Clinical practice guideline for
Pressure-relieving devices: the use of
pressure-relieving devices (beds,
mattresses and overlays) for the
prevention
of pressure ulcers in primary and
secondary
care

Draft for second consultation
April 2003
This work was undertaken by the National Collaborating Centre for Nursing and Supportive Care (NCC-NSC) and the Guideline Development Group (GDG) formed to develop this guideline. Funding was received from the National Institute for Clinical Excellence. The NCC-NSC consists of a partnership between the: Centre for Evidence-Based Nursing; Centre for Statistics in Medicine; Clinical Effectiveness Forum for Allied Health Professionals, College of Health; Health Economics Research Centre, Royal College of Nursing and UK Cochrane Centre.
Disclaimer

As with any clinical guideline, recommendations may not be appropriate for use in all circumstances. A limitation of a guideline is that it simplifies clinical decision-making (Shiffman 1997). Decisions to adopt any particular recommendations must be made by the practitioners in the light of:

- Available resources
- Local services, policies and protocols
- The patients circumstances and wishes
- Available personnel and devices
- Clinical experience of the practitioner
- Knowledge of more recent research findings.

Terminology

1. Where the term ‘carer’ is used, this refers to unpaid carers as opposed to paid carers (eg. careworkers).

2. There is much debate in the literature and amongst experts about the appropriateness of the term ‘pressure-relieving’. For the purposes of this guideline, pressure-relieving is used as an umbrella term for all pressure-reducing and pressure-redistributing devices. The term is also consistent with previous recent guidelines (NICE 2001a; RCN 2001) and the evidence review on which this guideline is partly based. A glossary of pressure-relieving devices is included in Appendix A.

3. Pressure ulcers have also been known previously as pressure sores, bed sores, decubitus ulcers.

4. The Guideline Development Group (GDG) decided to use the terms 'vulnerable to pressure ulcers' and 'at elevated risk of pressure ulcers' rather than the commonly used terms 'at risk' and 'at very high risk'. The latter terms imply that there are reliable cut-off points for identifying risk, yet there is little evidence to show that using a pressure ulcer risk scale alone is better than clinical judgement for assessing risk or that allocation of pressure-relieving devices can be linked to risk assessment scales.
5. Pressure-relieving devices (from Cullum et al. 2001)

*Low-tech devices:* these provide a conforming support surface that distributes the body weight over a large area. They include the following:

- Standard foam mattress.
- Alternative foam mattresses/overlays (for example, high-specification foam, convoluted foam, cubed foam); these are conformable and aim to redistribute pressure over a larger contact area.
- Gel-filled (viscoelastic) mattresses/overlays.
- Fluid-filled mattresses/overlays.
- Fibre-filled mattresses/overlays.
- Air-filled mattresses/overlays.

*High-tech devices:* these are dynamic systems that include the following:

- Alternating-pressure mattresses/overlays: the patient lies on air-filled sacks, which sequentially inflate and deflate and relieve pressure at different anatomical sites for short periods; these devices may incorporate a pressure sensor.
- Air-fluidised beds/mattresses/overlays: warmed air is circulated through fine ceramic beads covered by a permeable sheet; these allow support over a larger contact area.
- Low-air-loss overlays/mattresses/beds: patients are supported on air-filled sacks inflated at a constant pressure, through which air is able to pass.
- Turning beds/frames: (kinetic beds) beds that either aid manual repositioning of the patient or reposition the patient by motor-driven turning and tilting.
Abbreviations and general glossary

Abbreviations

Technical terms

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<thead>
<tr>
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<tbody>
<tr>
<td>AP</td>
<td>alternating pressure</td>
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<td>ARR</td>
<td>absolute relative risk</td>
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<td>CI</td>
<td>confidence intervals</td>
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<td>CLP</td>
<td>constant low pressure</td>
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<td>GDG</td>
<td>Guideline Development Group</td>
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<td>HTA</td>
<td>health technology assessment</td>
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<td>ICU</td>
<td>intensive care unit</td>
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<tr>
<td>LAL</td>
<td>low-air-loss</td>
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<tr>
<td>NNT</td>
<td>number needed to treat</td>
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<tr>
<td>OT</td>
<td>operating theatre</td>
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<tr>
<td>RCT</td>
<td>randomised controlled trial</td>
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<tr>
<td>RR</td>
<td>relative risk</td>
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Organizations

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<tr>
<th>Abbreviation</th>
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<tr>
<td>CRD</td>
<td>Centre for Reviews and Dissemination</td>
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<tr>
<td>CWG</td>
<td>Cochrane Wounds Group</td>
</tr>
<tr>
<td>DoH</td>
<td>Department of Health</td>
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<tr>
<td>NCC-NSC</td>
<td>National Collaborating Centre for Nursing and Supportive Care</td>
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<tr>
<td>NICE</td>
<td>National Institute for Clinical Excellence</td>
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<tr>
<td>OECD</td>
<td>Organization for Economic Co-operation and Development</td>
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<td>RCN</td>
<td>Royal College of Nursing</td>
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General Glossary

(partially based on Clinical epidemiology glossary by the Evidence Based Medicine Working Group, www.ed.ualberta.ca/ebm; Information for national collaborating centres and guideline development groups, NICE 2001 and the RCN guidelines on risk assessment and prevention (2001))

Absolute risk reduction: The difference between the observed event rates (proportions of individuals with the outcome of interest) in the 2 groups.

Bias: May result from flaws in the design of a study or in the analysis of results

Blanching erythema: The skin whitening that occurs when pressure is applied, indicating that microcirculation is intact

Case-control study: A study in which the effects of a treatment or management approach in a group of patients is compared with the effects of a similar group of people who do not have the clinical condition (the latter is called the control group)

Clinical effectiveness: The extent to which an intervention (for example, a device or treatment) produces health benefits (ie. more good than harm)

Cochrane Collaboration: An international organization in which people retrieve, appraise and review available randomised controlled trials. The Cochrane Database of systematic reviews contains regularly updated reviews on a variety of issues. The Cochrane library is the database for the collaboration, it is electronic and regularly updated

Cohort study: Follow-up of exposed and non-exposed groups of patients (the 'exposure' is either a treatment of condition), with a comparison of outcomes during the time followed-up

Co-interventions: Interventions/treatments etc other than the treatment under study that are applied differently to the treatment and control groups

Co-morbidity: Co-existence of a disease or diseases in a study population in addition to the condition that is the subject of study

Confidence interval (CI): The range of numerical values in which we can be confident that the population value being estimated were found. Confidence intervals indicate the strength of evidence; where confidence intervals are wide they indicate less precise estimates of effects
Cost effectiveness: the cost per unit of benefit of an intervention. In cost effectiveness analysis, the outcomes of different interventions are converted into health gains for which a cost can be associated, for example, cost per additional pressure ulcer prevented

Cost impact: The total cost to the person, the NHS or to society

Discounting: the process of converting future dollars and future health outcomes to their present value

Economic evaluation: comparative analysis of alternative courses of action in terms of both their costs and consequences

Effectiveness: The extent to which interventions achieve health improvements in real practice settings

Efficacy: The extent to which medical interventions achieve health improvements under ideal circumstances

Erythema: non-specific redness of the skin which can either be localised or general in nature and which may be associated with cellulitis, infection, prolonged pressure or reactive hyperaemia

Epidemiological study: A study which looks at how a disease or clinical condition is distributed across geographical areas

Extrinsic: Factors that are external to the individual

Follow-up: Observation over a period of time of an individual, group or population whose relevant characteristics have been assessed in order to observe changes in health status or health-related variables

Gold standard: A method, procedure or measurement that is widely accepted as being the best available

Health technology assessment: The process by which evidence on the clinical effectiveness and the costs and benefits of using a technology in clinical practice is systematically evaluated
Pressure-relieving devices: draft for consultation

**High-tech devices**: An alternating support surface where inflatable cells alternately inflate and deflate (Cullum et al. 2001)

**Incidence**: The number of new cases of illness commencing, or of persons falling ill during a specified time period in a given population

**Intrinsic**: Factors present within the individual

**Logistic regression model**: A data analysis technique to derive an equation to predict the probability of an event given one or more predictor variables. This model assumes that the natural logarithm of the odds for the event (the logit) is a linear sum of weighted values of the predictor variable. The weights are derived from data using the method of maximum likelihood

**Low-tech devices**: A conforming support surface which distributes the body weight over a large area (Cullum et al. 2001)

**Meta-analysis**: A statistical method of summarising the results from a group of similar studies

**Non-blanching erythema**: There is no skin colour change when light finger pressure is applied

**Number needed to treat**: The number of patients who need to be treated to prevent one event.

**Overlay**: term used to describe surfaces placed on top of a standard mattress or operating table

**Predictive validity**: A risk assessment tool would have high predictive validity if the predictions it makes of pressure ulcer development in a sample became true (ie. it has both high sensitivity and specificity)

**Prevalence**: The proportion of persons with a particular disease within a given population at a given time

**Quality adjusted life expectancy**: Life expectancy using quality adjusted life years rather than nominal life years
Quality adjusted life years (QALYs): A measure of health outcome which assigns to each time period a weight, ranging from 0-1, corresponding to the health related quality of life during that period, where a weight of 1 corresponds to optimal health, and a weight of 0 corresponds to a health state judged as equivalent to death: these are then aggregated across time periods.

Randomised controlled trial (RCT): A clinical trial in which the treatments are randomly assigned to subjects. The random allocation eliminates bias in the assignment of treatment to patients and establishes the basis for the statistical analysis.

Reactive hyperaemia: the characteristic bright flush of the skin associated with an increased volume of the pulse on the release of an obstruction to the circulation, or a vascular flush following the release of an occlusion of the circulation which is in direct response to incoming arterial blood.

Relative risk: An estimate of the magnitude of an association between exposure and disease which also indicates the likelihood of developing the disease among persons who are exposed relative to those who are not. It is defined as the ratio of incidence of disease in the exposed group divided by the corresponding incidence in the non-exposed group.

Retrospective cohort study: A study in which a defined group of persons with an exposure and an appropriate comparison group who are not exposed are identified retrospectively and followed from the time of exposure to the present, and in which the incidence (or mortality) rates for the exposed and unexposed are assessed.

Sensitivity: percentage of those who developed a condition who were predicted to be at risk.

Specificity: percentage of those correctly predicted not to be at risk.

Systematic review: A way of finding, assessing and using evidence from studies (usually RCTs) to obtain a reliable overview.

Validity: The extent to which a variable or intervention measures what it is supposed to measure or accomplish.

Internal validity: of a study refers to the integrity of the design.

External validity: of a study refers to the appropriateness by which its results can be applied to non-study patients or populations.
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1 EXECUTIVE SUMMARY

The National Institute for Clinical Excellence ('NICE' or 'the Institute') commissioned the National Collaborating Centre for Nursing and Supportive Care (NCC-NSC) to develop guidelines on the use of pressure-relieving devices (specifically beds, mattresses and overlays) for the prevention of pressure ulcers for use in the NHS in England and Wales to supplement the NICE inherited guideline on risk assessment and prevention published in 2001. This follows referral of the topic by the Department of Health and Welsh Assembly Government. This document describes the methods for developing the guidelines and presents the resulting recommendations. It is the source document for the short-form and patient versions of the guidelines which will be published by NICE. The guidelines were produced by a multidisciplinary guideline development group and the development process was undertaken by the NCC-NSC.

The main area examined by the guideline was:

- the most clinically and cost effective beds, mattresses or overlays for preventing pressure ulcers

Additional areas included:

- the evidence for linking risk assessment to allocation of pressure-relieving devices
- differences in comfort and acceptability ratings, ease of use and adverse events between the different devices
- quality of life implications associated with different use of pressure-relieving devices
- the groups are particularly high risk of developing pressure ulcers
- the costs of preventing pressure ulcers for both the health services and patients/carers and the costs to patients and carers of pressure-relieving devices.

Recommendations for good practice based on the best available evidence of clinical and cost effectiveness are presented. However, there was a lack of formal economic evaluations and quality of life data, and the clinical effectiveness data were of variable quality. Furthermore, very little published research relating to the paediatric population exists. Consequently, not all of the areas examined were able to be fully addressed. Evidence published after October 2002 was not considered.
The recommendations in this document are not designed to be used as a 'standalone' product and should be used in conjunction with the existing NICE (2001) guidelines on risk assessment and prevention. The NICE guidelines can be found on the NICE web-site at: http://www.nice.org.uk/Docref.asp?d=16477

Of particular importance in the NICE (2001) guidelines are the sections on risk assessment. The present guideline draws on some of that information to inform the recommendation on holistic assessment prior to allocation of pressure-relieving devices.

As mentioned above, the work described here completes the NICE-inherited guideline on risk assessment and prevention. It is likely that in the future, NICE will publish the current guideline, the inherited guideline on risk assessment and prevention, the forthcoming guidelines on management (treatment) of pressure ulcers (currently being developed jointly by the RCN and NICE) and guidelines on woundcare as one publication.

Healthcare professionals should use their clinical judgement and consult with patients when applying the recommendations which aim at reducing the negative physical, social and financial impact of pressure ulcers.

A short-form version for health professionals and a version for patients and carers (Information for the Public) are available.
2 PRINCIPLES OF PRACTICE (based on RCN 2001) AND SUMMARY OF NICE RECOMMENDATIONS

Principles of practice

2.1 Person-centred care

- Patients and their carers should be made aware of the guideline and its recommendations and be referred to the version for the public.
- Patients and their carers should be involved in shared decision-making about pressure-relieving devices.
- Health professionals are advised to respect and incorporate the knowledge and experience of people who have been at long-term risk of developing pressure ulcers and have been self-managing this risk.
- Patients and their carers should be informed about their risk of developing pressure ulcers, especially when they are transferred between care settings or discharged home.

2.2 A collaborative inter-disciplinary approach to care

- All members of the inter-disciplinary team should be aware of the guidelines and all care should be documented in the patient's healthcare records.

2.3 Organisational issues

- An integrated approach to pressure ulcer prevention is needed, with a clear strategy and policy supported by management.
- Care should be delivered in a context of continuous quality improvement where improvements to care following guideline implementation are the subject of regular feedback and audit.
- Commitment to and availability of education and training are needed to ensure that all staff, regardless of profession, are given the opportunity to update their knowledge base and are able to implement the guideline recommendations.
- Patients should be cared for by personnel who have undergone appropriate training in recognising the risk factors that contribute to the development of pressure ulcers, and who know how to initiate and maintain correct and suitable preventative measures. Staffing levels and skill mix should reflect the needs of patients.
Summary of guideline recommendations

1. Decisions about which pressure-relieving device to use should be based on an overall assessment of the individual. Holistic assessment should include:
   - identified levels of risk
   - skin assessment
   - comfort
   - general health state
   - lifestyle and abilities
   - critical care needs, and
   - acceptability of the proposed pressure-relieving equipment to the patient and/or carer

   and should not be based solely on scores from risk assessment scales. [D]

2. All individuals assessed as being vulnerable to pressure ulcers should as a minimum provision be placed on a high-specification foam mattress with pressure-relieving properties. [B]

3. Where patients are assessed as having an elevated risk of developing pressure ulcers, consideration should be given to the use of equipment such as alternating pressure mattresses or other high-tech pressure-relieving systems. [D]

4. All individuals undergoing surgery and assessed as being vulnerable to pressure ulcers should as a minimum provision be placed on either a high-specification foam theatre mattress or other pressure-redistributing surface. [D]

5. The provision of pressure-relieving devices needs a 24-hour approach. It should include consideration of all surfaces used by the patient. [D]

6. Support surface and positioning needs should be assessed and reviewed regularly and determined by the results of skin inspection, patient comfort, ability and general state. Thus repositioning should occur when individuals are on pressure-relieving devices. [D]

7. The management of a patient in a sitting position is also important. Even with appropriate pressure relief, it may be necessary to restrict sitting time to less than 2 hours until the condition of an individual with an elevated risk changes. [D]

8. A pressure ulcer reduction strategy should incorporate a co-ordinated approach to the acquisition, allocation and management of pressure-relieving equipment.
Pressure-relieving devices: draft for consultation

The time elapsing between assessment and use of the device should be specified in this strategy. [D]

9. Healthcare professionals should be educated about:
   - pressure ulcer risk assessment and prevention
   - selection, use and maintenance of pressure-relieving devices
   - patient education and information giving. [D]

10. Individuals vulnerable to or at elevated risk of developing pressure ulcers and their carers, should be informed verbally and in writing about:
   - the prevention of pressure ulcers using pressure-relieving strategies
   - the use and maintenance of pressure-relieving devices
   - where they can seek further advice and assistance. [D]

2.4 Equipment safety

Equipment safety is an important issue in relation to the use of pressure-relieving devices. In particular, cross-infection is possible where equipment is inadequately decontaminated between patients (Orr et al. 1994) and injury is possible if users of such equipment (patients, carers and health professionals) have not been educated about appropriate use. Guideline users are therefore referred to the standards on medical devices management and decontamination of re-usable medical devices (Medical Devices Agency 2002a, 2002b). Users of these guidelines are encouraged to familiarise themselves with the sections of these documents relevant to the use and de-contamination of pressure-relieving devices. Anecdotal evidence suggests that if there is no access to adequate decontamination facilities it may be desirable to lease of pressure-relieving devices. The advantage of leasing in these circumstances is that the devices can be returned to the manufacturer for thorough decontamination after each patient use.
3 BACKGROUND TO THE CURRENT GUIDELINES

In 1998, the Department of Health (DoH) commissioned the Royal College of Nursing (RCN) to develop clinical guidelines on pressure ulcer risk assessment and prevention. During the development of these guidelines, the National Institute of Clinical Excellence (NICE) was established. It was decided to submit the pressure ulcer risk assessment and prevention guidelines to the NICE guideline assessment process, to allow them to be considered for adoption by NICE under the ‘inherited’ clinical guidelines programme.

Because the NICE guideline assessment criteria and processes were being developed when the guidelines were submitted, there was a time delay of one year in assessing the guidelines. During this time, due to demand from nurses, the RCN decided to publish their full guideline on pressure ulcer risk assessment and prevention (Rycroft-Malone and McInnes 2001).

The guideline was also eventually published as a NICE ‘inherited’ clinical guideline in 2001 (due for review in 2005). This guideline adopted all the recommendations of the RCN guideline with the exception of those relating to pressure-relieving devices (ie. beds, mattresses and overlays) (National Institute of Clinical Excellence 2001). This was because the RCN guideline developers were not in a position to undertake a full assessment of the cost-effectiveness of these devices. Consequently, recommendations on the use of pressure-relieving devices for the prevention of pressure ulcers in the NICE inherited clinical guidelines were omitted, although recommendations on the use of aids (water-filled gloves, doughnut type devices etc) and seating were included.

In March 2002, the National Collaborating Centre for Nursing and Supportive Care (NCC-NSC) was commissioned by NICE to develop guidelines on pressure-relieving devices for the prevention of pressure ulcers in primary and secondary care that included information on cost-effectiveness. The remit from the DoH and Welsh Assembly Government was as follows:

The existing NICE guideline on pressure ulcer risk assessment and prevention is to be supplemented by a guideline on pressure-relieving devices that includes consideration of their cost-effectiveness.

