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CLINICAL PRACTICE GUIDELINES



The use of pressure-relieving devices (beds, mattresses and overlays) for the prevention of pressure ulcers in primary and secondary care

**Guidelines commissioned by the
National Institute for Clinical Excellence**

*National Collaborating Centre for
Nursing and Supportive Care*

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Background

This work was undertaken by the National Collaborating Centre for Nursing & Supportive Care (NCC-NSC) and the guideline development group (GDG), which was formed to develop this guideline. Funding was received from the National Institute for Clinical Excellence (NICE). The NCC-NSC consists of a partnership between the Centre for Evidence-Based Nursing; the Centre for Statistics in Medicine; the Clinical Effectiveness Forum for Allied Health Professionals; Health Care Libraries (University of Oxford); College of Health; the Health Economics Research Centre; Royal College of Nursing; and the UK Cochrane Centre.

Disclaimer

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

- ◆ available resources
- ◆ local services, policies and protocols
- ◆ the patient's circumstances and wishes
- ◆ available personnel and devices
- ◆ clinical experience of the practitioner
- ◆ knowledge of more recent research findings.

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Stakeholder involvement

The following stakeholders commented on draft versions of these guidelines:

3M Healthcare Ltd

Abbott Laboratories Ltd

All Wales Medical and Pharmaceutical Advisers Forum

Ambulance Service Association

British Association for Parenteral and Enteral Nutrition (BAPEN)

British Association of Plastic Surgeons

British Association for Prosthetists and Orthotists

British Dietetic Association

British Geriatrics Society

British Medical Association – Hospital Doctors Secretariat

BUPA

Chartered Society of Physiotherapists
 Clinical Interest Group in Orthotics, Prosthetics and Wheelchairs
 Cochrane Wounds Group
 College of Occupational Therapists
 Community Practitioners' and Health Visitors' Association
 Department of Health
 Frontier Therapeutics Ltd
 HMT Systems
 Judy Mead
 Kaymed
 Medical Support Systems Ltd
 National Association of Tissue Viability Nurses Southern Group
 Parkhouse Healthcare Ltd
 Pegasus Ltd
 Royal College of General Practitioners
 Royal College of Midwives
 Royal College of Nursing
 Royal College of Physicians
 Royal College of Surgeons of England
 Royal Pharmaceutical Society of Great Britain
 Smith & Nephew Healthcare
 Society of Chiropractors and Podiatrists
 Southern Alliance of Tissue Viability Nurses
 Spinal Injuries Association
 Talley Group Ltd
 Tissue Viability Nurses Association
 Tissue Viability Society (UK)
 Westmeria Healthcare Ltd
 Wyeth Laboratories

Terminology

1. Where the term 'carer' is used, this refers to unpaid carers as opposed to paid carers – for example, care workers.
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 both with recent guidelines (NICE 2001a; RCN 2001), and the evidence review on which this guideline is partly based. A glossary of pressure-relieving devices is given in Appendix 1.
3. Pressure ulcers have also been known previously as pressure sores, bedsores, decubitus ulcers and pressure injuries.
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. 'Vulnerable to pressure ulcers' means someone who is likely to develop pressure ulcers unless special care is given – special care meaning a planned intervention following holistic assessment. 'At elevated risk of pressure ulcers' means someone who is especially likely to develop pressure ulcers unless special care is given.
5. Pressure-relieving devices can be divided into low-tech and high-tech devices (Cullum et al 2001).

Low-tech devices. These provide a conforming support surface that distributes the body weight over a large area, and include the following:

- ◆ Standard foam mattresses.
- ◆ Alternative foam mattresses/overlays – for example, high-specification foam, viscoelastic, convoluted foam, cubed foam. These are conformable and aim to redistribute pressure over a larger contact area.
- ◆ Gel-filled 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 devices: 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.
- ◆ Air fluidised devices: warmed air is circulated through fine ceramic beads covered by a permeable sheet. These allow support over a larger contact area.
- ◆ Low air loss devices: patients are supported on air-filled sacs inflated at a constant pressure, through which air can pass.
- ◆ Turning beds/frames – kinetic or profiling beds: beds that either aid manual repositioning of the patient or reposition the patient by motor-driven turning and tilting.

Abbreviations

AP	alternating pressure
ARR	absolute relative risk
CI	confidence interval
CLP	constant low pressure
CRD	Centre for Reviews and Dissemination
CWG	Cochrane Wounds Group
DH	Department of Health
GDG	guideline development group
HTA	health technology assessment
ICU	intensive care unit
ITT	intention-to-treat
LAL	low air loss
MHRA	Medicines and Healthcare products Regulatory Agency, formerly Medical Devices Agency
NCC-NSC	National Collaborating Centre for Nursing & Supportive Care
NICE	National Institute for Clinical Excellence
OECD	Organisation for Economic Co-operation and Development
OT	operating theatre
QALY	quality-adjusted life year
RCN	Royal College of Nursing
RCT	randomised controlled trial
RR	relative risk

Glossary

This glossary is partially based on the clinical epidemiology glossary by the evidence-based medicine working group of the University of Alberta (<http://www.med.ualberta.ca/ebm/define.htm>), *Information for national collaborating centres and guideline development groups* (NICE 2001b) and the *Royal College of Nursing clinical practice guidelines: pressure ulcer risk assessment and prevention* (RCN, 2001).

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

Bias: May result from flaws in the design of a study or in the analysis of results and may result in either an underestimate or an overestimate of the effect.

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 an exposure in a group of patients (cases) who have a particular condition is compared with the effects of the exposure in 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 that do more good than harm.

Cochrane collaboration: An international organisation in which people retrieve, appraise and review available evidence of the effect of interventions in health care. The Cochrane database of systematic reviews contains regularly updated reviews on a variety of issues. The Cochrane library contains the central register of controlled trials (CENTRAL) and a number of other regularly updated databases, which are available as a CD-ROM or at: www.cochranelibrary.com.

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

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

Comorbidity: Coexistence of a disease or diseases in a study population, in addition to the condition that is the subject of study.

Confidence interval: The range of numerical values in which we can be confident that the population value being estimated will be 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 pounds 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.

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

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.

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 care professional: Includes nurses, allied health professionals and doctors.

Health technology assessment: The process by which evidence on the clinical effectiveness and the costs and benefits of using a technology in clinical practice are systematically evaluated.

High-tech devices: Dynamic pressure-relieving devices that include alternating pressure devices, low air loss devices and others (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 that 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.

Odds ratio: Odds in favour of being exposed in subjects with the target disorder, divided by the odds in favour of being exposed in control subjects – without the target disorder.

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 – that is it has both high sensitivity and specificity.

Pressure-relieving: In this document refers to both pressure-reducing and pressure-redistributing equipment that either remove pressure from different areas of the body at regular intervals, or moulds or contours around the body, spreading the load and relieving pressure over bony prominences.

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

Profiling bed – kinetic or turning bed: Motor-driven turning and tilting beds that either aid manual repositioning of the patient or reposition the patient.

Quality-adjusted life expectancy: Life expectancy using quality-adjusted life years rather than nominal life years.

Quality-adjusted life year: A measure of health outcome that assigns to each time period a weight, ranging from 0 to 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: 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 – for example, pressure, tourniquet – which is in direct response to incoming arterial blood.

Relative risk: An estimate of the magnitude of an association between exposure and disease that 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 randomised controlled trials – to obtain a reliable overview.

User: Anyone using the guideline.

Validity: The extent to which a variable or intervention measures what it is supposed to measure or accomplish. The internal validity of a study refers to the integrity of the design; the external validity of a study refers to the appropriateness by which its results can be applied to non-study patients or populations.

1 Executive summary

NICE commissioned the NCC-NSC to develop a guideline 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 followed referral of the topic by the Department of Health and the Welsh Assembly Government. This document describes the methods used to develop the guideline and presents the resulting recommendations. It is the source document for the NICE (abbreviated version for health professionals) and information for the public – patient – versions of the guideline, which are published by NICE. The guideline was produced by a multidisciplinary guideline development group and the development process was undertaken by the NCC-NSC.

