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The Prevention and Treatment of Pressure Sores:

How useful are the measures for scoring people's risk of developing a pressure sore?

How effective are pressure-relieving interventions for the prevention and treatment of pressure sores?

Pressure sores are relatively common and represent major costs to patients, their carers and the NHS.

- Pressure-relief by manual repositioning of patients, special mattresses, mattress overlays and beds is used to prevent sores in high risk patients, and to treat people with existing sores.
- Pressure sore prevalence rates should not be used as a measure of the quality of care; incidence rates may only be used as an indicator of the quality of preventive care if the risk of developing a sore is taken into account.
- The evidence for the accuracy of pressure sore risk scales is confusing, and it is not clear that these scales are better than clinical judgement or improve outcomes.
- The effectiveness of different schedules of manual repositioning has not been adequately studied.
- The standard hospital mattress is less effective at preventing sores than some low pressure foam mattresses.
- Most of the equipment available for the prevention and treatment of pressure sores has not been reliably evaluated, and no `best buy' can be recommended.
- Patients at raised risk should be provided either with an evaluated low pressure foam mattress, or if at higher risk, with a large-celled alternating pressure mattress or a proven low-air loss or air-fluidised bed. However there is insufficient research evidence on clinical- or cost-effectiveness to guide equipment choice.
- Randomised controlled trials accompanied by economic analysis could provide decision-makers with reliable evidence on the relative cost-effectiveness of different interventions and strategies within a relatively short time.

A. PRESSURE SORES

Pressure sores are common in hospital and community settings, represent a significant burden of suffering for patients and their carers and are costly to the NHS. Pressure sore prevalence rates should not be used as a measure of the quality of care and incidence rates may only be used as an indicator of the quality of preventive care if patients' risk of developing a sore is taken into account.

A.1 Pressure sores (also known as bedsores, pressure ulcers and decubitus ulcers) are areas of localised damage to the skin and underlying tissue, caused by pressure, shear or friction. They usually occur over bony prominences such as the base of the spine (Figure 1), hips and heels (Figure 2). Pressure sores occur in both hospital and community settings, most often in the elderly and immobile (eg. orthopaedic patients), those with severe acute illness (eg. patients in Intensive Care Units) and in people with neurological deficits (eg. people with spinal cord injuries).

A.2 The development of pressure sores in hospital and community settings is quite common. For example, new pressure sores occurred in 4% - 10% of patients admitted to a UK District General Hospital, depending on the case-mix[1]. They represent a major burden of sickness and reduced quality of life for patients and their carers, and are costly to the NHS. The cost of preventing and treating pressure sores in a 600-bedded large general hospital has been roughly estimated at between £600,000 and £3 million per year[2] .

A.3 It is commonly thought that most pressure sores are avoidable, and a number of initiatives have been established to prioritise their prevention[3,4]. The 1994/95 NHS Priorities and Planning Guidance[5] encouraged Health Authorities to set annual targets for an overall reduction in prevalence of at least 5%. However target setting in this area may not be sensible, and the achievement of targets not straightforward (see Appendix 1). For example, pressure sore prevalence surveys conducted on the same 29 wards in a DHA in 1986 and 1989 demonstrated an increase in prevalence from 6.8% to 14.2% despite a large investment in pressure sore prevention equipment during the intervening period[6]. Health care professionals attempt to reduce the incidence of severe pressure sores by the identification of people at high risk and the use of prevention strategies, such as pressure-relieving equipment (see Table 1). It is essential that initiatives are based on the best available evidence of clinical- and cost-effectiveness. This issue of *Effective Health Care* systematically reviews the evidence for the accuracy of pressure sore risk prediction, and the effectiveness of pressure-relieving interventions. A systematic review of the epidemiology of pressure sores is outside the scope of this bulletin.

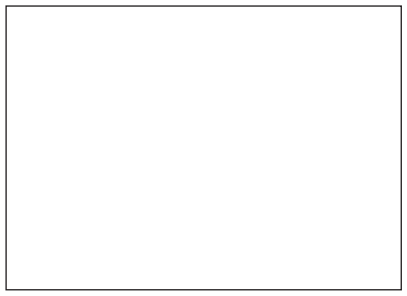

Figure 1 A Grade 1 pressure sore (persistent erythema) on the sacrum.

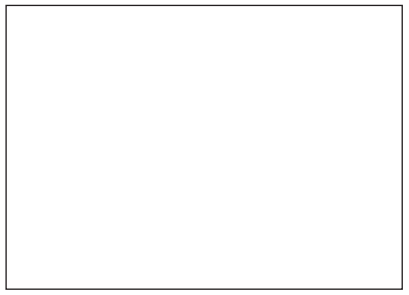

Figure 2 Grade 3 pressure sores affecting both heels of an elderly patient. There are black eschars covering areas of necrotic tissue.

Definition and staging of pressure sores

A.4 A pressure sore can been defined as *"a new or established area of skin and/or tissue discolouration or damage which persists after the removal of pressure and which is likely to be due to the effects of pressure on the tissues"*[13]. Various systems have been developed to grade pressure sores, mainly based on clinical presentation (see Box 1 and Figure 1 for examples). However, the detection and grading of sores, particularly in their very early stages, can be quite subjective and unreliable.

Grade 1:
Discolouration of intact skin, including non-blanchable erythema, blue/purple and black discolouration (Figure 1).

Grade 2:
Partial-thickness skin loss or damage involving epidermis and/or dermis.

