores - comfortable – pressure-reducing foam mattress (SOFTFOAM) versus standard 130mm NHS foam mattress[77]												

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**Constant low-pressure supports (CLP)**	**Standard foam mattresses (SFM)**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
1	Randomised trial	Very serious[d]	No serious inconsistency	No serious indirectness	No serious imprecision	None	62/90 (68.9%)	26/80 (32.5%)	RR 2.12 (1.5 to 2.99)	364 more per 1000 (from 162 more to 647 more)	Low	Critical
							-	32.5%		364 more per 1000 (from 162 more to 647 more)		
Comfort scores – very comfortable – pressure-reducing foam mattress (SOFTFOAM) versus standard 130mm NHS foam mattress[77]												
1	Randomised trial	Very serious[d]	No serious inconsistency	No serious indirectness	No serious imprecision	None	11/90 (12.2%)	0/80 (0%)	OR 7.45 (2.2 to 25.24)	120 more from 50 more to 190 more)	Low	Critical
Comfort – high specification foam mattress or cushion - visco-polymer energy absorbing foam mattress (CONFORM-ED) versus standard mattress or cushion (KING's FUND, LINKNURSE, SOFTFOAM, TRANSFOAM, KING'S FUND MATTRESS with a SPENCO or PROPAD mattress overlay [167]												
1	Randomised trial	Very serious[g]	No serious inconsistency	No serious indirectness	No serious imprecision	None	2.33 +/- 0.98 n=323	2.46 +/-1.01 n=383	-	MD 0.13 lower (0.28 lower to 0.02 higher)	Low	Critical
Length of stay in hospital (days) – cubed foam mattress (COMFORTEX DECUBE) versus standard hospital mattress (standard polypropylene SG40) [90]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	No serious	Very serious[h]	Median 21 days (range 5-64)	Median 23 days (range 4-120)	-	See footnote[h]	Very low	Important
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Constant low-pressure supports (CLP)	Standard foam mattresses (SFM)	Relative (95% CI)	Absolute	Quality	Importance
Time to development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There was unclear sequence generation and allocation concealment reported. No blinding was reported. It was unclear if incomplete outcome data was addressed. There was a higher drop-out than event rate in CLP arm for grade 2-4 ulcer outcome.
(b) The confidence interval crossed 1 MID point.
(c) There was inadequate sequence generation. There was unclear allocation concealment and blinding. Incomplete outcome data was not addressed(Goldstone (1982)).
(d) There was unclear sequence generation, allocation concealment, blinding, addressing of incomplete outcome data and if groups similar at baseline (Gray 1994).
(e) There was unclear sequence generation, allocation concealment, blinding and addressing of incomplete outcome data (Andersen (1982)).
(f) There was unclear sequence generation, allocation concealment and addressing of incomplete outcome data. No blinding was reported. It was unclear if groups were similar at baseline (Collier (1996)). There was unclear sequence generation, blinding and addressing of incomplete outcome data. The differential drop-out with higher drop-out in standard hospital mattress group (Santy (1994)).
(g) There was unclear allocation concealment. No blinding was reported (Russell (2003)).
(h) The datawere given as median and range so it was not possible to analyse data in Revman.
(i) The confidence interval crossed both MID points.
(j) Dutch consensus grading system (1985): 0= normal skin; 1= persistent erythema of the skin; 2= blister formation; 3= superficial (sub-cutaneous necrosis); 4= deep sub-cutaneous necrosis.
(k) Bullae, black necrosis and skin defects were evidence of pressure ulcers.
(l) Collier (1996) used RCN grading and Santy (1994) used NPUAP 1989.
(m) Torrance scale, where blanching erythema represents a Torrance grade I ulcer and non-blanching erythema represents a Torrance grade II ulcer.
(n) There were a limited number of events.

Table 53: Clinical evidence profile: constant low pressure support (inflated static overlay (ISO)) versus constant low pressure support (microfluid static overlay (MSO)) and alternating pressure support (low-air-loss dynamic mattress (LALDM))

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	CLP	CLP and AP	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers - all grades of pressure ulcers (NPUAP)[217]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	2/55 (3.6%)	6/55 (10.9%)	RR 0.33 (0.07 to 1.58)	73 fewer per 1000 (from 101 fewer to 63 more)	Very low	Critical
							-	10.9%		73 fewer per 1000 (from 101 fewer to 63 more)		
Comfort – all grades of pressure ulcers (NPUAP)[217]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	No serious imprecision	None	29/34 (85.3 %)	27/30 (90%)	RR 0.95 (0.79 to 1.14)	45 fewer per 1000 (from 189 fewer to 126 more)	Moderate	Important
							-	90%		45 fewer per 1000 (from 189 fewer to 126 more)		
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	CLP	CLP and AP	Relative (95% CI)	Absolute		
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) No details of sequence generation were reported by the authors. There was no blinding for participants, clinical staff or research evaluators.
(b) The confidence interval crossed both MID points.

Table 54: Clinical evidence profile: alternative foam mattress versus standard foam mattress

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Alternative foam mattress	Standard foam mattress	Relative (95% CI)	Absolute		
Incidence of pressure ulcers - various alternatives (pooled) – all grades of pressure ulcers[e35;90;167,174;77]												
5	Randomised trials	Very serious[a]	Very serious[b]	No serious indirectness	Serious[d]	None	102/1240 (8.2%)	124/776 (16%)	RR 0.43 (0.24 to 0.76)	91 fewer per 1000 (from 38 fewer to 121 fewer)	Very low	Critical
							-	26.6%		152 fewer per 1000 (from 64 fewer to 202 fewer		
Incidence of pressure ulcers (UK studies only) – all grades of pressure ulcers[e35;167;174;77]												
4	Randomised trials	Very serious[a]	Very serious[c]	No serious indirectness	Serious[d]	None	96/1223 (7.8%)	110/757 (14.5%)	RR 0.41 (0.19 to 0.87)	86 fewer per 1000 (from 19 fewer to 118 fewer)	Very low	Critical

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Alternative foam mattress	Standard foam mattress	Relative (95% CI)	Absolute	Quality	Importance
							-	18.7%		110 fewer per 1000 (from 24 fewer to 151 fewer)		
Incidence of pressure ulcers (pooled) – pressure-reducing foam mattress (SOFTFOAM) versus standard 130mm NHS foam mattress - grade 2 and above pressure ulcers[e90]; [77]												
2	Randomised trials	Very serious[a]	No serious	No serious indirectness	No serious imprecision	None	10/107 (9.3%)	40/99 (40.4%)	RR 0.24 (0.13 to 0.45)	307 fewer per 1000 (from 222 fewer to 352 fewer)	Low	Critical
							-	51.1%		388 fewer per 1000 (from 281 fewer to 445 fewer)		
Acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) *There was unclear sequence generation for 3 studies (Collier 1996, Gray 1994, Hofman 2003 and Santy 1994). There was unclear allocation concealment in 4 studies (Collier 1996, Gray 1994, Hofman 2003 and Santy, 1994). There was no blinding in 3 studies (Collier 1996, Hofman 1994, Russell 2003) and unclear blinding in 2 studies (Gray 1994 and Santy 1994) It was unclear if incomplete outcome data was addressed in 4 studies (Collier 1996, Gray 1994, Hofman 1994 and Santy 1994) It was unclear if similar at baseline in 2 studies (Collier 1996 and Gray 1994) There was different timing of outcome assessment in 2 studies (Collier 1996 and Gray 1994). Higher differential drop-out with higher rate in the standard hospital mattress group (Santy 1994). There was a higher drop-out than event rate for incidence of pressure ulcers, all grades and grade 2 and above (Hofman 1994).*

(b) *I^2 = 77%, p=0.004*

(c) *I^2 =84%, p=0.002*

(d) *The confidence interval crossed 1 MID point.*

(e) *Collier (1996) used RCN grading system, Gray (1994) had no details of grading system, Hofman (1994) used Dutch consensus, Russell (2003) used the Torrance scale, Santy (1994) used NPUAP 1989 grading system.*

12.1.3 Comparisons between alternative foam mattresses

Table 55: Clinical evidence profile: comparisons between alternative foam supports

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**Comparisons between alternative foam supports**	**Control**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
Incidence of pressure ulcers – pressure redistributing mattresses (CLINIFLOAT, OMNIFOAM, THERAREST, TRANSFOAM, VAPERM) versus standard NHS foam mattress (REYLON 150mm) – all grades of pressure ulcers (NPUAP)[h174]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	No serious imprecision	None	42/441 (9.5%)	17/64 (26.6%)	RR 0.36 (0.22 to 0.59)	170 fewer per 1000 (from 109 fewer to 207 fewer)	Low	Critical
							-	26.6%		170 fewer per 1000 (from 109 fewer to 207 fewer)		
Incidence of pressure ulcers - foam mattress replacement (MAXIFLOAT) versus foam mattress overlay (IRIS 3000)– all grades of pressure ulcers[i218]												
1	Randomised trial	Serious[b]	No serious inconsistency	No serious indirectness	Serious[c]	None	5/20 (25%)	12/20 (60%)	RR 0.42 (0.18 to 0.96)	348 fewer per 1000 (from 24 fewer to 492 fewer)	Very low	Critical
							-	60%		348 fewer per 1000 (from 24 fewer to 492		

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**Comparisons between alternative foam supports**	**Control**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
										fewer)		
Incidence of pressure ulcers - solid foam overlay versus convoluted foam overlay – all grades of pressure ulcers (NPUAP)[j103]												
1	Randomised trial	Very serious[g]	No serious inconsistency	No serious indirectness	Serious[c]	None	12/39 (30.8%)	21/45 (46.7%)	RR 0.66 (0.37 to 1.16)	159 fewer per 1000 (from 294 fewer to 75 more)	Low	Critical
							-	46.7%		159 fewer per 1000 (from 294 fewer to 75 more)		
Incidence of pressure ulcers - pressure-reducing foam mattress (TRANSFOAM) versus pressure-reducing foam mattress (TRANSFOAMWAVE) – all grades of pressure ulcers[k76]												
1	Randomised trial	Very serious[d]	No serious inconsistency	No serious indirectness	Very serious[e]	None	1/50 (2%)	1/50 (2%)	RR 1 (0.06 to 15.55)	0 fewer per 1000 (from 19 fewer to 291 more)	Very low	Critical
							-	2%		0 fewer per 1000 (from 19 fewer to 291 more)		
Incidence of pressure ulcers - foam mattress replacement (MAXIFLOAT) versus foam mattress overlay (IRIS 3000)– – grade 2 and above pressure ulcers[9218]												
1	Randomised trial	Serious[b]	No serious inconsistency	No serious indirectness	Serious[c]	None	3/20 (15%)	8/20 (40%)	RR 0.38 (0.12 to 1.21)	248 fewer per 1000 (from 352 fewer to 84 more)	Very low	Critical

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**Comparisons between alternative foam supports**	**Control**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
							-	40%		248 fewer per 1000 (from 352 fewer to 84 more)		
Time to pressure ulcer development (mean days) - foam mattress replacement (MAXIFLOAT) versus foam mattress overlay (IRIS 3000)– all grades of pressure ulcers[218]												
1	Randomised trial	Serious[b]	No serious inconsistency	No serious indirectness	No serious	Very serious[f]	9.2 days	6.5 days	p=0.3288	-	Very low	Important
Acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There was unclear sequence generation, allocation concealment, blinding and addressing of incomplete outcome data reported by the authors. Differential drop-out with higher drop-out in standard hospital mattress group.
(b) There was unclear allocation concealment and blinding. There were baseline differences. Vyhlidal (1997).
(c) The confidence interval crossed 1 MID.
(d) There were unclear sequence generation and addressing of incomplete outcome data. Baseline data were provided for the treatment arm only (Gray (1998)).
(e) The confidence interval crossed both MIDs and there were a limited number of events.
(f) There was not enough data to analyse in Revman.
(g) There was unclear allocation concealment, blinding and baseline differences reported by the authors and the authors did not address incomplete outcome data (Kemp (1993)).
(h) NPUAP 1989 grading system.
(i) There was an unclear grading system used, stage 0= no redness or breakdown; stage 1= erythema only, redness does not disappear for 24 hours after pressure is relieved; stage 2= break in skin such as blisters, or abrasions; stage 3= break in skin exposing subcutaneous tissue; stage 4= break in skin extending through tissue and subcutaneous layers, exposing muscle or bone.
(j) NPUAP1989.

(k) No details of grading system were provided by the authors.

12.1.4 Comparisons between 'low-tech' constant low-pressure supports

Table 56: Clinical evidence profile: comparisons between CLP supports

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	CLP supports	Control	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers – constant low pressure mattress (CARITAL OPTIMA) versus standard foam mattress (10cm thick foam density 35kg/m^3)– all grades of pressure ulcers (Shea)[p198]												
1	Randomised trial	Very serious [a]	No serious inconsistency	No serious indirectness	Serious[b]	None	0/21 (0%)	7/19 (36.8%)	RR 0.06 (0 to 0.99)	346 fewer per 1000 (from 4 fewer to 368 fewer)	Very low	Critical
							-	36.8%		346 fewer per 1000 (from 4 fewer to 368 fewer)		
Incidence of pressure ulcers – dry flotation mattress (SOFFLEX) versus dry flotation mattress (ROHO) – all grades of pressure ulcers (Stirling grade)[p42]												
1	Randomised trial	Very serious[c]	No serious inconsistency	No serious indirectness	Very serious[d]	None	3/41 (7.3%)	5/43 (11.6%)	RR 0.63 (0.16 to 2.47)	43 fewer per 1000 (from 98 fewer to 171 more)	Very low	Critical
							-	11.6%		43 fewer per 1000 (from 97 fewer to 171 more)		
Incidence of pressure ulcers - dry flotation mattress (SOFFLEX) versus dry flotation mattress (ROHO) – grade 2 and above pressure ulcers(Stirling grade)[p42]												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**CLP supports**	**Control**	**Relative (95% CI)**	**Absolute**		
1	Randomised trial	Very serious[c]	No serious inconsistency	No serious indirectness	Very serious[d]	None	1/41 (2.4%)	0/43 (0%)	Peto OR 7.76 (0.15 to 391.44)	20 more (from 40 more to 90 more	Very low	Critical
							-	0%		20 more (from 40 more to 90 more		
Incidence of pressure ulcers - gel mattress versus air-filled overlay (SOFCARE) – all grades of pressure ulcers (NPUAP)[p114]												
1	Randomised trial	Very serious[e]	No serious inconsistency	No serious indirectness	Very serious[d]	None	8/33 (24.2%)	10/33 (30.3%)	RR 0.8 (0.36 to 1.77)	61 fewer per 1000 (from 194 fewer to 233 more)	Very low	Critical
							-	15.2%		30 fewer per 1000 (from 97 fewer to 117 more)		
Incidence of pressure ulcers - gel mattress versus air-filled overlay (SOFCARE) – grade 2 and above pressure ulcers (NPUAP)[p114]												
1	Randomised trial	Very serious[e]	No serious inconsistency	No serious indirectness	Very serious[d]	None	4/33 (12.1%)	5/33 (15.2%)	RR 0.8 (0.24 to 2.72)	23 fewer per 1000 (from 2 fewer to 35 fewer)	Very low	Critical
							-	15.2%		30 fewer per 1000 (from 116 fewer to 261 more)		
Incidence of pressure ulcers - static air mattress (GAY MAR SOFCARE) versus water mattress (LOTUS PXM 3666)– all grades of pressure ulcers (grading system not reported)[16185]												
1	Randomised	Very	No serious	No serious	Very	None	1/20	2/17	RR 0.43	67 fewer	Very low	Critical

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**CLP supports**	**Control**	**Relative (95% CI)**	**Absolute**		
	trial	serious[f]	inconsistency	indirectness	serious[d]		(5%)	(11.8%)	(0.04 to 4.29)	per 1000 (from 113 fewer to 387 more)		
							-	11.8%		67 fewer per 1000 (from 113 fewer to 388 more)		
Incidence of pressure ulcers – inflated static overlay (RIK or THERAKAIR) versus microfluid static overlay – all grades of pressure ulcers (NPUAP)[217]												
1	Randomised trial	Serious[q]	No serious inconsistency	No serious indirectness	Very serious[d]	None	2/55 (3.6%)	6/50 (12%)	RR 0.3 (0.06 TO 1.43)	84 fewer per 1000 (from 13 fewer to 52 more)	Very low	Critical
							-	12%		84 fewer per 1000 (from 13 fewer to 52 more)		
Incidence of pressure ulcers - foam overlay versus Silicore overlay (SPENCO) – grade 2and above pressure ulcers[p192]												
1	Randomised trial	Very serious[g]	No serious inconsistency	No serious indirectness	Very serious[d]	None	14/34 (41.2%)	12/34 (35.3%)	RR 1.17 (0.64 to 2.14)	60 more per 1000 (from 127 fewer to 402 more)	Very low	Critical
							-	29.4%		60 more per 1000 (from 127 fewer to 402 more)		

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**CLP supports**	**Control**	**Relative (95% CI)**	**Absolute**		
Incidence of pressure ulcers – Australian medical sheepskin versus no sheepskin (all grades of pressure ulcers)[p130]; [126]; [101]												
3	Randomised trials	Very serious[h]	Serious[i]	No serious indirectness	No serious	None	59/644 (9.2%)	120/637 (18.8%)	RR 0.48 (0.31 to 0.74)	98 fewer per 1000 (from 49 fewer to 130 fewer)	Very low	Critical
							-	16.6%		86 fewer per 1000 (from 43 fewer to 115 fewer)		
Incidence of pressure ulcers - Australian medical sheepskin versus no sheepskin (grade 2 and above pressure ulcers)[p130]; [126]; [101]												
3	Randomised trials	Very serious[h]	No serious inconsistency	No serious indirectness	Serious[b]	None	18/644 (2.8%)	33/637 (5.2%)	RR 0.56 (0.32 to 0.97)	23 fewer per 1000 (from 2 fewer to 35 fewer)	Very low	Critical
							-	3.5%		15 fewer per 1000 (from 1 fewer to 24 fewer)		
Incidence of pressure ulcers - static air overlay (and cold foam mattress) versus cold foam mattress– grade 2 and above pressure ulcers[16209]												
1	Randomised trial	Very serious[k]	No serious inconsistency	No serious indirectness	Serious[b]	None	2/38 (5.3%)	7/36 (19.4%)	RR 0.27 (0.06 to 1.22)	142 fewer per 1000 (from 183 fewer to 43 more)	Very low	Critical
							-	19.4%		142 fewer		

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	CLP supports	Control	Relative (95% CI)	Absolute		
										per 1000 (from 182 fewer to 43 more)		
Incidence of pressure ulcers – 3D macroporous polyester overlay versus visco-elastic overlay (all grades of pressure ulcers)[30,163]												
2	Randomised trial	Serious[r]	No serious inconsistency	No serious indirectness	Serious[b]	None	0/60 (0%)	1/62 (1.6%)	Peto OR 0.14 (0.00 to 7.21)	20 fewer per 1000 (from 70 fewer to 40 more)	Low	Critical
Comfort - Australian medical sheepskin versus no sheepskin[101]												
1	Randomised trial	Very serious[h]	No serious inconsistency	No serious indirectness	No serious	Very serious[l]	-	-	-	See footnote[l]	Very low	Critical
Withdrawal due to discomfort – Australian medical sheepskin versus no sheepskin[126]												
1	Randomised trial	Serious[h]	No serious inconsistency	No serious indirectness	No serious	Very serious[m]	-	-	-	See footnote[m]	Very low	Critical
Patient acceptability – very uncomfortable - dry flotation mattress (SOFFLEX) versus dry flotation mattress (ROHO)[42]												
1	Randomised trial	Serious[c]	No serious inconsistency	No serious indirectness	No serious	None	0/41 (0%)	0/43 (0%)	Not pooled	Not pooled	Moderate	Critical
Patient acceptability – uncomfortable - dry flotation mattress (SOFFLEX) versus dry flotation mattress (ROHO)[42]												
1	Randomised trial	Serious[c]	No serious inconsistency	No serious indirectness	Serious[b]	None	0/41 (0%)	5/43 (11.6%)	OR 0.13 (0.02 to 0.77)	99 fewer per 1000 (from 24 fewer to 114 fewer)	Low	Critical
							-	11.6%		99 fewer per 1000 (from 24 fewer to		

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	CLP supports	Control	Relative (95% CI)	Absolute	Quality	Importance
										113 fewer)		
Patient acceptability – adequate - dry flotation mattress (SOFFLEX) versus dry flotation mattress (ROHO)[42]												
1	Randomised trial	Serious[c]	No serious inconsistency	No serious indirectness	Very serious[d]	None	4/41 (9.8%)	4/43 (9.3%)	RR 1.05 (0.28 to 3.92)	5 more per 1000 (from 67 fewer to 272 more)	Very low	Critical
							-	9.3%		5 more per 1000 (from 67 fewer to 272 more)		
Patient acceptability – comfortable - dry flotation mattress (SOFFLEX) versus dry flotation mattress (ROHO)[42]												
1	Randomised trial	Serious[c]	No serious inconsistency	No serious indirectness	Very serious[d]	None	24/41 (58.5%)	24/43 (55.8%)	RR 1.05 (0.72 to 1.52)	28 more per 1000 (from 156 fewer to 290 more)	Very low	Critical
							-	55.8%		28 more per 1000 (from 156 fewer to 290 more)		
Patient acceptability – very comfortable - dry flotation mattress (SOFFLEX) versus dry flotation mattress (ROHO)[42]												
1	Randomised trial	Serious[c]	No serious inconsistency	No serious indirectness	Very serious[d]	None	13/41 (31.7%)	10/43 (23.3%)	RR 1.36 (0.67 to 2.76)	84 more per 1000 (from 77 fewer to 409 more)	Very low	Critical
							-	23.3%		84 more		

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**CLP supports**	**Control**	**Relative (95% CI)**	**Absolute**		
										per 1000 (from 77 fewer to 410 more)		
Time to onset of first pressure ulcer - Australian medical sheepskin versus no sheepskin[101]												
1	Randomised trial	Very serious[h]	No serious inconsistency	No serious indirectness	No serious	Serious[n]	-	-	HR 0.39 (95% CI 0.22 to 0.69)	p<0.001	Very low	Important
Time to onset of first pressure ulcer - Australian medical sheepskin versus no sheepskin[130]												
1	Randomised trial	Very serious[h]	No serious inconsistency	No serious indirectness	No serious	Very serious[p]	12 days	9 days	-	-	Very low	Important
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There was unclear sequence generation reported by the authors but block randomisation may have been used. Some outcome assessors may have been blinded but it was unclear. No allocation concealment was reported. There was a higher drop-out than event rate for incidence of pressure ulcers(Takala (1996)).

(b) The confidence interval crossed 1 MID.

(c) There was unclear blinding reported by the authors. There was a higher drop-out than event rate for incidence of all grades of pressure ulcers and grade 2 and above pressure ulcers(Cooper (1998)).

(d) The confidence interval crossed both MIDs.

(e) There was unclear allocation concealment and blinding reported by the authors and methods used foraddressing incomplete outcome data were unclear (Lazzara (1991)).

(f) There was unclear sequence generation, allocation concealment and blinding reported by the authors and methods for addressing incomplete outcome data. Similarity at baseline was unclear(Sideranko (1992)).

(g) There was unclear sequence generation, allocation concealment and blinding reported by the authors. (Stapleton (1986)).

(h) There was unclear sequence generation (Jolley 2004), unclear allocation concealment (McGowan 2000) and no blinding (Jolley 2004, McGowan 2000 and Mistiaen 2009, 2010). Methods for addressing incomplete outcome data were unclear (Mistiaen 2009, 2010) and not addressed (Jolley 2004).It was unclear if there were baseline differences (Jolley 2004). There was a higher drop-out than event rate (Jolley 2004, Mistiaen 2009, 2010) for incidence of pressure ulcers, all grades and grade 2 and above.

(i) I^2 = 52%, p=0.12.
(j) The confidence interval crossed 1 MID.
(k) There were ethical issues of not using repositioning. Limited details of sequence generation and allocation concealment were reported by the authors. No details of blinding of outcome assessors were reported. There was a higher drop-out than event rate for incidence of pressure ulcers(Van Leen (2011))
(l) Comfort data was not given for both groups.Ten participants in the sheepskin group complained about its comfort (too hot= 6; sensitive to the wool surface= 2; uncomfortable= 2) and requested its removal.
(m) The study did not report details of comfort in both groups. Six participants in the experimental group withdrew before completion of data collection because the sheepskin caused an irritation, was too hot or uncomfortable.
(n) No data was given for each arm but HR presented. Kaplan-Meier survival curves used (p<0.001, log-rank test).
(o) There was not enough data to analyse in Revman.
(p) Takala (1996) used Shea 1975 grading system; Cooper (1998) used the Stirling grading system; Lazzara (1991) used NPUAP 1989 system; Sideranko (1992)did not report the grading system; Stapleton (1986) adapted the grading system from Kenedi et al (1976) bed sore biomechanics study, where category A= superficial/blister, category B = a break in skin (no crater) and category C= a break in skin (with crater) and category D= blackened tissue; Jolley (2004) and McGowan (2000) used the US Agency for Health Care and Policy Research grading system; Mistiaen (2009, 2010) and Van Leen 2011 used the EPUAP grading system.
(q) No details of sequence generation were reported. There was no blinding for patient, clinical staff or research evaluator.
(r) Ricci (2013) reported unclear allocation concealment and there were baseline differences in Norton scores. Cassino (2013) found baseline differences for grade of pressure ulcers.

12.1.5 'High-tech' pressure supports

This section outlines 3 main groups of supportsL alternating pressure devices (AP), low-air loss beds and air-fluidised low beds.

12.1.5.1 Alternating-pressure compared with constant low pressure

Table 57: Clinical evidence profile: alternating-pressure versus standard foam mattress

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Alternating-pressure	Standard foam mattress	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers – alternating air mattress or overlay versus standard foam mattress - all grades of pressure ulcers[c3];[172]												
2	Randomised trials	Very serious[a]	No serious inconsistency	No serious indirectness	No serious imprecision	None	13/221 (5.9%)	31/188 (16.5%)	RR 0.31 (0.17 to 0.58)	114 fewer per 1000 (from 69 fewer to 137 fewer)	Low	Critical
							-	25%		172 fewer per 1000 (from 105 fewer to 207 fewer)		
Incidence of pressure ulcers – alternating air mattress versus standard foam mattress - grade 2 and above pressure ulcers[c172]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	5/55 (9.1%)	6/27 (22.2%)	RR 0.41 (0.14 to 1.22)	131 fewer per 1000 (from 191 fewer to 49 more)	Very low	Critical
							-	22.2%		131 fewer per 1000 (from 191 fewer to		

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Alternating-pressure	Standard foam mattress	Relative (95% CI)	Absolute	Quality	Importance
										49 more)		
Acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There was unclear sequence generation, allocation concealment, blinding and addressing incomplete outcome data reported by the authors (Andersen 1982). There was unclear blinding and no addressing of incomplete outcome data. There was a higher drop-out than event rate for incidence of pressure ulcers for all grades and grade 2 and above (Sanada 2003).

(b) The confidence interval crossed 1 MID point.

(c) Andersen 1982 used the classification of Bullae, black necrosis, and skin defects as evidence of pressure sores. Sanada (2003) used NPUAP 1989 grading system.

12.1.5.2 Alternating-pressure compared with constant low pressure

Table 58: Clinical evidence profile: alternating-pressure versus constant low-pressure

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Alternating-pressure (AP)	Constant low-pressure	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers – alternating pressure (all studies meta-analysed all had various types of alternating pressure) versus constant low pressure (various types of constant low-pressure) - all grades of pressure ulcers[39; 48; 192; 223; 68; 3; 161; 185; 214]												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**Alternating-pressure (AP)**	**Constant low-pressure**	**Relative (95% CI)**	**Absolute**		
11	Randomised trials	Very serious[a,b,c,d,e]	No serious inconsistency	No serious indirectness	Serious[f]	None	125/785 (15.9%)	170/837 (20.3%)	RR 0.85 (0.65 to 1.11)	30 fewer per 1000 (from 71 fewer to 22 more)	Very low	Critical
							-	23.1%		35 fewer per 1000 (from 81 fewer to 25 more)		
Incidence of pressure ulcers – alternating pressure (various) versus constant low pressure (various) – all grades of pressure ulcers[68]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	No serious imprecision	None	15/115 (13%)	39/115 (33.9%)	RR 0.38 (0.22 to 0.66)	210 fewer per 1000 (from 115 fewer to 265 fewer)	Low	Critical
							-	33.9%		210 fewer per 1000 (from 115 fewer to 264 fewer)		
Incidence of pressure ulcers – alternating pressure versus Silicore or foam overlay[k] – all grades of pressure ulcers and all populations[l39; 48; 192; 223]												
4	Randomised trials	Very serious[b]	No serious inconsistency	No serious indirectness	Serious[f]	None	59/145 (40.7%)	81/186 (43.5%)	RR 0.91 (0.72 to 1.16)	39 fewer per 1000 (from 122 fewer to 70 more)	Very low	Critical
							-	31.6%		28 fewer per 1000		

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Alternating-pressure (AP)	Constant low-pressure	Relative (95% CI)	Absolute		
										(from 88 fewer to 51 more)		
Incidence of pressure ulcers – alternating pressure versus water or static air mattress – all grades of pressure ulcer[sl3,161,185]												
3	Randomised trials	Very serious[c]	No serious inconsistency	No serious indirectness	Very serious[h]	None	13/226 (5.8%)	12/232 (5.2%)	RR 1.31 (0.51 to 3.35)	16 more per 1000 (from 25 fewer to 122 more)	Very low	Critical
							-	5%		15 more per 1000 (from 25 fewer to 117 more)		
Incidence of pressure ulcers – alternating pressure setting on mattress (DUO 2) versus continuous low pressure setting on mattress (DUO 2) – all grades of pressure ulcers[l31]												
1	Randomised trial	Very serious[d]	No serious inconsistency	No serious indirectness	Very serious[h]	None	2/69 (2.9%)	1/71 (1.4%)	RR 2.06 (0.19 to 22.18)	15 more per 1000 (from 11 fewer to 298 more)	Very low	Critical
							-	1.4%		15 more per 1000 (from 11 fewer to 297 more)		
Incidence of pressure ulcers – alternating pressure air mattress (ALPHA-X-CELL) versus viscoelastic foam mattress (TEMPUR) – all grades of pressure ulcers[l214]												
1	Randomised trial	Serious[e]	No serious inconsistency	No serious indirectness	Very serious[g]	None	34/222 (15.3%)	35/225 (15.6%)	RR 0.98 (0.64 to 1.52)	3 fewer per 1000 (from 56 fewer to	Very low	Critical

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Alternating-pressure (AP)	Constant low-pressure	Relative (95% CI)	Absolute		
										81 more)		
							-	15.6%		3 fewer per 1000 (from 56 fewer to 81 more)		
Incidence of pressure ulcers – alternating pressure mattress (NIMBUS 3) versus dry flotation mattress overlay (ROHO) – all grades of pressure ulcers[l125]												
1	Randomised trial	Very serious[i]	No serious inconsistency	No serious indirectness	Very serious[g]	None	2/8 (25%)	2/8 (25%)	RR 1 (0.18 to 5.46)	0 fewer per 1000 (from 205 fewer to 1000 more)	Very low	Critical
							-	0%		-		
Incidence of pressure ulcers – alternating pressure mattress versus Silicore – participants not singularly with chronic neurological conditions – all grades of pressure ulcers[12192];[223]												
2	Randomised trials	Very serious[b]	No serious inconsistency	No serious indirectness	Very serious[g]	None	16/57 (28.1%)	32/94 (34%)	RR 0.89 (0.54 to 1.47)	37 fewer per 1000 (from 157 fewer to 160 more)	Very low	Critical
							-	30.7%		34 fewer per 1000 (from 141 fewer to 144 more)		
Incidence of pressure ulcers –alternating pressure overlay versus silicore overlay – participants with chronic neurological conditions – all grades of pressure ulcers[1239]; [48]												
2	Randomised trials	Very serious[b]	No serious inconsistency	No serious indirectness	Serious[f]	None	43/88 (48.9%)	49/92 (53.3%)	RR 0.92 (0.7 to 1.22)	43 fewer per 1000 (from 160 fewer to	Very low	Critical

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Alternating-pressure (AP)	Constant low-pressure	Relative (95% CI)	Absolute		
										117 more)		
								42.1%	-	34 fewer per 1000 (from 126 fewer to 93 more)		
Incidence of pressure ulcers – grade 2 and above pressure ulcers[68];[161,192,214];[125]												
6	Randomised trials	Very serious[b]	No serious inconsistency	No serious indirectness	Serious[f]	None	45/394 (11.4%)	70/432 (16.9%)	RR 0.80 (0.58 to 1.11)	34 fewer per 1000 (from 71 fewer to 19 more)	Very low	Critical
							-	14%		28 fewer per 1000 (from 59 fewer to 15 more)		
Drop out due to discomfort – alternating pressure overlay versus silicore overlay [39]												
1	Randomised trial	Very serious[b]	No serious inconsistency	No serious indirectness	Very serious[g]	None	19/93 (20.4%)	17/94 (18.1%)	RR 1.13 (0.63 to 2.03)	24 more per 1000 (from 67 fewer to 186 more)	Very low	Critical
								0%		-		
Comfort rating at 14 days dynamic flotation mattress (NIMBUS 2) and alternating pressure cushion versus low pressure inflatable mattress (REPOSE SYSTEM) and cushion (polyurethane) [161]												
1	Randomised trial	Very serious[c]	No serious inconsistency	No serious indirectness	Very serious[g]	None	60 (s.d 25) n= 26	67 (s.d 18) n= 24	-	MD 7 lower (19.01 lower to	Very low	Critical

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Alternating-pressure (AP)	Constant low-pressure	Relative (95% CI)	Absolute	Quality	Importance
										5.01 higher)		
Length of stay in hospital - alternating pressure setting on mattress (DUO 2) versus continuous low pressure setting on mattress (DUO 2) [31]												
1	Randomised trial	Very serious[d]	No serious inconsistency	No serious indirectness	No serious	Very serious[j]	-	-	-	See footnote10	Very low	Important
Rate of development of pressures ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There was not adequate sequence generation, allocation concealment and unclear blinding was reported by the authors. There was a higher drop-out than the event rate for incidence of pressure ulcers (Gebhardt 1996).

(b) There was unclear sequence generation reported by the authors (Conine 1990, Daeschel 1985, Stapleton 1986, Whitney 1984). There was unclear allocation concealment reported by the authors (Conine 1990, Daeschel 1985, Stapleton 1986). There was unclear blinding reported by the authors(Daeschel 1985, Stapleton 1986, Whitney 1984). There was unclear addressing of incomplete outcome data (Daeschel 1985).There were unclear baseline differences (Whitney 1984).

(c) There was unclear sequence generation reported by the authors (Anderson 1982, Sideranko 1992). There was unclear allocation concealment reported by the authors(Anderson 1982, Price 1999, Sideranko 1992). There was unclear blinding reported by the authors (Anderson 1982, Sideranko 1992) and no blinding (Price 1999). There was unclear addressing of incomplete outcome data (Anderson 1982, Price 1999, Sideranko 1992). There was a higher drop-out rate than event rate for incidence of all grades of pressure ulcers and comfort rating at 14 days (Price 1999).

(d) There was unclear sequence generation and allocation concealment reported by the authors. There were differences between groups at baseline. There was a higher drop-out rate than event rate(Cavicchioli (2007)).

(e) There was unclear blinding and addressing of incomplete outcome data(Vanderwee (2005)).

(f) The confidence interval crossed 1 MID.

(g) The confidence interval crossed both MIDs.

(h) The confidence interval crossed both MIDs and limited number of events.

(i) There were baseline differences; the allocation concealment unclear and only single blinding (Malbrain, 2010).

(j) There were no data presented, but the authors state that there was no difference in length of stay related to pressure ulcer development among high-risk participantsplaced on the intervention or control mattresses.

(k) Conine (1990) and Daeschel (1985) included participants with chronic neurological conditions, which we identified as a group to be stratified. However the Cochrane review included these studies together and in a subgroup test, no subgroup differences were found so the results are presented together. The results of those with and without chronic neurological conditions are also presented separately.

(l) Conine (1990) and Daechsel (1985) used Exton-Smith scale; Stapleton (1986) adapted the grading system from Kenedi et al (1976) bed sore biomechanics study, where category A= superficial/blister, category B = a break in skin (no crater) and category C= a break in skin (with crater) and category D= blackened tissue; Whitney (1984) used a system where stage 0 = no redness or skin breakdown; stage 1= skin redness, fades in 15 minutes or less; stage II inflammation of the skin, fading time exceeds 15 minutes, less than 1 hour; stage III= inflammation of the skin fading time exceeds 1 hour; stage IV= skin break with redness of surrounding skin, redness fades longer than 1 hour; Gebhardt (1996) used a grading system by Bliss (1966) grade 1= persistent erythema; grade 2= epidermal loss; grade 3= blue-black discoloration or cavity extending to dermis ; grade 4=cavity to subcutaneous tissue or deeper; Andersen (1982) used bullae, black necrosis and skin defects as evidence of pressure sores; Price (1999) used the Hofman 1994 scale where 0=normal skin, 1= persistent erythema of the skin; 2= blister formation; 3= superficial subcutaneous necrosis; 4= deep subcutaneous necrosis; Sideranko (1992) did not report grading system; Vanderwee (2005) did not report grading system but grade 1 was non-blanchable erythema or NBE; Malbrain (2010) used EPUAP and Cavicchioli (2007) used EPUAP 2007.

Table 59: Clinical evidence profile: alternating pressure and constant low pressure in ICU/post ICU (factorial design)

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**AP and CLP in ICU/post ICU (factorial design)**	**Control**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
Incidence of pressure ulcers – standard mattress in ICU/standard foam mattress post-ICU versus alternating pressure mattress (NIMBUS) in ICU/standard foam mattress post-ICU – grade 2 and above pressure ulcers[113]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	14/80 (17.5%)	10/80 (12.5%)	RR 1.40 (0.66 to 2.96)	50 more per 1000 (from 60 fewer to 160 more)	Very low	Critical
							-	12.5%		50 more per 1000 (from 60 fewer to 160 more)		
Acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	AP and CLP in ICU/post ICU (factorial design)	Control	Relative (95% CI)	Absolute	Quality	Importance
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There was unclear sequence generation, allocation concealment and no blinding(Laurent (1998)).
(b) The confidence interval crossed 1 MID.

Table 60: Clinical evidence profile: standard mattress in ICU/standard foam mattress post-ICU versus standard ICU/constant low pressure mattress (TEMPUR) post-ICU – grade 2 and above pressure ulcers

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	AP and CLP in ICU/post ICU (factorial design)	Control	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers – standard mattress in ICU/standard foam mattress post-ICU versus standard ICU/constant low pressure mattress (TEMPUR) post-ICU – grade 2 and above pressure ulcers [113]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	14/80 (17.5%)	11/75 (14.7%)	RR 1.19 (0.58 to 2.46)	28 more per 1000 (from 62 fewer to 214 more)	Very low	Critical
							-	14.7%		28 more per 1000 (from 62 fewer to 215 more)		
Acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There were unclear sequence generation, allocation concealment and no blinding. Laurent (1998).
(b) The confidence interval crossed both MIDs.

Table 61: Clinical evidence profile: alternating pressure (NIMBUS) ICU/SFM post-ICU versus standard ICU/constant low pressure mattress (TEMPUR) post-ICU – grade 2 and above pressure ulcers

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	AP and CLP in ICU/post ICU (factorial design)	Control	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers - alternating pressure (NIMBUS) ICU/SFM post-ICU versus standard ICU/constant low pressure mattress (TEMPUR) post-ICU – grade 2 and above pressure ulcers[113]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	10/80 (12.5%)	11/75 (14.7%)	RR 0.85 (0.38 to 1.89)	22 fewer per 1000 (from 91 fewer to 131 more)	Very low	Critical
							-	14.7%		22 fewer per 1000 (from 91 fewer to 131 more)		
Acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There was unclear sequence generation, allocation concealment and no blinding reported by the authors (Laurent (1998)).
(b) The confidence interval crossed both MIDs.

Table 62: Clinical evidence profile: standard ICU/standard foam mattress post-ICU versus slternating pressure mattress (NIMBUS) ICU/constant low pressure mattress (TEMPUR)CLP post-ICU – grade 2 and above pressure ulcers

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	AP and CLP in ICU/post ICU (factorial design)	Control	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers - standard ICU/standard foam mattress post-ICU versus alternating pressure mattress (NIMBUS) ICU/constant low pressure mattress (TEMPUR)CLP post-ICU – grade 2 and above pressure ulcers[113]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	14/80 (17.5%)	10/77 (13%)	RR 1.35 (0.64 to 2.85)	45 more per 1000 (from 47 fewer to 240 more)	Very low	Critical
							-	13%		46 more per 1000 (from 47 fewer to 240 more)		
Acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There was unclear sequence generation, allocation concealment and no blinding. Laurent (1998).
(b) The confidence interval crossed both MIDs.

Table 63: Clinical evidence profile: alternating pressure mattress (NIMBUS) ICU/standard foam mattress post-ICU versus alternating pressure mattress (NIMBUS) ICU/constant low pressure mattress (TEMPUR) post-ICU – grade 2 and above pressure ulcers

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	AP and CLP in ICU/post ICU (factorial design)	Control	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers – alternating pressure mattress (NIMBUS) ICU/SFM post-ICU versus alternating pressure mattress (NIMBUS) ICU/constant low pressure mattress (TEMPUR) post-ICU – grade 2 and above pressure ulcers[113]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	10/80 (12.5%)	10/77 (13%)	RR 0.96 (0.42 to 2.18)	5 fewer per 1000 (from 75 fewer to 153 more)	Very low	Critical
							-	13%		5 fewer per 1000 (from 75 fewer to 153 more)		
Acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There was unclear sequence generation, allocation concealment and no blinding reported by the authors(Laurent (1998)).

(b) The confidence interval crossed both MIDs.