Consequently, the clinical effectiveness evidence was updated based on the health technology assessment by Cullum et al. (2001) and an economic analysis was undertaken which included the development of reviews on the economic and costing evidence, epidemiology of pressure ulcers in the UK and quality of life issues.
Importantly, the present guideline recommendations are not intended for use as a ‘stand-alone’ guideline. The guideline recommendations outlined here must be used in conjunction with the NICE inherited guideline on risk assessment and prevention (2001) or the RCN guidelines (2001). Those guidelines give comprehensive recommendations on identifying individuals vulnerable to developing pressure ulcers, risk factors, skin inspection, use of aids (e.g. sheepskins, water-filled gloves and doughnut-type devices), positioning, seating and education and training. Many of these factors need to be considered in relation to decisions about the use of pressure-relieving devices, as pressure ulcer prevention strategies usually comprise a combination of interventions.

Of interest, is that the RCN is to commence the development of a guideline on the management (treatment) of pressure ulcers, in collaboration with NICE. It is envisaged that NICE will eventually package the ‘treatment’ guideline; the NICE inherited guidelines on risk assessment and prevention, guidelines on woundcare and the pressure-relieving devices guideline in one document.

### 3.1 Clinical need for the guideline

Pressure ulcers represent a major burden of sickness and reduced quality of life for patients and their carers (Franks et al. 1999). The financial costs to the NHS are also substantial (Cullum et al. 1995). Pressure ulcers have been recorded as occurring in 4–10% of patients admitted to a UK district general hospital (the precise rate depends on case mix), and occur in an unknown proportion of patients in the community (Cullum et al. 2001). A recent review of epidemiological studies (Kaltenthaler et al. 2001) suggests that prevalence ranges for UK hospitals range from 5-32% (case-mix unadjusted).

It has been estimated that preventing and treating pressure ulcers in a 600-bed general hospital costs between £600,000 and £3 million a year (Touche Ross 1993). The cost of treating a patient with a stage 4 pressure ulcer has been calculated as £40,000 (Collier 1999). In particular, there is a high cost associated with prevention of pressure ulcers using pressure-relieving surfaces and a need for robust economic evaluations to aid rational use of these devices (Cullum et al. 2001).

A growing body of knowledge about the effectiveness of pressure-relieving devices (such as mattresses) in preventing the development of pressure ulcers and an increased use of them in NHS hospitals has highlighted the need for clinical practice recommendations that incorporate an analysis of their potential cost-effectiveness.
3.2 What are pressure ulcers?

Pressure ulcers (also known as pressure damage, pressure injuries, pressure sores, bed sores, decubitus ulcers) are areas of localised damage to the skin and underlying tissue and are believed to be caused by a combination of pressure, shear and friction. They usually occur over bony prominences and are common among the very ill, those with neurological difficulties and the immobile. Some other groups at risk include: maternity patients who may be disabled through existing conditions such as spina bifida; individuals who have had epidural analgesia or anaesthesia and some paediatric patients, such as neonates requiring care in the neonatal intensive care unit.

Pressure ulcers can be graded to classify the degree of tissue damage that has occurred. An example of a common grading scheme is as follows:

**Stage 1:** Pressure ulcer is defined as an erythema of the intact skin. The reddened area remains reddened after pressure is relieved. Key features include: persistent discoloration of the skin, including non-blanchable erythema: blue black/ purple/ discoloration.

**Stage 2:** Pressure ulcer is defined as partial thickness skin loss involving epidermis or dermis. The ulcer is superficial and presents clinically as an abrasion, blister or swollen crater.

**Stage 3:** Pressure ulcer involves full thickness skin loss involving damage or necrosis of subcutaneous tissue that may extend down to, but not through, underlying fascia, bone, tendon or joint capsule.

**Stage 4:** Pressure ulcer presents as a full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone tendon or joint capsule.

(Adapted from pressure sores: a key quality indicator. DoH 1993)

3.3 Groups at risk

Groups at particularly high risk of having a pressure ulcer have been reported in depth in the RCN guidelines on pressure ulcer risk assessment and prevention (2001) and are summarised here. In brief, an individual's potential to develop pressure ulcers may be influenced by the following intrinsic risk factors: reduced mobility or immobility; sensory impairment; acute illness; level of consciousness; extremes of age; previous history of pressure damage; vascular disease; severe chronic or terminal illness; malnutrition. Extrinsic factors include: pressure; shearing, friction, medication, moisture to the skin.
3.4 What are pressure-relieving devices?

There are two main approaches to preventing pressure ulcers using pressure-relieving devices:

1. Use of a conforming support surface to distribute the body weight over a large area (low-tech devices)
2. Use of an alternating support surface where inflatable cells alternately inflate and deflate (high-tech devices) (Cullum et al. 2001).

Under the definitions set out by the RCN guideline (Rycroft-Malone and McInnes 2001), pressure-relieving devices covers all types of beds, mattresses, overlays (including those used in the operating theatre), cushions and other devices aimed at pressure redistribution (Cullum et al. 2002). However, as the NICE inherited guideline on risk assessment and prevention provided recommendations on cushions and aids, the remit of the present guideline is to provide recommendations only on the clinical and cost-effectiveness of pressure-relieving devices not included in the 2001 guideline, i.e. beds, mattresses and overlays.

Beds, mattresses and overlays differ considerably and can be classified in various ways. The classification of devices used for this guideline is explained under 'Interventions to be covered'. Pressure-relieving devices vary in the materials that they are constructed of and their pressure-relieving mechanisms. For example, constant low pressure (CLP) devices mould around the patient to distribute their weight over a larger area. Alternating pressure (AP) devices mechanically vary the pressure beneath patients so that the duration of pressure is reduced (Cullum et al. 2001). A glossary of devices is attached – see Appendix A.
4 AIMS OF THE GUIDELINE

- To evaluate and summarize the clinical and cost evidence for the use of pressure-relieving devices, as defined below, in preventing pressure ulcers;
- To highlight gaps in the research evidence;
- To formulate evidence-based and where possible, cost-effective clinical practice recommendations on the prevention of pressure ulcers using pressure-relieving devices based on the best evidence available to the GDG (guideline development group); and
- To consider the resource implications of using pressure-relieving devices to prevent pressure ulcers.

4.1 Who the guideline is for

The guideline is of relevance to:

- those who are vulnerable to or at elevated risk of developing pressure ulcers;
- families and carers;
- healthcare professionals who share in caring for those who are vulnerable to or at elevated risk of developing pressure ulcers;
- those with responsibilities for purchasing pressure-relieving devices.

However, as mentioned above, this guideline should be used in conjunction with the NICE ‘inherited’ guideline on risk assessment and prevention.

4.2 Groups covered by the guideline

The guideline recommendations apply to individuals of all ages (however, no trials were identified specific to the paediatric population).

Although the guideline does not cover treatment of existing pressure ulcers, the guideline is relevant for preventing pressure ulcers on other areas of the patient's body and further pressure damage to existing pressure ulcers.

4.3 Groups not covered

The guideline does not include recommendations on the treatment of existing pressure ulcers; this will be addressed in a separate guideline being jointly developed by NICE and the RCN which is due for publication in 2004.
4.4 Healthcare setting

The guideline covers the use of pressure-relieving devices by primary and secondary care professionals and carers who are involved in the care of individuals in hospital, nursing homes, supported accommodation and at home, who are vulnerable to or at risk of developing pressure ulcers (including those undergoing surgery and postoperative care). It also provides individuals with information relevant to care received as part of the process of pressure ulcer risk assessment and prevention.

This is an NHS guideline. Although it addresses the interface with other services, such as those provided by social services, secure settings and the voluntary sector, it does not include services exclusive to these sectors.

4.5 Interventions covered

The guideline includes information on whether the following pressure-relieving or pressure-redistributing devices are effective and cost-effective. The classification used in this guideline is based on that used in the Cullum et al. (2001) systematic review (published as a Health Technology Assessment report (HTA)), as this was agreed to be the most practical and the review was being updated for the purpose of this guideline. Further details on the devices listed below are in the ‘glossary of pressure-relieving devices’ (Appendix A).

4.5.1 Low-tech devices

2. Alternative foam mattresses/overlays (for example, convoluted foam, cubed foam); these are conformable and aim to redistribute pressure over a larger contact area.
3. Gel-filled (or viscoleastic) mattresses/overlays
4. Fibre-filled mattresses/overlays
5. Fluid-filled mattresses/overlays
6. Air-filled mattresses/overlays.

4.5.2 High-tech devices

1. Alternating-pressure mattresses/overlays: the patient lies on air-filled sacs, which sequentially inflate and deflate and relieve pressure at different anatomical sites for short periods; these devices may incorporate a pressure sensor.
2. Air-fluidised beds: warmed air is circulated through fine ceramic beads covered by a permeable sheet; these allow support over a larger contact area.
3. Low-air-loss overlays/mattresses/beds: patients are supported on air-filled sacs inflated at a constant pressure, through which air is able to pass.

4. Turning beds/frames: beds that either aid manual repositioning of the patient or reposition the patient by motor-driven turning and tilting.

4.6 Interventions not covered

The guideline is relevant to, but does not cover risk factors, skin inspection, seating, or general positioning of patients (unrelated to pressure-relieving devices) and pressure-relieving aids (ie. water-filled gloves). Although aspects of risk assessment related to the allocation of pressure-relieving devices are covered, the reader is referred to detailed discussion of this topic in the NICE (2001) guidelines.

Pressure-relieving aids such as water-filled gloves, sheepskins, doughnut-type devices, cushions, limb protectors and seating were not considered, as recommendations about their use were issued by NICE (due for review in 2005). The NICE (2001) guidelines reported that there is insufficient evidence for sheepskins, wheelchair cushions and limb protector pads as pressure-relieving devices.

4.7 Guideline Development Group

The guideline recommendations were developed by a multidisciplinary and lay Guideline Development Group (GDG) convened by the NICE-funded National Collaborating Centre for Nursing and Supportive Care (NCC-NSC) with membership approved by NICE. Members include representatives from:

- consumer groups;
- nursing;
- field of tissue viability and wound care
- medicine;
- allied health;
- researchers; and
- staff from the NCC-NSC

A list of GDG members is attached (Appendix B). The GDG met four times between May 2002 and March 2003. An additional meeting to formulate patient-related review questions relating to the guideline topic was held in July 2002.

All members of the GDG were required to make formal declarations of interest at the outset, which were recorded. GDG members were also asked to declare interests at the beginning of each GDG meeting. This information is recorded in the meeting minutes and kept on file at the NCC-NSC.
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For the sections on quality of life, epidemiology, cost and economics, staff from the NCC-NSC devised and undertook the literature searches and retrieved, appraised, and summarized the evidence. For the clinical effectiveness data, the Cochrane Wounds Group (CWG) searched for studies additional to those included in the Cullum et al. (2001) review until October 2002. Staff from the NCC-NSC undertook eligibility and quality assessments of potential articles forwarded by CWG and dual data extraction to update the existing clinical effectiveness review (Cullum et al. 2001). Writing up of the results of the updated review was done jointly by the NCC-NSC and CWG. NCC-NSC staff graded the evidence and composed successive drafts of the recommendations and the full guideline documents (which includes full version of guidelines; short-form version and patient version) based on the evidence reviews and GDG input and deliberations. The GDG formulated and graded the recommendations.
5 METHODS USED TO DEVELOP THE GUIDELINE

5.1 Summary of development process

The methods used to develop this guideline are based on those outlined by Eccles and Mason (2001). The structure of the recommendations section (section 6) (ie, recommendations; evidence statements, evidence narrative and guideline development group commentary) came from McIntosh et al. (2001).

The following sources of evidence were used to inform the guideline:

- update of the systematic review by Cullum et al. (2001);
- reviews of the evidence on costs and economic evaluations;
- reviews of quality of life and UK epidemiology studies;
- analysis of epidemiological data;
- analysis of clinical effectiveness data;
- economic modelling;

The stages used to develop this guideline were as follows:

- develop scope of guideline;
- convene multidisciplinary guideline development group;
- review questions set (see p. 19);
- identify sources of evidence;
- retrieve potential evidence;
- evaluate potential evidence relating to cost/economics; quality of life and epidemiology for eligibility quality and relevance;
- update HTA clinical effectiveness review by Cullum et al. (2001);
- extract relevant data from studies meeting methodological and clinical criteria;
- interpret each paper taking into account the results, including where reported, the beneficial and adverse effects of the interventions, cost, comfort and acceptability to patients, level of evidence, quality of studies, size and precision of effect and relevance and generalisability of included studies to the scope of the guideline;
- prepare evidence reviews and tables which summarize and grade the body of evidence;
- formulate conclusions about the body of available evidence based on the evidence reviews by taking into account factors above;
- agree final recommendations and apply recommendation gradings;
- submit first drafts (short version and full version) of guidelines for feedback from NICE registered stakeholders.
• consideration by GDG of stakeholders comments;
• submit final drafts of all guideline versions (including patient version, algorithm and audit criteria) to NICE for second stage of consultation;
• consideration by GDG of stakeholders comments;
• final copy submitted to NICE.

Because the remit from the DoH and Welsh Assembly Government was to complete the inherited version of the guidelines on risk assessment and prevention, the main clinical question was set by the DoH and Welsh Assembly Government remit as follows:

• What are the most clinically and cost effective beds, mattresses or overlays for preventing pressure ulcers?
  (Source of evidence: updated clinical effectiveness review and cost/economic evidence review)

Additional questions addressed by the evidence reviews included:

• What is the evidence for linking risk assessment to allocation of pressure-relieving devices?
• Are there any differences in comfort and acceptability ratings, ease of use and adverse events between the different devices?
  (Source of evidence: updated clinical effectiveness review)
• Are there quality of life implications associated with different pressure-relieving devices?
  (Source of evidence: updated clinical effectiveness review and ‘quality of life’ evidence review)
• Which groups are at particularly high risk of developing pressure ulcers?
  (Source of evidence: epidemiological review)
• What are the costs of preventing pressure ulcers for both the health services and patients/carers and what are the costs to patients and carers of pressure-relieving devices?
  (Source of evidence: cost/economic evidence reviews; economic modelling).

The methods for each review are reported in sections 5.2 and 5.3. The results are reported in 5.6-5.9.

More details are given in section 5.10.
5.2 Clinical effectiveness review methods

5.2.1 Background

In April 2001, a Health Technology Assessment was published on pressure-relieving devices for the prevention and treatment of pressure ulcers (Cullum et al. 2001). This review updated the earlier Cochrane systematic review ‘Beds, mattresses and cushions for pressure sore prevention and treatment’. For the purposes of this guideline, the HTA review by Cullum et al. (2001) was then updated by the CWG and NCC-NSC staff to provide the most up-to-date and rigorous source of clinical effectiveness evidence.

The review methods and results are summarised below from the updated systematic review. (NB: Although the guideline scope excludes pressure-relieving aids such as cushions and limb protectors, the review of evidence for the update included these devices. At the time of writing, the updated review had been forwarded to the CWG for editorial sign-off.

5.2.2 Objectives

The review sought to answer the following questions:

- Do pressure-relieving beds, mattresses and overlays reduce the incidence of pressure ulcers compared with standard support surfaces?
- Which types of pressure-relieving surfaces are the most effective in different patient groups and settings?

5.2.3 Selection criteria

Types of studies

RCTs comparing beds, mattresses, overlays which measured the incidence of new pressure ulcers as an objective measure of outcome.

RCTs are essential for the establishment of the safety and effectiveness of pressure-relieving devices and products (Ferrell 1998). Lack of data from RCTs may result in increased costs as a result of using devices, products and services that are not always safe, let alone effective (Ferrell 1998).

Economic evaluations were included only if they were part of an RCT.

No restriction on the basis of language or publication status or year of study.
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**Types of participants**

Patients receiving health care who were deemed to be at risk of pressure ulcer development, in any setting.

**Types of intervention**

Studies which evaluated the following interventions for pressure ulcer prevention or treatment were included in the update of the clinical effectiveness review. However, not all interventions listed were relevant for consideration by the GDG. This is because:

1. The interventions were either outside the remit of the guideline (12, 14 and 16)

2. The particular products evaluated are no longer available (these include 7 and 8, as although both water-filled and bead-filled mattresses were associated with a decrease in the incidence of pressure ulcers in two trials published in the early 1980s, the products are no longer available).

1. Standard foam mattresses
2. Alternative foam mattresses/overlays (e.g. high-specification foam, convoluted foam, cubed foam): these are conformable and aim to redistribute pressure over a larger contact area
3. Gel-filled (or viscoelastic) mattresses/overlays: mode of action as above
4. Fibre-filled mattresses/overlays: mode of action as above
5. Fluid-filled mattresses/overlays: mode of action as above
6. Air filled mattresses/overlays: mode of action as above
7. Water-filled mattresses/overlays: mode of action as above
8. Bead filled mattresses/overlays: mode of action as above
9. Alternating pressure mattresses/overlays: Patient lies on air filled sacs which sequentially inflate and deflate and relieve pressure at different anatomical sites for short periods; may incorporate a pressure sensor.
10. Air fluidised beds: warmed air circulated through fine ceramic beads covered by a permeable sheet; allows support over a larger contact area.
11. Low-air-loss devices: patients are supported on air-filled sacs inflated at a constant pressure, through which air is able to pass.
13. Turning beds/frames: these work by either aiding manual repositioning of the patient, or by motor driven turning and tilting.
14. Wheelchair cushions: may be conforming and therefore reduce contact pressures by increasing surface area in contact, or mechanical eg. alternating pressure.
15. Operating table overlays: as above.
16. Limb protectors: *pads and cushions of different forms to protect bony prominences.*

Items 1 – 8 were classified as low-tech surfaces and 9 – 11 as high-tech.

**Types of outcome**

Incidence of new pressure ulcers.

Grades of new pressure ulcers.

Where reported, information on comfort, acceptability, ease of use, adverse events, durability, reliability and costs was recorded.

Studies which used only subjective measures of outcome were excluded, as were studies which reported only proxy or intermediate measures such as the pressure on different parts of the body (interface pressure). The reason for excluding such studies is that interface pressure has serious limitations as a proxy for clinical outcome, as the mechanisms that lead to the development of pressure ulcers involves the complex interaction of a variety of factors (Cochrane 2002).

Some studies, when reporting outcome interventions of prevention do not differentiate between people developing stage 1 ulcers (in which the skin is unbroken) and those developing more severe ulcers. Studies which compared the incidence of pressure ulcers of stage 2 or greater are more likely to be reliable. However all studies were included, irrespective of whether stage 1 ulcers were described separately.

**5.2.4 Search strategy**

Nineteen electronic databases were searched between 1966 and June 1998 using a sensitive search strategy designed in collaboration with an information specialist in CRD.

Subsequently, the Specialist Trials Register of the Cochrane Wounds Group (compiled and regularly updated from searches of the Cochrane Controlled Trials Register), Medline, Cinahl, Embase, etc. was searched up to October 2002.

