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Ms Jo Rycroft-Malone

Research and Development Fellow
RCN Institute

Ms Elizabeth McInnes

Guidelines Co-ordinator
National Breast Cancer Centre
Sydney, Australia
(formerly Project Officer, RCN Institute)

Other contributors

See Appendix 1

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Chapter One

Introduction

I had an operation on my gall bladder. I told the staff I was prone to getting pressure sores. They assured me I would not get any while in their care. Low and behold when I came around from the anaesthetic, they found a beauty... it is now six and a half years old.

(person with a spinal injury)

The National Health Service Executive (NHSE) commissioned the Royal College of Nursing (RCN) to produce an evidence-linked national clinical guideline for pressure ulcer risk assessment and prevention. The guideline has been developed in collaboration with an inter-disciplinary group, including users and carers, to direct care towards clinically appropriate and cost-effective interventions based on best evidence (Shiffman, 1997).

The evidence considered for this guideline has come from a number of different sources:

- the Agency for Health Care Policy and Research (AHCPR, 1992) evidence-linked guideline, *Pressure ulcers in adults: prediction and prevention*
- an update of sections of their research base (Rycroft-Malone and McInnes, 2000)
- the *Effective Health Care Bulletin*: The prevention and treatment of pressure sores (EHCB, 1995)
- a systematic review of the effectiveness of pressure redistributing devices (Cullum et al, 2000) a systematic review of the effectiveness of risk assessment tools (McGough, 1999)
- and the results of a formal consensus process (Rycroft-Malone, 2000).

The guidelines have been published in three formats to give health care professionals the opportunity to choose which is most appropriate for their needs:

- quick reference guide
- recommendations and rationales

- technical report.

The reference guide and the recommendations are available from: RCN Publishing Ltd, Distribution Depot, PO Box 1, Portishead, Bristol BS20 9EG. Tel: 01275 847180, 9am to 5pm, Monday to Friday. The reference guide is free (plus £1.50 p&p). The recommendations are £5.50 to RCN members; £7.50 to non-members (plus £1.50 p&p). The technical report is available free to download from the RCN web site: www.rcn.org.uk

The purpose of this report is to provide guideline users with an audit trail of the guideline's development. It comprises the following chapters:

Chapter One: Introduction to the background of the guideline's development

Chapter Two: Method of guideline development

Chapter Three: Guideline recommendations with rationales and strength of evidences

Chapter Four: Conclusions and implications.

1.1 Background

Pressure ulcers, also known as pressure sores, decubitus ulcers and bed sores, are areas of localised damage to the skin and underlying tissue. They are believed to be caused by a combination of pressure, shear and friction (Allman, 1997). Collier (1996) defines them as:

"..skin ulceration as a result of pressure in combination with the effects of other variables"

Acute illness/ trauma and immobility are key variables. Others are identified in the proceeding recommendations.

Pressure ulcers usually occur over bony prominences and should be graded or staged to classify the degree of tissue damage observed. For example:

Stage 1: Pressure ulcer is defined as an erythema of intact skin. The reddened area remains reddened longer than 30 minutes after pressure is relieved. Key features include: persistent discoloration of the skin, including non-blanchable erythema; blue/purple/black discoloration.

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

Stage 3: Pressure ulcer involves full-thickness skin loss involving damage or necrosis of subcutaneous tissue that may extend down to, but not through, underlying fascia, bone, tendon or joint capsule. This type of ulcer will most likely involve destruction of both subcutaneous tissue and fat. It may include necrotic tissue, undermining, sinus tract formation, exudate, or infection. The wound base is usually not painful.

Stage 4: Pressure ulcer presents as a full-thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone, tendon or joint capsule. Presents as a deep crater. It may include necrotic tissue, undermining, sinus tract formation, exudate or infection. The wound base is usually not painful.

Stage 5: Includes ulcers that are covered with dark necrotic tissue (eschar). These ulcers are most frequently stage 2 or 3 ulcers and in some cases, stage 4.

(From: Agency for Health Care Policy and Research. *Pressure ulcers in adults: prediction and prevention*. 1992:8)

However, the grading and detection of pressure damage, particularly in the very early stages, can be subjective and unreliable (EHCB, 1995).

1.1.1 Aetiology

A combination of factors is thought to influence the development of pressure ulcers. Pressure ulcers can develop in any area of the body. They are likely to be caused by a combination of pressure, shear and friction forces where there are also other factors at work influencing a person's tissue tolerance.

Factors such as immobility or diminished activity, neurological deficits, incontinence, nutritional deficits and age may be associated with an increased risk of pressure ulcer development. Immobility, reduced activity and moisture/humidity (incontinence) are the most consistently reported predisposing factors. Therefore there are certain groups of people who are deemed to be more susceptible to developing them – for example:

- the elderly
- those with reduced mobility or who are immobile, such as orthopaedic patients
- those with severe/acute illness, such as patients in intensive care
- and those with neurological deficits, such as patients with spinal cord injuries.

Currently, it is not fully understood how all these factors interact when ulcers develop (Defloor, 1999).

Unfortunately, pressure ulcers are common. New pressure ulcers occur in 4%-10% of patients admitted to a UK District General Hospital (Clark and Watts, 1994). However, it is commonly thought that most pressure ulcers can be avoided (EHCB, 1995). A number of quality improvement initiatives have attempted to address this aspect of patient care (Health of the Nation targets, 1992; Pressure sores a key quality indicator, 1993; Benchmarking the fundamental aspects of nursing care, 2000).

1.1.2 The cost of pressure ulcers

Pressure ulcers represent a major burden of sickness and reduce quality of life for patients and their carers – requiring prolonged contact with the health care system, and causing pain, discomfort and inconvenience (Franks et al, 1999). The financial costs to the NHS are also substantial (Cullum et al, 1995). Preventing and treating pressure ulcers in a 600-bed general hospital costs between £600,000 and £3 million a year (Touche Ross, 1993), excluding litigation costs. Collier (1999a), applying a similar formula to Hibbs (1988), calculated the cost of treating a patient with a Grade IV pressure ulcer as £40,000.

The human suffering and financial costs of pressure ulcers, the variation in practice in the UK and a growing body of knowledge about effectiveness highlight the need for recommendations for practice. The timely commissioning of this evidence-linked clinical guideline on risk assessment and prevention of pressure ulcers complements and builds on the work of others, such as the European Pressure Ulcer Prevention Guidelines (EPUAP, 1999).

1.2 Aims of the guideline

The overall aim of this guideline is to provide health care professionals with recommendations that will help reduce pressure ulcer occurrence. More specifically, it aims to:

- provide health care professionals with the best means for assessing those at risk of pressure ulcer development
- provide health care professionals with the most effective interventions for preventing patients from developing pressure ulcers
- reduce the likelihood of unproven or harmful methods of assessment and prevention.

1.3 What the guideline covers

The guideline (Chapter Three) comprises six sections:

Quick reference guide and summary of recommendations

A philosophy of care which makes suggestions about the environment within which the recommendations should be implemented. Evidence-linked recommendations for:

- Identifying individuals at risk
- Use of risk assessment scales
- Recognising risk factors
- Skin inspection
- Pressure redistributing devices
- Use of aids
- Positioning
- Seating
- Education and training

Essentials of care

Identifies the practice issues of nutritional status, continence management and hygiene, and their role in pressure ulcer development.

Quality Improvement

- Quality improvement cycle
- Monitoring pressure ulcers
- Discharge planning

Audit Criteria

Glossary of terms

Two clinical issues have recently been the subject of systematic review: risk assessment scales (McGough, 1999) and pressure redistributing devices (EHCB, 1995; Cullum et al., 2000). Their results provided some research evidence that could be translated into recommendations. Both these authors reported the poor quality of the studies available for review and highlighted the need to conduct good quality research in these areas in the future.

The AHCPR guideline (1992) included a literature review of other relevant topics, such as skin care, positioning and education. An updated literature review (1991-1998) of these areas revealed that little additional good research evidence had emerged in the interim

period (Rycroft-Malone and McInnes, 2000). In the light of this, a formal consensus development process was used to integrate the different evidence sources and, where there was a weak research base, agree recommendations based on current best practice (Rycroft-Malone, 2000).

What the guideline does not cover

The guideline does not cover the epidemiology of pressure ulcers or make recommendations for wound care or surgical management of pressure damage.

1.4 Intended users of the guideline

Inter-disciplinary team members

To provide a co-ordinated approach and improve patient care, pressure ulcer risk assessment and prevention needs to be seen as an inter-professional issue. This guideline is intended for use by all health care staff including: managers, professionals allied to medicine, nurses, doctors, tissue viability specialists, bioengineers, health care assistants, portering staff, equipment suppliers and academics.

The guideline is not a textbook or training manual and cannot bridge all competency levels. Anyone not fully competent in any or all of the areas included in the guideline, or not familiar with a particular patient's condition, should refer the patient to an experienced and adequately trained health care professional or appropriate service – for example, tissue viability specialist or spinal injury centre.

Patients and carers

The guideline could also be used as a reference by patients and carers. Health care professionals need to be mindful that in its present form the guideline may require explanation. The RCN Institute are planning to develop a user version of this guideline in the near future.

1.5 Patients and settings to which the guideline will apply

The recommendations made in this guideline are aimed at adults and children, who are free of pressure ulcers and may be seen in hospital, nursing homes, supported accommodation and in the home. The guideline does not include treatment of existing pressure ulcers. Though in cases where a patient has a pressure ulcer, the guideline will be useful in preventing pressure ulcers on other areas of the body.

Throughout the guideline patients (adults and children) are referred to as individuals, persons or users.

The practice settings for which all sections of the guideline are applicable are those where the health care professional is responsible for the assessment of risk of pressure area damage and prevention of pressure ulcers.

1.6 Disclaimer

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

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

1.7 Expected health benefits

Quantification of the expected health care benefits resulting from the application of the recommendations was not possible, due to the poor quality and heterogeneity of much of the research literature. It is thought that early identification of at-risk individuals and initiation of preventive measures may reduce pressure ulcer development. The expected health benefit of following the recommendations would therefore be the absence of a pressure ulcer(s).

1.8 Costs associated with recommendations

There is an absence of economic evaluations in this area. Therefore the costs of the various strategies were not explicitly considered when developing the guideline. However, it is proposed that identifying at-risk patients and initiating preventive strategies are likely to be more cost-effective than allowing pressure ulcers to develop.

Collier (1999a) calculated the treatment costs of pressure ulcers of grades 0/1, 2, 3 and 4 as £2,500, £7,500, £15,000-20,000 and £40,000 respectively. The cost to the patient cannot be so easily expressed.

Established ulcers incur substantial costs in terms of wound care preparations, staff time, possible prolonged bed occupancy, and patient quality of life and should therefore be prevented where at all possible.

For some of the recommendations, a range of resources will need to be considered such as access to beds, pressure relieving devices, and moving and handling equipment. The cost of this equipment varies widely,

from over £30,000 for some bed replacements to less than £100 for some foam overlays (Cullum et al., 2000). Many clinical areas will already have access to equipment but this is not always the case – especially for the pressure redistributing overlays/mattresses on operating tables, which are supported by relatively recent and convincing evidence for use in high-risk individuals. Local decisions need to be made about the access and purchase of equipment in the light of available resources. Consideration also needs to be given to the ongoing costs of equipment maintenance and replacement.

1.9 Funding of the guideline

This guideline project has been funded by the NHSE and since 1999 the National Institute for Clinical Excellence (NICE).

No obvious biases of the funding bodies became apparent during the development of this guideline. Given the impact of pressure ulcers on patients and the NHS, both the NHSE and NICE are committed to improving pressure ulcer risk assessment and prevention and keen to ensure the speedy publication of the guideline.

At the time of going to press, funding had not been obtained to develop a patient version of this guideline.

Chapter Two

Guideline Development Method

2.0 Introduction

There is no universal blueprint for the development of clinical guidelines

(RCGP, 1995)

Thomson et al (1995) suggest the method of guideline development will depend upon the topic, the experience of the guideline group, the purpose of the guidelines and the evidence available.

For the topic of pressure ulcer risk assessment and prevention, the available evidence was of variable quantity and quality. This is not an uncommon problem in clinical guideline development. Field and Lohr (1992) suggest many courses of care are not supported by good evidence. Therefore, the aim was to develop an appropriate, systematic and acceptable method based on:

- The principles of current 'gold standard' methodology developed by other authors (Woolf, 1991; Eccles, 1996; Waddell, 1996; RCP, 1997)
- Formal consensus in guideline development (Murphy et al., 1998)
- Criteria used to appraise the robustness of national guidelines (Cluzeau, 1995).

This chapter provides details about each stage in the guideline's development in the following sequence:

- Method of updating AHCPR literature base
- Appraisal of systematic reviews (Cullum et al., 2000; McGough, 1999)
- Formal consensus procedure
- Recommendation development
- Peer review process.

2.1 Advisory Group

An inter-disciplinary guideline advisory group was convened to assist in the guideline's development, critically appraise research literature and provide comments on a draft guideline. The composition of the group reflected the full range of those to whom the guideline applies.

The following areas of expertise were represented:

- Tissue viability
- Nursing (including paediatric nursing)
- Medicine
- Gerontology
- Management
- Dietetics
- Physiotherapy
- Academia
- Nurse education
- Bioengineering
- Occupational therapy.

A number of participants agreed to critically appraise studies that met the inclusion criteria.

The following organisations provided patient/carer input into the guideline:

- Spinal Injuries Association
- College of Health
- Age Concern England
- Carers National Association

Participants in the advisory group were identified by their interest and commitment to pressure ulcer risk assessment and prevention – for example via regular publication of clinical research papers, a national profile, their professional organisation, and patient/carer significance of the topic.

A subset of this advisory group formed the consensus or nominal group.

Appendix 1 lists those in the advisory group and gives an indication of each participant's level of involvement in the guideline development process.

2.2 Method of updating the AHCPR evidence base

Topics selected for review were those chosen both on the basis of their practical relevance to health care professionals and because improvements in the management of these areas will have the greatest impact on patient outcomes.

Risk assessment tools and pressure redistributing devices have recently been the subject of systematic review (McGough, 1999 and Cullum et al., 2000). The reviews served as the evidence base for recommendations about these two topics. Other areas had not been the subject of recent systematic review but were included in the AHCPR guideline published in 1992. These included:

- Strategies to maintain tissue tolerance
- Skin care
- Manual repositioning
- Protecting against the adverse effects of external mechanical forces
- Effectiveness of educational strategies
- Nutritional assessment.