Grade 3:
Full-thickness skin loss involving damage or necrosis of subcutaneous tissues; but not through the underlying fascia and not extending to the underlying bone, tendon or joint capsule (see Figure 2).

Grade 4:
Full-thickness skin loss with extensive destruction, and tissue necrosis extending to the underlying bone, tendon or joint capsule.

Box 1: A pressure sore grading system.

B. IDENTIFYING PEOPLE AT RISK - RISK ASSESSMENT SCALES

Various scales have been developed to identify those patients at high risk of developing a pressure sore. Most scales have developed in an ad hoc fashion; it is unclear which is the most accurate. There is little evidence that using a pressure sore risk scale is better than clinical judgement or that it improves outcomes.

SUPPORT SURFACE	TYPE OF SURFACE	MANUFACTURER	PURCHASE COST (JAN' 1995) (£)	RENTAL COST WHERE APPLICABLE (£)
Quattro	Alternating pressure overlay	Talley Group	546	2.95/day
Quattro Deep Cel Home Care	lAlternating pressure mattress replacement	"	1295	7.00/day
Quattro Deep Cell Acute	"	"	1975	7.95/day
Pulsair	"	"	168	60p/day
Large Cell	"	"	295	1.50/day
NIMBUS II	Has both dynamic (alternating pressure)and static (constant low pressure) modes. Mattress replacement.	HNE Healthcare	2770	67.00/week + 30.00 installation fee if hire period < 14 days
Alpha X Cell	Alternating pressure overlay	"	695	38.00/week + 30.00 installation fee if hire period < 14 days
Autoexcel	Alternating pressure overlay	"	1550	50.00/week + 30.00 installation fee if hire period < 14 days
Pegasus Airwave	Alternating pressure mattress replacement	Pegasus	3450	70.00/week
Pegasus Biwave	Alternating pressure mattress replacement	"	2055	55.00/week
Transair PPS 2000	Alternating pressure mattress replacement	Karomed	2850	50.00/week
Mediscus Monarch	Low air loss bed	KCI Mediscus	14935	57.41/day
Clinitron	Air Fluidized bed	SSI	16,200	50.00/day
ROHO	Constant low pressure mattress (in four sections)	Raymar	1600 (450 per section)	-
Spenco	Silicore overlay	Spenco	Prices range - from 104.30 - 137.80 depending on covering	-
Modular Propad	Slashed foam overlay	Medical Support Systems	48.35 (covers cost either 9.51 or 32.76)	-
Clinifloat	Foam mattress	SSI Medical Services Ltd	220	-
Therarest	Foam mattress	KCI Therapeutic Services	200	-
Vaperm Foam Mattress	Foam mattress	HNE Healthcare	140 or 180 - depending on the cover	
Softform	Foam mattress	Medical Support Systems	165	-
Transfoam	Foam mattress	Karomed	5" thick - 134.62 6" thick - 157.14	-

All prices exclude VAT and carriage. It is important to note however, that individual sales agreements and bulk purchases cause costs to vary enormously. The level of service required will also have cost implications, and consumers are advised to check these carefully.

This list of surfaces is not intended to be exhaustive, but merely provides examples.

Table 1: Examples of available support surfaces with costs.

- to aid the rational allocation of limited resources (such as special beds) to those who are likely to benefit most
- to structure patient assessments and act as aide memoires of the risk factors[7]
- to act as case-mix adjusters to help make sensible comparisons of the incidence of pressure sores between units or over time
- as indicators of patient risk in order to judge the comparability of patients between different arms of trials

Box 2: Potential applications of risk assessment scales

B.1 Interventions to prevent pressure sores can be very expensive and it is important to ensure that resources are targeted towards patients who are at high risk of developing sores. Risk scales have been developed in order to try and identify people at raised risk. The potential applications of these scales are summarised in Box 2.

Box 3: The Norton Pressure Sore Prediction Score[8]

Physical Condition	Mental State	Activity	Mobility	Incontinence
4 Good	4 Alert	4 Ambulant	4 Full	4 Not
3 Fair	3 Confused	3 Walks with help	3 Limited	3 Occasional
2 Poor	2 Apathetic	2 Chairbound	2 Very limited	2 Usually urine
1 Bad	1 Stuporous	1 In bed	1 Immobile	1 Doubly incontinent

Factors included in risk assessment tools

B.2 A variety of risk scales has been developed[8-15]. They are based on assessments of a range of clinical variables such as mobility, incontinence, and activity; the total score is compared to a standard reference value to classify the level of risk. An example of a commonly used risk scale is shown in Box 3.