The main objective of the guideline was to establish the most clinically and cost effective beds, mattresses or overlays for preventing pressure ulcers. Additional areas examined included:

- ◆ the evidence for linking risk assessment to allocation of pressure-relieving devices
- ◆ differences between the various devices in terms of comfort and acceptability ratings, ease of use and adverse events
- ◆ quality of life implications associated with the use of different pressure-relieving devices
- ◆ the groups that are at 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 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 'stand-alone' product and should be used in conjunction with the existing NICE (2001a) guideline on risk assessment and prevention, which can be found on the NICE website at: <http://www.nice.org.uk/Docref.asp?d=16477>

Of particular importance in the NICE (2001a) guideline are the sections on risk assessment. The present guideline draws on some of that information to inform the recommendation on holistic assessment, before 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 as one document 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 forthcoming NICE guidelines on wound care.

Health care professionals should use their clinical judgement and consult with patients when applying the recommendations, which aim to reduce the negative physical, social and financial impact of pressure ulcers.

A version for health care professionals – NICE version – and a version for patients and carers – information for the public – are available at: www.nice.org.uk.

2 Principles of practice and summary of guideline recommendations

2.1 Principles of practice

The principles outlined below, based on RCN 2001, describe the ideal context in which to implement the recommendations in this guideline.

2.1.1 Person-centred care

- ◆ Patients and their carers should be made aware of the guideline and its recommendations and be referred to the information for the public version.
- ◆ Patients and their carers should be involved in shared decision-making about pressure-relieving devices.
- ◆ Health care 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.

2.1.2 A collaborative interdisciplinary approach to care

- ◆ All members of the interdisciplinary team should be aware of the guideline and all care should be documented in the patient's health care records.

2.1.3 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.

2.1.4 Equipment safety

Equipment safety is an important issue in relation to the use of pressure-relieving devices. In particular, cross-infection can happen if equipment is inadequately decontaminated between patients (Orr et al 1994) and injury is possible if users of such equipment – patients, carers and health care professionals – have not been educated about appropriate use. Therefore guideline users are referred to the standards on medical device management and decontamination of reusable medical devices (Medical Devices Agency 1999, 2002). [Note: the Medical Devices Agency (MDA) has merged with the Medicines Control Agency and is now called the Medicines and Healthcare products Regulatory Agency (MHRA).] Users of this guideline are encouraged to familiarise themselves with the sections of these documents relevant to the use and decontamination of pressure-relieving devices. Anecdotal evidence suggests that, if there is no access to adequate decontamination facilities, it may be preferable to lease rather than purchase 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.

2.2 Summary of guideline recommendations

Please refer to Table 8, page 33 for details of the system used to grade recommendations.

1. Decisions about which pressure-relieving device to use should be based on cost considerations and an overall assessment of the individual. Holistic assessment should include all of the following points, and should not be based solely on scores from risk assessment scales:
 - ◆ identified levels of risk
 - ◆ skin assessment
 - ◆ comfort
 - ◆ general health state
 - ◆ lifestyle and abilities
 - ◆ critical care needs
 - ◆ acceptability of the proposed pressure-relieving equipment to the patient and/or carer [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. Although there is no research evidence that high-tech pressure-relieving mattresses and overlays are more effective than high-specification – low-tech – foam mattresses and overlays, professional consensus recommends that consideration should be given to the use of alternating pressure or other high-tech pressure-relieving systems:
 - ◆ as a first-line preventative strategy for people at elevated risk, as identified by holistic assessment
 - ◆ when the individual's previous history of pressure ulcer prevention and/or clinical condition indicates that they are best cared for on a high-tech device
 - ◆ when a low-tech device has failed. [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-relieving 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 two 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. The time elapsing between assessment and use of the device should be specified in this strategy. [D]
9. All health care 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]

3 Background to the current guideline

In 1998, the DH commissioned the RCN to develop clinical guidelines on pressure ulcer risk assessment and prevention. During the development of these guidelines, NICE was established. It was decided to submit the RCN 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, because of 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 – beds, mattresses and overlays (NICE 2001a). 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 guideline were omitted, although recommendations on the use of aids – water-filled gloves, doughnut-type devices, etc – and seating were included.

In March 2002, the NCC-NSC was commissioned by NICE to develop guidelines on pressure-relieving devices for the prevention of pressure ulcers in primary and secondary care, to include information on cost effectiveness. The remit from the DH 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 review by Cullum and co-workers (2001), and an economic analysis was undertaken that 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 (2001a) 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 – for example, 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 developing a guideline on the management – treatment – of pressure ulcers, in collaboration with NICE, due for publication in 2005. It is envisaged that NICE will eventually publish as one document the 'treatment' guideline, the NICE inherited guideline on risk assessment and prevention, guidelines on wound care and the pressure-relieving devices guideline.

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 2002). Pressure ulcers have been recorded as occurring in 4 to 10 per cent of patients, following admission to a UK district general hospital – the precise rate depends on case-mix. They 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 in UK hospitals ranges from 5 to 32 per cent, case-mix unadjusted.

The financial costs to the NHS are also substantial (Cullum et al 1995). 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 1994). The cost of treating a patient with a stage 4 pressure ulcer (see Section 3.2 for definitions) has been calculated as £40,000 (Collier 1999). In particular, there is a high cost associated with the 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 increasing their use 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, bedsores or 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 people who are immobile. Other at-risk groups 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. One example of a common grading scheme (DH 1993) is:

Stage 1: Pressure ulcer is defined as an erythema of the intact skin. The reddened area remains red after pressure is relieved. Key features include: persistent discoloration of the skin, including non-blanchable erythema on light skins and blue-black discoloration on darker skins.

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 with 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 full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone tendon or joint capsule.

3.3 Groups at risk

Groups at particularly high risk of having a pressure ulcer have been reported in depth in the RCN (2001) guidelines 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, and 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 2001). 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 – namely, beds, mattresses and overlays.

Beds, mattresses and overlays differ considerably and can be classified in various ways (see Section 4.5, where the classification of devices used for this guideline is explained). Pressure-relieving devices vary in the materials they are made from and in their pressure-relieving mechanisms. For example, constant low pressure (CLP) devices mould around the patient to distribute their weight over a larger area, while 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 given in Appendix 1.

4 Aims of the guideline

The aims of this guideline are to:

- ◆ evaluate and summarise the clinical and cost evidence for the use of pressure-relieving devices, as defined below, in preventing pressure ulcers.
- ◆ highlight gaps in the research evidence.
- ◆ 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.
- ◆ 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
- ◆ health care 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 previously, this guideline should be used in conjunction with the NICE inherited guideline on risk assessment and prevention (NICE 2001a).

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, it is relevant to preventing pressure ulcers on other areas of the patient's body and further pressure damage to existing pressure ulcers.

4.3 Groups not covered by the guideline

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 2005.

4.4 Health care setting

The guideline covers the use of pressure-relieving devices by health care professionals in primary and secondary care 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 post-operative 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 pressure-relieving or pressure-redistributing devices described below are effective and cost effective. The classification used in this guideline is based on that used in the systematic review published as a health technology assessment (HTA) report (Cullum et al 2001), as this was agreed to be the most practical and the review was being updated for the purpose of this guideline. Further details of the devices listed below are given in the glossary of pressure-relieving devices in Appendix 1.

4.5.1 Low-tech devices

1. Standard foam mattresses.
2. Alternative foam mattresses/overlays, for example, high-specification foam, viscoelastic, convoluted foam, cubed foam. These are conformable and aim to redistribute pressure over a larger contact area.
3. Gel-filled mattresses/overlays.
4. Fluid-filled mattresses/overlays.
5. Fibre-filled mattresses/overlays.
6. Air-filled mattresses/overlays.

4.5.2 High-tech devices

1. AP devices: 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 devices: 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 (LAL) devices: patients are supported on air-filled sacs inflated at a constant pressure, through which air can pass.
4. Turning beds/frames – kinetic or profiling beds: beds that either aid manual repositioning of the patient or reposition the patient by motor-driven turning and tilting.