The electronic search was supplemented by a handsearch of five specialist wound care journals, twelve conference proceedings and a search of systematic reviews held on the NHS CRD Database of Abstracts of Reviews of Effectiveness (DARE). The bibliographies of all retrieved and relevant publications were searched for further studies. Relevant economic evaluations were searched for adding economic-related search terms to those used in the search for clinical trials. Authors of trials were contacted and asked to provide details of any associated economic evaluations.
Details of the search strategy are included in appendix C. Retrieved studies were assessed for relevance by a single reviewer and decisions on final inclusion checked by a second reviewer; disagreements were resolved by discussion with a third reviewer. Rejected studies were checked by the CWG. Where study details were lacking, the authors were invited to provide further information.

5.2.5 Data abstraction

Data from included trials were extracted by two reviewers into pre-prepared data extraction tables. Discrepancies were discussed and resolved. The following data were extracted from each study:

- patient inclusion/exclusion criteria
- care setting
- key baseline variables by group eg. age, sex, baseline risk, baseline area of existing ulcers
- description of the interventions and numbers of patients randomised to each intervention
- description of any co-interventions/standard care
- duration and extent of follow up
- outcomes (incidence and severity of new pressure ulcers)
- acceptability and reliability of devices if reported

If data were missing from reports then attempts were made to contact the authors to complete the information necessary for the critical appraisal. If studies were published more than once, the most detailed report was used as the basis of the data extraction.

5.2.6 Appraisal of methodological quality

The methodological quality of each trial was assessed by two researchers independently. The following quality criteria were used:

- description of inclusion and exclusion criteria used to derive the sample from the target population
- description of a priori sample size calculation
- evidence of allocation concealment at randomisation
- description of baseline comparability of treatment groups
- outcome assessment stated to be blinded
- incident ulcers described by severity grading as well as frequency (Stage 1 ulcers are not breaks in the skin and are subject to more inter-rater variation)
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- clear description of main interventions.

5.2.7 Data synthesis

For each trial, relative risk (RR) was calculated for outcomes such as number of patients developing ulcers and number of pressure ulcers healed. 95% confidence intervals (95% CI) were included when sufficient detail allowed their calculation. The results from replicated studies were plotted on to graphs and discussed by narrative review. Unique comparisons were not plotted and the relative risk is stated in the text. Individual study details are presented in the evidence table (Appendix G). Where there was more than one trial comparing similar devices using the same outcome, and in the absence of obvious methodological or clinical heterogeneity, statistical heterogeneity was tested for by chi-squared test. In the absence of significant statistical heterogeneity, studies with similar comparisons were pooled using a fixed effects model (Clarke 1999). If heterogeneity was observed, both random and fixed effects models were used to pool the data. All statistical analysis was performed on Revman (v3.1.1) and conducted by the CWG.

5.3 Cost effectiveness review methods

5.3.1 Background

To fulfil the DoH and Welsh Assembly Government remit, NICE requested that the cost effectiveness evidence of pressure-relieving devices be assessed. In accordance with the objectives of the scope, cost effectiveness was addressed in the following way:

- a comparison of the cost and cost effectiveness of pressure ulcer-relieving beds, mattresses and overlays compared with standard support surfaces; and
- an investigation of which types of pressure-relieving surfaces are the most cost effective for prevention of pressure ulcers.

In April 2001, a Health Technology Assessment was published on pressure-relieving devices for the prevention and treatment of pressure ulcers (Cullum et al. 2001). In this report, the variations in the costs of these devices was reported between £30,000 for some bed replacements and £100 for some foam overlays. The need to identify information on the cost effectiveness of this equipment was highlighted to aid rational use.

The aim of the review was two-fold. Firstly to identify economic evaluations that had been conducted alongside trials, but also to identify evidence that could be used in cost effectiveness modelling.
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Where there was no clear evidence of comparative clinical benefit - for example, between the various more expensive pressure-relieving devices - it was proposed that a simple graphical representation be constructed of the additional reduction in relative risk required for more expensive pressure-relieving devices to remain cost neutral.

Where comparative clinical effectiveness data between devices was available, it was proposed that models be developed to explore the incremental cost effectiveness of different devices.

The cost effectiveness estimates could be presented as follows:
• incremental cost per pressure ulcer averted and
• incremental cost per quality adjusted life year.

5.3.2 Incremental cost per pressure ulcer averted
In the first instance, the incremental cost-effectiveness between different devices could be reported in terms of the incremental cost per pressure ulcer averted. This is a ratio of the difference in costs to the health service of using different devices divided by the difference in the number of pressure ulcers averted. The cost to the health service includes any savings derived through using pressure ulcer relieving devices:

\[
\text{ Incremental cost per pressure ulcer averted } = \frac{\text{Difference in costs to the health service between pressure-relieving devices}}{\text{Difference in number of pressure ulcers averted}}
\]

5.3.3 Incremental cost per quality adjusted life year
If possible, the likely decrement in quality adjusted life years associated with a pressure ulcer of a particular stage could be estimated, and cost-effectiveness then be reported in terms of the cost per quality-adjusted life year gained (QALY). Costs incurred by patients and their informal carers is documented and reported where available.

\[
\text{ Incremental cost per quality adjusted life year } = \frac{\text{Difference in costs to the health service between pressure-relieving devices}}{\text{Difference in quality adjusted life years}}
\]

The information requirements for each type of analysis are shown in table 1.

Table 1: Information requirements for cost effectiveness models
5.3.4 Comparison of relative risk of developing a pressure ulcer between devices

This information was collected as part of the clinical effectiveness review. The extent that cost effectiveness can be estimated and the comparisons that can be made is dependent on the quality of the clinical effectiveness information. Where there was little evidence on the relative clinical effectiveness it was only possible to report the difference in costs.

5.3.5 Costs of pressure-relieving devices

In order to estimate the cost (direct cost to the health service) per day of using these devices the following information was required:

- purchase price of the device;
- life span of the device e.g. 8 years; and
- maintenance costs of the device.

There may also be additional costs such as training staff to use devices and storage whilst not in use.

Certain beds may require less nursing time than others, if it is easier to turn patients for example on certain products.

The cost of devices is further complicated by the use of different purchasing mechanisms used to purchase beds.
Consequently studies were sought that identified the costs of pressure-relieving devices in the UK.

5.3.6 Costs of treating pressure ulcers

In order to estimate the savings (to the health service) per pressure ulcer averted, estimates of the cost of treating patients with pressure ulcers are needed.

The literature was searched to identify patient level costs of treating pressure ulcers in the UK up until 2001 to estimate the cost per case of treating pressure ulcers.

5.3.7 Epidemiology of the absolute risk of developing pressure ulcers

Information was required about:
- the absolute risk of developing pressure ulcers for the groups to be covered by the guidelines; and
- which groups are at particularly high risk of having a pressure ulcer.

A review of the UK epidemiology literature was undertaken to obtain this information (see section 5.9).

5.3.8 Quality of life and estimates of quality adjusted life years

The effects of pressure ulcers on patients’ quality of life and length of life is an important consideration in valuing pressure ulcer prevention. A pressure ulcer can cause the patient restrictions in activities (physical and social), pain, psychological distress, as well as have a negative impact on social, emotional and financial areas of life. Lastly, distress at the patient's condition may be experienced by the patient's family and friends.

Consequently, studies were sought which:
- examined the quality of life implications of having a pressure ulcer for both patients and carers;
- measured quality of life implications of pressure ulcers that can be used to compare the implications of having a pressure ulcer with other health problems; and
- examined associations between quality of life and different pressure-relieving devices.

(See section 5.8).
5.3.9 Aims of literature search

The aims of the cost-effectiveness review were to identify the most up-to-date information that was generalisable to the UK context, to facilitate the cost effectiveness modelling process. Cost data, economic evaluations, epidemiological and quality of life evidence were all sought as part of this review in order to comprehensively inform UK estimates and uncertainty ranges of the cost of pressure-relieving devices, cost of treating pressure ulcers and quality of life estimates.

Consequently, searches were undertaken by the NCC-NSC to identify:
1. Economic evaluations and costing studies of pressure ulcers and/or pressure-relieving devices (cost-effectiveness review);
2. Quality of life measures for patients who have pressure ulcers and/or who use pressure-relieving devices (quality of life review); and
3. Studies which may provide information about the absolute risk of developing pressure ulcers for different patient groups in the UK (epidemiological review).

For economic evaluations, RCTs were sought. For costing studies and quality of life the study design inclusion criteria were necessarily broad in order to obtain maximize the likelihood of obtaining useful data. For the epidemiological studies, cohort designs were sought for incidence studies and cross-sectional designs for prevalence studies (Sackett et al. 2000). For all topics, systematic literature search methods were used covering a number of databases (see Appendix C).

5.3.10 Selection criteria

Economic evaluations

Comparative economic evaluations of pressure-relieving devices for the prevention of pressure ulcers including both costs and outcomes.

Economic evaluations include cost effectiveness, cost utility and cost benefit studies (economic evaluations are defined in the glossary).

Only economic evaluations based on clinical evidence from RCTs, or where modelling was based on either an RCT or meta-analysis of RCTs were considered for inclusion or quasi randomised trials.

No restriction on the basis of language or publication status.

Studies were included from 1990 until May 2002. This date restriction was imposed in order to obtain data relevant to current health care settings and costs.
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Only economic evaluations from OECD countries were included as the aim of the review is to identify cost effectiveness information relevant to the current UK context.

Selection criteria based on types of patients, settings and types of pressure ulcer relieving devices are identical to the clinical effectiveness section.

Information from all economic evaluations of pressure ulcers were considered for inclusion in the costing and/or quality of life reviews.

The quality assessment of the economic evaluations was based on the 32 point checklist used by the British Medical Journal to assist referees in appraisal of economic analyses (Drummond & Jefferson 1996). A score was assigned out of 32 points where each item should be included unless not applicable.

**Costing studies**

All types of costing studies were considered for inclusion, regardless of study design, subject to clear descriptions in the methods of how the resources were costed.

Costing studies included both:

- costs of pressure ulcer relieving devices;
- costs per case of treating pressure ulcers.

Costs to the patient were identified as part of the quality of life search.

No restriction on the basis of language or publication status.

Studies were included from 1992 until May 2002 for treating pressure ulcers and 1997-2002 for the cost of pressure-relieving devices. This date restriction was imposed in order to obtain data relevant to current health care settings and costs.

Only costing studies from the UK were included as the aim of the review was to identify costing information that is relevant to the current UK context.

Selection criteria based on types of patients, settings and types of pressure ulcer relieving devices are identical to the clinical effectiveness section.

**Quality of life**

Studies which investigated the impact of pressure ulcers on patient and carer quality of life and which reported quality of life measures including utilities associated with being bed-ridden were sought.

All quality of life studies involving patients with pressure ulcers were considered for inclusion.
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No restriction on the basis of language or publication status.

Studies were included from 1980 until May 2002. The lower limit of 1980 was chosen because it was considered likely that changes in-patient care practices after that time may have influenced quality of life.

Selection criteria based on types of patients, settings and types of pressure ulcer relieving devices are identical to the clinical effectiveness section.

Epidemiology

The review of epidemiology studies updates a recent review (Kaltenthaler et al. 2001) of UK, USA and Canadian epidemiological studies from 1980-1997. A few classic papers pre-1980 were also included by Kaltenthaler et al. Please refer to Kaltenthaler et al. (2001) for details of studies used in their review). The same criteria for selection were used to select studies for the update:

- UK studies which determined the prevalence and incidence of pressure ulcers
- Studies had to specify
  - the total number who participated
  - the number of patients with pressure ulcers
  - methods used in the calculation
- Date limit: 1997 to April 2002
- Unrestricted setting
- Cohort or cross-sectional designs
- English language studies only.

Data from the new studies were combined with those cited in the original review to examine the impact of study design, setting, and inclusion of stage 1 pressure ulcers on estimates of incidence and prevalence.

5.3.11 Search strategies for reviews of economic evaluations, costing studies, quality of life and epidemiology

The search strategies and the databases searched are presented in Appendix C. All searches were comprehensive and included a large number of databases (see Appendix C). All search strategies were adapted for smaller or simpler databases or for web-based sources which did not allow complex strategies or multi-term searching.

A combination of subject heading and free text searches were used for all areas. Free text terms were checked on the major databases to ensure that they captured descriptor terms and their exploded terms.
Except for the Cochrane review update, hand-searching was not undertaken following NICE advise that exhaustive searching on every guideline review topic is not practical and efficient (Mason et al. 2002).

Reference lists of articles were checked for articles of potential relevance.

Where necessary, data from the literature were supplemented by additional data from other sources for example, the current costs of devices from the NHS.

5.3.12 Sifting process

Once articles were retrieved the following sifting process took place:

- 1st sift: Sift for material that potentially meets eligibility criteria on basis of title/abstract;
- 2nd sift: Full papers ordered that appear relevant and eligible and where relevance/eligibility not clear from the abstract;
- 3rd sift: Full articles are appraised that meet eligibility criteria.

Sifting for relevance at stage one was carried out by one systematic reviewer. The cost/economic references were then sent to the health economist who selected which articles would be ordered. For the quality of life studies and epidemiology studies, the screening and selecting was done by a systematic reviewer. If there was insufficient information contained in the title/abstract to make a decision about eligibility, the full article was ordered.

5.3.13 Data abstraction

For the cost effectiveness studies, the following data were abstracted by a single abstractor:

- details of the study design;
- details of the study population;
- details of the pressure ulcer relieving device e.g. standard mattress versus alternating pressure device;
- details of individual outcome measures used e.g. cost per pressure ulcers prevented;
- details of and source of effectiveness data in economic models, for example, RCT;
- methods of collecting cost data - for example, micro level costing;
- assumptions made by authors developing economic models;
- estimates of the cost effectiveness and range;
- generalisability to the UK context.

For the cost studies, the following data were abstracted by a single abstractor:
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- study design or source of information, reference, date and potential problems with source;
- perspective of costing;
- device costed or severity of pressure ulcer costed;
- estimate of cost and range;
- generalisability to the UK setting.

For quality of life studies, the following data were abstracted by two reviewers:
- study design;
- patients and settings;
- type of measurement tool used;
- outcomes;
- quality of life estimate and range.

For epidemiological studies, the following data were abstracted by two reviewers:
- details of the study design;
- details of the study population (including sample selection);
- source of information, reference, date and potential problems with source;
- inclusion of stage 1 (blanching erythema) as can be argued that this artificially raises the incidence and prevalence and should be taken into account when making comparisons;
- comparability of groups (if more than one group sampled);
- follow-up period (if incidence study);
- calculations of prevalence/incidence.

No formal analysis of inter-rater reliability of dual data extraction was performed. Differences were resolved by discussion.

Masked assessment, whereby data extractors are blind to the details of journal, authors etc, was not undertaken because there is no evidence to support the claim that this minimizes bias (Cochrane 2001).

Once individual papers were retrieved, the articles were checked for methodological rigour (using quality checklists appropriate for each study design), applicability to the UK and clinical significance. Assessment of study quality concentrated on dimensions of internal validity and external validity. Information from each study which met the quality criteria was summarized and entered into evidence tables.

All data extraction forms are contained in Appendix E.
5.4 Submission of evidence process

In March 2002, stakeholders registered with NICE (see Appendix F), were invited to submit a list of evidence for consideration to ensure that relevant material to inform the evidence base was not missed. The criteria for the evidence included:

- systematic reviews;
- randomised controlled trials (RCTs) that examine clinical or cost effectiveness, and/or quality of life and economic analyses based on these findings;
- representative epidemiological observational studies which have assessed the incidence and prevalence of pressure ulcers in the UK;
- qualitative studies/surveys that examine patient/carer experiences of having a pressure ulcer;
- studies of any design which have attempted to formally:
  - assess the cost effectiveness/utility of pressure-relieving devices
  - assess the cost of having a pressure ulcer or using pressure-relieving devices
  - assess quality of life or used cost-utilities in relation to having a pressure ulcer.

Information not considered as evidence included:

- studies with ‘weak’ designs when better studies are available;
- commercial in confidence material;
- unpublished secondary endpoint trial data, ‘data-on-file’ and economic modelling;
- promotional literature;
- papers, commentaries or editorials that interpret the results of a published study;
- representations or experiences of individuals not collected as part of properly designed research.

Initial submissions were received from:

- Kaymed;
- Medical Support Systems;
- Pegasus;
- British Geriatrics Society;
- College of Occupational Therapists.

Two submissions were followed up to request the full references but these did not provide useful data for the guideline.
Other submitted material was irrelevant (ie, no costing; quality of life or epidemiological information) and full references were not sought.

A list of registered stakeholders is included in Appendix F.

5.5 Evidence synthesis and grading

For the update of the clinical effectiveness reviews, data from existing trials of effectiveness of pressure-relieving devices were synthesised with new trials in a narrative review. There were insufficient trials to necessitate the re-analysis of existing meta-analyses. The data from included studies pertaining to costs, economic evaluation, epidemiology and quality of life were also qualitatively synthesised into a narrative format. Information from the reviews on costs, economic evaluations and epidemiology was used in the economic modelling. All included studies are summarized in evidence tables (Appendices E-H) as well as discussed in the appropriate evidence reviews.

Evidence gradings were assigned to each evidence review using the evidence hierarchy shown below (Table 2).

**Table 2: Levels of Evidence**

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Evidence from meta-analysis of randomised controlled trials or at least one randomised controlled trial</td>
</tr>
<tr>
<td>II</td>
<td>Evidence from at least one controlled trial without randomization or at least one other type of quasi-experimental study</td>
</tr>
<tr>
<td>III</td>
<td>Evidence from non-experimental descriptive studies, such as comparative studies, correlation studies and case-control studies</td>
</tr>
<tr>
<td>IV</td>
<td>Evidence from expert committee reports or opinions and/or clinical experience of respected authorities</td>
</tr>
</tbody>
</table>


The evidence tables and reviews were distributed to GDG members for comment on the interpretation of the evidence and grading.
5.6 Results of clinical effectiveness evidence retrieval and appraisal

5.6.1 Details of studies included in the review

Forty-one relevant randomised clinical trials were identified (see Appendix G). Twenty-one trials involved patients without pre-existing pressure ulcers (intact skin); 4 included patients with ulcers greater than stage 1; 3 included both patients with and without ulcers and in 13 studies it was unclear. For the update, 54 articles were assessed for eligibility; 7 relevant articles were data extracted.

5.6.2 Study Settings

Four studies evaluated different operating table surfaces (Aronovitch 1999; Nixon et al. 1998; Russell and Lichtenstein 2000; Schultz 1999); six evaluated different surfaces in intensive care units (ICU) (Gentilello et al. 1998; Inman et al. 1993; Laurent 1997; Sideranko et al. 1992; Summer et al. 1989; Takala et al. 1994); eight studies confined their evaluation to orthopaedic patients (Cooper et al. 1998; Exton-Smith et al. 1982; Goldstone et al. 1982; Hofman et al. 1994; Price et al. 1999; Santy et al. 1994; Stapleton 1986; McGowan 2000) and one involved an accident and emergency department setting (Gunningberg 2000). The remaining studies looked at a variety of patients, for example those in nursing homes (n=8) and those on care of the elderly, medical and surgical wards.