Table 64: Clinical evidence profile: standard ICU/constant low pressure mattress (TEMPUR) post-ICU versus alternating pressure mattress (NIMBUS) ICU/constant low pressure mattress (TEMPUR) post-ICU – grade 2 and above pressure ulcers

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	AP and CLP in ICU/post ICU (factorial design)	Control	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers - standard ICU/constant low pressure mattress (TEMPUR) post-ICU versus alternating pressure mattress (NIMBUS) ICU/constant low pressure mattress (TEMPUR) post-ICU – grade 2 and above pressure ulcers[113]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	11/75 (14.7%)	10/77 (13%)	RR 1.13 (0.51 to 2.5)	17 more per 1000 (from 64 fewer to 195 more)	Very low	Critical
							-	13%		17 more per 1000 (from 64 fewer to 195 more)		
Acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There were unclear sequence generation, allocation concealment and no blinding. Laurent (1998).
(b) The confidence interval crossed both MIDs.

12.1.6 Comparisons between different alternating-pressure devices

Table 65: Clinical evidence profile: comparisons between alternating-pressure devices

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Comparisons between alternating-pressure devices	Control	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers – alternating-pressure mattress (TRINOVA) versus control – all grades of pressure ulcers[199]												
1	Randomised trial	Very serious[d]	No serious inconsistency	No serious indirectness	Very serious[e]	None	0/22 (0%)	2/22 (9.1%)	RR 0.2 (0.01 to 3.94)	73 fewer per 1000 (from 90 fewer to 267 more)	Very low	Critical
							-	9.1%		73 fewer per 1000 (from 90 fewer to 268 more)		
Incidence of pressure ulcers – alternating low pressure air mattress with multi-stage inflation and deflation of air cells versus standard (CLINACTIV, HILLROM) alternating low pressure air mattress with single-stage inflation and deflation of air cells – all grades of pressure ulcers[54]												
1	Randomised trial	Very serious[h]	No serious inconsistency	No serious indirectness	Serious[b]	None	68/298 (22.8%)	56/312 (17.9%)	RR 1.27 (0.93 to 1.74)	48 more per 1000 (from 13 fewer to 133 more)	Very low	Critical
							-	18%		49 more per 1000 (from 13 fewer to 133 more)		
Incidence of pressure ulcers – alternating-pressure mattress with 2 layers of air cells (PEGASUS AIRWAVE SYSTEM) versus alternating-pressure large cell ripple mattress – grade 2 and above pressure ulcers[61]												

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**Comparisons between alternating-pressure devices**	**Control**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	5/31 (16.1%)	12/31 (38.7%)	RR 0.42 (0.17 to 1.04)	225 fewer per 1000 (from 321 fewer to 15 more)	Very low	Critical
							-	38.7%		224 fewer per 1000 (from 321 fewer to 15 more)		
Incidence of pressure ulcers – alternating-pressure mattress (PEGASUS AIRWAVE SYSTEM) versus alternating-pressure mattress (PEGASUS CAREWAVE SYSTEM) – grade 2 and above pressure ulcers[87]												
1	Randomised trial	Very serious[c]	No serious inconsistency	No serious indirectness	No serious imprecision	None	0/36 (0%)	0/39 (0%)	Not pooled	Not pooled	Low	Critical
								0%		-		
Incidence of pressure ulcers - alternating-pressure mattress (TRINOVA) versus control – grade 2 and above pressure ulcers[199]												
1	Randomised trial	Very serious[d]	No serious inconsistency	No serious indirectness	Very serious[e]	None	0/22 (0%)	2/22 (9.1%)	RR 0.2 (0.01 to 3.94)	73 fewer per 1000 (from 90 fewer to 267 more)	Very low	Critical
							-	9.1%		73 fewer per 1000 (from 90 fewer to 268 more)		
Incidence of pressure ulcers – alternating pressure overlay versus alternating pressure mattress – grade 2 and above pressure ulcers[147]												
1	Randomised	Very	No serious	No serious	Serious[b]	None	106/989	101/982	RR 1.04	4 more	Very	Critical

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**Comparisons between alternating-pressure devices**	**Control**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
	trial	serious[f]	inconsistency	indirectness			(10.7%)	(10.3%)	(0.81 to 1.35)	per 1000 (from 20 fewer to 36 more)	low	
							-	10.3%		4 more per 1000 (from 20 fewer to 36 more)		
Incidence of pressure ulcers – alternating pressure bed (THERAPULSE) versus alternating pressure mattress (HILL-ROM DUO) – grade 2 and above pressure ulcers[200]												
1	Randomised trial	Very serious[g]	No serious inconsistency	No serious indirectness	Very serious[e]	None	3/30 (10%)	6/32 (18.8%)	RR 0.53 (0.15 to 1.94)	88 fewer per 1000 (from 159 fewer to 176 more)	Very low	Critical
							-	18.8%		88 fewer per 1000 (from 160 fewer to 177 more)		
Incidence of pressure ulcers - alternating low pressure air mattress with multi-stage inflation and deflation of air cells versus standard (CLINACTIV, HILLROM) alternating low pressure air mattress with single-stage inflation and deflation of air cells – grade 2 and above pressure ulcers[54]												
1	Randomised trial	Very serious[h]	No serious inconsistency	No serious indirectness	Very serious[e]	None	17/298 (5.7%)	18/312 (5.8%)	RR 0.99 (0.52 to 1.88)	1 fewer per 1000 (from 28 fewer to 51 more)	Very low	Critical
							-	0%		-		
Withdrawal due to discomfort- alternating low pressure air mattress with multi-stage inflation and deflation of air cells versus standard (CLINACTIV, HILLROM) alternating low												

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**Comparisons between alternating-pressure devices**	**Control**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
pressure air mattress with single-stage inflation and deflation of air cells[54]												
1	Randomised trial	Very serious[h]	No serious inconsistency	No serious indirectness	Very serious[e]	None	11/298 (3.7%)	17/312 (5.4%)	RR 0.68 (0.32 to 1.42)	17 fewer per 1000 (from 37 fewer to 23 more)	Very low	Critical
							-	0%		-		
Comfort alternating-pressure mattress (TRINOVA) versus control[199]												
1	Randomised trial	Very serious[c]	No serious inconsistency	No serious indirectness	No serious imprecision	Very serious[i]	n=18	-	-	-	Very low	Critical
Length of stay in hospital (mean days) for people who did develop a pressure ulcer - alternating pressure bed (THERAPULSE) versus alternating pressure mattress (DUP) [200]												
1	Randomised trial	Very seriousc	No serious inconsistency	No serious indirectness	No serious imprecision	Very serious[j]	26 (range 23-37.3)	24 (range 13-59)	-	-	Very low	Important
Length of stay in hospital (days) for people who did develop a pressure ulcer- alternating pressure bed (THERAPULSE) versus alternating pressure mattress (DUP) [200]												
1	Randomised trial	Very serious[c]	No serious inconsistency	No serious indirectness	No serious imprecision	Very serious[j]	18 (range 5-127)	20 (range 5-49)	-	-	Very low	Important
Time to develop new pressure ulcer (days) - alternating low pressure air mattress with multi-stage inflation and deflation of air cells versus standard (CLINACTIV, HILLROM) alternating low pressure air mattress with single-stage inflation and deflation of air cells[54]												
1	Randomised trial	Serious[h]	No serious inconsistency	No serious indirectness	No serious imprecision	Very serious[j]	5.0 (IQR 3.0-8.5)	8.0 days (IQR 3.0-8.5)	p=0.18211	-	Very low	Important
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Comparisons between alternating-pressure devices	Control	Relative (95% CI)	Absolute		
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There was inadequate sequence generation reported by the authors. There was unclear allocation concealment, blinding and addressing of incomplete outcome data (Exton-Smith 1982).
(b) The confidence interval crossed 1 MID.
(c) There was unclear sequence generation, allocation concealment, blinding and addressing of incomplete outcome data reported by the authors. There were baseline differences (Hampton 1997).
(d) There was unclear sequence generation, blinding and addressing incomplete outcome data reported by the authors. There was selective reporting (Taylor 1999).
(e) The confidence interval crossed both MIDs.
(f) There was no blinding reported by the authors. There was a high drop-out in both groups (Nixon 2006).
(g) There was unclear sequence generation and addressing of incomplete outcome data reported by the authors (Theaker 2005).
(h) There was no blinding of outcome assessors reported by the authors. There was a high drop-out in both groups (Demarre 2012).
(i) Only comfort data for the intervention studied was reported. 18/22 participants completed the comfort questionnaire, 11/18 (61.1%) described the mattress as being comfortable. Most 10/18 (55.5%) found the mattress to be acceptable; overall opinion was that the mattress was unacceptable 5/18.
(j) There was not enough data provided to analyse in Revman.
(k) Mann-Whitney U-test=113, p=0.182.
(l) Taylor (1999) did not report the grading system used but both pressure ulcers were superficial 1 was non-blanching erythema and 1 was a superficial break in the skin. Demarre (2012) used EPUAP 1999 grading system; Exton-Smith (1982) unclear grading system but included grade 3 and 4 which were superficial or deep sores; Hampton (1997) did not report the grading system; Nixon (2006) used EPUAP 2004 and NPUAP 1999; Theaker (2005) used the Lowthian scale.

12.1.7 Low-air-loss (LAL) beds

Three studies evaluated the use of low-air-loss beds. Such devices provide a flow of air that assists in controlling the microclimate of the person's skin (NPUAP 2007).[20] Two studies (Inman 1993 and Cobb 1997) were pooled as they included people in ICU.[33,93] A further study (Bennett) considered a low-air-loss hydrotherapy bed compared to a variety of mattresses which was not in people in ICU, and therefore was not pooled.[14]

12.1.7.1 Comparisons between LAL and other devices

Table 66: Clinical evidence profile: low air loss versus standard bed

Quality assessment	No of patients	Effect	Quality	Importance

No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**Low air loss**	**Standard bed**	**Relative (95% CI)**	**Absolute**		
Incidence of pressure ulcers – low-air-loss bed (KINAIR) versus static air mattress overlay (EHOB WAFFLE) or standard ICU bed - people in ICU - all grades of pressure ulcers[e33,94]												
2	Randomised trials	Very serious[a]	No serious inconsistency	No serious indirectness	No serious	None	12/111 (10.8%)	37/110 (33.6%)	RR 0.32 (0.18 to 0.58)	229 fewer per 1000 (from 141 fewer to 276 fewer)	Low	Critical
							-	35.4%		241 fewer per 1000 (from 149 fewer to 290 fewer)		
Incidence of pressure ulcers – low-air-loss hydrotherapy bed (CLENSICAIR) versus standard care (standard bed or foam, air, alternating-pressure mattresses) - grade 2 and above pressure ulcers[e15]												
1	Randomised trial	Very serious[a,d]	No serious inconsistency	No serious indirectness	Serious imprecision[b]	None	8/42 (19%)	4/56 (7.1%)	RR 2.67 (0.86 to 8.27)	119 more per 1000 (from 10 fewer to 519 more)	Low	Critical
							-			119 more per 1000 (from 10 fewer to 516 more)		
Incidence of pressure ulcers – low-air-loss bed (KINAIR) versus static air mattress overlay (EHOB WAFFLE) or standard ICU bed – people in ICU - grade 2 and above pressure ulcers[e33,93]												
2	Randomised trials	Very serious[a]	No serious inconsistency	No serious indirectness	No serious imprecision	None	9/111 (8.1%)	36/110 (32.7%)	RR 0.25 (0.13 to 0.49)	245 fewer per 1000 (from 167 fewer to 285 fewer)	Low	Critical
							-	34.5%		259 fewer		

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**Low air loss**	**Standard bed**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
										per 1000 (from 176 fewer to 300 fewer)		
Comfort – low air loss hydrotherapy (CLENSICAIR) versus standard care (standard bed or foam, air , alternating-pressure mattresses) [15]												
1	Randomised trial	Very serious[a,d]	No serious inconsistency	No serious indirectness	No serious imprecision	Very low[c]	n=10	-	-	See footnote4	Very low	Critical
Patient acceptability– low air loss hydrotherapy (CLENSICAIR) versus standard care (standard bed or foam, air , alternating-pressure mattresses) [15]												
1	Randomised trial	Very serious[a,d]	No serious inconsistency	No serious indirectness	No serious imprecision	Very low[c]	-	-	-	See footnote5	Very low	Critical
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) Unclear sequence generation (Cobb 1997, Inman 1993) and allocation concealment (Bennett 1998, Inman 1993) was reported by the authors. Unclear blinding was reported (Cobb 1997, Inman 1993, Bennett 1998). No addressing of incomplete outcome data was reported (Inman 1993). There were differences at baseline (Cobb 1997).

(b) Confidence interval crossed 1 MID point.

(c) Data on comfort was only from the intervention group and only 10/42 participants completed the questionnaire. 5/10 thought it was comfortable, 4/10 thought it was uncomfortable.

(d) It should be noted that there were more drop-outs overall from the treatment than the control group 24/48 (35%) versus 2/58 (3%) (p=0.0001). Six participants receiving low airloss hydrotherapy exited the study on the first day because either a participant or family member complained about the bed. This was due to being wet, cold or uncomfortable on the specialty bed. Two participants were removed by the research investigators or nurses as a result of hypothermia within the first 24 hours of enrolment.

(e) Bennett (1998) used NPUAP 1989; Cobb (1997) used NPUAP 1989 and Shea 1975; Inman (1993) used Shea 1975.

12.1.8 Other devices

12.1.8.1 Operating room mattress

Table 67: Clinical evidence profile: indentation load deflection (IDL) (25%) operating room foam mattress (density 1.3 cubic feet, IDL 30lb) versus operating room usual care (padding as required, including gel pads, foam mattresses, ring cushions)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	ILD operating room mattress	Usual care	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers - all grades of pressure ulcers[180]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	55/206 (26.7%)	34/207 (16.4%)	RR 1.63 (1.11 to 2.38)	103 more per 1000 (from 18 more to 227 more)	Low	Critical
							-	16.4%		103 more per 1000 (from 18 more to 226 more)		
Incidence of pressure ulcers - grade 2 and above pressure ulcers[180]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	Very serious[c]	None	6/206 (2.9%)	3/207 (1.4%)	RR 2.01 (0.51 to 7.93)	15 more per 1000 (from 7 fewer to 100 more)	Very low	Critical
							-	1.5%		15 more per 1000 (from 7 fewer to 104 more)		

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**ILD operating room mattress**	**Usual care**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
Patient acceptability – postoperative skin changes[180]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	No serious	Very serious[d]	-	-	p=0.0111	See footnote[e]	Very low	Critical
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There was no allocation concealment reported by the authors.
(b) The confidence interval crossed 1 MID point.
(c) The confidence interval crossed both MID points.
(d) No details given for number of participants in each arm for postoperative skin changes.
(e) People on the experimental mattress (IDL) were significantly more likely to have skin changes than those on the usual care operating room table, no further details were given.

12.1.8.2 Operating table overlay

Table 68: Clinical evidence profile: operating table overlay versus no overlay

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	ILD operating room mattress	Usual care	Relative (95% CI)	Absolute		
Incidence of pressure ulcers - viscoelastic polymer pad versus no overlay- all grades of pressure ulcers[148]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	22/205 (10.7%)	43/211 (20.4%)	RR 0.53 (0.33 to 0.85)	96 fewer per 1000 (from 31 fewer to 137 fewer)	Low	Critical
							-	20.4%		96 fewer per 1000 (from 31 fewer to 137 fewer)		
Incidence of pressure ulcers - viscoelastic foam overlay versus no overlay[f] – all grades of pressure ulcers[62]												
1	Randomised trial	Very serious[c]	No serious inconsistency	No serious indirectness	Very serious[d]	None	13/85 (15.3%)	9/90 (10%)	RR 1.53 (0.69 to 3.39)	53 more per 1000 (from 31 fewer to 239 more)	Very low	Critical
							-	10%		53 more per 1000 (from 31 fewer to 239 more)		
Incidence of pressure ulcers – viscoelastic foam overlay versus no overlay – grade 2 and above pressure ulcers[f62]												

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**ILD operating room mattress**	**Usual care**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
1	Randomised trials	Very serious[c]	No serious inconsistency	No serious indirectness	Very serious[e]	None	13/85 (15.3%)	9/90 (10%)	RR 2.12 (0.2 to 22.93)	12 more per 1000 (from 9 fewer to 244 more)	Very low	Critical
							-	10%		12 more per 1000 (from 9 fewer to 241 more)		
Acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There were differences at baseline. The standard mattress group had a longer length of operation, longer pre-operative stay and more time in hypotensive state than the dry polymer pad group (Nixon 1998).
(b) The confidence interval crossed 1 MID.
(c) There was unclear sequence generation, allocation concealment and addressing of incomplete outcome data (Feuchtinger 2006).
(d) The confidence interval crossed both MIDs.
(e) The confidence interval crossed both MID points and limited number of events.
(f) Nixon (1998) used the Torrance 1983 grading system; Feuchtinger (2006)used EPUAP 2005 grading system.

12.1.8.3 Face pillows in the operating theatre

Table 69: Clinical evidence profile: disposable polyurethane foam prone head positioner (OSI) versus neoprene air filled bladder (dry flotation) device (ROHO)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	OSI face pillow	ROHO face pillow	Relative (95% CI)	Absolute		
Incidence of pressure ulcers – all grades of pressure ulcers[d82]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	10/22 (45.5%)	0/22 (0%)	Peto OR 12.55 (3.11 to 50.57)	450 more (from 240 more to 670 more)	Very low	Critical
							-	0%		450 more (from 240 more to 670 more)		
Incidence of pressure ulcers – grade 2 and above pressure ulcers[d82]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b,c]	None	2/22 (9.1%)	0/22 (0%)	Peto OR 7.75 (0.47 to 128.03)	90 more from 50 fewer to 230 more)	Very low	Critical
							-	0%		90 more from 50 fewer to 230 more		
Acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to development of pressure ulcers												

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	OSI face pillow	ROHO face pillow	Relative (95% CI)	Absolute	Quality	Importance
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) Grisell (2008): did not provide details of baseline data. No blinding was reported by the authors. There was a higher drop-out than event rate.
(b) There were a limited number of events.
(c) The confidence interval crossed both MID points.
(d) NPUAP grading system.

Table 70: Clinical evidence profile: disposable polyurethane foam prone head positioner (OSI) versus prone view protective helmet system with a disposable polyurethane foam prone head positioner (DUPACO)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	OSI face pillow	Dupaco face pillow	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers – all grades of pressure ulcers[d82]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	10/22 (45.5%)	0/22 (0%)	Peto OR 12.55 (3.11 to 50.57)	450 more (from 240 more to 670 more)	Very low	Critical
							-	0%		450 more (from 240 more to 670 more)		
Incidence of pressure ulcers – grade 2 and above pressure ulcers[d82]												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**OSI face pillow**	**Dupaco face pillow**	**Relative (95% CI)**	**Absolute**		
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b,c]	None	2/22 (9.1%)	0/22 (0%)	Peto OR 7.75 (0.47 to 128.03)	90 more from 50 fewer to 230 more	Very low	Critical
							-	0%		90 more from 50 fewer to 230 more		
Acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) Grisell (2008) did not provide details of baseline data. No blinding was reported by the authors. There was a higher drop-out than event rate.
(b) There were a limited number of events.
(c) The confidence interval crossed both MID points.
(d) NPUAP grading system.

Table 71: Clinical evidence profile: neoprene air filled bladder (dry flotation) device (ROHO) versus prone view protective helmet system with a disposable polyurethane foam prone head positioner (DUPACO)

Quality assessment	No of patients	Effect	Quality	Importance

No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**ROHO face pillow**	**Dupaco face pillow**	**Relative (95% CI)**	**Absolute**		
Incidence of pressure ulcers – all grades of pressure ulcers[b82]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	No serious imprecision	None	0/22 (0%) -	0/22 (0%) 0%	Not pooled	Not pooled Not pooled	Low	Critical
Incidence of pressure ulcers – grade 2 and above pressure ulcers[b82]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	No serious imprecision	None	0/22 (0%) -	0/22 (0%) 0%	Not pooled	Not pooled Not pooled	Low	Critical
Acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) Grisell (2008): No details of baseline data were reported or blinding was reported by the authors. There was a higher drop-out than event rate.
(b) NPUAP grading system.

Table 72: Clinical evidence profile: multi-cell pulsating dynamic mattress system (MICROPULSE) versus standard mattress for people undergoing surgery

Quality assessment							**No of patients**	**Effect**	**Quality**	**Importance**

No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Micropulse System for surgical patients	Control	Relative (95% CI)	Absolute		
Incidence of pressure ulcers – all grades of pressure ulcers[d6];[164]												
2	Randomised trials	Very serious[a]	No serious inconsistency	No serious indirectness	No serious imprecision	None	3/188 (1.6%)	14/180 (7.8%)	RR 0.21 (0.06 to 0.7)	61 fewer per 1000 (from 23 fewer to 73 fewer)	Low	Critical
							-	7.9%		62 fewer per 1000 (from 24 fewer to 74 fewer)		
Incidence of pressure ulcers – grade 2 and above pressure ulcers[d6];												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[c]	None	0/90 (0%)	6/80 (7.5%)	RR 0.07 (0 to 1.2)	70 fewer per 1000 (from 75 fewer to 15 more)	Very low	Critical
							-	7.5%		70 fewer per 1000 (from 75 fewer to 15 more)		
Time in hospital[6]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	No serious imprecision	Very seriou[sa]	-	-	-	See footnote[b]	Very low	Important
Acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Micropulse System for surgical patients	Control	Relative (95% CI)	Absolute	Quality	Importance
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There was unclear sequence generation (quasi-randomised), allocation concealment and blinding, and a higher drop-out than event rate (Aronovitch 1999). The conventional management group were at higher risk at baseline (Knoll score). There was unclear sequence generation method, no blinding and higher-drop-out rate than the event rate (Russell 2000).

(b) The data were given only for those who developed ulcers - 6/8 who developed ulcers had a length of stay longer than average for the specific diagnosis. The average length of stay for those developing ulcers was 14 days, which was6.7 days longer than the hospital's average of 7.3 days for this Diagnosis Related Group. The authors state that this represents an increase in length of stay of 92%.

(c) The confidence interval crossed 1 MID point.

(d) Aronovitch (1999) used NPUAP and WOCN and Russell (2000) used NPUAP 1997.

Table 73: Clinical evidence profile: viscoelastic foam (TEMPUR-PEDIC) A&E overlay and ward mattress versus standard A&E overlay and ward mattress

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Accident and emergency overlay and ward mattress	Control	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers – grade 2 and above pressure ulcers[c83]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious imprecision[b]	None	4/48 (8.3%)	8/53 (15.1%)	RR 0.55 (0.18 to 1.72)	68 fewer per 1000 (from 124 fewer to 109 more)	Very low	Critical
							-	15.1%		68 fewer per 1000 (from 124 fewer to 109 more)		
Incidence of pressure ulcers – all grades of pressure ulcers[c83]												
1	Randomised	Very	No serious	No serious	Very serious	None	12/48 (25%)	17/53	RR 0.78	71 fewer	Very	Critical

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**Accident and emergency overlay and ward mattress**	**Control**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
	trial	serious[a]	inconsistency	indirectness	imprecision[b]			(32.1%)	(0.42 to 1.46)	per 1000 (from 186 fewer to 148 more	low	
							-	32.1%		71 fewer per 1000 (from 186 fewer to 148 more)		
Acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There was unclear sequence generation, allocation concealment, blinding and addressing of incomplete outcome data reported by the authors.
(b) The confidence interval crossed both MID points.
(c) EPUAP 1999 grading system.

12.1.9 Profiling beds

12.1.9.1 Comparison between profiling bed and flat-based bed

Table 74: Clinical evidence profile: profiling bed with a pressure-reducing foam mattress versus flat-based bed with a pressure-reducing mattress

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Profiling bed	Flat-based bed	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers – all grades of ulcer[b104]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	No serious imprecision	None	0/35 (0%)	0/35 (0%)	Not pooled	Not pooled	Low	Critical
							-	0%		Not pooled		
Acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There was unclear blinding, unclear addressing of incomplete outcome data reported by the authors and a higher drop-out than event rate.
(b) EPUAP 1991 grading system.

12.1.10 Seat cushions

12.1.10.1 Comparison between different cushions

Table 75: Clinical evidence profile: comparisons between different seat cushions

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Seat cushions	Control	Relative (95% CI)	Absolute		
Incidence of pressure ulcers - slab foam versus bespoke contoured foam[38]; [117]												
2	Randomised trials	Very serious[a]	No serious inconsistency	No serious indirectness	No serious imprecision	None	104/151 (68.9%)	102/149 (68.5%)	RR 1.01 (0.86 to 1.17)	7 more per 1000 (from 96 fewer to 116 more)	Low	Critical
Incidence of pressure ulcers - Jay Gel cushion versus foam[38]												
1	Randomised trial	Serious[b]	No serious inconsistency	No serious indirectness	Serious[c]	None	17/68 (25%)	30/73 (41.1%)	RR 0.61 (0.37 to 1)	160 fewer per 1000 (from 259 fewer to 0 more)	Low	Critical
Incidence of pressure ulcers- pressure reducing cushion versus standard foam cushion[70]												
1	Randomised trial	No serious risk of bias	No serious inconsistency	No serious indirectness	Very serious[d]	None	6/15 (40%)	10/17 (58.8%)	RR 0.68 (0.33 to 1.42)	188 fewer per 1000 (from 394 fewer to 247 more)	Low	Critical
Incidence of pressure ulcers - skin protection cushion versus segmented foam cushion - sitting related ischial tuberosities[27]												
1	Randomised trial	Serious[e]	No serious inconsistency	No serious indirectness	Serious[c]	None	1/113 (0.88%)	8/119 (6.7%)	RR 0.13 (0.02 to 1.04)	58 fewer per 1000 (from 66 fewer to 3 more)	Low	Critical
							-	0%		-		
Pressure ulcer incidence - skin protection cushion versus segmented foam cushion - combined ischial tuberosities and sacral orcoccyx[27]												
1	Randomised trial	Serious[e]	No serious inconsistency	No serious indirectness	Serious[c]	None	12/113 (10.6%)	21/119	RR 0.60 (0.31 to	71 fewer per 1000 (from	Low	Critical

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Seat cushions	Control	Relative (95% CI)	Absolute	Quality	Importance
								(17.6 %)	1.17)	122 fewer to 30 more)		
								0%		-		
Withdrawal due to discomfort[38]												
1	Randomised trial	Serious[b]	No serious inconsistency	No serious indirectness	Very serious[d]	None	1/83 (1.2%)	6/80 (7.5 %)	RR 0.16 (0.02 to 1.3)	63 fewer per 1000 (from 73 fewer to 22 more)	Very low	
							-	0%		-		
Acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There was unclear sequence generation, allocation concealment and blinding reported by the authors(Conine 1993, Lim 1988).
(b) There was unclear sequence generation and allocation concealment reported by the authors(Conine 1994).There was no participant or healthcare provider blinding but outcome assessors were blinded (Geyer 2001).
(c) The confidence interval crossed 1 MID.
(d) The confidence interval crossed both MIDs.
(e) There were baseline differences. There was a higher drop-out rate than the event rate. The study could not control for the use of other support surfaces (Brienza 2010).
(f) Conine (1993) and (1994) used Exton Smith 1982; Lim (1988) used NPUAP 1989; Geyer (2001) used NPUAP 1992; Brienza (2010) used NPUAP 2001.

12.1.11 Economic evidence (adults)

Published literature

Nine studies were included with relevant comparisons.[65,96,115,131,149,159,160,167,217] These are summarised in the economic evidence profiles below (Table 76 - Table 80). See also the study selection flow chart in Appendix D and study evidence tables in Appendix G.

Four studies that met the inclusion criteria were selectively excluded due to methodological limitations and availability of more applicable evidence.[13,92,93,206] These are summarised in Appendix K, with reasons for exclusion given.

Six further studies were found which included devices for the prevention of pressure ulcers as part of more complex prevention strategies.[121,124,153,202,226,227] These studies were not included as they evaluated the cost-effectiveness of the prevention strategies as a whole, and did not provide information on the cost-effectiveness of the devices alone.

It is clear from Table 77 that 2 of the included studies[65,149] demonstrate conflicting results, despite both being conducted from the perspective of the UK NHS, with costs based on 2003 UK prices. Nixon and colleagues found that alternating pressure replacement mattresses (AR) dominate alternating pressure overlays (AO), whilst Fleurence found that AOs are cost effective. Both studies indicate that ARs have a greater effectiveness, with Nixon reporting greater time to pressure ulcer development and Fleurence a small increase in QALYs associated with an increase in pressure ulcer free days. However, the incremental pressure ulcer free days in Nixon are 10 times greater than those reported in Fleurence. This is most likely due to the different methods of collecting effectiveness data (Nixon is based on a within trial analysis whilst Fleurence is based on an estimation validated by experts) and the 2 different approaches to modelling (a regression analysis to calculate additional costs and pressure ulcer free days in Nixon, and a decision tree in Fleurence). Unit costs of devices presented in these 2 papers are almost identical, both obtained from Huntleigh Healthcare and reported in 2003 prices, yet Fleurence assumes a 2 year time horizon for overlays and an 8 year horizon for mattresses, whilst Nixon and colleagues assume a 2 year time horizon for both devices. Of note, a zero cost of pressure ulcer management is assumed in Nixon, whilst a value of £1,133 is used to represent this cost in Fleurence. There are also differences in assumptions surrounding the proportion of mattresses that were rented or purchased.

Table 76: Economic evidence profile: alternating pressure verses alternative foam

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effects	Cost effectiveness	Uncertainty
Fleurence 2005 [65](UK)	Partially applicable[a]	Potentially serious limitations[b]	A decision analytic model which compared 3 alternatives: alternating pressure overlays (AO), alternating pressure mattress replacements (AR), high-specification foam mattresses (SC)	Four week horizon AR-AO = £20.52 SC-AR = £43.21	Four week horizon (QALYs) AR-AO = 0.00008 SC-AR = -0.00032	Four week horizon SC is dominated AR v AO = £253,367 per QALY gained	At a ceiling ratio of £5,000/QALY the optimal strategy was SC, beyond this value it switches to AO. Scenario analysis revealed that it was less expensive for the hospital to own devices than to rent them.

(a) Based on the UK NHS but costs are based on 2003 prices

(b) Quality of life data is obtained from health care professionals rather than from patients, short time horizon may not capture full economic impact of these devices. Estimates of health effect estimated rather than obtained from the literature, baseline health outcomes not based on randomised data.

Table 77: Economic evidence profile: comparisons between alternating pressure devices

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effects	Cost effectiveness	Uncertainty
Fleurence 2005 [65](UK)	Partially applicable[a]	Potentially serious limitations[b]	A decision analytic model which compared 3 alternatives: alternating pressure overlays (AO), alternating pressure mattress replacements (AR), high-specification foam mattresses[c]	Four week horizon AR-AO = £20.52	Four week horizon (QALYs) AR-AO = 0.00008	Four week horizon AR v AO = £253,367 per QALY gained	Above a willingness to pay threshold of £5,000 per QALY gained, the optimal strategy is AO. Scenario analysis revealed that it was less expensive for the hospital to own devices than to rent them.
Nixon 2006[149] (UK)	Partially applicable[a]	Potentially serious limitations[d]	Within trial analysis with analysis of individual level data for time to pressure ulcer development and duration of stay. Patients	AO – AR: £74.50	AO – AR: -10.63 days until pressure ulcer development	AR dominates AO with a longer period until pressure ulcer	Probability AR cost-saving: 64% Three additional scenarios were presented: All mattresses

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effects	Cost effectiveness	Uncertainty
			randomised to receive alternating pressure replacement mattresses (AR) or alternating pressure overlays (AO).			development at a lower cost	rented rather than purchased , lifespan of both surfaces increased from 2 to 5 years, and lifespan of both surfaces increased to 7 years. AR remained the cost-saving strategy in all 3 scenarios.

(e) Based on the UK NHS but costs are based on 2003 prices

(c) Quality of life data is obtained from health care professionals rather than from patients, short time horizon may not capture full economic impact of these devices. Estimates of health effect estimated rather than obtained from the literature, baseline health outcomes not based on randomised data.

(d) Results for high specification foam are not presented in this table as they are not directly relevant to the comparison addressed here – see Table 48 for results.

(e) QALYs are not reported. Treatment costs of pressure ulcers are not included (it is stated that this is because 70% of patients with grade 2 pressure ulcers do not receive dressings even though 8 of the PUs developed were grade 3) and all results are based on a within trial analysis which means estimates are taken from 1 trial only.

Table 78: Economic evidence profile: high specification foam verses standard practice

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effects	Cost effectiveness	Uncertainty
Legood 2005[115] (UK)	Partially applicable[a]	Minor limitations[b]	High specification foam mattresses versus standard mattresses, based on calculations of additional cost of high specification foam, net of any saving from reduced incidence of pressure ulcers. Patients separated into four risk groups; A has lowest risk and D highest.	Group A: -£2.16 Group B: -£25.79 Group C: -£52.04 Group D: -£104.54	Group A (Incremental mean incidence of pressure ulcers): -0.0035 Group B: -0.035 Group C: -0.07 Group D: -0.14	High specification foam dominates standard mattress for all patient risk groups.	An extreme scenario is presented, when only 1 in 1 hundred patients develops a pressure ulcer. The pressure relieving mattress still dominates.
Pham 2011a[159] (Canada)	Partially applicable[c]	Potentially serious limitations[d]	Markov model Markov model comparing pressure redistribution foam mattresses for all residents	-£76	0.00085 QALYs	Pressure redistribution mattresses dominate	Probability cost-effective: 82% at willingness to pay of $50,000 per QALY. When excess mortality associated with

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effects	Cost effectiveness	Uncertainty
			to current practice. Model includes states for different grades of pressure ulcer and no pressure ulcer.			current practice.	pressure ulcers (7.23%) was considered (the ICER was £58,321. When looking at costs from a long-term care perspective the overlays remained dominant.
Russell 2003[167] (UK)	Partially applicable[e]	Minor limitations[f]	Within trial analysis (RCT) with analysis of individual level data. Comparison of visco-polymer energy absorbing foam mattress (CONFOR-Med)/cushion combination verses standard mattress/cushion combination	-£154	0.07 pressure ulcers avoided	Visco-polymer energy absorbing foam mattress dominates standard mattress, with reduced costs and reduced incidence of pressure ulcer.	None reported

(f) Based on the UK NHS but costs are based on 2004 prices

(f) The baseline probability of developing a pressure ulcer is based on GDG estimate, as it the cost of treating pressure ulcers. Both of these estimates are tested in sensitivity analyses. The model does not address people at long term risk of developing pressure ulcers.

(g) Conducted in a Canadian setting

(h) Utility data is not calculated from EQ-5D or SF-36 data. Baseline health estimates and progression of pressure ulcers through the various stages are estimated from RAI-MDS instead of obtained via a systematic procedure. Total costs and effect sizes are unclear as current practice is reported to include 45.5% of individuals already receiving the intervention, yet it is not clear whether reported per patient results reflect this or not – this should not affect the ICER

(i) Based on the UK NHS but old study; no cost year reported

(j) Only the costs of dressings are included to represent the costs of treating pressure ulcers. Resource use and health outcomes are based on entirely on this study.

Table 79: Economic evidence profile: constant low pressure supports compared to standard care

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effects	Cost effectiveness	Uncertainty
Mistiaen 2010[131]	Partially applicable[a]	Potentially serious	Within trial analysis with modelled post trial	£137	0.060 pressure ulcers avoided	Incremental cost per	The cost of investment is sensitive to the frequency of

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effects	Cost effectiveness	Uncertainty
(Netherlands)		limitations[b]	extrapolation. Patients are randomised to receive usual care plus Australian medical sheepskin, or usual care only. Additional costs of the intervention are weighed against saved costs from reduces pressure ulcers.		when sheepskin in use	pressure ulcer avoided: £2,298	AMS washing, and the cost of washing. Treatment costs, initial purchase price, durability of AMS and effectiveness of AMS are less influential.
Jackson 2011 [96] (US)	Partially applicable[c]	Potentially serious limitations[d]	Analysis of patient level resource use in a before-and-after study, with unit costs applied. A preventative treatment protocol and Clinitron Rite-Hite Air Fluidised Therapy bed compared to Standard care on standard ICU bed.	-£3,624	0.68 pressure ulcers avoided when preventative protocol and air fluidised bed in place	Preventative protocol and air fluidised bed dominate standard care	No analysis of uncertainty was undertaken.
Vermette2012 [217] (Canada)	Partially applicable[e]	Potentially serious limitations[f]	Analysis of patient level resource use within an RCT, with unit costs applied. An Inflated Static Overlay was compared to Standard care (comprised of Microfluid Static Overlay or Low-Air-Loss Dynamic Mattress).	-£125	0.07 pressure ulcers avoided when the inflated static overlay is used	The ISO was shown to be cost saving and more effective (decreased incidence of PU) than standard care.	No analysis of uncertainty was undertaken.

(a) Conducted in the Netherlands from the perspective of a Dutch nursing home; quality of life is not considered

(b) Only sacral ulcers were considered in the economic analysis, therefore the effectiveness estimate may not be a true reflection of the effectiveness on pressure ulcers overall. In addition 1 particular assumption of the model is that the 3 month estimates of pressure ulcer development obtained from the trial will apply over the 1 year time horizon (ie no further PUs will develop between 3 and 12 months) which may not be realistic. The majority of the parameter inputs are obtained from the associated trial, therefore evidence is based on 1 study only. The model only considers grade 1 and 2 ulcers thus may underestimate the cost of treating pressure ulcers.

(c) Study based in the US; quality of life is not considered.

(d) The cost of the standard care mattresses are not included, thus the costs of standard care are based on treatment costs alone. As no severe pressure ulcers developed in intervention 2, the costs are based only on the rental cost of the device. The unit costs and health outcomes are based on entirely on this stud and are not collect via a systematic proceedure.

(e) Study based in the Canada; quality of life is not considered.

(f) Health outcomes, resource and cost data are based on evidence from 1 trial. This analysis only considers the cost of devices and fails to include the cost of pressure ulcer treatment (amongst other costs). Omission of the treatment costs of pressure ulcers biases away from the more effective intervention.

Table 80: Economic evidence profile: constant low pressure supports compared to standard care in operating theatre

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effects	Cost effectiveness	Uncertainty
Pham 2011[160] (Canada)	Partially applicable[g]	Minor limitations[h]	Markov model comparing dry, viscoelastic polymer overlays on operating tables to current practice. Model includes states for different grades of pressure ulcer and no pressure ulcer. Analysis specific to patients undergoing scheduled surgical procedures lasting ≥90mins in the supine or lithotomy position.	-£25	0.000006 QALYs (reported as 0.0021 QALDs)	Dry viscose polymer overlays dominates current practice	Probability cost-effective: 99.41% between thresholds $50,000 (£27,304) and $100,000 (£54,609) per QALY The cost-effectiveness of the overlay increased with duration of surgery. The overlay was also cost-effective amongst individuals with low intra-operative risk. The overlay remained cost-effective with an increase in price of the overlays up to $2,000 ($878 in base case), and across the 95% CI of the relative risk estimate of developing pressure ulcers.

(g) Conducted in a Canadian setting, applicable only to patients undergoing surgery expected to last >90 mins

(k) Utility data is not calculated from EQ-5D or SF-36 data

Unit costs

The following unit costs were presented to aid consideration of cost effectiveness (Table 81).

Table 81: Unit costs

Device	Purchase cost	Rental cost	Source
High specification foam mattresses			
Softform premiere	£199.00	NA	Correspondence with manufacturer
Harvest Reflect 2 Replacement Mattress	£140.00	NA	Correspondence with manufacturer
Harvest Prime Comfort Plus	£120.00	NA	Correspondence with manufacturer
Pentaflex (4 way turn, acute)	£204.14	NA	Correspondence with manufacturer
Constant low pressure			
Breeze	£3,453.70	£12.85 per day[a]	Correspondence with manufacturer
Alternating pressure			
Nimbus 3	£3,565.18	£13.56 per day[a]	Correspondence with manufacturer

(a) Minimum of 10 day rental

Note - these prices have been obtained directly from manufacturers, and represent the list price for the NHS. It is acknowledged that prices vary locally, therefore these prices are illustrative only. The devices included in the table are those identified by GDG members as being commonly used, and should not be interpreted as recommended devices.

12.1.12 Clinical evidence (neonates, infants, children and young people)

No RCTs or cohort studies were identified. Recommendations were developed using a modified Delphi consensus technique. Further details can be found in Appendix N.

12.1.13 Economic evidence (neonates, infants, children and young people)

Published literature

No relevant economic evaluations were identified.

Economic considerations

In the absence of economic evidence, the GDG considered relevant UK NHS unit costs of various mattresses and overlays (

Table 82). These were considered alongside clinical evidence obtained from the Delphi consensus panel to inform qualitative judgement about cost-effectiveness.

Table 82: Unit costs

Device	Cost	Source
High specification foam mattresses and overlays		
Softform incubator pad (high specification foam)	£49.48	NHS supply chain catalogue[1]
Softform cot mattress (high specification foam)	£107.63	NHS supply chain catalogue[1]
Repose babytherm redistributing overlay (with pump)	£91.55	NHS supply chain catalogue[1]
Repose paediatric mattress Overlay (with pump)	£91.55	NHS supply chain catalogue[1]
Repose mattress overlay (with pump)	£106.11	NHS supply chain catalogue[1]
Softform premiere	£199.00	Correspondence with manufacturer
Dynamic support surfaces		
Nimbus paediatric mattress	£13.56 per day rental (purchase price £3,293)	Correspondence with manufacturer
Nimbus 3 mattress	£13.56 per day rental (purchase price £3,565)	Correspondence with manufacturer
Wheelchair pressure redistribution		
Stimulite contoured paediatric cushion	£185.00	Correspondence with manufacturer
Occipital pressure redistribution		
Gel-E Donut (soft gel pillow)	£6.83 (based on £82 for 12 for extra small size)	Correspondence with manufacturer

Note: the costs above are included for illustrative purposes only and should not be interpreted as recommendations in favour of these particular devices. These are list prices only and local prices may vary.