Study	Scale (Scores for group at risk)	Setting	Sample Size	Proportion developing sores	Follow -up	Sensitivity** (95% CI)	Specificity** (95% CI)	Masking of Outcome Assessment	Masking of Score to Nurses	Lowest Grade Sore Included
Bergstrom et al, 1992[60]	Braden (16 or less)	Medical-Surgical Unit (Shorter stay)	100	7%	Not clear	100%* (59%, 100%)	90% (82%, 96%)			Grade I
Bergstrom et al, 1992[60]	Braden (16 or less)	Medical-Surgical Unit (Longer stay)	100	9%	Not clear	100%* (66%, 100%)	90% (53%, 74%)			Grade I
Bergstrom et al, 1992[61]	Braden (16 or less)	Adult Intensive Care Unit (with follow-up on other units)	60	40%	2 weeks (or discharge if earlier)	83% (63%, 95%)	90% (46%, 79%)	✓	✓	Grade I
Langemo et al, 1991[62] (e)	Braden (16 or less)	Medical-Surgical & Orthopaedic Acute Care	74	15%	2 weeks (or discharge	64% (30%, 89%)	87% (75%, 95%)	✓	✓	Grade I
Salvadalena et al, 1992[63] (f)	Braden (16 or less)	Medical Acute Care Unit	99	20%	3 weeks (or discharge	40% (19%, 64%)	70% (59%, 80%)	✓	✓	Grade I
Barnes et al, 1993[64]	Braden (16 or less)	General Medical and Cardiovascular Unit	361	6%	15 days (or discharge if earlier)	73% (50%, 89%)	91% (87%, 94%)	?	?	Grade I
Braden et al, 1994[17]	Braden (16 or less)	Nursing Home	102	28%	4 weeks (or discharge if earlier)	46% (28%, 66%)	88% (78%, 94%)	✓	?	Grade I
Norton et al, 1962[8]	Norton (14 or less)	Care of the Elderly Unit	250	24%	8 weeks (or discharge if earlier)	63% (50%, 75%)	70% (64%, 77%)	?	?	Grade II
Goldstone et al, 1982[65] (a)	Norton (14 or less)	Orthopaedic Unit (emergency elderly admissions)	40	45%	Until discharge	89% (65%, 99%)	36% (17%, 59%)	?	?	Not clear
Lincoln et al, 1986[66] (b) (c)	Norton (14 or less)	Medical-Surgical Unit (elderly patients)	36	14%	Until discharge (max length of stay was 4weeks)	0% * (0%, 52%)	94% (79%, 99%)		✓	Grade II
Stotts 1988[67]	Norton (14 or less)	Elective Cardiovascular and Neurosurgury Units	387	17%	3 weeks	16% (8%, 28%)	94% (91%, 97%)	?	✓	Grade I
Smith 1989[22] (c) (g)	Norton (16 or less)	Elective and Emergency Orthopaedic Admissions	101	30%	Until discharge	60% (41%, 77%)	31% (21%, 43%)			Grade I
Towey et al, 1988[13]	Knoll (12 or less)	Long-term Care (elderly patients)	60	47%	4 weeks (or transfer if earlier)	86% (67%, 96%)	56% (38%, 74%)			Grade I
Lowthian 1989[12]	PSPS (6 or above)	Orthopaedic Patients	1244	4%	3 weeks	89% (77%, 96%)	76% (74%, 78%)			Grade I
Andersen et al,1982[68]	Own (2 or more)	General Hospital Acute Care Admissions	3398	1%	3 months	88% (73%, 96%)	86% (85%, 87%)			Grade II
Gosnel 1973[14]	Gosnell (15 or less)	Long-term Care (elderly patients)	30	13%	3 weeks (or discharge if earlier)	50%* (7%, 93%)	73% (52%, 88%)			Unclear
Smith 1989[22] (c) (g)	Waterlow (20 or more)	Elective and Emergency Orthopaedic Admissions	101	30%	Until discharge	73% (54%, 88%)	38% (27%, 50%)			Grade I

Notes

* These results are calculated on data from less than 10 individuals

** Calculation of all confidence intervals and many of the sensitivities and specificities was performed by the author

(a) Patients with 'unique factors' were excluded

(b) Patients staying less than 3 days were excluded (26%)

(c) Surgical patients were evaluated prior to surgery

(d) Categories in the Norton scale were defined re Gosnell

(e) Only patients with expected length of stay of at least 5 days were included

(f) Only patients with expected length of stay of at least 3 days were included

(g) Only patients with expected length of stay of at least 7 days were included

Table 2: Studies of the Predictive validity of risk assessment tools.

B.3 Most scales have been developed in an *ad hoc* fashion, based on opinions of the relative importance of possible risk factors. However, the most valid way of constructing such a scale involves the use of statistical regression models to choose and weight the factors which best predict the development of a sore. No risk assessment scale has been developed in this way, thus it is unlikely that the existing scales optimally discriminate between those who will and will not go on to develop pressure sores.

Use of risk assessment scales in different settings

B.4 Scales developed in one setting are not necessarily transferable to another. For example, the duration of surgery is a risk factor for pressure sores in surgical patients16 but is irrelevant to patients in extended care facilities. Some people have suggested varying the threshold value of the scale (beyond which a patient is defined as being at high risk) in order to improve predictive validity and to make it more relevant to different settings[17]. However such threshold modification must be empirically derived and validated.

Evidence of the effectiveness of using assessment scales

B.5 There is no published evaluation that reliably assesses whether the use of a risk scale as an adjunct to care results in a reduction in the incidence of pressure sores. One published study[18] compared the assessment of pressure sore risk by nurses with that calculated by using the Braden score. However, whilst the study showed a high level of agreement, patients were not followed up and so it is not known whether this risk scale *predicts* better than clinical judgement.

Studies of predictive validity

B.6 The studies which used valid techniques[19] to assess how well risk scales predict whether or not a person will develop a pressure sore (predictive validity) are shown in Table 2. All judgements on inclusion, the quality assessment and data extraction were made by one reviewer. Due to a variety of potential biases most of these studies will have underestimated the accuracy of the scales[20].

B.7 Use of a scale with high specificity ensures that expensive resources are not wasted on those patients who would not have developed a sore. Scales with high sensitivity ensure that patients at high risk will not be missed, and in whom the risk of pressure sores will decrease if they subsequently receive effective preventive measures.