No trials were identified that specifically examined the effectiveness of pressure-relieving devices in paediatric settings. Most trials were conducted on patients over 18 years of age (one was conducted on patients over 15 and one on patients over 17).

Three trials evaluated cushions, two evaluated the use of sheepskins, and three looked at turning beds/kinetic therapy. The remaining studies evaluated different mattresses, overlays and beds.

5.6.3 Study quality

A summary of the methodological quality of each of the trials is shown in Appendix H. Though the majority of trials discussed the criteria for including patients, approximately 50% of the reports gave information that indicated that patients were truly randomly allocated (Schulz 1995). Ten of trials adopted blinded assessment of outcomes. Small sample size was a major limitation of many of the studies; the median sample size was 80 (range 12-1166) and only 14 studies described an a priori sample size. High attrition rates, lack of an intention-to-treat analysis and
underpowered trials were also common. For most comparisons there is a lack of replication.

Characteristics of excluded studies are shown in Appendix I.

5.6.4 Comparisons

The comparisons, relevant to this guideline, able to be made on the basis of the included studies were:

Low-tech constant pressure supports

- Comparisons of standard foam mattress with other low-tech constant-pressure supports;
- Comparisons between foam alternatives - ie. head-to-head comparisons of high-specification foam products (ie. contoured foam, supports comprising foam of different densities);
- Comparisons between constant low-pressure supports (head-to-head comparisons of the following types of support: foams, fluid-filled; static air-filled supports (including dry flotation), water-filled supports, gel-filled supports, silicone-filled supports and heel elevators).

High-tech pressure relief

- Comparisons between alternating pressure supports and standard hospital mattresses; CLP devices and other AP supports;
- Comparisons between low-air-loss beds and standard intensive care beds;
- Comparisons between low-air-loss hydrotherapy with standard care;
- Air-fluidized beds versus dry flotation;
- Kinetic turning tables versus standard beds (with and without pressure-relieving mattresses).

Other

- Operating theatre overlays (viscopolymer pad with a standard table);
- Accident and emergency trolley overlays;
- Sheepskin overlays.

5.6.5 Summary of results (the full evidence reviews are included in section 6)

Foam alternatives (high-specification foam) to the standard hospital foam mattress can reduce the incidence of pressure ulcers in people at risk of developing pressure ulcers.
The relative merits of alternating and constant low pressure devices, and of the different alternating pressure devices for pressure ulcer prevention are unclear.

Pressure-relieving overlays on the operating table have been shown to reduce postoperative pressure ulcer incidence.

There is insufficient evidence to draw conclusions on the value of kinetic turning tables, seat cushions, limb protectors and various constant low pressure devices as pressure ulcer prevention strategies.

One Australian trial indicated that natural medical sheepskins manufactured to Australian standards prevented pressure ulcers.

Evidence from one study of A&E trolley overlays did not show a significant impact on pressure ulcer incidence.

Out of all included trials, there were 13 reports of comfort and acceptability; 13 reports of performance characteristics and ease of use of the equipment and 2 reports of adverse events. Most of this information relates to high-tech devices. These outcomes were considered by the GDG alongside the clinical effectiveness and economic data and included in the clinical effectiveness evidence table (Appendix G).

A study (Bennett et al. 1998) which investigated a low-air-loss hydrotherapy bed, found it was neither safe nor effective (with the caveat that these findings may not relate to subsequent products since developed). Eight subjects were withdrawn from the experimental group with hypothermia and complaints of being wet, cold and uncomfortable.

Foot waffle heel elevators were associated with a trebling of the incidence of pressure ulcers but this result was not statistically significant (Tymec 1997).

An American trial (Schultz 1999) investigated the effectiveness of an alternative foam overlay used in the operating theatre. Results suggest that patients placed on the intervention devices were significantly more likely to experience postoperative skin changes (ie. mainly stage 1 pressure ulcers). However, it is difficult to separate out the role of postoperative care and padding which was used as a concomitant intervention, either of which may have caused the skin changes (mainly found on buttock and coccyx) and the presentation of results could be clarified, therefore it is difficult to assess the clinical importance of these findings. Further information on the study and product are being requested from the author.
5.7 Results of evidence retrieval and appraisal for cost effectiveness evidence

In this section, we report the results of two literature searches to identify a) economic evaluations comparing devices for the prevention of pressure ulcers, and b) studies containing cost and other data relevant to cost effectiveness modelling. We also present a simple cost effectiveness model.

Table 3: Results of search/sift for economic evaluations and cost studies

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of hits</td>
<td>1352</td>
</tr>
<tr>
<td>Potentially relevant from title/abstract</td>
<td>240</td>
</tr>
<tr>
<td>Full article ordered</td>
<td>141</td>
</tr>
<tr>
<td>Final number of economic evaluations included</td>
<td>3</td>
</tr>
<tr>
<td>Final number of costing studies included</td>
<td>11</td>
</tr>
</tbody>
</table>

For both of the above searches, 240/1352 studies were selected on the basis of the first sift. Of those, 141 were ordered. The studies included are shown in Appendix J.

5.7.1 Economic evaluations

Only three economic evaluations (Reynolds et al 2002; Gebhardt 1996; Inman 1993) of pressure-relieving devices for the prevention of pressure ulcers were identified which used evidence from RCTs or quasi-randomised trials.

Reynolds et al (2002) compared the cost effectiveness of standard mattresses with viscoelastic mattresses for elderly patients with Waterlow scores 15-20 using data from a randomised controlled trial. They concluded that there was a 95% chance that the cost per pressure ulcer averted was less than £100.

Gebhardt (1996) used a quasi-randomised design to compare the cost effectiveness of constant low-pressure supports with alternating pressure mattresses in acutely ill patients in an intensive care unit. He concluded that alternating pressure supports were less expensive and more effective than constant low-pressure supports and thus the dominant strategy. However, it should be noted that the methods used to estimate the costs of the supports are unclear from the article.

Inman (1993) assessed the use of standard intensive care beds with air suspension therapy in patients identified as being at high risk of developing pressure ulcers in
intensive care using data from an RCT. They concluded that air suspension beds were the dominant strategy in the US context.

Although the studies were based on Level I or II clinical evidence, the studies did not score highly on the validity checklist for economic evaluations, with scores ranging from 11-17/32 (Drummond 1996). In particular, uncertainties in the data had not been explored and there was poor presentation of disaggregated resource use data.

None of the studies identified, incorporated the costs to the patient of having a pressure ulcer.

5.7.2 Cost of devices

The cost of pressure ulcer relieving devices is complex. Pressure ulcer relieving devices can be purchased outright, leased or hired on a daily basis. There is also a shift towards contracting out the purchase of beds to one or a number of suppliers and this is sometimes known as Total Bed Management. No analytical studies were identified in the literature that assessed the effects of different purchasing strategies in the UK.

Some Trusts have also employed tissue viability nurses to manage the allocation of pressure-relieving devices and/or set up in-house systems for allocating and maintaining devices such as equipment libraries. The cost effectiveness of these policies is unknown.

Five articles were identified which examined the costs of pressure-relieving devices (Hibbert 1999; Hampton 1998; Cullum 2001; Cowan 1997; Cowan 1998) and the NHS Purchasing and Supplies agency was also contacted to give estimates of costs and members of the GDG. These articles mainly focussed on the purchase price of the devices; however the full costs of devices are dependent on a number of factors:

- maintenance costs of the device;
- running costs of devices eg. electricity for hi-tech devices; and
- lifespan of devices.

There may also be additional costs such as training staff to use devices and storage whilst not in use. It may also be that certain beds may require less nursing time than others; for example it may be easier to turn patients on certain products.

It is not possible to draw conclusions for the total costs of different devices across the wide range of products available.

In Table 4, a summary is given of the range of purchase costs (adjusted to 2000/2001 prices) of different devices using the data from the costing studies, NHS supplies and the GDG members.
Pressure-relieving devices: draft for consultation

There is wide variation in the cost of devices. Standard hospital mattresses range in price from £39-£62 and pressure-relieving mattresses range in price from £97-£422. Other mattresses such as alternating pressure and low-air-loss mattresses are significantly more expensive, ranging in price from £2,722 to £5,645. Overlay costs for operating theatre tables range between £100-£3,500.

<table>
<thead>
<tr>
<th>Type of device</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mattresses</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard hospital mattress -</td>
<td>£39</td>
<td>£62</td>
</tr>
<tr>
<td>Air filled mattress</td>
<td>£79</td>
<td></td>
</tr>
<tr>
<td>Pressure-relieving mattress</td>
<td>£97</td>
<td>£422</td>
</tr>
<tr>
<td>Alternating pressure mattress</td>
<td>£870</td>
<td>£4,473</td>
</tr>
<tr>
<td>Dry flotation mattress</td>
<td>£1,499</td>
<td></td>
</tr>
<tr>
<td>Dynamic air mattress</td>
<td>£2,722</td>
<td>£4,356</td>
</tr>
<tr>
<td>Low-air-loss mattress</td>
<td>£2,722</td>
<td>£5,645</td>
</tr>
<tr>
<td><strong>Overlays</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foam overlay</td>
<td>£49</td>
<td>£390</td>
</tr>
<tr>
<td>Alternating pressure overlay</td>
<td>£125</td>
<td>£1,750</td>
</tr>
<tr>
<td>Low-air-loss overlay</td>
<td>£1,806</td>
<td>£3,500</td>
</tr>
<tr>
<td><strong>Bed systems</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dynamic pressure-relieving bed systems</td>
<td>£8,488</td>
<td></td>
</tr>
<tr>
<td>Therapy Beds -</td>
<td>£10,449</td>
<td>£36,000</td>
</tr>
<tr>
<td><strong>Beds</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 section electric profiling beds</td>
<td>£1,120</td>
<td>£2,995</td>
</tr>
<tr>
<td>4 section non electric profiling beds</td>
<td>£725</td>
<td>£915</td>
</tr>
<tr>
<td><strong>Hospital trolleys</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pressure-relieving systems for hospital trolleys</td>
<td>£595</td>
<td>£905</td>
</tr>
<tr>
<td><strong>Overlay devices for operating theatre</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range of devices</td>
<td>£100</td>
<td>£3500</td>
</tr>
</tbody>
</table>

5.7.3 Cost of treating pressure ulcers

To model the cost effectiveness of preventing pressure ulcers it is necessary to have estimates of the additional cost of treating a patient if they have developed a pressure ulcer, in order to calculate savings that might accrue. The literature search aimed to identify estimates of the cost of pressure ulcers relevant to the current UK context.

In 1994, the Touche Ross report concluded that the cost of pressure ulcers is likely to be higher for treatment than prevention on a per case basis because of the following factors:

- extended length of hospital stay;
- need for plastic surgery on severe ulcer sites; and
- greater dressing costs for severe ulcer sites, each day for hospital care.
Measuring the additional length of stay for patients with pressure ulcers is complicated by the existence of co-morbidity and the difficulty of defining an appropriate control or reference group. It would be inappropriate simply to analyse the lengths of stay of patients with pressure ulcers and compare these with lengths of stay for patients who do not develop pressure ulcers, as they may still require acute care even if they were pressure ulcer free because of co-morbidity.

In the UK, no research has been identified where adjusted additional lengths of stay for pressure ulcer patients have been calculated. However a recent study in the US has used regression-based methods to determine whether the development of a stage 2 pressure ulcer (or greater) has increased associated hospital costs and lengths of stay after adjusting for admission severity of illness, co-morbidities, nosocomial infections, and other hospital complications (Allman et al. 1999). The authors concluded that the incidence of pressure ulcers was associated with substantial and significant increase in hospital costs and lengths of stay. The difference in average length of stay for those with and without incident pressure ulcers when adjusted for admission predictors and occurrence of nosocomial infections and other complications was 20.9 vs 12.7 days.

The cost of treating pressure ulcers is likely to have increased in recent years because of increases in the costs of dressings and devices. Previous studies such as Clarke et al. (1992) and Collier et al. (1994) are based on different management strategies.

Bennett et al. (2002) provide the most recent additional cost per pressure ulcers estimates for the UK. Assumptions were based on a review of the literature and current guidelines. It was estimated that the additional cost of pressure ulcers varies between £1,080 (grade 1 ulcer) and £15,000 (grade 4 ulcer). However, this paper is unpublished and is not in the public domain.

After discussion with the GDG it was established that there were no estimates of the cost of pressure ulcers available in the public domain that would be suitable for use in a cost effectiveness model. It was therefore decided to use the GDG as an expert panel. Estimates of the additional costs of care for a grade 1 pressure ulcer in hospital care were £750 at baseline (ranging from £500-£1000).

### 5.7.4 Cost effectiveness modelling

Where there is very little evidence of comparative clinical effectiveness of different devices it is difficult to model the difference in cost effectiveness between devices. In these cases it is only possible to show the comparative costs of the devices. For most devices included in the guideline it was not possible to combine the clinical
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evidence with the cost evidence. Furthermore, in section 5.8 the outcome to the patient in terms of quality of life was subject to a literature review. Unfortunately, data are not available to quantify patient outcomes in the cost effectiveness model.

However, there is strong clinical evidence that pressure-relieving mattresses that use high specification foam are more effective than standard hospital mattresses (defined as mattresses without pressure-relieving qualities) (Cullum et al 2001). In order to explore the cost effectiveness of using these mattresses compared to standard mattresses for patients at different levels of risk a simple cost effectiveness model was constructed.

The model explores the difference in costs and effects of treating 100 patients on either a standard hospital mattress or a pressure-reducing mattress. Different scenarios are presented for the absolute level of risk of patients developing pressure ulcers on a standard mattress. For example, if the absolute level of risk is 5% then 5 patients out of 100 will develop a pressure ulcer on a standard hospital mattress.

The results of a meta-analysis show that pressure-relieving mattresses reduce the risk of pressure ulcers compared to standard hospital mattresses by 71% (Cullum, 2001). This estimate was used to calculate an adjusted level of risk for patients cared for on pressure-relieving mattresses compared to standard mattresses. For example if 5 out of 100 patients developed pressure ulcers on a standard mattress it was predicted that 1.5 patients would develop pressure ulcers on a pressure-relieving mattress.

The cost of treating pressure ulcers for a group of 100 patients was calculated by multiplying the number of pressure ulcers predicted to occur by the cost of developing a pressure ulcer. A baseline estimate was used for the cost of developing a grade 1 pressure ulcer of £750 based on the expert opinion of the GDG. It is assumed that treatment costs occur in the same year and therefore they are not discounted.

The equivalent annual cost of each device was estimated using the purchase costs (midpoint of range in table 4) and the assumption that the lifespan of each device was 8 years with interest rates of 6%. To calculate a cost per patient of each device it was assumed that there was 100% bed occupancy and the average length of stay was 5 days.

The difference in costs and effects between a standard mattress and a pressure-relieving mattress were then compared. The incremental cost effectiveness ratio was calculated by dividing the difference in costs by the difference in effects.
### Table 5: Comparison of costs of standard hospital mattress with pressure-relieving mattress (high specification foam)

<table>
<thead>
<tr>
<th></th>
<th>Standard hospital mattress</th>
<th>Pressure-relieving mattresses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients predicted to develop a pressure ulcer from 100 patient episodes</td>
<td>0.5</td>
<td>5</td>
</tr>
<tr>
<td>Cost of treating pressure ulcers</td>
<td>£375</td>
<td>£3,750</td>
</tr>
<tr>
<td>Cost of standard foam mattress</td>
<td>£11</td>
<td>£11</td>
</tr>
<tr>
<td>Total cost</td>
<td>£386</td>
<td>£3,761</td>
</tr>
</tbody>
</table>

| Number of patients predicted to develop a pressure ulcer after adjusting for the reduction in risk | 0.15 | 1.5 | 3 | 6 |
| Total cost of treating pressure ulcers | £113 | £1,125 | £2,250 | £4,500 |
| Total cost of pressure-relieving mattress | £57 | £57 | £57 | £57 |
| Total cost | £170 | £1,182 | £2,307 | £4,557 |

**Incremental cost** (Difference in cost) **Incremental effect** (Difference in number of pressure ulcers) **Incremental cost per pressure ulcer averted**

- £216 | -£2,579 | -£5,204 | -£10,454
- 0.35 | 3.5 | 7 | 14

**Dominates**

*The device is both more effective and costs less*

**Assumptions:**

- There is a 71% reduction in the risk of developing a pressure ulcer (Cullum 2001), therefore for example if 5/100 patients developed a pressure ulcer on a standard mattress only 1.5/100 are predicted to develop a pressure ulcer on a pressure-relieving mattress.
- Treatment of grade 1 pressure ulcer £750 (GDG estimate)
- Device costs: Purchase costs base on midpoint of range presented in table 4; average length of stay is 5 days and there is 100% occupancy and the lifespan of bed is 8 years.

The results presented in table 5 indicate that although pressure-relieving mattresses cost more to purchase than standard hospital mattress, the treatment savings accruing through the reduced number of pressure ulcers developing more than offset the increased costs. This result holds true even in groups where only 1 patient in 200 (0.5 in 100 patients) develops a pressure ulcer on a standard hospital mattress. It is likely that pressure-relieving mattresses are cost effective compared to standard hospital mattress for all groups of patients vulnerable to developing pressure ulcers.

There is considerable uncertainty about the estimates used in the model. To explore the effect of this uncertainty, a worst-case scenario sensitivity analysis was performed using less favourable estimates of the pressure-relieving mattress. These included: the lowest estimate of the additional cost of treating grade 1 pressure ulcer of £500, only a 41% reduction in the risk of developing a pressure ulcer based on the lower 95% confidence interval from the meta-analysis (Cullum et al, 2001), the maximum purchase cost of pressure-relieving mattresses in table 4 and an estimated lifespan of the pressure-relieving mattress of 4 years. The results showed that even in this scenario and for groups where only 1 patient in 100 develops a pressure ulcer the...
pressure-relieving mattress was still cost dominant, that is, pressure-relieving mattresses overall cost less and were more effective in reducing pressure ulcers.

A formal analysis of the incremental cost effectiveness of different devices compared to pressure-relieving devices is not included. However, using the same costing methods to calculate the cost of alternating devices if 6/100 patients develop a pressure ulcer on a pressure-relieving mattress; alternating pressure mattresses would have to reduce the risk of pressure ulcer development by 23.5% to remain cost neutral.

5.7.5 Discussion

There are very few economic evaluations in the literature comparing different pressure-relieving devices. It is not possible to draw any conclusions on the cost effectiveness from these studies alone. Further research is needed assessing the cost effectiveness of different devices.

There are wide differences in the cost of different pressure-relieving devices. Other factors influencing the costs of different devices include the lifespan of the bed, associated nursing time and maintenance costs. The cost to the health service of purchasing the bed will also vary depending on the purchasing strategy used, for example, hiring beds on a daily basis or using managed contracts. There is no clear evidence as to the best purchasing mechanism. Further research is needed on the costs of different devices.