It was therefore necessary to update the AHCPR literature base on these topics. The aim of this review was to critically appraise the research literature that had emerged since 1991.

2.2.1 Evidence model

To represent how clinical outcomes will be influenced by the guideline as a whole and the type of evidence that must be gathered to verify those expectations, an evidence model (Wolf, 1991) was developed (see Figure 1). It represents the aspects for which evidence is required and provides an explicit model for addressing broad review questions that involve linkages among multiple bodies of both indirect and direct evidence (Mulrow et al, 1997).

A set of questions was generated from this model to structure the guideline and aid the retrieval of research evidence.

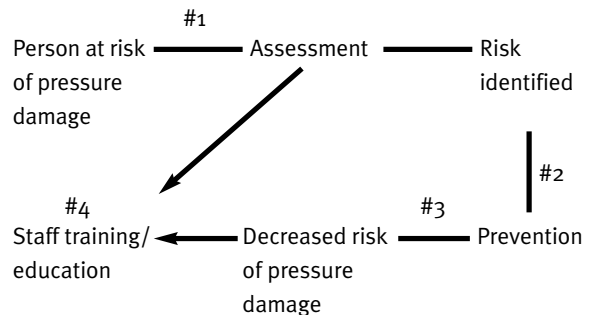
Linkage 1: What risk assessment tools identify patients who proceed to develop pressure ulcers?

Linkage 2: What is the most effective pressure relieving intervention?

Linkage 3: What is the most effective strategy for maintaining tissue tolerance?

Linkage 4: What is the most effective training/education method for preventing pressure ulcers?

Figure 1: Model for examining risk assessment and prevention of pressure ulcers



2.2.2 What was considered as evidence?

Table 1 illustrates specific criteria by guideline sub-topic and area to be reviewed. This assisted with generating search strategies and developing quality criteria specific to each topic.

2.2.3 Search strategy

Computerised searches were developed with a systematic reviews librarian. MEDLINE, CINAHL, EMBASE, SIGLE, DISSERTATION ABSTRACTS and PSYCHLIT were searched using the key words: pressure sores, pressure ulcer, pressure damage; decubitus ulcer or sore; bed sore and other related index or MESH terms (see Appendix 2 for search strategy). The period of the search was from 1991 to mid-1998, to follow on from the AHCPR cut-off date.

In the first instance, the search strategy did not exclude any pressure ulcer article and picked up a full range of material from letters to primary research studies.

Hand-searches of material not indexed on these databases (such as conference proceedings) were also carried out.

Journal hand-searches

Decubitus 1991-mid 1999

Journal of Tissue Viability 1991-mid 1999

Journal of Wound Care 1991-2000

	Most sensitive method of identifying people at risk	Whether risk assessment results in improved outcomes	Effectiveness of pressure relieving interventions	Others: (skin care, manual repositioning)	Patient and staff education
Source of evidence	Review by McGough	Review by McGough	Cochrane review by Cullum et al	RCN update of AHCPR evidence base	RCN update of AHCPR evidence base
Guideline audience	All health professionals and patients/ carers	All health professionals and patients/ carers	All health professionals and patients/ carers	All health professionals and patients/ carers	All health professionals and patients/ carers
Types of patients	Asymptomatic patients	Asymptomatic patients	At risk and existing pressure sores (often grade not specified)	At risk and existing pressure sores (often grade not specified)	All
Settings of interest	All settings	All settings	All settings	All settings	All settings
Interventions	Systematic assessment for new sores	Risk assessment tool	Different pressure redistributing devices (mattresses)	Mixed (see above)	Effectiveness of interventions to increase knowledge and change behaviour
Outcomes	Proportion developing sores sensitivity/ specificity	Decreased incidence of pressure sores	No ulcers or changes in size/severity of sores	Mixed	Mixed; improved knowledge; changed behaviour
Studies	Cohort	RCT	RCT	Mixed	RCT; controlled trials

Table 1. Evidence criteria by sub-topic**Conferences proceedings**

Proceedings of European Conferences on Advances in Wound Management 1991-1999

Annual Symposium on Advanced Wound Care 1990-1999

Efforts to identify unpublished studies

SIGLE, NHS Research Register, British Library databases (humanities and social sciences; science reference and information service; document supply centre: books and reports/conference proceedings), CINAHL (also includes books and non-journal materials) were searched for all topics. The advisory group was also asked to nominate any unpublished research that had been missed by the above strategies.

General inclusion criteria

The emphasis was on identifying research of the highest quality related to the review topics.

Articles were eligible for inclusion if they were:

- primary research studies or reviews of primary studies
- published/written up between 1991 and mid-1998
- published in peer reviewed journals
- human studies
- reported to the highest standards of methodology and results
- of any language.

General exclusion criteria

Articles were excluded based on the following criteria:

- they were covered by dates from the two externally-used systematic reviews (checked off at a later date)
- they did not meet the quality criteria – such as case reports, uncontrolled studies – or were severely flawed
- when methods were not presented and/or methods lacked rigour
- when the advisory group made a decision not to include – for example if not clinically relevant to the guideline
- when the material was not within the scope of the guideline, such as wound care or surgical management.

Specific inclusion and exclusion criteria for pressure ulcer risk assessment and prevention**Methodological criteria specific to risk assessment (based on Deeks, 1996)**

- study based on an inception cohort of patients entering a health care facility
- patients initially free from pressure ulcers
- follow-up data are available on at least 75% of those originally recruited
- patients systematically assessed for new ulcers
- paper presents adequate data for calculation of sensitivity and specificity
- data used to assess predictive validity were not used to derive the scale.

Methodological criteria specific to interventions to relieve pressure

- randomised controlled trials
- clear inclusion/exclusion criteria
- sample size calculation
- true randomisation with allocation concealment
- baseline comparability of treatment groups
- blinded outcome assessment
- Grade 1 ulcers excluded or presented separately
- main interventions well described
- adequate description of associated care
- appropriate clinical outcome measures (such as change in ulcer size, deterioration of pressure areas, wound breakdown, pressure ulcer healing, changes in skin condition – interface pressure, measuring the pressure on different parts of the body in contact with the support surface, is an intermediate or surrogate outcome measure)
- withdrawals reported by treatment groups with reasons
- analysis by intention to treat.

Methodological criteria specific to staff education/training

- randomised controlled trials of well-described educational interventions with adequate follow-up periods.

Methodological criteria for other 'grey' areas

Inter-disciplinary group advised very little 'hard' evidence for these areas. Therefore it was pointless to specify criteria. Literature of all descriptions was trawled to note consistency of expert/clinical opinion.

2.2.4 Sifting process

Having downloaded the results of the literature searches from various electronic databases (CINAHL, MEDLINE, CAB HEALTH, PSYCHLIT, SIGLE, BIOSIS), the abstract was scanned for clinical relevance.

Articles that failed this first sift, conducted on the basis of the downloaded abstract, were clearly not of clinical relevance and/or were not the gold standard study design. Having obtained full articles of those that passed the first sift, articles then failed the second sift if on closer inspection they were not as promising as appeared from the abstract – for example, not an RCT or other designated gold standard study design.

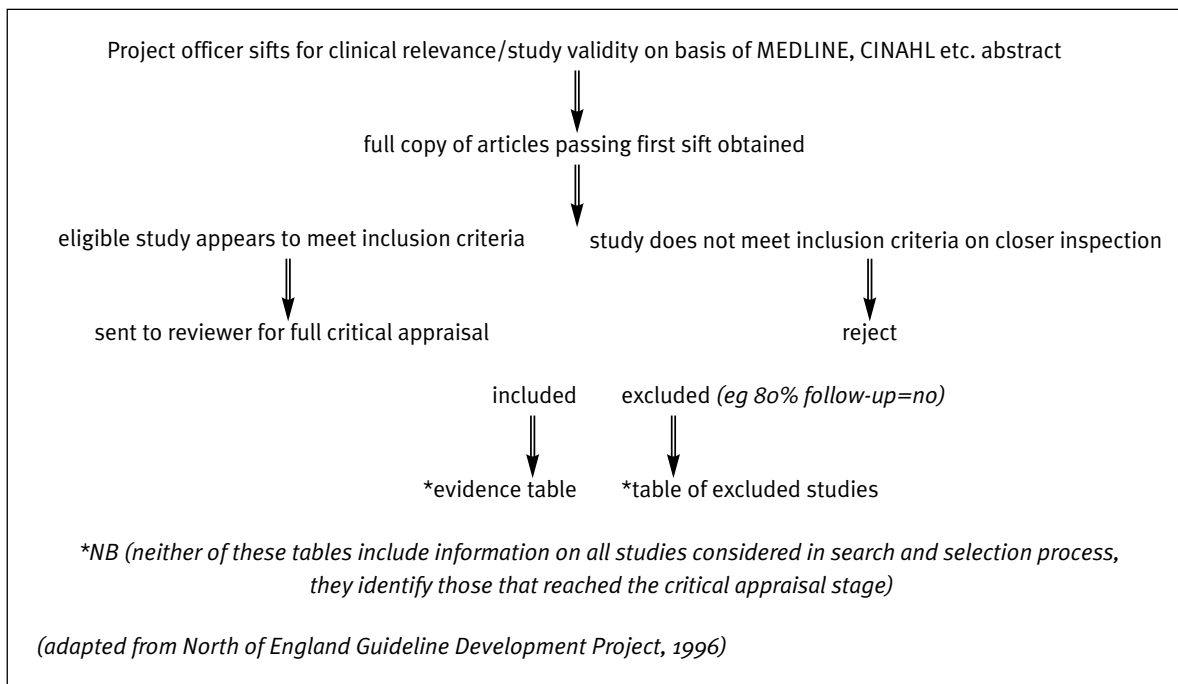


Table 2. The sifting process

However, some studies that had some (minor) methodological errors but appeared to have some important messages were forwarded for critical comment.

2.2.5 Critical appraisal process

Standardised critical appraisal checklist sheets incorporated both a structured data extraction form to record details from the studies in a reproducible fashion and quality criteria pertinent to each research design (see Appendix 3 for checklists). These were used to assess articles for applicability of findings, validity, design characteristics and study conduct in a reproducible fashion. These were based on formats recommended by both the Cochrane Collaboration (1996) and the NHS Centre for Reviews and Dissemination (1997). The data extraction and quality checklist forms were used in previous guideline development work – see *The management of patients with venous leg ulcers* (RCN, 1998).

There were two main categories of flaws in the quality checklist:

- fatal – as indicated by * on data extraction/quality checklist forms
- minor – for example risk of Type II error; no power calculations; inadequate description of inclusion/exclusion criteria for entry into the study – as indicated by ** on data extraction/quality checklist forms.

The fatal flaw criteria were developed following other authors (Dowell et al., 1995; Greenhalgh, 1997; North of England Evidence Based Guideline Development Project, 1996). Articles with a fatal flaw were rejected outright.

Minor flaws were not considered sufficient grounds to reject a study but required explicit consideration in summing up the value of the study. Articles with multiple minor flaws and/or those with inadequate reporting of results and methods were also rejected.

Fatal flaws for each of the major study designs are shown below.

Although there is a degree of subjectivity involved in making these decisions, the use of standardised quality criteria was thought to minimise subjectivity in the appraisal process.

Depending on the study design and review question, data were extracted as follows: design, objective(s), methods, participants/setting, sampling strategies, measurement tools, interventions, outcomes, length of follow-up, attrition, results, analysis.

Data extraction and validity assessments were made by one un-blinded reviewer, who had previous training in critical appraisal, a background in nursing or medicine and in pressure ulcer risk assessment and prevention. If there were questions over a particular article's validity or applicability on first appraisal, it was subsequently sent for appraisal by a second reviewer.

Fatal flaws by study design	
RCTS	<ul style="list-style-type: none"> no blinding (if could have been blinded) no report of an approach to allocation concealment if no power calculation and group sizes less than 20 ↔ 80% randomised sample included in analysis
COHORT	<ul style="list-style-type: none"> diagnostic criteria not stated clearly no evidence that sample representative of the population from which they were drawn ↔ 80% followed up (unless alternative source of data used and specified)
CASE CONTROL	<ul style="list-style-type: none"> matching criteria not clearly stated or adequate inclusion/exclusion criteria not clear or inadequate ↔ 80% response rate (unless alternative source of data used and specified)
SYSTEMATIC REVIEWS	<ul style="list-style-type: none"> no explicit assessment of validity of included studies no clear methods section studies inappropriate to combine sub-group analyses inappropriate sensitivity analyses not conducted (if relevant)
CROSS-SECTIONAL	<ul style="list-style-type: none"> eligibility criteria not explicit sample drawn not representative of population
STUDIES OF ASSESSMENT/DIAGNOSIS	<ul style="list-style-type: none"> inadequate case definition un-blinded comparisons with gold standard
QUALITATIVE	<ul style="list-style-type: none"> no respondent validation of results analysis and interpretation procedures unclear interpretations not grounded by data

Table 3. Reasons for rejecting at second sift

2.3 Results

Number of articles identified

Table 2 illustrates the results of the sifting and appraisal process.

Reasons for rejecting studies

Articles that failed the first sift (by abstract) were clearly not of clinical relevance, were not of appropriate study design or were not research based. Having obtained the full articles of those that passed the first sift (n=56), they then failed the second sift if they did not meet the expectation of the abstract and did not meet the criteria outlined.

Common reasons why studies were rejected at the second stage of critical appraisal are outlined in Table 3.

Stages of sifting	Number of articles
Number of articles appearing to be clinically relevant and fulfilling first sift criteria	56
Number of articles sent for review fulfilling criteria	12
Number of articles accepted to inform evidence base of guideline	5

As only five articles were to be included in the update of the AHCPR guideline literature base, only one evidence table was developed (see Appendix 4 for table). This table includes a brief overview of each study, including design and sampling strategy, comments on any potential weakness inherent in the study, findings and conclusions. A table of excluded studies (following the critical appraisal process) can be found in Appendix 5.

Main reasons for rejecting at 2nd sift (n=7)

- sampling not adequately described
- poor reporting overall
- conclusions not relevant to guideline's aims
- limited transferability/generalisability to UK/Europe.

Summary

As the process outlined revealed little good recent research evidence about strategies to maintain tissue tolerance; skin care; manual repositioning; protecting against the adverse effects of external mechanical forces; effectiveness of educational strategies and nutritional assessment, it was decided that the guideline should contain a mixture of evidence-linked and consensus-based recommendations.

2.4 Systematic reviews

Two systematic reviews developed by Cullum et al (2000) and McGough (1999) were included as part of the evidence base for the recommendations.