B.8 There is great variation in the estimates of predictive validity both across scales and between assessments of the same scale (Table 2). Because the variation in methods of assessment and care settings is so great, it is not possible to make valid comparisons of the predictive validity of the scales. Although some of the estimates of predictive validity are quite high, there is great variation between them, and none of the scales appears to be unambiguously superior. For example, whilst one study found six different scales to have similar predictive validity when applied to the same patients[21] another study comparing two scales on a cohort of orthopaedic patients showed that the Waterlow had both higher sensitivity and specificity than the Norton[22].

C. TYPES OF PRESSURE-RELIEVING INTERVENTIONS

Pressure-relief can be achieved by the manual repositioning of patients, the use of special mattresses, mattress overlays and beds and is used to prevent sores in high risk patients, and to treat people with existing sores.

C.1 The aim of *prevention* strategies is to reduce the pressure beneath a patient. This may be achieved by regular manual repositioning, or the use of pressure-relieving support surfaces such as mattress overlays, replacement mattresses or whole bed replacements. The cost of these interventions vary accordingly (see Table 1). Pressure-relieving beds and mattresses act by either moulding around the shape of the patient to distribute the patient's weight over a larger area (constant low pressure devices), or by mechanically varying the pressure beneath the patient, so reducing the duration of the applied pressure (alternating pressure devices). Pressure sore *treatment* strategies usually comprise a combination of pressure-relief and wound care.

C.2 This issue of *Effective Health Care* focuses only on the effectiveness of risk prediction, manual repositioning, and pressure relieving beds and mattresses. Other aspects of pressure sore management, including the use of creams and dressings, wound care, and a thorough examination of the economic aspects, are the subject of a review recently commissioned by the Health Technology Assessment Programme which will be completed in 1996.

C.3 Pressure-relieving beds and mattresses are classified as alternating pressure, constant low pressure and turning devices[23]. Alternating pressure devices generate alternating high and low interface pressures between body and support, usually by alternate inflation and deflation of air-filled cells. Such devices are available as mattress overlays, and single- or multi-layer mattress replacements (see Figure 3).

C.4 Constant low pressure devices (either overlays, mattresses or replacement beds) can be grouped according to their construction (foam, foam and air, foam and gel, profiled foam, hammocks, air suspension, water suspension and air-particulate suspension/air-fluidised. These devices fit or mould around the body so that the pressure is dispersed over a large area (see Figure 4).

C.5 Turning beds, such as turning frames, net beds, and turning/tilting beds move those patients, either manually or automatically, who are unable to turn themselves.

D. EVALUATING PRESSURE-RELIEVING INTERVENTIONS

Thirty randomised controlled trials evaluating the effectiveness of pressure-relieving interventions were identified. The studies are generally of poor quality and are often too small to be informative.

D.1 Literature searching methods

Studies were identified by systematic searching of health-related databases and by handsearching pressure sore journals. The strategy used for the identification of relevant research is detailed in Appendix 2.

D.2 Only randomised controlled trials (RCTs) were included because, when well-designed, they provide the most reliable evidence for the efficacy of interventions. Random allocation of patients to treatment and control groups improves the comparability of the groups and so differences in outcomes can be more confidently attributed to a particular treatment, once random error is excluded by significance testing[19].

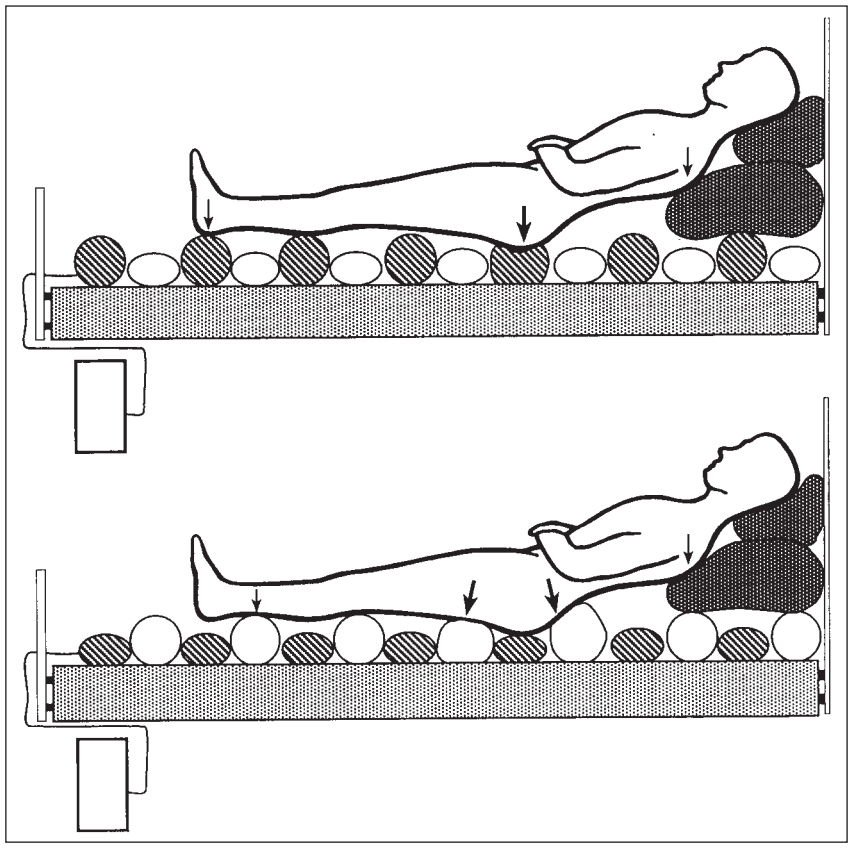

Figure 3 Diagram showing the mechanism of action of alternating pressure devices. Alternate rows of cells inflate and deflate, thus providing a continuous redistruibution of the pressure beneath the patient.