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.

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, for example, 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 (2001a) 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 have been issued by NICE, due for review in 2005. The NICE (2001a) 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 GDG convened by the NICE-funded NCC-NSC, with membership approved by NICE. Members included representatives from:

- ◆ patient groups
- ◆ nursing
- ◆ field of tissue viability and wound care
- ◆ medicine
- ◆ allied health
- ◆ researchers
- ◆ staff from the NCC-NSC.

A list of GDG members is given on page 4. The GDG met six times between May 2002 and July 2003. An additional meeting to formulate patient-related review questions relating to the guideline topic was held in July 2002.

5 Methods used to develop the guideline

5.1 Summary of the 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) – recommendations, evidence statements, evidence narrative and GDG 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
- ◆ RCN (2001) evidence review on risk assessment.

The stages used to develop this guideline were to:

- ◆ develop the scope of the guideline
- ◆ convene the multidisciplinary GDG
- ◆ review the questions set
- ◆ 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, and 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 the generalisability of included studies to the scope of the guideline
- ◆ prepare evidence reviews and tables that summarise and grade the body of evidence
- ◆ formulate conclusions about the body of available evidence based on the evidence reviews by taking into account the above factors
- ◆ agree final recommendations and apply

recommendation gradings

- ◆ submit first drafts – short version and full version- of the guideline for feedback from NICE-registered stakeholders
- ◆ allow the GDG to consider stakeholders' comments
- ◆ submit final drafts of all guideline versions – including Information for the public version, algorithm and audit criteria – to NICE for second stage of consultation
- ◆ allow the GDG to consider stakeholders' comments
- ◆ submit final copy NICE.

Because the remit from the DH and Welsh Assembly Government was to complete the inherited version of the guidelines on risk assessment and prevention, the main clinical question set by them was 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?
(*Source of evidence: RCN (2001) review of evidence relating to risk assessment*)
- ◆ 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*).

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 summarised the evidence. For the clinical effectiveness data, the Cochrane Wounds Group (CWG) searched for studies additional to those included in the Cullum review (Cullum et al 2001) 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 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 – including the full version of the guideline, the NICE version and the information for the public version – based on the evidence reviews and GDG input and deliberations. The GDG formulated and graded the recommendations.

The methods used for each review are reported in Sections 5.2 and 5.3. The results are reported in Sections 5.6 to 5.9. More details are given in Section 5.10.

5.2 Clinical effectiveness review methods

5.2.1 Background

In April 2001, an HTA review 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 and co-workers (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 of the updated systematic review are summarised below. Note: 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

Randomised controlled trials (RCTs) comparing beds, mattresses and overlays that measured the incidence of new pressure ulcers as an objective measure of outcome.

RCTs are essential to establish the safety and effectiveness of pressure-relieving devices and products (Ferrell 1998). Lack of data from RCTs may result in increased costs, because devices, products and services may be used that are not always safe, let alone effective (Ferrell 1998).

Economic evaluations were included only if they were part of an RCT. There was no restriction on the basis of language, publication status or year of study.

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 that evaluated the interventions below 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, because:

- ◆ the interventions were either outside the remit of the guideline (12, 14 and 16)
- ◆ the particular products evaluated were 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 – for example, high-specification foam, viscoelastic, convoluted foam, cubed foam. *These are conformable and aim to redistribute pressure over a larger contact area.*
 3. Gel-filled 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. AP devices: *patient lies on air-filled sacs that sequentially inflate and deflate and relieve pressure at different anatomical sites for short periods; may incorporate a pressure sensor.*
10. Air fluidised devices: *warmed air circulates through fine ceramic beads covered by a permeable sheet; allows support over a larger contact area.*
11. LAL devices: *patients are supported on air-filled sacs inflated at a constant pressure, through which air can pass.*
12. Sheepskins: *proposed mode of action unclear.*
13. Turning beds/frames, including profiling and kinetic beds: *these work by either aiding manual repositioning of the patient, or by motor-driven turning and tilting.*
14. Wheelchair cushions: *may be conforming; reduce contact pressures by increasing surface area in contact or by 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 items 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 that used only subjective measures of outcome were excluded, as were studies that 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 involve the complex interaction of a variety of factors (Cullum et al 2003).

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 that compared the incidence of pressure ulcers of stage 2 or greater are more likely to be reliable as there is a greater potential for misclassification of grade 1 ulcers. 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 from the Centre for Reviews and Dissemination (CRD).

Subsequently, the specialist trials register of the CWG – compiled and regularly updated from searches of the Cochrane controlled trials register – MEDLINE, Cinahl, Embase, etc were searched up to October 2002.

The electronic search was supplemented by a hand search of five specialist wound care journals, 12 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 to add 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 given in Appendix 2.

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 previously 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, for example, 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.
- ◆ 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. Ninety-five per cent confidence intervals (95 per cent CIs) were included when sufficient detail allowed their calculation. The results from replicated studies were plotted onto 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 3). 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 and Oxman 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 DH 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-relieving beds, mattresses and overlays compared with standard support surfaces

- ◆ an investigation of which types of pressure-relieving surfaces are the most cost effective for prevention of pressure ulcers.

In April 2001, an HTA review was published on pressure-relieving devices for the prevention and treatment of pressure ulcers (Cullum et al 2001). In this report, the costs of these devices were reported as £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, and secondly to identify evidence that could be used in cost effectiveness modelling.

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 RR 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
- ◆ incremental cost per quality-adjusted life year (QALY).

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-relieving devices:

= **Difference in costs to the health service between pressure-relieving devices**

Difference in number of pressure ulcers averted

5.3.3 Incremental cost per QALY

If possible, the likely decrement in QALYs associated with a pressure ulcer of a particular stage could be estimated, and cost effectiveness then be reported in terms of the cost per QALY gained. Costs incurred by patients and their informal carers is documented and reported where available:

TABLE 1
INFORMATION REQUIREMENTS FOR COST EFFECTIVENESS MODELS

	Comparison of the relative risk of developing a pressure ulcer between devices	Epidemiology of the absolute risk of developing a pressure ulcer for patient groups	Cost of device per patient	Cost of treating pressure ulcers	Estimate of QALYs
Incremental cost per pressure ulcer averted	Yes	Yes	Yes	Yes	No
Incremental cost per QALY	Yes	Yes	Yes	Yes	Yes

= Difference in costs to the health service between pressure-relieving devices

Difference in QALYs

The information requirements for each type of analysis are shown in Table 1 (above).

It was proposed that the evidence from the clinical effectiveness review on the RR would be combined with additional information on the epidemiology, costs and outcomes to model the cost effectiveness of different devices. These information requirements are discussed in turn below.

5.3.4 Comparison of the relative risk of developing a pressure ulcer

This information was collected as part of the clinical effectiveness review. The extent to which 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 to the health service per day of using these devices, the following information was required:

- ◆ purchase price of the device
- ◆ lifespan of the device, for example, eight years
- ◆ 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, for example if it is easier to turn patients on certain products.

The cost of devices is further complicated by the use of different purchasing mechanisms 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 were 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
- ◆ which groups are at particularly high risk of developing 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 QALYs

The effects of pressure ulcers on patients' quality and length of life is an important consideration in valuing pressure ulcer prevention. A pressure ulcer can restrict a patient's activities – physical and social – cause pain and psychological distress, as well as having a negative impact on social, emotional and financial areas of life. Lastly, the patient's family and friends may suffer distress over the patient's condition.

Consequently, studies were sought that:

- ◆ 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
- ◆ examined associations between quality of life and different pressure-relieving devices.

Further details are given in Section 5.8.

5.3.9 Aims of literature search

The aim of the cost effectiveness review was to identify the most up-to-date information that could be generalised 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:

- ◆ Economic evaluations and costing studies of pressure ulcers and/or pressure-relieving devices – cost effectiveness review.
- ◆ Quality of life measures for patients who have pressure ulcers and/or who use pressure-relieving devices – quality of life review.
- ◆ Studies that 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 and quality of life studies, the study design inclusion criteria were necessarily broad in order to maximise 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 2).