Cullum et al (2000) 'Beds, mattresses and cushions for pressure sore prevention and treatment'

A copy of this review can be found in Appendix 6.

The objective of this review was to assess the effectiveness of pressure redistributing beds, mattresses

and cushions in the prevention and treatment of pressure ulcers. In the light of the guideline's focus, aspects relating to prevention were of interest.

Critical appraisal of the review was conducted using a quality checklist proforma (see Appendix 3 for checklists) by a reviewer who had previous experience in critical appraisal, and a background in nursing and research (including statistics). In the light of this appraisal process, the review was accepted as the evidence base from which to develop recommendations about pressure redistributing devices.

McGough 1999 'A systematic review of the effectiveness of risk assessment scales used in the prevention and management of pressure sores'

A summary of this review can be found in Appendix 7.

The objective of this review was to determine whether the use of risk assessment scales is effective in reducing the incidence of pressure ulcers and to examine their predictive validity.

The review was accepted as the evidence base from which to develop recommendations about the use of risk assessment tools following the same critical appraisal process outlined above.

The authors of both of these systematic reviews report the poor quality of the studies available for review and highlight the need for conducting good quality research in these areas in the future (see Chapter Four for research implications).

2.5 Formal consensus process

2.5.1 Background

Clinicians need to make decisions even where there is a variable or undetermined evidence base. Limiting recommendations to where evidence exists may reduce the scope of guidelines and thus limit their value to clinicians (Eccles et al., 1996). Woolf (1992) describes three methods of guideline development but also adds that in reality these are not mutually exclusive and it is possible to draw from each one.

In evidence-linked guideline development

recommendations are based on a systematic review of the literature and make explicit linkage to the level of supporting evidence, which should enable clinicians to make decisions about adhering to them. Grimshaw et al (1995) argue that in cases where there is a strong level of supporting evidence clinicians should have a very good reason for choosing not to comply with them. However, as Woolf (1992) states, while this approach can be credited with enhancing the scientific rigour of guidelines, in the absence of acceptable evidence one is unable to produce recommendations.

Woolf (1992) suggests that the most common method of guideline development is informal consensus. This method is probably most frequently used at a local level where committees formulate recommendations without drawing on research evidence (Grimshaw and Hutchinson, 1995). By definition, this method tends to be based on poorly defined criteria and lacks the adoption of explicit consensus. Consequently, the resulting guidelines tend to be subjective and ill-defined in nature.

Formal consensus development methods, such as Delphi or Nominal Group Technique, provide a structure to the group decision-making process by, for example, adopting rating methods to represent extent of agreement about predefined issues or questions. In reality, given situations such as poor or lacking evidence, guideline developers have to adopt strategies based on a framework that utilises facets of more than one guideline development method.

As already described above, the evidence base available for this guideline was variable. Two systematic reviews were made use of (but even these reported on the poor quality of the research reviewed) and an update of the AHCPR literature base revealed little good recent research evidence. Given this, it was decided to devise and implement a formal consensus process to augment the weak and variable evidence base. The premise for this decision was that a guideline that contained both evidence-linked and consensus-based recommendations would be more useful to

practitioners than one confined to the limited outcomes of available research-based evidence.

Authors such as Grimshaw and Russell (1993a) and Shekelle et al (1999) have acknowledged the use of opinion to formulate recommendations in cases where there is an absence of evidence. They stress however, that the process adopted has to be explicit and that the source of recommendations made in the resulting guideline clearly documented. The following provides such details.

2.5.2 Formal consensus development method

An overview of the process is diagrammatically represented in Figure 2. One of the issues when developing it, highlighted by Grimshaw and Russell (1993b), is that very few guideline developers provide comprehensive details about their own methods. This lack of detail from others is additional to the general issue of lack of guidance on the best way to incorporate consensus development, although this has begun to be addressed (for example McIntosh, 1999).

To construct a framework that would allow a comprehensive, systematic approach, we drew upon the reported experiences of others (for example Trickey et al., 1998), literature which explores consensus development (for example Murphy et al., 1998), and, entered into dialogue with key informants (for example Dr Nick Black, London School Hygiene and Tropical Medicine).

A recent systematic review of consensus development in relation to clinical guidelines provided a useful basis upon which to make decisions about the details of the process. It also highlighted the considerable amount of research that needs to be conducted about this topic (Murphy et al., 1998). Thus the process devised and used here is based on current best practice of formal consensus in guideline development.

The resulting stages outlined correspond to the numbered boxes on the process diagram. Some of the early stages of the process refer to issues already reported in Chapter One and this Chapter.

- 1 The aims and scope of the guideline were defined during the initial stages of its inception. This was conducted in collaboration with a multi-disciplinary advisory group, with representatives from other professions' organisations and from patient organisations (see Section 2.1 above).
- 2 A review of guideline development literature and discussions with key informants were conducted to seek the most appropriate method.
- 3 Other national pressure ulcer guidelines were

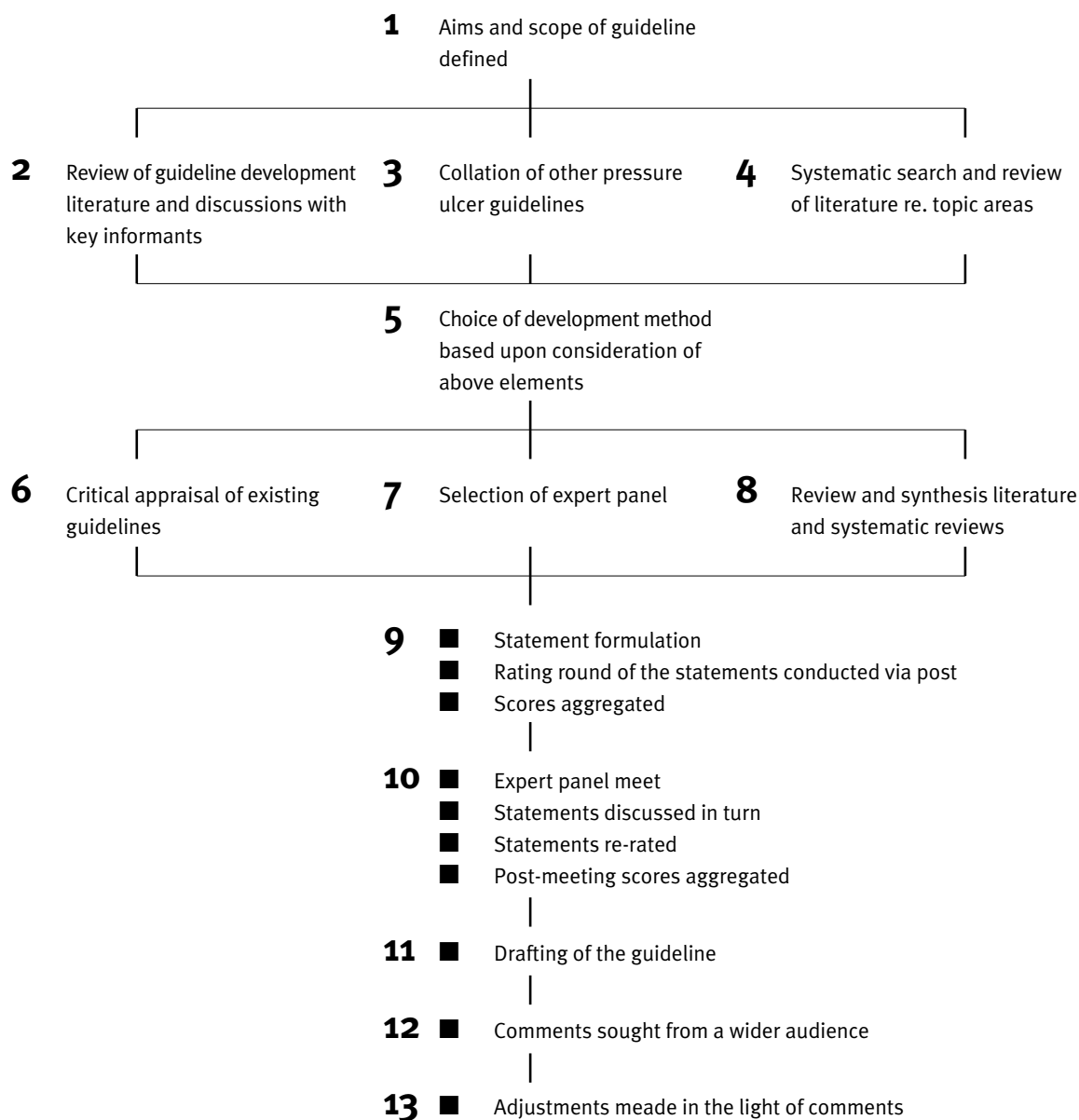


Figure 2. Guideline development process

collated to facilitate the process outlined in point 6.

4 A systematic search, retrieval and review of literature (not covered by the two systematic reviews) was completed on the risk assessment and prevention of pressure ulcers. Studies that met the inclusion criteria were critically appraised using critical appraisal checklists (see Appendix 3).

5 Based on a consideration of the above activities, and due to the nature of the evidence that exists about this clinical area, it was decided to use a formal method. Formal methods of consensus development are preferred to informal methods, based on a number of assumptions about the principles of group work such as: safety in numbers; authority; rationality; controlled processes and scientific credibility (see Murphy et al.,

1998).

A modified Nominal Group Technique (NGT) was favoured above Delphi and consensus development conference methods because reportedly a) it would allow participants to discuss issues face-to-face and b) the structured process is believed to facilitate contributions from all members of the group and limit dominance of the proceedings by eminent or eloquent individuals (Murphy et al., 1998; Trickey et al., 1998). Previously the NGT has been used successfully in the field of health generally (for example Buchan et al., 1991; McKee and Black, 1993) and to develop clinical guidelines (for example Scott and Black, 1991; Hunter et al, 1994; Trickey et al, 1998).

6 To incorporate the work of others in pressure ulcer risk assessment and prevention, critical appraisal

(Cluzeau et al., 1997) of existing national evidence-based/linked guidelines on this topic area were added to the theoretical base on which to facilitate the nominal group's discussions.

7 The group was composed of ten people, a figure based on limited research which suggests that large numbers can cause co-ordination problems and a smaller group could result in diminished reliability (Richardson, 1972).

The participants reflected the full range of people to which the guideline will apply (as identified above) – for example, individuals with expertise in tissue viability, patients, physicians, academics and physiotherapists. Thus, the group's composition was heterogeneous, allowing areas of uncertainty to be fully explored (Black et al., 1998) and better group decision-making performance (Murphy et al., 1998). To ensure heterogeneity, participants were purposively sampled. Participants were asked to participate on the basis of their status (as UK-recognised authorities in pressure ulcer management within their specialty), their knowledge of the research base, and their intended commitment to the process. Acquaintance with the guideline developer or the RCN was not used as a criterion for selection (see Appendix 1 for participants and their area of expertise).

8 Research shows that without a synthesis of pertinent information, participants in the consensus process are more likely to rely entirely on their own particular experiences (Fink et al., 1984). Also, when such information is used during deliberation, the consensus process tends to be more straightforward (Jacoby, 1988) and reflect the research evidence (Murphy et al., 1998). In the light of this, the consensus group received relevant research and the two systematic reviews prior to the group's meeting with the statements referred to in point.

9. This approach was also designed to help to focus the group's attention to the task and encourage them to view it as a research-based exercise rather than purely an opinion-based one. Group members were encouraged to bring the research evidence to the meeting, including any notes they may have made on it (Black et al., 1998).

Before the nominal group meeting, respondents were asked to consider a number of statements (n=200) that had been formulated around the issues included in the scope of the guideline (see Table 4 for examples). These statements were developed from a knowledge of the literature on pressure ulcer risk assessment and prevention, current debates about issues in practice and from issues raised in other national evidence-linked guidelines (AHCP, 1992 and EPUAP, 1999).

Each participant was asked to rate on a 1-9 scale (where 1 represented least agreement and 9 most agreement) their agreement with the statements, taking into account a) the research evidence b) their opinion/clinical expertise and c) the realities of health care delivery in the UK. The first rating round was conducted via mail.

Frequency of response to each statement was calculated. For each statement, the pattern of responses for the group was presented alongside each member's response to that statement. This allowed participants to see the spread of agreement and how their response related to this during the nominal group meeting (see Table 5 for examples). Data were managed and analysed throughout this process using SPSS for Windows.

10 The nominal group meeting was held in November 1999. Research suggests that a facilitative chairperson is one of the most important ingredients for successful meetings (Vinokur et al., 1985; Wortman et al., 1988). This meeting was facilitated by an experienced NGT facilitator which helped to ensure that the process ran smoothly and that good quality decisions were made (Murphy et al., 1998).

The statements which the participants had already rated were discussed in turn, focusing primarily on those that were the source of the most disagreement. When all members had been given the opportunity to respond there was a discussion to clarify, defend or dispute the issues. There was then an opportunity for each participant to privately re-rate the statements (Murphy et al 1998).

Post-meeting feedback from participants, collected by a short questionnaire, indicated that all members of the group felt they had been free to express their opinions during the meeting, that adequate time had been spent discussing relevant issues and that they had had the opportunity to discuss all the issues they wished to.

To provide context to the rated statements, the meeting discussion was audio-recorded and later transcribed verbatim. This enabled the guideline developer to clarify issues and draw upon the text when writing up the recommendations and their rationales at a later date.

There is no agreement as to the best method of mathematical aggregation (Murphy et al., 1998). However there are some suggested principles that were adhered to. The median and inter-quartile range were used as measures of central tendency and dispersion. The median (measurement of central tendency or average) and inter-quartile range (measure of distribution) were calculated for each statement from the ratings of the second round. The recommendations were drafted based on the panel's level of agreement

Formal assessments of risk should be made accessible to all members of the inter-disciplinary team									
	1	2	3	4	5	6	7	8	9
Disagree									
Agree									
Risk assessment tools should be used when assessing the risk of an individual for developing pressure ulcer(s)									
	1	2	3	4	5	6	7	8	9
Disagree									
Agree									
Clinical judgement can be as accurate at predicting risk as assessment tool scores									
	1	2	3	4	5	6	7	8	9
Disagree									
Agree									
Risk assessment tools should only be used in conjunction with clinical judgement when assessing the risk of an individual for developing pressure ulcer(s)									
	1	2	3	4	5	6	7	8	9
Disagree									
Agree									

Table 4. Example of statements and rating scale

Assessments of risk should be made accessible to all members of the inter-disciplinary team									
	1	2	3	4	5	6	7	8	9
Disagree									10*
Agree									
Risk assessment tools should always be used when assessing the risk of an individual for developing pressure ulcer(s)									
	2		1	1	1		3*	1	1
Disagree	1	2	3	4	5	6	7	8	9
Agree									
Clinical judgement can be as accurate at predicting risk as assessment tool scores									
							1	4	5*
Disagree	1	2	3	4	5	6	7	8	9
Agree									
Risk assessment tools should only be used in conjunction with clinical judgement when assessing the risk of an individual for developing pressure ulcer(s)									
	1					1		1	7*
Disagree	1	2	3	4	5	6	7	8	9
Agree									

* indicates the rating of the participant on the statement

Table 5. Example of spread of agreement for statement responses

about issues. If a statement's median was 7–9, it was developed into a practice recommendation.