Where there is very little evidence of comparative clinical effectiveness of different devices it is difficult to model the difference in cost effectiveness between devices. In these cases it is only possible to show the comparative costs of the devices. For most devices in the guideline it was not possible to combine the clinical evidence with the cost evidence.

However, there is clinical evidence of a difference in risk of developing pressure ulcer when using pressure-relieving mattresses compared to standard hospital mattresses. This evidence was used to model the incremental cost effectiveness of pressure-relieving devices in patients at different risk levels of developing pressure ulcers.

The model indicates that due to the savings accruing through treating fewer pressure ulcers, pressure-relieving mattresses are likely to cost less overall and are more effective than standard hospital mattresses.

The model highlighted a lack of evidence for key model parameters for estimating the cost effectiveness of different pressure-relieving devices. However, the prevention of pressure ulcers has benefits both for the health related quality of life of the
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patient/carer and also savings in time and resources for the patient/carer and the health services. Empirical research is needed to quantify the magnitude of the benefits of preventing pressure ulcers.

5.8 Results of quality of life evidence retrieval and appraisal

In this section, the results of the search and appraisal of the studies on quality of life is presented. This information was used to inform the review of economic evaluations and costing studies and also to provide information on patient-related issues not captured by the clinical effectiveness review.

<table>
<thead>
<tr>
<th>Table 6: Results of search/sift for quality of life studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of hits</td>
</tr>
<tr>
<td>Potentially relevant from title/abstract</td>
</tr>
<tr>
<td>Meets eligibility criteria</td>
</tr>
<tr>
<td>Full article ordered and appraised</td>
</tr>
<tr>
<td>Final number included</td>
</tr>
</tbody>
</table>

Nine studies out of 302 potential articles (1980-2002) were retrieved on the basis of title/abstract. Seven were included - 5 primary research (2 case-control, 1 survey and 2 qualitative) and 2 non-systematic reviews. All evidence is Level III-IV using the level of evidence hierarchy described above and is summarized in the evidence tables (Appendix K).

No articles measured QALYs in people with pressure ulcers. Franks (1999) used the SF36 (Franks 1999) but found it to be an insensitive measure among people with pressure ulcers. Consequently, quality of life measures cannot be quantitatively incorporated into estimates of cost effectiveness.

Because the data provided insufficient information to derive quantitative estimates of the quality of life effects of pressure ulcers, these effects are described qualitatively below.

Four studies addressed the experience of caring for someone with pressure ulcers or the impact of having a pressure ulcer (Baharestani 1994; Franks 2001; Langemo 2000; Unalan 2001). Unalan found no difference in health state between caregivers to people with pressure ulcers and a spinal cord injury. However, the qualitative study of caregivers of people with stage 3 or 4 pressure ulcers by Baharestani (1994) found that carers were frail, had limited social support systems and opportunities for socialization. Care-giving also had an emotional, physical and financial impact.
The study by Franks (2001) found that people with pressure ulcers had poorer health and experienced deficits in self-care and mobility; while the qualitative study by Langemo (2000) reported that pressure ulcers had a profound negative effect on the physical, social and financial realms of peoples lives.

The two reviews confirmed that there have been very few studies that address quality of life in people with pressure ulcers.

Two articles relevant to the impact of bed-rest on quality of life were found but rejected as they were of little relevance for the purpose of this guideline. These reported experiments in young, healthy individuals on the effect of bed-rest on psychological stress, depression or mood state (Ishizaki et al. 1997; Styf et al. 2001) and confirmed that a tendency towards depression (as well as pain and physiological changes) occurred during periods of bed-rest.

No studies were found which investigated quality of life in actual patients who were bed-ridden (with or without pressure ulcers) or which surveyed patient preferences for particular devices.

Some of the clinical effectiveness studies included in the Cochrane review did include ratings of comfort of particular devices made by a subsample of patients able to complete a questionnaire or interview (see Appendix G, ‘notes’ column for details). However, because this data is not routinely collected in trials, it is not possible to say whether one category of devices is more likely to be associated with negative feedback by patients (and clinicians) than others. Furthermore, particular products listed in the evidence table for which there is information on comfort, etc. may already have been superseded by later models. Quality of life was not measured in association with these devices.

Clearly, this is an understudied area. Some reasons why quality of life may be difficult to measure in pressure ulcer patients may be that:

- it is difficult to separate out the quality of life effect of the pressure ulcer from the effects of co-morbidity
- patients with severe pressure ulcers are usually often chronically ill and unable to respond to self-report questionnaires
- the quality of life measures used in studies are not sufficiently sensitive to quality of life issues in those with pressure ulcers.

Despite the diversity of study designs, patient groups and outcomes, the included articles consistently show that having pressure ulcers or caring for someone with a pressure ulcer is associated with a decreased quality of life, poorer health and has a negative impact on social life, financial and functional status.
5.9 Results of epidemiology evidence retrieval and appraisal

In this section, the results of the search and appraisal of epidemiology studies is reported. This information was used to inform the cost effectiveness review.

Results of search/sift for articles to update the Kaltenhauler et al. (2001) review

<table>
<thead>
<tr>
<th>Table 7: Results of search/sift process for epidemiology update</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of hits</td>
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<td>Potentially relevant from title/abstract</td>
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<tr>
<td>Full article ordered and appraised</td>
</tr>
<tr>
<td>Final number included</td>
</tr>
<tr>
<td>Number excluded</td>
</tr>
</tbody>
</table>

The features of the included studies are set out below.

Prevalence studies n= 8 (all Level III)

Setting

4=general hospital
1=community hospitals/mental health
2=nursing home/residential care
1=paediatric

Stage 1 included

6=yes

Incidence studies n=7

Study design

4 were prospective cohort studies (Level III)
3 were retrospective (Level III)

Setting

2=general hospital
5.9.1 Results of review update

Fifteen studies published since 1997, fulfilled the inclusion criteria and were included (see Appendix L). Study quality and reporting of detail was variable and only one study adjusted for case-mix (Williams 2001). All studies that met the inclusion criteria were included. However, sensitivity analyses were conducted to explore the impact of study design and settings on incidence and prevalence estimates. The information provided by the epidemiological review was used in the economic modelling.

Studies were undertaken in hospitals (adult and paediatric), labour wards, nursing and residential homes. Some studies provided breakdown by type of setting within a trust, but for two studies (Hanson 1997; Willcock 2000), the figures either did not make sense or the denominator used was for the overall trust rather than for the type of setting. Most (n=13) studies used the number of patients rather than the number of ulcers as the numerator. In one study this was unclear.

One study (Willcock 2000) reported both incidence and prevalence studies. These are separately reported in the evidence table.

In 5/7 incidence studies, it was unclear or not stated as to whether subjects were free of the outcome of interest at the study’s inception. In one incidence study, those admitted with a pressure ulcer were also included but reported separately.

Summarized information is shown in Appendix L. Confidence intervals were calculated for prevalence and incidence estimates.

5.9.2 Prevalence in the UK (see appendix L)

The Kaltenthaler et al. (2001) review reported prevalence ranges for UK hospitals of 5 to 32.1% based on 17 studies (2 in nursing homes; 2 in community settings; 1 in palliative care unit and 12 in hospitals). For community settings, the range was 4.4-6.8% and that for nursing homes was 4.5-7.5%. The highest reported prevalence was 37% for a palliative care unit.
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Studies included in the update of Kaltenthaler et al.’s work gives pressure ulcer estimates for nursing homes of 7.9% (Shiels and Roe 1999) and 7.4% (Levett and Smith 2002). Shiels and Roe (1999) also give a prevalence figure of 3.5% for residential homes.

For hospitals the highest estimate was 59% (Cockbill 1999) but a small sample was used (n=22); the confidence interval was wide and the representativeness of the sample in terms of the general population of the hospital from which it was drawn is unclear. If discounting this figure, the range was 1.2% (heel ulcers only) – 11%.

5.9.3 Incidence in the UK (see appendix L)

The Kaltenthaler review identified 8 incidence studies (5 in high risk settings and 3 in hospital settings). In that review, incidence figures reported for hospitals ranged from 2.2% per annum to 29% over a maximum period of six weeks. Only one study, which included patients who were bedfast and chairfast, was reported for community settings, giving an estimate of 20% over a maximum period of six weeks. No incidence studies were found for nursing homes. The highest reported incidence was for older patients with hip fractures: 66% over an 18-month period.

For the update, incidence figures obtained retrospectively (3 studies) ranged from 0.3% (labour ward) over 18 months – 37.7% (among ‘lower limb amputees in Hereford’) over a year. Incidence figure ranges for prospective data were 1.7% (over a period of 28 days) – 8.7% (median duration 8 days). Except for the lower limb amputee study, studies reporting incidence in community or nursing home/residential care settings were not found. An incidence of 7.3% was found in a small sample of paediatric patients (Willcock et al 2000).

Including only general hospital studies (ie. excluding paediatrics, burns unit, critical care and palliative care unit) the range was 1.7-8.7%.

5.9.4 Discussion

As in the earlier review (Kaltenthaler et al. 2001), the studies obtained show large variations in reported pressure ulcer prevalence and incidence and methods used. Many of the confidence intervals were wide. Adjustment of case-mix within wards/settings/hospitals was not undertaken in the majority of studies.

The prevalence figures for nursing home and residential settings were similar to figures reported in the earlier review. The hospital figures were different: excluding the study that only reported heel ulcers (Monaghan 2000) and the study with the
small sample (Cockbill 1999) the range for the new studies was 6.5-11% compared to the earlier range of 5-32%.

In terms of the incidence figures, we separated retrospective from prospective studies. However, if collapsed our incidence ranges were 0.3–37.7% compared with 2.2%–29% for the earlier studies.

Combining studies 1980 to 2002, the prevalence ranges remain the same, whereas the lower range of incidence is now 1.7%. In terms of prevalence, this indicates that any new practices implemented to prevent pressure ulcers may not have had a significant impact, thus as Kaltenthaler et al. reported there may be a minimum rate below which it is hard to go.

In terms of incidence figures, similarly there are little reported changes in the last 5 years, again indicating that risk assessment practices and prevention policies have not been able to make an impact on some groups of patients. Case-mix adjusted data and subgroup analysis may help to further define the patient groups for which little impact has been made on the prevalence and incidence of pressure ulcers.

There were several sources of possible heterogeneity in the incidence and prevalence data. Sources of heterogeneity included study setting; days in study; whether or not stage 1 ulcers were included in incidence or prevalence estimates. It is likely that data which were collected prospectively are more likely to be reliable and less biased than data collected retrospectively.

Furthermore, only published studies were reviewed. It is acknowledged that acute and community trusts undertake prevalence surveys as part of audit programmes which may not be published and that inclusion of these could alter the findings.

5.10 Formulating and grading recommendations

In order for the GDG to formulate a clinically useful recommendation, it was agreed that the following factors be considered:

- The best available evidence with preference given to empirical evidence over expert judgement, including:
  - a profile of the cost data
  - results of economic modelling
  - effectiveness data taking into account the strength of evidence (the level, quality, precision) as well as the size of effect and relevance of the evidence
  - where reported, data regarding additional outcomes such as comfort, adverse effects and patient acceptability associated with the use of pressure-relieving devices.
• A comparison between the outcomes for alternative interventions where possible (this was limited because as indicated in section 6, key comparisons such as that between high-tech devices and high specification foam mattresses are not available).
• The feasibility of interventions, including the cost of the intervention, acceptability to clinicians, patients and carers and appropriateness of device.
• The balancing of benefits against risks - including, where reported, all patient-relevant endpoints (including adverse effects; comfort and acceptability where reported) and the results of the economic modelling.
• The applicability of the evidence to groups defined in the scope of the guideline, having considered the profile of patients recruited to the trials and data obtained from our review of the epidemiological data and quality of life literature.

This information was presented to the group in the form of evidence tables and accompanying summaries which were discussed at GDG meetings. Where the GDG identified issues which impacted on considerations of the evidence and the ability to formulate ‘implementable’ and pragmatic guideline recommendations, these were summarized in the GDG commentary sections.

Issues with the available data identified by the GDG included:
• a lack of robust economic evaluations;
• that the relative merits of some devices for pressure ulcer prevention are unclear (for example, alternating and CLP devices; high-specification foam versus high-tech devices);
• the diversity in patients, outcomes and interventions in trials;
• the lack of evaluations of devices in the community/home setting;
• the lack of population based epidemiological data;
• poor quality of some of the trials and epidemiological studies as well as low power;
• lack of evidence to link risk assessment to choice of devices;
• subjective definitions of high and very high risk due to insufficient evidence to recommend one risk assessment scale as unambiguously superior to another or a scale that is appropriate for use in all care settings (McGough 1999 cited in RCN guidelines on risk assessment and prevention 2001);
• due to limitations in the trial data, inability to consider whether the effects of the pressure-relieving devices under scrutiny varied in different patient groups;
• the lack of routinely collected data in trials on comfort, ease of use, acceptability, quality of life ratings, adverse events, safety, costs; and
- difficulty defining what is the ‘standard’ NHS hospital mattress, as in some clinical areas specialised foam mattresses are routinely replacing standard mattresses.

The GDG agreed that the existing RCN guideline recommendations on pressure-relieving devices would provide a useful starting point for formulating recommendations in the light of the additional evidence pertaining to clinical effectiveness and the new economic evidence. These guideline recommendations were subsequently revised to reflect the views of the GDG and their interpretation of the current evidence. Issues with the data, interpretation of the evidence and the wording were discussed until there was agreement on the wording and grading.

Where the GDG decided that ‘hard’ evidence was essential before any recommendations could be considered, recommendations for future research were made (see section 7). The group then ranked these in order of importance so that the top 5 could be included in the short-form version. As described above, there were shortcomings in the data, therefore some of the review questions could not be fully and satisfactorily answered by empirical evidence. In some instances extrapolated evidence was used – in some instances, this resulted in level I evidence being graded as level IV, particularly where the evidence was extrapolated beyond trial subjects and settings (see section 6).

The grading of the recommendations was agreed at a GDG meeting using the scheme below.

### Table 8: Recommendation grading

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>directly based on category I evidence</td>
</tr>
<tr>
<td>B</td>
<td>directly based on category II evidence or extrapolated recommendation from category I evidence</td>
</tr>
<tr>
<td>C</td>
<td>directly based on category III evidence or extrapolated recommendation from category I or II evidence</td>
</tr>
<tr>
<td>D</td>
<td>directly based on category IV evidence or extrapolated recommendation from category I, II or III evidence</td>
</tr>
</tbody>
</table>


The recommendations with accompanying evidence reviews are presented in section 6.
6 GUIDELINE RECOMMENDATIONS WITH SUPPORTING EVIDENCE REVIEWS

Each recommendation below has an associated level of evidence and recommendation grading. However, it was the view of the GDG that the gradings do not differentiate the recommendations in terms of their importance to the guideline as a whole - all recommendations are endorsed equally by the GDG.

6.1 Deciding which pressure-relieving device to use

6.1.1 Recommendation

1. Decisions about which pressure-relieving device to use should be based on an overall assessment of the individual. Holistic assessment should include:

- identified levels of risk;
- skin assessment;
- comfort;
- general health state;
- lifestyle and abilities;
- critical care needs; and
- acceptability of the proposed pressure-relieving equipment to the patient and/or carer (Level IV).

and should not be based solely on scores from risk assessment scales (Level II) [D].

6.1.2 Evidence

<table>
<thead>
<tr>
<th>Level of evidence</th>
<th>Evidence statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level II</td>
<td>There is little evidence that using a pressure ulcer risk scale is better than clinical judgement or that the use of such a scale improves outcomes</td>
</tr>
<tr>
<td>Level IV</td>
<td>There is little evidence to support the use of risk assessment scales to make decisions about allocation of devices</td>
</tr>
</tbody>
</table>

Clinical evidence

Various scales have been developed to identify high-risk patients. These scales have been developed in an ad hoc fashion; it is unclear which is the most accurate (RCN 2001). A systematic review (McGough 1999) concluded that there was insufficient
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evidence to recommend using scores from risk assessment scales on which to base or support decisions about choice of pressure-relieving surfaces.

A recent study to evaluate whether risk assessment scales can be used to identify individuals who are likely to get pressure ulcers found that although risk assessment scales predict the occurrence of pressure ulcers to some extent, routine use of these scales leads to inefficient use of preventive measures (Schoonhoven et al. 2002).

The area of risk assessment is vexed. Although the RCN recommendations (2001) states that ‘risk assessment tools should only be used as an aide memoire and should not replace clinical judgement’, this raises many complex issues. For example, on the one hand such scales may facilitate systematic assessment. On the other hand, the three scales most commonly used to assess the risk of developing pressure ulcers (Norton, Braden and Waterlow) do not satisfactorily predict pressure ulcer development in patients admitted to hospital (Schoonhoven et al. 2002). This may be because risk assessment scales are based on clinical observation and pathophysiological insights and not on adequate prospective or prognostic research (Schoonhoven et al. 2002). Clinical judgement itself is difficult to define and its accuracy has not been tested in research.

The principles under ‘identifying individuals at risk’ and ‘use of risk assessment scales’ are covered in more depth in the RCN guidelines (2001). It was not in the remit to revisit this area in terms of updating the evidence reviews and producing revised recommendations. However, the recommendations relating to these areas are reproduced from the NICE guidelines (2001) below to enhance the comprehensiveness of this guideline.
Identifying individuals ‘at risk’

Assessing an individual’s risk of developing pressure ulcers should involve both informal and formal assessment processes.

Risk assessment should be carried out by personnel who have undergone appropriate and adequate training to recognize the risk factors that contribute to the development of pressure ulcers and how to initiate and maintain correct and suitable preventive measures.

The timing of risk assessment should be based on each individual case. However, it should take place in under six hours of the start of admission to the episode of care.

If considered not at risk on initial assessment, reassessment should occur if there is a change in an individual’s condition.

All formal assessments of risk should be documented/recorded and made accessible to all members of the interdisciplinary team.

Use of risk assessment scales

Risk assessment scales should only be used as an aide memoire and should not replace clinical judgement.

If use of a risk assessment tool is preferred (to assist with clinical judgement), it is recommended that a scale that has been tested for use in the same specialty is chosen.

Risk factors

An individual’s potential to develop pressure ulcers may be influenced by the following intrinsic risk factors which therefore should be considered when performing a risk assessment:
- reduced mobility or immobility
- sensory impairment
- acute illness
- level of consciousness
- extremes of age
- previous history of pressure damage
- vascular disease
- severe chronic or terminal illness
- malnutrition

The following extrinsic risk factors are involved in tissue damage and should be removed or diminished to prevent injury:
- pressure
- shearing
- friction

An individual’s potential to develop pressure ulcers may be exacerbated by the following factors which therefore should be considered when performing a risk assessment:
- medication
- moisture to the skin

(Reproduced from NICE guidelines for pressure ulcer risk assessment and prevention 2001)

6.1.3 Guideline Development Group comment

It was impossible to make recommendations for pressure-relieving devices divorced from considerations of risk assessment, although risk assessment (recommendations
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and evidence reviews) was outside the official scope for this guideline. Although the area was comprehensively covered in the NICE (2001) guidelines, it was necessary for the GDG to revisit this area in order to consider the definition and meaning of the terms such as ‘at-risk’ and ‘high-risk’ (which imply that there are safe and reliable cut-off scores) and their applicability to allocation of pressure-relieving devices.