12.1.14 Evidence statements

12.1.14.1 Clinical (adults)

12.1.14.1.1 Cubed foam mattress (COMFORTEX DECUBE) versus standard hospital mattress (standard polypropylene SG40)

- One study (n=44) showed a cubed foam mattress is potentially more clinically effective at reducing the incidence of pressure ulcers (grade 2-4) when compared to a standard hospital mattress (very low quality).
- One study (n=44) showed a cubed foam mattress is potentially more clinically effective at reducing the incidence of pressure ulcers (all grades) when compared to a standard hospital mattress (very low quality).
- One study (n=44) reported medians for a cubed foam mattress and standard hospital mattress for length of stay in hospital. The median for a cubed foam mattress was 21 days (range 5-64) and 23 days (range 4-120) for the standard hospital mattress. No estimate for effect or precision could be derived (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Health-related quality of life

12.1.14.1.2 Bead filled mattress (BEAUFORT) versus standard hospital mattress

- One study (n=75) showed a bead filled mattress is potentially more clinically effective at reducing the incidence of pressure ulcers (all grades) when compared to a standard foam mattress (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.3 Softform mattress versus standard 130mm NHS foam mattress

- One study (n=170) showed a softform mattress is more clinically effective at reducing the incidence of pressure ulcers (grade 2-4) when compared to a standard 130mm NHS foam mattress (low quality).
- One study (n=170) showed there is no clinical difference between a softform mattress and a standard 130mm NHS foam mattress for perception of comfort being very uncomfortable (low quality).
- One study (n=170) showed there may be no clinical difference between a softform mattress and a standard 130mm NHS foam mattress for perception of comfort being uncomfortable, but the direction of the estimate of effect favoured the softform mattress (very low quality).
- One study (n=170) showed a softform mattress is more clinically effective for perception of comfort being adequate when compared to a standard 130mm NHS foam mattress (low quality).
- One study (n=170) showed a softform mattress is more clinically effective for perception of comfort being comfortable when compared to a standard 130mm NHS foam mattress (low quality).
- One study (n=170) showed a softform mattress is more clinically effective for perception of comfort being very comfortable when compared to a standard 130mm NHS foam mattress (low quality).
- No evidence was found for the following outcomes:
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.4 Water-filled mattress versus standard hospital mattress

- One study (n=316) showed a water-filled mattress is potentially more clinically effective at reducing the incidence of pressure ulcers (all grades) when compared to a standard hospital mattress (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.5 Alternative foam pressure-reducing mattress (CLINIFLOAT, OMNIFORM, SOFTFORM, STM5, THERAREST, TRANSFOAM, VAPOURLUX) versus standard hospital mattress

- Two studies (n=696) showed an alternative foam pressure-reducing mattress is more clinically effective at reducing the incidence of pressure ulcers (all grades) when compared to a standard hospital mattress (low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.6 High-specification foam mattress (visco-polymer energy absorbing foam mattress (CONFORM-ED) versus standard mattress (KING's FUND, LINKNURSE, SOFTFOAM, TRANSFOAM, KING's FUND MATTRESS with a SPENCO or PROPAD overlay)

- One study (n=1166) showed there is potentially no clinical difference between a high-specification foam mattress and a standard mattress for reducing the incidence of pressure ulcers (all grades), the direction of the estimate of effect favoured the high-spec foam mattress (very low quality).
- One study (n=706) showed there is no clinical difference between a high-specification foam mattress and a standard mattress for perception of comfort , the direction of the estimate of effect favoured the standard mattress (low quality).
- No evidence was found for the following outcomes:
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.7 Inflated static overlay versus microfluid static overlay and low-air-loss dynamic mattress

- One study (n=110) showed there may be a clinical benefit for a constant low-pressure support (inflated static overlay) compared to a constant low-pressure support (microfluid static overlay) and alternating-pressure support (low-air-loss dynamic mattress) for reducing the incidence of pressure ulcers (all grades) (very low quality).
- One study (n=64) showed there is no clinical benefit of a constant low-pressure support (inflated static overlay) for patient acceptability (comfort) when compared with a constant low-pressure support (microfluid static overlay) and alternating-pressure support (low-air-loss dynamic mattress) (moderate quality).
- No evidence was found for the following outcomes:
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.8 Alternative foam mattress versus standard foam mattress

- Five studies (n=2016) showed an alternative foam mattress is potentially more clinically effective at reducing the incidence of pressure ulcers (all grades) when compared to a standard foam mattress (very low quality).

- Four UK studies (n=1980) showed an alternative foam mattress is potentially more clinically effective at reducing the incidence of pressure ulcers (all grades) when compared to a standard foam mattress (very low quality).
- Two studies (n=206) showed an alternative foam mattress is more clinically effective at reducing the incidence of pressure ulcers (grade 2-4) when compared to a standard foam mattress (low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.9 Pressure redistributing mattress (CLINIFLOAT, OMNIFOAM, THERAREST, TRANSFOAM, VAPERM) versus standard NHS foam mattress (REYLON 150mm)

- One study (n=505) showed a pressure redistributing mattress is more clinically effective at reducing the incidence of pressure ulcers (all grades) when compared to standard NHS foam mattress (low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.10 Foam mattress replacement (MAXIFLOAT) versus foam mattress overlay (IRIS 3000)

- One study (n=40) showed a foam mattress replacement (Maxifloat) is potentially more clinically effective at reducing the incidence of pressure ulcers (all grades) when compared to a foam mattress overlay (very low quality).
- One study (n=40) showed a foam mattress replacement (Maxifloat) is potentially more clinically effective at reducing the incidence of pressure ulcers (grade 2 and above) when compared to a foam mattress overlay (very low quality).
- One study (n=40) reported means for a foam mattress replacement (Maxifloat) and foam mattress overlay for time to develop new pressure ulcers. The median for a foam mattress replacement (Maxifloat) was 9.2 days and 6.5 days (range 4-120) for the foam mattress overlay. No estimate for effect or precision could be derived. (very low quality)
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.11 Solid foam overlay versus convoluted foam overlay

- One study (n=84) showed a solid foam overlay is potentially more clinically effective at reducing the incidence of pressure ulcers (all grades) when compared to a convoluted foam overlay (low quality).
- No evidence was found for the following outcomes:

- Patient acceptability
- Rates of development of pressure ulcers
- Time to develop new pressure ulcers
- Time in hospital or NHS care
- Health related quality of life

12.1.14.1.12 Pressure-reducing foam mattress (TRANSFOAM) versus pressure-reducing foam mattress (TRANSFOAMWAVE)

- One study (n=100) showed there may be no clinical difference between a pressure-reducing TRANSFOAM foam mattress and a pressure-reducing TRANSFOAMWAVE foam mattress for reducing the incidence of pressure ulcers (all grades), but the direction of the estimate of effect could favour either intervention (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.13 Constant low-pressure mattress (CARITAL OPTIMA) versus standard foam mattress (10cm thick foam density 35kg/m^3)

- One study (n=40) showed a constant low-pressure mattress is potentially more clinically effective at reducing the incidence of pressure ulcers (all grades) when compared to a standard foam mattress (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.14 Dry flotation mattress (SOFFLEX) versus dry flotation mattress (ROHO)

- One study (n=84) showed there may be a clinical benefit for a SOFFLEX dry flotation mattress compared to a ROHO dry flotation mattress for reducing the incidence of pressure ulcers (all grades) (very low quality).
- One study (n=84) showed that there may not be a clinical benefit of a ROHO dry flotation mattress compared to a SOFFLEX dry flotation mattress for reducing the incidence of pressure ulcers (grade 2 and above) (very low quality).
- One study (n=84) showed there is no clinical difference between a SOFFLEX dry flotation mattress and a ROHO dry flotation mattress for patient acceptability (perception of comfort being very uncomfortable) (moderate quality).
- One study (n=84) showed a SOFFLEX dry flotation mattress is potentially more clinically effective for patient acceptability (perception of comfort being uncomfortable) when compared to a ROHO dry flotation mattress (low quality).
- One study (n=84) showed there may be no clinical difference between a SOFFLEX dry flotation mattress and a ROHO dry flotation mattress for patient acceptability (perception of comfort being adequate), but the direction of the estimate of effect could favour either intervention (very low quality).

- One study (n=84) showed there may be no clinical difference between a SOFFLEX dry flotation mattress and a ROHO dry flotation mattress for patient acceptability (perception of comfort being comfortable), but the direction of the estimate of effect could favour either intervention (very low quality).
- One study (n=84) showed there may be no clinical difference between a SOFFLEX dry flotation mattress and a ROHO dry flotation mattress for patient acceptability (perception of comfort being very comfortable), but the direction of the estimate of effect could favour either intervention (very low quality).
- No evidence was found for the following outcomes:
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.15 Gel mattress versus air-filled overlay (SOFCARE)

- One study (n=66) showed there may be a clinical benefit for a gel mattress compared to an air-filled overlay for reducing the incidence of pressure ulcers (all grades) (very low quality).
- One study (n=66) showed there may be a clinical benefit for a gel mattress compared to an air-filled overlay for reducing the incidence of pressure ulcers (grade 2 and above) (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.16 Static air mattress (GAY MAR SOFCARE) versus water mattress (LOTUS PXM 3666)

- One study (n=37) showed there may be a clinical benefit for a water mattress compared to a static air mattress for reducing the incidence of pressure ulcers (all grades) (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.17 Inflated static overlay (RIK or THERAKAIR) versus microfluid static overlay

- One study (n=105) showed there may be a clinical benefit for an inflated static overlay compared to a microfluid static overlay for reducing the incidence of pressure ulcers (all grades) (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.18 Foam overlay versus Silicore overlay (SPENCO)

- One study (n=68) showed there may be a clinical benefit of a Silicore overlay compared to a foam overlay for reducing the incidence of pressure ulcers (grade 2 and above) (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.19 Australian medical sheepskin versus no sheepskin

- Three studies (n=1281) showed Australian medical sheepskin is more clinically effective at reducing the incidence of pressure ulcers (all grades) when compared to no sheepskin (very low quality).
- Three studies (n=1281) showed there is potentially no clinical difference between an Australian medical sheepskin and no sheepskin for reducing the incidence of pressure ulcers (grade 2 and above), the direction of the estimate of effect favoured the Australian medical sheepskin (very low quality).
- One study (n=539) reported 10 participants in the sheepskin group complained about its comfort. The clinical importance is unknown (very low quality).
- One study (n=297) reported 6 participants in the sheepskin group withdrew before study completion due to the sheepskin causing irritation, was too hot or uncomfortable. The clinical importance is unknown (very low quality).
- One study (n=539) reported a clinical benefit of Australian medical sheepskin when compared to no sheepskin for delaying the time to develop new pressure. The hazard ratio was 0.39 (95% CI 0.22 -0.69; p<0.001) (very low quality).
- One study (n=543) reported a clinical benefit for Australian medical sheepskin when compared to no sheepskin for delaying the time to develop new pressure ulcers. The mean for Australian medical sheepskin was 12 days and 9 days for no sheepskin. No estimate of clinical effect or precision could be derived (very low quality).
- No evidence was found for the following outcomes:
  - Rates of development of pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.20 Static air overlay and cold foam mattress versus cold foam mattress alone

- One study (n=74) showed a static air overlay and cold foam mattress is potentially more clinically effective at reducing the incidence of pressure ulcers (grade 2 and above) when compared to a cold foam mattress alone (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.21 3D macroporous polyester overlay versus visco-elastic overlay

- Two studies (n=122) showed there is potentially no clinical difference between a macroporous polyester overlay and a visco-elastic overlay for reducing the incidence of pressure ulcers, the direction of the estimate of effect favoured the macroporous polyester overlay (low quality).

12.1.14.1.22 Alternating-pressure versus standard foam mattress

- Two studies (n=409) showed an alternating-pressure air mattress is more clinically effective at reducing the incidence of pressure ulcers (all grades) when compared to a standard foam mattress (low quality).
- One study (n=82) showed an alternating-pressure air mattress is potentially more clinically effective at reducing the incidence of pressure ulcers (grade 2 and above) when compared to a standard foam mattress (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.23 Alternating-pressure versus constant low-pressure for pressure ulcer prevention

- Eleven studies (n=1622) showed alternating-pressure is potentially more clinically effective at reducing the incidence of pressure ulcers (all grades) when compared to constant low-pressure (very low quality).
- Six studies (n=826) showed alternating-pressure is potentially more clinically effective at reducing the incidence of pressure ulcers (grade 2 and above) when compared to constant low-pressure (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.24 Alternating pressure (various devices) versus constant low pressure (various devices)

- One study (n=230) showed an alternating-pressure mattress is more clinically effective at reducing the incidence of pressure ulcers (all grades) when compared to a constant low-pressure mattress (low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.25 Alternating-pressure versus Silicore or foam overlay

- Four studies (n=331) showed there is potentially no clinical difference between alternating-pressure and a Silicore or foam overlay for reducing the incidence of pressure ulcers (all grades),

the direction of the estimate of effect favoured the alternating-pressure mattress (very low quality).

- Two studies (n=180) showed that, for people with chronic neurological conditions, there is potentially no clinical difference between an alternating-pressure overlay and a silicore overlay for reducing the incidence of pressure ulcers (all grades), the direction of the estimate of effect favoured the alternating-pressure mattress (very low quality).
- Two studies (n=151) showed that, for people without chronic neurological conditions, there may be no clinical difference between an alternating-pressure mattress and silicore or foam overlay for reducing the incidence of pressure ulcers (all grades) but the direction of the estimate of effect could favour either intervention (very low quality).
- One study (n=187) showed that there may not be a clinical difference between a silicore overlay when compared to an alternating-pressure overlay for patient acceptability (drop out due to discomfort), but the direction of the estimate of effect could favour the silicore overlay (very low quality).
- No evidence was found for the following outcomes:
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.26 Alternating-pressure versus water or static air mattress

- Three studies (n=458) showed there may be no clinical difference between alternating-pressure and water or static air mattress for reducing the incidence of pressure ulcers (all grades) but the direction of the estimate of effect could favour the water or static air mattress (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.27 Alternating-pressure setting on mattress (DUO2) versus continuous low-pressure setting on mattress (DUO2)

- One study (n=140) showed there may be no clinical difference between a continuous low-pressure setting on mattress and an alternating-pressure setting on mattress for reducing the incidence of pressure ulcers (all grades), the direction of the estimate of effect favoured continuous low-pressure setting on mattress (very low quality).
- One study (n=170) reported that there was no difference in length of stay related to pressure ulcer development among people at high-risk placed on the intervention or control mattresses. The clinical importance is unknown. (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.28 Alternating-pressure air mattress (ALPHA-X-CELL) versus visco-elastic foam mattress (TEMPUR)

- One study (n=447) showed there may be no clinical difference between alternating-pressure air mattress and visco-elastic foam mattress for the incidence of pressure ulcers (all grades) but the direction of the estimate of effect could favour the visco-elastic foam mattress (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.29 Alternating-pressure mattress (NIMBUS 3) versus dry flotation mattress overlay (ROHO)

- One study (n=16) showed there may be no clinical difference between an alternating-pressure mattress and a dry flotation mattress overlay for reducing the incidence of pressure ulcers (all grades), but the direction of the estimate of effect could favour either intervention (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.30 Dynamic flotation mattress (NIMBUS2) and alternating-pressure cushion versus low-pressure inflatable mattress (REPOSE SYSTEM) and cushion (polyurethane)

- One study (n=50) showed there may be no clinical difference between dynamic flotation mattress with alternating-pressure cushion and low-pressure inflatable mattress and cushion for reducing the incidence of pressure ulcers (grade 2 and above), but the direction of the estimate of effect could favour either intervention (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.31 Standard foam mattress in ICU/Standard foam mattress post-ICU versus Alternating-pressure mattress (NIMBUS) in ICU/Standard foam mattress post-ICU

- One study (n=160) showed no clinical difference between a standard foam mattress in ICU followed by a standard foam mattress post-ICU and an alternating-pressure mattress in ICU followed by a standard foam mattress post-ICU for reducing the incidence of pressure ulcers (all grades), the direction of the estimate of effect favoured the standard foam mattress in ICU followed by a standard foam mattress post-ICU (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers

- Time in hospital or NHS care
- Health related quality of life

12.1.14.1.32 Standard mattress in ICU/Standard foam mattress post-ICU versus Standard foam mattress ICU/constant low-pressure mattress (TEMPUR) post-ICU

- One study (n=155) showed there may be no clinical difference between a standard foam mattress in ICU followed by a constant low-pressure mattress post-ICU and a standard foam mattress in ICU followed by a standard foam mattress post-ICU for reducing the incidence of pressure ulcers (all grades), the direction of the estimate of effect favoured standard foam mattress in ICU followed by a constant low-pressure mattress post-ICU (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.33 Alternating-pressure mattress (NIMBUS) in ICU/Standard foam mattress post-ICU versus Standard foam mattress ICU/constant low-pressure mattress (TEMPUR) post-ICU

- One study (n=155) showed there may be no clinical difference between an alternating-pressure mattress in ICU followed by a standard foam mattress post-ICU and a standard foam mattress in ICU followed by a constant low-pressure mattress post-ICU for reducing the incidence of pressure ulcers (all grades), the direction of the estimate of effect favoured the alternating-pressure mattress in ICU (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.34 Standard foam mattress in ICU/Standard foam mattress post-ICU versus Alternating-pressure mattress (NIMBUS) in ICU/ constant low-pressure mattress (TEMPUR) post-ICU

- One study (n=157) showed there may be no clinical difference for a standard foam mattress in ICU followed by a standard foam mattress post-ICU and an alternating-pressure mattress in ICU followed by a constant low-pressure mattress post-ICU for reducing the incidence of pressure ulcers (all grades), the direction of the estimate of effect favoured the standard foam mattress in ICU followed by a standard foam mattress post-ICU (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.35 Alternating-pressure mattress (NIMBUS) in ICU/Standard foam mattress post-ICU versus alternating-pressure mattress (NIMBUS) in ICU/constant low-pressure mattress (TEMPUR) post-ICU

- One study (n=157) showed there may be no difference for an alternating-pressure mattress in ICU followed by a standard foam mattress post-ICU compared to an alternating-pressure mattress in ICU followed by a constant low-pressure mattress post-ICU for reducing the incidence of pressure ulcers (all grades) (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.36 Standard foam mattress ICU/constant low-pressure mattress (TEMPUR) post-ICU versus alternating-pressure mattress (NIMBUS) in ICU/ constant low-pressure mattress (TEMPUR) post-ICU

- One study (n=142) showed there may be no clinical difference for a standard foam mattress in ICU followed by a constant low-pressure mattress post-ICU compared to an alternating-pressure mattress in ICU followed by a constant low-pressure mattress post-ICU for reducing the incidence of pressure ulcers (all grades) (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.37 Alternating-pressure mattress with 2 layers of air cells (PEGASUS AIRWAVE SYSTEM) versus alternating-pressure large cell ripple mattress

- One study (n=62) showed an alternating-pressure mattress with 2 layers of air cells is potentially more clinically effective at reducing the incidence of pressure ulcers (grade 2 and above) when compared to an alternating-pressure large cell ripple mattress (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.38 Alternating-pressure mattress (PEGASUS AIRWAVE SYSTEM) versus alternating-pressure mattress (PEGASUS CAREWAVE SYSTEM)

- One study (n=75) showed there is no clinical difference between a Pegasus airwaves alternating-pressure mattress system and a Pegasus care wave alternating-pressure mattress system for reducing the incidence of pressure ulcers (grade 2 and above) (low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers

- Time to develop new pressure ulcers
- Time in hospital or NHS care
- Health related quality of life

12.1.14.1.39 Alternating-pressure mattress (TRINOVA) versus control

- One study (n=44) showed there may be a clinical benefit for a Trinova alternating-pressure mattress compared to a control for reducing the incidence of pressure ulcers (all grades) (very low or moderate quality).
- One study (n=44) showed there may be a clinical benefit for a Trinova alternating-pressure mattress compared to a control for reducing the incidence of pressure ulcers (grade 2 and above) (very low quality).
- One study (n=44) reported data for the Trinova alternating-pressure mattress for patient acceptability (comfort). 11/18 participant thought the mattress was comfortable, 10/18 participants thought that the mattress was acceptable and 5/18 found the mattress comfort unacceptable. No estimate of effect or precision could be derived (very low quality).
- No evidence was found for the following outcomes:
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.40 Alternating-pressure overlay versus alternating-pressure mattress

- One study (n=1971) showed there is potentially no difference for an alternating-pressure mattress alternating-pressure overlay compared to for reducing the incidence of pressure ulcers (grade 2 and above) (low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.41 Alternating-pressure bed (THERAPULSE) versus alternating-pressure mattress (HILL-ROM DUO)

- One study (n=62) showed there may be a clinical benefit for an alternating-pressure THERAPULSE bed compared to an alternating-pressure (HILL-ROM DUO) mattress for reducing the incidence of pressure ulcers (grade 2 and above) (very low quality).
- One study (n=62) reported means for an alternating-pressure THERAPULSE bed and an alternating-pressure (HILL-ROM DUO) mattress for length of stay in hospital for people who developed a pressure ulcer. The mean for an alternating-pressure (HILL-ROM DUO) mattress was 26 days (range 23-37.3) and 24 days (range 13-59) for an alternating-pressure (HILL-ROM DUO) mattress. No estimate for effect or precision could be derived (very low quality).
- One study (n=62) reported means for an alternating-pressure THERAPULSE bed and an alternating-pressure (HILL-ROM DUO) mattress for length of stay in hospital for people who did not develop a pressure ulcer. The mean for an alternating-pressure (HILL-ROM DUO) mattress was 18 days (range 5-127) and 20 days (range 5-49) for an alternating-pressure (HILL-ROM DUO) mattress. No estimate for effect or precision could be derived (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability

- Rates of development of pressure ulcers
- Time to develop new pressure ulcers
- Health related quality of life

12.1.14.1.42 Alternating low-pressure air mattress with multi-stage inflation and deflation of air cells versus standard (CLINACTIV, HILLROM) alternating low-pressure air mattress with single-stage inflation and deflation of air cells

- One study (n=610) showed there is potentially no clinical difference between an alternating low-pressure air mattress with single-stage inflation and deflation of air cells compared to an alternating low-pressure air mattress with multi-stage inflation and deflation of air cells for reducing the incidence of pressure ulcers (all grades), the direction of the estimate of effect favoured the low-pressure air mattress with single-stage inflation and deflation of air cells (very low quality).
- One study (n=610) showed there may be no clinical difference between an alternating low-pressure air mattress with multi-stage inflation and deflation of air cells and an alternating low-pressure air mattress with single-stage inflation and deflation of air cells for reducing the incidence of pressure ulcers (grade 2 and above), but the direction of the estimate of effect could favour either intervention (very low quality).
- One study (n=610) showed there may be a clinical benefit for an alternating low-pressure air mattress with multi-stage inflation and deflation of air cells compared to an alternating low-pressure air mattress with single-stage inflation and deflation of air cells for patient acceptability (withdrawal due to discomfort) (very low quality).
- One study (n=610) reported a benefit for an alternating low-pressure air mattress with multi-stage inflation and deflation of air cells compared to an alternating low-pressure air mattress with single-stage inflation and deflation of air cells for time to develop a new pressure ulcer. The medians for an alternating low-pressure air mattress with multi-stage inflation and deflation of air cells was 5.0 days (Interquartile range 3.0-8.5) and 8 days (interquartile range 3.0 8.5) for an alternating low-pressure air mattress with single-stage inflation and deflation of air cells. No estimate of clinical effect or precision could be derived (very low quality).
- No evidence was found for the following outcomes:
  - Rates of development of pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.43 Low-air-loss bed (KINAIR/THERAKAIR) versus static air mattress overlay/inflated static overlay (EHOB WAFFLE) or standard ICU bed

- One study (n=123) showed a low-air-loss bed is potentially more clinically effective at reducing the incidence of pressure ulcers (all grades) when compared to a static air mattress overlay (very low quality).
- Two studies (n=183) showed there may be a clinical benefit for a low-air-loss bed compared to static air mattress overlay/inflated static overlay for reducing the incidence of pressure ulcers (all grades) (very low quality).
- Two studies (n=221) showed a low-air-loss bed is more clinically effective at reducing the incidence of pressure ulcers (grade 2and above)when compared to a static air mattress overlay or standard ICU bed (low quality).
- One study (n=98) showed a low air loss hydrotherapy bed is more clinically effective at reducing the incidence of people developing multiple ulcers when compared to a standard care (standard bed or foam, air or alternating-pressure mattress) (low quality).

- Three studies (n=319) showed a low-air-loss bed is more clinically effective at reducing the incidence of pressure ulcers (grade 2 and above) when compared to static air mattress overlay/standard ICU bed or standard care (standard bed or foam, air or alternating-pressure mattress) (low quality).
- One study (n=98) reported some information about patient acceptability (comfort) for the low air loss hydrotherapy mattress. 10/42 provided information about comfort, of these 5/10 participants though it was comfortable and 4/10 participants thought it was uncomfortable. The clinical importance is unknown (very low quality).
- One study (n=98) reported some information about patient acceptability (withdrawal from the study) for the low air loss hydrotherapy mattress compared with standard care (standard bed or foam, air or alternating-pressure mattress). In the low air loss hydrotherapy mattress group, 24/48 participantstients withdrew from the study, 6 on the first day of the study because a participant or family member complained about the bed (wet, cold or uncomfortable). In the standard care group 2/58 participants withdrew from the study. The clinical importance is unknown (very low quality).
- No evidence was found for the following outcomes:
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.44 Indentation load deflection (IDL) (25%) operating room foam mattress (density 1.3 cubic feet, IDL 30lb) versus operating room usual care (padding as required, including gel pads, foam mattresses, ring cushions (donuts))

- One study (n=413) showed an indentation load deflection operating room foam mattress has a potential for clinical harm at reducing the incidence of pressure ulcers (all grades) when compared to operating room usual care (low quality).
- One study (n=413) showed that there was potentially no clinical difference of an indentation load deflection operating room foam mattress compared to operating room usual care for reducing the incidence of pressure ulcers (grade 2 and above), but the direction of the estimate of effect favoured usual care (very low quality).
- One study (n=413) reported that participants on the indentation load deflection operating room foam mattress were significantly more likely to have skin changes than those on the usual care operating room table. The clinical importance is unknown (very low quality).
- No evidence was found for the following outcomes:
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.45 Viscoelastic polymer pad versus no overlay

- One study (n=416) showed a viscoelastic polymer pad is potentially more clinically effective at reducing the incidence of pressure ulcers (all grades of pressure ulcers) when compared to no overlay (low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers

- Time in hospital or NHS care
- Health related quality of life

12.1.14.1.46 Viscoelastic foam overlay versus no overlay

- One study (n=175) showed there may be no clinical difference for a viscoelastic foam overlay compared to no overlay for reducing the incidence of pressure ulcers (all grades), the direction of the estimate of effect favoured the viscoelastic foam overlay (very low quality).
- One study (n=175) showed there may be no clinical difference between viscoelastic foam overlay and no overlay for reducing the incidence of pressure ulcers (grade 2 and above), but the direction of the estimate of effect could favour either intervention (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.47 Neoprene air filled bladder (dry flotation) device compared to a disposable polyurethane foam prone head positioner

- One study (n=44) showed there is potentially a clinical benefit for a neoprene air filled bladder (dry flotation) device compared to a disposable polyurethane foam prone head positioner for reducing the incidence of pressure ulcers (all grades) (very low quality).
- One study (n=44) showed there may be a clinical benefit for a neoprene air filled bladder (dry flotation) device compared to a disposable polyurethane foam prone head positioner for reducing the incidence of pressure ulcers (grade 2and above) (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.48 A prone view protective helmet system with a disposable polyurethane foam prone head positioner versus a disposable polyurethane foam prone head positioner

- One study (n=44) showed a prone view protective helmet system with a disposable polyurethane foam prone head positioner has a potential for clinical benefit for reducing the incidence of pressure ulcers (all grades) when compared to a disposable polyurethane foam prone head positioner (very low quality).
- One study (n=44) showed there may be a clinical benefit for a prone view protective helmet system with a disposable polyurethane foam prone head positioner compared to a disposable polyurethane foam prone head positioner for reducing the incidence of pressure ulcers (grade 2 and above) (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care

- Health related quality of life

12.1.14.1.49 A neoprene air filled bladder (dry flotation) device versus a prone view protective helmet system with a disposable polyurethane foam prone head positioner

- One study (n=44) showed there is no clinical difference between a neoprene air filled bladder (dry flotation) device and a prone view protective helmet system with a disposable polyurethane foam prone head positioner for reducing the incidence of pressure ulcers (all grades) (low quality).
- One study (n=44) showed there is no clinical difference between a neoprene air filled bladder (dry flotation) device and a prone view protective helmet system with a disposable polyurethane foam prone head positioner for reducing the incidence of pressure ulcers (grade 2 and above) (low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.1.50 A multi-cell pulsating dynamic mattress versus a standard mattress

- Two studies (n=368) showed that for people undergoing surgery, a multi-cell pulsating dynamic mattress system is more clinically effective at reducing the incidence of pressure ulcers (all grades) when compared to a standard mattress (low quality).
- One study (n=170) showed that for people undergoing surgery, a multi-cell pulsating dynamic mattress system is potentially more clinically effective at reducing the incidence of pressure ulcers (grade 2 and above) when compared to a standard mattress (very low quality).
- One study (n=170) reported information about the length of stay in hospital for people who developed pressure ulcers. The average length of stay for those developing pressure ulcers was 14 days. Six of the 8 people who developed ulcers had a length of stay longer than average for the specific diagnosis. The clinical importance is unknown (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Health related quality of life

12.1.14.1.51 A visco-elastic foam accident and emergency (A&E) overlay and ward mattress versus standard A&E overlay and ward mattress

- One study (n=101) showed there may be a clinical benefit for visco-elastic foam A&E overlay and ward mattress compared to a standard A&E overlay and ward mattress for reducing the incidence of pressure ulcers (grade 2 and above) (very low quality).
- One study (n=101) showed there may be a clinical benefit for visco-elastic foam A&E overlay and ward mattress compared to standard A&E overlay and ward mattress for reducing the incidence of pressure ulcers (all grades) (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care

- Health related quality of life

12.1.14.2 Wheelchair cushions

12.1.14.2.1 Slab foam cushion versus bespoke contoured foam cushion

- Two studies (n=300) showed there is no clinical difference between a slab foam cushion when compared with a bespoke contoured foam cushion for reducing the incidence of pressure ulcers (all grades) (low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.2.2 Gel cushion with foam base (JAY) versus foam cushion

- One study (n=141) showed a gel cushion with foam base is potentially more clinically effective at reducing the incidence of pressure ulcers (all grades of pressure ulcers) when compared to a foam cushion (low quality).
- One study (n=163) showed there may be a clinical benefit for a gel cushion with foam base compared to a foam cushion for patient acceptability (withdrawal due to discomfort) (very low quality).
- No evidence was found for the following outcomes:
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.2.3 Pressure reducing cushion (not specified – chosen by nurse based on the individual) versus standard 3 inch convoluted foam cushion (EGGRATE)

- One study (n=32) showed there may be a clinical benefit for a pressure reducing cushion compared to a standard 3 inch convoluted foam cushion for reducing the incidence of pressure ulcers (all grades), (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rates of development of pressure ulcers
  - Time to develop new pressure ulcers
  - Time in hospital or NHS care
  - Health related quality of life

12.1.14.2.4 Skin protection cushion versus segmented foam cushion

- One study (n=232) showed a skin protection cushion is potentially more clinically effective at reducing the incidence of sitting related ischial tuberosities when compared to a segmented foam cushion (very low quality).
- One study (n=232) showed a skin protection cushion is potentially more clinically effective at reducing the incidence of pressure ulcers of the combined ischial tuberosities and sacral/coccyx areas when compared to a segmented foam cushion (very low quality).
- No evidence was found for the following outcomes:

- Patient acceptability
- Rates of development of pressure ulcers
- Time to develop new pressure ulcers
- Time in hospital or NHS care
- Health related quality of life

12.1.14.3 Economic (adults)

12.1.14.3.1 Alternating pressure verses alternative foam

- One cost–utility analysis found that alternating pressure overlays and alternating pressure mattress replacements dominate (less costly and more effective) high specification foam mattresses in the prevention of pressure ulcers. This analysis was assessed as partially applicable with potentially serious limitations.

12.1.14.3.2 Comparisons between alternating pressure devices

- One cost–utility analysis found that alternating pressure mattress replacements were not cost effective compared to alternating pressure overlays for the prevention of pressure ulcers (ICER: £253,000 per QALY gained). This analysis was assessed as partially applicable with potentially serious limitations.
- Conversely, 1 cost-effectiveness analysis found alternating pressure mattress replacements dominate alternating overlays, with a longer time to pressure ulcer development and reduced costs. This analysis was assessed as partially applicable with potentially serious limitations.

12.1.14.3.3 High specification foam verses standard practice

- One cost–effectiveness analysis found that high specification foam mattresses dominate standard mattresses in the prevention of pressure ulcers, with a reduced incidence of pressure ulcers at a lower cost. This analysis was assessed as partially applicable with minor limitations.
- One cost–utility analysis found that use of pressure redistribution foam mattresses (for all residents) dominates standard practice in the prevention of pressure ulcers, with an increase in QALYs at a lower cost. This analysis was assessed as partially applicable with potentially serious limitations
- One cost-effectiveness analysis found that visco-polymer energy absorbing foam mattresses dominate standard mattresses, with reduced costs and reduced incidence of pressure ulcer. This analysis was assessed as partially applicable with minor limitations.

12.1.14.3.4 Constant low pressure supports compared to standard care

- One cost–effectiveness analysis found that usual care plus Australian medical sheepskin was more costly and more effective than usual care alone (ICER: £2,298 per sacral pressure ulcer avoided). This analysis was assessed as partially applicable with potentially serious limitations.
- One cost–effectiveness analysis found that a preventative treatment protocol and use of a Clinitron Rite-Hite Air Fluidised Therapy bed dominates standard care on an ICU bed (reduction in pressure ulcer incidence and reduced costs). This analysis was assessed as partially applicable with potentially serious limitations.
- One cost–effectiveness analysis found that use of an inflated static overlay dominated (reduction in pressure ulcer incidence and reduced costs) standard care in the prevention of pressure ulcers. This analysis was assessed as partially applicable with potentially serious limitations.

12.1.14.3.5 Constant low pressure supports compared to standard care in operating theatre

- One cost–utility analysis found that use of viscoelastic polymer overlays on operating tables (for people undergoing surgery expected to last ≥90 minutes) dominates current practice, yielding

higher QALYs at a lower cost. This analysis was assessed as partially applicable with minor limitations.

12.1.14.4 Clinical (neonates, infants, children and young people)

No evidence was identified

12.1.14.5 Economic (neonates, infants, children and young people)

No evidence was identified

12.2 Recommendations and link to evidence

12.2.1 Adults

Recommendations	**30. 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** **31. Consider a high-specification foam theatre mattress or an equivalent pressure redistributing surface for all adults who are undergoing surgery.** **32. Consider the seating needs of people at risk of developing a pressure ulcer who are sitting for prolonged periods.** **33. Consider a high-specification foam or equivalent pressure redistributing cushion for adults who use a wheelchair or who sit for prolonged periods.**
Relative values of different outcomes	The GDG identified that the proportion of people developing new pressure ulcers and patient acceptability were the most critical outcomes to inform decision making, given that the primary goal of pressure ulcer prevention was to limit the number of new pressure ulcers. Acceptability was identified as being critical from the perspective of the patient, as it was noted that this could have a significant impact upon quality of life. Rate of development of new pressure ulcers, time to develop new pressure ulcers, time in hospital or NHS care and health related quality of life were considered important outcomes to inform decision making.
Trade-off between clinical benefits and harms	There was low to very low quality evidence to suggest that high specification foam mattresses were better than standard foam mattress for preventing pressure ulcers. All studies showed a clinical benefit of higher specification foam mattresses (cubed foam mattress, soft foam mattress, pressure redistributing foam mattress), in reducing the incidence of pressure ulcers when compared to standard hospital mattresses (standard polypropylene SG40, standard 130mm NHS foam mattress, standard 150mm NHS foam mattress). A study published in 2003 which included a visco-polymer energy absorbing foam mattress compared to a standard mattress or cushion (which was a variety of foam mattresses or overlays), showed no clinical difference for the prevention of pressure ulcers or comfort of surface. The softfoam mattress was judged to be adequate to very comfortable in comparison to the

standard 130mm NHS foam mattress.

The GDG recognised that the standard hospital mattress used in the studies was likely to have varied yearly and by hospital. Current standard hospital mattresses are likely to be higher specification foam mattresses than those included in the studies (as the majority of the studies were undertaken greater than 10 years ago). The GDG further acknowledged that the type of mattress used in community settings will vary.

Both a bead-filled mattress and a water-filled mattress showed a clinical benefit for reducing the incidence of pressure ulcers when compared to standard hospital mattresses (type not specified). However these studies were published in 1982 and the type of standard hospital mattress used in the study is unlikely to be representative of the mattress used in current clinical practice. One small study found a foam mattress to be of clinical benefit in reducing the incidence of pressure ulcers compared to a foam overlay. Another small study found solid foam to be clinically beneficial for reducing the incidence of pressure ulcers compared to convoluted foam.

Sheepskin overlay was found to be of clinical benefit compared to no sheepskin overlay for preventing all grades of pressure ulcers (using the AHCPR classification) but this did not follow for pressure ulcers of grade 2 and above. The sheepskin overlay had comfort issues that were specific to the nature of the sheepskin, such as irritation and being too hot.

The following were clinically beneficial for reducing the incidence of pressure ulcers; a constant low pressure mattress compared to a standard foam mattress, an alternating pressure mattress compared to a standard foam mattress, various types of alternating pressure mattresses compared to various constant low pressure mattresses, and a variety of alternating-pressure devices compared to other alternating-pressure devices. A mattress with a single-stage inflation system delayed the onset until the development of pressure ulcers compared to a multi-stage inflation system.

In 3 studies low air loss beds were found to be of clinical benefit for reducing the incidence of pressure ulcers when compared to a standard bed. In addition, a static air overlay on a cold foam (a form of polyurethane) mattress was of clinical benefit compared to no overlay on a cold foam mattress, a gel mattress was found to be more clinically beneficial than an air-filled overlay, an inflated static overlay was more clinically beneficial than a microfluid static overlay and a silicore overlay was more beneficial than a foam overlay, for reducing incidence of pressure ulcers. No clinical benefit was found for an alternating-pressure compared to silicore or foam overlay.

Operating theatre

A viscoelastic polymer pad was clinically beneficial for reducing the incidence of pressure ulcers compared to no overlay. A pressure redistributing (indentation load deflection) operating room foam mattress was not beneficial in comparison to operating room usual care (using padding, gel pads, foam mattresses and ring cushions) for reducing the incidence of all grades of pressure ulcers (grade 1 and above). However grade 2 and above pressure ulcers demonstrated no clinical difference. A multi-cell pulsating dynamic mattress system was more beneficial than the standard mattress (gel pad or standard pad in operating room or a replacement mattress postoperatively or a standard hospital mattress with a 6 inch or 4 inch overlay) for reducing the incidence of all grades of pressure ulcer and, in particular, grade 2 and above. The GDG considered that for people in the operating theatre, a high specification foam theatre mattress should be given as a minimum, as people

undergoing surgery were likely to be at risk of developing a pressure ulcer. The group also recognised that in some operating theatres, equivalent pressure redistributing surfaces may be used and that these may provide similar benefits. Therefore a separate recommendation for people undergoing surgery (in the operating theatre) was developed.

Accident and Emergency

A visco-elastic overlay was more beneficial than the standard Accident and Emergency overlay for reducing the incidence of pressure ulcers. The GDG wished to highlight that individuals awaiting admission in Accident and Emergency, particularly those on trolleys, should be provided with high specification foam mattresses as a minimum, in line with those who have been admitted to secondary care, as these individuals may be at risk of developing pressure ulcers.

Intensive care

There was no clinical benefit of alternating pressure or constant low pressure mattresses for the prevention of pressure ulcers in people in intensive care. The GDG considered that for these individuals, a high specification foam mattress, provided on admission to intensive care, should be given as a minimum.

Wheelchair cushions

Two studies suggest no clinical difference between a high specification foam cushion and a slab foam cushion. A gel filled pad and a pressure-reducing cushion (designed to improve tissue tolerance in sitting by providing more surface area and reducing peak pressure) were clinically beneficial compared to foam cushions for reducing the incidence of pressure ulcers in people who use a wheelchair. A skin protection cushion was clinically beneficial compared to a segmented foam cushion for reducing the incidence of pressure ulcers. Fewer people in the pre-contoured foam plus gel filled pad group withdrew due to discomfort than in the foam cushion group. The GDG highlighted that people who use wheelchairs were likely to be at risk of developing pressure ulcers and that pressure redistribution was likely to be needed. The GDG noted that the evidence suggested a benefit of high specification foam cushions. The GDG therefore developed a recommendation for this population to emphasise the need to provide high specification foam cushions to prevent pressure ulcers.

The following comparisons were not thought to inform the recommendation: alternative foam mattress versus standard foam mattress, pressure-reducing foam mattress compared to a pressure-reducing foam mattress or a dry flotation mattress compared to dry flotation mattress

The GDG discussed the needs of individuals who are likely to be sitting for long periods of time. Although limited evidence was identified specifically in this population, the GDG felt that these individuals were likely to have similar pressure redistributing requirements as adults who use a wheelchair. The GDG therefore chose to develop a recommendation highlight that the needs of these individuals should be considered and to further recommend that these people are provided with a pressure redistributing cushion.