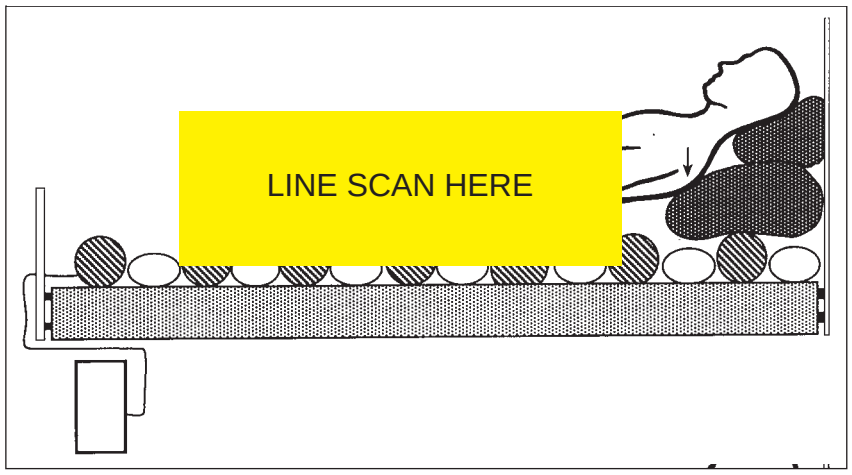

Figure 4 Diagram showing the mechanism of action of constant low pressure devices (such as foam mattresses/overlays, low-air-loss and air-fluidised beds.

D.3 Many evaluations have simply measured the pressure on different parts of the body in contact with the support surface (interface pressure). However interface pressure is an intermediate or surrogate outcome measure which has serious limitations as a proxy for clinical outcome, since the process which leads to the development of a pressure sore almost certainly involves the complex interplay of several factors[24]. Unfortunately, because it is relatively simple, quick and inexpensive to measure, most evaluations only compare interface pressure. This is also true of Department of Health comparative evaluations of mattresses[25]. In this

				RESULTS		
STUDY	**PATIENTS**	**DEVICES (SAMPLE SIZE)**	**FOLLOW-UP PERIOD**	**INCIDENCE OF PRESSURE SORES IN PATIENTS WITHOUT SORES AT ENTRY**	**SEVERITY OF PRESSURE SORES**	**ACCEPTABILITY & RELIABILITY**
Allman et al, 1987[52]	Patients (>18 years) from surgical units with pressure sores, activity expected to be limited to bed/ chair in the hospital	1. Clinitron air-fluidised bed (31) 2. Conventional treatment, including two-hourly turning, heel and elbow protectors, alternating air-mattress plus 19mm foam (34) for at least 1week	13 days (mean)		Median change in total sore surface area: air fluidised, -1.2 vs. conventional treatment, +0.5 (P=0.01). The differences between air-fluidised beds and alternating air mattress were more marked for larger sores (median -5.3 vs +4.0, P=0.01)	Four patients withdrew because of difficulty in transferring in/out of the air fluidised bed
Andersen et al, 1982[30]	Acute patients with high risk of pressure sores (own sore scale) without existing pressure sores.	1. Alternating air mattress (AP) (166) 2. Water-filled mattress (155) 3. Standard mattress (161)	10 days	Grade 2 or greater sores: Alternating mattres: 4.2% (7/166) Water mattress: 4.5% (7/155) Standard mattress: 13.0% (21/161)		AP easily punctures and in this study was not always set at optimun pressure. Water bed is heavy and time-consuming to fill. Patients more statisfied with ordinary bed: complained of the noise and pressure changes of AP
Bliss, 1966[27] & 1967[40]	Geriatric patients with Norton score >6.	**Series I (1963)** 1. Semi-celled ripple bed (50) 2. Foam mattress (48) 3. Regular turning (23) 4. Normal ward care(63) **Series II (1964)** 1. Large-celled ripple bed (42) 2. Small-celled ripple bed (35) 3. Sierex air mattress (39) 4. Ordinary hospital mattress (41)	2 weeks	**Series I (1963)** Trunk sores (grade 2 or greater) Small-celled ripple: 24% (6/25) Foam mattress:39% (9/23) Regular turning: 50% (5/10) Normal ward care: 59% (23/39) Heel sores (including grade 1) Small-celled ripple: 17% (6/35) Foam mattress:18% (6/33) Regular turning: 0% (0/13) Normal ward care: 32% (14/44) **Series II (1964)** Trunk sores (grade 2 or greater) Large-celled ripple: 27% (4/15) Small-celled ripple: 47% (7/15) Sierex air mattress: 17% (2/12) Ordinary matress: 67% (12/18) Heel sores (including grade 1) Large-celled ripple: 7% (2/29) Small-celled ripple: 15% (3/20) Sierex air mattress: 4% (1/23) Ordinary matress: 38% (9/24)	Mean and standard error of pressure sore indices in patients with superficial sores at entry: **Series I (1963)** Small-celled ripple: 18.4 (4.2,n=13) Foam mattress: 22.2 (3.0, n=14) Regular turning: 6.3 (2.2, n=3) Normal ward care: 29.3 (4.0, n=20) **Series II (1964)** Large-celled ripple: 11.7 (1.4, n=20) Small-celled ripple: 15.1 (1.6, n=14) Sierex air mattress: 10.5 (1.4, n=22) Ordinary matress: 29.9 (4.4, n=17)	**Series I (1963):** 3 patients on small-celled ripple bed withdrew because of faulty mattress or because mattress had been repeatedly switched off. **Series II (1964):** 3 patients on large-celled ripple bed and 2 on small-celled ripple bed had to be removed from trial because of mattress breakdown.
Bliss, 1995[37]	Long termelderly patients at risk as shown by superficial skin breaks.	1. Large-celled ripple: (71 2. Suricgoods hollow core (41) 3. Spenco (63) 4. Water mattress (32) 5. Modular Propad (60) 6. Groove prototypes (66) 7. Preventix (25)	17.7 days (mean)		13% of patients on Large Cell Ripple Beds showed deterioration of pressure areas compared with 54% and 51% respectively on fibre fills (Surgicgoods Hollowcare and Spenco), 47% on the water mattress, 37% on Modular Propad, 35% on groove prototypes, 32% on Preventix, (Ripple bed vs fibre fills vs foam overlays,P<0.01)	Supports were frequently used incorrectly, e.g. ripple-bed tubes detatched/kinked or pressure dial wrongly set.
Brown, 1985[28]	Geriatric patients in nursing homes, Norton score <14	All received standard care: 1. Small shifts in body position (8) 2. Control (6)	2 weeks	No patient developed pressure sore in the 'small shift' group; one developed a sore in the control group.		Positive reactions of the nursing staff to the assessment guide and small shifts of body positions were reported.
Caley et al, 1994[51]	Acute care patients with exisitng pressure ulcers for whom low-air-loss therapy had been recommended by their physiucian or nurse.	1. Low-air-loss bed (23) 2. Low-air-loss overlay (32)	24 days (mean)		There was no significant difference in the change in ulcer size between subjects in the two groups. Low-air -loss overlays may be as effective as low-air-loss beds and are much cheaper.	Staff satisfaction was similar for both products.
Conine et al, 1990[42]	Non-geriatric adult patients in an extended care facility for chronic neurological conditions, Norton score ≤14.	1. Alternating air overlay (72) 2. Silicore (Spenco) overlay (76)	3 months	Included grade I sores: Alternating air overlay:54% (39/72) Spenco overlay: 59% (45/76)	The alternating air overlay group had a slightly lower than average 'Exton-Smith severity score' (1.59 vs 1.69); a shorter than average healing duration (25 days), not statistically significant.	Alternating air overlay needed frequent monitoring and expensive, prolonged repairs. It was reported that the patients sank into the Spenco overlay and found it difficult to move. Patients complained of bad colour build-up, instability (especially Spenco), and noise of the alternating pressure motor. High dropout rate due to discomfort.