Consequently, the GDG agreed that due to the lack of well-validated risk assessment tools and the absence of evidence linking risk assessment scores to allocation of pressure-relieving devices, the terms ‘vulnerable to pressure ulcers’ and ‘at elevated risk of pressure ulcers’ would be used.

The GDG also agreed that prior to allocating beds, mattresses or overlays, guideline users should be aware of the NICE (2001) recommendations on risk assessment. The ‘Essentials of Care’ section in the RCN guidelines (RCN 2001:20) is another important source of information for informing holistic and ongoing assessment.

The GDG summarized important commonsense principles relating to risk assessment as follows:

- an informal risk assessment on all individuals admitted to clinical settings should be conducted – a process should be in place whereby this is documented for all patients;
- a formal assessment of risk should be routinely conducted on those people whose initial assessment highlight factors which may render them vulnerable to, or at elevated risk, for developing pressure ulcers;
- risk assessment should also be conducted for inpatient admissions to A&E and for those cared for in the community. (NB: the RCN guidelines (p.22) state that a formal assessment of risk should be conducted routinely for in-patients and those visited on domiciliary visits);
- risk assessment should be holistic and multidisciplinary to ensure comprehensiveness of risk assessment. The ‘Essentials of care’ as outlined on p.20 (RCN 2001) will help to facilitate a multidisciplinary and holistic assessment and ongoing review;
- risk assessment scales should not be used in isolation to identify individuals vulnerable to pressure ulcers, or used in isolation to instigate prevention strategies;
- in particular, assessment and allocation of devices should not be driven solely by artificial cut-off points on risk assessment scales that denote ‘at-risk’ and ‘very high risk’;
- assessment should be on-going throughout an individual’s episode of care regardless of setting;
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- healthcare practitioners should be aware that clients who would not normally be viewed as at elevated risk of pressure ulcers, may be at risk because of a different situation (for example, those having epidural analgesia or anaesthesia);
- the type of pressure relief support should be changed to suit any alteration in level of risk;
- risk assessment should be carried out by personnel who have undergone appropriate training to recognize the risk factors that contribute to the development of pressure ulcers and know how to initiate and maintain correct and suitable preventative measures (NICE 2001a:2).

6.2 Minimum provision for individuals vulnerable to pressure ulcers

6.2.1 Recommendation

2. All individuals assessed as being vulnerable to pressure ulcers should, as a minimum provision, be placed on a high-specification foam mattress with pressure-relieving properties (Level I) [B].

6.2.2 Evidence

<table>
<thead>
<tr>
<th>Level of evidence</th>
<th>Evidence statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level I</td>
<td>Foam alternatives (high-specification foam) to the standard hospital foam mattress can reduce the incidence of pressure ulcers in people at risk</td>
</tr>
<tr>
<td>Modelling using Level I clinical evidence</td>
<td>It is likely that high specification foam mattresses with pressure-relieving properties are cost-effective in people vulnerable to developing pressure ulcers.</td>
</tr>
</tbody>
</table>

Clinical evidence

The clearest conclusions are that standard hospital mattresses have been consistently out-performed by a range of foam-based, low-pressure mattresses and that in people at ‘high risk’ of developing pressure ulcers, consideration should be given to the use of higher specification foam mattresses rather than standard hospital foam mattresses (Cullum et al. 2001). Although the ‘standard’ is poorly described in the studies (and what is ‘standard’ varies by hospital, country and over time) the ‘effects of using alternative foam mattresses are noteworthy in their consistency’ (Cullum et al. 2001:23). These conclusions are unchanged by the update of the review. The updated evidence is summarized below.
Eight RCTs comparing ‘standard’ mattresses/surfaces with ‘low-tech’ supports for the prevention of pressure ulcers were identified (Andersen et al. 1982; Collier 1996; Ewing et al. 1964; Goldstone et al. 1982; Gray and Campbell 1994; Hofman et al. 1994; Russell 2002; Santy et al. 1994). When compared with standard hospital mattresses, the incidence and severity of pressure ulcers in ‘high risk’ patients were reduced when patients were placed on either the Comfortex DeCube mattress (Hofman et al. 1994), (RR 0.34, 95% CI 0.14-0.85) the Beaufort bead bed (Goldstone et al. 1982) (RR 0.32, 95% CI 0.14-0.76), the Softform mattress (Gray and Campbell 1994) (RR 0.2, 95% CI 0.09-0.45), or the water-filled mattress (Andersen et al. 1982) (RR 0.35, 95% CI 0.15-0.79) (Figures 1 & 2, Appendix M). In an unpublished British study of older people with hip fractures admitted to orthopaedic trauma wards, patients allocated to receive a NHS standard foam mattress (manufactured by Relyon) experienced over three times the rate of pressure ulcers as those using one of a number of foam alternatives (Clinifloat, Therarest, Transfoam and Vaperm) (Santy et al. 1994). Another study (currently in press), found a significant difference in the incidence of stage 1 pressure ulcers between the intervention group who were allocated a high-specification foam mattress (Confor-Med) with visco-elastic cushion (20%), compared with those allocated a standard mattress and cushion combination (26%) (p=0.0004) (Russell 2002).

The four trials comparing foam alternatives with the standard hospital foam (Collier 1996; Gray and Campbell 1994; Hofman et al. 1994; Santy et al. 1994) were pooled in the absence of significant statistical heterogeneity (chi-square 1.64, 2df) (Figure 1, Appendix M). These trials were of mixed quality; three of the four provided evidence of allocation concealment but none used blinded outcome assessment. To avoid double counting, the control patients in the trials with more than two comparisons and in the absence of major differences between the effects of different foams, the foam alternatives were pooled. This approach maintains the randomisation but results in comparison groups of unequal size. This analysis yielded a pooled relative risk of 0.29 (95% CI 0.19-0.43), or a relative reduction in pressure ulcer incidence of 71% (95% CI 57%-81%). Therefore foam alternatives to the standard hospital mattress can reduce the incidence of pressure ulcers in at risk patients, including patients with fractured neck of femur.

One small trial of the standard hospital mattress with and without sheepskin overlays was inconclusive and of poor quality (Ewing et al. 1964). Another trial conducted on 297 orthopaedic patients (McGowan 2000), found that pressure ulcer incidence was reduced in those assigned a sheepskin produced to Australian standards (RR for sheepskins relative to standard treatment was 0.28, 95%CI 0.16-0.46). Although the results from this trial are promising, it should be replicated using a similar product on...
a large sample. It is not possible at this stage to say whether these Australian medical sheepskins are comparable to those available elsewhere in the world.

**Comparison between foam alternatives:**

[Head-to-head comparisons of high-specification foam products (ie. contoured foam, supports comprising foam of different densities).]

Five RCTs (Collier 1996; Gray and Smith 2000; Kemp et al. 1993; Santy et al. 1994; Vyhlidal et al. 1997) compared different foam alternatives. Santy (1994) and colleagues compared 5 alternative foam mattresses (Clinifloat, Vaperm, Therarest, Transfoam, NHS standard foam) and found significant reductions in pressure ulcer incidence associated with Clinifloat, Therarest, Vaperm and Transfoam compared with standard; and Vaperm compared with Clinifloat. Vyhlidal (1997) and colleagues compared a 4 inch thick foam overlay (Iris 3000) with a foam and fibre mattress replacement (Maxifloat) and reported a significant reduction in pressure ulcer incidence (RR 0.42, 95% CI 0.18-0.96) with the mattress replacement, however this trial appeared to have used neither allocation concealment nor blinded outcome assessment. The RR translates to a relative reduction in the incidence of pressure ulcers of 58% associated with use of the 5-section foam and fibre mattress replacement (an ARR of 0.35, or 35% and a number needed to treat (NNT) of 3, or one additional pressure ulcer prevented for every 3 patients receiving a Maxifloat mattress replacement).

No patient developed a pressure ulcer in the Collier (1996) trial. Kemp et al. (1993) compared a convoluted foam overlay with a solid foam overlay in only 84 patients and found no significant difference in pressure ulcer incidence rates; however this may be a Type 2 error, in that the small sample size may have precluded detection of a significant difference. Gray and Smith (2000) compared the Transfoam and Transfoamwave foam mattresses but only one patient in each group developed a ulcer.

**Comparisons between 'low-tech' constant low pressure supports:**

[This section covers head-to-head comparisons of the following types of support: foams; static air-filled supports (including dry flotation); water-filled supports; gel-filled (and viscoelastic) supports; Silicore-filled supports; heel elevators.]

Seven RCTs have compared different low-tech CLP devices for prevention (Andersen et al. 1982; Cooper et al. 1998; Lazzara and Buschmann 1991; Sideranko et al. 1992; Stapleton 1986; Takala et al. 1994; Tymec et al. 1997). Most of these trials are seriously underpowered and/or have other methodological flaws.
A trial from Finland (Takala et al. 1994), comparing the Optima (Carital) constant low pressure mattress – which comprises 21 double air bags on a base – with the standard hospital mattress, found that 37% of patients on the standard mattress developed ulcers compared with none on the Optima (RR 0.06; 95% CI 0-0.99). The report of this study did not describe either allocation concealment or blinded outcome assessment.

One trial compared a proprietary heel elevation device (Foot Waffle) comprising a vinyl boot with built in foot cradle, with elevation of the heels using a hospital pillow (Tymec et al. 1997). More heel ulcers developed in the group using the Foot Waffle (6 vs. 2) although this difference was not statistically significant (the trial involved 52 patients). The remaining trials were all unique comparisons with low power and none found statistically significant differences between the surfaces tested.

**Accident and emergency overlay**

Gunningberg (2000) examined the effects of an A&E overlay on 101 patients with a suspected hip fracture. No difference in pressure ulcer incidence was found between those assigned a visco-elastic foam mattress on arrival in A&E with a visco-foam overlay on the standard ward mattress and those assigned a standard trolley mattress and ward mattress. The rate of stage 2-4 incidence was lower in the intervention group (4/48) compared with the control group (8/53) but this was not statistically significant.

**Economic evidence**

Only one economic evaluation was identified which compared the cost effectiveness of using standard foam mattresses with visco-elastic polymer mattresses (Russell 2002 in press). The study found that the higher specification mattress was the cost dominant strategy, lower cost per patient and more effective.

Economic modelling using the evidence on the reduction in relative risk of pressure ulcers from the systematic review suggests that high specification foam mattresses are cost effective in comparison to standard hospital mattresses for all patients vulnerable to developing pressure ulcers.

6.2.3 **Guideline Development Group comment**

The evidence supporting this recommendation was considered to be the strongest and clearest emerging from the updated systematic review. However, there was debate about whether the recommendation should be extended to all patients, regardless of risk, because:
many patients may not be routinely assessed for risk of developing a pressure ulcer; and

it is difficult to reliably identify and predict who is ‘at risk’.

However, there was also a strong view that there are people who are categorically not vulnerable to developing pressure ulcers, [eg. most day-stay, most maternity (although those with sensory loss due to epidural anaesthesia and analgesia may be at risk) and most psychiatric patients] who are relatively easy to identify. Therefore to reduce the possibility that patients unlikely to develop pressure ulcers will be allocated costly devices, it was agreed that the recommendation should be applicable to those vulnerable to pressure ulcers. Most of the trials included in the clinical effectiveness review were conducted on ‘high-risk’ (non-paediatric) populations such as those admitted to orthopaedic; neurology; geriatric and critical care units which is why the recommendation attracted a lower recommendation grading. The GDG was aware that the studies reviewed did not apply to the paediatric population and the findings may not be appropriate to this group.

6.3 Patients at elevated risk of developing pressure ulcers

6.3.1 Recommendation

3. Where patients are assessed as having an elevated risk of developing pressure ulcers, consideration should be given to the use of equipment such as alternating pressure mattresses or other high-tech pressure-relieving systems (Level IV) [D].

6.3.2 Evidence

<table>
<thead>
<tr>
<th>Level of evidence</th>
<th>Evidence statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level I</td>
<td>Standard hospital mattresses have been consistently outperformed by high-tech pressure-relieving mattresses</td>
</tr>
<tr>
<td></td>
<td>The relative merits of AP and CLP devices and of the different AP devices, for pressure ulcer prevention are unclear</td>
</tr>
<tr>
<td></td>
<td>There is little evidence on the clinical or cost-effectiveness of comparing high specification foam mattresses/overlays and high-tech mattresses/overlays However, high-tech devices are significantly more expensive.</td>
</tr>
</tbody>
</table>

Clinical evidence

The updated review did not change the main conclusion of the HTA report in relation to high-tech devices, which is that: standard hospital mattresses have been
outperformed not only by a range of foam-based low pressure mattresses and overlays but also by higher-tech pressure-relieving mattresses (Cullum et al. 2001). However, the evidence is somewhat difficult to interpret and apply to clinical practice because a) the relative merits of more sophisticated constant low-pressure and alternating pressure (AP) devices and of the different alternating pressure devices for the prevention of pressure ulcers are unclear; b) most of the trials of AP supports do not adequately describe the devices being evaluated, including the size of the air cells and; c) thorough evaluation of AP devices compared to high-specification foam is required, as the former are viewed as standard preventive interventions in some areas and not others, varying widely in cost (<£1,000 to >£4,000) (Cullum et al. 2001).

The different comparisons are summarized below.

*Alternating pressure supports:*

A variety of alternating pressure (AP) supports are used in hospital and the community. The depth of the air-cells and the mechanical robustness vary between devices and these factors may be important in determining effectiveness. Most of the RCTs of AP supports did not adequately describe the devices being evaluated, including the size of the air cells.

Twelve RCTs of AP supports for pressure ulcer prevention were identified: comparing between AP and standard hospital mattresses in one study (Andersen et al. 1982); between AP and various CLP devices in eight studies such as water (Andersen et al. 1982; Sideranko et al. 1992), static air (Price et al. 1999; Sideranko et al. 1992), Silicore (Conine et al. 1990; Daechsel and Conine 1985; Sideranko et al. 1992), foam (Sideranko et al. 1992; Whitney et al. 1984), various (Gebhardt 1994); and with other alternating pressure supports in 3 studies (Exton-Smith et al. 1982; Hampton 1997; Taylor 1999).

*Alternating pressure compared with standard hospital mattress*

One RCT (Andersen et al. 1982) reported that the use of AP surfaces reduced the incidence of pressure ulcers as compared with standard hospital mattresses (RR 0.32, 95% CI 0.14-0.74). The report of this large trial, involving 482 patients at 'high-risk' of pressure ulcers, gave no indication that either allocation concealment or blinded outcome assessment had been used.

*Alternating pressure compared with constant low pressure*

Eight trials compared alternating pressure devices with various constant low pressure devices; however there is conflicting evidence as to their relative effectiveness. One compared a range of AP supports with a range of CLP supports in a range of
specialties in acute care settings (Gebhardt 1994) and reported significantly more pressure ulcers in patients in the CLP group (34% compared with 13% in the AP group) (RR 0.38, 95% CI 0.22-0.66). This trial is difficult to interpret given the wide variety of surfaces used within the study – there is currently insufficient evidence to support a class effect for all AP devices and all CLP devices.

In contrast, eight small RCTs comparing different types of alternating pressure supports and a variety of constant low pressure devices such as the Silicore overlay (Conine et al. 1990; Daechsel and Conine 1985; Stapleton 1986), a water mattress (Sideranko et al. 1992; Andersen et al. 1982), a foam pad (Stapleton 1986; Whitney et al. 1984), and static air mattresses (Price et al. 1999; Sideranko et al. 1992) reported no difference in effectiveness although many were too small to be able to detect clinically important differences as statistically significant

Four studies which compared AP with Silicore or foam overlays were pooled (Conine et al. 1990; Daechsel and Conine 1985; Stapleton 1986; Whitney et al. 1984). To avoid double counting of the patients in the AP arm of the Stapleton 3-arm trial, and in the absence of obvious heterogeneity in the outcomes for Silicore and foam, the Silicore and foam arms were pooled against the AP arm (maintaining the randomisation, avoiding double counting, but resulting in unequal comparison groups). Overall the pooled relative risk for AP v Silicore or foam overlays (using a fixed effects model; Chi-square 0.03, df=3) was 0.91, (95% CI 0.71-1.17) indicating no statistically significant difference between Silicore or foam overlays and AP (Figure 3, Appendix M).

The studies which compared AP with static water or static air mattresses were similarly considered together (Andersen et al. 1982; Price et al. 1999; Sideranko et al. 1992). The Sideranko trial also had 3 comparison groups and for the purposes of the meta-analysis, the water and static air arms of this study were considered sufficiently similar to pool together against AP to avoid double counting of the AP patients. Pooling these three trials to answer the question of whether AP is more effective than air or water filled mattresses using a random effects model (Chi-square 2.67, df=2) yielded a pooled RR of 1.26 (95% CI 0.6 –2.61) indicating no statistically significant difference (Figure 4, Appendix M).

It is worth emphasising, however, that all these studies were small, and, even when pooled were too underpowered to detect clinically important differences in effectiveness as statistically significant.

All eight RCTs comparing the various CLP devices and AP devices were pooled to try to answer the question of whether AP is more effective than CLP in pressure ulcer prevention. Double counting was avoided for the Sideranko and Stapleton trials as...
before. In view of the different devices evaluated in the studies, and the Chi-square of 12.81 (df=7), a random effects model was applied. This yielded an overall relative risk of 0.82 (95% CI 0.57-1.19) suggesting no statistically significant difference between the rates of pressure ulcer incidence on AP versus CLP (Figure 5, Appendix M). This means that the data is consistent with AP being associated with a reduction in risk of up to 19% compared with the CLP devices. Further trials are needed to determine whether the CLP and AP devices are associated with a clinically important difference in risk of pressure ulceration.

Finally, one trial used a complex factorial design to compare various combinations of standard, constant low pressure and alternating pressure support in surgical intensive care patients intra- and post-intensive care unit (ICU). This trial (which involved only 75 – 80 patients in each group) did not identify any significant effect of using alternating pressure in the ICU (Laurent 1997).

Comparisons between different alternating pressure devices

Alternating pressure devices differ somewhat in structure, including the size of the inflatable air cells. One early study of pressure ulcer prevention (Exton-Smith et al. 1982) compared two large-celled alternating pressure devices (Pegasus Airwave and the Large Cell Ripple – similar except the Airwave has two layers of cells). The authors reported that the Airwave System was significantly more effective than the Large Cell Ripple in preventing and reducing severity of pressure ulcers in a high risk group of elderly patients. However, the allocation was not truly random, and an intention-to-treat analysis would not have shown a statistically significant difference in the rate of pressure ulcers (16% vs 34%, P >0.05).

Hampton (1997) compared the Pegasus Airwave mattress with a new Cairwave Therapy system by the same manufacturer, in 75 patients. No patients developed a ulcer in either the intervention or control group.