11 The recommendations for the guideline were drafted based on the panel's level of agreement about the statements and the tape transcription (see section 2.7 for more detail).

12 The draft guideline was then disseminated to a wider audience – advisory group and patient/carer representatives – in order to elicit comment and endorsement (see section 2.7 for more detail).

13 From this process of dissemination, comments will be incorporated into a re-draft of the guideline (see Section 2.7 for more detail).

2.5.2 Summary

The modified NGT used here was successful in that it made the best use of both research evidence and the collective experience of participants via a systematic process. The NGT resulted in a pool of statements that participants 'agreed' with about the issues the guideline was to cover (based on the definition of agreement outlined in point 10 above). The next stage in the process was to formulate recommendations.

Recommendations

2.6.1 Developing recommendations

As McIntosh (1999) points out, there is a difference between the passivity of 'evidence' statements and recommendations, which should be 'statements of action'.

The recommendations for this guideline were derived directly from the statements agreed in the formal consensus process and from key evidence-based findings from the systematic reviews. The existing format of the statements allowed a straightforward revision to 'active' recommendations, thus reducing further risk of subjectivity entering into the process. As the key findings of the systematic reviews were limited in number and unambiguous, they were also easily transformed to recommendations.

2.6.2 Format and grading of recommendations

Rationales accompany each recommendation. The rationales have been kept to a minimum to make the guideline as user friendly as possible. The main purpose of the rationale is to give an abridged summary of the evidence supporting the guideline recommendations. In the case of the consensus-based recommendations, the rationales were also informed by the transcript of the nominal group discussions. Further details about the evidence can be found in the reviews and evidence tables.

The recommendations were graded on their evidence base as follows:

- I Generally consistent finding in a majority of multiple acceptable studies.
- II Either based on a single acceptable study, or a weak or inconsistent finding in multiple acceptable studies.
- III Limited scientific evidence which does not meet all the criteria of acceptable studies or absence of directly applicable studies of good quality. This includes expert opinion.

(adapted from Waddell et al., 1996)

The evidence grade shows the type of evidence supporting each recommendation. However, it does not indicate the strength of each recommendation. All recommendations are endorsed equally and none are regarded as optional. However, for those recommendations where there is little available research, or where a review of the research has been inconclusive in its findings, guidance is provided for local application. For example, because the systematic review of risk assessment tools suggested a limited use of scales in practice and did not identify the superiority of one scale over another for predicting at-risk individuals, the choice of whether or not to use one is left up to individual health care delivery services.

Some of the recommendations have figures next to them – for example (m 9, iqr 1.25). These show the results of the formal consensus process. The figures refer to the median (m) and inter-quartile range (iqr) calculated from the consensus ratings. With the example above, 9 was median (or average) rating, and an inter-quartile range of 1.25 shows that not everyone rated 9 – that is there was a distribution of scores. If everyone rated 9, the inter-quartile range would be 0. Therefore the larger this number, the lower the level of agreement within the nominal group.

Including these scores gives guideline users a clear idea of the extent of agreement. Although these are consensus rating scores, the nominal group did consider research evidence in conjunction with their clinical opinion/expertise to make these judgements.

2.7 Review process

A draft copy of the guideline was circulated for review by the advisory group prior to its publication. This was conducted by mail. All group members were asked to comment on the same issues to ensure standardisation. Written comments were received from 30 members of the group. These 30 people were felt to reflect an appropriate cross section of those to whom the

guideline will apply and represented 85% of the potential respondents. Comments were mainly confined to wording, organisation of material and typographical errors (n=28). This written feedback was incorporated into the guideline prior to publication.

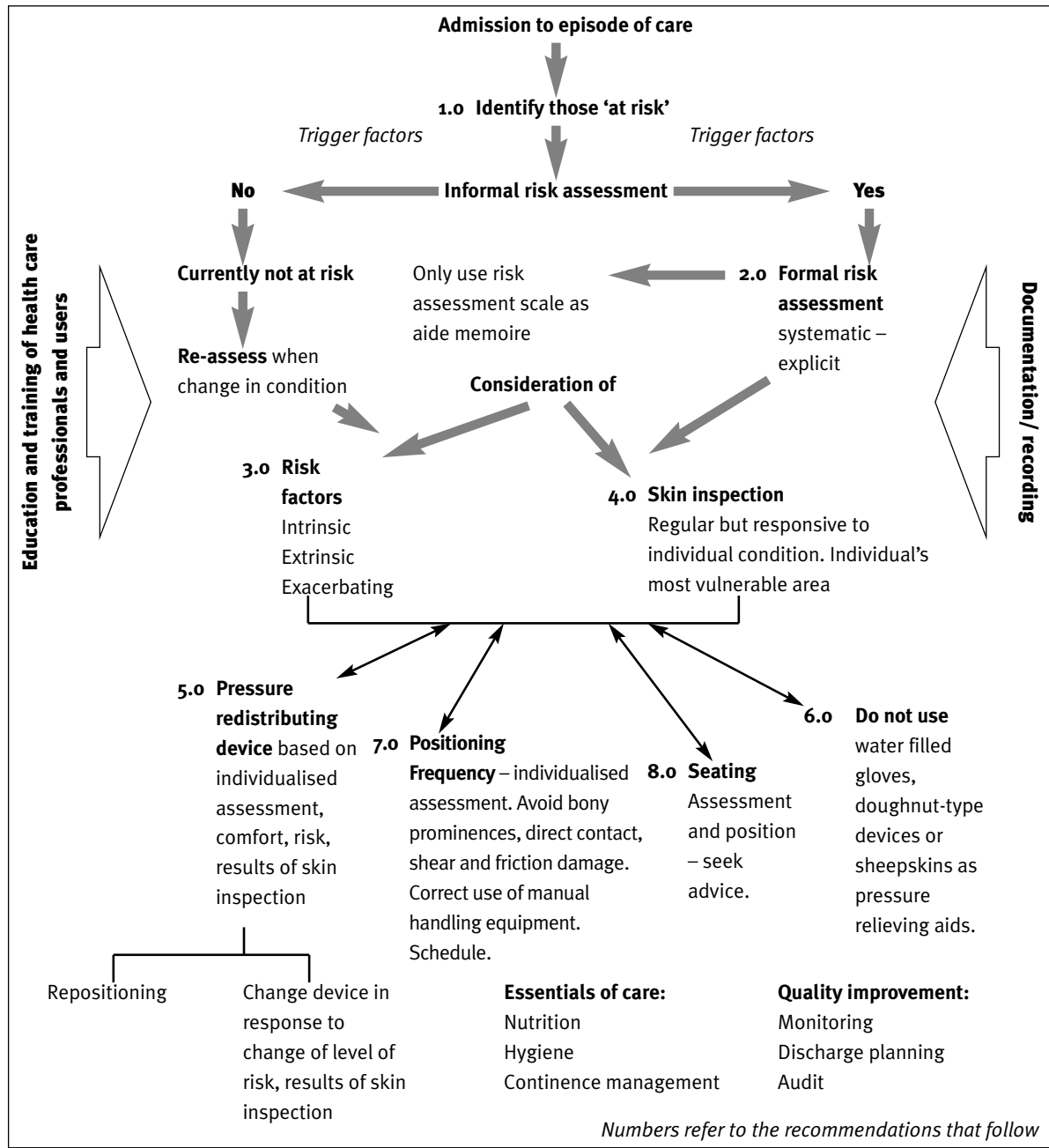
Additionally, a representative of NHS Supplies reviewed a pre-publication draft of the recommendations to consider their potential impact on the supply and cost of devices to the NHS.

The guideline is presented in the following Chapter.

Chapter Three

Guideline Recommendations

Quick Reference Guide



Summary of recommendations

1.0 Identifying individuals 'at risk'

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

- 1.1** 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.
- 1.2** 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.
- 1.3** If considered not at risk on initial assessment, reassessment should occur if there is a change in an individual's condition.
- 1.4** All formal assessments of risk should be documented/recorded and made accessible to all members of the inter-disciplinary team.

2.0 Use of risk assessment scales

- 2.1** Risk assessment tools should only be used as an aide memoire and should not replace clinical judgement.
- 2.2** If use of a risk assessment tool is preferred, it is recommended that a scale that has been tested for use in the same specialty is chosen.

3.0 Risk factors

- 3.1** An individual's potential to develop pressure ulcers may be influenced by the following intrinsic risk factors which therefore should be considered when performing a risk assessment: reduced mobility or immobility; sensory impairment; acute illness; level of consciousness; extremes of age; vascular disease; severe chronic or terminal illness; previous history of pressure damage; malnutrition and dehydration.
- 3.2** The following extrinsic risk factors are involved in tissue damage and should be removed or diminished to prevent injury: pressure; shearing and friction.
- 3.3** 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 and moisture to the skin.

4.0 Skin inspection

- 4.1** Skin inspection should occur regularly and the frequency determined in response to changes in the individual's condition in relation to both deterioration or recovery.
- 4.2** Skin inspection should be based on the individualised assessment of the most vulnerable areas of risk and therefore may include different or more areas which require inspection than those identified here: heels; sacrum; ischial tuberosities; parts of the body affected by anti-embolic stockings; parts of the body where pressure, friction and shear is exerted in the course of an individual's daily living activities; parts of the body where there are external forces exerted by equipment and clothing; elbows; temporal region of skull; shoulders; back of head and toes.
- 4.3** Individuals who are willing and able should be encouraged, following education, to inspect their own skin.
- 4.4** Individuals who are wheelchair users should use a mirror to inspect the areas that they cannot see easily or get others to inspect them.
- 4.5** Health care professionals should be vigilant to the following signs which may indicate incipient pressure ulcer development: persistent erythema; non-blanching erythema; blisters; discolouration; localised heat; localised oedema and localised induration. In those with darkly pigmented skin: purplish/bluish localised areas of skin; localised heat which, if tissue becomes damaged, is replaced by coolness; localised oedema and localised induration.
- 4.6** Any skin changes should be documented/recorded immediately.

5.0 Pressure redistributing devices

- 5.1** Decisions about which pressure redistributing device to use should be based on an overall assessment of the individual and not solely on the basis of scores from risk assessment scales. Holistic assessment should include level of risk, comfort and general health state.
- 5.2** 'At risk' individuals should not be placed on standard foam mattresses.
- 5.3** Patients at very high risk of developing pressure ulcers should be placed on alternating pressure mattresses or other high-tech pressure redistributing systems.

- 5.4** Pressure redistributing overlays should be used on the operating table of individuals assessed to be at high risk of pressure ulcer development.
- 5.5** To ensure continuity of preventive care, post-operative management of at risk individuals should include the use of pressure redistributing mattresses.
- 5.6** Repositioning should occur when individuals are on pressure redistributing devices.
- 5.7** The benefits of a pressure redistributing device should not be undermined by prolonged chair sitting.

6.0 Use of aids

- 6.1** The following should not be used as pressure relieving aids: water filled gloves; synthetic sheepskins; genuine sheepskins and doughnut-type devices.

7.0 Positioning

- 7.1** Individuals who are 'at risk' of pressure ulcer development should be repositioned and the frequency of reposition determined by the results of skin inspection and individual needs not by a ritualistic schedule.
- 7.2** Repositioning should take into consideration other aspects of an individual's condition – for example medical condition, comfort, overall plan of care and support surface.
- 7.3** Individuals who are considered to be acutely at risk of developing pressure ulcers should sit out of bed for less than two hours.
- 7.4** Positioning of patients should ensure that: prolonged pressure on bony prominences is minimised; bony prominences are kept from direct contact with one another and friction and shear damage is minimised.
- 7.5** A written/recorded re-positioning schedule agreed with the individual, should be established for each person 'at risk'.
- 7.6** Individuals/carers who are willing and able should be taught to redistribute their own weight.
- 7.7** Manual handling devices should be used correctly in order to minimise shear and friction damage. After manoeuvring, slings, sleeves or other parts of the handling equipment should not be left underneath individuals.

8.0 Seating

- 8.1** Seating assessments for aids and equipment should be carried out by trained assessors who have the acquired specific knowledge and expertise (for example, physiotherapists/occupational therapists).
- 8.2** Advice from trained assessors with acquired specific knowledge and expertise should be sought about correct seating positions.
- 8.3** Positioning of individuals who spend substantial periods of time in a chair or wheelchair should take into account: distribution of weight; postural alignment and support of feet.
- 8.4** No seat cushion has been shown to out-perform another, therefore no recommendation can be made about which type to use for pressure redistribution purposes.

9.0 Education and training

- 9.1** Health care professionals should be trained/educated in pressure ulcer risk assessment and prevention.
- 9.2** Health care professionals with recognised training in pressure ulcer management should cascade their knowledge and skills to their local health care teams.
- 9.3** An inter-disciplinary approach to the training and education of health care professionals should be adopted.

Philosophy of care

This philosophy of care describes the ideal context in which to implement the recommendations in this guideline.

Person-centred care

The rights of patients and their carers to be fully informed and share in decision-making is a central tenet of a number of recent policy documents – for example *The New NHS. Modern. Dependable* (DoH, 1997); *Our Healthier Nation* (DoH, 1999); and, specifically about the rights of the child, the United Nations convention (United Nations, 1991).

Involvement and partnership in care are central to the delivery of a service which responds to users' individual needs.

- users should be made aware of the guideline and its recommendations
- users should be involved in all aspects of pressure ulcer risk assessment and prevention, from involvement in assessment to shared decision-making about pressure redistributing devices
- health professionals are advised to respect and incorporate the knowledge and experience of people who have been at long-term risk of developing pressure ulcers and have been self-managing this risk
- users should be informed of their risk of developing pressure ulcers, especially when they are transferred between care settings or discharged home.