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.

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.

There was 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.

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-relieving devices are identical to the clinical effectiveness section.

Information from all economic evaluations of pressure ulcers was 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 and 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-relieving devices
- ◆ costs per case of treating pressure ulcers.

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

There was no restriction on the basis of language or publication status.

Studies were included from 1992 until May 2002 for treating pressure ulcers and from 1997 to 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-relieving devices are identical to the clinical effectiveness section.

Quality of life

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

All quality of life studies involving patients with pressure ulcers were considered for inclusion.

There was 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-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, US and Canadian epidemiological studies from 1980 to 1997. A few classic papers pre-1980 were also included in the Kaltenthaler review (refer to Kaltenthaler et al 2001 for details of the studies used in their review). The same criteria for selection were used to select studies for the update:

- ◆ UK studies that determined the prevalence and incidence of pressure ulcers
- ◆ studies had to specify
 - ◆ the total number participating
 - ◆ 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

The search strategies and the databases searched are listed in Appendix 2. All searches were comprehensive and included a large number of databases. All search strategies were adapted for smaller or simpler databases or for web-based sources that did not allow complex strategies or multi-term searching.

A combination of subject heading and free text searches was 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 advice that exhaustive searching on every guideline review topic is not practical or efficient (Mason et al, unpublished paper, 2002).

Reference lists of articles were checked for potentially relevant articles.

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:

- ◆ Stage 1: Sift for material that potentially meets eligibility criteria on basis of title/abstract.
- ◆ Stage 2: Order full papers that appear relevant and eligible and where relevance/eligibility not clear from the abstract.
- ◆ Stage 3: Appraise full articles that meet eligibility criteria.

Sifting for relevance at Stage 1 was carried out by one systematic reviewer. The cost/economic references were then sent to the health economist who selected which articles to order. For the quality of life and epidemiology studies, the screening and selection 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 reviewer:

- ◆ details of the study design
- ◆ details of the study population
- ◆ details of the pressure-relieving device, for example, standard mattress versus AP device
- ◆ details of individual outcome measures used, for example, cost per pressure ulcer 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 reviewer:

- ◆ 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 the 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 the 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 it 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 statistical 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 minimises bias (Cullum et al 2003).

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

All data extraction forms are given in Appendix 4.

5.4 Submission of evidence process

In March 2002, stakeholders registered with NICE (see page 6) 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
- ◆ RCTs that examine clinical or cost effectiveness, and/or quality of life and economic analyses based on these findings
- ◆ representative epidemiological observational studies that 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 that 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 – no costing, quality of life or epidemiological information – and full references were not sought.

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 reanalysis 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 summarised in evidence tables (Appendices 7 to 9) as well as discussed in the appropriate evidence reviews.

Evidence gradings were assigned to each evidence review using the evidence hierarchy shown in Table 2, which is the only hierarchy recommended by NICE at the time of

writing. It should be noted that the hierarchy strictly applies to questions of effectiveness.

The evidence tables and reviews were distributed to GDG members for comment on the interpretation of the evidence and grading.

TABLE 2
LEVELS OF EVIDENCE

I	Evidence from meta-analysis of RCTs or at least one RCT.
II	Evidence from at least one controlled trial without randomisation or at least one other type of quasi-experimental study.
III	Evidence from non-experimental descriptive studies, such as comparative studies, correlation studies and case-control studies.
IV	Evidence from expert committee reports or opinions and/or clinical experience of respected authorities.

Source: Adapted from Eccles and Mason (2001).

5.6 Results of clinical effectiveness evidence retrieval and appraisal

5.6.1 Details of studies included in the review

For the update of the clinical effectiveness review, 54 articles were assessed for eligibility; seven relevant articles were data extracted and included. In total, 41 RCTs were included in the review, including the seven new studies identified (see Appendix 3). Twenty-one trials involved patients without pre-existing pressure ulcers – intact skin; four included patients with ulcers greater than stage 1; three included both patients with and without ulcers and in 13 studies it was unclear.

5.6.2 Study settings

Four studies evaluated different operating table surfaces (Aronovitch et al 1999; Nixon et al 1998; Russell and Lichtenstein 2000; Schultz et al 1999); six evaluated different surfaces in ICUs (Gentilello et al 1988; 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; McGowan et al 2000; Price et al 1999; Santy et al 1994; Stapleton 1986) and one involved an accident and emergency department setting (Gunningberg et al 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 natural sheepskins, and three looked at turning or profiling 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 5. Although most trials discussed the criteria for including patients, only about 50 per cent of the reports gave information that indicated that patients were truly randomly allocated (Schulz et al 1995). Ten 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 (ITT) analysis and underpowered trials were also common. For most comparisons there was a lack of replication.

Characteristics of excluded studies are given in Appendix 6.

5.6.4 Comparisons

The comparisons able to be made on the basis of the included studies and relevant to this guideline are given below.

Low-tech constant pressure supports

- ◆ Comparisons of standard foam mattresses with other low-tech supports.
- ◆ Comparisons between foam alternatives, namely, head-to-head comparisons of high-specification foam products – for example, contoured foam, supports comprising foam of different densities.
- ◆ Comparisons between CLP supports – head-to-head comparisons of 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 AP supports and standard hospital mattresses.
- ◆ Comparison between AP supports and other CLP devices.
- ◆ Comparisons between different AP supports.
- ◆ Comparisons between LAL beds and standard intensive care beds.
- ◆ Comparisons between LAL hydrotherapy and standard care.
- ◆ Air fluidised beds versus dry flotation.

- ◆ Kinetic turning device and profiling beds versus standard beds, with and without pressure-relieving mattresses.

Other

- ◆ Operating theatre overlays – viscopolymer pad with a standard theatre mattress – versus standard mattresses.
- ◆ Accident and emergency trolley overlays versus standard.
- ◆ Sheepskin overlays versus no overlays.

5.6.5 Summary of results

The full evidence reviews are included in Section 6.

- ◆ Foam alternatives – high-specification foam – can reduce the incidence of pressure ulcers in people at risk of developing pressure ulcers, compared to the standard hospital foam mattress.
- ◆ The relative merits of AP and CLP devices, and of the different AP devices, for pressure ulcer prevention are unclear.
- ◆ Pressure-relieving overlays on the operating table have been shown to reduce post-operative pressure ulcer incidence.
- ◆ There is insufficient evidence to draw conclusions on the value of kinetic turning tables or profiling beds, seat cushions, limb protectors and various CLP 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 accident and emergency 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 two 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 3).
- ◆ A study that investigated an LAL device – permeable fast-drying filter sheet over LAL cushions, circulating air, also referred to as a hydrotherapy bed – found it was neither safe nor effective, with the caveat that these findings may not relate to products developed later (Bennett et al 1998). 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 three times the incidence of pressure ulcers, but this result was not statistically significant (Tymec et al 1997).
- ◆ An American trial (Schultz et al 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 post-operative skin changes, namely mainly stage 1 pressure ulcers. However, it is difficult to separate out the role of post-operative care and padding that 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 not be clarified. Therefore it is difficult to assess the clinical importance of these findings. Further information on the study and product has been requested from the author.

5.7 Results of cost effectiveness evidence retrieval and appraisal

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 (Table 3). We also present a simple cost effectiveness model.

TABLE 3
RESULTS OF SEARCH/SIFT FOR ECONOMIC EVALUATIONS
AND COST STUDIES

Total number of hits	1352
Potentially relevant from title/abstract	240
Full article ordered	141
Final number of economic evaluations included	3
Final number of costing studies included	11

For both of the above searches, 240/1352 studies were selected on the basis of the first sift. Of those, 141 were ordered. The included studies are shown in Appendix 7.

5.7.1 Economic evaluations

Only three economic evaluations (Gebhardt et al 1996; Inman et al 1993; Russell et al (2003) of pressure-relieving devices for the prevention of pressure ulcers were identified that used evidence from RCTs or quasi-randomised trials.