Primary and community care settings

The GDG noted that there was limited evidence available focusing on people in primary and community care settings such as nursing homes. The GDG considered that this group of people were likely to be at risk of developing pressure ulcers and would benefit from specific preventative care. Despite the lack of evidence, the GDG considered that the benefits of high specification foam mattresses were likely to be

	applicable to this population, in line with those being admitted to secondary care. People in primary and community care settings were therefore included in the recommendation to highlight that this population should be provided with a high specification foam mattress to prevent the development of pressure ulcers. **Summary** Given the available evidence, the GDG noted that the provision of a high-specification foam mattress was likely to significantly reduce the risk of pressure ulcer development. No potential harms for the provision of high-specification foam mattresses were identified. As such, the GDG agreed that all individuals considered at risk of developing pressure ulcers should be considered for a high-specification foam mattress, including the specific populations outlined above. The GDG noted that this was likely to include all individuals admitted to secondary care, dependent upon individual characteristics (for example, their clinical condition), as well as people requiring ongoing care in primary care settings, people with significant limited mobility and all other individuals considered at risk of developing pressure ulcers. The GDG considered the use of overlays as an alternative to the provision of a high specification mattress. Although there was evidence to suggest that there was some benefit of using an overlay such as sheepskin in some scenarios, the provision of high specification foam mattresses was considered to be adequate as a minimum. Any further benefit from the use of an overlay in addition to a high specification mattress was unclear.
Economic considerations	The GDG considered evidence from 9 economic evaluations, alongside relevant UK unit costs of devices. Three economic evaluations found high specification foam to dominate standard practice, as they reduce the incidence of pressure ulcers and reduces costs. The GDG therefore agreed that the use of high specification foam would be cost-effective and potentially cost saving, compared to standard mattresses, for the population outlined in the recommendation above. The GDG did not consider the evidence (either clinical or economic) to be clear enough to make a recommendation in favour of other types of support surface, over the use of high specification foam, for the prevention of pressure ulcers in these people. Note that at present high specification foam is generally considered to be standard care in the UK NHS, thus this recommendation is not expected to have a large impact on resources. One cost-utility analysis found that the use of viscoelastic polymer overlays on operating tables led to an increase in QALYs and a reduction in costs. The clinical evidence also showed that the use of support surfaces reduces the incidence of pressure ulcers in theatre, which implies an increase in quality of life and a reduction in treatment costs. The GDG therefore felt that the use of high specification foam theatre mattresses or equivalent pressure redistributing surfaces would be cost effective, and may even be cost-saving, for people who are undergoing surgery. No economic evidence was identified specifically relating to pressure redistributing cushions for people who use a wheelchair. The GDG noted that the clinical evidence showed clinical benefit (reduction in incidence of pressure ulcers) when pre-contoured foam plus a gel filled pad and a pressure -reducing cushion were used in this population, compared to foam cushions. The clinical benefit of these cushions indicates that they prevent pressure ulcer related reductions in quality of life, and that they reduce treatment costs. The GDG agreed that the use of high specification foam, or other pressure redistributing cushions, would be highly likely to be cost-effective, and may even be cost saving, for people who use a wheelchair.
Quality of evidence	There was low to very low quality evidence for high specification foam mattresses compared to standard foam mattresses for the prevention of pressure ulcers. The

	type of mattresses included in the studies (both as intervention and comparison) were highly variable. Studies of other types of mattresses, overlays, beds and cushions had low to very low quality evidence. Most of the studies had serious to very serious imprecision and risk of bias. Only limited evidence was identified for people who were in primary care or community care settings such as nursing homes.
Other considerations	The GDG highlighted that all people in secondary care are considered to be at risk of developing a pressure ulcer and should therefore receive a high specification foam mattress.

12.2.2 Neonates, infants, children and young people

Recommendations	**34. Use a high-specification foam cot mattress or overlay for all neonates and infants who have been identified as being at high risk of developing a pressure ulcer as part of their individualised care plan.** **35. 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.**
Relative values of different outcomes	The GDG identified that the proportion of people developing new pressure ulcers and patient acceptability were the most critical outcomes to inform decision making, given that the primary goal of pressure ulcer prevention was to limit the number of new ulcers. Acceptability was identified as being critical from the perspective of the patient, as it was noted that this could have a significant impact upon quality of life. Rate of development of new pressure ulcers, time to develop new pressure ulcers, time in hospital or NHS care and health related quality of life were considered important outcomes to inform decision making.
Trade-off between clinical benefits and harms	The GDG used 2 statements from the Delphi consensus survey to inform the recommendations on the use of pressure redistributing devices for the prevention of pressure ulcers. The statement was 'Healthcare professionals should use a high specification cot mattress for all neonates and infants, or a high specification foam mattress for all children and young people'. In developing the recommendation, the GDG also considered evidence from the statement 'Healthcare professionals should use a high specification pressure redistributing overlay for all neonates, infants, children and young people at risk of developing a pressure ulcer'. Both statements were accepted by the Delphi consensus panel. Further detail on the Delphi consensus survey can be found in Appendix N. The statement on mattresses was included in Round 1 of the Delphi consensus survey. A number of comments from panel members suggested that the provision of pressure redistributing mattresses would be dependent upon the risk of the individual, following risk assessment. Further responses suggested that there may be potential harms when providing a high specification mattress, notably that these mattresses can limit the child's ability to move which may affect rehabilitation. A large proportion of comments highlighted the need to ensure that care is tailored to the individual. For example, 1 panel member emphasised that the need for a pressure redistributing mattress would be dependent upon the child's clinical condition, the length of stay, risk level and mobility. The statement on overlays was included in Round 1 of the Delphi consensus survey. A number of comments from panel members suggested that the use of mattresses was generally preferable to overlays, however there were specific situations in which

	overlays could provide a benefit. Panel members iilustrated this with the example of a delay in the provision of a high specification mattress which could result in potential harm (namely, the development of a pressure ulcer), or in community or home settings. However, some panel members also highlighted specific harms of using an overlay in place of a mattress. For example, panel members emphasised that some overlays could raise a child above the bed rails resulting in a falling hazard. Other comments noted that the weight of a child (particularly for neonates) should be considered when using specific pressure redistributing devices. Another comment noted that there were issues relating to cleaning and decontamination with regards to overlays. The GDG discussed the statement on mattresses and agreed that a recommendation should be developed. On further reflection and consideration of the qualitative comments received, the group agreed that pressure redistributing mattresses should be provided to all neonates, infants, children and young people who would be considered to be at significant risk of developing a pressure ulcer in a hospital setting. The GDG felt that those in community settings who required a pressure redistributing mattress were likely to be neonates, infants, children and young people at significant risk of developing a pressure ulcer. Further discussion on the statement on overlays from the GDG took into account the potential harms raised by the consensus panel. The GDG however, felt that the use of overlays for neonates and infants was common place and agreed that for these populations, the use of a high specification cot overlay might be an option in place of a high specification cot mattress. The GDG felt that the benefits of recommending pressure redistribution in the form of a high specification mattress were likely to be substantial in the subsequent prevention of pressure ulcer development, particularly in such a large population. Although potential harms were identified by the consensus panel in the use of cot and bed mattresses (for example, by limiting movement and potentially preventing rehabilitation) and cot overlays the GDG considered that these were likely to be outweighed by a significant benefit in pressure ulcer prevention.
Economic considerations	There are costs associated with high specification foam cot and bed mattresses, and overlays. The estimated purchase costs are £50-£199 (typical products identified by GDG members), and the devices can be used over a number of years, therefore the expected cost per patient is low. The GDG considered these costs likely to be offset by the benefits of the intervention in terms of improvement in the person's quality of life, and reduction in future treatment costs through reduction in pressure ulcer incidence. The GDG felt there was insufficient evidence to recommend the use of more expensive dynamic support surfaces for prevention of pressure ulcers in this population.
Quality of evidence	No RCTs or cohort studies were identified for neonates, infants, children or young people. Formal consensus using a modified Delphi was therefore used to develop the recommendation. To inform the recommendation, the GDG used 2 statements which were included in Round 1 of the Delphi consensus survey and both reached 83% consensus agreement. Further details can be found in Appendix N.
Other considerations	There were no other considerations.

Recommendations	**36. Offer infants, children and young people who are long-term wheelchair users, regular wheelchair assessments and provide pressure relief or redistribution.**
Relative values of different outcomes	The GDG identified that the proportion of people developing new pressure ulcers and patient acceptability were the most critical outcomes to inform decision making, given that the primary goal of pressure ulcer prevention was to limit the number of new pressure ulcers. Acceptability was identified as being critical from the perspective of the patient, as it was noted that this could have a significant impact upon quality of life. Rate of development of new pressure ulcers, time to develop new pressure ulcers, time in hospital or NHS care and health related quality of life were considered important outcomes to inform decision making.
Trade-off between clinical benefits and harms	The GDG used 1 statement from the Delphi consensus panel to develop the recommendation. The statement was 'Healthcare professionals should offer infants, children and young people who are long term wheel chair users appropriate wheelchair assessments.' The statement was accepted by the GDG in Round 1 of the survey. Further detail on the Delphi consensus survey can be found in Appendix N. The statement was included in Round 1 of the Delphi consensus. Qualitative responses gathered from panel members suggested that there were a variety of methods for assessing the pressure ulcer development in people who use wheelchairs (for example, pressure mapping) and that it was important to ensure that infants, children and young people who use wheelchairs received education in the importance of pressure ulcer prevention. A number of panel members highlighted the importance of ensuring that the assessments took place regularly because the growth of children may affect the appropriateness of their wheelchair size and the need to consider wheel chair cushions. There is also the potential for rapid change in clinical condition in these children. One comment identified that assessment should be carried out by a healthcare professional who is appropriately trained in carrying out assessment. A second comment suggested that this would be in co-ordination with paediatric occupational therapists/physiotherapists. One panel member noted that there is a lack of paediatric occupational therapists available in their area. There were also comments from panel members regarding difficulty in providing timely wheel chair assessments in their area. One panel member noted that this was often due to wheel chair users travelling from outside of their local area to access services, whilst a second stated that this would be because of the lack of paediatric occupational therapists available. The GDG discussed the statement and agreed that a recommendation should be developed. The GDG felt that there were likely to be a range of benefits, including but not limited to the prevention of pressure ulcer development, from providing infants, children and young people with regular wheelchair assessments and that doing so represented good practice. The group felt that this was supported by qualitative comments received identifying that these individuals often changed physical and clinical state rapidly (for example, they were likely to grow or their clinical condition may change quickly) meaning that regular assessment was important. The GDG acknowledged that there may be some areas in which the lack of paediatric occupational therapists, or occupational therapists with experience of working with

	children may be limited. The GDG therefore did not wish to recommend who should be carrying out the assessment, as it was acknowledged that this was likely to vary across the UK.
Economic considerations	There are costs associated with wheelchair assessments and provision of pressure redistribution. The GDG noted that this is a very high risk population, and provision of pressure redistribution is crucial. The GDG considered the likely cost implications (for example the cost of a paediatric pressure relieving cushion, £185), and concluded that the benefits of the intervention in terms of improvement in quality of life and reduction in future treatment costs (through reduction in incidence of pressure ulcers) are likely to far outweigh the costs.
Quality of evidence	No RCTs or cohort studies were identified for neonates, infants, children or young people. Formal consensus using a modified Delphi was therefore used to develop the recommendation. To inform the recommendation, the GDG used 1 statement which was included in Round 1 of the Delphi consensus survey and reached 97% consensus agreement. Further details can be found in Appendix N.
Other considerations	There were no other considerations.

Recommendations	**37. 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).**
Relative values of different outcomes	The GDG identified that the proportion of people developing new pressure ulcers and patient acceptability were the most critical outcomes to inform decision making, given that the primary goal of pressure ulcer prevention was to limit the number of new ulcers. Acceptability was identified as being critical from the perspective of the patient, as it was noted that this could have a significant impact upon quality of life. Rate of development of new pressure ulcers, time to develop new pressure ulcers, time in hospital or NHS care and health related quality of life were considered important outcomes to inform decision making.
Trade-off between clinical benefits and harms	The GDG used 1 statement from the Delphi consensus panel to develop the recommendation. The statement was 'Pressure redistributing surfaces should be used to prevent occipital pressure ulcers in neonates / infants / children / young people at risk of developing pressure ulcers.' During Round 1 of the Delphi consensus panel, qualitative feedback to a number of statements on the prevention of pressure ulcers highlighted that the sites at risk from pressure damage were different in neonates, infants, children and young people, those in adults. For these populations members of the panel considered the occiput to be a site at great risk of pressure ulcer development. As such, the GDG felt that a statement should be developed for the use of specific pressure redistributing devices for the prevention of occipital pressure ulcers for inclusion in Round 2 of the survey. The statement 'Pressure redistributing surfaces should be used to prevent occipital pressure ulcers in neonates / infants / children / young people at risk of developing pressure ulcers' was therefore developed. The statement was accepted by the Delphi panel in Round 2 of the survey. Further detail on the Delphi consensus survey can be found in Appendix N. During Round 2 of the Delphi consensus survey, qualitative responses gathered highlighted that the clinical condition of the child may prevent the use of pressure

	redistributing devices for the prevention of occipital pressure ulcers (for example, those with a cervical spine injury may have their head mobilised in skull traction). Other comments suggested that the method of pressure redistribution may come from the use of repositioning strategies, or devices such as gel pads or cushions. The GDG discussed the statement and the qualitative responses received and agreed that a recommendation should be developed. The GDG felt that responses received from the panel were helpful and agreed that the recommendation should reflect that the exact pressure redistributing strategy employed would need to be tailored to the individual, accounting for factors such as clinical condition. The GDG therefore developed a recommendation to reflect that any neonates, infants, children and young people considered at risk of developing an occipital pressure ulcer should be provided with a pressure redistributing surface. The GDG agreed that the benefits of preventing occipital ulcers, that were to come from the provision of a pressure redistributing surface, were likely to outweigh any possible harms (for example, the possibility of increasing pressure on other sites).
Economic considerations	The GDG acknowledged that there would be cost implications of providing occipital pressure redistributing surface. The GDG considered the example of a gel pillow which costs £6.83. This device could be used by a number of patients; therefore the cost per patient would be small. Prevention of pressure ulcers prevents detrainments to quality of life, and future treatment costs. The GDG therefore agreed that provision of an appropriate pressure redistribution surface was highly likely to be cost-effective for people at risk of developing occipital pressure ulcers.
Quality of evidence	No RCTs or cohort studies were identified for neonates, infants, children or young people. Formal consensus using a modified Delphi was therefore used to develop the recommendation. To inform the recommendation, the GDG used 1 statement which was included in Round 2 of the Delphi consensus survey and reached 76% consensus agreement. Further details can be found in Appendix N.

13 Pressure redistributing devices for the prevention of heel pressure ulcers

13.1 Introduction

Heel pressure ulcers occur as a result of the effects of both intrinsic and extrinsic factors such as an individual's medical condition (for example, the presence of lower limb ischaemia), the support surface on which the individual may have been placed and their mobility. Ischaemia may cause heel pressure ulcer development due to the effects of pressure transmitted from the surface of the skin through the underlying tissues and arteries or as a result of peripheral vascular changes. A support surface may cause heel pressure ulcer development as the person or healthcare professional may be unaware of the pressure being exerted on the heel over time. When and if this time is prolonged (possibly as little as 20 minutes) such as when an individual lies or sits in the same position without moving, then damage can occur without any external signs initially being reported. In addition, the cover used on the support surface may increase the shear friction co-efficient when moving their lower limbs. Where this is associated with moisture on the skin, this can result in an increase in risk status, should this not be recognised and appropriately dealt with. Other major causes of heel pressure ulcers are immobility of the lower leg as a result of injury, disease processes such as multiple sclerosis, medical investigations and interventions (such as surgical procedures undertaken with general anaesthesia; and prescribed medications).

The consequences of heel pressure ulcers for the individual and their family can be devastating, as a relatively small heel (in size) pressure ulcer can have an impact upon an individual's life, for example due to associated pain experiences; their inability to mobilise normally and their ability to work and socialise and even lead to amputation.

Given the importance of preventing heel pressure ulcers, particularly from a patient perspective, as well as the suggestion that some pressure redistributing devices can impact upon the development of heel pressure ulcers, the GDG were interested in the effectiveness of pressure redistributing devices in preventing heel pressure ulcers.

13.2 Review question: What is the clinical and cost effectiveness of pressure redistributing devices for the prevention of heel pressure ulcers?

For full details see review protocol in Appendix C.

13.2.1 Clinical evidence (adults)

Sixteen studies were included in the review.[6,28,48,54,56,68,71,78,99,149,164,172,173,198,207,214] Evidence from these are summarised in the clinical GRADE evidence profile below. See also the study selection flow chart in Appendix D, forest plots in Appendix I, study evidence tables in Appendix G and exclusion list in Appendix J. One meta-analysis (Nicosia, 2007)[145] was used as a reference for some of the meta-analyses in this review.

Table 83: Summary of studies included in the review

Study	Intervention/comparison	Population	Outcomes	Study length
Aronovitch 1999[6]	Alternating pressure system intra and postoperatively (Micropulse) versus conventional management (gel pad in operating room and a replacement mattress postoperatively)	People undergoing elective surgery under general anaesthetic	• Incidence of heel pressure ulcer within 7 days of surgery.	7-day follow-up
Cadue 2008[28]	Foam body support and standard pressure prevention protocol (half-seated position, water mattress preventive massage 6 times/day) versus standard pressure ulcer protocol (as above).	People in an intensive care setting	• Incidence of non-blanching pressure ulcer or worse on the heel.	Maximum follow-up 3 months
Daeschesel 1985[48]	Alternating-pressure mattress versus silicore overlay.	Neurological conditions in a long-term care hospital at high risk	• Incidence of grade 1 and above heel pressure ulcers.	3-month follow-up
Demarre 2012[54]	Alternating air pressure mattress (ALPAM) with multi-stage inflation and deflation of the air cells versus standard ALPAM.	People in hospital. The wards were neurology, rehabilitation, cardiology, dermatology, pneumology, oncology and chronic care or a combination of different types of medical conditions.	• Incidence of all grades of heel pressure ulcer and ≤grade 2 heel pressure ulcer; withdrawal due to discomfort; time to develop new pressure ulcers.	14 days
Donnelly 2011[56]	Heel elevation (Heelift suspension boot) plus pressure redistributing support surface versus standard care plus pressure redistributing surface alone.	People who had a hip fracture.	• Incidence of heel pressure ulcers (all categories).	12 days
Gebhardt 1996[68]	Alternating-pressure air mattresses (shallow small cell overlays, medium depth large cell overlays, deep mattresses and deep pulsating low air loss bed) versus constant low-pressure supports (fibre overlays, foam mattresses/overlays, static air overlays, gel overlay, water overlay, bead overlay, low air	People in ICU with a Norton score less than 13 with no pressure ulcers.	• Incidence of heel pressure ulcers; support provided; cost.	unclear

Study	Intervention/comparison	Population	Outcomes	Study length
	loss mattresses, static air overlay, low-air-loss beds and air-fluidised bead beds).			
Gilcreast 2005[71]	Bunny boot (fleece) high cushion heel protector versus egg crate heel lift positioner versus foot waffle cushion.	People in a military tertiary-care academic medical centre at moderate or high risk of pressure ulcer development, Braden score of 14 or under.	• Incidence of heel pressure ulcers.	Follow-up period unclear
Gray 2000[78]	Transfoamwave versus standard hospital mattress (transfoam) (in clinical use for 3 years).	People in a general hospital	• Incidence of heel pressure ulcers.	10 days follow-up
Jesurum 1996[99]	Low air loss bed (designed to maintain low interface tissue pressure of 12 to 45mmHg) versus standard bed (fit with extra pressure reduction capabilities for the heel area).	People undergoing cardio vascular surgery who requiring intra-ortic ballon pump for failure to wean from cardiopulmonary bypass surgery	• Incidence of heel pressure ulcers; rate of development of new heel pressure ulcers.	unclear
Nixon 2006[147]	Alternating-pressure overlay (alternating cell height minimum 8.5cm, max 12.25cm; cell cycle time 7.5-30 minutes Group 2: Alternating-pressure mattress (alternating cell height min 19.6cms, max 29.4cms; cell cycle time 7.5-30minutes).	People undergoing acute or elective care from 11 hospitals	• Incidence of heel pressure ulcers grade 2 and above; patient acceptability: requests for mattress change.	60 day follow-up
Russell 2000A[164]	MicroPulse system in the operating room and postoperatively versus conventional care (gel pad in the operating room and standard mattress postoperatively).	People aged 18 years or over; undergoing scheduled cardiothoracic surgery under general anaesthetic; surgery of at least 4 hours duration; free of pressure ulcers	• Incidence and severity of heel pressure ulcers.	7-day follow-up
Sanada 2003[172]	Double-layer cell overlay (2 layers consisting of 24 narrow cylinder air cells) versus single-layer air cell overlay (single layer consisting of 20 round air cells) versus standard hospital	People in an acute care unit; Braden score of 16 or less; bed bound; free of pressure ulcers	• Incidence of heel pressure ulcers.	Follow-up duration not reported

Study	Intervention/comparison	Population	Outcomes	Study length
	mattress.			
Santamaria 2013[173]	Usual pressure ulcer prevention strategies plus multi-layered (3 layers) soft silicone foam heel dressing. Elastic tubular bandages were also used to retain the dressings versus usual pressure ulcer prevention strategies.	Trauma patients and critically ill people in the intensive care unit (ICU)	• Incidence of heel pressure ulcers.	Follow-up duration not reported
Takala 1996[198]	Carital optima constant low pressure mattress (21 double air bags on a base) versus standard hospital foam mattress (10cm thick foam density 35kg/m^3).	Non-trauma patients admitted to ICU	• Incidence of heel pressure ulcers.	14-day follow-up
Tymec 1997[207]	Foot waffle versus hospital pillow under both legs from below knee to the achilles tendon.	People in selected nursing units of large hospital; Braden score less than 1 (risk); intact skin on heels	• Incidence of heel pressure ulcers.	unclear
Torra [204]	Special polyurethane foam hydrocellular dressing for the protection of the heel (Allevyn Heel) versus protective bandage of the heel (Soffban and gauze bandage).	People in a nursing home and undergoing a home care program from primary health care centres.	• Incidence of heel pressure ulcers.	8 weeks
Vanderwee 2005[214]	Alternating pressure mattress (APAM) versus visco-elastic foam mattress. Heels were elevated with a pillow beneath the lower legs for both groups.	People in hospital for surgical, internal medicine or geriatric care; at risk of developing pressure ulcer (Braden score less than 17)	• Incidence of heel pressure ulcers.	Unclear

Table 84: Clinical evidence profile: bunny boot fleece cushion heel protector versus egg crate heel lift positioner (people in ICU, medical, surgical wards and people receiving cardiology care)

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**Bunny boot**	**Egg crate**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance of outcome**
Incidence of heel pressure ulcers –grade of heel pressure ulcers unclear (NPUAP)[71]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	3/77 (3.9%)	4/87 (4.6%)	RR 0.85 (0.2 to 3.67)	7 fewer per 1000 (from 37 fewer to 123 more)	Very low	Critical outcome
							-	4.6%		7 fewer per 1000 (from 37 fewer to 123 more)		
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcer												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There was inadequate allocation concealment reported by the authours; no blinding and limited details of baseline data were provided. It was unclear how many participants were randomised to each group and therefore which arms the drop-outs came from but there were 29% of participants who did not have follow-up data.

(b) The confidence interval crossed both MID points.

Table 85: Clinical evidence profile: bunny boot fleece cushion heel protector versus foot waffle air cushion (people in ICU, medical, surgical wards and people receiving cardiology care)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Bunny boot	Foot waffle	Relative (95% CI)	Absolute	Quality	Importance of outcome
Incidence of heel pressure ulcers - unclear grade of heel pressure ulcers (NPUAP)[71]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	3/77 (3.9%)	5/76 (6.6%)	RR 0.59 (0.15 to 2.39)	27 fewer per 1000 (from 56 fewer to 91 more)	Very low	Critical outcome
							-	6.6%		27 fewer per 1000 (from 56 fewer to 92 more)		
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcer												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There was inadequate allocation concealment reported by the authors; no blinding and limited details of baseline data were provided. It was unclear how many participants were randomised to each group and therefore which arms the drop-outs came from but there were 29% of participants who did not have follow-up data.

(b) The confidence interval crossed both MID points.

Table 86: Clinical evidence profile: eggcrate heel lift positioner versus foot waffle air cushion (people in ICU, medical, surgical wards and people receiving cardiology care)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Egg crate	Foot waffle	Relative (95% CI)	Absolute	Quality	Importance of outcome
Incidence of heel pressure ulcers - unclear which grade of heel pressure ulcers (NPUAP) [71]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	4/87 (4.6%)	5/76 (6.6%)	RR 0.7 (0.19 to 2.51)	20 fewer per 1000 (from 53 fewer to 99 more)	Very low	Critical outcome
							-	6.6%		20 fewer per 1000 (from 53 fewer to 100 more)		
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcer												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There was inadequate allocation concealment reported by the authors; no blinding and limited details of baseline data were provided. It was unclear how many participants were randomised to each group and therefore which arms the drop-outs came from but there were 29% of participants who did not have follow-up data.

(b) The confidence interval crossed both MID points.

Table 87: Clinical evidence profile: foot waffle heel elevation device versus heel elevation pillow (people from selected nursing units at a hospital)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Foot waffle	Pillow	Relative (95% CI)	Absolute	Quality	Importance of outcome
Incidence of heel pressure ulcers – grade 2 and above heel pressure ulcers (AHCPR) [207]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	0/26 (0%)	1/26 (3.8%)	Peto OR 0.14 (0 to 6.82)	33 fewer per 1000 (from 38 fewer to 176 more)	Very low	Critical outcome
							-	3.9%		33 fewer per 1000 (from 39 fewer to 178 more)		
Time to heel pressure ulcer – grade 2 and above heel pressure ulcers (AHCPR) [207]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	No serious	Very serious[c]	10 days	13 days	-	Log-rank test p=0.036	Very low	Critical outcome
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcer (time to event data)												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There was unclear allocation concealment reported by the authors, blinding and reporting of incomplete outcome data was not provided. Eight participants who developed grade 1 pressure ulcers were removed from the study.

(b) The confidence interval crossed both MID points.

(c) No standard deviations were reported so the data could not be analysed in Revman.

Table 88: Clinical evidence profile: eggcrate suspension boot heel elevation device plus pressure redistributing support surface versus standard care (pressure redistributing surface alone for example cut foam mattress, mattress overlays and alternating pressure mattresses) (older people with fractured hips)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Heel elevation device	Standard care	Relative (95% CI)	Absolute	Quality	Importance of outcome
Incidence of heel pressure ulcers – all grades of heel pressure ulcers (NPUAP) [56]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	No serious imprecision	None	0/120 (0%)	17/119 (14.3%)	Peto OR 0.12 (0.04 to 0.31)	123 fewer per 1000 (from 94 fewer to 136 fewer)	Low	Critical outcome
							-	14.3%		123 fewer per 1000 (from 94 fewer to 136 fewer)		
Comfort[56]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	No serious imprecision	Very serious[c]	See footnote[b]	See footnote[b]	See footnote[b]	See footnote[b]	Very low	Critical outcome
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcer												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There was no blinding of participants or health care practitioners reported. The study was underpowered. There was a higher drop-out than event rate.

(b) Comfort was analysed by a themed analysis of participants' opinions - 32% of participants felt the boots interfered with sleep and 41% felt that they adversely affected movement in bed, 59% rated them as comfortable overall. Poor concordance reasons were the weight and bulk of the boot (36%), heat (particularly at night) (31%) and discomfort (24%).
(c) It was not possible to analyse the data in Revman as data was not provided for both arms of the trial.

Table 89: Clinical evidence profile: silicone multi-layered foam dressing versus standard care

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**Silicone multi-layered foam dressing**	**Standard care**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
Incidence of pressure ulcers – trauma and critically ill patients in ICU – all grades of heel pressure ulcers (Australian Wound Management Association)[173]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	5/161 (3.1%)	19/152 (12.5%)	RR 0.25 (0.1 to 0.65)	94 fewer per 1000 (from 44 fewer to 112 fewer)	Very low	Critical
							-	12.5%		94 fewer per 1000 (from 44 fewer to 112 fewer)		
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcers (time to event data)												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												

(a) There was no blinding and unclear allocation concealment. The drop-out rate higher than event rate.
(b) The confidence interval crossed 1 MID point.

Table 90: Clinical evidence profile: foam support surface (perpendicular foam blocks covered with jersey) plus usual care versus usual care (half-seated position, water mattress preventive massage 6 times per day) (people in ICU)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Foam body support plus usual care	Usual care	Relative (95% CI)	Absolute	Quality	Importance of outcome
Incidence of heel pressure ulcers (follow-up 3 months) – non-blanching pressure ulcer or worse[28]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	No serious imprecision	None	3/35 (8.6%)	19/35 (54.3%)	RR 0.16 (0.05 to 0.49)	456 fewer per 1000 (from 277 fewer to 516 fewer)	Moderate	Critical
							-	54.3%		456 fewer per 1000 (from 277 fewer to 516 fewer)		
Mean time to heel pressure ulcer - non-blanching pressure ulcer or worse[28]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	No serious imprecision	Very serious[b]	5.6 days	2.8 days	-	p=0.01	Very low	Critical
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcers (time to event data)												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There was unclear blinding reported by the authors. No a priori sample size calculation was carried out and the study used a small sample size.
(b) No standard deviations were provided so it was not possible to analyse data in Revman.

Table 91: Clinical evidence profile: air mattress versus standard hospital mattress (people undergoing cardiac surgery (Aronovitch, Jesurum and Russell), people in ICU (Takala))

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Air mattress	SHM	Relative (95% CI)	Absolute	Quality	Importance of outcome
Incidence of heel pressure ulcers – studies meta-analysed – all grades of heel pressure ulcers (Jesurum) Aronovitch (NPUAP and the WOCN), Jesurum (NPUAP), Russell (NPUAP), Takala – grade 1 occurred (Shea)[6];[99];[164];[198]												
4	Randomised trials	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	2/237 (0.8%)	7/238 (2.9%)	RR 0.45 (0.14 to 1.49)	16 fewer per 1000 (from 25 fewer to 14 more)	Very low	Critical
							-	3.9%		21 fewer per 1000 (from 34 fewer to 19 more)		
Incidence of heel pressure ulcers - alternating air mattress (Micropulse) versus standard hospital mattress (Action Pad in operating room on top of a standard pad and a pressure guard II replacement mattress) – all grades of heel pressure ulcers (NPUAP and the WOCN)[6]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	0/112 (0%)	2/105 (1.9%)	Peto OR 0.13 (0.01 to 2.02)	17 fewer per 1000 (from 19 fewer to 19 more)	Very low	Critical
							-	2.9%		25 fewer per 1000 (from 29 fewer to 28 more)		
Incidence of heel pressure ulcers – low-air-loss bed versus standard hospital mattress (pressure-reducing foam mattress replacement designed to reduce interface pressure) – all grades of heel pressure ulcers (NPUAP)[99]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[c]	None	2/16 (12.5%)	1/20 (5%)	RR 2.5 (0.25 to	75 more per 1000 (from 38 fewer to	Very low	Critical outcome

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Air mattress	SHM	Relative (95% CI)	Absolute	Quality	Importance of outcome
									25.15)	1000 more)		
							-	5%		75 more per 1000 (from 38 fewer to 1000 more)		
Incidence of heel pressure ulcers - multi-cell pulsating dynamic mattress system versus standard hospital mattress (gel pad on operating table then standard hospital mattress of 6 inches or 4 inches of hospital foam) – all grades of heel pressure ulcers (NPUAP)[164]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	0/98 (0%)	1/100 (1%)	Peto OR 0.14 (0 to 6.96)	9 fewer per 1000 (from 10 fewer to 56 more)	Very low	Critical
							-	1%		9 fewer per 1000 (from 10 fewer to 56 more)		
Incidence of heel pressure ulcers - double air cell mattress versus standard hospital mattress (10cm thick foam mattress) – all grades of heel pressure ulcer, grade 1 occurred (Shea) [198]												
1	Randomised trials	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	0/11 (0%)	2/13 (15.4 %)	Peto OR 0.15 (0.01 to 2.49)	127 fewer per 1000 (from 152 fewer to 158 more)	Very low	Critical
							-	15.4%		127 fewer per 1000 (from 152 fewer to 158 more)		
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Air mattress	SHM	Relative (95% CI)	Absolute	Quality	Importance of outcome
Time to develop new pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) Aronovitch: quasi-randomised, unclear allocation concealment and blinding, no power calculation given and higher drop-out than the event rate; the conventional management group were at higher risk at baseline (Knoll score);Jesurum: quasi-experimental; unclear allocation concealment; blinding; no a priori sample size calculation and small sample size; no details on the location of the late phase ulcers. Russell:no details of sequence generation or a priori power calculation. Higher drop-out than event rate. Unclear if day 7 was the first sign of pressure ulcers. One participant who got a pressure ulcer in the dynamic mattress group spent several hours sitting on a chair on post-op day 4 and 5. Takala: unclear allocation concealment, blinding, randomisation and higher drop-out rate than event rate.

(b) Confidence interval crossed both MID points.

(c) Confidence interval crossed 1 MID point.

Table 92: Clinical evidence profile: foam mattress (Transfoamwave) versus standard hospital mattress (Transfoam) (people in hospital)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Foam mattress (Transfoamwave)	SHM (Transfoam)	Relative (95% CI)	Absolute	Quality	Importance
Incidence of heel pressure ulcers – all grades of pressure ulcers, grade 4 occurred (Torrance scale)[79]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	0/50 (0%)	1/50 (2%)	OR 0.14 (0 to 6.82)	17 fewer per 1000 (from 20 fewer to 102 more)	Very low	Critical
							-	2%		17 fewer per 1000 (from 20 fewer to		

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Foam mattress (Transfoamwave)	SHM (Transfoam)	Relative (95% CI)	Absolute	Quality	Importance
										102 more)		
Comfort perception - very uncomfortable[79]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	No serious imprecision	None	0/47 (0%)	0/48 (0%)	Not pooled	Not pooled	Moderate	Critical
							-	0%		Not pooled		
Comfort perception - adequate[79]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	3/47 (6.4%)	2/48 (4.2%)	RR 1.53 (0.27 to 8.76)	22 more per 1000 (from 30 fewer to 323 more)	Very low	Critical
							-	4.2%		22 more per 1000 (from 31 fewer to 326 more)		
Comfort perception - uncomfortable[79]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	0/47 (0%)	1/48 (2.1%)	OR 0.14 (0 to 6.97)	18 fewer per 1000 (from 21 fewer to 108 more)	Very low	Critical
							-	2.1%		18 fewer per 1000 (from 21 fewer to 109 more)		
Comfort perception - comfortable[79]												
1	Randomised	Serious[a]	No serious	No serious	Serious[c]	None	26/47	34/48	RR 0.78 (0.57 to	156 fewer per 1000	Low	Critical

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**Foam mattress (Transfoamwave)**	**SHM (Transfoam)**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
	trial		inconsistency	indirectness			(55.3%)	(70.8%)	1.07)	(from 305 fewer to 50 more)		
							-	70.8%		156 fewer per 1000 (from 304 fewer to 50 more)		
Comfort perception - very comfortable[79]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	Serious[c]	None	18/47 (38.3%)	11/48 (22.9%)	RR 1.67 (0.89 to 3.15)	154 more per 1000 (from 25 fewer to 493 more)	Low	Critical
							-	22.9%		153 more per 1000 (from 25 fewer to 492 more)		
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcer												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) Gray did not report clear sequence generation method or provide details of incomplete outcome data.
(b) The confidence interval crossed 1 MID point.
(c) The confidence interval crossed both MID points.

Table 93: Clinical evidence profile: silicore overlay versus air overlay (people with chronic neurological conditions)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Silicore overlay	Air overlay	Relative (95% CI)	Absolute	Quality	Importance of outcome
Incidence of heel pressure ulcers – all grades of pressure ulcers (Exton-Smith Scale)[48]												
1	Randomised trial	Very serious[a]	No serious inconsistency	Serious[b]	Very serious[c]	None	0/16 (0%)	1/16 (6.3%)	Peto OR 0.14 (0.00 to 6.82)	53 fewer per 1000 (from 62 fewer to 250 more)	Very low	Critical
							-	6.3%		54 fewer per 1000 (from 63 fewer to 251 more)		
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcer												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) Daechshel did not report clear randomisation methods, allocation concealment or blinding. No a priori sample size calculation and the study used a small sample size.
(b) Additional preventive aids, such as heel and ankle protectors were used where occupational therapist thought required.
(c) The confidence interval crossed both MID points.

Table 94: Clinical evidence profile: double-layer air-cell overlay versus standard hospital mattress (polyester mattress) (acute care population)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Double-layer air-cell overlay	Control	Relative (95% CI)	Absolute	Quality	Importance of outcome
Incidence of heel pressure ulcers - all grades of ulcers, grade 1 and 2 occurred (NPUAP)[172]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	2/29 (6.9%)	2/27 (7.4%)	RR 0.93 (0.14 to 6.15)	5 fewer per 1000 (from 64 fewer to 381 more)	Very low	Critical
							-	7.4%		5 fewer per 1000 (from 64 fewer to 381 more)		
Incidence of heel pressure ulcers - grade 2 (NPUAP)[172]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	0/29 (0%)	2/27 (7.4%)	Peto OR 0.12 (0.01 to 1.99)	65 fewer per 1000 (from 73 fewer to 63 more)	Very low	Critical
							-	7.4%		65 fewer per 1000 (from 73 fewer to 63 more)		
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcer												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcer												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Double-layer air-cell overlay	Control	Relative (95% CI)	Absolute	Quality	Importance of outcome
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) No blinding of nurses was carried out, but participants were blinded. There was a higher drop-out rate than the event rate. No a priori sample size calculation was conducted. There was a mistake in the numbers reported in the double-layer and the single-layer air-cell groups; we have reported those denominators most commonly used.

(b) The confidence interval crossed both MID points.

Table 95: Clinical evidence profile: single-layer air-cell overlay versus standard hospital mattress (polyester mattress) fo (acute care population)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Single-layer air-cell overlay	Control	Relative (95% CI)	Absolute	Quality	Importance
Incidence of heel pressure ulcers - all grades of ulcers, grade 1 and 2 occurred (NPUAP)[172]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	0/26 (0%)	2/27 (7.4%)	Peto OR 0.14 (0.01 to 2.22)	63 fewer per 1000 (from 73 fewer to 77 more)	Very low	Critical
							-	7.4%		63 fewer per 1000 (from 73 fewer to 77 more)		
Incidence of heel pressure ulcers - grade 2 (NPUAP)[172]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	1/26 (3.8%)	2/27 (7.4%)	RR 0.52 (0.05 to 5.39)	36 fewer per 1000 (from 70 fewer to 325 more)	Very low	Critical

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Single-layer air-cell overlay	Control	Relative (95% CI)	Absolute	Quality	Importance
							-	7.4%)		36 fewer per 1000 (from 70 fewer to 325 more)		
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcer												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) No blinding of nurses was carried out, but participants were blinded. There was a higher drop-out rate than the event rate. No a priori sample size calculation was conducted. There was a mistake in the numbers reported in the double-layer and the single-layer air-cell groups; we have reported those denominators most commonly used.

(b) The confidence interval crossed both MID points.

Table 96: Clinical evidence profile: double-layer versus single layer air-cell overlay (people in acute care)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Double -layer	Single layer air-cell overlay	Relative (95% CI)	Absolute	Quality	Importance of outcome
Incidence of heel pressure ulcers- all grades of ulcers, grade 1 and 2 occurred (NPUAP)[172]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	2/29 (6.9%)	0/26 (0%)	Peto OR 6.91 (0.42 to 113.79)	70 fewer per 1000 (from 190 fewer to 40 more)	Very low	Critical
								0%		70 fewer per 1000 (from 190 fewer to 40 more)		
Incidence of heel pressure ulcers - grade 2 (NPUAP)[172]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	0/29 (0%)	1/26 (3.8%)	Peto OR 0.12 (0 to 6.11)	34 fewer per 1000 (from 38 fewer to 158 more)	Very low	Critical
								3.9%		34 fewer per 1000 (from 39 fewer to 160 more)		
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcer												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Double -layer	Single layer air-cell overlay	Relative (95% CI)	Absolute	Quality	Importance of outcome
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) No blinding of nurses was carried out, but participants were blinded. There was a higher drop-out rate than the event rate. No a priori sample size calculation was conducted. There was a mistake in the numbers reported in the double-layer and the single-layer air-cell groups; we have reported those denominators most commonly used.

(b) The confidence interval crossed both MID points. There was a limited number of events.

Table 97: Clinical evidence profile: multi-stage versus single-stage inflation and deflation alternating pressure mattress (mixed population)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Multi-stage versus single-stage inflation and deflation AP mattress	Control	Relative (95% CI)	Absolute	Quality	Importance
Incidence of heel pressure ulcers – grade 2 and above heel pressure ulcers (EPUAP)[54]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	4/298 (1.3%)	5/312 (1.6%)	RR 0.84 (0.23 to 3.09)	3 fewer per 1000 (from 12 fewer to 33 more)	Very low	Critical
							-	1.6%		3 fewer per 1000 (from 12 fewer to 33 more)		
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Multi-stage versus single-stage inflation and deflation AP mattress	Control	Relative (95% CI)	Absolute	Quality	Importance
Rate of development of pressure uclers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcer												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) There was no blinding of outcome assessors and a high drop-out in both groups.
(b) The confidence interval crossed both MID points.

Table 98: Clinical evidence profile: combined alternating pressure mattress or overlay versus combined constant low pressure mattress or overlay (people in ICU)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Combined AP	Combined CLP	Relative (95% CI)	Absolute	Quality	Importance
Incidence of heel pressure ulcers – grade 2 and above heel pressure ulcers, grade 3 occurred (NPUAP)[68]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	0/23 (0%)	1/20 (5%)	Peto OR 0.12 (0 to 5.93)	44 fewer per 1000 (from 50 fewer to 188 more)	Very low	Critical
								5%		44 fewer per		

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Combined AP	Combined CLP	Relative (95% CI)	Absolute	Quality	Importance
										1000 (from 50 fewer to 188 more)		
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcer												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) The study was quasi-randomised; there was unclear allocation concealment and a higher drop-out rate than the event rate. It was unclear how many participants developed heel or pressure ulcers

(b) The confidence interval crossed both MID points.

Table 99: Clinical evidence profile: alternating pressure air mattress plus cushion versus viscoelastic foam mattress plus cushion (mixed population)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	AP plus cushion	Visco-elastic foam mattress plus cushion	Relative (95% CI)	Absolute	Quality	Importance
Incidence of heel pressure ulcers – grade 2 and above heel pressure ulcers (EPUAP) [214]												
1	Randomised	Serious[a]	No serious	No serious	Serious[b]	None	5/222	16/225	RR 0.32	48 fewer	Low	Critical

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	AP plus cushion	Visco-elastic foam mattress plus cushion	Relative (95% CI)	Absolute	Quality	Importance
Incidence of heel pressure ulcers – grade 2 and above heel pressure ulcers (EPUAP) [214]												
	trial		inconsistency	indirectness			(2.3%)	(7.1%)	(0.12 to 0.85)	per 1000 (from 11 fewer to 63 fewer)		
							-	7.1%		48 fewer per 1000 (from 11 fewer to 62 fewer)		
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcer												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) Drop-outs and blinding unclear.
(b) The confidence interval crossed 1 MID point.