A collaborative inter-disciplinary approach to care

Pressure ulcer risk assessment and prevention should be seen as an inter-disciplinary issue. Adopting a team approach requires each member of the team to take responsibility for facilitating and improving communication, sharing care and responsibility for care. Such an approach requires health care professionals to understand and respect each other's roles in the delivery of that care.

- all members of the inter-disciplinary team should be aware of the guideline and its recommendations
- health care teams need to articulate the role of each member in the management of risk assessment and prevention of pressure ulcers.

Organisational issues

Organisational issues influence the quality of pressure ulcer risk assessment and prevention. Health care service providers need to ensure:

- an integrated approach to pressure ulcer prevention with clear strategy and policy supported by management
- care 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 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 are cared for by trained staff, and that staffing levels and skill mix reflect the needs of patients.

Recommendations

1.0 Identifying individuals 'at risk'

One of the first activities in preventing pressure ulcers is the early identification of individuals who are susceptible to developing them. If a person is identified as susceptible or 'at risk', it is the health care professional's duty to ensure that preventive measures are implemented. The earliest phases of pressure ulcer development may show no outward visible signs of damage. Therefore it is important that individuals at risk are given an immediate prevention plan.

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

On initial contact with the health care system:

- all individuals should have an informal risk assessment, based on their clinical presentation and consideration of risk factors

Trigger factors which identify a susceptible individual – for example immobility, acute illness or trauma, altered level of consciousness (see 3.0 Risk factors for further triggers) – will alert practitioners to conduct a full:

- formal assessment, where an individual's risk is systematically and explicitly conducted via a structured risk assessment framework. Formal assessments should be routine for all in-patients (m 9, iqr 1.5) and all those seen on domiciliary visits (m 7, iqr 4.5).

1.2 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.

Traditionally, the preferred member of the team to perform the risk assessment has been a trained nurse who has the acquired specific knowledge and expertise (m 9, iqr 0). However, if training has been completed, and knowledge and expertise acquired, risk assessment should also be carried out by doctors (m 9, iqr 2), ambulance personnel (m 9, iqr 3), therapists (m 8.5, iqr 3.75), health care assistants (m 8.5, iqr 3.75) and/or carers.

1.3 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 (m 9, iqr 1).

It should be recognised that in some situations – for example acute and critical care – risk assessment should be carried out immediately so as not to delay appropriate preventive measures.

1.4 If considered not at risk on initial assessment, reassessment should occur if there is a change in an individual's condition (m 9, iqr 0.25).

Risk assessment should be regarded as a dynamic process. Individuals, regardless of their initial admission status, could become 'at risk' during their contact with the health care system – for example because of a general deterioration in condition or undergoing surgery.

1.5 All formal assessments of risk should be documented/recorded (m 9 iqr 0) and made accessible to all members of the inter-disciplinary team (m 9, iqr 0).

Good documentation provides an accurate record of an individual's progress and risk status, and is key for accountability, responsibility, risk management and evaluation.

Strength of Evidence III

These recommendations are based on principles of good practice and the nominal group's clinical experience and opinion.

2.0 Use of risk assessment scales

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

Various scales have been developed to identify individuals at risk of developing pressure ulcers. Most scales have been developed in an ad hoc fashion based on opinions of the relative importance of possible risk factors (EHCB, 1995). A recently completed systematic review (McGough, 1999) revealed that only the Braden scale has been tested for its predictive validity in comparison to nursing clinical judgement (Salvadarena et al., 1992; VandenBosch et al., 1996, cited McGough, 1999). These two clinical trials did not demonstrate the scale to be of greater predictive value than clinical judgement.

There is 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 the predictive validity of the six risk assessment scales (Anderson, Braden, Knoll, Norton, Pressure Sore Prediction Scale and Waterlow) is variable, both in comparison with each other and in relation to assessments made of the same scale, on evidence to date it is not possible to make valid comparisons.

Strength of Evidence I

McGough (1999) selected 18 studies which met the criteria for inclusion in her systematic review of the effectiveness of risk assessment tools. Findings from prospective cohort studies led her to conclude risk assessment scales may be useful 'aide memoires' for staff but should not replace clinical judgement (see Appendix 2 for table of included studies). McGough found:

- 61% of the scales that have been the subject of study are modifications of original scales, where the risk factors included in the original versions have never been questioned
- 86% of the scales had not been tested for their reliability and validity
- many of the studies reviewed were of poor quality in respect of methodological rigour, sample sizes and populations, and outcome measurement, resulting in them being susceptible to bias.

2.2 If use of a risk assessment tool is preferred, it is recommended that a scale that has been tested for use in the same specialty is chosen.

If a risk assessment tool is to be used to assist with

clinical judgement, McGough suggests that local testing should establish an appropriate cut-off point to indicate risk ('threshold'), that is, the score at which an individual falls into the 'at risk' category.

Strength of Evidence III

This recommendation is based on the opinion of the systematic review author (McGough, 1999).

3.0 Risk factors

3.1 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 (m 8, iqr 2.5) A key factor in the development of pressure ulcers is reduced mobility or immobility. A number of studies have identified reduced mobility as an independent risk factor in pressure ulcer development. In a prospective inception cohort study of patients fulfilling certain criteria admitted to a US tertiary university teaching hospital, Allman et al (1995) found that a significant risk factor in patients who went on to develop sores was immobility.

Sensory impairment (m 9, iqr 0) For example neurological disease results in reduced sensation and thus insensitivity to pain or discomfort. This results in a reduced or lacking stimulus to move to relieve pressure. There are certain groups of individuals that may suffer from sensory neuropathy, for example those with diabetes and spinal injuries.

Acute illness (m 9, iqr 1) Clinical experience, observation and emerging research suggests that acutely ill patients are vulnerable to developing pressure ulcers. This is because of heart failure, vasomotor failure, vasoconstriction due to shock, pain, low blood pressure (Bliss, 1990) and temperature change – for example during and after anaesthesia (Scott, 2000).

Level of consciousness (m 8, iqr 2) A reduced level of consciousness may reduce an individual's awareness of the need to relieve pressure. Likewise an anaesthetised person has no independence to reposition themselves.

Extremes of age (>65 and <5 years of age) (m 7, iqr 3.25) Advancing age is associated with an increase in cardiovascular and neurological disease, and changes to the resilience and elasticity of the skin. Individuals over 65 years of age are at greater risk than the general population of developing pressure ulcers (Verluisen, 1986; Bergstrom et al., 1996; Bergstrom and Braden, 1992). Neonates and very young children are also at a greater risk. Their skin is still maturing and their head-to-body weight is disproportionate. It is currently thought that the factors that place children (m 8, iqr 3) and neonates (m 7, iqr 3.5) at risk are the same that place adults at risk, but the sites of greatest risk for pressure damage and the nature of the injury may differ. For example, there is greater risk of pressure damage to points on the head, on the ears from repeated oxygen saturation measurement, from repeated heel pricks for blood monitoring and an increased risk from extravasation.

Previous history of pressure damage (m 9, iqr 2) places individuals at a greater risk of developing further ulcers than previously pressure ulcer free patients (Berlowitz and Wilking, 1990; Bergstrom and Braden, 1992; Clark and Watts, 1994).

Vascular disease (m 8.5, iqr 2) reduces total blood flow and impairs micro circulation potentially making patients more vulnerable to pressure necrosis.

Severe chronic or terminal illness (m 8, iqr 2.25) places individuals at greater risk because of, for example, multi-organ failure, poor perfusion and immobility.

Malnutrition (m 7.5, iqr 3.5) and dehydration (m 8.5, iqr 2.25) While not directly linked to pressure ulcer development, malnutrition may increase an individual's risk of organ failure and serious illness. Related to this is body weight, both emaciated (Allman et al., 1995) and obese individuals may be more vulnerable to pressure damage. Dehydration may reduce the elasticity of tissues and thus increase tissue deformability under pressure or friction (see Essentials of care section).

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

Pressure which causes compression and possible capillary occlusion, which if prolonged can lead to ischaemia. How high the pressure must be and how long it must be exerted to cause damage depends on the individual's tissue tolerance. The key factors are intensity and duration of pressure.

Shearing occurs when the skeleton and deep fascia slide downwards with gravity, whilst the skin and upper fascia remain in the original position. Deep necrosis can occur when the shearing between two layers of tissue leads to stretching, kinking and tearing of vessels in the subcutaneous tissues. Shearing forces should not be considered separately from pressure: they are an integral part of the effect of pressure. Shearing most often occurs when individuals slide down or are dragged up a bed or chair.

Friction occurs when two surfaces move across each other. It often removes superficial layers of skin. Friction damage often occurs as a result of poor lifting techniques.

(Defloor, 1999)

3.3 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 (m 7.5, iqr 2.5) – for example:

- sedatives and hypnotics may make an individual excessively sleepy and thus reduce mobility
- analgesics may reduce normal stimulus to relieve pressure
- inotropes cause peripheral vasoconstriction and tissue hypoxia
- non-steroidal anti-inflammatory drugs impair inflammatory responses to pressure injury.

This medication list is not exhaustive, practitioners should refer to pharmacists for specialist advice.

Moisture to the skin (m7, iqr 1.75) – for example urinary and faecal incontinence, wound drainage and sweat (see section on Essentials of care) are potential irritants to the skin.

Strength of Evidence II

These recommendations have been identified from cohort studies (Bergstrom and Braden, 1992; Papantonio et al., 1994; Brandeis et al., 1994; Allman et al., 1995; Bergstrom et al., 1996), the logic and principles of physiology, and are supported by opinion and experience. There is a need for further epidemiological research to improve our understanding of risk factors and the relative contribution they make to the development of pressure ulcers (McGough, 1999).

4.0 Skin inspection

Skin inspection provides essential information for both assessment and prevention. Although the precise role that skin inspection plays in decreasing the incidence of pressure ulcers has not been determined, regular assessment of the most vulnerable parts of the body will enable early detection of incipient pressure damage.

4.1 Skin inspection should occur regularly and the frequency determined in response to changes in the individual's condition in relation to both deterioration or recovery (m9, iqr 0).

4.2 Skin inspection should be based on the individualised assessment of the most vulnerable areas of risk and therefore may include different or more areas which require inspection than the examples identified below:

4.3 Individuals who are willing and able should be encouraged, following education, to inspect their own skin (m 9 iqr 0)

4.4 Individuals who are wheelchair users should use a mirror to inspect the areas that they cannot see easily (m9 iqr 0) or get others to inspect them

4.5 Health care professionals should be vigilant to the following signs which may indicate incipient pressure ulcer development:

- Heels (m 9, iqr 0)
- Sacrum (m 9, iqr 0)
- Ischial tuberosities (m 9, iqr 0)
- Parts of the body that are affected by the wearing of anti-embolic stockings (m 9, iqr 0)
- Trochanter (m 9, iqr 0)
- Parts of the body where pressure, friction or shear is exerted in the course of an individual's daily living activities e.g. on the hands of wheelchair users (m 9, iqr 1)
- Part of the body where there are external forces exerted by equipment and clothing e.g. endotracheal tubes, intravenous lines, sites of pulse oximetry, catheters, shoes, elastic clothing) (m 9, iqr 1)
- Elbows (m 7, iqr 1)
- Temporal region of the skull (m 7, iqr 1.25)
- Shoulders (m 7, iqr 2.25)
- Back of head (m 7, iqr 1.75)
- Toes (m 7, iqr 2.5)

*previously identified as 'non-blanching erythema' - see glossary.

It may not be possible to see the redness/erythema associated with tissue damage in people with darkly pigmented skin. Health care professionals need to be vigilant to the following signs, which may indicate incipient pressure ulcer development in people with darkly pigmented skin (Bennett, 1995):

- Persistent erythema (m 9, iqr 0.25)
- *Non-blanching hyperaemia (m 8.5, iqr 2)
- Blisters (m 8, iqr 3.25)
- Discolouration (m 7.5, iqr 4)
- Localised heat (m 7, iqr 2.5)
- Localised oedema (m 7, iqr 1.5)
- Localised induration (m 7.5, iqr 2)

4.6 Any skin changes should be documented/recorded immediately (m 9, iqr 0) including a detailed description of what is observed and any action taken.

- Purplish/bluish localised areas of skin (m 6.5, iqr 4)
- Localised heat which, if tissue becomes damaged, is replaced by coolness (m 7, iqr 2.25)
- Localised oedema (m 7, iqr 1.5)
- Localised induration (m 7.5, iqr 1.5)

Strength of Evidence III

These recommendations are supported by principles of best practice and the nominal group's clinical experience and opinion.

5.0 Pressure redistributing devices

5.1 Decisions about which pressure redistributing device to use should be based on an overall assessment of the individual and not solely on the basis of scores from risk assessment scales.

A recent systematic review (McGough, 1999) concluded that there was insufficient evidence to recommend using risk assessment scale scores on which to base or support decisions about choices of pressure redistributing surfaces. It follows that if risk assessment scales should not be used in isolation to identify individuals at risk, they should not be used in isolation to instigate prevention strategies.

Decisions about support surfaces should be influenced by holistic assessment of an individual's risk (m 9, iqr 4), his/her comfort (m 8, iqr 2.25) and general health state (m 8.5, iqr 1.25). Interface pressure measurements should not be used to make decisions about pressure redistributing devices (m 8.5, iqr 5.25) because they have not been demonstrated to predict reliably the performance of support surfaces (Cullum et al., 2000). Assessment should be on-going throughout an individual's episode of care and the type of pressure relief support changed to suit any alteration in risk (m 7, iqr 5.5).

Strength of evidence I

Findings from prospective cohort studies led the reviewer to conclude that staff should not rely solely on risk assessment scale scores (McGough, 1999).

Strength of evidence III

This recommendation and suggested decision-making practice regarding choice of pressure redistributing devices is also supported by the nominal group's clinical experience and opinion.

5.2 'At risk' individuals should not be placed on standard foam mattresses.

A recently completed systematic review (Cullum et al., 2000) concluded that standard foam mattresses have been consistently outperformed by a range of foam-based, low pressure mattresses and overlays, and also by 'higher-tech' pressure redistributing beds and mattresses. The results from four trials comparing foam alternatives with the standard hospital foam mattress (Gray and Campbell, 1994; Hofman, 1994; Santy, 1994 and Collier 1996, – cited Cullum et al., 2000) were pooled to reveal that various foam alternatives can reduce the incidence of pressure ulcer development in at risk patients. Another randomised, controlled trial

(RCT) (Andersen, 1982 cited Cullum et al., 2000) comparing alternating pressure surfaces to standard foam mattresses, also reported a reduction in the incidence of pressure ulcers. Cullum et al (2000) note that 'standard' was poorly described in many of the studies included in their review. 'Standard' varies by country, setting and over time.