Russell and co-workers (2003) compared the cost effectiveness of standard mattresses with viscoelastic mattresses for elderly patients with Waterlow scores of 15–20, using data from an RCT. They concluded that there was a 95 per cent chance that the cost per pressure ulcer averted was less than £100.

Gebhardt et al (1996) used a quasi-randomised design to compare the cost effectiveness of CLP supports with AP mattresses in acutely ill patients in an ICU. They concluded that AP supports were less expensive and more effective than CLP supports and so were 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 and co-workers (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 to 17/32 (Drummond and Jefferson 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 costing of pressure ulcer devices is complex. Pressure-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. 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 examining the costs of pressure-relieving devices (Cowan 1997; Cowan and Woollons 1998; Cullum et al 2001; Hampton 1998; Hibbert et al 1999). In addition, the NHS Purchasing and Supplies Agency and members of the GDG provided cost estimates. These articles mainly focused 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, for example, electricity for hi-tech devices
- ◆ 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.

Table 4 provides a summary of the range of purchase prices, adjusted to 2000/2001, of different devices, using the data from the costing studies, the NHS Purchasing and Supplies Agency and GDG members.

There is wide variation in the cost of devices. Standard hospital mattresses range in price from £39 to £62 and high-specification foam mattresses from £97 to £422. Other mattresses, such as AP and LAL mattresses, are significantly more expensive, ranging in price from £2,722 to £5,645. Overlay costs for operating theatre tables range from £100 to £3,500.

TABLE 4
SUMMARY OF PURCHASE PRICES OF PRESSURE-RELIEVING DEVICES
2000/2001

Type of device	Minimum (£)	Maximum (£)
Mattresses		
Standard hospital mattress	39	62
Air-filled mattress	79	
High-specification foam mattress	97	422
AP mattress	870	4473
Dry flotation mattress	1499	
Dynamic air mattress	2722	4356
LAL mattress	2722	5645
Overlays		
Foam overlay	49	390
AP overlay	125	1750
LAL overlay	1806	3500
Bed systems		
Dynamic pressure-relieving bed systems	8488	
Therapy beds	10,449	36,000
Beds		
Four-section electric profiling beds	1120	2995
Four-section non-electric profiling beds	725	915
Hospital trolleys		
Pressure-relieving systems for hospital trolleys	595	905
Overlay devices for operating theatre tables		
Range of devices	100	3500

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
- ◆ 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 comorbidity 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 comorbidity.

No UK research was identified that calculated adjusted additional lengths of stay for patients with pressure ulcers. However, a study in the USA 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 severity of illness at admission, comorbidities, nosocomial infections, and other hospital complications (Allman et al 1999). The authors concluded that the incidence of pressure ulcers was associated with a 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 – for example, Clark et al 1992; Collier et al 1999 – are based on different management strategies.

A paper by Bennett et al (in press) provides the most recent UK estimates of additional cost per pressure ulcer. 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 to £1,000.

5.7.4 Cost effectiveness modelling

Where there is very little evidence of the comparative clinical effectiveness of different devices it is difficult to model the difference in cost effectiveness between them. 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 evidence with the cost evidence. Furthermore, as shown in Section 5.8, data are not available to quantify patient outcomes within the cost effectiveness model.

However, there is strong clinical evidence that pressure-relieving mattresses comprised of 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 high-specification foam pressure-relieving 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 per cent then five patients out of 100 will develop a pressure ulcer on a standard hospital mattress.

The results of a meta-analysis showed that high-specification pressure-relieving mattresses reduce the risk of pressure ulcers compared to standard hospital mattresses by 71 per cent (Cullum et al 2001). This estimate was used to calculate an adjusted level of risk for patients cared for on these mattresses, compared to standard mattresses. For example, if five out of 100 patients developed pressure ulcers on a standard mattress it was predicted that 1.5 patients would develop pressure ulcers on a high-specification foam 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. Two of the GDG members have written papers on this area and were able to provide appropriate estimates. They presented their estimates to the GDG and 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. Recognising the uncertainty in this estimate, a sensitivity analysis was conducted (see Table 5, below). 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 eight years, with interest rates of 6 per cent. To calculate a cost per patient of each device it was assumed that there was 100 per cent bed occupancy and the average length of stay was five days. The uncertainties of the estimates of the bed lifespan and length of stay were explored in the sensitivity analysis.

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.

The results are presented in Table 5 (below). They indicate that although high-specification foam pressure-relieving mattresses are more expensive to buy than standard hospital mattresses, 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 one patient in 200 – 0.5 in 100 patients – develops a pressure ulcer on a standard hospital mattress. It is likely that these mattresses are cost effective, compared to standard hospital mattresses for all groups of patients vulnerable to developing pressure ulcers.

Assumptions:

1. There is a 71 per cent reduction in the risk of developing a pressure ulcer (Cullum et al 2001). 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.
2. Treatment of grade 1 pressure ulcer £750 (GDG estimate).
3. Device costs: purchase costs based on midpoint of range presented in Table 4; average length of stay is five days, there is 100 per cent occupancy and the lifespan of the bed is eight years.

There is considerable uncertainty about the estimates used in this model. To explore the effect of this uncertainty, a worst-case scenario sensitivity analysis was performed

TABLE 5
COMPARISON OF COSTS OF STANDARD HOSPITAL MATTRESS WITH PRESSURE-RELIEVING MATTRESS (HIGH-SPECIFICATION FOAM)

Standard hospital mattress				
Number of patients predicted to develop a pressure ulcer from 100 patient episodes	0.5	5	10	20
Cost of treating pressure ulcers	£375	£3750	£7500	£15,000
Cost of standard foam mattress	£11	£11	£11	£11
Total cost	£386	£3761	£7511	£15,011
High-specification foam mattress				
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	£1125	£2250	£4500
Total cost of pressure-relieving mattress	£57	£57	£57	£57
Total cost	£170	£1182	£2307	£4557
Incremental cost (difference in cost)	-£216	-£2579	-£5204	-£10,454
Incremental effect (difference in number of pressure ulcers)	0.35	3.5	7	14
Incremental cost per pressure ulcer averted (difference in cost/difference in effect)	Dominates*	Dominates*	Dominates*	Dominates*

* The device is both more effective and costs less.

using less favourable estimates of the pressure-relieving mattress. These included the lowest estimate of the additional cost of treating a grade 1 pressure ulcer of £500, only a 41 per cent reduction in the risk of developing a pressure ulcer based on the lower 95 per cent confidence interval from the meta-analysis (Cullum et al 2001), the maximum purchase cost of high-specification foam mattresses in Table 4 and an estimated lifespan of these mattresses of four years. The results showed that even in this scenario and for groups where only one patient in 100 develops a pressure ulcer, the pressure-relieving mattress was still cost-dominant. In other words, high-specification foam pressure-relieving mattresses overall cost less and were more effective in reducing pressure ulcers.

A formal analysis of the incremental cost effectiveness of other pressure-relieving devices is not included. However, using the same costing methods to calculate the cost of AP devices if six out of 100 patients develop a pressure ulcer; AP mattresses would have to reduce the risk of pressure ulcer development by 23.5 per cent 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 cost effectiveness from these studies alone. Further research is needed to assess the cost effectiveness of different devices.

There are wide variations in the costs 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 ulcers when using high-specification foam mattresses, compared to standard hospital mattresses. This evidence was used to model the incremental cost effectiveness of these devices in patients at different risk levels of developing pressure ulcers.

The model indicates that because of the savings accruing through treating fewer pressure ulcers, high-specification foam 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 patient/carer and 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, we report the results of the search and appraisal of the studies on quality of life (Table 6). 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 6
RESULTS OF SEARCH/SIFT FOR QUALITY OF LIFE STUDIES

Total number of hits	302
Potentially relevant from title/abstract	9
Meets eligibility criteria	9
Full article ordered and appraised	9
Final number included	7

Nine studies out of 302 potential articles (1980 to 2002) were retrieved on the basis of title/abstract. Seven were included – five primary research (two case-control, one survey and two qualitative) and two non-systematic reviews. All evidence is level III–IV using the level of evidence hierarchy described previously and is summarised in the evidence tables (Appendix 8).