Table 100: Clinical evidence profile: alternating pressure overlay versus alternating pressure mattress (people in acute or elective care)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	AP overlay	AP mattress	Relative (95% CI)	Absolute	Quality	Importance
Incidence of heel pressure ulcers – grade 2 and above ulcers (EPUAP)[149]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	21/989 (2.1%)	21/982 (2.1%)	RR 0.99 (0.55 to 1.81)	0 fewer per 1000 (from 10 fewer to 17 more)	Very low	Critical
								2.1%		0 fewer per 1000 (from 9 fewer to 17 more)		
Acceptability - requests for mattress change[149]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[c]	None	230/989 (23.3%)	186/982 (18.9%)	RR 1.23 (1.03 to 1.46)	44 more per 1000 (from 6 more to 87 more)	Very low	Critical
								18.9%		43 more per 1000 (from 6 more to 87 more)		
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcer												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	AP overlay	AP mattress	Relative (95% CI)	Absolute	Quality	Importance
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) Unblinded study. High drop-out in both groups.
(b) Confidence interval crossed both MID points.

Table 101: Clinical evidence profile: polyurethane hydrocellular foam dressing versus protective bandage (people in a nursing home or on a home care programme)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Polyurethane hydrocellular foam dressing	Protective bandage	Relative (95% CI)	Absolute	Quality	Importance
Incidence of heel pressure ulcers – unclear grade of heel pressure ulcer (classification system not specified)[203]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	3.3%	44%	RR 13.42 (95% CI 3.3 to 54)	N/A3	Very low	Critical
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcer												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) Open study. It was unclear how many participants were in each group but relative risk reported. No details of allocation concealment and randomisation method. Unclear addressing of incomplete outcome data.
(b) Limited number of events.
(c) Absolute values not available as number of participants in each group not given.
(d) The study states that the intervention is a dressing, however the photos show a device.

13.2.2 Economic evidence (adults)

Published literature

Two studies were included with relevant comparisons.[123,203] These are summarised in the economic evidence profile below (Table 102). See also the study selection flow chart in Appendix D and study evidence tables in Appendix H.

Two studies were excluded as they were not specific to devices for prevention of pressure ulcers on the heel[37,149]. These are summarised in Appendix H.

Table 102: Economic evidence profile: Devices for the prevention of heel pressure ulcers

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effects	Cost effectiveness	Uncertainty
Lyman 2009[123] (US)	Partially applicable[a]	Potentially serious limitations[b]	Comparison of costs and effects before and after the implementation of a quality improvement (QI) strategy within which the focus was on the use of a heel support.	QI project – standard care = -£15	Incidence of pressure ulcers : QI project – standard care = -0.067	QI strategy dominates standard care	Different estimates for the cost of treating pressure ulcers were employed. The QI strategy remained cost effective in all presented scenarios.
Torra 2009[203] (Canada)	Partially applicable[c]	Potentially serious limitations[d]	Within trial analysis of protective heel bandage (soffban and gauze) and a specially shaped hydrocellular dressing (Allevyn heel).	Allevyn heel – bandage = £6	Incidence of pressure ulcers : Allevyn heel – bandage = -0.407	The Allevyn heel costs an additional £15 per pressure ulcer avoided	Two additional scenarios presented: nursing time doubled and a decrease in hourly rate for nursing time. The Allevyn heel cost an additional £26 and £11 per pressure ulcer avoided respectively.

(a) Neither discounting nor QALYs (or any measure of quality of life) appear to be considered, and the time horizon is not made explicit. Limited information is provided on the characteristics of the study patents. This is a US study published in 2009 thus applicability to the UK NHS today is limited.

(b) Effectiveness evidence is based on a simple before and after study; no attempt is made to base the analysis on randomised trial data or any systematic search procedure. Little information on the costs used for the treatment of pressure ulcers is provided, thus it is unclear why these figures have been selected for use in the analysis. Limited sensitivity analysis does not adequately explore uncertainty.

(c) QALYs are not included in the analysis and quality of life is not considered. This is a Canadian study thus applicability to the UK NHS today is limited.

(d) Costs savings associated with avoided pressure ulcers are not included (thus the analysis does not include all relevant cost components) and the analysis is based on a short trial of only 8 weeks. Limited sensitivity analysis does not adequately explore uncertainty

13.2.3 Clinical evidence (neonates, infants, children and young people)

No RCTs or cohort studies were identified. Recommendations were developed using a modified Delphi consensus technique. Further details can be found in Appendix N.

13.2.4 Economic evidence (neonates, infants, children and young people)

Published literature

No relevant economic evaluations were identified.

Economic considerations

In the absence of economic evidence for this review question, the GDG considered the expected impact of strategies to offload heel pressure on resource use, and relevant UK NHS unit costs. These economic implications were considered alongside clinical evidence obtained from the Delphi consensus panel to inform their qualitative judgement about cost-effectiveness.

Different strategies for offloading heel pressure would have different resource implications. The GDG explained that existing resources such as pillows are often used for offloading heel pressure, but also considered devices specifically to protect the heels, such as Repose foot protectors which cost £81 for a pair (including pump).[1] Note that this cost is included as an illustrative example, and should not be taken as a recommendation in favour of this particular device.

13.2.5 Evidence statements

13.2.5.1 Clinical (adults)

13.2.5.1.1 Bunny boot fleece cushion heel protector versus egg crate heel lift positioner

- One study (n=164) showed there may be no clinical difference between a bunny boot fleece cushion heel protector and an egg crate heel lift positioner for reducing the incidence of heel pressure ulcers, but the direction of the estimate of effect favoured the bunny boot fleece cushion heel protector (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rate of development of pressure ulcers
  - Time to develop new pressure ulcer
  - Time in hospital or NHS care
  - Health-related quality of life

13.2.5.1.2 Bunny boot fleece cushion heel protector versus foot waffle air cushion

- One study (n=153) showed there may be no clinical difference between a bunny boot fleece cushion heel protector and foot waffle air cushion for reducing the incidence of heel pressure ulcers, but the direction of the estimate of effect favoured the bunny boot fleece cushion heel protector (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rate of development of pressure ulcers
  - Time to develop new pressure ulcer

- Time in hospital or NHS care
- Health-related quality of life

13.2.5.1.3 Egg crate heel lift positioner versus foot waffle air cushion

- One study (n=163) showed there may be no clinical difference between an egg crate heel lift positioner and a foot waffle air cushion for reducing the incidence of heel pressure ulcers, but the direction of the estimate of effect favoured the eggcrate heel lift positioner (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rate of development of pressure ulcers
  - Time to develop new pressure ulcer
  - Time in hospital or NHS care
  - Health-related quality of life

13.2.5.1.4 Foot waffle heel elevation device versus heel elevation pillow

- One study (n=52) showed there may be no clinical difference between a foot waffle heel elevation device and a heel elevation pillow for reducing the incidence of heel pressure ulcers, but the direction of the estimate of effect favoured the foot waffle heel elevation device (very low quality).
- One study (n=52) reported no clinical difference between a foot waffle heel elevation device and a heel elevation pillow for time to heel pressure ulcer, the direction of the estimate of effect favoured the pillow (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rate of development of pressure ulcers
  - Time in hospital or NHS care
  - Health-related quality of life

13.2.5.1.5 Eggcrate suspension boot heel elevation device plus a pressure redistributing support surface versus a pressure redistributing surface alone

- One study (n=239) showed an eggcrate suspension boot heel elevation device plus a pressure redistributing support surface is more clinically effective at reducing the incidence of heel pressure ulcers when compared to a pressure redistributing surface alone (low quality).
- One study (n=240) reported themed analysis for the opinions of participants on the comfort of an eggcrate suspension boot heel elevation device. 32% of participants felt the boots interfered with sleep, 41% felt it adversely affected movement in bed, 59% rated them as comfortable overall. Poor concordance reasons were given as the weight and bulk of the boot (36%), heat (particularly at night) (31%) and discomfort (24%). The clinical importance is not known (very low quality).
- No evidence was found for the following outcomes:
  - Rate of development of pressure ulcers
  - Time to develop new pressure ulcer
  - Time in hospital or NHS care
  - Health-related quality of life

13.2.5.1.6 Multi-layered soft silicone heel pressure ulcer dressing with elastic tubular bandages versus usual care (usual pressure ulcer prevention strategies)

- One study (n=440) showed a multi-layered soft silicone heel pressure ulcer dressing with elastic tubular bandages is potentially more clinically effective at reducing the incidence of pressure ulcers when compared to usual care (usual pressure ulcer prevention strategies) (low quality).

- No evidence for the following outcomes:
  - Patient acceptability
  - Rate of development of pressure ulcers
  - Time in hospital or NHS care
  - Health-related quality of life

13.2.5.1.7 Foam body support (perpendicular foam blocks covered with jersey) versus usual care (half-seated position, water mattress and preventative massage 6 times per day)

- One study (n=70) showed a foam body support (perpendicular foam blocks covered with jersey) is more clinically effective at reducing the incidence of pressure ulcers when compared to usual care (half-seated position, water mattress and preventative massage 6 times per day) (moderate quality).
- One study (n=70) showed there may be no clinical difference between a foam body support (perpendicular foam blocks covered with jersey) and usual care (half-seated position, water mattress and preventative massage 6 times per day) for the mean time without a heel pressure ulcer, but the direction of the effect favoured the foam body support. No estimate of precision could be derived (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rate of development of pressure ulcers
  - Time in hospital or NHS care
  - Health-related quality of life

13.2.5.1.8 Air mattress versus standard hospital mattress

- Four studies (n=475) showed there may be no clinical difference between air mattress and standard hospital mattresses for reducing the incidence of heel pressure ulcers, but the direction of the estimate of effect favoured the air mattresses (very low quality).
- One study (n=217) showed there may be no clinical difference between an alternating air mattress and a standard hospital mattress (action pad in operating room on top of a standard pad and a replacement mattress) for reducing the incidence of heel pressure ulcers, but the direction of the estimate of effect favoured the alternating air mattress (very low quality).
- One study (n=36) showed there may be no clinical difference between a low-air-loss bed and a standard mattress (pressure-reducing foam mattress replacement) for reducing the incidence of heel pressure ulcers, but the direction of estimate of effect favoured the standard hospital mattress (very low quality).
- One study (n=198) showed there may be no clinical difference between a multi-cell pulsating dynamic mattress system and a standard hospital mattress (gel pad on operating table then standard hospital mattress of 6 inches or 4 inches of hospital foam) for reducing the incidence of heel pressure ulcers, but the direction of estimate of effect favoured the multi-cell pulsating dynamic mattress (very low quality).
- One study (n=24) showed there may be a clinical benefit for a double-air-cell mattress when compared to a standard hospital mattress (10cm thick foam) for reducing incidence of heel pressure ulcers (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rate of development of pressure ulcers
  - Time to develop new pressure ulcer
  - Time in hospital or NHS care
  - Health-related quality of life

13.2.5.1.9 Foam mattress versus a standard hospital mattress

- One study (n=100) showed there may be no clinical difference between a foam mattress (transfoamwave) and a standard hospital mattress (transfoam) for reducing the incidence of heel pressure ulcers, the direction of the estimate of effect favoured the transfoamwave mattress (very low quality).
- One study (n=95) showed there is no clinical difference between a transfoamwave mattress and a standard hospital mattress for the perception of being very uncomfortable, the direction of the estimate of effect favoured either intervention (moderate quality).
- One study (n=95) showed there may be no clinical difference between a transfoamwave mattress and a standard hospital mattress for perception of comfort being adequate, but the direction of the estimate of effect favoured the transfoamwave mattress (very low quality).
- One study (n=95) showed there may be no clinical difference between a transfoamwave mattress and a standard hospital mattress for perception of comfort being uncomfortable, but the direction of the estimate of effect favoured the transfoamwave (very low quality).
- One study (n=95) showed there is potentially a clinical benefit for transfoamwave mattress when compared to a standard hospital mattress for the perception of being very comfortable (low quality).
- One study (n=95) showed there is potentially no clinical difference between a transfoamwave mattress and a standard hospital mattress for the perception of being comfortable, the direction of estimate of effect favoured the transfoamwave mattress (low quality).
- No evidence was found for the following outcomes:
  - Rate of development of pressure ulcers
  - Time to develop new pressure ulcer
  - Time in hospital or NHS care
  - Health-related quality of life

13.2.5.1.10 Silicore overlay versus air overlay

- One study (n=32) showed there may be no clinical difference between silicore overlay and an air overlay for reducing the incidence of heel pressure ulcers, but the direction of the estimate of effect favoured the silicore overlay (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rate of development of pressure ulcers
  - Time to develop new pressure ulcer
  - Time in hospital or NHS care
  - Health-related quality of life

13.2.5.1.11 Double-layer air-cell overlay versus a standard hospital mattress (polyester mattress)

- One study (n=53) showed there may be no clinical difference between a double-layer air-cell overlay and a standard hospital mattress (polyester mattress) for reducing the incidence of heel pressure ulcers (grade 1 and 2), but the direction of the estimate of effect favoured the double-layer air-cell mattress (very low quality).
- One study (n=56) showed there may be no clinical benefit for a double-layer air-cell overlay when compared to a standard hospital mattress (polyester mattress) for reducing the incidence of heel pressure ulcers (grade 2), but the direction of the estimate of effect favoured the double-layer air-cell overlay (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rate of development of pressure ulcers

- Time to develop new pressure ulcer
- Time in hospital or NHS care
- Health-related quality of life

13.2.5.1.12 Single- layer air-cell overlay versus a standard hospital mattress (polyester mattress)

- One study (n=56) showed there may be no clinical difference between a single- layer air-cell overlay and a standard hospital mattress (polyester mattress) for reducing the incidence of heel pressure ulcers (grade 1 and 2), but the direction of the estimate of effect favoured the single-layer air-cell (very low quality).
- One study (n=53) showed there may be no clinical difference between a single-layer air-cell overlay and a standard hospital mattress (polyester mattress) for reducing the incidence of heel pressure ulcers (grade 2), but the direction of the estimate of effect favoured the single-layer air-cell overlay (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rate of development of pressure ulcers
  - Time to develop new pressure ulcer
  - Time in hospital or NHS care
  - Health-related quality of life

13.2.5.1.13 Double-layer air-cell overlay versus a single-layer air-cell

- One study (n=55) showed there may be no clinical difference between a double-layer air-cell overlay and a single-layer air-cell for reducing the incidence of heel pressure ulcers (grade 1 and 2), but the direction of the estimate of effect favoured the single-layer air-cell overlay (very low quality).
- One study (n=55) showed there may be no clinical difference between a double-layer air-cell overlay and a single-layer air-cell for reducing the incidence of heel pressure ulcers (grade 2), but the direction of the estimate of effect favoured the double-layer air-cell overlay (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rate of development of pressure ulcers
  - Time to develop new pressure ulcer
  - Time in hospital or NHS care
  - Health-related quality of life

13.2.5.1.14 Multi-stage inflation and deflation mattress versus a single-stage inflation and deflation mattress

- One study (n=610) showed there may be no clinical difference between a multi-stage inflation and deflation mattress and a single-stage inflation and deflation mattress for reducing the incidence of heel pressure ulcers, but the direction of the estimate of effect favoured multi-stage inflation and deflation mattress (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rate of development of pressure ulcers
  - Time to develop new pressure ulcer
  - Time in hospital or NHS care
  - Health-related quality of life

13.2.5.1.15 Combined alternating-pressure air mattress versus a combined constant low pressure mattress plus cushion

- One study (n=43) showed there may be no clinical difference between a combined alternating-pressure air mattress and a combined constant low pressure mattress plus cushion for reducing the incidence of heel pressure ulcers (grade 2 and above), but the direction of the estimate of effect favoured the combined alternating pressure mattress/overlay (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rate of development of pressure ulcers
  - Time to develop new pressure ulcer
  - Time in hospital or NHS care
  - Health-related quality of life

13.2.5.1.16 Alternating pressure mattress plus cushion versus a visco-elastic foam mattress plus cushion

- One study (n=447) showed there is potentially no clinical difference between alternating pressure mattress plus cushion and a visco-elastic foam mattress plus cushion for reducing the incidence of heel pressure ulcers (grade 2 and above), the direction of effect favoured alternating pressure plus cushion (low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rate of development of pressure ulcers
  - Time to develop new pressure ulcer
  - Time in hospital or NHS care
  - Health-related quality of life

13.2.5.1.17 Alternating pressure overlay versus an alternating pressure mattress

- One study (n=1971) showed there may be no clinical difference between an alternating-pressure overlay and an alternating-pressure mattress for reducing the incidence of heel pressure ulcers, the direction of the estimate of effect favoured either intervention (very low quality).
- One study (n=1971) showed there is potentially no clinical difference between an alternating-pressure overlay and an alternating-pressure mattress for reducing the requests for mattress change, the direction of effect favoured the alternating pressure mattress (very low quality).
- No evidence was found for the following outcomes:
  - Rate of development of pressure ulcers
  - Time to develop new pressure ulcer
  - Time in hospital or NHS care
  - Health-related quality of life

13.2.5.1.18 Polyurethane hydrocellular foam dressing versus a protective bandage

- One study (n=unclear) showed a polyurethane hydrocellular foam dressing may be more clinically effective when compared to a protective bandage for reducing the incidence of heel pressure ulcers (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rate of development of pressure ulcers
  - Time to develop new pressure ulcer
  - Time in hospital or NHS care

- Health-related quality of life

13.2.5.2 Economic evidence (adults)

- One cost-effectiveness analysis found that a quality improvement project (which included the use of a heel protector) dominated standard care, with lower incidence of pressure ulcers and lower costs. This analysis was assessed as partially applicable with potentially serious limitations.
- One cost-effectiveness analysis found that use of a specially shaped hydrocellular dressing (Allevyn heel) was more costly and more effective than a protective heel bandage (soffban and gauze) for preventing pressure ulcers (ICER: £15 per pressure ulcer avoided). This analysis was assessed as partially applicable with potentially serious limitations.

13.2.5.3 Clinical evidence (neonates, infants, children and young people)

- No evidence was identified.

13.2.5.4 Economic evidence (neonates, infants, children and young people)

- No evidence was identified.

13.3 Recommendations and link to evidence

13.3.1 Adults

Recommendations	**38. 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.**
Relative values of different outcomes	The GDG identified that the proportion of people developing new pressure ulcers and patient acceptability were the most critical outcomes to inform decision making, given that the primary goal of pressure ulcer prevention was to limit the number of new ulcers. Acceptability was identified as being critical from the perspective of the patient, as it was noted that this could have a significant impact upon quality of life. Rate of development of new pressure ulcers, time to develop new pressure ulcers, time in hospital or NHS care and health related quality of life were considered important outcomes to inform decision making.
Trade off between clinical benefits and harms	There was low quality evidence to suggest a benefit of egg crate heel elevation devices and perpendicular foam blocks on the incidence of heel pressure ulcers, in a study of people considered at high risk of developing pressure ulcers (including people over the age of 85 years, people in a trauma unit, people who had a hip fracture and people in an intensive care unit). A study of a protective bandage (which elevated the heel) compared to a polyurethane hydrocellular foam dressing showed a clinically beneficial reduction in incidence of pressure ulcers in people in a nursing home or receiving home care for the polyurethane hydrocellular foam dressing. A multi-layered soft silicone heel pressure ulcer dressing was more clinically effective at reducing the incidence of pressure ulcers compared to usual pressure ulcer prevention strategies. There was no clinical benefit found between different heel elevation devices such as bunny boots, egg crates, foot waffles and pillows. There was some evidence from studies of beds and mattresses to suggest that double-air-cell mattresses were of clinical benefit for reducing the incidence of heel pressure ulcers compared to standard hospital mattresses. No other studies of overlays, mattresses or beds showed a clinical difference for incidence of pressure ulcers. The GDG highlighted that these devices are not primarily intended to be used for the prevention of heel pressure ulcers.

	The GDG agreed that there was evidence to suggest that offloading pressure to the heel by use of a heel elevation strategy was of clinical benefit in the prevention of heel pressure ulcers. The GDG considered whether this was likely to be of benefit to all people in NHS care, or whether people considered to be at specific risk of developing a heel pressure ulcer were likely to gain the most benefit from the provision of a heel elevation strategy. The GDG highlighted that not all people considered at risk of developing a pressure ulcer were at risk of developing a heel pressure ulcer and that preventative strategies should be tailored to the specific needs of the individual, accounting for the specific sites at risk. The GDG considered whether there was a specific pressure redistributing device which would offer the most benefit to those at risk of developing heel pressure ulcers.The limited evidence available did not support the recommendation of 1 specific heel pressure redistributing device. The GDG therefore felt that providing people at high risk of developing heel pressure ulcers with a heel elevation strategy was likely to be of benefit and developed a recommendation to reflect this.
Economic considerations	One cost-effectiveness analysis found that the use of a quality improvement strategy (including use of a heel protector) dominated standard care, with a reduction in the incidence of pressure ulcer and a reduction in costs. The reduction in costs was due to the lower incidence of pressure ulcers leading to a reduction in treatment costs. Another existing economic evaluation found that using a specially shaped hydrocellular dressing (Allevyn heel) lead to an increased cost of £15 per pressure ulcer avoided when compared to a protective heel bandage (soffban and gauze). A major limitation of the latter study is that the cost savings associated with the avoided pressure ulcers were not included. The GDG noted that had these costs been accounted for, the device would most likely have been cost-saving. However, the GDG recognised the limitations and limited applicability of both of these studies. The clinical evidence revealed a reduction in pressure ulcers when using heel elevation techniques in high risk populations. Based on this clinical evidence and the economic evidence summarised above, the GDG felt that the cost of the heel devices would likely be outweighed by the increase in quality of life from the reduction in pressure ulcer incidence, and the associated reduction in treatment costs. It was agreed that heel elevation strategies would be cost-effective, and may even be cost-saving in a high risk population.
Quality of evidence	Overall, the quality of the evidence was moderate to very low for devices specifically aimed at reducing the incidence of heel pressure ulcers (heel elevation devices). Many of the studies had small sample sizes and a small number of events. Evidence was included for devices (for example mattresses), where the incidence of heel pressure ulcers was reported. However the evidence for these devices was of limited applicability as they were designed for other purposes and the studies often showed a small number of events and a grade rating of very low quality of evidence. This was mainly due to very serious imprecision and risk of bias in the studies. The GDG noted that the standard care provided to participants was rarely reported and that, due to the age of the studies, this was not likely to be representative of the care provided in current clinical practice. For example, the standard of mattresses provided is now likely to be improved.
Other considerations	The GDG felt that it was important to note that individual preference, tolerability and other co-morbidities should be considered when offering a heel elevation strategy as part of the individualised care provided. The GDG acknowledged people with a physical condition which limits sensation or mobility (for example people with a spinal cord injury) may develop heel pressure ulcers as a result of the position of wheelchair foot rests. However, the group highlighted that although this is an important consideration, the prevention of pressure ulcers caused by devices is not within the remit of this review question.

	The GDG emphasised that as a person's risk status can change in a short period of time, it is important to ensure that all people in NHS care are risk assessed regularly. This was considered by the GDG to be particularly important given that people at high risk of developing a heel ulcer may be a distinct population to those at high risk of developing a pressure ulcer on another site.

13.3.2 Neonates, infants, children and young people

Recommendations	**39. 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.**
Relative values of different outcomes	The GDG identified that the proportion of people developing new pressure ulcers and patient acceptability were the most critical outcomes to inform decision making, given that the primary goal of pressure ulcer prevention was to limit the number of new ulcers. Acceptability was identified as being critical from the perspective of the patient, as it was noted that this could have a significant impact upon quality of life. Rate of development of new pressure ulcers, time to develop new pressure ulcers, time in hospital or NHS care and health related quality of life were considered important outcomes to inform decision making.
Trade-off between clinical benefits and harms	The GDG used 1 statement from the Delphi consensus panel to develop the recommendation. The statement was 'Healthcare professionals should offer children and young people at high risk of developing heel pressure ulcers a heel elevation strategy or pressure redistribution strategy that can be tolerated by children and young people.' The statement was accepted by the GDG in Round 1 of the survey. Further detail on the Delphi consensus survey can be found in Appendix N. The statement was included in Round 1 of the Delphi consensus. Qualitative responses gathered from panel members suggested that any heel pressure reduction strategy should be tailored to the needs of the individual child and in particular, should account for the child's clinical condition. Other panel members identified that this should form part of a care package, developed by the clinical team. The GDG discussed the statement and agreed that a recommendation should be developed. The GDG agreed that providing children and young people at risk of developing a heel pressure ulcer with a strategy for offloading pressure was likely to result in a reduction in the number of heel pressure ulcers developed. Although the group did identify that some strategies for offloading heel pressure (for example, using cushions) can result in an increase in pressure on other sites, the GDG identified that the possible harms in providing heel pressure redistribution were likely to be outweighed by the benefit in heel ulcer prevention.'
Economic considerations	Evidence from the Delphi consensus panel suggested there is a clinical benefit to providing heel elevation techniques amongst high risk populations. They noted that existing resources such as pillows are often used, and also considered the cost of a heel protector (£81 for 2). The GDG felt that the cost of heel devices would be outweighed by the associated reduction in treatment costs from the reduction in pressure ulcer incidence, and would also lead to an increase in quality of life.
Quality of evidence	No RCTs or cohort studies were identified for neonates, infants, children or young people. Formal consensus using a modified Delphi was therefore used to develop the recommendation. To inform the recommendation, the GDG used 1 statement which was included in

	Round 1 of the Delphi consensus survey and reached 97% consensus agreement. Further details can be found in Appendix N.
Other considerations	Comments received during the Delphi consensus process identified that there were likely to be other areas in which neonates, infants, children and young people were at risk of developing pressure ulcers (for example, the occiput). Recommendations on preventing pressure ulcers in these sites can be found in Chapter 12.

14 Barrier creams

The skin is the largest organ of the body and our first line of defence against microbial invasion, minor trauma or a chemical breach. The skin's most outer layer called the stratum corneum provides a protective barrier. This outer layer can be damaged in many ways and a common cause of damage is through moisture. Moisture offers an increasing challenge to the skin barrier, through the corrosive effects of excess sweat, exudate, urine and faeces. It is therefore essential for people who are at risk of skin damage, their carers and health professionals to ascertain if moisture can be managed appropriately with barrier creams.

Healthy skin has a pH of 5.5, which can help to protect against bacterial and fungal infection. Excess moisture on the skin in the form of urine, sweat and faeces are alkaline in nature therefore increasing the pH level through an immediate chemical reaction, which causes irritation to the skin, therefore decreasing the barrier function. This can put the skin at greater risk of breakdown, hence increasing the risk of pressure ulcers. Increased moisture in the form of exudate may result in maceration of the skin. This makes the skin more susceptible to damage from physical forces of pressure and friction.

The GDG was interested in the economic and clinical evidence of the use of barrier creams in the prevention of skin damage resulting from excess moisture on the skin.

14.1 Review question: What are the most clinically and cost-effective topical barrier preparations for the prevention of pressure ulcers and moisture lesions?

For full details see review protocol in Appendix C.

14.1.1 Clinical evidence (adults)

Six studies were included in the review.[23,41,80,188,208,216] Evidence from these are summarised in the clinical GRADE evidence profile below (Table 103). See also the study selection flow chart in Appendix C, forest plots in Appendix I, study evidence tables in Appendix G and exclusion list in Appendix J.

Summary of included studies

Study	Intervention/comparison	Population	Outcomes	Comments
BOU2005[23]	Mepentol (hyperoxygenated fatty acid compound) versus placebo cream. Treatment time: 1 month	People in hospital and residential homes with medium, high or very high risk of developing pressure ulcers.	• Incidence of new pressure ulcers. • Time until pressure ulcer developed.	Some people had pressure ulcers at the start of the trial, but the RCT reported new ulcers developed so these were included in the results.
COOPER2001[41]	Clinisan foam cleanser (which includes barrier properties) versus standard hospital soap. Treatment time: 14 days	Elderly people with incontinence.	• Changes in skin integrity. • Broken skin.	Only results for people who had healthy skin at the start of the trial are reported in this review.
GREEN1974[80]	Dermalex: Lotion containing Cosbiol and Allantoin (moisturising properties) versus placebo (oil in water). Treatment time: 3 weeks	Elderly people at risk of developing pressure ulcers.	• Skin deterioration (erythema and sores). • Skin deterioration (sores) • Time to skin deterioration.	Old and poorly reported study.
SMITH1985[188]	Conotrane (Silicone/antiseptic cream) versus placebo (Unguentum). Treatment time: 24 weeks	Elderly people.	• Incidence of pressure ulcers (Grade 3 - 4). • Patient acceptability.	-
VANDERCAMMEN1987[208]	Prevasore versus Dermalex: Lotion containing Cosbiol and Allantoin (moisturising properties). Treatment time: 3 weeks	People in hospital who are chair bound.	• Skin deterioration. • Blistering.	Old and poorly reported study.
VERDU2012[216]	IPARZINE4A-SKR cream versus placebo.	People in hospital scoring less than 15 on the Braden Scale.	• Incidence of pressure ulcers (grade I).	-

Study	Intervention/comparison	Population	Outcomes	Comments
	Treatment time: 2 weeks			

Table 103: Clinical evidence profile: hyperoxygenated fatty acid compound (Mepentol) versus placebo cream

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**Mepentol**	**Placebo cream**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
Incidence of new pressure ulcers (follow-up 30 days; unclear how the ulcers were assessed from study)[23]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	12/164 (7.3%)	29/167 (17.4%)	RR 0.42 (0.22 to 0.8)	101 fewer per 1000 (from 35 fewer to 135 fewer)	Low	Critical
Time to development of pressure ulcer (follow-up 30 days) [23]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	Not able to evaluate	None	-	-	p=0.00543	-	Low	Important
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) No details were provided for the measurement of outcomes. The baseline characteristics showed that 59% of participants were using barrier creams at the start of the trial but there was no discussion on whether these were continued or stopped. It was unclear what happened to those who developed pressure ulcers during the trial.

(b) Confidence interval crosses 1 MID point.

(c) Comparison of Kaplan-Meier survival curves with log-rank test was statistically significant (p=0.0054). Cox's proportional hazards regression model found that gender, frequency of night-time repositioning and use of barrier products were all significant variables.

Table 104: Clinical evidence profile: foam cleanser (Clinisan) versus standard hospital soap

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Clinisan foam cleanser (inc. emollients and silicone cream)	Standard hospital soap	Relative (95% CI)	Absolute	Quality	Importance
Changes in skin integrity (for those with initially healthy skin) (follow-up 14 days; assessed with: Stirling Pressure Sore Severity Scale)[41]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	6/33 (18.2%)	16/33 (48.5%)	RR 0.38 (0.17 to 0.84)	301 fewer per 1000 (from 78 fewer to 402 fewer)	Very low	Critical
Broken skin (for those with initially healthy skin) (follow-up 14 days; assessed with: Stirling Pressure Sore Severity Scale) [41]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[b]	None	0/33 (0%)	4/33 (12.1%)	Peto OR 0.12 (0.02 to 0.91)	105 fewer per 1000 (from 10 fewer to 118 fewer)	Very low	Critical
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcer												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) Randomisation schedule changed during the trial from individual basis to randomisation by ward. There were differences between the participants (length of stay) and clinical practices (incontinence aids used) which may have influenced the results. The methods of allocation concealment use was unclear.
(b) Limited number of events. Confidence intervals crossed 1 MID point.

Table 105: Clinical evidence profile: lotion containing Cosbiol and Allantoin versus placebo lotion

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**Lotion containing Cosbiol and Allantoin**	**Placebo lotion**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
Skin deterioration (erythema and sores) (follow-up 3 weeks; assessed by research nurses using 5 point scale)[80]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	34/141 (24.1%)	47/178 (26.4%)	RR 0.91 (0.62 to 1.34)	24 fewer per 1000 (from 100 fewer to 90 more)	Very low	Critical
Skin deterioration (sores only) (follow-up 3 weeks; assessed by research nurses using 5 point scale) [80]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Serious[c]	None	14/141 (9.9%)	32/178 (18%)	RR 0.57 (0.32 to 1.03)	77 fewer per 1000 (from 122 fewer to 5 more)	Very low	Critical
Time to develop skin deterioration (follow-up 3; measured by a research nurse 3 times per week); range of scores: 0-21; better indicated by higher values) [80]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	-	None	9.8 days4	8.7 days4	-	-	Very low	Important
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) Poorly reported study with confusing results. No information about randomisation or allocation concealment was reported. There was unclear information about blinding reported.
(b) Confidence interval crossed both MID points.
(c) Confidence interval crossed 1 MID point.
(d) Average times as prevented in the paper. No measure of variation was provided.

Table 106: Clinical evidence profile: Conotrane versus placebo cream

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Conotrane	Placebo cream (Unguentum)	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers (any grade) (follow-up 24 weeks; assessed with: Barbarel scale by independent assessor)[188]												
1	Randomised trial	Serious[a, b]	No serious inconsistency	No serious indirectness	Very serious[c]	None	35/129 (27.1%)	47/129 (36.4%)	RR 0.75 (0.17 to 3.28)	91 fewer per 1000 (from 302 fewer to 831 more)	Very low	Critical
Incidence of pressure ulcers (grade 3) (follow-up 24 weeks; assessed with: Barbarel scale by independent assessor) [188]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	Very serious[d]	None	5/129 (3.9%)	4/129 (3.1%)	RR 1.25 (0.34 to 4.55)	8 more per 1000 (from 20 fewer to 110 more)	Very low	Critical
Incidence of pressure ulcers (grade 4) (follow-up 24 weeks; assessed with: Barbarel scale by independent assessor) [188]												
1	Randomised trial	Serious[a]	No serious inconsistency	No serious indirectness	Very serious[d]	None	0/129 (0%)	1/129 (0.78%)	Peto OR 0.14 (0 to 6.82)	7 fewer per 1000 (from 8 fewer to 43 more)	Very low	Critical
Patient acceptability (number who found it unacceptable) (follow-up 240 weeks; assessed with: withdrawals due to side effects) [188]												
1	Randomised trial	Serious[a]	No serious inconsistency	Serious[b]	Very serious[d]	None	4/129 (3.1%)	3/129 (2.3%)	RR 1.33 (0.30 to 5.84)	8 more per 1000 (from 16 fewer to 113 more)	Very low	Critical
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcer												

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Conotrane	Placebo cream (Unguentum)	Relative (95% CI)	Absolute	Quality	Importance
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) No details of randomisation or allocation concealment were provided in the paper.
(b) Study only records participants withdrawn from study and not those who were unhappy with treatment but who persisted.
(c) Confidence interval crossed both MID points.
(d) Confidence interval crossed both MID points. Limited number of events.

Table 107: Clinical evidence profile: Prevasore versus Dermalex (lotion containing Cosbiol and Allantoin)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Prevasore	Lotion containing Cosbiol and Allantoin	Relative (95% CI)	Absolute	Quality	Importance
Skin deterioration (follow-up 3 weeks; assessed with an assessment on a 5 point scale)[208]												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[b]	None	7/54 (13%)	11/50 (22%)	RR 0.59 (0.25 to 1.4)	90 fewer per 1000 (from 165 fewer to 88 more)	Very low	Critical
Skin blistering (follow-up 3 weeks; assessed with an a ssessment on 5 point scale)												
1	Randomised trial	Very serious[a]	No serious inconsistency	No serious indirectness	Very serious[c]	None	0/54 (0%)	3/50 (6%)	Peto OR 0.12 (0.01 to 1.18)	52 fewer per 1000 (from 59 fewer to 10 more)	Very low	Critical

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Prevasore	Lotion containing Cosbiol and Allantoin	Relative (95% CI)	Absolute	Quality	Importance
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcer												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) Poorly reported study with unclear randomisation and allocation concealment. No information about any blinding, so it is assumed that it was not done.
(b) Confidence interval cross both MID points.
(c) Confidence interval crosses both MID points. Limited number of events.

Table 108: Clinical evidence profile: IPARZINE4A-SKR versus placebo

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	IPARZINE4A-SKR	Placebo cream	Relative (95% CI)	Absolute	Quality	Importance
Incidence of pressure ulcers (Category 1) (follow-up 2 weeks; methods of assessment unclear)[216]												
1	Randomised trial	No serious risk of bias	No serious inconsistency	No serious indirectness	Very serious[a]	None	6/99 (6.1%)	7/95 (7.4%)	RR 0.82 (0.29 to 2.36)	13 fewer per 1000 (from 52 fewer to 100 more)	Low	Critical
Patient acceptability												
-	-	-	-	-	-	-	-	-	-	-	-	-
Rate of development of pressure ulcers												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time to develop new pressure ulcer												
-	-	-	-	-	-	-	-	-	-	-	-	-
Time in hospital or NHS care												
-	-	-	-	-	-	-	-	-	-	-	-	-
Health-related quality of life												
-	-	-	-	-	-	-	-	-	-	-	-	-

(a) Confidence interval crossed both MID points. Limited numbers of events

14.1.2 Economic evidence (adults)

14.1.2.1 Published literature

Two studies were included with relevant comparisons.[9,159] These are summarised in the economic evidence profiles below (Table 109- Table 111). See also the study selection flow chart in Appendix D and study evidence tables in Appendix H.

Six studies that met the inclusion criteria were selectively excluded due to methodological limitations and availability of more applicable evidence[13,22,137,220,224,229] – these are summarised in Appendix K, with reasons for exclusion given.

One additional study was found which included a barrier preparation as part of a more complex prevention strategy.[66] This study was not included as it evaluated the cost-effectiveness of the prevention strategy as a whole, and did not provide information on the cost-effectiveness of the barrier preparations alone.

Table 109: Economic evidence profile: skin care protocol verses standard care

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effects	Cost effectiveness	Uncertainty
Bale 2004[9] (UK)	Partially applicable[a]	Potentially serious limitations[b]	A within study analysis based on a before-and-after study. Analysis of individual level resource use, with unit costs applied. A skin care protocol (cleanser and barrier cream/barrier film) is compared to standard care.	Skin care protocol – standard care: -£9	Incidence of pressure ulcers and incontinence dermatitis decreased once the skin care protocol was in place (p=0.042, p=0.021 respectively)	Skin care protocol dominates standard care, with reduced costs and a reduction in incontinence dermatitis and pressure ulcers.	Lower costs of staff time were included to reflect unqualified nurse costs; the skin care protocol remained cost saving (£3 cost saving).

(a) UK health setting but study published in 2004; cost year not reported and quality of life not considered.
(b) The effectiveness data and resource use were collected from this small single study. The study design and methodology is not adequately described. Study doesn't include the costs of treating the incontinence dermatitis or pressure ulcers. Cost sources are not reported.

Table 110: Economic evidence profile: Skin emollient verses current practice

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effects	Cost effectiveness	Uncertainty
Pham 2011[159] (Canada)	Partially applicable[a]	Potentially serious limitations[b]	A decision analytic model that uses a Markov model of 1 week cycle length and considers patients of both high and low risk. Daily application of a skin emollient is compared to current practice.	£13	0.0003 QALYs	£42,751 per QALY gained	The skin emollient has a probability of being cost effective at willingness to pay of $50,000 (£27,498) per QALY of 43%. When staff costs were excluded the skin emolient was cost saving. Allowing for excess mortality associated with pressure ulcers, or conducting the analysis from a long-term care perspective, made the intervention less cost-effective

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effects	Cost effectiveness	Uncertainty
							than in the base case.

(a) Canadian health care setting
(b) The clinical evidence is derived from 1 study. Utility data is not calculated from EQ-5D or SF-36.

Table 111: Economic evidence profile: Foam cleanser verses current practice

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effects	Cost effectiveness	Uncertainty
Pham 2011[159] (Canada)	Partially applicable[c]	Potentially serious limitations[d]	A decision analytic model that uses a Markov model of 1 week cycle length and considers patients of both high and low risk. The model considers stage 1-4 pressure ulcers (as defined by the NPUAP), and healing. Foam cleanser (containing an emollient, a water-repellent barrier and a water deodorant) is compared to current practice for incontinence care.	-£98	0.00055 QALYs	Foam cleansing dominates standard care (50% soap and water, 50% skin care products)	Probability of foam cleansing being cost-effective: 94% at willingness to pay of $50,000 (£27,498) per QALY. When accounting for excess mortality associated with pressure ulcers the ICER (Intvn 2 v Intvn 1) was £30,370 per QALY gained. When looking at costs from a long-term care perspective, or when excluding staff costs, foam cleansing dominated standard care.

(a) Canadian health care setting, long term residential care homes
(b) The clinical evidence is derived from 1 small study. Utility data is not calculated from EQ-5D or SF-36 data. Baseline health estimates and progression of pressure ulcers through the various stages are estimated from RAI-MDS instead of obtained via a systematic procedure.

14.1.3 Clinical evidence (neonates, infants, children and young people)

No RCTs or cohort studies were identified. Recommendations were developed using a modified Delphi consensus technique. Further details can be found in Appendix N.

14.1.4 Economic (neonates, infants, children and young people)

No economic evidence was identified.

14.1.5 Evidence statements

14.1.5.1 Clinical (adults)

14.1.5.1.1 Hyperoxygenated fatty acid compound versus placebo

- One study (n=331) showed a hyperoxygenated fatty acid compound is potentially more clinically effective at reducing the incidence of pressure ulcers when compared to a placebo cream (low quality).
- One study (n=331) reported a higher time to development of a pressure ulcer for a hyperoxygenated fatty acid when compared to a placebo cream. The clinical importance and precision is unknown (low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rate of development of pressure ulcers
  - Time in hospital or NHS care
  - Health-related quality of life

14.1.5.1.2 Foam cleanser versus standard hospital soap

- One study (n=66) showed foam cleanseris potentially more clinically effective for reducing changes in skin integrity when compared to a standard hospital soap (very low quality).
- One study (n=66) showed foam cleanseris potentially more clinically effective for reducing broken skin when compared to a standard hospital soap (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rate of development of pressure ulcers
  - Time to develop a new pressure ulcer
  - Time in hospital or NHS care
  - Health-related quality of life

14.1.5.1.3 Lotion containing cosbiol and allantoin versus placebo lotion

- One study (n=319) showed there may be no clinical difference between a lotion containing cosbiol and allantoin and a placebo lotion for skin deterioration (erythema and sores), the direction of effect favoured the lotion containing cosbiol and allantoin (very low quality).
- One study (n=319) showed there is potentially no clinical difference between a lotion containing cosbiol and allantoin and a placebo lotion for skin deterioration (sores only), the direction of effect favoured the lotion containing cosbiol and allantoin (very low quality).
- One study (n=319) reported no difference between a lotion containing cosbiol and allantoin and a placebo lotion for time to develop skin deterioration, the direction of effect favoured the lotion containing cosbiol and allantoin, the estimate of precision could not be derived (very low quality).

- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rate of development of pressure ulcers
  - Time in hospital or NHS care
  - Health-related quality of life

14.1.5.1.4 Silicone or antiseptic cream versus placebo

- One study (n=258) showed there may be a clinical benefit for silicone or antiseptic cream when compared to a placebo cream for reducing the incidence of pressure ulcers (any grade) (very low quality).
- One study (n=258) showed there may be no clinical difference between silicone or antiseptic cream and placebo cream for the reduction of incidence of pressure ulcers (grade 3) the direction of the estimate of effect favoured placebo
- One study (n=258) showed there may be no clinical difference between silicone or antiseptic cream and placebo cream for the reduction of incidence of pressure ulcers (grade 4) the direction of the estimate of effect favoured Conotrone (very low quality).
- One study (n=258) showed there may be no clinical difference between silicone or antiseptic cream and placebo cream for patient acceptability the direction of the estimate of effect favoured Conotrone (very low quality).
- No evidence was found for the following outcomes:
  - Rate of development of pressure ulcers
  - Time to develop new pressure ulcer
  - Time in hospital or NHS care
  - Health-related quality of life

14.1.5.1.5 A preparation containing the active ingredients hexyl nicotinate, zinc stearate, isopropyl myristate, dimethicone 350, cetrimide and glycerol versus a lotion containing cosbiol and allantoin

- One study (n=104) showed there may be a clinical difference for a preparation containing the active ingredients hexyl nicotinate, zinc stearate, isopropyl myristate, dimethicone 350, cetrimide and glycerol for skin deterioration when compared to a lotion containing cosbiol and allantoin, the direction of the estimate of effect favoured Prevasore (very low quality).
- One study (n=104) showed there may be no clinical difference for a preparation containing the active ingredients hexyl nicotinate, zinc stearate, isopropyl myristate, dimethicone 350, cetrimide and glycerol for skin deterioration when compared to a lotion containing cosbiol and allantoin, the direction of the estimate of effect favoured the preparation containing the active ingredients hexyl nicotinate, zinc stearate, isopropyl myristate, dimethicone 350, cetrimide and glycerol (very low quality).
- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rate of development of pressure ulcers
  - Time to develop new pressure ulcer
  - Time in hospital or NHS care
  - Health-related quality of life

14.1.5.1.6 Iparzine4A-skr versus placebo

- One study (n=194) showed there may be no clinical difference for iparzine4A-skr and placebo for reducing the incidence of pressure ulcers, the direction of effect favoured iparzine4A-skr (low quality).

- No evidence was found for the following outcomes:
  - Patient acceptability
  - Rate of development of pressure ulcers
  - Time to develop new pressure ulcer
  - Time in hospital or NHS care
  - Health-related quality of life

14.1.5.2 Economic (adults)

- One cost-consequence analysis found that in people in a nursing home, implementation of a skin care protocol (cleanser and barrier cream/film), dominated standard care, with a reduction in costs and a reduction in the incidence of incontinence dermatitis and pressure ulcers. This analysis was assessed as partially applicable with potentially serious limitations.
- One cost–utility analysis found that in long term care residents, daily application of a skin emollient was not cost effective compared to current practice (ICER: £42,751 per QALY gained). The study also found that a foam cleanser (containing an emollient, a water-repellent barrier and a water deodorant) dominates current practice, with a reduction in costs and an increase in QALYs. This analysis was assessed as partially applicable with potentially serious limitations.

14.1.5.3 Clinical (neonates, infants, children and young people)

- No evidence was identified.

14.1.5.4 Economic (neonates, infants, children and young people)

- No evidence was identified.

14.2 Recommendations and link to evidence

14.2.1 Adults

Recommendations	**40. 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).**
Relative values of different outcomes	The GDG identified the proportion developing new pressure ulcers, or moisture lesions and patient acceptability were the most critical outcomes to inform decision making, given that the primary goal of pressure ulcer prevention was to limit the number of new pressure ulcers. Acceptability was identified as being critical from the perspective of the patient, as it was noted that this could have a significant impact upon quality of life. Rate of development of new pressure ulcers, time to develop new pressure ulcers, time in hospital or NHS care and health related quality of life were considered important outcomes to inform decision making.
Trade off between clinical benefits and harms	The limited evidence showed there were clinical benefits in using a barrier preparation for incidence of new pressure ulcers when compared to placebo. A hyperoxygenated fatty acid compound and a silicone/antiseptic cream both showed a clinical benefit when compared to a placebo cream (cream containing trisostearin and unguentum respectively) for incidence of new pressure ulcers. However, there was no difference between a silicone/antiseptic cream and placebo for the incidence of grade 3 and 4 pressure ulcers and for patient acceptability. The hyperoxygenated fatty acid was beneficial for having a longer time to develop new pressure ulcers.

	There was a clinical benefit of lotion with Cosbiol and Allantoin compared to placebo lotion (oil in water lotion) for skin deterioration (erythema and sores) and time to develop skin deterioration. There was no clinical benefit of iparzine4a-SKR compared to placebo cream (no details of consistency) for the incidence of category 1 pressure ulcers. A foam cleanser showed a clinical benefit when compared to standard hospital soap for changes in skin integrity and the incidence of broken skin. Two active barrier preparations were compared, 1 including the active ingredients hexyl nicotinate, zinc stearate, isopropyl myristate, dimethicone 350, cetrimide and glycerol and the other a lotion containing cosbiol and allantoin. There was a clinical benefit of of the hexyl nicotinate, zinc stearate, isopropyl myristate, dimethicone 350, cetrimide and glycerol preparation compared to the lotion containing cosbiol and allantoin for skin deterioration. There was no clinical benefit on skin blistering. The GDG felt that there were some potential benefits of the application of a barrier preparation in preventing skin damage after skin cleansing. The GDG noted that this may have a subsequent impact on the development of pressure ulcers. The GDG felt that the benefit would likely to apply to a range of people who are at risk of skin damage, outside of those who are incontinent and the GDG developed some examples of these populations for inclusion in the recommendation. The GDG felt that some of the barrier preparations which may be used include those containing dimethicone and white soft paraffin, however there was insufficient evidence to allow for a recommendation on a specific barrier preparation.
Economic considerations	The GDG considered 2 economic studies, containing 3 relevant comparisons. A skin care protocol (cleanser and barrier cream/barrier film), and a foam cleanser were found to be cost-effective compared to standard care/current practice. However, daily application of a skin emollient was not found to be cost effective compared with current practice. All studies were only partially applicable to the UK NHS and had potentially serious limitations. In particular, the GDG noted that the skin emollient which was not found to be cost-effective was specifically applied to residents with dry skin, rather than those more generally at risk of developing moisture lesions, thus the findings may not directly apply to this recommendation. The GDG considered the cost of the barrier preparations to be small, and the benefits (in terms of reduced treatment costs and increased quality of life) to far outweigh the initial costs of selectively using barrier preparations for people who are at significant risk of developing a moisture lesion. The use of barrier preparations is therefore considered to be cost-effective in this population.
Quality of evidence	The evidence was very limited with studies which looked at different interventions so the results could not be meta-analysed. The barrier preparations were compared to placebo or other inert substances rather than to other barrier preparations. The evidence was low to very low quality, this was due to serious to very serious imprecision and serious to very serious risk of bias in the studies.
Other considerations	The GDG noted that barrier preparations were not always likely to be licensed and would not always be included in the BNF.

14.2.2 Neonates, infants, children and young people

Recommendations	41. Use barrier preparations to help prevent skin damage, such as moisture lesions, for neonates, infants, children and young people who are incontinent.
Relative values of different outcomes	The GDG identified the proportion developing new pressure ulcers, or moisture lesions and patient acceptability were the most critical outcomes to inform decision making, given that the primary goal of pressure ulcer prevention was to limit the number of new ulcers. Acceptability was identified as being critical from the perspective of the patient, as it was noted that this could have a significant impact upon quality of life. Rate of development of new pressure ulcers, time to develop new pressure ulcers, time in hospital or NHS care and health related quality of life were considered important outcomes to inform decision making.
Trade-off between clinical benefits and harms	The GDG used 2 statements from the Delphi consensus panel to develop the recommendation, 'Healthcare professionals should not use barrier creams (for example cavilon and securar cream) for the prevention of pressure ulcers in neonates, infants, children and young people' and 'Healthcare professionals should not use barrier creams for the prevention of moisture lesions in neonates, infants, children and young people'. Neither statement was accepted by the Delphi consensus panel in Round 1 of the survey. The GDG discussed the statements and amended these as 1 statement for inclusion in Round 2. Qualitative responses from panel members identified that although barrier creams had little direct impact upon the development of pressure ulcers, they played a role in the protection of skin and reduction of friction and shear in neonates and infants, as well as children and young people who are incontinent. The GDG therefore amended the statements and clarified that the use of barrier creams was only appropriate to help prevent skin damage such as moisture lesions in neonates, infants, children and young people who are incontinent. The amended statement was included in Round 2 of the survey and was agreed by the panel. Qualitative responses gathered in Round 2 suggested that there were some contraindications for some barrier creams in neonates. Other comments noted that the use of barrier creams would not prevent the development of pressure ulcers directly as it would not prevent pressure, friction or shear. The GDG agreed with the majority of comments received and emphasised that the use of barrier creams was unlikely to have a direct effect upon the prevention of pressure ulcers. However, the GDG noted that the use of barrier creams may prevent other skin damage, notably moisture lesions, in those who are incontinent.
Economic considerations	The GDG considered the cost of the barrier preparations to be small, and the benefits (in terms of reduced treatment costs and increased quality of life) to far outweigh the initial costs of selectively using barrier preparations for people who are incontinent. The use of barrier preparations is therefore considered to be cost-effective in this population.
Quality of evidence	No RCTs or cohort studies were identified for neonates, infants, children or young people. Formal consensus using a modified Delphi was therefore used to develop the recommendation. To inform the recommendation, the GDG used 1 statement which was included in Round 1 of the Delphi consensus survey and reached 10% and 23% consensus agreement. An amended statement was therefore included in Round 2, where it

	reached 89% consensus and was accepted by the panel. Further details can be found in Appendix N.
Other considerations	There were no other considerations.

15 Information for patients and their carers

15.1 Introduction

Pressure ulcers present a major healthcare challenge however, they most can be prevented if care is taken by people at risk, health care professionals and their carers. Potentially anyone is at risk and all adults in secondary care are considered to be at risk of developing a pressure ulcer. Certain categories of people however, are at a further risk, for example, older adults, people who have neurological conditions, people who have a deformity or those who have sensory or physical impairment or mobility issues.

To help prevent a pressure ulcer occurring, people who are at risk of developing a pressure ulcer require appropriate information to ensure they understand the increased risk that they face. As pressure ulcers can develop quickly and have a significant impact upon a person's quality of life, it is particularly important that individuals at risk and their carers' are guided as to how they can help prevent them occurring.

The GDG were interested in identifying what information would be helpful to people at risk of developing a pressure ulcer to prevent them from developing 1. Studies of people that developed pressure ulcers which had reported what information could have been provided to them and their carers to help prevent the occurrence of the pressure ulcer were considered.

15.2 Review question: What information is required for patients/carers to prevent the occurrence of pressure ulcers?

For full details see review protocol in Appendix C.

15.2.1 Clinical evidence (adults)

A search was conducted for qualitative studies examining what information people with pressure ulcers (or their carers) felt they required to prevent the occurrence of their pressure ulcers.

Eleven studies were included in the review: Akkuzu 2009 [2], Baharestani 1994 [8], Basta 1991 [12], Gorecki 2009 [75], Jackson 2010 [95], King 2008 [106], Langemo 2000 [110], Middleton 2008 [129], Schubart 2008 [178], Spisbury 2007 [191] and Stockton 1994 [193]. Table 112 outlines the studies included in the review, as well as their population, and the methods and analysis used.

Evidence from these are summarised in the qualitative studies checklist below (Table 112). See also the study selection flow chart in Appendix D, study evidence tables in Appendix G and exclusion list in Appendix J.

Table 112: Patient information and support- study quality

Study	Population	Methods	Analysis	Relevance to guideline population
Akkuzu 2009 [2]	Well reported	Well reported	Unclear	People admitted to Baskent University Ankara Hospital's medical, surgical, gynaecology, gynaecological oncology, neurology, cardiovascular, general surgery and urology units over a 1-year period
Baharestani 1994 [8]	Well reported	Well reported	Well reported	Caregivers' homes, New York
Basta 1991 [12]	Well reported	Unclear	Well reported	Inpatient rehabilitation facility
Gorecki 2009 [75]	Well reported	Well reported	Well reported	Acute, community and long-term care settings across Europe, the US, Asia and Australia
Jackson 2010 [95]	Well reported	Well reported	Well reported	Pressure Ulcer Management Clinic at Rancho Los Amigos National Rehabilitation Centre (RLANRC), a leading rehabilitation facility in the US
King 2008 [106]	Well reported	Well reported	Well reported	Two free-standing rehabilitation hospitals in the US
Langemo 2000 [110]	Well reported	Well reported	Unclear	Home, hospital or nursing home in the US
Middleton 2008 [129]	Well reported	Well reported	Well reported	Community patients, regional and remote areas of New South Wales, Australia
Schubart 2008 [178]	Well reported	Well reported	Well reported	Recruited from Rehabilitation Center and local Paralyzed Veterans of America chapters, USA
Spilsbury 2007 [191]	Well reported	Unclear	Well reported	Hospital inpatients (medical, elderly care, orthopaedic and vascular surgery wards), 4 UK NHS hospitals
Stockton 1994 [193]	Well reported	Well reported	Unclear	Community, Warrington Wheelchair Centre, UK

15.2.1.1 Clinical summary of findings

Three themes were identified relating to what information people with pressure ulcers (or their carers) felt they required to prevent the occurrence of their pressure ulcers. These were identified from studies of people with pressure ulcers, in their own homes, in rehabilitation centres and hospitals:

- Perceived causation of pressure ulcers.
- Patients' and carers' preferred mode of education on pressure ulcers.
- Prevention of pressure ulcers.

Some of these themes overlap.

Theme 1- Perceived causation of pressure ulcers

Five studies [8,75,106,191,193] described patient and carer beliefs about the perceived causation of pressure ulcers.

It was reported that wives caring for their frail, homebound, elderly husbands with pressure ulcers thought they were a 'normal or expected occurrence among the bedbound'. They perceived pressure ulcers to be a 'symbol of poor circulation' and of their 'husband's body breaking down'.[8]

Individuals with spinal cord injury in 1 study[106] believed they were at low risk of developing a pressure ulcer because they had not yet had 1.

In some cases, it was reported that people blamed themselves for the development of a pressure ulcer, for example, for failing to inspect their skin, having reduced mobility, for not reducing risk factors (with some citing intrinsic factors such as incontinence or moisture), for being unable to move or walk. Individuals also reported blaming extrinsic factors, such as inadequate or poor healthcare, the inadequate use of equipment or delays in noticing or treating people who reported early signs of pressure ulcer development.[75] Caregivers in 1 study[8] found they were blamed by hospital staff for having provided poor care. A UK study[191] described many reasons people gave for the cause of their ulcer: their level of mobility (confined to bed, scuffing/rubbing); dependence to move (repositioning not carried out by staff as often as patients would like but more damage if tried to move on their own); bed/chair-bound; skin condition (thin skin); shearing pressure in bed; delay noticing ulcer; delay treating first signs; poor health; poor diet/appetite; lack of knowledge (ignorance or naivety such that they did not seek advice or treatment); actions of 'another' (healthcare professionals failing to attach priority to their reports of ulcer of delays in skin inspection; ill-fitting splint, misuse of hoist, delay in providing pressure-relieving interventions); being 'susceptible' or blaming themselves **.**

In a study of young wheelchair users in the community, [193] beliefs included: 'pressure sores are unavoidable' as they were seen as 'all part of being a wheelchair user'', (*"As the years go by, you become more resilient to pressure sores", "You build up immunity to pressure sores the longer you sit (like hardening skin on hands by doing manual work"),* as well as the belief that pressure redistribution cushions provide total pressure redistribution and negate the need to perform pressure-relieving movements/lifts.

Theme 2- Patients' and carers' preferred mode of education on pressure ulcers

Nine studies reported on this theme. [2,8,12,75,106,110,129,178,191]

In a study[110] identifying knowledge of patients with pressure ulcers, it was found that some were previously unaware of pressure ulcers, they had been ignorant 'until experienced an ulcer'. They also described confusion regarding the word 'ulcer' (that is, a pressure ulcer differs from gastric ulcer).

Another study[75] showed that some people were aware of risk factors and recognised them as the cause of their pressure ulcers; others lacked knowledge and understanding about pressure ulcer development and prevention. Specifically, people needed more information about causes, risks, prevention, physiological processes and treatment interventions. Of those who demonstrated knowledge of these factors, many had spinal cord injury and had been educated about pressure ulcer risk, for example, from discussion with people who had previously developed pressure ulcers.

A study [8] designed to describe and gain an understanding of the experience of wives caring for their frail, homebound, elderly husbands with pressure ulcers highlighted a lack of education and understanding of pressure ulcers. Each caregiver reported to have learned by experience, and 5 out of 6 did not know how to place a bedpan or to turn their husbands in bed or transfer them to a chair safely. They had to seek advice from neighbours, dermatologists and doctors on call. Educational or referral opportunities were often missed by the healthcare professionals contacted. It was not until their husbands became septic and hospitalised that education would begin and community referrals were made.

The need for specific education on skin care was highlighted in a study[129] of people with spinal cord injury living in rural areas. Another study[106] included suggestions of what rehabilitation nurses can tell people to help them understand the need to perform skin care regularly and to motivate them to do so.

In a study[12] aimed at exploring and describing what an young person with a spinal cord injury could learn from preventive skin care, a young person described routine skin-related nursing measures as part of a learning experience. The young person admitted that because he had not had any skin problems during rehabilitation, he did not think he had to worry about performing skin care measures during the day (as opposed to at night when he got into bed- night time measures were perceived as most important). Importantly, he equated the difficulty in carrying out these tasks and the extent to which nurses themselves performed this routine with the degree of importance of carrying out specific pressure ulcer prevention measures. It is important, therefore, for healthcare professionals to clarify which measures are of higher priority when providing people with information on preventing a pressure ulcer.

However, in another study,[178] people did not look for information related to keeping their skin healthy. They reported that they had opportunities to learn about pressure ulcers when they were being treated for them, and this was delivered by their health care team and was specific to their pressure ulcer. People agreed on the preferred delivery method: they chose reading materials less frequently than video or internet forms of learning.

Timing of education was a key theme in the evidence identified. Some individuals believed that addressing the topic of pressure ulcers too soon when the person at risk is in shock or denial was not likely to be effective. Others said that learning about the skin would just happen naturally during the course of rehabilitation. Several individuals were concerned about aging skin and wanted current information, relating to the specific stage of their life.

One study [2] evaluated the opinions and recommendations of people considered to be at moderate to high risk of pressure ulceration and their caregivers, about discharge education and an educational brochure about pressure ulcer prevention. A minority of caregivers (6.1%) wanted more information about air mattresses, however no one at risk of developing a pressure ulcer desired additional information. Two caregivers desired more comprehensive information about pressure ulcers and 1 patient and 2 caregivers stated that content of the educational intervention was presented too quickly. 60% or more of respondents found the language used, comprehensiveness of information, adequacy of information, learning environment, clarity of information and usability of information adequate. The majority of the remainder found it partially adequate, whilst a small minority reported that these factors were inadequate. With regards to the written brochure: 66% or more of respondents found the language used, information, adequacy of information and beneficial status of

information adequate; over 50% of respondents rated the usefulness of information adequate. Most of the rest found the brochure to be partially adequate, with a small minority reporting these factors as inadequate

A study[191] of inpatients in UK hospitals reported receiveing conflicting information and a lack of advice, especially about how long a pressure ulcer would take to heal.

Theme 3- Prevention of pressure ulcers

Four studies reported on this theme.[12], [95], [110], [178]

In a study[178] assessing the educational needs of adults with spinal cord injury in the prevention and early detection of pressure ulcers it showed that awareness of risk varied; those who considered themselves at risk were more likely to have experienced a pressure ulcer or to have had a long rehabilitation hospital period after injury. They could describe basic prevention strategies, for example pressure shifts or weight releases, appropriate cushioning and skin checks and recognised that pressure ulcers are potentially very serious. Those who had never experienced a pressure ulcer perceived their risks of developing an ulcer to be decreasing over time. Those who did not participate in preventive behaviours tended to believe they were not at risk. Those who had had a pressure ulcer in the past were motivated to avoid pressure ulcers in the future. They reported learning the most about pressure ulcers when they had a current pressure ulcer and were trying to stop it progressing to a more serious stage.

A study[110] assessed people's knowledge of prevention: 'Patient should be turned every 20 minutes', 'warning signs are really important – if you see any form of red spot...you have to get off it'. People described the importance of using the correct equipment in good repair, vulnerability to pressure ulcers after a time as a paraplegic and of the importance of on-going skin assessment. Some reported being angry at themselves for not using the knowledge they had to prevent the pressure ulcer developing.

In a study[12] aimed at exploring and describing what young person with a spinal cord injury could learn from preventive skin care, the consistent performance of particular skin care measures by the healthcare professional emphasised to the individual that these manoeuvres were important for him to carry out and it was concluded that all staff needed to be consistent in reinforcing the client's performance of pressure ucler prevention measures, for example wheelchair pressure redistribution measures, skin inspection and good transfer techniques.

A study[95]aimed at identifying overarching principles that explain how daily lifestyle considerations affect the development of a pressure ulcer as perceived by people with a spinal cord injury. Avoiding pressure ulcers requires prevention awareness for both long and short term prevention. For long-term prevention, for example knowledge about needing to perform regular pressure relieving movements, effective routines, planning and awareness of risk situations in general is needed. For short-term prevention attentional considerations such as the need to perform immediate relief, and assessing the current risk situation are needed. The motivation (commitment to avoid pressure ulcers, sound decision-making) to put practices into action was also identified. A key message from this study was that initial generalised knowledge about pressure ulcers and prevention techniques in hospital settings during rehabilitation could lead to lasting motivational commitment, or the person might only be motivated after they personally experienced a pressure ulcer.

15.2.2 Economic evidence (adults)

No relevant economic evaluations were identified.

15.2.3 Clinical evidence (neonates, infants, children and young people)

No qualitative studies were identified. Recommendations were developed using a modified Delphi consensus technique. Further details can be found in Appendix N.

15.2.4 Economic evidence (neonates, infants, children and young people)

No relevant economic evaluations were identified.

15.2.5 Evidence statements

15.2.5.1 Clinical (adults)

- The qualitative evidence found was of high quality, as the populations, methods and analyses were all generally well-reported. A thematic analysis was conducted to identify common themes in the qualitative evidence. The information those with pressure ulcers (or their carers) felt was required in order to prevent pressure ulcers were identified based on the themes identified from the data. One theme was the perceived causation of pressure ulcers held by people who had developed a pressure ulcer. Beliefs such as pressure ulcers are unavoidable, or feeling to blame, may contribute to how a person will react to carrying out prevention strategies. Another theme identified was the individuals' and carers' preferred mode of education for learning about pressure ulcers. This highlighted that, prior to having a pressure ulcer, many people did not know much about pressure ulcers and had learned about them from experience. This emphasised the need for people to have appropriate information about how to prevent pressure ulcers before a pressure ulcer developed. In 1 study, video or internet forms of learning were preferred to reading materials. The final theme that emerged regarded people's knowledge of how to prevent pressure ulcers. The studies found awareness of risk varied and again was higher in those who had experienced a pressure ulcer. Most could describe basic prevention strategies, such as pressure shifts. Those who did not believe they were at risk did not participate in preventive behaviours. Some people thought that warning signs such as red spots were very important and had the knowledge of what to do should this occur. Some were angry for not using the knowledge they had to help prevent pressure ulcer development. It was thought that healthcare professional consistency, in reinforcing preventative measures were important to ensure patients would continue prevention routines. Prevention awareness needs to be continuous and routines regularly performed. Generalised knowledge of pressure ulcers and prevention techniques were seen to be required to ensure lasting motivation to pressure ulcer prevention.

15.2.5.2 Economic (adults)

No relevant economic evaluations were identified.

15.2.5.3 Clinical (neonates, infants, children and young people)

No evidence was identified.

15.2.5.4 Economic (neonates, infants, children and young people)

No relevant economic evaluations were identified.

15.3 Recommendations

The GDG considered that the information needs of patients and their carers were likely to be applicable for all populations (that is, neonates, infants, children, young people and adults) and therefore, recommendations apply to all age groups.

Recommendations	**42. Offer timely, tailored information to people who have been assessed as being at high risk of developing a pressure ulcer, and their 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.**
Relative values of different outcomes	This recommendation was based on the evidence from 2 qualitative reviews; 1 on patient information provision and the second on health care practitioner training and education therefore no outcomes are stated in the protocol as the outcomes are established through a review of the qualitative papers.
Trade off between clinical benefits and harms	The recommendation was developed using the themes found in the health-care practitioner training and education qualitative review, which included that health care practitioners need to have a greater understanding of the causes of pressure ulcers. Knowledge of pressure ulcers and confidence in provision of prevention care was lacking. Pressure ulcers and their prevention were often given a lower status and left to less qualified staff to deal with. Early identifiers of pressure ulcers were often not being recognised. It was acknowledged that more education for healthcare professionals was required, and that this would need to be more frequent and obligatory. A multidisciplinary team approach was identified as being necessary. Education regarding the correct use of skin care products, equipment, beds, protective devices, risk score use and accuracy were also required. A wound education resource manual, and a physician lead to assist with the education and training of doctors and nurses was thought to be useful. The recommendation was also based upon the themes found in the patient information qualitative review. It was noted that before having a pressure ulcer many patients did not have a lot of knowledge about pressure ulcers therefore highlighting the need for patients to receive appropriate information about how to prevent pressure ulcers. Awareness of risk varied and again was higher in those who had experienced a pressure ulcer. Those who did not believe they were at risk did not participate in preventive behaviours. Some patients had the knowledge of what to do but did not use it. It was thought that staff consistency in reinforcing preventative measures were important to ensure patients would continue prevention routines. Prevention awareness needs to be continuous and routines regularly performed. Generalised knowledge of pressure ulcers and prevention techniques were seen to be required to ensure lasting motivation to pressure ulcer prevention. Identifying the patients preferred method of learning was also stated as being important. The GDG felt that people identified as being at risk of developing a pressure ulcer would benefit from receiving relevant information, to assist in the prevention of a pressure ulcer. It was acknowledged that this information would need to be provided to a large proportion of individuals in the community, as well as primary and secondary care. The benefits of preventing pressure ulcers in these individuals were likely to outweigh any minimal resource implications and the long term consequences of pressure ulcer development.

	The GDG considered what information people at risk may require to best help prevent a pressure ulcer developing. The group developed a list of relevant information needs, based upon informal consensus.
Economic considerations	The GDG expected that the impact of providing patient information on time and resource use would be minimal, and would likely be offset by an improvement in quality of life.
Quality of evidence	For both reviews the evidence came from qualitative studies, which included questionnaires, interviews, participant observations, surveys and group discussions. The qualitative evidence found was generally of high quality as the population was well reported in all papers, methods and analyses were well reported in the majority of papers. The populations in the patient information studies included inpatients in both general hospital wards and rehabilitation centres and carers of patients with pressure ulcers in their own homes. The populations in the healthcare practitioner training and education studies included members of the multidisciplinary team working on a variety of hospital wards, rehabilitation centres, nursing homes and students on a radiography course.
Other considerations	NICE clinical guideline 138 'Patient experience in adult NHS services' includes recommendations on the provision of information to patients and their carers.

Recommendations	**43. 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).**
Relative values of different outcomes	This recommendation was based on the evidence from a qualitative review of patient information provision therefore no outcomes are stated in the protocol as the outcomes were established through a review of the qualitative papers.
Trade off between clinical benefits and harms	The 3 main themes identified from the patient information qualitative review were; perceived causation of pressure ulcers, patients' and carers' preferred mode of education about pressure ulcers, prevention of pressure ulcers. Before developing a pressure ulcer many patients stated they did not have a lot of knowledge of about pressure ulcers. Awareness of risk varied and again was higher in those who had experienced a pressure ulcer. Those who did not believe they were at risk did not participate in preventive behaviours, thus highlighting the need for patients to receive appropriate information about the prevention of pressure ulcers prior to a first episode. Some patients knew about prevention but for unknown reasons chose not to follow the advice. It was thought that staff consistency in reinforcing preventative measures were important to ensure patients would continue prevention routines indicating that prevention awareness needs to be continuous and routines regularly performed. Generalised knowledge of pressure ulcers and prevention techniques were seen to be required to ensure lasting motivation to pressure ulcer prevention. The importance of suiting the learning style to the patient was also noted.

	The GDG acknowledged that this recommendation covered a variety of people who are likely to have a range of clinical conditions. They also recognised that some people will have additional risk factors (for example, deteriorating skin condition or scolisosi) which will develop further throughout the course of time, particularly for long term conditions or conditions which may deteriorate. The GDG felt that it was therefore important that individuals with these conditions receive regular, age appropriate and timely information throughout the course of their continuing care. It was highlighted that it was important to ensure that information was specific to the condition as information could then be targeted for example, people with spinal cord injury. The GDG felt that information should be available in a variety of formats, including pictorial and text formats. Limited evidence was identified on the preferred formats of information however, the GDG identified that it was likely that a mixture of verbal and written information methods would be the best way of communicating information. The GDG highlighted that all healthcare professionals who are responsible for the provision of information to patients and their carers should be appropriately trained in how this should be provided.
Economic considerations	The GDG expected that the impact of providing patient information on time and resource use would be minimal, and would likely be offset by an improvement in quality of life.
Quality of evidence	All evidence came from qualitative studies, which included questionnaires, interviews, participant observations, surveys and group discussions. The qualitative evidence found was generally of high quality as the population was well reported in all papers, methods and analyses were were well reported in the majority of papers. The populations in the studies included inpatients in both general hospital wards and rehabilitation centres and carers of patients with pressure ulcers in their own homes.
Other considerations	Recommendations on the provision of information to patients and their carers can be found in NICE clinical guideline 138 ‘Patient experience in adults NHS services’.

16 Training and education of healthcare professionals

16.1 Introduction

The prevention, assessment and management of pressure ulcers requires a comprehensive, multidisciplinary approach for the understanding of the multifactorial causes and treatment approaches beyond the focus of the pressure ulcer itself. The purpose of training and educating healthcare professionals is to ensure both individual understanding and a team approach with shared knowledge, skills and attitudes towards the prevention (and management) of this condition. The prevention of pressure ulcers is becoming ever more important given an increase in the number of; older adults in the population, people with a disability and people being cared for in the community. People at risk of and who develop pressure ulcers exist within the entire healthcare framework, from people in their own home, to people in long term facilities such as residential and nursing home environments and those in acute care hospital settings. A range of healthcare professionals are likely to be involved in the care of a person at risk, including nursing staff, doctors, allied health professionals and healthcare assistants. Training and education needs to address at risk populations across the age spectrum from neonates to older people with particular focus on specific groups such as individuals with spinal injuries. In addition, training to aid healthcare staff to recognise the change in a persons' risk status, for example because may be at a higher risk due to a change in clinical status or because of a pre-existing condition which may mean they are at greater risk of developing a pressure ulcer, is equally important.Traditionally, the roles and responsibilities of managing pressure ulcers in all settings have been seen to rest with nursing staff. Education for nursing students is included in the undergraduate curriculum and is embedded in their training and development. On the other hand curricula coverage for undergraduate medical students is variable with little mention of pressure ulcer management in postgraduate education for doctors. Some specialities such as geriatric medicine have clearly identified training in their curriculum but . the delivery of most post graduate training for doctors is opportunist, with doctors often learning through their association with nursing staff in ward environments. It is this gap that was identified as needing addressing.

The GDG were therefore interested in identifying what training and education should be provided for healthcare professionals in order to prevent the occurrence of pressure ulcers.

16.2 Review question: What training and education is required for healthcare professionals to prevent the occurrence of pressure ulcers?

For full details see review protocol in Appendix C.

16.2.1 Clinical evidence (adults)

A search was conducted for qualitative studies looking at training and education of healthcare professionals involved in patient care where pressure ulcers may be a risk.

Seven studies were included in the review: Athlin 2010 [7], Blanche 2011 [21], Jankowski 2011 [98], Justham 2002 [102], Meesterberends 2011 [128], Middleton 2008 [129] and Samuriwo 2010 [171].

Evidence from these are summarised in the qualitative studies checklist below (see Table 113). See also the study selection flow chart in Appendix D and study evidence tables in Appendix G and exclusion list in Appendix J.

Table 113: Qualitative studies checklist: healthcare professional education and information

Study	Population	Methods	Analysis	Relevance to guideline population
Athlin 2010[7]	Well reported	Well reported	Unclear	Two hospitals (different units: medicine 4, surgery 11, intensive care 11) and community care (large, small, urban and rural) in Sweden.
Blanche 2011 [21]	Well reported	Adequately reported	Well reported	University of Southern California (USC)/Rancho Los Amigos National Rehabilitation Centre (RLANRC).
Jankowski 2011 [98]	Well reported	Well reported	Well reported	Joint Commission Resources (JCR) and Hill-Rom created the Nurse Safety Scholar-In-Residence program to foster the professional development of expert nurse clinicians to become translators of evidence into practice; 4 hospitals with established pressure ulcer prevention programs participated in the pressure ulcer prevention implementation project.
Justham2002 [102]	Well reported	Well reported	Well reported	Pre-registration radiography course providers, UK.
Meesterberends 2011 [128]	Well reported	Well reported	Well reported	Nursing homes in the Netherlands.
Middleton 2008 [129]	Well reported	Well reported	Poorly reported	Community patients, regional and remote areas of New South Wales, Australia.
Samuriwo 2010 [171]	Well reported	Unclear	Well reported	Non-acute adult medical wards of 14 hospitals in 1 NHS trust, and a university.

16.2.1.1 Clinical summary of findings

Three main themes were identified relating to the training and education of healthcare professionals involved in patient care where people may be a risk of a pressure ulcer developing. These were identified from studies with people with pressure ulcers, including individuals with spinal cord injury, in both nursing homes and in the community:

- Perceived causation of pressure ulcers.
- Attitude towards pressure ulcers.
- Recommendations for education of healthcare professionals involved in the care of patients with pressure ulcers.

Some of these themes overlap.

Theme 1- perceived causation of pressure ulcers

Understanding pressure ulcer risk was 1 of 6 main topics identified in the development of a manual aimed at helping people at risk of developing a pressure ulcer and occupational therapists understand the development of pressure ulcers.[21] This is a theme common to Chapter 15 'Information for patients and their carers'. It was recognised that many healthcare professionals, as well as people at risk and their carers, need to have a greater understanding of the causes of pressure ulcers.

Theme 2- attitude towards pressure ulcers

Two studies [7] [102] described the attitudes of healthcare professionals towards people with pressure ulcers.

In a study[7] of nurses in Sweden with at least 5 years' experience, it was found that pressure ulcers and preventative interventions were often given low status, as they were seen as mainly a concern of less qualified staff. Early signs of pressure ulcers, for example erythema, were not judged as pressure ulcers and not reported on admission to or discharge from hospital. Pressure ulcers were reported to be connected with shame and guilt which often led to neglect and lack of treatment. Pressure ulcers were considered to be relatively uncommon which healthcare professionals recognised may mean they were not noticing them.

A UK study [102] described how pressure ulcer prevention was not seen as the responsibility of radiography staff. It was found that there was a low awareness of pressure ulcers among radiographers as they consider most procedures to pose little threat. Radiography course providers considered that the prevention and care of pressure ulcers should be given more attention in undergraduate training and that all radiographers should have regular updates on the importance of pressure ulcers.

Theme 3 – recommended improvements to the education of healthcare professionals involved in the care of patients with pressure ulcers

Four studies [98] [128] [129] [171] described specific issues relating to pressure ulcer education, either identifying knowledge gaps or making recommendations for future learning for healthcare professionals.

One study [129] which aimed to develop and implement a service model for people with spinal cord injury living in rural regions of Australia, highlighted that most health professionals 'showed a lack of knowledge and self-confidence in most if not all areas' of practice relating specifically to people with this type of condition.

In a US study [98] whose aims included developing tools to evaluate pressure ulcer prevention programmes and protocol implementation, identifying gaps in pressure ulcer prevention programmes and disseminating learning, the roles of all members of the healthcare team were evaluated, as well as an overall evaluation of how the management of patients with pressure ulcers could be managed. Key barriers identified included: education regarding skin care supplies and products and the education of doctors. The key recommendations for pressure ulcer education included: education regarding skin care supplies and products, staff education relating to the pressure ulcer protocol, increasing the participation of nursing assistants, developing and implementing a wound education resource manual, identifying a 'physician champion' to assist with the education of doctors about pressure ulcer prevention and train-the-trainer nurses for unit-based education. An important theme from this study was the multidisciplinary team approach (team building; pressure ulcer prevention; peer education (for example, using the correct skin care products), life equipment, beds, protective devices; patient advocacy). Education on risk score accuracy was also identified as being important.

One study [128] investigated pressure ulcer guideline dissemination and implementation in Dutch nursing homes, and reported findings relating to the education of staff on pressure ulcer prevention and treatment. There was no obligation for the nursing staff to follow a specific amount of education in any of the homes. They were free to choose subjects of interest which may or may not have included pressure ulcer care . Therefore, not all staff received a specific number of hours of education in this area. There was a perception that knowledge of nursing staff regarding pressure ulcer care was lacking, there were many nursing trainees and nursing assistants, but relatively few qualified staff. Some nurses and nursing assistants perceived that there was not enough education in the area of pressure ulcer care. They also reported that education should be offered more frequently and should be mandatory.

A UK study [171] to determine the value that nurses (16 participants ranging from second year nursing students to senior nurse managers) place on pressure ulcer prevention and how this value is formed found post-registration education to be 'invaluable' and equipped them for their current role. They reported a 'desire to keep updated' yet interestingly the education appeared to affect the participants only after they had had personal experience of an individual with a pressure ulcer.

16.2.2 Economic evidence (adults)

No economic evaluations were identified that directly addressed what training and education is required to prevent pressure ulcers. However, the GDG did consider 4 studies (5 papers)[121,123,124,226,227] which assessed the cost-effectiveness of various education programmes compared to no education, or to standard training. These studies were discussed because the interventions have an explicit focus on education, rather than on a more complex protocol or intervention. However they were not formally included in the review because they do not directly answer the review question. These studies are summarised below for information.

Makai and colleagues[124] constructed a Markov model to evaluate a quality improvement strategy, which was based around a training and education programme. Learning sessions were focused on quality improvement methods and preventative nursing measures, however no further details were provided. The study revealed a decrease in pressure ulcer incidence and an increase in quality of life. However health care costs also increased, and results showed that the QIC was not cost-effective at the £20,000 per QALY gained threshold over a 2 year time horizon.

Lyman and colleagues[123] evaluated a quality improvement process which was based around a tailored protocol and in-service education programme, in combination with a heel protective device. The authors found a reduction in pressure ulcer incidence leading to a reduction in costs. A reduction in pressure ulcer incidence was also found by Lyder and colleagues,[121] who investigated the of a series of educational sessions for nurses and physicians on treatment and prevention of ulcers.

Nurses were educated on the use of the Braden scale, various skin care products, and nursing assistants educated on basic pressure ulcer prevention. Although pressure ulcer incidence decreased, costs remained high.

Xakellis and colleagues[226,227] investigated the impact (in terms of costs and pressure ulcers developed) of mandatory staff education as part of a protocol for the prevention of pressure ulcers. Education was focused on risk assessment and associated stratification of preventative interventions. Costs remained largely the same (a decrease in treatment costs was balanced out by higher intervention costs), but the incidence of pressure ulcer development had decreased the year after the protocol was implemented. Two years later, however, initial reductions had not been sustained.

16.2.3 Clinical evidence (neonates, infants, children and young people)

No qualitative studies were identified. Recommendations were developed using a modified Delphi consensus technique. Further details can be found in Appendix N

16.2.4 Economic evidence (neonates, infants, children and young people)

No economic evaluations were identified.

16.2.5 Evidence statements

16.2.5.1 Clinical

- The qualitative evidence found was high quality, as population, methods and analyses were all generally well-reported. A thematic analysis was conducted to identify the main themes relating to training and education requirement of healthcare professionals in order to prevent the risk of pressure ulcers. One theme was the perceived causation of pressure ulcers, and it was found that healthcare professionals need to have a greater understanding of the causes of pressure ulcers. Another theme was attitude towards pressure ulcers, with pressure ulcers and preventative interventions often given a low status and it was generally less qualified staff left to deal with pressure ulcer prevention. Early signs of pressure ulcers were often not noted as being pressure ulcers. The final theme was recommendations for improvement of education of healthcare professionals which identified that there was a lack of knowledge and self-confidence in health care practitioners in the provision of prevention of pressure ulcers. More education was required, and it was thought that this should be conducted more frequently and should be mandatory. it was identified that a multidisciplinary team approach, education on the correct use of skin care products, equipment, beds, protective devices risk score accuracy were required. The following was recognised as being useful; increased participation of nursing assistants, development and implemention of a wound education resource manual, a physician lead to assist with education and training of doctors and nurses.

16.2.5.2 Economic (adults)

No evidence was identified.

16.2.5.3 Clinical (neonates, infants,children and young people)

No evidence was identified.

16.2.5.4 Economic (neonates, infants,children and young people)

No evidence was identified.

16.3 Recommendations and link to evidence

The GDG considered that the following recommendations on the training and education of healthcare professionals was likely to be applicable for all populations (neonates, infants, children, young people and adults) and therefore, recommendations apply to all age groups.