Other studies comparing alternating pressure devices with a variety of constant low-pressure devices have not shown significant benefits to using one device over another. At present the clearest recommendation is that at risk individuals should be placed on an alternative to the standard foam mattress.

Strength of evidence I

This recommendation is supported by the findings of a systematic review including 29 RCTs of support surfaces for pressure ulcer prevention (Cullum et al., 2000).

5.3 Patients at very high risk of developing pressure ulcers should be placed on alternating pressure mattresses or other high-tech pressure redistributing systems.

The EHC (1995) advises that in the absence of clear evidence for an optimal strategy, patients at high risk such as those in intensive care, orthopaedic units or with neurological deficits should be placed on higher-tech surfaces. Cullum et al (2000) report that the relative merits of alternating and constant low pressure, and of different alternating pressure devices are unclear. Many of the studies which compared devices did not adequately describe the equipment being used, and were small and thus under-powered to detect clinically important differences, even when studies were pooled. There is limited evidence to suggest that low air loss beds (compared to standard ICU beds) reduce the incidence of pressure ulcers in intensive care (Inman, 1993, cited Cullum et al., 2000).

Strength of evidence II

Advice from EHC (1995) and one controlled trial.

Individuals undergoing surgery

5.4 Pressure redistributing mattresses/overlays should be used on the operating table of individuals assessed to be at high risk of pressure ulcer development.

Three RCTs have evaluated different methods of pressure relief on the operating table (Nixon et al., 1998; Aronovitch, 1998; Dunlop, 1998, cited Cullum et al., 2000). Their results suggest that a reduction in post-operative pressure ulcers can be achieved using an

alternative support surface to a standard operating table.

The three RCTs evaluated different methods of pressure relief, however it is currently unclear which type is the most effective (Cullum et al., 2000). Nixon et al (1998) found dry visco-elastic polymer pads (Action Products Inc.) to be more effective than a standard table. Whilst Aronovitch (1998) and Dunlop (1998) reported in favour of the Micropulse system (an alternating pressure overlay) in comparison to gel pads during surgery and a standard mattress post-operatively.

Some laboratory research has suggested that the 'standard' operating table mattress may be difficult to define and that any pressure redistributing properties are dependent on each product's construction (Scott et al., 1999). Individuals that may be at a high risk are those undergoing vascular surgery (m 8, iqr 2.25), orthopaedic surgery (m 9, iqr 3.25), surgery classed as major (m 8.5, iqr 1.5) and those with one of more risk factors (m 7.5, iqr 3.25).

Strength of evidence I

This recommendation is supported by the findings of a systematic review (Cullum et al., 2000) including three RCTs that evaluated support surfaces for pressure ulcer prevention on the operating table.

Strength of evidence III

Identified individuals based on the nominal group's clinical experience and opinion.

Post-operative care

5.5 To ensure continuity of preventive care, post-operative management of at risk individuals should include the use of pressure redistributing mattresses (m 9, iqr 1.25).

Strength of evidence III

This recommendation for practice is supported by the nominal group's clinical experience.

General issues

5.6 Repositioning should occur when individuals are on pressure redistributing devices (m 8.5, iqr 0.25). Frequency of repositioning should be determined by the results of skin inspection (m 9, iqr 1.25), patient comfort (m 8, iqr 1.25) and general state (m 8, iqr 1.25). A change of support surface and/or a change in the frequency of repositioning may be necessary.

5.7 The benefits of a pressure redistributing device should not be undermined by prolonged chair sitting (m 8.5, iqr 6.5) (EHCB, 1995).

Strength of evidence III

These recommendations for practice are supported by the nominal group's clinical experience and opinion, and the EHCB (1995).

6.0 Use of aids

6.1 The following should not be used as pressure relieving aids:

- water-filled gloves (m 9 iqr 0)
- synthetic sheepskins (m 9, iqr 2)
- genuine sheepskins (m 5, iqr 2.25).
- doughnut-type devices.

Doughnut-type devices are believed to adversely affect lymphatic drainage and circulation, and thus are likely to cause rather than prevent pressure ulcers (AHCPR, 1992). Water-filled gloves under heels are not effective because the small surface area of the heel means it is not possible to redistribute pressure by this localised method. Sheepskins do provide comfort to some individuals, but they are not pressure relieving or redistributing aids. If sheepskins are used for comfort rather than perceived pressure relief, care is needed with regard to cross-infection and correct laundering processes.

Strength of Evidence III

This recommendation is based on the nominal group's clinical experience and opinion, AHCPR recommendations (1992 M9 p26) and one trial. Cullum et al (2000) reviewed one small trial of a standard hospital mattress with and without sheepskin overlays (Ewing et al., 1964). The trial was of poor quality and the results inconclusive.

7.0 Positioning

7.1 Individuals who are 'at risk' of pressure ulcer development should be repositioned

(m 9, iqr 0.25).

The frequency of repositioning should be determined by the results of skin inspection and individual needs (m 9, iqr 1.25) not by a ritualistic schedule. This will help to determine and ensure a responsiveness to the time it takes for an individual to show signs of incipient damage. Repositioning should entail adequate position changes avoiding an individual's vulnerable areas. In cases where individuals have determined their own routine to prevent the development of pressure ulcers, for example those with spinal injury, their knowledge and routine should be respected by health care professionals.

7.2 Repositioning should take into consideration other aspects of an individual's condition – for example breathing and medical condition (m 9, iqr 0.25), their comfort (m 9, iqr 1.25), how it fits into their overall plan of care (for example in relation to other activities such as physiotherapy or occupational therapy, meal times, attending to personal hygiene) (m 8, iqr 2.25) and the surface they may be lying or sitting on.

7.3 Individuals who are considered to be acutely at risk of developing pressure ulcers should restrict chair sitting to less than two hours (m 8.5, iqr 0.5) until their general condition improves.

7.4 Positioning of patients should ensure that:

- prolonged pressure on bony prominences is minimised (m 8, iqr 1.25)
- bony prominences are kept from direct contact with one another (m 9, iqr 0.25)
- friction and shear damage is minimised.

7.5 A written/recorded re-positioning schedule agreed with the individual should be established for each person at risk (m 9, iqr 1.25). This record should also include actual position changes.

7.6 Individuals/carers who are willing and able should be taught to redistribute their own weight (m 9, iqr 1).

7.7 Manual handling devices should be used correctly in order to minimise shear and friction damage. After manoeuvring, slings, sleeves or other parts of the handling equipment should not be left underneath individuals (m 8, iqr 4) , as this practice may result in tissue damage. Correct lifting and handling techniques will also reduce the risk to carers' backs.

Strength of Evidence III

These recommendations are supported by the nominal group's clinical experience and opinion and some of the AHCPR (1992) guideline recommendations (M1 p22, M6 p24, M11 p27). While manual repositioning is an established part of pressure ulcer prevention practice, there is little research demonstrating its effectiveness or the optimal frequency for manual repositioning (EHCB, 1995). However, the nominal group felt that repositioning where appropriate, should form part of pressure relieving practice and should incorporate the principles identified in the above recommendations.

Additionally, a study conducted by Gebhardt and Bliss (1994) compared the outcomes of two groups of elderly orthopaedic patients – one group sat out for unlimited periods and the other sat out for no more than two hours. They found a positive correlation between pressure ulcer development and length of time sitting in a chair.

There is an increasing body of knowledge about the use of the 30 degree lateral tilt (Defloor, 1997; Colin et al., 1996). A study of a small sample of healthy volunteers (n=20) found an impairment of oxygen supply to the skin in the 90 degree laterally inclined individuals but not in the 30 degree laterally inclined position (Colin et al., 1996). This is a promising approach to positioning that requires further systematic evaluation before it can be recommended as 'standard' practice. However it is a lying position that could be used for individuals who find it comfortable.

8.0 Seating

8.1 Seating assessments for aids and equipment should be carried out by trained assessors who have the acquired specific knowledge and expertise (for example, physiotherapists/ occupational therapists) (m 9, iqr 1.25).

8.2 Advice from trained assessors with acquired specific knowledge and expertise should be sought about correct seating positions (m 8, iqr 2).

8.3 Positioning of individuals who spend substantial periods of time in a chair or wheelchair should take into account:

- distribution of weight (m 9, iqr 1.25)
- postural alignment (m 9, iqr 1)
- support of feet (m 9, iqr 1).

8.4 No seat cushion has been shown to out-perform another, therefore no recommendation can be made about which type to use for pressure redistribution purposes.

Strength of Evidence III

These recommendations are supported by the nominal group's clinical experience and opinion.

Cullum et al (2000) reviewed two RCTs that compared different types of seating cushions. Lim et al (1988) compared a slab with a bespoke contoured foam cushion and found no difference in pressure ulcer incidence. The other trial (Conine et al 1994) compared Jay gel and foam wheel chair cushion with a foam cushion. Although they reported a reduced incidence of pressure ulcer development, this was not found to be statistically significant.

9.0 Education and training

The education of staff and users should be an integral part of any pressure ulcer prevention strategy (Dealey, 1997).

The training and education of users and health care professionals should be tailored to the needs and requirements of the individual and particular professional group. However, there are generic components that should be included in all training programmes.

For all health care professionals

9.1 Health care professionals should be trained/educated in pressure ulcer risk assessment and prevention

9.2 Health care professionals with recognised training in pressure ulcer management should cascade their knowledge and skills to their local health care teams (m 9, iqr 0)

9.3 An inter-disciplinary approach to the training and education of health care professionals should be adopted (m 9, iqr 0)

9.4 Training and education programmes should include the following:

- risk factors for pressure ulcer development (m 9, iqr 2.25)
- pathophysiology of pressure ulcer development (m 9, iqr 0.5)
- the limitations and potential applications of risk assessment tools (m 9, iqr 2.25)
- skin assessment (m 9, iqr 0.5)
- skin care (m 9, iqr 2.25)
- selection of pressure redistributing equipment (m 9, iqr 0.25)
- use of pressure redistributing equipment (m 9, iqr 1)
- maintenance of pressure redistributing equipment (m 8.5, iqr 1.25)
- methods of documenting risk assessments and prevention activities (m 9, iqr 1)
- positioning to minimise pressure, shear and friction damage, including the correct use of manual handling devices (m 9, iqr 0.25)

- roles and responsibilities of inter-disciplinary team members in pressure ulcer management (m 9, iqr 1.25)
- policies and procedures regarding transferring individuals between care settings (m 9, iqr 1)
- patient education and information giving. (m 9, iqr 1)

Strength of Evidence II

Findings from observational studies by Bergstrom et al (1995) and Moody et al (1988) (cited McGough systematic review, 1999) suggest that education programmes may reduce incidence and prevalence of pressure ulcer development.

A continuous quality assurance approach would advocate that increasing people's awareness about pressure ulcer risk assessment and prevention, via a co-ordinated and structured educational programme, is more likely to result in benefits for patients than providing no programme, although the effectiveness of educational programmes and what they consist of is currently lacking a reliable research base. These recommendations are supported by AHCPR guideline recommendations (1992, E2:p28), consensus opinion and principles of patient education.

For users and carers

9.5 Patients who are able and willing should be informed and educated about risk assessment and resulting prevention strategies. This strategy where appropriate should include carers. This information should be tailored to individual requirements. Written information can enhance verbal explanation. The education process should be two way, and patients'/carers' previous knowledge and experience respected.

9.6 Patient/carer education should include providing information on the following:

- risk factors that are associated with developing pressure ulcers (m 9, iqr 1)
- sites that are of the greatest risk of pressure damage (m 9, iqr 1)
- how to inspect skin and recognise skin changes (m 9, iqr 0.25)
- how to care for skin (m 9, iqr 0.25)
- methods for pressure relief/reduction (m 9, iqr 0.25)

- where they can seek further advice and assistance should they need it (m 9, iqr 0)
- emphasis on the need for immediate visits to a health care professional should signs of skin damage be noticed.

Strength of Evidence III

These recommendations are supported by AHCPR guideline recommendations (E1:p27, 1992), consensus opinion, principles of patient education and one survey which found that individuals who waited longer to go to a clinic presented with more severe pressure damage (Garber et al., 1996).

Essentials of care

Nutritional status, continence management and hygiene are essential aspects of care. Their association with pressure ulcer risk assessment and prevention is well documented but not fully understood from the current evidence base, including consensus opinion. Therefore separate recommendations about these issues have not been devised, but in recognition that they are key to raising standards of care (RCN, 1999), this section outlines some principles for practitioners to consider.

Nutritional status

Malnutrition is frequently cited as a risk factor for the presence, development and non-healing of pressure ulcers. Nutritional status influences the integrity of the skin and support structures, and a lack of vitamins and trace elements may predispose the patient to increased risk of pressure damage (Cullum and Clark, 1992). Emaciated and obese people have also been associated with being at a higher risk (Allman et al., 1995; Pope, 1999).

However the relationship between nutritional status and pressure ulcers is complex. For example, the poor nutritional status of a person with pressure ulcers may be as much a marker of poor overall health status than as a result of poor nutritional intake. In which case, improving nutritional status per se would not improve the outcome for the patient (Finucane, 1995). Despite a general belief among health care professionals that there is a link between pressure ulcer development and nutritional status, there is currently no research evidence to make this causative association.

Best practice entails monitoring the nutritional status of individuals as part of a holistic assessment procedure and as an ongoing process throughout an individual's episode of care. Initially, this assessment should include documentation and monitoring of the following factors:

- current weight and height
- recent weight loss
- usual eating habits
- recent changes in eating habits and intake.

If nutritional risk is suspected, practitioners should undertake more detailed screening. A formal nutritional risk assessment scale may be preferred to help with this and nutritionally compromised individuals should be referred to a dietitian.

Continence management

Incontinence is often said to increase the risk of developing pressure ulcers. As with nutritional status, the relationship between incontinence and pressure ulcers is not as obvious as is presumed (Defloor, 1999). Some studies have supported the role of incontinence as a risk factor (Goldstone and Goldstone, 1982) and others have not (Berlowitz and Wilking, 1989).

The key factor is moisture to the skin, which puts it at greater risk from maceration, friction and shearing forces. Therefore the key practice issue is the presence or absence of wet skin (Defloor, 1999). As such, effective management of incontinence is an essential part of skin care and fundamental to maintaining a person's dignity and comfort.