No articles measured QALYs in people with pressure ulcers. Franks et al (2002) used the SF-36 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 et al 2002; Langemo et al 2000; Unalan et al 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 socialisation. Care giving also had an emotional, physical and financial impact.

The study by Franks et al (2002) found that people with pressure ulcers had poorer health and experienced deficits in self-care and mobility; while the qualitative study by Langemo and co-workers (2000) reported that pressure ulcers had a profound negative effect on the physical, social and financial realms of people's lives.

The two reviews (Rintala 1995; Franks and Moffatt 1999) 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 were rejected as they were of little relevance to 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 that investigated quality of life in actual patients who were bedridden, with or without pressure ulcers, or that surveyed patient preferences for particular devices.

Some of the clinical effectiveness studies included in the Cochrane review included ratings of comfort of particular devices made by a sub-sample of patients able to complete a questionnaire or interview (see Appendix 3, 'notes' column for details). However, because this data is not routinely collected in trials, it is not possible to say whether one category of device 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. Quality of life may be difficult to measure in pressure ulcer patients because:

- ◆ it is difficult to separate out the quality of life effect of the pressure ulcer from the effects of comorbidity
- ◆ patients with severe pressure ulcers are often chronically ill and may be 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, and financial and functional status.

5.9 Results of epidemiology evidence retrieval and appraisal

In this section, we report the results of the search and appraisal of epidemiology studies (Table 7). This information was used to inform the cost effectiveness review.

TABLE 7
RESULTS OF SEARCH/SIFT PROCESS FOR EPIDEMIOLOGY UPDATE
(ARTICLES TO UPDATE THE KALTENTHALER ET AL 2001 REVIEW)

Total number of hits	2431
Potentially relevant from title/abstract	182
Meets eligibility criteria from title/abstract	30
Full article ordered and appraised	20
Final number included	15

The features of the included studies are set out below.

Prevalence studies n = 8 (all level III)

Setting

4 = general hospital

1 = community hospital/mental health

2 = nursing home/residential care

1 = paediatric

Stage 1 included

6 = yes

Incidence studies n = 7

Study design

Four were prospective cohort studies (level III)

Three were retrospective (level III)

Setting

2 = general hospital

5 = high-risk setting (defined as burns units, palliative care, spinal injuries, amputees, critical/intensive care, elderly hip fracture patients)

0 = nursing home/residential care settings

0 = paediatric ward

Stage 1 pressure ulcer included

4 = yes

5.9.1 Results of review update

Fifteen studies published since 1997 fulfilled the inclusion criteria and were included (Appendix 9). Study quality and reporting of detail was variable and only one study adjusted for case-mix (Williams et al 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 homes and residential homes. Some studies provided breakdown by type of setting within a trust, but for two studies (Hanson 1997; Willock et al 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 (Willock et al 2000) reported both incidence and prevalence studies. These are separately reported in the evidence table.

In five of seven 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.

Summarised information is shown in Appendix 9. Confidence intervals were calculated for prevalence and incidence estimates.

5.9.2 Prevalence in the UK

The review by Kaltenthaler and co-workers (2001) reported prevalence ranges for UK hospitals of 5–32.1 per cent, based on 17 studies (two in nursing homes; two in community settings; one in a palliative care unit and 12 in hospitals). For community settings, the range was 4.4–6.8 per cent and that for nursing homes was 4.5–7.5 per cent. The highest reported prevalence was 37 per cent for a palliative care unit.

Studies included in the update of work by Kaltenthaler and co-workers gives pressure ulcer estimates for nursing homes of 7.9 per cent (Shiels and Roe 1999) and 7.4 per cent (Levett and Smith 2000). Shiels and Roe (1999) also give a prevalence figure of 3.5 per cent for residential homes.

For hospitals, the highest estimate was 59 per cent (Cockbill et al 1999) but a small sample was used (n = 22); the confidence interval was wide and the representation 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 per cent (heel ulcers only) to 11 per cent.

5.9.3 Incidence in the UK

The Kaltenthaler review identified eight incidence studies (five in high-risk settings and three in hospital settings). In this review, incidence figures reported for hospitals ranged from 2.2 per cent per annum to 29 per cent over a maximum period of six weeks. Only one study, which included patients who were bed-fast and chair-fast, was reported for community settings, giving an estimate of 20 per cent 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 per cent over an 18-month period.

For the update, incidence figures obtained retrospectively (three studies) ranged from 0.3 per cent (labour ward) over 18 months to 37.7 per cent (among 'lower limb amputees in Hereford') over a year. Incidence figure ranges for prospective data were 1.7 per cent (over a period of 28 days) to 8.7 per cent (median duration eight days). Except for the lower limb amputee study, no studies were found reporting incidence in community or nursing home/residential care settings were not found. An incidence of 7.3 per cent was found in a small sample of paediatric patients (Willock et al 2000).

Including only general hospital studies (i.e. excluding paediatrics, burns units, critical care and palliative care units) the range was 1.7–8.7 per cent.

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 et al 1999) the range for the new studies was 6.5–11 per cent, compared to the earlier range of 5–32 per cent.

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

Combining studies from 1980 to 2002, the prevalence

ranges remain the same, whereas the lower range of incidence is now 1.7 per cent. 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 and co-workers reported, there may be a minimum rate below which it is hard to go.

Similarly, in terms of incidence figures, there are few reported changes in the last five 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 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 that 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 – 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 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 that impacted on considerations of the evidence and the ability to formulate ‘implementable’ and pragmatic guideline recommendations, these were summarised in the GDG commentary sections.
- Issues with the available data identified by the GDG included:
- ◆ a lack of robust economic evaluations
 - ◆ the relative merits of some devices for pressure ulcer prevention are unclear, for example, AP 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, because of 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), as cited in the RCN (2001) guidelines)
 - ◆ because of 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
 - ◆ 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 five could be included in the NICE version. As described previously, there were shortcomings in the data, and so some of the review questions could not be fully and satisfactorily answered by empirical evidence. In some instances extrapolated evidence was used – this sometimes 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 in Table 8.

The recommendations, with accompanying evidence reviews, are presented in Section 6.

TABLE 8
RECOMMENDATION GRADING

A	Directly based on category I evidence
II	Directly based on category II evidence or extrapolated recommendation from category I evidence
III	Directly based on category III evidence or extrapolated recommendation from category I or II evidence
IV	Directly based on category IV evidence or extrapolated recommendation from category I, II or III evidence.

Source: Adapted from Eccles and Mason (2001).

6 Guideline recommendations, with supporting evidence

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 Patient factors to consider in selecting a pressure-relieving device

6.1.1 Recommendation

- Decisions about which pressure-relieving device to use should be based on cost considerations and an overall assessment of the individual. Holistic assessment should include all of the following, and should not be based solely on scores from risk assessment scales (level II):
 - ◆ identified levels of risk
 - ◆ skin assessment
 - ◆ comfort
 - ◆ general health state
 - ◆ lifestyle and abilities
 - ◆ critical care needs
 - ◆ acceptability of the proposed pressure-relieving equipment to the patient and/or carer (level IV) [D].

6.1.2 Evidence

Level of evidence	Evidence statements
Level II	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.
Level IV	There is little evidence to support the use of risk assessment scales to make decisions about allocation of devices.

Clinical evidence

The principles under 'identifying individuals at risk' and 'use of risk assessment scales' are covered in more depth in the RCN (2001) and NICE (2001a) guidelines. It was not in the remit to revisit this area in terms of updating the

evidence reviews and producing revised recommendations.

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 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 could 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 NICE recommendations (2001) state 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.

Recommendations relating to these areas are reproduced from the NICE (2001a) guidelines 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 recognise 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 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 speciality 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
- ◆ neurological disease
- ◆ 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.

Source: Reproduced from NICE (2001a).