				RESULTS		
STUDY	**PATIENTS**	**DEVICES (SAMPLE SIZE)**	**FOLLOW-UP PERIOD**	**INCIDENCE OF PRESSURE SORES IN PATIENTS WITHOUT SORES AT ENTRY**	**SEVERITY OF PRESSURE SORES**	**ACCEPTABILITY & RELIABILITY**
Daechsel & Conine, 1985[43]	Patients in a long-term care hospital for chronic neurological conditions, 19-60 years of age, at high risk of developing pressure sores.	1. Alternating air overlay (16) 2. Silicore (Spenco) overlay (16)	3 months	Included grade I sores: Alternating overlay: 25% (4/16) Spenco overlay: 25% (4/16)	No statistically significant differences were found between the two groups with regard to location and severity of pressure sores.	Patients' satisfaction was similar for both devices.
Devine 1995[48]	Patients in a geriatric unit with pressure sores (grade 2 or above).	1. Alternating air mattress (Nimbus 1) (22) 2. Alternating air mattress (Pegasus Airwave) (19)	4 weeks		11 patients died or moved to other hospitals. Thje rate of complete healing was higher for the Nimbus mattress but not statistically significant (10/16 vs 5/14). The reduction in size of pressure sores was similar in two groups.	Neither Pegasus Airwave or Nimbus I mattresses showed any significant breakdown. No significant difference in patients/staff acceptability.
Econo-mides et al, 1995[55]	12 patients who had stage 4 pressure sores needing myocutaneous flap closure.	1. Roho dry floataion mattress (6) 2. Air-fluidised Clinitron bed (6)	2 weeks		Wound breakdown:2/6 on Robo vs 2/5 on Clinitron. No significant difference between two support surfaces in the prevention of flap breakdown in the immediate post-operative period.	
Ewing, 1964[31]	Patients in the geriatric unit of a convalescent hospital.	1. The sheepskins were adjusted so that both legs were supported on the wooly fleece (18) 2. Control, without sheepskins (18) All were submitted to the same 4-hourly routine skin care.	6 months		The study was too small and poorly designed to detect a difference.	
Exton -Smith, et al, 1982[47]	Newly-admitted geriatric patients, patients with fractured neck of femur, and long-stay patients; without pressure sores of grade 2 or greater. Norton score ≤14.	1. Pegasus Airwave system (31) 2. Large Cell Ripple mattress (31)	2 weeks	Grade 2 or greater Airwave (AWS): 16.1% (5/31) Large Cell Ripple (LCR): 38.7% (12/31)	Superfical or deep sores (grade 3-4) developed in 38.7% of the LCR patients and only 6.5% of AWS patients.	During the trial period, no breakdowns with AWS, 10 breakdowns on LCR.
Ferrell et al, 1993[49]	Elderly nursing home residents with multiple medical problems, and with trunk or trochanter pressure ulcers (Shea stage 2 or greater).	1. Low-air-loss bed (43) 2. Convoluted foam mattress (41)	33-40 days		Decrease in size of ulcers was 9.0mm²/day for low- air-loss beds compared with 2.5mm²/day for foam mattress (P=0.0002). 26 (60%) completely healed on low-air-loss-loss vs 19 (46%) on foam mattress (P=0.19). Number of patients died: 11 (26%) on low-air-loss vs 7 on foam mattress.	
Gebhardt et al, 1995[41]	Newly-admitted patients (>18 years in intensive care units (ICU). With Norton sores <13 and without exisitng pressure sores.	1. Alternating pressure air mattress (23) 2. Constant low pressure (foam, fibrefill, air, water, gel) supports.	Mean 11 days	Grade 2 or greater sore: Alternating pressure: 0% (0/23) Constant low pressure: 40% (8/20)		Mechanical unreliability and poor management of alternating pressure supports was a problem.
Gentilello et al, 1988[57]	Critically ill patients immobolized because of head injury or traction.	1. Kinetic Treatment Table (27) 2. Conventional beds (38)	?	Kinetic Treatment Table 29.6% Conventional: 26.3%		
Gold-stone et al, 1992[32]	Patients (>60 years with femur fracture. (Mean Norton score 13).	1. Beaufort (32) 2. Standard supports (43)	?	Grading of sores was not given. Beaufort bed: 15.6% Standard surface: 48.8%	Maximum width of broken skin (mean): 6.4 mm on Beaufort beds vs. 29.5 mm on standard surfaces.	Patients were removed from Beaufort bed due to unknown reasons.
Gray & Campbell 1994[33]	Patients from orthopaedic trauma, vascular and medical oncology units without breaks in the skin (Waterlow score ≥15)	1. Softform matress (90) 2. Standard NHS matress (80)	10 days	Grade 2 or greater sore: Softform: 7% Standard: 34%	Rate of transfer to dynamic support surface: 19% in standard group vs. 2% in Softform group.	Nurses were more positive and patients gave higher comfort scores to Softform mattress.