Where the source of moisture cannot be controlled, the use of moisture-absorbing or continence aids could be considered. The use of such aids should not interfere with any pressure redistributing surface an individual may be placed on. Referral to a continence advisor should also be considered on an individual basis.

Hygiene

An individual's skin may be exposed to a variety of moist substances – urine, faeces, perspiration and wound drainage – which may make it more susceptible to injury. The AHCPR (1992) guideline recommends that: skin cleansing should occur at the time of soiling; mild detergents should be used and warm (rather than hot) water to minimise irritation and drying; and moisturisers should be applied to areas of dry skin. Skin rubbing and massage, particularly over bony prominences should be avoided (Dyson, 1978).

Quality improvement

Quality improvement is about constantly looking for ways to do things better (Morrell and Harvey, 1999). It is an iterative process, and requires the commitment of the whole organisation and its stakeholders to work effectively. The following figure offers an example of a quality improvement cycle and related activities for pressure ulcer prevention.

Monitoring pressure ulcers

The presence or absence of pressure sores is often seen as an indicator of quality of care and as such is high on the political agenda (*Benchmarking*, DoH, 2000; *Pressure sores: a key quality indicator*, DoH, 1993; and *Health of the Nation*, DoH, 1992).

Incidence and **prevalence** are the two ways to measure pressure ulcer frequency.

Prevalence is the proportion of people with pressure ulcers in a defined period of time. This is affected by for example people admitted with existing ulcers, patient healing rates, rates of discharge and successful treatment.

Incidence is the rate at which people initially admitted without an ulcer develop one during a specific period of time. This may be determined by the type of patients admitted (for example those at high risk) and the effectiveness of preventive care.

Comparisons of prevalence between and within care settings are difficult to interpret because they are affected by incidence, healing rates, admission and discharge policies. The measurement of incidence gives a more accurate picture of the success and effectiveness of risk assessment and prevention policies because it identifies those people who have developed ulcers over time and in a particular place of care. Measures of incidence need to be adjusted in the light of the type and number of at risk patients admitted into the particular care settings.

The Benchmarking Fundamental Aspects of Nursing Care project (NHSE, 2000) will also provide a staged approach for practitioners to facilitate the development of practice in pressure area care. Benchmarks are being developed based on opinion about best practice, with the intention that practitioners use them to score their own current practice and compare this with 'best practice', by sharing examples and networking with others.

Discharge planning

Effective, successful discharge depends on the setting up of care packages based on the needs of the individual. When transferring an at risk patient between care settings and/or to their home, the following factors need to be addressed and communicated:

- identification of a specific professional who will be responsible for the management of the patient following discharge
- assessment and indication of level of risk, including date of last assessment – if a risk assessment scale has been used, then the name of the scale should be

documented **not the score**, as scores on one scale mean a different thing on another

- a description of the condition of the person's pressure areas
- details of any tissue damage, including size, grade, position and treatment
- preventive measures the person has required, including the type of pressure re-distributing device(s) used
- ensuring appropriate measures and equipment are in place prior to transfer or discharge
- written and verbal information for users/carers about assessment and prevention should be provided.

Audit criteria

Clinical audit should form an integral of organisations' clinical effectiveness activities. The principles and process of clinical audit are well documented (see for greater detail Morrell and Harvey, 1999). It has been defined as:

"...a clinically led initiative which seeks to improve the quality and outcome of patient care through clinicians examining and modifying their practices according to standards of what could be achieved, based on best evidence available or authoritative expert opinion where no objective research-based evidence exists." (Mann 1996)

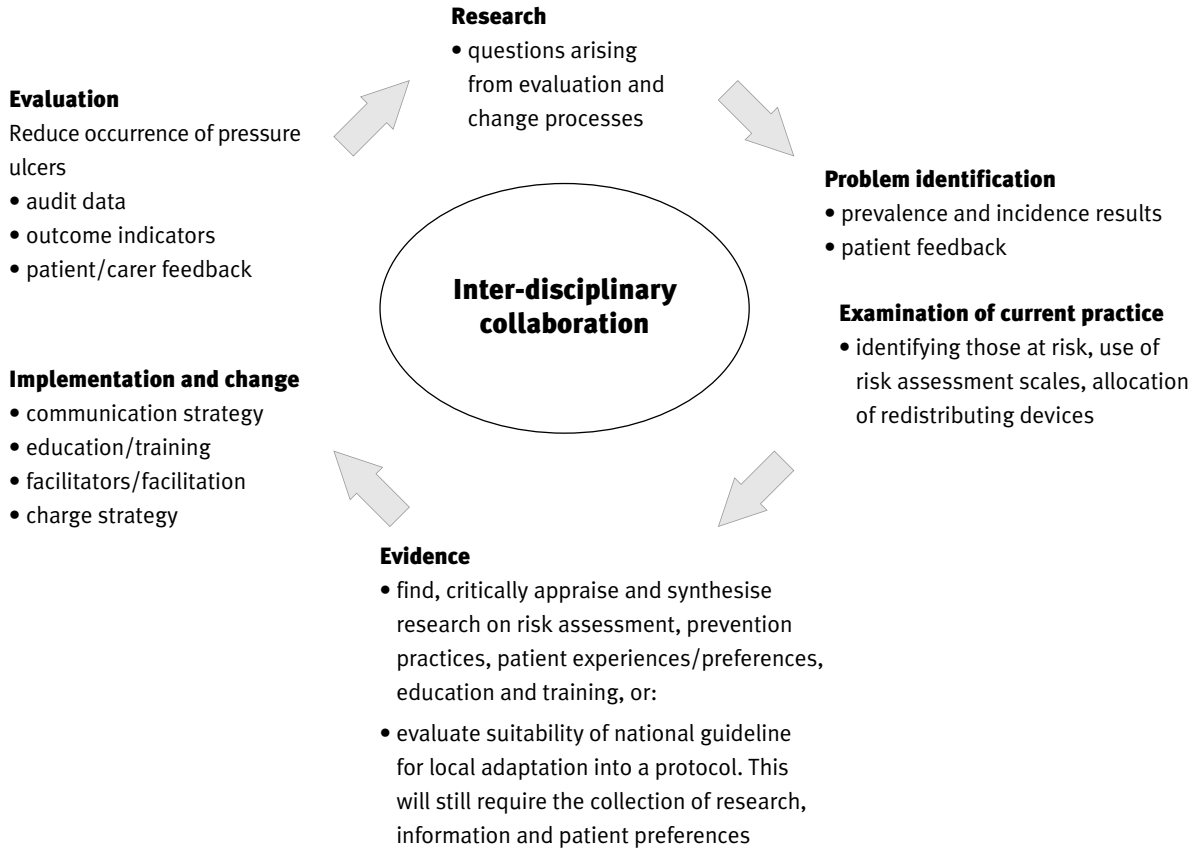
Clinical audit should be based on the best available evidence and where national guidelines do exist they should be used as a basis for audit activity. The following table provides some evaluative and descriptive statements derived from the recommendations, which could be incorporated into an audit tool. Those developing measurement tools need to consider and adapt these into structure, process and outcome criteria (see Morrell and Harvey, 1999). Any tools or frameworks developed from the guideline should suit the particular characteristics of the clinical environment and patient caseload(s), and be piloted.

Recommendations

Identifying at risk individuals

Assess and record individuals' level of risk of developing pressure ulcers

Quality improvement cycle for pressure ulcer prevention – an example



	Audit criteria	How to audit
Who carries out risk assessment?	<p>Has level of risk been assessed?</p> <p>On initial contact with the health care system:</p> <p>Has an informal risk assessment on all individuals been conducted?</p> <p>Has a formal assessment of risk been conducted on those people whose initial assessment highlighted factors (triggers) which place them at risk?</p> <p>Has a formal assessment of risk been conducted routinely for in-patients and those visited on domiciliary visits?</p> <p>Is the timing of risk assessment suitable for the patient's condition?</p> <p>In other cases has it taken place in under six hours of admission to the episode of care?</p> <p>Are the results of the assessment recorded/documentated?</p> <p>Is an individual's level of risk accessible to all members of the inter-disciplinary team?</p> <p>Does reassessment of risk occur when an individual's condition alters?</p>	<p>Documentation/recording of process and results of risk assessment: time, date, personnel.</p> <p>If individual's condition alters, is there a record of reassessment?</p> <p>Is the documentation/records held in a place accessible to all members of the inter-disciplinary team?</p>
Risk assessment scales	<p>Has a suitably trained member of staff carried out the risk assessment(s)?</p> <p>How has risk assessment been performed?</p> <p>Is there evidence that clinical judgement has also been involved in risk assessment activities?</p> <p>If a risk assessment tool is used – is it appropriate to the clinical specialty in which it is being used?</p>	<p>Documentation/records to identify personnel carrying out risk assessment.</p> <p>Records of training and education/induction programmes reflect attendees carrying out risk assessment. Risk assessment scales</p> <p>Documentation/recording of risk –</p> <ul style="list-style-type: none"> ~ name of the scale? ~ evidence of scores? ~ evidence of consideration of broader issues/risk factors (intrinsic/extrinsic/exacerbating)? <p>Ask health care personnel how level of risk has been assessed</p>
Skin inspection	<p>Does skin inspection occur regularly and frequently in response to changes in an individual's condition?</p> <p>Does skin inspection focus on areas of known vulnerability and also on areas of the body that are susceptible based on individualised assessment?</p> <p>Are changes documented immediately?</p>	<p>Documentation/records show times, dates and results of skin inspection.</p> <p>Also documentation/records of action taken.</p> <p>Observation of practice.</p> <p>Ask health care professionals how skin inspection is performed and what signs they look out for.</p> <p>Ask patients if their skin was inspected.</p>
Pressure redistributing devices	<p>Is the choice of pressure redistributing device based on an overall assessment of the individual?</p>	<p>Documentation/records to include decision trail and factors taken into account when making decisions</p>

	<p>What other factors were taken into account?</p> <p>Are individuals assessed to be at risk on an alternative to a standard mattress?</p> <p>Are individuals assessed to be at high risk on an alternating pressure mattress or other high-tech device?</p> <p>Are support surfaces changed to meet alterations in an individual's condition?</p> <p>Are individuals at high risk placed on pressure redistributing overlays during surgical procedures?</p> <p>Does post-operative care for these individuals include similar support surfaces?</p> <p>Are individuals repositioned whilst on pressure redistributing devices?</p>	<p>about support surfaces, including documentation/recording of any organisational constraints.</p> <p>Accurate recording of what support surfaces individuals are on (e.g. care plans, records of hiring or equipment library records).</p> <p>Mattress and support surface audits.</p>
Aids	<p>Is there any evidence to suggest that inappropriate aids such as:</p> <ul style="list-style-type: none"> • water- filled gloves • synthetic/genuine sheepskins • donut type devices <p>are being used?</p>	<p>Documentation/records and observation of practice.</p>
Repositioning	<p>Is there evidence that individuals assessed to be at risk are being repositioned?</p> <p>Are repositioning schedules being tailored to individual needs and results of skin inspection?</p> <p>Do individuals have written repositioning schedules?</p> <p>Are correct lifting and handling procedures being adhered to?</p> <p>Is repositioning avoiding pressure on bony prominences?</p> <p>Do individuals, who can and who are willing, reposition themselves?</p> <p>Is the knowledge of individuals who have determined their own routine to prevent tissue damage being respected?</p>	<p>Documentation/records to reflect individualised repositioning schedules.</p> <p>Observation of practice.</p> <p>Ask users about their involvement in care.</p>
Seating	<p>Are seating assessments carried out by appropriately trained assessors?</p> <p>Does positioning take into account:</p> <ul style="list-style-type: none"> • distribution of weight • postural alignment • support of feet? <p>Is chair sitting limited to a maximum of two hours for those at risk of developing pressure ulcers? .</p>	<p>Documentation/records to reflect advice and assessment by appropriate assessors?</p> <p>Asking staff about their practice.</p> <p>Observation of practice.</p>
Education and training	<p>Are health care professionals trained in pressure ulcer risk assessment and prevention?</p> <p>What is included in this training?</p> <p>How is competence assessed?</p> <p>How is competence maintained/knowledge updated?</p>	<p>Induction/training and education records.</p> <p>Ask trainers.</p> <p>Ask health professionals about their training.</p>
• health care professionals		

- users

Are users a) informed and b) educated about

- pressure ulcer risk assessment,
- prevention strategies?

What does this education include?

How has understanding been assessed ?

Ask users if they have received a) information and b) education. What did this entail?

Ask health care professionals about what information and education they gave users.

Glossary

Alternating pressure device: device that mechanically varies the pressure beneath the individual thus reducing the duration of applied pressure.

Bias: the deviation of results from 'the truth', due to systematic error(s) in the methods used.

Cellulitis: a spreading infection of connective tissue, especially subcutaneous tissue.

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

Constant low pressure devices: devices that mould around the shape of the patient to distribute weight over a large area.

Critical appraisal: the process of assessing the validity, results and relevance of evidence, often in conjunction with a structured framework/tool.

Effectiveness: the extent to which an intervention does more good than harm.

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.

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

Blanching hyperaemia: is the distinct erythema caused by reactive hyperaemia, when the skin blanches or whitens if light finger pressure is applied, indicating that the patient's micro-circulation is intact.

Non-blanching hyperaemia (previously identified as non-blanching erythema): is indicated when there is no skin colour change of the erythema when light finger pressure is applied, indicating a degree of microcirculatory disruption often associated with other clinical signs, such as blistering, induration and oedema.

(See Collier 1999b for more details about how to recognise these signs)

Extrinsic: not belonging, lying outside, in the case of pressure ulcer development, factors that are external to the individual.

Incipient: initial stages, beginning to exist.

Induration: the abnormal hardening of tissue (or organ).

Intrinsic: inherent, thus in the case of pressure ulcer development, factors present within the individual.

Maceration: a softening or sogginess of the tissue caused by the retention of excessive moisture.

Necrosis: the local death of tissue, often black/brown in colour and leathery in texture.

Oedema: increase in fluid in inter-cellular space, swelling.

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 sore development in a sample largely came true – i.e. it has both high sensitivity and high specificity.

RCT: randomised controlled trial – a trial in which subjects are randomly assigned to either a group receiving an intervention that is being tested or another group receiving an alternative or no intervention. The results compare the outcomes of the different groups.

Search strategy: the method used for searching for articles to answer particular questions.

Sensitivity: what percentage of those who developed pressure ulcers in the study were predicted to be at risk by the score.

Specificity: what percentage of participants were correctly predicted to be not at risk by the score (a specificity of 100% means that all the participants who did not develop ulcers had been predicted to be not at risk).