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 and evidence reviews) was outside the official scope of this guideline. Although the area was comprehensively covered in the NICE (2001a) guidelines, it was necessary for the GDG to revisit this area in order to consider the definition and meaning of 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, because of 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 before allocating beds, mattresses or overlays, guideline users should be aware of the NICE (2001a) 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 summarised important common sense principles relating to risk assessment as follows:

- ◆ An informal risk assessment - for example, skin assessment, taking into account past history and condition of patient - 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 - using validated tools in addition to other features of a holistic assessment - should be routinely conducted on those people whose initial assessment highlights factors that may render them vulnerable to, or at elevated risk of, developing pressure ulcers.
- ◆ Risk assessment should also be conducted for in-patient admissions to accident & emergency and for those cared for in the community. Note: The RCN guidelines state on page 22 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' outlined on page 20 of the RCN guidelines 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 ongoing throughout an individual's episode of care, regardless of setting.
- ◆ Health care 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 recognise 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 all 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

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

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 high-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 summarised 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 et al (2003); 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 per cent CI, 0.14–0.85); the Beaufort bead bed (Goldstone et al 1982) (RR 0.32, 95 per cent CI, 0.14–0.76); the Softform mattress (Gray and Campbell 1994) (RR 0.2, 95 per cent CI, 0.09–0.45); or the water-filled mattress (Andersen et al 1982) (RR 0.35, 95 per cent CI, 0.15–0.79) (Figures 1 and 2, Appendix 10). In an unpublished British study of older people with hip fractures admitted to orthopaedic trauma wards, patients allocated to receive an 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 (Russell et al 2003) 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 viscoelastic cushion (20 per cent), and those allocated a standard mattress and cushion combination (26 per cent) ($p = 0.0004$).

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 ($I^2 = 1.64, 2 \text{ df}$) (Figure 1, Appendix 10). 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 per cent CI, 0.19–0.43), or a relative reduction in pressure ulcer incidence of 71 per cent (95 per cent 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 et al 2000) found that pressure ulcer incidence was reduced in those assigned a sheepskin produced to Australian standards (relative risk for sheepskins relative to standard treatment was 0.28; 95 per cent 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 (contoured foam, supports comprising foam of different densities).

Five RCTs (Collier 1996; Gray and Smith 2000; Kemp et al 1993; Santy et al 1994; Vyhliidal et al 1997) compared different foam alternatives. Santy and colleagues (1994) compared five 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, as well as Vaperm compared with Clinifloat. Vyhliidal and colleagues (1997) compared a four-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 per cent CI, 0.18–0.96) with the mattress replacement, however this trial appeared to have used neither allocation concealment nor blinded outcome assessment. The relative risk translates to a relative reduction in the incidence of pressure ulcers of 58 per cent associated with use of the five-section foam and fibre mattress replacement (an absolute risk reduction of 0.35, or 35 per cent, and a number needed to treat of three, or one additional pressure ulcer prevented for every three patients receiving a Maxifloat mattress replacement).

No patients developed pressure ulcers in the Collier (1996) trial. Kemp and co-workers (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 an ulcer.

Comparisons between low-tech CLP supports:

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 gel) supports; Silicore-filled supports; heel elevators.

Seven RCTs compared different low-tech CLP devices for

prevention of pressure ulcers (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). However, most of these trials were seriously underpowered and/or had other methodological flaws.

A trial from Finland (Takala et al 1994) comparing the Optima (Carital) CLP mattress – which comprises 21 double air bags on a base – with the standard hospital mattress found that 37 per cent of patients on the standard mattress developed ulcers compared with none on the Optima (RR 0.06; 95 per cent CI, 0.0–0.99). 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 overlays:

Gunningberg and co-workers (2000) examined the effects of an accident & emergency overlay on 101 patients with a suspected hip fracture. No difference in pressure ulcer incidence was found between those assigned a viscoelastic foam mattress on arrival in accident & emergency with a viscofoam 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 that compared the cost effectiveness of using standard foam mattresses with viscoelastic polymer mattresses (Russell et al 2003). The study found that the higher specification mattress was the cost-dominant strategy, with a lower cost per patient, and was 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
- ◆ 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, for example, 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 are 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.

A recent retrospective review of all voluntary reports of deaths in beds with air mattresses, found 35 deaths involving many product lines (Miles 2002). Twenty-one deaths involved overlay air mattresses placed on top of a regular mattresses; 13 patients died in beds with built-in air mattresses. Compression of the mattress allowed an off-centre person to slide against the rail, where re-expansion of the mattress keeps the person compressed against the rail (Miles 2002). Manufacturers attributed the deaths to poor clinical decision-making or inadequate monitoring. The author of the study suggests that redesign of some products and risk awareness by clinicians is needed to prevent death by asphyxiation.

Users of this guideline are referred to manufacturer's information on other contraindications.

6.3 Patients at elevated risk of developing pressure ulcers

6.3.1 Recommendation

3. Although there is no research evidence that high-tech pressure-relieving mattresses and overlays are more effective than high-specification (low-tech) foam mattresses and overlays, professional consensus recommends that consideration should be given to the use of AP or other high-tech pressure-relieving systems:

- ◆ as a first-line preventative strategy for people at elevated risk as identified by holistic assessment
- ◆ when the individual's previous history of pressure ulcer prevention and/or clinical condition indicates that they are best cared for on a high-tech device
- ◆ when a low-tech device has failed. (level IV) [D]

6.3.2 Evidence

Level of evidence	Evidence statements
Level I	Standard hospital mattresses have been consistently outperformed by high-tech pressure-relieving mattresses.
Level IV	The relative merits of AP and CLP devices and of the different AP devices for pressure ulcer prevention are unclear.
Level IV	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.

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 high-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 CLP and AP devices and of the different AP devices for the prevention of pressure ulcers are unclear and (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 preventative interventions in some areas and not others, varying widely in cost (< £1000 to > £4000) (Cullum et al 2001).

The different comparisons are summarised below.

AP supports:

A variety of 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: one study compared AP and standard

hospital mattresses (Andersen et al 1982); eight studies compared AP and various CLP devices 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 three studies compared other AP supports (Exton-Smith et al 1982; Hampton 1997; Taylor 1999).

AP compared with standard hospital mattress:

One RCT (Andersen et al 1982) reported that the use of AP surfaces reduced the incidence of pressure ulcers compared with standard hospital mattresses (RR 0.32; 95 per cent 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.

AP compared with CLP:

Eight trials compared AP devices with various CLP devices, but 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 per cent compared with 13 per cent in the AP group) (RR 0.38; 95 per cent 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 AP supports and a variety of CLP devices such as the Silicore overlay (Conine et al 1990; Daechsel and Conine 1985; Stapleton 1986), a water mattress (Andersen et al 1982; Sideranko et al 1992), 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 several trials were too small to be able to detect clinically important differences as statistically significant.

Four studies that 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 three-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 versus Silicore or foam overlays (using a fixed effects model; χ^2 0.03, $df = 3$) was 0.91 (95 per cent CI, 0.71–1.17), indicating no statistically

significant difference between Silicore or foam overlays and AP (Figure 3, Appendix 10).

The studies comparing AP with static water or static air mattresses were also considered together (Andersen et al 1982; Price et al 1999; Sideranko et al 1992). The Sideranko trial also had three 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 (χ^2 2.67, $df = 2$) produced a pooled relative risk of 1.26 (95 per cent CI, 0.60–2.61), indicating no statistically significant difference (Figure 4, Appendix 10).

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 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 χ^2 of 12.81 ($df = 7$), a random effects model was applied. This yielded an overall relative risk of 0.82 (95 per cent CI, 0.57–1.19), suggesting no statistically significant difference between the rates of pressure ulcer incidence on AP versus CLP (Figure 5, Appendix 10). This means that the data are consistent with AP being associated with a reduction in risk of up to 19 per cent, 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, CLP and AP support in surgical intensive care patients intra- and post-ICU. This trial, which involved only 75–80 patients in each group, did not identify any significant effect of using AP in the ICU (Laurent 1997).