				RESULTS		
STUDY	**PATIENTS**	**DEVICES (SAMPLE SIZE)**	**FOLLOW-UP PERIOD**	**INCIDENCE OF PRESSURE SORES IN PATIENTS WITHOUT SORES AT ENTRY**	**SEVERITY OF PRESSURE SORES**	**ACCEPTABILITY & RELIABILITY**
Hofman et al, 1994[34]	Patients with a femoral-neck fracture and risk score ≥ 18 (Dutch consensus scale). Excluded patients with pressure sores of grade 2 or greater on admission.	1. Comfortex DeCube mattress (21) 2. Standard hospital mattress (23)	2 weeks	Grade 2 or greater sores: Comfortex DeCube: 24% (4/17) Standard: 68% 913/19)	Maximum pressure sore gradings were significantly higher for the standard mattress than the DeCube mattress at 1 and 2 weeks.	DeCube mattress was not always used correctly and its size was not optimum for all patients.
Inman et al, 1993[50]	Patients (>17) with an Acute Physiology and Chronic Health Evaluation (APACHE II) score greater than 15 who had an exp[ected intensive care unit stay of ≥3 days.	1. Low-air-loss beds (49) 2. Standard ICU bed (49)	17 days (mean)	Grade 2 or greater sores: Low-air-loss beds: 12% Standard ICU bed: 51%	Patients with multiple pressure sores: 2% on low-air-loss beds and 24% on standard ICU bed.	
Kemp et al, 1993[36]	Geriatric patients (>65 years) without pressure ulcers, Braden score ≤16.	1. Convoluted foam overlay (45) 2. Solid foam overlay (39)	1 month or discharge	Included grade I sores. Convoluted foam overlay: 46.7% Solid foam overlay: 30.8%		
Lazzara & Buschmann, 1991[39]	Elderly private nursing home residents (Norton score ≤15).	1. Air overlay (33) 2. Gel mattress (33)	6 months	Grade 2 or greater sores: Air overlay: 16.1% (5/31) Gel mattress: 15.4% (4/26)	All pressure sores of grade 1 or 2.	It was difficult to maintain inflation of the air overlay; it also punctured easily. During the trial , 110 air overlays were used for 76 patients. Gel mattress was heavy.
Lim et al, 1988[38]	Residents of an extended-care facility (>60 years), using a wheelchair for 3 or more hours daily, at high risk of developing pressure sores (Norton Score (≤14).	1. Polyurethane foam wheelchair cushions in slab form (33) 2. Customized contoured foam wheelchair cushions.(29)	5 months	Included grade I sores. Slab foam: 73.1% (19/26) Contoured foam: 69.2% (18/26)	Mean severity score was 1.9 in the slab and 1.7 in the contoured (P>0.05), and the mean healing duration was 6.2 weeks in the slab and 5.4 weeks in the contoured group (P>0.05).	
Munro et al, 1989[53]	Patients with pressure sores of grade 2-3 who were expected to remain in the hospital for at least 15 days. Excluded: patients with grade 4 ulcers and those weighing >250lb or who were malnourished.	1. Clinitron air-fluidised bed (20) 2. Standard bed plus usual nursing measures such as sheepskin or gel pads placed beneath pressure areas (20).	15 days		Mean size of ulcers was reduced in the Clinitron group, and increased in 'standard bed' group (P=0.05). Pressure sore healing was enhanced on the Clinitron bed; fewer medications were used to treat the sores in the Clinitron group than in the 'standard hospital bed' group.	The air-fluidised group rated their satisfaction higher than the control group (P=0.067).
Santy et al, 1994[35]	Patients (>55 years) with hip fracture with or without pressure sores. Excluded: those with a pressure sore of grade 3 or 4 at entry.	1. Clinifloat (87) 2. NHS contract (150mm) (64) 3. Vaperm (116) 4. Theraest (136) 5. Transfoam (102)	14 days	Rates of removal from study due to skin deterioration: Clinifloat 9.19% NHS contract 26.56% Transfoam 10.29% Theraest 10.78% Vaperm 7.75%		Omnifoam mattress showed foam collapse after six weeks; and were withdrawn from use, and replaced with Vaperm mattresses. Problems with mattress cover found on two Theraset mattresses, three Transfoam mattress covers, and three times with the Clinfloat mattress
Sideranko et al, 1992[46]	Adult, surgical intensive care unit patients: SICU stay >48 hr, without existing skin breakdown on admission.	1. Alternating air mattress (20) 2. Static air mattress (20) 3. Water mattress (17)	9.4 days	Grade sores not reported. Alternating air mattress: 25% (5/20) Static air mattress: 5% (1/10) Water mattress: 12% (2/17)		
Stapleton 1986[44]	Female elderly patients with fractured neck of femur without existing pressure sores, Norton score ≤14.	1. Large Cell Ripple (32) 2. Polyether foam pad(34) 3. Spenco pad (34)	?	Sores of Grade 2 or greater. Large Cell Ripple: 34% (11/23) Polyether foam pad: 41% (14/34) Spenco pad: 35% (12/34)	Grade 3 and greater: Large Cell Ripple:0%; Foam pad: 23.5%; PSpenco pad: 5.9%	45 Large Cell Ripple mattresses required 50 motor repairs and 90 material repairs during 12 month study. Patients did not like the feel of the ripples.