Recommendations	**44. 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.**
Relative values of different outcomes	This recommendation was based on the evidence from 2 qualitative reviews on patient information provision and healthcare practitioner training and education, therefore no outcomes are stated in the protocol as the outcomes are established through a review of the qualitative papers.
Trade off between clinical benefits and harms	The recommendation was developed using the themes found in the health-care practitioner training and education qualitative review, which included that health care practitioners need to have a greater understanding of the causes of pressure ulcers. Knowledge of pressure ulcers and confidence in provision of prevention care was lacking. Pressure ulcers and their prevention were often given a lower status and left to less qualified staff to deal with. Early identifiers of pressure ulcers were often not being recognised. It was acknowledged that more education for healthcare professionals was required, and that this would need to be more frequent and obligatory. A multidisciplinary team approach was identified as being necessary. Education regarding the correct use of skin care products, equipment, beds, protective devices, risk score use and accuracy were also required. A wound education resource manual, and a physician lead to assist with the education and training of doctors and nurses was thought to be useful. The recommendation was also based upon the themes found in the patient information qualitative review. It was noted that before having a pressure ulcer many patients did not have a lot of knowledge about pressure ulcers therefore highlighting the need for patients to receive appropriate information about how to prevent pressure ulcers. Awareness of risk varied and again was higher in those who had experienced a pressure ulcer. Those who did not believe they were at risk did not participate in preventive behaviours. Some patients had the knowledge of what to do but did not use it. It was thought that staff consistency in reinforcing preventative measures were important to ensure patients would continue prevention routines. Prevention awareness needs to be continuous and routines regularly performed. Generalised knowledge of pressure ulcers and prevention techniques were seen to be required to ensure lasting motivation to pressure ulcer prevention. Identifying the patients preferred method of learning was also stated as being important. The GDG felt that all healthcare professionals would benefit from receiving specific training in the prevention of pressure ulcers and agreed, via informal consensus, what this should involve. During this discussion, the group agreed that basic training, covering the causes of pressure ulcers, consideration of who is likely to be at risk and how best to identify pressure ulcer damage would allow for healthcare professionals to identify the risk of potential pressure ulcer development in a timely and effective manner. Additionally, the GDG felt that healthcare professionals should receive training on what steps to take to prevent new or further pressure damage and information on who to contact for further information and action.

	The GDG felt that the benefits of providing training to healthcare professionals included an improvement in care and an increased understanding of where further information can be obtained, and therefore prevention of significant numbers of pressure ulcers, of varying severity. Therefore, it was acknowledged that any impact upon resources for providing training was likely to be outweighed by the benefits. The GDG highlighted that it was important for staff of all levels to receive training in pressure ulcers prevention, as the prevention of pressure ulcers was the joint responsibility of all healthcare professionals. The GDG also noted that this training may be beneficial to other members of staff, for example, hospital porters, who have contact with patients and other individuals in settings in which NHS care is provided. There may be situations in which non-healthcare professionals (for example, non-clinical staff such as social care staff who may be responsible for transporting people who have a pressure ulcer) in contact with people at significant risk of developing pressure ulcers would benefit from training, particularly on the causes of pressure ulcers. No evidence was identified on healthcare professional training and education specifically aimed at educating healthcare professionals on preventing pressure ulcers in neonates, infants, children and young people. The GDG considered that the training requirements of healthcare professionals for preventing pressure ulcers in these populations were likely to be similar to those in adults and therefore, no separate recommendations were developed for these populations.
Economic considerations	No economic studies were formally included in the review, however the GDG did discuss several economic evaluations of training programmes (compared to no training): all programmes led to a reduction in pressure ulcers, and the majority were cost neutral or cost reducing. However, it was not possible to draw clear conclusions about the cost-effectiveness of various training components from these studies, as the description of the training given was vague in all cases, and cost-effectiveness would be highly dependent on the preventative interventions used. The GDG acknowledged the costs of training, but felt that the benefits of appropriate care (in terms of reduced pressure ulcer incidence, increased healing and improved quality of life) would outweigh this initial cost when averaged over the amount of patients who would benefit. No economic evaluations were identified which compared specific elements of training programmes, therefore the GDG expect the most clinically effective training programme to be the most cost-effective.
Quality of evidence	The evidence came from qualitative studies, which included questionnaires, interviews, participant observations, surveys and group discussions. The qualitative evidence found was generally of high quality as the population was well reported in all papers, methods and analyses were well reported in the majority of papers. The populations in the studies included members of the multidisciplinary team working on a variety of hospital wards, rehabilitation centres, nursing homes and students on a radiography course.
Other considerations	NICE clinical guideline 138 ‘Patient experience in adult NHS services’ includes recommendations on the provision of information to patients and their carers.

Recommendations	**45. 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.**
Relative values of different outcomes	This recommendation was based on the evidence from 2 qualitative reviews on patient information provision and healthcare practitioner training and education, therefore no outcomes are stated in the protocol as the outcomes are established through a review of the qualitative papers.
Trade off between clinical benefits and harms	The recommendation was developed using the themes found in the health-care practitioner training and education qualitative review, which included that health care practitioners need to have a greater understanding of the causes of pressure ulcers. Knowledge of pressure ulcers and confidence in provision of prevention care was lacking. Pressure ulcers and their prevention were often given a lower status and left to less qualified staff to deal with. Early identifiers of pressure ulcers were often not being recognised. It was acknowledged that more education for healthcare professionals was required, and that this would need to be more frequent and obligatory. A multidisciplinary team approach was identified as being necessary. Education regarding the correct use of skin care products, equipment, beds, protective devices, risk score use and accuracy were also required. A wound education resource manual, and a physician lead to assist with the education and training of doctors and nurses was thought to be useful. The GDG noted that there were healthcare professionals such as social care staff who have regular contact with people who are at increased risk of developing a pressure ulcer. The GDG highlighted that this was likely to include staff in the community, as well as primary and secondary care. The GDG felt that it was important that these individuals received enhanced training, which include the training elements previously outlined, as well as further training focusing on the needs of people at increased risk. The GDG agreed, via informal consensus, what aspects of care this enhanced training should include. The GDG felt that this should reflect the increased likelihood that these people would develop a pressure ulcer, including a focus on how to carry out a risk and skin assessment, the importance of repositioning and more detailed knowledge of pressure redistributing devices. Additionally, the GDG felt that the training should provide information on how to engage with people at increased risk of developing a pressure ulcer and their carers, and information on where to go for further help. No evidence was identified on healthcare professional training and education specifically aimed at educating healthcare professionals on preventing pressure ulcers in neonates, infants, children and young people. The GDG considered that the training requirements of healthcare professionals for preventing pressure ulcers in these populations were likely to be similar to those in adults and therefore, no separate recommendations were developed for these populations.
Economic considerations	No economic evaluations were formally included in the review, however the GDG did discuss several economic evaluations of training programmes (compared to no training): all programmes led to a reduction in pressure ulcers, and the majority were cost neutral or cost reducing. However, it was not possible to draw clear conclusions about the cost-effectiveness of various training components from these studies, as the description of the training given was vague in all cases, and the economic impact would be highly dependent on the preventative interventions used.

	The GDG acknowledged the costs of training, but felt that the benefits of appropriate care (in terms of reduced pressure ulcer incidence, increased healing and improved quality of life) would outweigh this initial cost when averaged over the amount of patients who would benefit. No economic evaluations were identified which compared specific elements of training programmes, therefore the GDG expect the most clinically effective training programme to be the most cost-effective.
Quality of evidence	The evidence came from qualitative studies, which included questionnaires, interviews, participant observations, surveys and group discussions. The qualitative evidence found was generally of high quality as the population was well reported in all papers, methods and analyses were well reported in the majority of papers. The populations in the studies included members of the multidisciplinary team working on a variety of hospital wards, rehabilitation centres, nursing homes and students on a radiography course.
Other considerations	Recommendations on the provision of information to patients and their carers can be found in NICE clinical guideline 138 ‘Patient experience in adult NHS services’..

17 Reference list

1 NHS Supply Chain Catalogue. NHS Supply Chain, 2013 Available from: http://www.supplychain.nhs.uk/

2 Akkuzu G, Arslantas S, Kosker SB, Sen S. Evaluation by patients and caregivers of the effectiveness of a brochure developed to prevent pressure ulcers. Journal of Wound, Ostomy and Continence Nursing. 2009; 36(6):610-615

3 Andersen KE, Jensen O, Kvorning SA, Bach E. Prevention of pressure sores by identifying patients at risk. BMJ. 1982; 284(6326):1370-1371

4 Anthony D, Parboteeah S, Saleh M, Papanikolaou P. Norton, Waterlow and Braden scores: a review of the literature and a comparison between the scores and clinical judgement. Journal of Clinical Nursing. 2008; 17(5):646-653

5 Anthony D, Reynolds T, Russell L, Anthony D, Reynolds T, Russell L. A regression analysis of the Waterlow score in pressure ulcer risk assessment. Clinical Rehabilitation. 2003; 17(2):216-223

6 Aronovitch SA, Wilber M, Slezak S, Martin T, Utter D. A comparative study of an alternating air mattress for the prevention of pressure ulcers in surgical patients. Ostomy/Wound Management. 1999; 45(3):34

7 Athlin E, Idvall E, Jernfält M, Johansson I. Factors of importance to the development of pressure ulcers in the care trajectory: perceptions of hospital and community care nurses. Journal of Clinical Nursing. 2010; 19(15-16):2252-2258

8 Baharestani MM. The lived experience of wives caring for their frail, homebound, elderly husbands with pressure ulcers. Advances in Wound Care. 1994; 7(3):40-assim

9 Bale S, Tebble N, Jones V, Price P. The benefits of implementing a new skin care protocol in nursing homes. Journal of Tissue Viability. 2004; 14(2):44-50

10 Banks MD, Graves N, Bauer JD, Ash S. Cost effectiveness of nutrition support in the prevention of pressure ulcer in hospitals. European Journal of Clinical Nutrition. 2013; 67(1):42-46

11 Barnes D, Payton RG. Clinical application of the Braden Scale in the acute-care setting. Dermatology Nursing. 1993; 5(5):386-388

12 Basta SM. Pressure sore prevention education with the spinal cord injured. Rehabilitation Nursing. 1991; 16(1):6-8

13 Bayoumi A, John-Baptiste A, Chen MH, Chen W, Farahati F, Krahn M et al. The cost-effectiveness of prevention strategies for pressure ulcers in long-term care homes in Ontario: projections of the Ontario pressure ulcer model. Toronto Health Economics and Technology Assessment Collaborative, 2008

14 Bennett G, Dealey C, Posnett J. The cost of pressure ulcers in the UK. Age and Ageing. 2004; 33(3):230-235

15 Bennett RG, Baran PJ, DeVone LV, Bacetti H, Kristo B, Tayback M et al. Low airloss hydrotherapy versus standard care for incontinent hospitalized patients. Journal of the American Geriatrics Society. 1998; 46(5):569-576

16 Bergquist S. Subscales, subscores, or summative score: evaluating the contribution of Braden Scale items for predicting pressure ulcer risk in older adults receiving home health care. Journal of Wound, Ostomy and Continence Nursing. 2001; 28(6):279-289

17 Bergstrom N, Braden B, Kemp M, Champagne M, Ruby E. Predicting pressure ulcer risk: a multisite study of the predictive validity of the Braden Scale. Nursing Research. 1998; 47(5):261-269

18 Bergstrom N, Braden BJ, Laguzza A, Holman V. The Braden Scale for Predicting Pressure Sore Risk. Nursing Research. 1987; 36(4):205-210

19 Bergstrom N, Demuth PJ, Braden BJ. A clinical trial of the Braden Scale for Predicting Pressure Sore Risk. Nursing Clinics of North America. 1987; 22(2):417-429

20 Black J, Baharestani M, Cuddigan J, Dorner B, Edsberg L, Langemo D et al. National Pressure Ulcer Advisory Panel's (NPUAP) updated pressure ulcer staging system (USA). World Council of Enterostomal Therapists Journal. 2007; 27(2):18-23

21 Blanche EI, Fogelberg D, Diaz J, Carlson M, Clark F. Manualization of occupational therapy interventions: illustrations from the pressure ulcer prevention research program. American Journal of Occupational Therapy. 2011; 65(6):711-719

22 Bliss DZ, Zehrer C, Savik K, Smith G, Hedblom E. An economic evaluation of four skin damage prevention regimens in nursing home residents with incontinence: economics of skin damage prevention. Journal of Wound, Ostomy and Continence Nursing. 2007; 34(2):143-152

23 Bou JE, Segovia GT, Verdu SJ, Nolasco BA, Rueda LJ, Perejamo M. The effectiveness of a hyperoxygenated fatty acid compound in preventing pressure ulcers. Journal of Wound Care. 2005; 14(3):117-121

24 Bourdel-Marchasson I, Barateau M, Rondeau V, Dequae-Merchadou L, Salles-Montaudon N, Emeriau JP et al. A multi-center trial of the effects of oral nutritional supplementation in critically ill older inpatients. GAGE Group. Groupe Aquitain Geriatrique d'Evaluation. Nutrition. 2000; 16(1):1-5

25 Boyle M, Green M. Pressure sores in intensive care: defining their incidence and associated factors and assessing the utility of two pressure sore risk assessment tools. Australian Critical Care. 2001; 14(1):24-30

26 Braden BJ, Bergstrom N. Predictive validity of the Braden Scale for pressure sore risk in a nursing home population. Research in Nursing and Health. 1994; 17(6):459-470

27 Brienza D, Kelsey S, Karg P, Allegretti A, Olson M, Schmeler M et al. A randomized clinical trial on preventing pressure ulcers with wheelchair seat cushions. Journal of the American Geriatrics Society. 2010; 58(12):2308-2314

28 Cadue JF, Karolewicz S, Tardy C, Barrault C, Robert R, Pourrat O. [Prevention of heel pressure sores with a foam body-support device. A randomized controlled trial in a medical intensive care unit]. Presse Medicale. 2008; 37(1 Pt 1):30-36

29 Capobianco ML, McDonald DD. Factors affecting the predictive validity of the Braden Scale. Advances in Wound Care. 1996; 9(6):32-36

30 Cassino R, Ippolito AM, Cuffaro C, Corsi A, Ricci E. A controlled, randomised study on the efficacy of two overlays in the treatment of decubitus ulcers. Minerva Chirurgica. 2013; 68(1):105-116

31 Cavicchioli A, Carella G. Clinical effectiveness of a low-tech versus high-tech pressure-redistributing mattress. Journal of Wound Care. 2007; 16(7):285-289

32 Chan WS, Pang SM, Kwong EW. Assessing predictive validity of the modified Braden scale for prediction of pressure ulcer risk of orthopaedic patients in an acute care setting. Journal of Clinical Nursing. 2009; 18(11):1565-1573

33 Cobb GA, Yoder LH, and Warren JB. Pressure ulcers: patient outcomes on a KinAir bed or EHOB waffle mattress. TriService Nursing Research Program (TSNRP), 1997 Available from: http://www.ntis.gov/search/product.aspx?ABBR=PB2002107655

34 Coleman S, Gorecki C, Nelson EA, Closs SJ, Defloor T, Halfens R et al. Patient risk factors for pressure ulcer development: systematic review. International Journal of Nursing Studies. 2013; 50(7):974-1003

35 Collier ME. Pressure-reducing mattresses. Journal of Wound Care. 1996; 5(5):207-211

36 Compton F, Hoffmann F, Hortig T, Strauss M, Frey J, Zidek W et al. Pressure ulcer predictors in ICU patients: nursing skin assessment versus objective parameters. Journal of Wound Care. 2008; 17(10):417-424

37 Conine TA, Daechsel D, Choi AKM, Lay MS. Costs and acceptability of two special overlays for the prevention of pressure sores. Rehabilitation Nursing. 1990; 15(2):133-137

38 Conine TA, Daechsel D, Hershler C. Pressure sore prophylaxis in elderly patients using slab foam or customised contoured foam wheelchair cushions. Occupational Therapy Journal of Research. 1993; 13(2):101-116

39 Conine TA, Daechsel D, Lau MS. The role of alternating air and Silicore overlays in preventing decubitus ulcers. International Journal of Rehabilitation Research. 1990; 13(1):57-65

40 Conine TA, Hershler C, Daechsel D, Peel C, Pearson A. Pressure ulcer prophylaxis in elderly patients using polyurethane foam or Jay wheelchair cushions. International Journal of Rehabilitation Research. 1994; 17(2):123-137

41 Cooper P, Gray D. Comparison of two skin care regimes for incontinence. British Journal of Nursing. 2001; 10(6 Suppl):S6, S8, S10

42 Cooper PJ, Gray DG, Mollison J. A randomised controlled trial of two pressure-reducing surfaces. Journal of Wound Care. 1998; 7(8):374-376

43 Craig LD, Nicholson S, Silverstone FA, Kennedy RD. Use of a reduced-carbohydrate,modified-fat enteral formula for improving metabolic control and clinical outcomes in long-term care residents with type 2 diabetes: results of a pilot trial. Nutrition. 1998; 14(6):529-534

44 Curley MAQ, Quigley SM, Lin M. Pressure ulcers in pediatric intensive care: incidence and associated factors. Pediatric Critical Care Medicine. 2003; 4(3):284-290

45 Curley MAQ, Razmus IS, Roberts KE, Wypij D. Predicting pressure ulcer risk in pediatric patients: the Braden Q Scale. Nursing Research. 2003; 52(1):22-33

46 Curtis L. Unit costs of social health care. Personal Social Services Reseach Unit, University of Kent; 2010. Available from: http://www.pssru.ac.uk/pdf/uc/uc2010/uc2010.pdf

47 Curtis L. Unit costs of health and social care 2012. Personal Social Services Reseach Unit, University of Kent; 2012. Available from: http://www.pssru.ac.uk/archive/pdf/uc/uc2012/full-with-covers.pdf

48 Daechsel D, Conine TA. Special mattresses: effectiveness in preventing decubitus ulcers in chronic neurologic patients. Archives of Physical Medicine and Rehabilitation. 1985; 66(4):246-248

49 de Souza DM, Santos VL, Iri HK, Sadasue Oguri MY. Predictive validity of the Braden Scale for Pressure Ulcer Risk in elderly residents of long-term care facilities. Geriatric Nursing. 2010; 31(2):95-104

50 Dealey C, Posnett J, Walker A. The cost of pressure ulcers in the United Kingdom. Journal of Wound Care. 2012; 21(6):261-2, 264, 266

51 Defloor T, De BD, Grypdonck MH. The effect of various combinations of turning and pressure reducing devices on the incidence of pressure ulcers. International Journal of Nursing Studies. 2005; 42(1):37-46

52 Defloor T, Grypdonck MF. Pressure ulcers: validation of two risk assessment scales. Journal of Clinical Nursing. 2005; 14(3):373-382

53 Delmi M, Rapin CH, Bengoa JM, Delmas PD, Vasey H, Bonjour JP. Dietary supplementation in elderly patients with fractured neck of the femur. Lancet. 1990; 335(8696):1013-1016

54 Demarre L, Beeckman D, Vanderwee K, Defloor T, Grypdonck M, Verhaeghe S. Multi-stage versus single-stage inflation and deflation cycle for alternating low pressure air mattresses to prevent pressure ulcers in hospitalised patients: A randomised-controlled clinical trial. International Journal of Nursing Studies. 2012; 49(4):416-426

55 Dennis MS, Lewis SC, Warlow C. Routine oral nutritional supplementation for stroke patients in hospital (FOOD): a multicentre randomised controlled trial. Lancet. 2005; 365(755):763

56 Donnelly J, Winder J, Kernohan WG, Stevenson M. An RCT to determine the effect of a heel elevation device in pressure ulcer prevention post-hip fracture. Journal of Wound Care. 2011; 20(7):309-8

57 Duimel-Peeters IG, Halfens JG, Ambergen AW, Houwing RH, Berger PF, Snoeckx LH. The effectiveness of massage with and without dimethyl sulfoxide in preventing pressure ulcers: a randomized, double-blind cross-over trial in patients prone to pressure ulcers. International Journal of Nursing Studies. 2007; 44(8):1285-1295

58 Economides NG, Skoutakis VA, Carter CA, Smith VH. Evaluation of the effectiveness of two support surfaces following myocutaneous flap surgery. Advances in Wound Care. 1995; 8(1):49-53

59 Edwards M. The levels of reliability and validity of the Waterlow pressure sore risk calculator. Journal of Wound Care. 1995; 4(8):373-378

60 Ewing MR, Garrow C, Presley TA, Ashley C, Kisella NM. Further experiences in the use of sheep skins as an aid in nursing. Australian Nurses' Journal. 1964;215-219

61 Exton-Smith AN, Overstall PW, Wedgwood J, Wallace G. Use of the 'air wave system' to prevent pressure sores in hospital. Lancet. 1982; 1(8284):1288-1290

62 Feuchtinger J, de BR, Dassen T, Halfens R. A 4-cm thermoactive viscoelastic foam pad on the operating room table to prevent pressure ulcer during cardiac surgery. Journal of Clinical Nursing. 2006; 15(2):162-167

63 Feuchtinger J, Halfens R, Dassen T. Pressure ulcer risk assessment immediately after cardiac surgery--does it make a difference? A comparison of three pressure ulcer risk assessment instruments within a cardiac surgery population. Nursing in Critical Care. 2007; 12(1):42-49

64 Fineman LD, LaBrecque MA, Shih MC, Curley MAQ. Prone positioning can be safely performed in critically ill infants and children. Pediatric Critical Care Medicine. 2006; 7(5):413-422

65 Fleurence RL. Cost-effectiveness of pressure-relieving devices for the prevention and treatment of pressure ulcers. International Journal of Technology Assessment in Health Care. 2005; 21(3):334-341

66 Frantz RA, Xakellis GC, Jr., Harvey PC, Lewis AR. Implementing an incontinence management protocol in long-term care. Clinical outcomes and costs. Journal of Gerontological Nursing. 2003; 29(8):46-53

67 Fuentelsaz GC. Validation of the EMINA scale: tool for the evaluation of risk of developing pressure ulcers in hospitalized patients. Enfermeria Clinica. 2001; 11(3):97-103

68 Gebhardt KS, Bliss MR, Winwright PL, Thomas J. Pressure-relieving supports in an ICU. Journal of Wound Care. 1996; 5(3):116-121

69 Gentilello L, Thompson DA, Tonnesen AS, Hernandez D, Kapadia AS, Allen SJ et al. Effect of a rotating bed on the incidence of pulmonary complications in critically ill patients. Critical Care Medicine. 1988; 16(8):783-786

70 Geyer MJ, Brienza DM, Karg P, Trefler E, Kelsey S. A randomized control trial to evaluate pressure-reducing seat cushions for elderly wheelchair users. Advances in Skin and Wound Care. 2001; 14(3):120-129

71 Gilcreast DM, Warren JB, Yoder LH, Clark JJ, Wilson JA, Mays MZ. Research comparing three heel ulcer-prevention devices. Journal of Wound, Ostomy and Continence Nursing. 2005; 32(2):112-120

72 Goldstone LA, Norris M, O'Reilly M, White J. A clinical trial of a bead bed system for the prevention of pressure sores in elderly orthopaedic patients. Journal of Advanced Nursing. 1982; 7(6):545-548

73 Goodridge DM, Sloan JA, LeDoyen YM, McKenzie JA, Knight WE, Gayari M. Risk-assessment scores, prevention strategies, and the incidence of pressure ulcers among the elderly in four Canadian health-care facilities. Canadian Journal of Nursing. 1998; 30(2):23-34

74 Gordon TJ. Current methods of futures research. Institute for the Future; 1971

75 Gorecki C, Brown JM, Nelson EA, Briggs M, Schoonhoven L, Dealey C et al. Impact of pressure ulcers on quality of life in older patients: A systematic review: Clinical investigations. Journal of the American Geriatrics Society. 2009; 57(7):1175-1183

76 Gray D, Smith M. A randomized controlled trial of two pressure-reducing foam mattresses. European Wound Management Association Conference; Harrogate, UK. 1998;

77 Gray DG, Campbell M. A randomized clinical trial of two types of foam mattresses. Journal of Tissue Viability. 1994; 4(4):128-132

78 Gray DG, Smith M. Comparison of a new foam mattress with the standard hospital mattress. Journal of Wound Care. 2000; 9(1):29-31

79 Gray M, Jones DP. The effect of different formulations of equivalent active ingredients on the performance of two topical wound treatment products. Ostomy/Wound Management. 2004; 50(3):34-44

80 Green MF, Exton SAN, Helps EPW. Prophylaxis of pressure sores using a new lotion. Modern Geriatrics. 1974; 4(9):376-384

81 Griffiths P, Jull A. How good is the evidence for using risk assessment to prevent pressure ulcers? Nursing Times. 2010; 106(14):10-13

82 Grisell M, Place HM. Face tissue pressure in prone positioning: a comparison of three face pillows while in the prone position for spinal surgery. Spine. 2008; 33(26):2938-2941

83 Gunningberg L, Lindholm C, Carlsson M, Sjoden PO. Effect of visco-elastic foam mattresses on the development of pressure ulcers in patients with hip fractures. Journal of Wound Care. 2000; 9(10):455-460

84 Gunningberg L, Lindholm C, Carlsson M, Sj”d,n PO. Implementation of risk assessment and classification of pressure ulcers as quality indicators for patients with hip fractures. Journal of Clinical Nursing. 1999; 8(4):396-406

85 Hagisawa S, Barbenel J. The limits of pressure sore prevention. Journal of the Royal Society of Medicine. 1999; 92(11):576-578

86 Halfens RJG, Van Achterberg T, Bal RM. Validity and reliability of the Braden scale and the influence of other risk factors: a multi-centre prospective study. International Journal of Nursing Studies. 2000; 37(4):313-319

87 Hampton S. Evaluation of the new Cairwave Therapy System in one hospital trust. British Journal of Nursing. 1997; 6(3):167-170

88 Hartgrink HH, Wille J, Konig P, Hermans J, Breslau PJ. Pressure sores and tube feeding in patients with a fracture of the hip: a randomized clinical trial. Clinical Nutrition. 1998; 17(6):287-292

89 Hatanaka N, Yamamoto Y, Ichihara K, Mastuo S, Nakamura Y, Watanabe M et al. A new predictive indicator for development of pressure ulcers in bedridden patients based on common laboratory tests results. Journal of Clinical Pathology. 2008; 61(4):514-518

90 Hofman A, Geelkerken RH, Wille J, Hamming JJ, Hermans J, Breslau PJ. Pressure sores and pressure-decreasing mattresses: controlled clinical trial. Lancet. 1994; 343(8897):568-571

91 Houwing RH, Rozendaal M, Wouters-Wesseling W, Beulens JWJ, Buskens E, Haalboom JR. A randomised, double-blind assessment of the effect of nutritional supplementation on the prevention of pressure ulcers in hip-fracture patients. Clinical Nutrition. 2003; 22(4):401-405

92 Iglesias C, Nixon J, Cranny G, Nelson EA, Hawkins K, Phillips A et al. Pressure relieving support surfaces (PRESSURE) trial: cost effectiveness analysis. BMJ. 2006; 332:1416-1418

93 Inman KJ, Dymock K, Fysh N, Robbins B, Rutledge FS, Sibbald WJ. Pressure ulcer prevention: a randomized controlled trial of 2 risk-directed strategies for patient surface assignment. Advances in Wound Care. 1999; 12(2):72-80

94 Inman KJ, Sibbald WJ, Rutledge FS. Clinical utility and cost-effectiveness of an air suspension bed in the prevention of pressure ulcers. Journal of the American Medical Association. 1993; 269:1139-1143

95 Jackson J, Carlson M, Rubayi S, Scott MD, Atkins MS, Blanche EI et al. Qualitative study of principles pertaining to lifestyle and pressure ulcer risk in adults with spinal cord injury. Disability & Rehabilitation. 2010; 32(7):567-578

96 Jackson M, McKenney T, Drumm J, Merrick B, Lemaster T, Vangilder C. Pressure ulcer prevention in high-risk postoperative cardiovascular patients. Critical Care Nurse. 2011; 31(4):44-53

97 Jalali R, Rezaie M. Predicting pressure ulcer risk: comparing the predictive validity of 4 scales. Advances in Skin and Wound Care. 2005; 18(2):92-97

98 Jankowski IM, Nadzam DM. Identifying gaps, barriers, and solutions in implementing pressure ulcer prevention programs. Joint Commission Journal on Quality and Patient Safety. 2011; 37(6):253-264

99 Jesurum J, Joseph K, Davis JM, Suki R. Balloons, beds, and breakdown. Effects of low-air loss therapy on the development of pressure ulcers in cardiovascular surgical patients with intra-aortic balloon pump support. Critical Care Nursing Clinics of North America. 1996; 8(4):423-440

100 Joint Formulary Committee. British national formulary. 61st edition. London: British Medical Association and Royal Pharmaceutical Society; 2011. Available from: http://www.bnf.org.uk

101 Jolley DJ, Wright R, McGowan S, Hickey MB, Campbell DA, Sinclair RD et al. Preventing pressure ulcers with the Australian Medical Sheepskin: an open-label randomised controlled trial. Medical Journal of Australia. 2004; 180(7):324-327

102 Justham D, Rolfe J. The experience and opinions of teachers of radiography students regarding pressure ulcer prevention and management in x-ray departments. Journal of Tissue Viability. 2002; 12(1):5-9

103 Kemp MG, Kopanke D, Tordecilla L, Fogg L, Shott S, Matthiesen V et al. The role of support surfaces and patient attributes in preventing pressure ulcers in elderly patients. Research in Nursing and Health. 1993; 16(2):89-96

104 Keogh A, Dealey C. Profiling beds versus standard hospital beds: effects on pressure ulcer incidence outcomes. Journal of Wound Care. 2001; 10(2):15-19

105 Kim E, Lee S, Lee E, Eom M. Comparison of the predictive validity among pressure ulcer risk assessment scales for surgical ICU patients. Australian Journal of Advanced Nursing. 2009; 26(4):87-94

106 King RB, Porter SL, Vertiz KB. Preventive skin care beliefs of people with spinal cord injury. Rehabilitation Nursing. 2008; 33(4):154-162

107 Konishi C, Sugama J, Sanada H, Okuwa M, Konya C, Nishizawa T et al. A prospective study of blanchable erythema among university hospital patients. International Wound Journal. 2008; 5(3):470-475

108 Kottner J, Dassen T. Pressure ulcer risk assessment in critical care: interrater reliability and validity studies of the Braden and Waterlow scales and subjective ratings in two intensive care units. International Journal of Nursing Studies. 2010; 47(6):671-677

109 Kwong E, Pang S, Wong T, Ho J, Shao-ling X, Li-jun T. Predicting pressure ulcer risk with the modified Braden, Braden, and Norton scales in acute care hospitals in Mainland China. Applied Nursing Research. 2005; 18(2):122-128

110 Langemo DK, Melland H, Hanson D, Olson B, Hunter S. The lived experience of having a pressure ulcer: a qualitative analysis. Advances in Skin and Wound Care. 2000; 13(5):225-235

111 Langemo DK, Olson B, Hunter S, Hanson D, Burd C, Cathcart-Silberberg T. Incidence and prediction of pressure ulcers in five patient care settings. Decubitus. 1991; 4(3):25-36

112 Langer G, Schloemer G, Knerr A, Kuss O, Behrens J. Nutritional interventions for preventing and treating pressure ulcers. Cochrane Database of Systematic Reviews. 2003; Issue 4:CD003216. DOI:10.1002/14651858.CD003216

113 Laurent S. Effectiveness of pressure decreasing mattresses in cardiovascular surgery patients: a controlled clinical trial. 3rd European Conference for Nurse Managers; Brussels, Belgium. 1998;

114 Lazzara DJ, Buschmann MT. Prevention of pressure ulcers in elderly nursing home residents: are special support surfaces the answer? Decubitus. 1991; 4(4):42-4, 46, 48

115 Legood R, McInnes E. Pressure ulcers: guideline development and economic modelling. Journal of Advanced Nursing. 2005; 50(3):307-314

116 Lewicki LJ, Mion LC, Secic M. Sensitivity and specificity of the Braden Scale in the cardiac surgical population. Journal of Wound, Ostomy and Continence Nursing. 2000; 27(1):36-41

117 Lim R, Sirett R, Conine TA, Daechsel D. Clinical trial of foam cushions in the prevention of decubitis ulcers in elderly patients. Journal of Rehabilitation Research and Development. 1988; 25(2):19-26

118 Lincoln R, Roberts R, Maddox A, Levine S, Patterson C. Use of the norton pressure sore risk assessment scoring system with elderly patients in acute care. Journal of Enterostomal Therapy. 1986; 13:132-138

119 Lindgren M, Unosson M, Krantz AM, Ek AC. A risk assessment scale for the prediction of pressure sore development: reliability and validity. Journal of Advanced Nursing. 2002; 38(2):190-199

120 Lothian P. Identifying and protecting patients who may get pressure sores. Nursing Standard. 1989; 18(4):26-29

121 Lyder CH, Shannon R, Empleo-Frazier O, McGeHee D, White C. A comprehensive program to prevent pressure ulcers in long-term care: exploring costs and outcomes. Ostomy/Wound Management. 2002; 48(4):52-62

122 Lyder CH, Yu C, Emerling J, Mangat R, Stevenson D, Empleo-Frazier O et al. The Braden Scale for pressure ulcer risk: evaluating the predictive validity in Black and Latino/Hispanic elders. Applied Nursing Research. 1999; 12(2):60-68

123 Lyman V. Successful heel pressure ulcer prevention program in a long-term care setting. Journal of Wound, Ostomy and Continence Nursing. 2009; 36(6):616-621

124 Makai P, Koopmanschap M, Bal R, Nieboer AP. Cost-effectiveness of a pressure ulcer quality collaborative. Cost Effectiveness and Resource Allocation. 2010; 8:11

125 Malbrain M, Hendriks B, Wijnands P, Denie D, Jans A, Vanpellicom J et al. A pilot randomised controlled trial comparing reactive air and active alternating pressure mattresses in the prevention and treatment of pressure ulcers among medical ICU patients. Journal of Tissue Viability. 2010; 19(1):7-15

126 McGowan S, Montgomery K, Jolley D, Wright R. The role of sheepskins in preventing pressure ulcers in elderly orthopaedic patients. Primary Intention. 2000; 8(4):1-8

127 McInnes E, Jammali-Blasi A, Bell-Syer Sally EM, Dumville JC, Cullum N. Support surfaces for pressure ulcer prevention. Cochrane Database of Systematic Reviews. 2011; Issue 4:CD001735. DOI:10.1002/14651858.CD001735.pub4

128 Meesterberends E, Halfens RJG, Lohrmann C, Schols JMGA, de Wit R. Evaluation of the dissemination and implementation of pressure ulcer guidelines in Dutch nursing homes. Journal of Evaluation in Clinical Practice. 2011; 17(4):705-712

129 Middleton JW, McCormick M, Engel S, Rutkowski SB, Cameron ID, Harradine P et al. Issues and Challenges for Development of a Sustainable Service Model for People With Spinal Cord Injury Living in Rural Regions. Archives of Physical Medicine and Rehabilitation. 2008; 89(10):1941-1947

130 Mistiaen P, Achterberg W, Ament A, Halfens R, Huizinga J, Montgomery K et al. The effectiveness of the Australian Medical Sheepskin for the prevention of pressure ulcers in somatic nursing home patients: A prospective multicenter randomized-controlled trial (ISRCTN17553857). Wound Repair and Regeneration. 2010; 18(6):572-579

131 Mistiaen P, Ament A, Francke AL, Achterberg W, Halfens R, Huizinga J et al. An economic appraisal of the Australian Medical Sheepskin for the prevention of sacral pressure ulcers from a nursing home perspective. BMC Health Services Research. 2010; 10:226

132 Mistiaen P, Jolley D, McGowan S, Hickey M, Spreeuwenberg P, Francke A. The Australian medical sheepskin prevents pressure ulcers: a combined multilevel analysis of three RCTs... Fourth European Nursing Congress. Journal of Clinical Nursing. 2010; 19(Supplement):20

133 Moore Z, Cowman S, Posnett J. An economic analysis of repositioning for the prevention of pressure ulcers. Journal of Clinical Nursing. 2013; 22(15-16):2354-2360

134 Moore ZEH, Cowman S. Risk assessment tools for the prevention of pressure ulcers. Cochrane Database of Systematic Reviews. 2008; Issue 3:CD006471. DOI:10.1002/14651858.CD006471.pub2

135 Moore Z, Cowman S, Conroy RM. A randomised controlled clinical trial of repositioning, using the 30degrees tilt, for the prevention of pressure ulcers. Journal of Clinical Nursing. 2011; 20(17-18):2633-2644

136 Murphy MK, Black NA, Lamping DL, McKee CM, Sanderson CF, Askham J et al. Consensus development methods, and their use in clinical guideline development. Health Technology Assessment. 1998; 2(3):i-88

137 Narayanan S, Van VJ, Strunk B, Ross RN, Gray M. Comparison of pressure ulcer treatments in long-term care facilities: clinical outcomes and impact on cost. Journal of Wound, Ostomy and Continence Nursing. 2005; 32(3):163-170

138 National Clinical Guideline Centre. Stroke rehabilitation: long term rehabilitation after stroke. NICE clinical guideline 162. London. National Clinical Guideline Centre, 2013 Available from: http://guidance.nice.org.uk/CG162

139 National Collaborating Centre for Women's and Children's Health. When to suspect child maltreatment. NICE clinical guideline 89. London. RCOG Press, 2009 Available from: http://guidance.nice.org.uk/CG89

140 National Institute for Health and Clinical Excellence. Guide to the methods of technology appraisal. London: National Institute for Health and Clinical Excellence; 2008. Available from: http://www.nice.org.uk/media/B52/A7/TAMethodsGuideUpdatedJune2008.pdf

141 National Institute for Health and Clinical Excellence. Social value judgements: principles for the development of NICE guidance. 2nd edition. London: National Institute for Health and Clinical Excellence; 2008. Available from: http://www.nice.org.uk/media/C18/30/SVJ2PUBLICATION2008.pdf

142 National Institute for Health and Clinical Excellence. The guidelines manual. London: National Institute for Health and Clinical Excellence; 2009. Available from: http://www.nice.org.uk/aboutnice/howwework/developingniceclinicalguidelines/clinicalguidelinedevelopmentmethods/GuidelinesManual2009.jsp

143 National Institute for Health and Clinical Excellence. The guidelines manual. London: National Institute for Health and Clinical Excellence; 2012. Available from: http://publications.nice.org.uk/the-guidelines-manual-pmg6/

144 Newman P, Davis NH. Thermography as a predictor of sacral pressure sores. Age and Ageing. 1981; 10(1):14-18

145 Nicosia G, Gliatta AE, Woodbury MG, Houghton PE. The effect of pressure-relieving surfaces on the prevention of heel ulcers in a variety of settings: A meta-analysis. International Wound Journal. 2007; 4(3):197-233

146 Nixon J, Cranny G, Bond S. Skin alterations of intact skin and risk factors associated with pressure ulcer development in surgical patients: a cohort study. International Journal of Nursing Studies. 2007; 44(5):655-663

147 Nixon J, Cranny G, Iglesias C, Nelson EA, Hawkins K, Phillips A et al. Randomised, controlled trial of alternating pressure mattresses compared with alternating pressure overlays for the prevention of pressure ulcers: PRESSURE (pressure relieving support surfaces) trial. BMJ. 2006; 332(7555):1413

148 Nixon J, McElvenny D, Mason S, Brown J, Bond S. A sequential randomised controlled trial comparing a dry visco-elastic polymer pad and standard operating table mattress in the prevention of post-operative pressure sores. International Journal of Nursing Studies. 1998; 35(4):193-203

149 Nixon J, Nelson EA, Cranny G, Iglesias CP, Hawkins K, Cullum NA et al. Pressure relieving support surfaces: a randomised evaluation. Health Technology Assessment. 2006; 10(22):1-163

150 Olofsson B, Stenvall M, Lundstrom M, Svensson O, Gustafson Y. Malnutrition in hip fracture patients: An intervention study. Journal of Clinical Nursing. 2007; 16(11):2027-2038

151 Ongoma C, Schmollgruber S, Langley GC. Predictive validity of pressure risk assessment scales in a private sector trauma intensive care unit. Southern African Journal of Critical Care. 2005; 21(2):78-86

152 Organisation for Economic Co-operation and Development (OECD). Purchasing power parities (PPP). 2013. Available from: http://www.oecd.org/std/ppp [Last accessed: 10 July 2013]

153 Padula WV, Mishra MK, Makic MB, Sullivan PW. Improving the quality of pressure ulcer care with prevention: a cost-effectiveness analysis. Medical Care. 2011; 49(4):385-392

154 Page KN, Barker AL, Kamar J. Development and validation of a pressure ulcer risk assessment tool for acute hospital patients. Wound Repair and Regeneration. 2011; 19(1):31-37

155 Pancorbo-Hidalgo PL, Garcia-Fernandez FP, Lopez-Medina IM, Alvarez-Nieto C. Risk assessment scales for pressure ulcer prevention: a systematic review. Journal of Advanced Nursing. 2006; 54(1):94-110

156 Pang SM, Wong TK. Predicting pressure sore risk with the Norton, Braden, and Waterlow scales in a Hong Kong rehabilitation hospital. Nursing Research. 1998; 47(3):147-153

157 Papanikolaou P, Lyne PA, Lycett EJ. Pressure ulcer risk assessment: application of logistic analysis. Journal of Advanced Nursing. 2003; 44(2):128-136

158 Perneger TV, Rae AC, Gaspoz JM, Borst F, Vitek O, Heliot C. Screening for pressure ulcer risk in an acute care hospital: development of a brief bedside scale. Journal of Clinical Epidemiology. 2002; 55(5):498-504

159 Pham B, Stern A, Chen W, Sander B, John-Baptiste A, Thein HH et al. Preventing pressure ulcers in long-term care: a cost-effectiveness analysis. Archives of Internal Medicine. 2011; 171(20):1839-1847

160 Pham B, Teague L, Mahoney J, Goodman L, Paulden M, Poss J et al. Support surfaces for intraoperative prevention of pressure ulcers in patients undergoing surgery: A cost-effectiveness analysis. Surgery. 2011; 150(1):122-132

161 Price P, Bale S, Newcombe R, Harding K. Challenging the pressure sore paradigm. Journal of Wound Care. 1999; 8(4):187-190

162 Ramundo JM. Reliability and validity of the Braden Scale in the home care setting. Journal of Wound, Ostomy and Continence Nursing. 1995; 22(3):128-134

163 Ricci E, Roberto C, Ippolito A, Bianco A, Scalise M. A new pressure-relieving mattress overlay. EWMA Journal. 2013; 13(1):27-32

164 Russell JA, Lichtenstein SL. Randomized controlled trial to determine the safety and efficacy of a multi-cell pulsating dynamic mattress system in the prevention of pressure ulcers in patients undergoing cardiovascular surgery. Ostomy/Wound Management. 2000; 46(2):46-5

165 Russell L, Reynolds TM, Carr J, Evans A, Holmes M. Randomised controlled trial of two pressure-relieving systems. Journal of Wound Care. 2000; 9(2):52-55

166 Russell L, Reynolds TM, Towns A, Worth W, Greenman A, Turner R. Randomized comparison trial of the RIK and the Nimbus 3 mattresses. British Journal of Nursing. 2003; 12(4):254, 256-254, 259