More recently, Taylor (1999) compared the Pegasus Trinova 3-cell alternating pressure air mattress combined with a pressure-redistributing cushion with a 2-cell alternating pressure air mattress combined with a pressure-redistributing cushion. There were 22 patients in each group and two patients developed a superficial ulcer in the control group.

Low air-loss beds

One trial showed that low air-loss beds were more cost-effective at decreasing the incidence of pressure ulcers in critically ill patients than a standard (but poorly described) ICU bed (RR 0.24, 95% CI 0.11-0.53) (Inman et al. 1993). A second trial compared low-air-loss hydrotherapy (LAL-hydro) with standard care (some patients
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received alternating pressure in this group); more patients developed ulcers stage 2 or greater in the LAL-hydro group (19%) than the standard care group (7%) though this did not reach significance (the trial involved only 98 patients) (Bennett et al. 1998).

Air fluidised beds vs. dry flotation

One small trial in patients after plastic surgical repair of pressure ulcers showed no difference between an air-fluidised bed and the Roho dry flotation mattress in post-operative tissue breakdown rates (Economides et al. 1995).

Kinetic turning tables

Turning beds contain motors which constantly turn and tilt the patient, and are used in critical care settings primarily to prevent pneumonia and atelectasis. Four RCTs were identified in a meta-analysis of kinetic therapy (Choi and Nelson 1992) however only two of the trials could be obtained (Gentilello et al. 1998; Summer et al. 1989). Sample sizes in all the trials was small, and no beneficial effect of kinetic therapy on pressure ulcer incidence was detected. A recent trial (Keogh and Dealey 2001) with 35 patients in each arm found no pressure ulcers developed in either the group assigned the profiling bed with a pressure-relieving foam mattress/cushion combination nor the group assigned a flat-based bed with a pressure-relieving/redistributing foam mattress/cushion combination.

Economic evidence

No economic evaluations were identified comparing the cost effectiveness of using alternating or other high-tech devices in patients at very high risk. Two economic evaluations showed that alternating pressure supports and air suspension therapy might be cost effective in high-risk intensive care patients (Hibbert et al. 1999; Inman et al. 1993).

However, there is evidence that there are very large cost differences between mattresses. If there is little clinical difference between high specification foam mattresses and between high-tech devices in preventing pressure ulcers, consideration should be given to selecting devices with lower costs.

6.3.3 Guideline Development Group comment

Because of the high cost of these devices, it would have been preferable to have made recommendations on the use of high-tech devices on the basis of clinical and cost effectiveness data relating to the most clinically useful comparisons (such as high-tech versus high-specification foam). However, the clinical and cost effectiveness evidence is lacking on many aspects of high-tech devices as highlighted
above, which is reflected in the evidence level and recommendation grading accorded to this recommendation. Given that it was agreed that there is a role for high-tech devices in the prevention of pressure ulcers (either as a first line preventative strategy for some people or when a low-tech device has failed), it was considered important to make a recommendation regarding their use.

As well as the clinical effectiveness evidence, the GDG also considered the following information:

*Use of high-tech devices in practice*

There is very little published evidence available. The GDG stated that most use was mainly in specialist centres (burns, spinal cord injuries) or intensive care settings. However, not all patients on alternating devices have actual pressure damage; in particular, the young disabled and older patients. High-tech devices may be the equipment of choice for certain extremely vulnerable individuals although there is no empirical evidence of the circumstances in which particular patients should be allocated this equipment. Currently, this seems to depend on clinical judgement.

An (unpublished, personal communication) audit of acute wards, orthopaedic wards, care of the older person and medical wards showed that 80/291 (27.5%) were placed on alternating or low-air-loss support surfaces; nine were placed on a profiling bed and seven were cared for on alternating overlays. Within the nursing care setting, the audit found that, 18 residents out of 51 (35%) were on alternating or low-air-loss bed support surfaces; a profiling bed was used to care for a young disabled patient and eight were cared for on an alternating overlay. The audit identified that 4% patients would have benefited from an increase in provision, these were equally divided between the care homes and the acute trusts.

Clark and Cullum (1992) found that alternating pressure mattresses are widely used in both pressure ulcer prevention and treatment. Low-air-loss and air-fluidized beds are relatively rarely used and tend to be restricted to pressure ulcer treatment and treatment of burns in the case of air-fluidized beds.

*Criteria to decide when an individual should be placed on a high-tech device or upgraded to a high-tech from a low-tech device*

There are no formal validated methods of deciding when to allocate a patient to a high-tech device. In practice, this decision is based on formal risk assessment; consideration of other factors such as changes in condition, clinical criteria, patient wishes; failure of the low-tech device in preventing pressure ulcers and other factors relevant to the patient and their circumstances (see recommendation one). The young
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disabled and some older patients may be allocated a high-tech device as first line prevention and/or therapy in their episode of care.

Criteria (based for example on risk assessment scores and nutritional scores) are often used at a local level to assist decision-making regarding the provision of high-tech devices and that provision outside of suggested criteria has to be justified by the requisitioner. However, this approach has not been formally demonstrated to result in improved patient outcomes.

There was other information that practitioners should be aware of:

- Some high-tech devices may be detrimental in some circumstances. For example, those with mobility disorders placed on air-fluidized therapy may lose postural control; some devices provide an unstable surface for transfers and an overlay may make a bed too high. Clark and Cullum (1992) reported that over 40% of AP systems in hospital were in use but used incorrectly.
- If a patient’s condition changes, then the device may need to change.

6.4 Individuals undergoing surgery

6.4.1 Recommendation

4. All individuals undergoing surgery, and assessed as being vulnerable to pressure ulcers, should as a minimum provision be placed on either a high-specification foam theatre mattress or other pressure-redistributing surface (Level IV) [D].

6.4.2 Evidence

<table>
<thead>
<tr>
<th>Level of evidence</th>
<th>Evidence statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level I</td>
<td>Pressure-relieving overlays used on the operating table and in the postoperative period have been shown to reduce postoperative pressure ulcer incidence. However, it is unclear which form of pressure relief on the operating table is the most effective</td>
</tr>
<tr>
<td>Level IV</td>
<td>Individuals that may be at an elevated risk are those undergoing vascular surgery, orthopaedic surgery, surgery classed as major and those with one or more risk factors for pressure ulcers</td>
</tr>
<tr>
<td></td>
<td>No UK evidence was identified on the comparative cost of pressure-relieving overlays for operating tables</td>
</tr>
</tbody>
</table>
Clinical evidence

Studies (n=3) of pressure-relieving overlays on the operating table have shown a reduction in postoperative pressure ulcer incidence in high-risk surgical patients (Cullum et al. 2001). Individuals that may be at a high risk are those undergoing vascular surgery, orthopaedic surgery, surgery classed as major and those with one or more risk factors for pressure ulcer development (RCN 2001). However, at present, the most effective means of pressure relief on the operating table is unclear (eg. gel-filled or alternating pressure overlays) (Cullum et al. 2001). This conclusion is unchanged by the updated review, with the caveat that further details are being sought about the study by Schultz (1999).

The studies are summarized below.

Four RCTs have evaluated different methods of pressure relief on the operating table. The first compared a visco-elastic polymer pad with a standard table and found a relative reduction in the incidence of post-operative pressure ulcers of 47% associated with using the polymer pad for patients undergoing elective major general, gynaecological or vascular surgery (supine or lithotomy) (RR 0.53; 95% CI 0.33-0.85) (Nixon et al. 1998).

Two further RCTs have compared the Micropulse alternating system (applied both during surgery and post-operatively) with a gel pad during surgery and standard mattress post-op and report a pooled relative risk (fixed effects) of 0.21, (95% CI 0.06-0.7) in favour of the Micropulse system (Aronovitch 1999; Russell and Lichtenstein 2000) (Figure 6, Appendix M). It is not clear from these 2 trials whether the effect is due to the intra-operative or the post-operative pressure relief, or both.

An American trial compared an operating theatre overlay with usual care (which included padding as required, for example gel pads, foam mattresses) (Schultz 1999). People in the experimental group were significantly more likely to experience postoperative skin changes (p=0.0111), including six experimental group patients with ulcers of stage 2 or more compared with three people with ulcers of stage 2 or more in the control group. No attempt was made to gather information on postoperative skin care of the patient. Details regarding stage of ulcer by group and of the unnamed and undescribed product are currently being sought from the authors. In the absence of this information, the clinical importance of the findings is difficult to assess.

Economic evidence

No evidence was identified on the comparative cost of pressure-relieving overlays for operating tables relevant to the UK.
6.4.3 Guideline Development Group comment

There is very little published evidence on the extent of use of operating theatre overlays in the UK. Anecdotal evidence from the GDG suggests that they are increasingly being used in the UK. For the sake of continuity of care, individuals vulnerable to or at elevated risk should be placed on pressure-relieving surfaces before, during and after surgery. The level of evidence and recommendation gradings reflect the lack of clarity about which form of pressure-relief is most effective in operating theatres.

6.5 Repositioning and 24-hour approach to provision of pressure-relieving devices

6.5.1 Recommendations

5. The provision of pressure-relieving devices needs a 24-hour approach. It should include consideration of all surfaces used by the patient (Level IV) [D].

6. Support surface and positioning needs should be assessed and reviewed regularly and determined by the results of skin inspection, patient comfort, ability and general state. Thus repositioning should occur when individuals are on pressure-relieving devices (Level IV) [D].

7. The management of a patient in a sitting position is also important. Even with appropriate pressure relief, it may be necessary to restrict sitting time to less than 2 hours until the condition of an individual with an elevated risk changes (Level IV) [D].

6.5.2 Evidence

Clinical evidence

The recommendations above are consensus based.

The RCN guidelines have a section on positioning (see section 7.0, p.17) which elaborates on the recommendations above. The main message in that section is that the frequency of repositioning should be determined by the results of skin inspection and individual needs, not by a ritualistic schedule and that repositioning, where appropriate, should form part of preventive practice (RCN 2001).

There was also concern that practitioners should adopt a 24-hour approach to pressure relief and repositioning which is responsive to each patient’s individual needs and is regularly reviewed.
6.6  Using a co-ordinated, time-specified approach

6.6.1  Recommendation

8. A pressure ulcer reduction strategy should incorporate a co-ordinated approach to the acquisition, allocation and management of pressure-relieving equipment. The time elapsing between assessment and use of the device should be specified in this strategy (Level IV) [D].

6.6.2  Guideline Development Group comment

This is a consensus-based statement but it was considered highly important that trusts should consider that a key part of pressure ulcer reduction strategies is a systematic and co-ordinated approach to the acquisition, allocation and management of equipment. Management also includes safety of devices and decontamination policies and ensuring that the relevant personnel are familiar with the relevant Medical Devices Agency policies. Timeliness is also of paramount importance – each Trust should have a policy which specifies the timelines for each setting (hospital and community) in terms of allocation of devices to individuals.

6.7  Education and information giving

6.7.1  Recommendations

9. Health care professionals should be educated about:
   - pressure ulcer risk assessment and prevention;
   - selection, use and maintenance of pressure-relieving devices; and
   - patient education and information giving (Level IV) [D].

10. Individuals vulnerable to or at elevated risk of developing pressure ulcers and their carers, should be informed verbally and in writing about:
   - the prevention of pressure ulcers using pressure-relieving strategies;
   - the use and maintenance of pressure-relieving devices; and
   - where they can seek further advice and assistance (Level IV) [D].
6.7.2 Guideline Development Group comment

These are consensus-based statements that are based on those included in the NICE (2001) guidelines. The GDG advises that these should be used in the context of additional recommendations on staff and patient education contained in the NICE guidelines.

7 RECOMMENDATIONS FOR RESEARCH

The following research gaps were identified by the GDG:

Comparisons of alternating pressure devices with:
- ‘lower tech’ alternatives (eg different types of high-specification foam mattresses, other constant low-pressure devices)
- other ‘high-tech’ devices (eg low-air-loss and air-fluidized devices) in groups at elevated risk.
Comparisons should include cost-effectiveness and economic cost of devices as well as the difference in relative risk of using devices for different groups of patients.

Investigation of the impact of having a pressure ulcer on the quality of life of patients and carers and on the quality of life achieved with different forms of pressure relief.

Evaluation of the impact/effectiveness of formal assessment at the point of entry into healthcare (including acute care, care homes and in the community) and the impact of delays to this process.

The need for and frequency of manual repositioning, including:
- requirement for repositioning on any pressure-relieving device;
- methods of repositioning of patients on different pressure-relieving devices;
- nursing time involved in repositioning.

Large-scale prospective epidemiological research to improve understanding of risk factors and the relative contribution they make to the development of pressure ulcers thus facilitating the development of risk assessment scales based on adequate prospective research.

UK trials further testing the use of sheepskins, similar to those used in the Australian study, in preventing pressure ulcers among patients vulnerable to pressure ulcers.
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Research investigating patients’ need for and use of various pressure-relieving devices across a 24-hour period.

Studies of the longevity of different mattress types under laboratory and clinical tests, to help economic evaluations by giving clear indications of the lifespan of products and the minimum performance specifications; (NB: Evaluation of the technical performance of mattresses is currently being undertaken by the Medical Devices Agency).

Evaluation of the reductions in pressure ulcer incidence (or severity) that may result from mattress use in different clinical settings (including standardised tools for recording pressure ulcers and risk-adjustment of the data gathered).

The physiological indicators eg. blood flow, which correlate to the clinical outcomes achieved using mattresses.

Impact of organizational factors (such as staffing levels and bed crises) on pressure ulcer incidence.

General: better reporting of studies, including adequate descriptions of devices; inclusion of outcomes such as comfort, adverse effects and quality of life associated with the pressure-relieving intervention; formal economic evaluations; conduct of effectiveness research in community settings.

8 AUDIT CRITERIA

The audit criteria below are to assist with implementation of the guideline recommendations. The criteria presented here are considered to be the key criteria associated with the guideline recommendations. They are suitable for use in primary and secondary care, for all patients vulnerable to or at elevated risk of developing pressure ulcers who are admitted to hospital for medical or surgical management or who are discharged to an extended care facility or home.

- Users of these guidelines are reminded that the criteria presented here need to be used in conjunction with audit criteria presented in the RCN guidelines (2001) and the implementation points in the NICE (2001) guidelines on risk assessment and prevention.
- Equipment allocation cannot be driven by risk assessment alone and percentages of patients within different risk groups who should be allocated specific equipment cannot be specified.
• As well as formal risk assessment, clinical judgement, patient condition, lifestyle and prior experiences of pressure-relieving devices require consideration when allocating devices.

8.1 Objectives for an audit

Audits can be carried out in different care settings to ensure that patients who are vulnerable to developing pressure ulcers, or who are at elevated risk of developing pressure ulcers, are offered appropriate pressure-relieving devices, are involved in decisions about their care and have been informed about the rationale and use of pressure-relieving devices.

Because the allocation of pressure-relieving devices is only one part of a pressure ulcer reduction strategy, pressure ulcer incidence as the subject of audit is not appropriate for evaluating the implementation of this guideline.

8.2 Individuals to be included in an audit

An audit could be conducted in settings where people are at elevated risk of developing pressure ulcers, for example ICU, orthopaedic, neurological, spinal injuries units and selected patients discharged to the community.

8.3 Data sources and documentation of audit

Systems for recording the necessary information (which will provide data sources for audit) should be agreed by Trusts.

Whatever method is used for documentation, the process and results of risk assessment and equipment allocation should be accessible to all members of the multidisciplinary team. In relation to risk assessment, this should include name of the scale used, evidence of scores and evidence of holistic assessment prior to allocating pressure-relieving devices.

Documentation of the factors taken into consideration when deciding the most appropriate pressure-relieving device for a patient, the devices allocated and reasons for any changes in devices should occur.

The fact that carers and patients have been informed about pressure ulcer prevention using pressure-relieving devices and educated about the use, operation and management of the equipment should be documented. Patients and carers should be directly questioned about their satisfaction with, and the adequacy of, the information provided and this should be documented in either the patient notes or in another source as agreed by the Trust.
Trusts should establish a system of recording when staff have been educated in pressure ulcer risk assessment and the handling of pressure-relieving devices and implement a process for reviewing education needs relating to risk assessment and pressure-relieving devices.
### Table 9: Measures that could be used as a basis for an audit

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Standard</th>
<th>Exception</th>
<th>Definition of terms</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Allocation of pressure-relieving devices (includes mattresses and overlays, both high-tech and low-tech)</strong></td>
<td>100%</td>
<td>100%</td>
<td>The device is appropriate for the individual (for example, a high-tech device which may be unstable for patients with fractures). The patient declares a particular device. The device has been reported by the patient, or their carer or is known to the health professional to be harmful or unacceptable to that patient.</td>
</tr>
<tr>
<td><strong>Repositioning while being cared for on pressure-relieving devices</strong></td>
<td>100%</td>
<td>None</td>
<td>The holistic assessment as described in recommendation 1 will assist with identification of patients deemed as vulnerable to or at elevated risk of developing pressure ulcers.</td>
</tr>
<tr>
<td><strong>Patient/carer Information</strong></td>
<td>100%</td>
<td>None</td>
<td>Trusts should agree on the type of information to be made available, by whom and when</td>
</tr>
<tr>
<td><strong>Staff education/knowledge</strong></td>
<td>100%</td>
<td>None</td>
<td>Trusts should ensure that each clinical setting has access to advice on handling pressure-relieving devices (including safety, decontamination and the reporting of adverse events)</td>
</tr>
</tbody>
</table>

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9 DISSEMINATION OF GUIDELINES

- The Guideline will be produced in a full and summary format and a version for the public.
- Full copies of the Guideline will be available through the NICE website (http://www.nice.org.uk) in PDF format and summary through the National Electronic Library for Health NeLH (http://www.nelh.nhs.uk/) and National Guideline Clearinghouse (http://www.guidelines.gov).

10 VALIDATION

The guideline will be validated through two stakeholder consultation processes. The first and second drafts will be submitted to NICE in 2003, who will obtain and collate stakeholders comments for consideration by the GDG.

11 SCHEDULED REVIEW OF GUIDELINE

The process of reviewing the evidence is expected to begin 4 years after the date of issue of this guideline. Reviewing may begin earlier than 4 years if significant evidence that affects the guideline recommendations is identified sooner. The updated guideline will be available within 2 years of the start of the review process.
Pressure-relieving devices: draft for consultation

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Appendix A: Glossary of support surface equipment by Fiona Stephens, Project Co-ordinator, RCN Pressure Ulcer Audit

**Pressure-relieving:** equipment removes pressure from different areas of the body at regular intervals.¹

**Pressure redistributing:** equipment moulds or contours around the body, spreading the load and relieving pressure over bony prominences

**Categories of equipment**

**Basic/standard mattress**

Basic ‘old-style’ hospital mattresses. Usually single piece of polyurethane foam confined by non-stretch plastic or nylon cover which has few pressure-relieving properties.²³

**Air-fluidized devices (high-air-loss)**

Designed for the high-risk individual who cannot tolerate any pressure. Warmed airflow through sand-like grains or beads contained in an air permeable fabric create a dry floatation system.⁷

**Alternating pressure devices (mattresses and overlays)**

Works on the principle of cyclical inflation and deflation of air cells over a short period of time. This cycle of inflation and deflation changes interface pressure temporarily, thus relieving pressure and creating a pressure gradient that enhances blood flow.⁴⁵ Available as overlays for beds or chairs or replacement mattresses. Overlays can be made up of ‘bubble cells’ with 3-5cm diameters, or large cell with 10cm or more diameters. Replacement mattresses are more sophisticated and can adjust to patient weight and change of position without bottoming out. Mattresses tend to have more sophisticated operating systems and alarms than overlays.