Systematic review: a review in which evidence on a topic has been systematically identified, appraised and summarised according to pre-determined criteria.

Validity: a study is valid if the way it is designed and carried out means that the results are unbiased.

30 degree lateral tilt: the patient is placed in the laterally inclined position, supported by pillows, with their back making a 30 degree angle with the support surface.

95% confidence intervals: while a study will give single values of sensitivity and specificity for a risk score, these are based on the experience of the handful of people in the study and are the best guesses as to what would happen if the study was to be repeated. Where sample sizes are small, there will be high imprecision in the estimates of sensitivity and specificity.

Sources: Collier M.E. (1999b); Harding K. (2000); Baillière's Nurses Dictionary (1997); Cullum et al (2000); Heinemann Medical Dictionary (1986).

Chapter Four

Conclusions & Implications

4.0 Guideline dissemination and implementation

Passive dissemination of the guideline will be achieved via:

- the RCN networks and fields of practice
- database of interested parties wishing to receive the guideline
- the partner/collaborating organisations
- tissue viability networks
- publications in specialist and professional journals and press
- presentations at conferences.

Funding for active implementation has yet to be secured. The NHSE funding covered development costs only. The audit criteria included in the guideline will help practitioners to develop their own context specific audit tools. Additionally, as part of the on-going work of the RCN's Quality Improvement Programme, we are planning to develop a set of documents on the pressure ulcer risk assessment and prevention guideline, including:

- the guideline (in all its formats)
- a patient version
- an implementation guide including the audit protocol and how to involve users in audit.

This type of package has been developed for the clinical practice guideline *The management of patients with venous leg ulcers* (RCN, 1998).

This planned implementation initiative is funding dependent.

4.1 Local adaptation

Decisions to adopt any particular recommendations must be made by the practitioner in the light of: available resources; local services, policies and protocols; the particular patient's circumstances and wishes; available personnel and equipment; clinical experience of the practitioner, and, knowledge of more

recent research findings. For example, if a risk assessment tool is the preferred option for formal risk assessment, local guideline groups will have to decide which scale to use in the light of the recommendation about context specificity and risk thresholds. Other recommendations will also require local consideration, for example documentation/recording procedures, training provision and decisions about which pressure redistributing products to use.

See Morrell and Harvey (1999) for process guidance on local adaptation.

4.2 Patient considerations

The development of the guideline did include a patient perspective, directly during the consensus process and also by collaborating with patient organisations. The Philosophy of Care included in the guideline refers to the role that individuals can play in this aspect of care. Unfortunately at present there is little research to guide practitioners as to the best means of achieving this.

The recommendations highlight how users' preferences should be taken into account when applying the guideline. The guideline could also be used by practitioners as a vehicle to discuss care. There are plans by the RCN's Quality Improvement Programme to develop a patient version of this guideline in consultation with users.

4.3 Quality of the research evidence

The authors of both systematic reviews report on the generally poor quality of the studies and trials available for review. Cullum et al (2000) cite methodological flaws such as open randomisation, lack of baseline comparability and lack of blind outcome assessment, in addition to inadequate sampling and thus under-powered trials. McGough (1999), again citing methodological flaws, comments on a general lack of attention to randomisation, inter-rater reliability, reliability of risk assessment scales, poor descriptions of wound/skin assessment and lack of blinding of nurses carrying out risk assessment.

Such methodological inadequacies make studies susceptible to bias and non-generalisable to the population as a whole. The same issues were encountered in the update of the AHCPR guideline's literature base in addition to the generally inadequate reporting of design, sample, interventions and results which hampered critical appraisal.

4.4 Implications for research

As the evidence base for pressure ulcer risk assessment and prevention is so variable the potential future research agenda is large.

Future primary research studies should pay more attention to current methodological standards for the conduct and reporting of research, such as those produced by CONSORT statement (Altman 1996). There is also a need for the researchers to adopt a structured approach to abstracts which would help reviewers to focus on the essential detail.

On research about pressure redistributing devices, Cullum et al (2000) suggest there is a need for well designed, independent, multi-centred, randomised controlled trials that compare the clinical and cost effectiveness of different types of devices in a variety of settings. On risk assessment, McGough (1999) suggests that more epidemiological research needs to be conducted to better understand risk factors. She recommends that the data, gathered by prospective cohort studies conducted in different health care settings, could generate an 'item pool' which could then be used to develop a new risk assessment scale. The effectiveness of such a scale could then be evaluated in a prospective randomised controlled trial.

Further research about the effectiveness of other interventions such as re-positioning is required. The practice of routinised two- and four-hour turning is largely historical artefact with very little quality research support (for example Norton et al., 1975; Smith and Malone, 1990). Studies such as DeFloor (1999b), on the effect of different turning intervals on the development of pressure ulcers, may contribute to understanding this practice.

Similarly, further research which systematically compares the 30 degree/lateral tilt with other positions, in differing patient groups and clinical contexts, including the collection of data on patient comfort as well as physiological measures, would be of value. Ultimately as Clark points out (1998), the possibility that all repositioning schedules may fail to adequately protect vulnerable individuals cannot be ignored.

Further research is required evaluating the effect of educational programmes. Limited research suggests that educational programmes may have an effect in reducing pressure ulcer incidence. Clinicians' reported experiences indicate that education is key to effective pressure area management. However more conclusive research evidence is required on what should be included in training, at what level, how training and education should be delivered, and how competency is assessed and updated.

There is also a paucity of research exploring patients' and carers' perceptions and experiences of pressure ulcers, their involvement in pressure area care and their educational requirements. This may be achieved by well designed studies using a mixture of qualitative and quantitative approaches to data collection via, for example semi-structured interviews and focus groups, and pre-validated quality of life measures.

4.5 Guideline development

4.5.1 Method

The guideline recommendations were formed on the basis of a number of different evidence sources. Given that in a seemingly 'objective' guideline development process, the opportunities for subjectivity to interfere are many and varied (McIntosh, 1999), the possibility of elements of subjectivity creeping into this guideline's development is recognised. The following provides a more detailed critique of involving consensus development methods in the development of a clinical guideline.

4.5.2 Potential weakness of incorporating consensus development

"Clinical guidelines are valid if, when followed, they lead to the health gains and costs predicted for them" (Grimshaw and Russell, 1993a p245).

The 'validity' of the guideline, resulting from a process such as the one outlined above, could be questioned. Grimshaw and Russell (1993a) argue that validity is dependent upon: how the evidence was identified and synthesised, how many guideline users and key disciplines were included in the guideline group, and, how the guideline was developed. Based on these criteria, guidelines with greater scientific validity will be those that:

- are developed from systematic reviews (or even better: meta analysis)
- include few guideline users but most key disciplines and

- ensure the explicit linkage of recommendations with evidence.

Guidelines developed with a mixture of evidence derived from systematic reviews and from consensus opinion not entirely based on research evidence, would, by the same criteria, be viewed as less scientifically valid (Grimshaw and Hutchinson, 1995).

Limiting recommendations to where evidence exists “would reduce the scope of the guidelines and limit their value to clinicians and policy makers who need to make decisions in the presence of imperfect knowledge” (Eccles et al, 1996 p47). Perhaps as Murphy et al (1998) suggest, the best we can do is try to identify a method that will produce more, on average, ‘good’ judgements than other methods. This begs the questions: what method ensures arrival at ‘good’ judgements and what is a good judgement?

Murphy et al (1998) suggest a number of ways to assess validity in consensus development processes which include predictive validity, concurrent validity and internal logic. For example, if validity were concurrently assessed, it would mean that decisions made within a group that directly conflict with the research-based evidence without good reason, would be invalid. However, there is no absolute means by which to judge whether, at the time a decision was made, it was valid and thus no means to assess the validity of the method via which it was made (Murphy et al., 1998).

Prospectively, the recommendations may be able to be assessed directly by, for example, an audit of guideline implementation.

Issues b) and c) from above are met within the method outlined in this report. Key disciplines are involved in the consensus and guideline development process, and recommendations are explicitly linked to the form of evidence from which they were derived. So, for example, where a recommendation is based solely on expert opinion, this is stated and the extent of agreement identified.

4.5.3 Potential strengths

There are some potential strengths associated with the guideline development approach described here. Firstly, it provides an opportunity for collaborative working between a number of different disciplines at all stages of the guideline development process. Equally as important, this method also provides a forum for patient and/or carer participation. This may be particularly useful in situations where there is very little research about patients’ and carers’ experiences of certain conditions and/or care. Finally, using this interdisciplinary collaborative approach may enhance the

credibility of the guideline in the eyes of the end users. That is, if the participants involved in the development process are recognised professionals in the particular field of practice, it may have a positive influence on the uptake of the resultant guideline.

The consensus development process reported in Chapter Two was an attempt to ensure that clinical expertise and opinion contributed to the process in the most explicit and systematic way possible. Careful consideration of factors such as the type of formal consensus process, nominal group membership, definition of agreement, evidence and statement presentation, rating aggregation and recommendation formulation, should have served to limit the influence of subjectivity. The decision process reported in this report should be evidence of that.

4.5.3 Constraints

Project time and financial constraints meant that the cut off date for retrieval of new research was 1998. This was also the case for the two systematic reviews. Should there have been any groundbreaking research in the interim time period that would have met the criteria for inclusion in the evidence base, it would have been considered. However, this was not the case.

4.6 Guideline update

The guideline was completed in the Spring of 2000. The NHSE funded the guideline’s development – thus its updating is resource allocation dependent. Resources permitting, the guideline would be reviewed and updated on a two-yearly basis by the RCN. The first revision would therefore begin in 2002.

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Appendix 1

Contributors to the guideline's development

* feedback on draft of guideline

** feedback on draft of guideline and critical appraiser for research papers

Guideline developers

Ms Jo Rycroft-Malone
Research and Development Fellow (RCN Institute)

Ms Elizabeth McInnes (update of AHCPR review)
(formerly Project Officer RCN Institute, currently
National Breast Cancer Centre, Sydney, Australia)

Consensus development method guidance

*Dr Nick Black, Professor of Health Services Research
London School of Hygiene and Tropical Medicine
Also, facilitator of the nominal group meeting

Systematic review authors

*Ms Amanda McGough (1999)
Research and Development Advisor/Teaching Fellow
Clinical Development Unit
North Tees Health NHS Trust
Hardwick
Stockton on Tees

Cullum N, Deeks J, Sheldon TA, Song F and Fletcher AW
(2000)

Contact address:
Dr Nicky Cullum
Reader, Centre for Evidence Based Nursing
Department of Health Studies
University of York, Genesis 6
York YO10 5DQ

Nominal technique group

**Ms Maureen Benbow
Tissue Viability Nurse
Leighton Hospital

Dr Mary R. Bliss
Consultant Geriatrician
Bryning Day Hospital

*Ms Linda Clarke
Patient Services Manager
Spinal Injuries Association
London

**Dr Michael Clark
Senior Research Fellow
University of Wales College of Medicine, Cardiff

*Mrs Carol Dealey
Research Fellow
University Hospital Birmingham NHS Trust

**Dr Krzysztof Gebhardt
CNS for Pressure Sore Prevention
St. George's Hospital, London

**Ms Deborah Hofman
Clinical Nurse Specialist
Wound Healing Unit
The Churchill Hospital
Oxford

*Ms Pennie Roberts
Head of Physiotherapy Studies
Leeds Metropolitan University

*Dr Shyam Rithalia
Senior Lecturer
University of Salford

**Professor John Young
Consultant Geriatrician
St. Lukes Hospital
Bradford

Advisory group

*Ms Betty Arrol
Policy Officer
Age Concern England

Dr DL Bader
University of London

*Professor Nancy Bergstrom
University of Texas
Houston

*Ms C de Normanville
Clinical Audit & Research Manager
North Derbyshire Community Healthcare
Service

*Dr G Cherry
Wound Healing Unit
The Churchill Hospital
Oxford

*Mr Mark Collier
Nurse Consultant and Senior Lecturer
Tissue Viability Centre for Research
and Implementation of Clinical Practice
Thames Valley University
London

*Ms Susanne Cox
Research and Audit Nurse PICU
Guy's & St. Thomas' Hospital Trust
London

*Dr JGC Cox
Consultant Physician
Medicine for the Elderly
Wansbeck General Hospital
Ashington
Northumberland

**Ms Jacqui Fletcher
Senior Lecturer
University of Hertfordshire
Hatfield

**Professor Dinah Gould
South Bank University
London

*Mr Ralph Hammond
Professional Advisor
The Chartered Society of Physiotherapy

**Mrs Val Henderson
Tissue Viability Nurse
Northumberland Healthcare NHS Trust

Ms Emily Holzhausen
Carers National Association

*Ms Karen Hyland
Chair of Nutrition Advisory Group for the Elderly
of the British Dietetic Association
c/o Colindale Hospital
London

Ms Elizabeth Jenks
Chief Nurse
United Leeds Teaching Hospital

*Mr Richard G Lynham
British Geriatrics Society

*Mr Nick Malone
Head of Nursing for Medicine
King's College Hospital
London

*Ms Jane Nixon
Research Associate
Centre for Health Services Research
University of Newcastle
21 Claremont Place
Newcastle-Upon-Tyne

**Ms Aideen Tarpey
Practice Development Nurse
STEP Project
University Hospital Lewisham
London

Ms Marianne Rigge
Director
College of Health

*Ms Lesley Stockton
Occupational Therapist
Psychology Department
University of Manchester

*Ms Eileen Scott
Research and Development Co-ordinator
North Tees & Hartlepool NHS Trust
Teeside

*Ms Judy Waterlow
Independent Consultant
Newtons, Curland
Taunton

Royal College of Nursing's Quality Improvement Programme

Dr Lesley Duff
Senior Research and Development Officer

Mrs Jackie Shepherd
Programme Administrator

Mrs Maggie Robson
Programme Secretary

Appendix 2

Search strategy for pressure ulcer material for update of AHCPR literature base

- #1 pressure ulcer or pressure sore or decubitus ulcer or pressure damage or bed sore
 - #2 massage or skin care or repositioning or reposition? or pressure relieving or pressure relief or alternating or nutrition or nutritional or wheelchairs or pillows or cushions or protective devices or pressure physiology or prevention and control or skin assessment scale or risk calculator or evaluation or education or risk prediction or complications or diagnosis or equipment & supplies or patient education or staff education or classification
 - #3 (study or research or study type or research design or study design) in ti, ab, de
 - #4 py>=1991
- human studies
- all languages