167 Russell LJ, Reynolds TM, Park C, Rithalia S, Gonsalkorale M, Birch J et al. Randomized clinical trial comparing 2 support surfaces: results of the Prevention of Pressure Ulcers Study. Advances in Skin and Wound Care. 2003; 16(6):317-327

168 Rypkema G, Adang E, Dicke H, Naber T, de Swart B, Disselhorst L et al. Cost-effectiveness of an interdisciplinary intervention in geriatric inpatients to prevent malnutrition. Journal of Nutrition, Health and Aging. 2004; 8(2):122-127

169 Saleh M, Anthony D, Parboteeah S. The impact of pressure ulcer risk assessment on patient outcomes among hospitalised patients. Journal of Clinical Nursing. 2009; 18(13):1923-1929

170 Salvadalena GD, Snyder ML, Brogdon KE. Clinical trial of the Braden Scale on an acute care medical unit. Journal of Enterostomal Therapy Nursing. 1992; 19(5):160-165

171 Samuriwo R. Effects of education and experience on nurses' value of ulcer prevention. British Journal of Nursing. 2010; 19(20):S8-18

172 Sanada H, Sugama J, Matsui Y, Konya C, Kitagawa A, Okuwa M et al. Randomised controlled trial to evaluate a new double-layer air-cell overlay for elderly patients requiring head elevation. Journal of Tissue Viability. 2003; 13(3):112-4, 116, 118

173 Santamaria N, Gerdtz M, Sage S, McCann J, Freeman A, Vassiliou T et al. A randomised controlled trial of the effectiveness of soft silicone multi-layered foam dressings in the prevention of sacral and heel pressure ulcers in trauma and critically ill patients: the border trial. International Wound Journal. 2013; [E publication]

174 Santy JE, Butler MK, and Whyman JD. A comparison study of 6 types of hospital mattress to determine which most effectively reduces the incidence of pressure sores in elderly patients with hip fractures in a District General Hospital. Report to Northern & Yorkshire Regional Health Authority, 1994

175 Schoonhoven L, Defloor T, Grypdonck MH. Incidence of pressure ulcers due to surgery. Journal of Clinical Nursing. 2002; 11(4):479-487

176 Schoonhoven L, Defloor T, van dT, I, Buskens E, Grypdonck MH. Risk indicators for pressure ulcers during surgery. Applied Nursing Research. 2002; 15(3):163-173

177 Schoonhoven L, Haalboom JRE, Bousema MT, Algra A, Grobbee DE, Grypdonck MH et al. Prospective cohort study of routine use of risk assessment scales for prediction of pressure ulcers. BMJ. 2002; 325(7368):797

178 Schubart JR, Hilgart M, Lyder C. Pressure ulcer prevention and management in spinal cord-injured adults: analysis of educational needs. Advances in Skin and Wound Care. 2008; 21(7):322-329

179 Schultz A, Bien M, Dumond K, Brown K, Myers A. Etiology and incidence of pressure ulcers in surgical patients. AORN Journal. 1999; 70(3):434, 437-440, 443-449

180 Schultz AA. Study results: prediction and prevention of pressure ulcers in surgical patients. Advances in Wound Care. 1998; 11(3 Suppl):11

181 Schuurman JP, Schoonhoven L, Defloor T, van E, I, van RB, Buskens E. Economic evaluation of pressure ulcer care: a cost minimization analysis of preventive strategies. Nursing Economics. 2009; 27(6):390-400

182 Seongsook RNJ, Ihnsook RNJ, Younghee RNL. Validity of pressure ulcer risk assessment scales; Cubbin and Jackson, Braden, and Douglas scale. International Journal of Nursing Studies. 2004; 41(2):199-204

183 Serpa LF, de Gouveia Santos VL, Gomboski G, Rosado SM. Predictive validity of Waterlow Scale for pressure ulcer development risk in hospitalized patients. Journal of Wound, Ostomy and Continence Nursing. 2009; 36(6):640-646

184 Serpa LF, Santos VL, Campanili TC, Queiroz M. Predictive validity of the Braden scale for pressure ulcer risk in critical care patients. Revista Latino-Americana De Enfermagem. 2011; 19(1):50-57

185 Sideranko S, Quinn A, Burns K, Froman RD. Effects of position and mattress overlay on sacral and heel pressures in a clinical population. Research in Nursing and Health. 1992; 15(4):245-251

186 Smith AM, Malone JA. Preventing pressure ulcers in institutionalized elders: assessing the effects of small, unscheduled shifts in body position. Decubitus. 1990; 3(4):20-24

187 Smith I. Waterlow/Norton scoring system: a ward view. Care: Science and Practice. 1989; 7(4):93-95

188 Smith RG, Everett E, Tucker L. A double blind trial of silicone barrier cream in the prevention of pressure sores in elderly patients. Journal of Clinical and Experimental Gerontology. 1985; 7(4):337-346

189 Soares MO, Dumville JC, Ashby RL, Iglesias CP, Bojke L, Adderley U et al. Methods to assess cost-effectiveness and value of further research when data are sparse: negative-pressure wound therapy for severe pressure ulcers. Medical Decision Making. 2013; 33(3):415-436

190 Specht JP, Bergquist S, Frantz RA. Adoption of a research-based practice for treatment of pressure ulcers. Nursing Clinics of North America. 1995; 30(3):553-563

191 Spilsbury K, Nelson A, Cullum N, Iglesias C, Nixon J, Mason S. Pressure ulcers and their treatment and effects on quality of life: hospital inpatient perspectives. Journal of Advanced Nursing. 2007; 57(5):494-504

192 Stapleton M. Preventing pressure sores--an evaluation of three products. Geriatric Nursing. 1986; 6(2):23-25

193 Stockton L. Preventing pressure sores in wheelchair users. Nursing Standard. 1994; 8(20):54-56

194 Stotts NA. Predicting pressure ulcer development in surgical patients. Heart and Lung. 1988; 17(6 Pt 1):641-647

195 Summer WR, Curry P, Haponikm EF, Nelson S, Elston R. Continuous mechanical turning of intensive care unit patients shortens length of stay in some diagnostic-related groups. Journal of Critical Care. 1989; 4:45-53

196 Suriadi, Sanada H, Sugama J, Thigpen B, Subuh M. Development of a new risk assessment scale for predicting pressure ulcers in an intensive care unit. Nursing in Critical Care. 2008; 13(1):34-43

197 Suriadi, Sanada H, Sugama J, Thigpen B, Kitagawa A, Kinosita S et al. A new instrument for predicting pressure ulcer risk in an intensive care unit. Journal of Tissue Viability. 2006; 16(3):21-26

198 Takala J, Varmavuo S, Soppi E. Prevention of pressure sores in acute respiratory failure: a randomised controlled trial. Clinical Intensive Care. 1996; 7(5):228-235

199 Taylor L. Evaluating the Pegasus Trinova: a data hierarchy approach. British Journal of Nursing. 1999; 8(12):771-778

200 Theaker C, Kuper M, Soni N. Pressure ulcer prevention in intensive care - a randomised control trial of two pressure-relieving devices. Anaesthesia. 2005; 60(4):395-399

201 Theilla M, Singer P, Cohen J, Dekeyser F. A diet enriched in eicosapentanoic acid, gamma-linolenic acid and antioxidants in the prevention of new pressure ulcer formation in critically ill patients with acute lung injury: A randomized, prospective, controlled study. Clinical Nutrition. 2007; 26(6):752-757

202 Thomson JS, Brooks RG. The economics of preventing and treating pressure ulcers: a pilot study. Journal of Wound Care. 1999; 8(6):312-316

203 Torra I Bou J, Rueda Lopez J, Camanes G, Herrero Narvaez E, Blanco BJ, Balleste TJ et al. Preventing pressure ulcers on the heel: a Canadian cost study. Dermatology Nursing. 2009; 21(5):268-272

204 Torra I Bou J, Rueda LJ, Camanes G, Herrero NE, Blanco BJ, Martinez-Esparza EH et al. [Preventing pressure ulcers on heels. Comparative study of heel protective bandages and a specially shaped hydrocellular dressing for the heel]. Revista De Enfermeria. 2002; 25(5):370-376

205 Towey AP, Erland SM. Validity and reliability of an assessment tool for pressure ulcer risk. Decubitus. 1988; 1(2):40-48

206 Trueman P, Whitehead SJ. The economics of pressure relieving surfaces: an illustrative case study of the impact of high-specification surfaces on hospital finances. International Wound Journal. 2010; 7(1):48-54

207 Tymec AC, Pieper B, Vollman K. A comparison of two pressure-relieving devices on the prevention of heel pressure ulcers. Advances in Wound Care. 1997; 10(1):39-44

208 van der Cammen TJ, O'Callaghan U, Whitefield M. Prevention of pressure sores. A comparison of new and old pressure sore treatments. British Journal of Clinical Practice. 1987; 41(11):1009-1011

209 van Leen M, Hovius S, Neyens J, Halfens R, Schols J. Pressure relief, cold foam or static air? A single center, prospective, controlled randomized clinical trial in a Dutch nursing home. Journal of Tissue Viability. 2011; 20(1):30-34

210 van Nieuwenhoven CA, Vandenbroucke-Grauls C, van Tiel FH, Joore HC, van Schijndel RJ, van dT, I et al. Feasibility and effects of the semirecumbent position to prevent ventilator-associated pneumonia: a randomized study. Critical Care Medicine. 2006; 34(2):396-402

211 VandenBosch T, Montoye C, Satwicz M, Durkee-Leonard K, Boylan-Lewis B. Predictive validity of the Braden Scale and nurse perception in identifying pressure ulcer risk. Applied Nursing Research. 1996; 9(2):80-86

212 Vanderwee K, Clark M, Dealey C, Gunningberg L, Defloor T. Pressure ulcer prevalence in Europe: a pilot study. Journal of Evaluation in Clinical Practice. 2007; 13(2):227-235

213 Vanderwee K, Grypdonck M, Defloor T. Non-blanchable erythema as an indicator for the need for pressure ulcer prevention: a randomized-controlled trial. Journal of Clinical Nursing. 2007; 16(2):325-335

214 Vanderwee K, Grypdonck MH, Defloor T. Effectiveness of an alternating pressure air mattress for the prevention of pressure ulcers. Age and Ageing. 2005; 34(3):261-267

215 Vanderwee K, Grypdonck MHF, De Bacquer D, Defloor T. Effectiveness of turning with unequal time intervals on the incidence of pressure ulcer lesions. Journal of Advanced Nursing. 2007; 57(1):59-68

216 Verdu J, Soldevilla J. IPARZINE-SKR study: Randomized, double-blind clinical trial of a new topical product versus placebo to prevent pressure ulcers. International Wound Journal. 2012; 9(5):557-565

217 Vermette S, Reeves I, Lemaire J. Cost Effectiveness of an Air-inflated Static Overlay for Pressure Ulcer Prevention: A Randomized, Controlled Trial. Wounds: A Compendium of Clinical Research and Practice. 2012; 24(8):207-214

218 Vyhlidal SK, Moxness D, Bosak KS, Van Meter FG, Bergstrom N. Mattress replacement or foam overlay? A prospective study on the incidence of pressure ulcers. Applied Nursing Research. 1997; 10(3):111-120

219 Wai-Han C, Kit-Wai C, French P, Yim-Sheung L, Lai-Kwan T. Which pressure sore risk calculator? A study of the effectiveness of the Norton scale in Hong Kong. International Journal of Nursing Studies. 1997; 34(2):165-169

220 Warshaw E, Nix D, Kula J, Markon CE. Clinical and cost effectiveness of a cleanser protectant lotion for treatment of perineal skin breakdown in low-risk patients with incontinence. Ostomy/Wound Management. 2002; 48(6):44-51

221 Webster J, Coleman K, Mudge A, Marquart L, Gardner G, Stankiewicz M et al. Pressure ulcers: effectiveness of risk-assessment tools. A randomised controlled trial (the ULCER trial). BMJ Quality and Safety. 2011; 20(4):297-306

222 Weststrate JT, Hop WC, Aalbers AG, Vreeling AW, Bruining HA. The clinical relevance of the Waterlow pressure sore risk scale in the ICU. Intensive Care Medicine. 1998; 24(8):815-820

223 Whitney JD, Fellows BJ, Larson E. Do mattresses make a difference? Journal of Gerontological Nursing. 1984; 10(9):20-25

224 Whittingham K, May S. Cleansing regimens for continence care. Professional Nurse. 1998; 14(3):167-172

225 Xakellis GC, Frantz RA. The cost-effectiveness of interventions for preventing pressure ulcers. Journal of the American Board of Family Medicine. 1996; 9(2):79-85

226 Xakellis GC, Frantz RA, Lewis A, Harvey P. Cost-effectiveness of an intensive pressure ulcer prevention protocol in long-term care. Advances in Wound Care. 1998; 11(1):22-29

227 Xakellis GC, Frantz RA, Lewis A, Harvey P. Translating pressure ulcer guidelines into practice: it's harder than it sounds. Advances in Skin and Wound Care. 2001; 14(5):249-256, 258

228 Young T. The 30 degree tilt position vs the 90 degree lateral and supine positions in reducing the incidence of non-blanching erythema in a hospital inpatient population: a randomised controlled trial. Journal of Tissue Viability. 2004; 14(3):88-96

229 Zehrer CL, Lutz JB, Hedblom EC, Ding L. A comparison of cost and efficacy of three incontinence skin barrier products. Ostomy/Wound Management. 2004; 50(12):51-58

18 Acronyms and abbreviations

ACA	Available case analysis
APAM	Alternative pressure air mattress
AUC	Area under the curve
CBA	Cost benefit analysis
CCA	Cost consequences analysis
CEA	Cost effectiveness analysis
CUA	Cost utility analysis
CI	Confidence interval
CLP	Continuous low pressure
CLP	Continuous low pressure
DMSO	Dimethyl sulfoxide
EPUAP	European pressure ulcer advisory panel
GDG	Guideline Development Group
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HBOT	Hyperbaric oxygen therapy
HR	Hazard ratio
ICER	Incremental cost effectiveness ratio
ICU	Intensive care unit
IDL	Indentation load deflection
INB	Incremental net benefit
IQR	Inter quartile range
ISO	Inflated static overlay
ITT	Intention to treat
LALDM	Low air loss dynamic mattress
MID	Minimal important difference
MSO	Microfluid static overlay
NBE	Non-blanchable erythema
NCGC	National Clinical Guideiline Centre
NHS	National health service
NICE	National Institute for Health and Care Excellence
NNT	Number needed to treat
NPV	Negative predictive value
NPWT	Negative pressure wound therapy
OR	Odds ratio
PPV	Positive predictive value
PUM	Poly-urethane mattress
QALY	Quality adjusted life year
RCT	Randomised controlled trial
ROC	Receiver operator curve
RR	Relative risk
SD	Standard deviation
SFC	Standard foam cushion

SFM	Standard foam mattress
SHM	Standard hospital mattress

19 Glossary

Abstract	Summary of a study, which may be published alone or as an introduction to a full scientific paper.
Algorithm (in guidelines)	A flow chart of the clinical decision pathway described in the guideline, where decision points are represented with boxes, linked with arrows.
Allocation concealment	The process used to prevent advance knowledge of group assignment in an RCT. The allocation process should be impervious to any influence by the individual making the allocation, by being administered by someone who is not responsible for recruiting participants.
Applicability	How well the results of a study or NICE evidence review can answer a clinical question or be applied to the population being considered.
Arm (of a clinical study)	Subsection of individuals within a study who receive 1 particular intervention, for example placebo arm
Association	Statistical relationship between 2 or more events, characteristics or other variables. The relationship may or may not be causal.
Autolysis	Autolysis is the disintegration of devitalised cells or tissues by natural enzymes. During autolytic debridement, the process may be facilitated by the use of a dressing.
Baseline	The initial set of measurements at the beginning of a study (after run-in period where applicable), with which subsequent results are compared.
Bias	Influences on a study that can make the results look better or worse than they really are. (Bias can even make it look as if a treatment works when it does not.) Bias can occur by chance, deliberately or as a result of systematic errors in the design and execution of a study. It can also occur at different stages in the research process, for example, during the collection, analysis, interpretation, publication or review of research data. For examples see selection bias, performance bias, information bias, confounding factor, and publication bias.
Blanchable erythema	See erythema
Blinding	A way to prevent researchers, doctors and patients in a clinical trial from knowing which study group each patient is in so they cannot influence the results. The best way to do this is by sorting patients into study groups randomly. The purpose of 'blinding' or 'masking' is to protect against bias. A single-blinded study is 1 in which patients do not know which study group they are in (for example whether they are taking the experimental drug or a placebo). A double-blinded study is 1 in which neither patients nor the researchers/doctors know which study group the patients are in. A triple blind study is 1 in which neither the patients, clinicians or the people carrying out the statistical analysis know which treatment patients received.
Carer (caregiver)	Someone who looks after family, partners or friends in need of help because they are ill, frail or have a disability.
Categorisation	The process of determining the severity of the pressure ulcer in order to guide management.
Child	Person aged between 1 to 13 years
Clinical efficacy	The extent to which an intervention is active when studied under controlled research conditions.
Clinical effectiveness	How well a specific test or treatment works when used in the 'real world' (for example, when used by a doctor with a patient at home), rather than in a carefully controlled clinical trial. Trials that assess clinical effectiveness are sometimes called management trials. Clinical effectiveness is not the same as efficacy.

Clinician	A healthcare professional who provides patient care. For example, a doctor, nurse or physiotherapist.
Cochrane Review	The Cochrane Library consists of a regularly updated collection of evidence-based medicine databases including the Cochrane Database of Systematic Reviews (reviews of randomised controlled trials prepared by the Cochrane Collaboration).
Cohort study	A study with 2 or more groups of people - cohorts - with similar characteristics. One group receives a treatment, is exposed to a risk factor or has a particular symptom and the other group does not. The study follows their progress over time and records what happens. See also observational study.
Comorbidity	A disease or condition that someone has in addition to the health problem being studied or treated.
Comparability	Similarity of the groups in characteristics likely to affect the study results (such as health status or age).
Confidence interval (CI)	There is always some uncertainty in research. This is because a small group of patients is studied to predict the effects of a treatment on the wider population. The confidence interval is a way of expressing how certain we are about the findings from a study, using statistics. It gives a range of results that is likely to include the 'true' value for the population. The CI is usually stated as '95% CI', which means that the range of values has a 95 in a 100 chance of including the 'true' value. For example, a study may state that 'based on our sample findings, we are 95% certain that the 'true' population blood pressure is not higher than 150 and not lower than 110'. In such a case the 95% CI would be 110 to 150. A wide confidence interval indicates a lack of certainty about the true effect of the test or treatment - often because a small group of patients has been studied. A narrow confidence interval indicates a more precise estimate (for example, if a large number of patients have been studied).
Confounding factor	Something that influences a study and can result in misleading findings if it is not understood or appropriately dealt with. For example, a study of heart disease may look at a group of people that exercises regularly and a group that does not exercise. If the ages of the people in the 2 groups are different, then any difference in heart disease rates between the 2 groups could be because of age rather than exercise. Therefore age is a confounding factor.
Consensus methods	Techniques used to reach agreement on a particular issue. Consensus methods may be used to develop NICE guidance if there is not enough good quality research evidence to give a clear answer to a question. Formal consensus methods include Delphi and nominal group techniques.
Control group	A group of people in a study who do not receive the treatment or test being studied. Instead, they may receive the standard treatment (sometimes called 'usual care') or a dummy treatment (placebo). The results for the control group are compared with those for a group receiving the treatment being tested. The aim is to check for any differences. Ideally, the people in the control group should be as similar as possible to those in the treatment group, to make it as easy as possible to detect any effects due to the treatment.
Cost–benefit analysis (CBA)	Cost-benefit analysis is 1 of the tools used to carry out an economic evaluation. The costs and benefits are measured using the same monetary units (for example, pounds sterling) to see whether the benefits exceed the costs.
Cost–consequences analysis	Cost-consequence analysis is 1 of the tools used to carry out an economic

(CCA)	evaluation. This compares the costs (such as treatment and hospital care) and the consequences (such as health outcomes) of a test or treatment with a suitable alternative. Unlike cost-benefit analysis or cost-effectiveness analysis, it does not attempt to summarise outcomes in a single measure (like the quality-adjusted life year) or in financial terms. Instead, outcomes are shown in their natural units (some of which may be monetary) and it is left to decision-makers to determine whether, overall, the treatment is worth carrying out.
Cost-effectiveness analysis (CEA)	Cost-effectiveness analysis is 1 of the tools used to carry out an economic evaluation. The benefits are expressed in non-monetary terms related to health, such as symptom-free days, heart attacks avoided, deaths avoided or life years gained (that is, the number of years by which life is extended as a result of the intervention).
Cost-effectiveness model	An explicit mathematical framework, which is used to represent clinical decision problems and incorporate evidence from a variety of sources in order to estimate the costs and health outcomes.
Cost–utility analysis (CUA)	Cost-utility analysis is 1 of the tools used to carry out an economic evaluation. The benefits are assessed in terms of both quality and duration of life, and expressed as quality-adjusted life years (QALYs). See also utility.
Debridement	The process of removal of devitalised (dead or dying) tissue from an ulcer. Types of debridement include: Autolytic: the removal of devitalised tissue by the body's own mechanisms Mechanical: the removal of devitalised tissue by physical forces such as with scissors or scalpels. Larval: the use of maggots to remove devitalised tissue
Decision analysis	An explicit quantitative approach to decision-making under uncertainty, based on evidence from research. This evidence is translated into probabilities, and then into diagrams or decision trees which direct the clinician through a succession of possible scenarios, actions and outcomes.
Diascopy	A test, used to identify non-blanchable erythema, by putting pressure on the surface of the skin and observing colour changes. Pressure may be placed on the skin using a transparent disk or a finger.
Discounting	Costs and perhaps benefits incurred today have a higher value than costs and benefits occurring in the future. Discounting health benefits reflects individual preference for benefits to be experienced in the present rather than the future. Discounting costs reflects individual preference for costs to be experienced in the future rather than the present.
Dominance	A health economics term. When comparing tests or treatments, an option that is both less effective and costs more is said to be 'dominated' by the alternative.
Dressings	Materials applied to a wound for a variety of reasons, including protection, absorption, and hydration.
Drop-out	A participant who withdraws from a trial before the end.
Economic evaluation	An economic evaluation is used to assess the cost effectiveness of healthcare interventions (that is, to compare the costs and benefits of a healthcare intervention to assess whether it is worth doing). The aim of an economic evaluation is to maximise the level of benefits - health effects - relative to the resources available. It should be used to inform and support the decision-making process; it is not supposed to replace the judgement of healthcare professionals. There are several types of economic evaluation: cost-benefit analysis, cost-consequence analysis, cost-effectiveness analysis, cost-minimisation analysis and cost-utility analysis. They use similar methods to define and evaluate costs, but differ in the way they estimate the benefits of a

	particular drug, programme or intervention.
Effect (as in effect measure, treatment effect, estimate of effect, effect size)	A measure that shows the magnitude of the outcome in 1 group compared with that in a control group. For example, if the absolute risk reduction is shown to be 5% and it is the outcome of interest, the effect size is 5%. The effect size is usually tested, using statistics, to find out how likely it is that the effect is a result of the treatment and has not just happened by chance (that is, to see if it is statistically significant).
Effectiveness	How beneficial a test or treatment is under usual or everyday conditions, compared with doing nothing or opting for another type of care.
Efficacy	How beneficial a test, treatment or public health intervention is under ideal conditions (for example, in a laboratory), compared with doing nothing or opting for another type of care.
Electrotherapy	The use of an electrical current, delivered in various ways, to stimulate wound healing.
Epidemiological study	The study of a disease within a population, defining its incidence and prevalence and examining the roles of external influences (for example, infection, diet) and interventions.
Erythema	Redness of the skin due to dilation of superficial capillaries. Erythema is blanchable when the area turns white or pale temporarily with the application of pressure. Non-blanchable erythema retains redness on the application of pressure.
EQ-5D (EuroQol 5 dimensions)	A standardised instrument used to measure health-related quality of life. It provides a single index value for health status.
Evidence	Information on which a decision or guidance is based. Evidence is obtained from a range of sources including randomised controlled trials, observational studies, expert opinion (of clinical professionals or patients).
Exclusion criteria (literature review)	Explicit standards used to decide which studies should be excluded from consideration as potential sources of evidence.
Exclusion criteria (clinical study)	Criteria that define who is not eligible to participate in a clinical study.
Extended dominance	If Option A is both more clinically effective than Option B and has a lower cost per unit of effect, when both are compared with a do-nothing alternative then Option A is said to have extended dominance over Option B. Option A is therefore more cost effective and should be preferred, other things remaining equal.
Extrapolation	An assumption that the results of studies of a specific population will also hold true for another population with similar characteristics.
Follow-up	Observation over a period of time of an individual, group or initially defined population whose appropriate characteristics have been assessed in order to observe changes in health status or health-related variables.
Generalisability	The extent to which the results of a study hold true for groups that did not participate in the research. See also external validity.
Gold standard	A method, procedure or measurement that is widely accepted as being the best available to test for or treat a disease.
GRADE, GRADE Profile	A system developed by the GRADE (Grading of Recommendations Assessment, Development and Evaluation) Working Group to address the shortcomings of present grading systems in healthcare. The GRADE system uses a common, sensible and transparent approach to grading the quality of evidence. The results of applying the GRADE system to clinical trial data are displayed in a table known as a GRADE profile.

Harms	Adverse effects of an intervention.
Health economics	Study or analysis of the cost of using and distributing healthcare resources.
Health-related quality of life (HRQoL)	A measure of the effects of an illness to see how it affects someone's day-to-day life.
Heel devices	Equipment or materials with known pressure redistributing/alleviating properties to minimise the effects of pressure on the heel.
Heterogeneity or Lack of homogeneity	The term is used in meta-analyses and systematic reviews to describe when the results of a test or treatment (or estimates of its effect) differ significantly in different studies. Such differences may occur as a result of differences in the populations studied, the outcome measures used or because of different definitions of the variables involved. It is the opposite of homogeneity.
High risk	Neonates, infants, children and young people considered to be at high risk of developing a pressure ulcer will usually have more than 1 risk factor (for example, significantly limited mobility, nutritional deficiency, inability to reposition themselves, significant cognitive impairment) identified during risk assessment with or without a validated scale. Those with a history of pressure ulcers are also considered to be at high risk.
High specification foam mattress	Mattresses made of high density foam or visco-elastic foam which conforms to the body contours resulting in superior pressure reduction to the standard hospital foam mattress.
Hydration	The provision of an adequate fluid intake to meet all bodily needs and replace any losses.
Hyperbaric oxygen therapy	The use of above atmospheric pressure to increase the oxygen supply to the wound bed and possibly promote wound healing.
Imprecision	Results are imprecise when studies include relatively few patients and few events and thus have wide confidence intervals around the estimate of effect.
Inclusion criteria (literature review)	Explicit criteria used to decide which studies should be considered as potential sources of evidence.
Infant	Person under 1 year of age
Incremental analysis	The analysis of additional costs and additional clinical outcomes with different interventions.
Incremental cost	The extra cost linked to using 1 test or treatment rather than another. Or the additional cost of doing a test or providing a treatment more frequently.
Incremental cost-effectiveness ratio (ICER)	The difference in the mean costs in the population of interest divided by the differences in the mean outcomes in the population of interest for 1 treatment compared with another.
Incremental net benefit (INB)	The value (usually in monetary terms) of an intervention net of its cost compared with a comparator intervention. The INB can be calculated for a given cost-effectiveness (willingness to pay) threshold. If the threshold is £20,000 per QALY gained then the INB is calculated as: (£20,000 x QALYs gained) – Incremental cost.
Indirectness	The available evidence is different to the review question being addressed, in terms of PICO (population, intervention, comparison and outcome).
Intention to treat analysis (ITT)	An assessment of the people taking part in a clinical trial, based on the group they were initially (and randomly) allocated to. This is regardless of whether or not they dropped out, fully complied with the treatment or switched to an alternative treatment. Intention-to-treat analyses are often used to assess clinical effectiveness because they mirror actual practice: that is, not everyone complies with treatment and the treatment people receive may be changed according to how they respond to it.

Intervention	In medical terms this could be a drug treatment, surgical procedure, diagnostic or psychological therapy. Examples of public health interventions could include action to help someone to be physically active or to eat a more healthy diet.
Intraoperative	The period of time during a surgical procedure.
Kappa statistic	A statistical measure of inter-rater agreement that takes into account the agreement occurring by chance.
Length of stay	The total number of days a participant stays in hospital.
Licence	See 'Product licence'.
Life years gained	Mean average years of life gained per person as a result of the intervention compared with an alternative intervention.
Likelihood ratio	The likelihood ratio combines information about the sensitivity and specificity. It tells you how much a positive or negative result changes the likelihood that a patient would have the disease. The likelihood ratio of a positive test result (LR+) is sensitivity divided by (1 minus specificity).
Long-term care	Residential care in a home that may include skilled nursing care and help with everyday activities. This includes nursing homes and residential homes.
Markov model	A method for estimating long-term costs and effects for recurrent or chronic conditions, based on health states and the probability of transition between them within a given time period (cycle).
Mattress overlay	An overlay which lies on top of the base mattress and may have pressure reducing, pressure redistributing or pressure relieving properties.
Meta-analysis	A method often used in systematic reviews. Results from several studies of the same test or treatment are combined to estimate the overall effect of the treatment.
Moisture lesion	A moisture lesion can be defined as localised injury to the skin initiated by the effects of moisture.
Multivariate model	A statistical model for analysis of the relationship between 2 or more predictor (independent) variables and the outcome (dependent) variable.
Negative predictive value (NPV)	In screening or diagnostic tests: A measure of the usefulness of a screening or diagnostic test. It is the proportion of those with a negative test result who do not have the disease, and can be interpreted as the probability that a negative test result is correct.
Negative pressure wound therapy (NPWT)	The use of negative pressure with the aim of promoting wound healing by enhancing nutrient and oxygen delivery, removal of wound exudate, promotion of granulation tissue, promotion of angiongenesis, and the removal of wound inhibitory factors.
Neonate	A baby under 4 weeks of age
Non-blanchable erythema	See erythema
Number needed to treat (NNT)	The average number of patients who need to be treated to get a positive outcome. For example, if the NNT is four, then 4 patients would have to be treated to ensure 1 of them gets better. The closer the NNT is to 1, the better the treatment. For example, if you give a stroke prevention drug to 20 people before 1 stroke is prevented, the number needed to treat is 20. See also number needed to harm, absolute risk reduction.
Nutrition	The provision of all essential food components (including macro and micro nutrients) to maintain current body function and growth whilst also meeting any additional needs associated with promoting pressure ulcer healing and other metabolic stresses.
Observational study	Individuals or groups are observed or certain factors are measured. No attempt is made to affect the outcome. For example, an observational study

	of a disease or treatment would allow 'nature' or usual medical care to take its course. Changes or differences in 1 characteristic (for example, whether or not people received a specific treatment or intervention) are studied without intervening. There is a greater risk of selection bias than in experimental studies.
Odds ratio	Odds are a way to represent how likely it is that something will happen (the probability). An odds ratio compares the probability of something in 1 group with the probability of the same thing in another. An odds ratio of 1 between 2 groups would show that the probability of the event (for example a person developing a disease, or a treatment working) is the same for both. An odds ratio greater than 1 means the event is more likely in the first group. An odds ratio less than 1 means that the event is less likely in the first group. Sometimes probability can be compared across more than 2 groups - in this case, 1 of the groups is chosen as the 'reference category', and the odds ratio is calculated for each group compared with the reference category. For example, to compare the risk of dying from lung cancer for non-smokers, occasional smokers and regular smokers, non-smokers could be used as the reference category. Odds ratios would be worked out for occasional smokers compared with non-smokers and for regular smokers compared with non-smokers. See also confidence interval, relative risk, risk ratio.
Opportunity cost	The loss of other health care programmes displaced by investment in or introduction of another intervention. This may be best measured by the health benefits that could have been achieved had the money been spent on the next best alternative healthcare intervention.
Outcome	The impact that a test, treatment, policy, programme or other intervention has on a person, group or population. Outcomes from interventions to improve the public's health could include changes in knowledge and behaviour related to health, societal changes (for example, a reduction in crime rates) and a change in people's health and wellbeing or health status. In clinical terms, outcomes could include the number of patients who fully recover from an illness or the number of hospital admissions, and an improvement or deterioration in someone's health, functional ability, symptoms or situation. Researchers should decide what outcomes to measure before a study begins.
P-value	The p value is a statistical measure that indicates whether or not an effect is statistically significant. For example, if a study comparing 2 treatments found that 1 seems more effective than the other, the p value is the probability of obtaining these results by chance. By convention, if the p value is below 0.05 (that is, there is less than a 5% probability that the results occurred by chance) it is considered that there probably is a real difference between treatments. If the p value is 0.001 or less (less than a 1% probability that the results occurred by chance), the result is seen as highly significant. If the p value shows that there is likely to be a difference between treatments, the confidence interval describes how big the difference in effect might be.
Perioperative	The period from admission through surgery until discharge, encompassing the pre-operative and post-operative periods.
Placebo	A fake (or dummy) treatment given to participants in the control group of a clinical trial. It is indistinguishable from the actual treatment (which is given to participants in the experimental group). The aim is to determine what effect the experimental treatment has had - over and above any placebo effect caused because someone has received (or thinks they have received) care or attention.

Polypharmacy	The use or prescription of multiple medications.
Positive predictive value (PPV)	In screening or diagnostic tests: A measure of the usefulness of a screening or diagnostic test. It is the proportion of those with a positive test result who have the disease, and can be interpreted as the probability that a positive test result is correct.
Postoperative	Pertaining to the period after patients leave the operating theatre, following surgery.
Power (statistical)	The ability to demonstrate an association when 1 exists. Power is related to sample size; the larger the sample size, the greater the power and the lower the risk that a possible association could be missed.
Preoperative	The period before surgery commences.
Pressure redistributing devices	The use of a support surface to distribute weight over the contact areas of the human body. This term replaces prior terminology of pressure reduction and pressure redistribution surfaces.
Pressure ulcer	A pressure ulcer is a localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear. A number of contributing or confounding factors are also associated with pressure ulcers; the significance of these factors is yet to be elucidated. This term replaces prior terminology pressure sore or bed sore.
Prevention	To keep something from happening. Interventions before the initial onset of a condition through the reduction of risk factors and the enhancement of protective factors in a targeted population
Primary care	Healthcare delivered outside hospitals. It includes a range of services provided by GPs, nurses, health visitors, midwives and other healthcare professionals and allied health professionals such as dentists, pharmacists and opticians.
Primary outcome	The outcome of greatest importance, usually the 1 in a study that the power calculation is based on.
Prognosis	A probable course or outcome of a disease. Prognostic factors are patient or disease characteristics that influence the course. Good prognosis is associated with low rate of undesirable outcomes; poor prognosis is associated with a high rate of undesirable outcomes.
Prospective study	A research study in which the health or other characteristic of participants is monitored (or 'followed up') for a period of time, with events recorded as they happen. This contrasts with retrospective studies.
Publication bias	Publication bias occurs when researchers publish the results of studies showing that a treatment works well and don't publish those showing it did not have any effect. If this happens, analysis of the published results will not give an accurate idea of how well the treatment works. This type of bias can be assessed by a funnel plot.
Quality of life	See ‘Health-related quality of life’.
Quality-adjusted life year (QALY)	A measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. One QALY is equal to 1 year of life in perfect health. QALYS are calculated by estimating the years of life remaining for a patient following a particular treatment or intervention and weighting each year with a quality of life score (on a zero to 1 scale). It is often measured in terms of the person's ability to perform the activities of daily life, freedom from pain and mental disturbance.
Randomisation	Assigning participants in a research study to different groups without taking any similarities or differences between them into account. For example, it could involve using a random numbers table or a computer-generated

	random sequence. It means that each individual (or each group in the case of cluster randomisation) has the same chance of receiving each intervention.
Randomised controlled trial (RCT)	A study in which a number of similar people are randomly assigned to 2 (or more) groups to test a specific drug or treatment. One group (the experimental group) receives the treatment being tested, the other (the comparison or control group) receives an alternative treatment, a dummy treatment (placebo) or no treatment at all. The groups are followed up to see how effective the experimental treatment was. Outcomes are measured at specific times and any difference in response between the groups is assessed statistically. This method is also used to reduce bias.
RCT	See 'Randomised controlled trial'.
Receiver operated characteristic (ROC) curve	A graphical method of assessing the accuracy of a diagnostic test. Sensitivity is plotted against 1 minus specificity. A perfect test will have a positive, vertical linear slope starting at the origin. A good test will be somewhere close to this ideal.
Reference standard	The test that is considered to be the best available method to establish the presence or absence of the outcome – this may not be the 1 that is routinely used in practice.
Relative risk (RR)	The ratio of the risk of disease or death among those exposed to certain conditions compared with the risk for those who are not exposed to the same conditions (for example, the risk of people who smoke getting lung cancer compared with the risk for people who do not smoke). If both groups face the same level of risk, the relative risk is 1. If the first group had a relative risk of 2, subjects in that group would be twice as likely to have the event happen. A relative risk of less than 1 means the outcome is less likely in the first group. Relative risk is sometimes referred to as risk ratio.
Reporting bias	See 'Publication bias'.
Resource implication	The likely impact in terms of finance, workforce or other NHS resources.
Retrospective study	A research study that focuses on the past and present. The study examines past exposure to suspected risk factors for the disease or condition. Unlike prospective studies, it does not cover events that occur after the study group is selected.
Review question	In guideline development, this term refers to the questions about treatment and care that are formulated to guide the development of evidence-based recommendations.
Risk assessment	A method of assessing the likelihood of developing pressure ulcers.
Risk assessment tools	Tools used to assess the likelihood of developing pressure ulcers, which can be used in combination with clinical judgement. A validated risk assessment tool has been co-oborated within the population it is designed for.
Secondary outcome	An outcome used to evaluate additional effects of the intervention deemed a priori as being less important than the primary outcomes.
Selection bias	Selection bias occurs if: a) The characteristics of the people selected for a study differ from the wider population from which they have been drawn, or b) There are differences between groups of participants in a study in terms of how likely they are to get better.
Sensitivity	How well a test detects the thing it is testing for. If a diagnostic test for a disease has high sensitivity, it is likely to pick up all cases of the disease in people who have it (that is, give a 'true positive' result). But if a test is too sensitive it will sometimes also give a positive

	result in people who don't have the disease (that is, give a 'false positive'). For example, if a test were developed to detect if a woman is 6 months pregnant, a very sensitive test would detect everyone who was 6 months pregnant, but would probably also include those who are 5 and 7 months pregnant. If the same test were more specific (sometimes referred to as having higher specificity), it would detect only those who are 6 months pregnant, and someone who was 5 months pregnant would get a negative result (a 'true negative'). But it would probably also miss some people who were 6 months pregnant (that is, give a 'false negative'). Breast screening is a 'real-life' example. The number of women who are recalled for a second breast screening test is relatively high because the test is very sensitive. If it were made more specific, people who don't have the disease would be less likely to be called back for a second test but more women who have the disease would be missed.
Sensitivity analysis	A means of representing uncertainty in the results of economic evaluations. Uncertainty may arise from missing data, imprecise estimates or methodological controversy. Sensitivity analysis also allows for exploring the generalisability of results to other settings. The analysis is repeated using different assumptions to examine the effect on the results. One-way simple sensitivity analysis (univariate analysis): each parameter is varied individually in order to isolate the consequences of each parameter on the results of the study. Multi-way simple sensitivity analysis (scenario analysis): 2 or more parameters are varied at the same time and the overall effect on the results is evaluated. Threshold sensitivity analysis: the critical value of parameters above or below which the conclusions of the study will change are identified. Probabilistic sensitivity analysis: probability distributions are assigned to the uncertain parameters and are incorporated into evaluation models based on decision analytical techniques (for example, Monte Carlo simulation).
Shear	The pressure caused when layers of skin are caused to slide over 1 another. This can happen when a person slides down a bed or is pulled up in bed. Stress caused by shear can contribute to the development of a pressure ulcer.
Significance (statistical)	A result is deemed statistically significant if the probability of the result occurring by chance is less than 1 in 20 ($p<0.05$).
Skin assessment	Methods used to assess skin status to identify potential risk of pressure ulcer development, or early signs of pressure damage. This may include the use of diascopy or the measurement of skin temperature.
Skin massage	Rubbing or kneading of parts of the skin, with the aim of reducing pressure ulceration.
Specificity	The proportion of true negatives that are correctly identified as such. For example in diagnostic testing the specificity is the proportion of non-cases correctly diagnosed as non-cases. See related term ‘Sensitivity’. In terms of literature searching a highly specific search is generally narrow and aimed at picking up the key papers in a field and avoiding a wide range of papers.
Stakeholder	An organisation with an interest in a topic that NICE is developing a clinical guideline or piece of public health guidance on. Organisations that register as stakeholders can comment on the draft scope and the draft guidance. Stakeholders may be: • manufacturers of drugs or equipment

	• national patient and carer organisations • NHS organisations • organisations representing healthcare professionals.
Systematic review	A review in which evidence from scientific studies has been identified, appraised and synthesised in a methodical way according to predetermined criteria. It may include a meta-analysis.
Systemic antimicrobials	An agent, that acts directly on a microorganism to destroy bacteria and prevent the development of new bacteria, viruses and fungi colonies, that is ingested by an individual as a means of treatment. These may include antiseptics, antiviral, antibiotic and antibacterial agents.
Time horizon	The time span over which costs and health outcomes are considered in a decision analysis or economic evaluation.
Topical antimicrobials	An agent, that acts directly on a microorganism to destroy the bacteria, viruses or fungi and prevent the development of new bacterial colonies, that is applied to the body's surface as a means of prevention/treatment of infection. These may include antiseptics, antibiotics and antibacterial agents.
Treatment allocation	Assigning a participant to a particular arm of a trial.
Ulcer assessment	Methods used to determine the area, depth and volume of a pressure ulcer.
Univariate	Analysis which separately explores each variable in a data set.
Utility	In health economics, a 'utility' is the measure of the preference or value that an individual or society places upon a particular health state. It is generally a number between zero (representing death) and 1 (perfect health). The most widely used measure of benefit in cost-utility analysis is the quality-adjusted life year, but other measures include disability-adjusted life years (DALYs) and healthy year equivalents (HYEs).
Young person	Person aged 13-18.

Appendices

Appendices A-O can be found in separate documents.