**Constant low pressure**

Devices that mould around the shape of the patient to distribute weight over a large area.

**High-specification foam pressure-relieving devices (‘foam alternatives’)**

Available in a variety of sizes and thickness. Used for overlays on beds, trolleys and operating theatre (OT) tables and cushions. Easily shaped for specific bony
prominences, for example, heels and heads. Newer formulations of foam have increased resilience and fire retardant abilities – making it safer, more durable and compressible. Ten centimetre foam overlays have improved pressure-relieving capabilities when compared to five centimetre foam overlays or basic hospital mattresses. Pressure-relieving foam mattresses consist of foam layers of varying densities, or sections or cubes of foam that can be temporarily removed to provide greater pressure relief to specific areas. Foam replacement mattresses may include combinations of foam and gel or foam and air filled chambers.

**Fibre filled overlays/mattresses**

Synthetic fibres in a series of connected cushions. The fibre may be silicone coated, or formed into balls to reduce shear and friction. Dependent on the covering fabric characteristics, air may be able to circulate freely around the fibres minimising moisture accumulation and maintaining an even temperature around the patient’s skin. A variety of these are available with differing properties.

**Fluid-filled overlays or mattresses**

The fluid conforms to the micro-contours of the body, consistently moving and reducing sheer as well as providing overall pressure relief.

**Gel (viscoelastic) filled pads**

Frequently used on OT tables to protect head, heels and ankles.

**Low-air-loss devices**

Provide a continuous flow of air from the entire surface of the mattress. A powerful fan maintains air cell inflation at lowest possible level despite constant air loss. This inflation supplies adequate patient support and alignment. Available as an overlay, replacement mattress or whole bed system.

**Sheepskins**

A natural fleece considered a comfort measure, that may reduce friction and improve vapour loss.

**Turning beds (kinetic therapy)**

Devices that assist in turning the patient. May be manually or mechanically controlled, and may provide intermittent or continuous movement.
Pressure-relieving devices: draft for consultation

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Appendix B: Guideline Development Group Members

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Mr Mark Collier, United Lincolnshire Hospitals NHS Trust
Mr Louis Hecht, Tissue Viability Society
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Ms Sally Bell-Syer (CWG)
Ms Colette Marshall (NICE)
Dr Jo Rycroft-Malone (RCN Institute)
Appendix C: Generic search strategies and databases searched

Costing and economic evaluations

#1 (decubitus or pressure sore* or pressure ulcer* or bed?sore* or bed sore* or pressure damage or skin breakdown) in ti, ab, mesh
#2 “Decubitus-Ulcer”/ all subheadings
#3 #1 and #2
#4 mattress* or overlay* or pressure?relie* pressure relie* or air?support* or air support* or air?fluidi?ed or air fluidi?ed or support?surface* or support surface* or pressure?relieving or pressure relieving or low air loss bed*
#5 (cost* or economic* or pric* or pricing or budget* or expenditure* or financ* or charge*) in ti, ab, mesh
#6 #3 and #5
#7 #4 and #5

Quality of life studies

#1 (decubitus or pressure sore* or pressure ulcer* or bed sore* or bed?sore* or skin breakdown or pressure area*) in ti,ab,mesh
#2 (quality near life) in ti,ab,mesh
#3 (well being or well?being) near quality
#4 (utility or utilities or rosser* or ihql or euro qol or euro?qol or eq?5d or 12d or 15d or qwb) in ti,ab,mesh
#5 (12 or 15) near4 dimension*
#6 (life near4 table*) in ti,ab,mesh
#7 (health near related near quality) in ti,ab,mesh
#8 (qol or ql or hrqol or hrql) in ti,ab,mesh
#9 #2 or #3 or #4 or #5 or #6 or #7 or #8
#10 #1 and #9

#2 - #9 also added to bedridden search on MEDLINE, Cinahl, Embase: bed?rid* or bed ridden or bed?bound or bed bound or bed rest or bed?rest

Epidemiology studies

#1 pressure sore* or decubitus or pressure area* or bed?sore* or bed sore* or pressure ulcer* or skin breakdown
#2 epidemiol* or incidenc* or freq* or preval* or survey* or audit*

NB: These searches were adapted to each database.
### Databases searched for costing/economic/quality of life/epidemiology studies

<table>
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<th>Database</th>
<th>Cost/economic</th>
<th>Epidemiology</th>
<th>QOL/cost-utility</th>
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<td><strong>Dates searched</strong></td>
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<td>Econlit</td>
<td>Oct 19&lt;sup&gt;th&lt;/sup&gt;</td>
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<td>Mar 2002</td>
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<tr>
<td>Medline</td>
<td>Oct 17&lt;sup&gt;th&lt;/sup&gt;</td>
<td>May 2002</td>
<td>Mar 2002</td>
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<td>EMBASE</td>
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<td>May 2002</td>
<td>Mar 2002</td>
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<tr>
<td>PSYCHLIT</td>
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<td>Mar 2002</td>
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<td>Cochrane Library Controlled trials via CWG</td>
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<td>Current Controlled Trials</td>
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<td>May 2002</td>
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<td>Apr 2002</td>
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<td>Bio abstracts</td>
<td>Nov 2001</td>
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<td>HEED</td>
<td>Dec 2001</td>
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<td>ASSIA</td>
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<td>Apr 2002</td>
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<tr>
<td>GLAMM (Quality of life assessment in medicine)</td>
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<td>Not relevant</td>
<td>Apr 2001</td>
</tr>
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</table>

**GREY LITERATURE**

| Index to theses                               | Dec 2001      | Dec 2001      | Dec 2001         |

date=indicates when last searched  
*not relevant*=indicates unlikely to obtain relevant material from this source

**Clinical effectiveness review - search strategies (from Cochrane Wounds Group)**

The review was compiled using RCTs from the Cochrane Wounds Group Specialist Trials Register. Multiple and repeated searches have been carried out since 1995, and our searching has, to some extent, been validated by searches carried out by BMJ Publishing Ltd for the *Clinical Evidence* publication. It is not possible at this stage to present a flowchart describing search yields and exclusions as the search has been ongoing for so many years, and initially was part of a larger search covering 8 related wound management topics.
The Wounds Group Trials Register was searched up to April 2000 and has been assembled and maintained as follows:

**Electronic searches**

1. **Medline**

MEDLINE (Silver Platter version 4.0) has been searched for randomised controlled trials (RCTs) and controlled clinical trials (CCTs) from 1966 to December 1997 using a mixture of free text terms and MeSH headings: From January 1998 it has been unnecessary to search Medline as this is searched centrally by the UK Cochrane Centre for all trials and the results are transferred to Central/CCTR. Since January 1998, Central/CDSR is searched instead of Medline for all issues of the Cochrane Library.

The MEDLINE (Silver Platter version 4.0) search strategy used was as follows:

1. decubitus ulcer/ or foot ulcer/
2. leg ulcer/ or varicose ulcer/
3. pilonidal cyst/
4. skin ulcer/
5. diabetic foot/
6. ((plantar or diabetic or heel or venous or stasis or arterial) adj ulcer$).tw.
7. ((decubitus or foot or diabetic or ischaemic or pressure) adj ulcer$).tw.
8. ((pressure or bed) adj sore$).tw.
9. ((pilonidal adj cyst) or (pilonidal adj sinus) or bedsore$).tw.
10. ((diabetic adj foot) or (cavity adj wound)).tw.
11. ((varicose or leg or skin) adj ulcer$).tw.
12. (decubitus or (chronic adj wound$)).tw.
13. ((sinus adj wound$) or (cavity adj wound$)).tw.
14. or/1-13
15. debridement/ or biological dressings/ or bandages/
16. occlusive dressings/ or clothing/ or wound healing/
17. antibiotics/ or growth substances/ or platelet-derived growth factor/
18. fibroblast growth factor/ or electrical stimulation therapy .ti,ab,sh.
19. lasers/ or nutrition/ or surgery/ or surgery, plastic/
20. surgical flaps/ or skin transplantations/ or homeopathy/ or homeopathic/
21. acupuncture therapy/ or acupuncture/ or alternative medicine/
22. alternative medicine/ or massage/ or iloprost/ or alginates/
23. zinc/ or zinc oxide/ or ointments/ or anti-infective agents/
24. dermatologic agents/ or colloids/ or cushions/ or wheelchairs/
25. beds/ or wound dressings/
26. (debridement or dressing$ or compress$ or cream$ or (growth adj factor$)).tw.
27. (pressure-relie$ or (recombinant adj protein$) or bandag$ or stocking$).tw.
28. (antibiotic$ or (electric adj therapy) or laser$ or nutrition$ or surg$).tw.
Pressure-relieving devices: draft for consultation

29. (homeopath$ or acupuncture or massage or reflexology or ultrasound).tw.
30. (iloprost or alginate$ or zinc or paste$ or ointment$ or hydrocolloid$).tw.
31. ((compression adj therapy) or (compression adj bandag$) or wrap$).tw.
32. (bed$ or mattress$ or wheelchair$ or (wheel adj chair) or cushion$).tw.
33. ((wound adj dressing$) or vitamin$ or bind$ or gauze$ or heals or healing).tw.
34. (diet or lotion$ or infect$ or reduc$ or (wound adj healing)).tw.
35. (treat$ or prevent$ or epidemiol$ or aetiol$ or etiol$ or therap$ or prevalence or incidence).tw.
36. or/15-35
37. 14 and 36
38. random allocation/ or randomised controlled trials/  
39. controlled clinical trials/ or clinical trials phase I/ or clinical trials phase II/  
40. clinical trials phase III/ or clinical trials phase IV/ or clinical trials overviews/  
41. single-blind method/ or double-blind method/  
42. publication bias/ or review/ or review, academic/  
43. review tutorial/ or meta-analysis/ or systematic review/  
44. ((random$ adj controlled adj trial$) or (prospective adj random$)).tw.
45. ((random adj allocation) or random$ or (clinical adj trial$) or control$).tw.
46. ((standard adj treatment) or compar$ or single-blind$ or double-blind$).tw.
47. (blind$ or placebo$ or systematic$ or (systematic adj review)).tw.
48. (randomised controlled trial or clinical trial).pt. or comparative study.sh.
49. or/38-48
50. 37 and 49
51. limit 50 to human
52. burns/ or wounds, gunshot/ or corneal ulcer/ or exp dentistry/  
53. peptic ulcer/ or duodenal ulcer/ or stomach ulcer/
54. ((peptic adj ulcer) or (duodenal adj ulcer) or traum$).tw.
55. ((aortocaval adj fistula) or (arteriovenous adj fistula)).tw.
56. (bite adj wound$).tw.
57. or/52-56
58. 51 not 57

2. CENTRAL / CDSR SEARCH STRATEGY (on the Cochrane Library CD-Rom)
1. ((DECUBITUS and ULCER*) or (VARICOSE and ULCER*))
2. ((LEG or LEGS) and ULCER*)
3. ((FOOT or FEET) and ULCER*)
4. ((LEG or LEGS) and VARICOSE)
5. (SKIN and ULCER*)
6. SKIN-ULCER*:ME
7. ((FOOT or FEET) and DIABETIC)
Pressure-relieving devices: draft for consultation

8. ((((PLANTAR or DIABETIC) or HEEL) or VENOUS) or STASIS) or ARTERIAL) and ULCER*)
9. (ISCHEMIC or PRESSURE) and ULCER*)
10. ((BED or BEDS) near (SORE or SORES))
11. (PRESSURE near (SORE or SORES))
12. (PILOMIDAL and CYST*)
13. (PILOMIDAL and SINUS*)
14. (PILOMIDAL and ABSCES*)
15. ((WOUND or WOUNDS) and CAVITY)
16. ((WOUND or WOUNDS) and SINUS*)
17. ((WOUND or WOUNDS) and CHRONIC)
18. ((WOUND or WOUNDS) and DECUBITUS)
19. WOUND-INFECTION*:ME
20. ((WOUND or WOUNDS) and MALIGNANT)
21. WOUND-HEALING*:ME
22. WOUNDS-GUNSHOT*:ME
23. ((GUN or GUNS) or GUNSHOT)
24. WOUNDS-STAB*:ME
25. LACERATION*
26. SURGICAL-WOUND-DEHISCENCE*:ME
27. BITES-AND-STINGS*2:ME
28. ((BITING or BITES) or BITING)
29. TRAUMATOLOGY*:ME
30. BURNS*:ME
31. (WOUND* and BURN*)
32. (BURN* or SCALD*)
33. (SITE or SITES) near DONOR)
34. SELF-MUTILATION*:ME
35. ((STAB or STABS) or STABBING)
36. SOFT-TISSUE-INJURIES*:ME
37. (((((((#1 or #2) or #3) or #4) or #5) or #6) or #7) or #8) or #9) or #10) or #11) or #12)
38. (((((((#13 or #14) or #15) or #16) or #17) or #18) or #19) or #20) or #21) or #22) or #23) or #24)
39. (((((((#25 or #26) or #27) or #28) or #29) or #30) or #31) or #32) or #33) or #34) or #35) or #36)
40. (#37 or #38 OR #39)
41. DENTAL
42. (#40 not #41)
3. CINAHL

CINAHL (Cumulative Index of Nursing and Allied Health Literature - Silver Platter version 4.0) has been searched from inception to July 1999.

The CINAHL (Silver Platter version 4.0) search strategy used is as follows:
1. (pressure-ulcer* or foot-ulcer* or leg-ulcer* or skin-ulcer*) in de
2. (diabetic-foot* or diabetic-neuropathies*) in de
3. ((diabetic-angiopathies*) in de) or diabetes-mellitus/complications / all age subheadings
4. (pilonidal-cyst* or surgical-wound-infection*) in de
5. (plantar or diabetic or heel or venous or stasis or (arterial near ulcer*)) in ti,ab
6. (decubitus or foot or diabetic or ischaemic or (pressure near ulcer*)) in ti,ab
7. (pressure or (bed near sore*)) in ti,ab
8. ((pilonidal near cyst ) or (pilonidal near sinus ) or bedsore) in ti,ab
9. (diabetic near foot) or ((cavity near wound) in ti,ab)
10. (varicose or leg or (skin near ulcer*)) in ti,ab
11. ((decubitus or chronic) near wound*) in ti,ab
12. (sinus near wound*) or ((cavity near wound*) in ti,ab)
13. ((burn near wound*) or (gunshot near wound*) or (bite near wound*) or trauma) in ti,ab
14. #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13
15. (clinical-trials or single-blind-studies or double-blind-studies) in de
16. (control-group or placebo or meta-analysis) in de
17. (random* near clinical near trial*) or ((prospective near random*) in ti,ab)
18. ((random near allocation ) or random* or controlled-clinical-trial* or control) in ti,ab
19. (comparison group* or (standard near treatment ) or compar* ) in ti,ab
20. (single-blind* or ( single near blind ) or double-blind or (double near blind)) in ti,ab
21. (blind* or placebo* or systematic or ( systematic near review)) in ti,ab
22. ((meta analysis or meta-analysis) or (trial* or prospective)) in ti,ab
Pressure-relieving devices: draft for consultation

23. ((clinical-trials ) or (comparative-studies)) in de
24. #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23
25. #14 and #24
26. explode dentistry/ all topical subheadings / all age subheadings
27. (peptic-ulcer*) or (duodenal-ulcer*) or ((corneal-ulcer*)in de)
28. (peptic near ulcer) or (duodenal near ulcer) or ((corneal near ulcer) in ti,ab)
29. dentist* in de
30. #26 or #27 or #28 or #29
31. #25 not #30

Other databases that have been searched from the earliest date available until 1997 are:
- EMBASE - Silver Platter version 4.0
- ISI Science Citation Index (on BIDS)
- BIOSIS (on EDINA)
- British Diabetic Association Database
- CISCOM (Complementary Medicine Database of the RCCM)
- Conference Proceedings (on BIDS)
- Dissertation Abstracts
- British Nursing Index (on ARC) to December 1998

Hand searching

JOURNAL HANDSEARCHES

The following wound care specialist journals are being prospectively hand searched for all RCTs as follows:
- CARE - Science and Practice 1979-1990 (later Journal of Tissue Viability - searched until present)
- Decubitus 1987 - 1993
- Journal of Tissue Viability 1991 - present
- Journal of Wound Care 1991 - present
- Phlebology 1986 - present.

CONFERENCE PROCEEDINGS

Wound care conference proceedings that have been hand searched for RCTs:
- Proceedings of the 1st European Conference on Advances in Wound Management, September 1991, Cardiff, UK
- Proceedings of the 2nd European Conference on Advances in Wound Management, October 1992, Harrogate, UK
- Proceedings of the 3rd European Conference on Advances in Wound Management, October 1993, Harrogate, UK
Pressure-relieving devices: draft for consultation

- Proceedings of the 4th European Conference on Advances in Wound Management, September 1994, Copenhagen, Sweden
- Proceedings of the 5th European Conference on Advances in Wound Management, November 1995, Harrogate, UK
- Proceedings of the 6th European Conference on Advances in Wound Management, October 1996, Amsterdam, Netherlands
- Proceedings of the 7th European Conference on Advances in Wound Management, November 1997, Harrogate, UK
- Proceedings of the 8th European Conference on Advances in Wound Management, April 1998, Madrid, Spain
- 3rd Annual Symposium on Advanced Wound Care, March 1990, Orlando, USA
- 4th Annual Symposium on Advanced Wound Care, April 1991, San Francisco, USA
- 5th Annual Symposium on Advanced Wound Care, April 1992, New Orleans, USA
- 8th Annual Symposium on Advanced Wound Care & Medical Research Forum on Wound Repair, April 1995, San Diego, USA
- 9th Annual Symposium on Advanced Wound Care, April 1996, Atlanta, USA
- Proceedings of: Going into the '90s: The Pharmacist and Wound Care, September 1992, London, UK
- Symposium on Venous Leg Ulcers, 1985
- Venous Forum of the Royal Society of Medicine, 16th April 1999, Leeds

Other strategies

EFFORTS TO IDENTIFY UNPUBLISHED STUDIES

Several databases have been searched (up to December 1997) to attempt to identify unpublished studies. These include:

- CRIB (Current Research in Britain)
- DHS Database
- SIGLE
- UK National Research Register

Experts in the field of wound care have been contacted to enquire about ongoing and recently published trials in the field of wound care. In addition, manufacturers of wound care materials have been contacted for details of the trials they are conducting.

Citations within obtained reviews and papers were scrutinised to identify additional studies.
Note: Appendices E to M are available as separate files