Comparisons between different AP devices:

AP 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 AP 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 the severity of pressure ulcers in a high-risk group of elderly patients. However, the

allocation was not truly random, and an ITT analysis would not have shown a statistically significant difference in the rate of pressure ulcers (16 per cent vs 34 per cent, $p > 0.05$).

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

More recently, Taylor (1999) compared the Pegasus Trinova three-cell AP air mattress combined with a pressure-redistributing cushion with a two-cell AP 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.

LAL beds

One trial showed that LAL 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 per cent CI, 0.11–0.53) (Inman et al 1993). A second trial compared LAL hydrotherapy (LAL-hydro) with standard care (some patients received AP in this group); more patients developed ulcers stage 2 or greater in the LAL-hydro group (19 per cent) than the standard care group (7 per cent), although this did not reach statistical 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 and beds:

Turning beds contain motors that 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), but only two of the trials could be obtained (Gentilello et al 1988; Summer et al 1989). Sample sizes in all the trials were 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, or 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 AP or other high-tech devices in patients at very high risk. Two economic evaluations showed that AP 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. Where appropriate, consideration should be given to selecting lower-cost devices.

6.3.3 Guideline development group comment

Because of the high cost of these devices, it would have been preferable to have made recommendations about 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 use was mainly in specialist centres - burns, spinal cord injuries - or intensive care settings. However, not all patients on AP devices have actual pressure damage, in particular young disabled people 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 audit of acute wards, orthopaedic wards, care of the older person and medical wards showed that 80/291 (27.5 per cent) were placed on AP or LAL support surfaces, nine were placed on a profiling bed and seven were cared for on AP overlays (Stephens F: personal communication, 2003). Within the nursing care setting, the audit found that 18 residents out of 51 (35 per cent) were on AP or LAL bed support surfaces, a profiling bed was used to care for a younger disabled patient and eight were cared for on an AP overlay. The audit identified that 4 per cent of patients would have benefited from an increase in provision, equally divided between the care homes and the acute trusts.

Clark and Cullum (1992) found that AP mattresses are widely used in both pressure ulcer prevention and treatment. LAL and air fluidised beds are relatively rarely used and tend to be restricted to pressure ulcer treatment and for the treatment of burns in the case of air fluidised 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 validated methods of deciding when to allocate a patient to a high-tech device. In practice, this decision is based on 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 1). Young disabled people 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 demonstrated to result in improved patient outcomes.

There is other information that practitioners should be aware of:

- ◆ Some high-tech devices may be detrimental in certain circumstances. For example, those with mobility disorders placed on air fluidised 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 more than 40 per cent of AP systems in hospital were in use, but being used incorrectly.

Users of this guideline are referred to manufacturer's information on other contraindications.

- ◆ If a patient's condition changes, then the device may need to change.

6.4 Individuals undergoing surgery

6.4.1 Recommendation

- 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-relieving surface (level IV) [D].

6.4.2 Evidence

Level of evidence	Evidence statements
Level I	Pressure-relieving overlays used on the operating table and in the post-operative period have been shown to reduce post-operative pressure ulcer incidence. However, it is unclear which form of pressure relief on the operating table is the most effective.
Level IV	Individuals who 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.
	No UK evidence was identified on the comparative cost of pressure-relieving overlays for operating tables.

Clinical evidence

Studies (n = 3) of pressure-relieving overlays on the operating table have shown a reduction in post-operative pressure ulcer incidence in high-risk surgical patients (Cullum et al 2001). Individuals who 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, for example, gel-filled or AP 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 and co-workers (1999).

The studies are summarised below:

- ◆ Four RCTs evaluated different methods of pressure relief on the operating table. The first compared a viscoelastic polymer pad with a standard table and found a relative reduction in the incidence of post-operative pressure ulcers of 47 per cent associated with using the polymer pad for patients undergoing elective major general, gynaecological or vascular surgery - supine or lithotomy (RR 0.53; 95 per cent CI, 0.33–0.85) (Nixon et al 1998).
- ◆ Two further RCTs compared the Micropulse AP system - applied both during surgery and post-operatively - with a gel pad during surgery and standard mattress post-operatively and reported a pooled relative risk (fixed effects) of 0.21 (95 per cent CI, 0.06–0.70) in favour of the Micropulse system (Aronovitch et al 1999; Russell and Lichtenstein 2000) (Figure 6, Appendix 10). It is not clear from these two trials whether the effect is due to intra-operative or 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 et al 1999). People in the experimental group were significantly more likely to experience post-operative 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 post-operative 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 these 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, although anecdotal evidence from the GDG suggests that their use is increasing. For the sake of continuity of care, individuals vulnerable to or at elevated risk of pressure ulcers 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 two hours until the condition of an individual with an elevated risk changes (level IV) [D].

6.5.2 Evidence

Clinical evidence

The recommendations are consensus-based.

The RCN guidelines have a section on positioning (Section 7.0, page 17), which elaborates on these recommendations. The main message 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 preventative practice (RCN 2001).

There was also concern that practitioners should adopt a 24-hour approach to pressure relief and repositioning that 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 any pressure ulcer reduction strategy 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 MHRA policies. Timeliness is also of paramount importance. Each trust should have a policy specifying 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. All health care professionals should be educated about:
 - ◆ pressure ulcer risk assessment and prevention
 - ◆ selection, use and maintenance of pressure-relieving devices
 - ◆ 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
- ◆ where they can seek further advice and assistance (level IV) [D].

6.7.2 Guideline development group comment

These are consensus-based statements based on those included in the NICE (2001a) 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. Following NICE requirements, the first five are those that were prioritised by the GDG, using a group consensus process in which each group member ranked every research recommendation:

1. Comparisons of AP devices with:
 - ◆ low-tech alternatives, for example, different types of high-specification foam mattresses, other CLP devices
 - ◆ other high-tech devices - for example, LAL and air fluidised 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, including paediatrics.
2. 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.
3. Evaluation of the impact/effectiveness of assessment at the point of entry into health care, including acute care, care homes and in the community, and the impact of delays to this process.
4. 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.
5. 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.
6. UK trials further testing the use of natural sheepskins, similar to those used in the Australian study, in preventing pressure ulcers among patients vulnerable to pressure ulcers.
7. Research investigating patients' need for and use of various pressure-relieving devices across a 24-hour period.

8. 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. Note: evaluation of the technical performance of mattresses is currently being undertaken by the MHRA.
9. 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.
10. The physiological indicators - for example, blood flow – that correlate to the clinical outcomes achieved using mattresses.
11. Impact of organisational factors, such as staffing levels and bed crises, on pressure ulcer incidence.

In 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; economic evaluations; conduct of effectiveness research in community settings.

8 Audit criteria

The audit criteria presented here are intended to assist with implementation of the guideline recommendations and 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 this guideline are reminded that the criteria presented here need to be used in conjunction with the audit criteria presented in the RCN (2001) guidelines and the implementation points in the NICE (2001a) 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 risk assessment, clinical judgement, patient condition, lifestyle and prior experiences of pressure-relieving devices should be considered when allocating devices.

8.1 Objectives of 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 ICUs, orthopaedic, neurological and spinal injuries units and on 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 an audit, should be agreed by trusts.

Whichever 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 information should include the name of the scale used, evidence of scores and evidence of holistic assessment prior to allocating pressure-relieving devices.

There should be 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 made.

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 (page 46) summarises the measures that could be used as a basis for an audit.

9 Dissemination of the guideline

- ◆ The guideline has been produced in both full and summary formats and as a version for the public (Information for the Public).
- ◆ Full copies of the guideline are available through the NICE website (<http://www.nice.org.uk>) in PDF format and the 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 has been validated through two stakeholder consultation processes. The first and second drafts were submitted to NICE in 2003, which collated stakeholders' comments for consideration by the GDG.

11 Scheduled review of the guideline

The process of reviewing the evidence is expected to begin four years after the date of issue of this guideline. Reviewing may begin earlier, if significant evidence affecting the guideline recommendations is identified sooner. The updated guideline will be available within two years of the start of the review process.

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