				RESULTS		
STUDY	**PATIENTS**	**DEVICES (SAMPLE SIZE)**	**FOLLOW-UP PERIOD**	**INCIDENCE OF PRESSURE SORES IN PATIENTS WITHOUT SORES AT ENTRY**	**SEVERITY OF PRESSURE SORES**	**ACCEPTABILITY & RELIABILITY**
Strauss et al, 1991[54]	Patients (>16 years) at home with grade 3-4 pressure sores, Norton score ≤14.	1. Clinitron air-fluidised beds (47) 2. Conventional care including alternating pressure pads (50)	36 weeks		A higher proportion of air-fluidised bed patients was classified as improved (P>0.05; not reliable since considerable missing data). Air-fluidised bed patients had significantly fewer pressure-sore-related hospitalizations per patient (0.23 vs 0.58, P<0.05). Note: Withdrawal rate: 50% on AF vs 44% on control bed. Number of deaths: 24% vs 35%. Blinded assessment.	Six AF beds had minor bead leaks and seven overheated. Several patients noted dry skin and one experienced mild dehydration.
Smith & Malone, 1990[29]	Geriatric patients, Norton score <14. 2. Control (10)	All were turned every two hours: 1. small unscheduled shifts of position (9)	2 weeks	One patient devloped a pressure sore in each of the two groups.	There were three patients in the 'small shift' group and one in the control group with pressure sores at entry. the size of the pressure sores was reduced in two patients in the 'small shift' group and one in the control group. The size of sore in the other patient in the shift group did not change.	
Summer et al, 1989[58]	Patients admitted to the Intensive Care Unit.	1. Kinetic Treatment Table (43) 2. Routine turning on conventional beds (43)	?	1 patient developed small facial ulcer on Kinetic Treatment Table; none on conventional beds.		
Whitney et al, 1984[48]	Patients on medical-surgical units who were in bed for ≥ 20 hours daily. Most patients had relatively little skin breakdown.	1. Alternating pressure mattress (25) 2. Convoluted foam pad (Eggcrate) (26) In both groups patients were turned every two hours	8 days		Changes in skin condition did not differ significantly between patients using the alternating pressure air mattress and the foam mattress (better: 20% vs 19.2%; same: 60% vs 57.7%; worse: 20% vs 23.1%).	Alternating pressure mattress: pump maintenence was costly, patients objected to the movement. The alternating mattress was more easily cleaned and retained its original properties over several weeks compared to the foam which compressed and flattend.

Table 3: Randomised controlled trials of pressure revieving interventions for the prevention and treatment of pressure sores.

bulletin we have only considered trials which report clinical outcome measures.

D4 Some studies, when reporting outcomes of interventions for prevention, did not differentiate between those developing grade 1 sores and those developing more severe sores. Studies which compared the incidence of pressure sores of grade 2 or greater are more likely to be reliable.

D.5 In trials evaluating the treatment of existing sores, changes in the size (or severity) of sores are usually measured. The methods used include direct measurement of length, width, and depth; tracing of the ulcer outline onto transparent material; standard photography; volume measurement and subjective appraisal of improvement or deterioration.

D.6 Methodological quality.

The methodological quality of each trial was assessed by two researchers independently. Thirty relevant randomised clinical trials were identified (see Table 3). Sixteen trials involved high risk patients without pre-existing pressure sores (intact skin) to assess the effectiveness of pressure-relieving interventions in the prevention of pressure sores. Eight trials involved patients with pressure sores, to assess treatment efficacy of pressure-relieving supports and six trials involved a mixture of patients with and without pre-existing sores.

D.7 A summary of the methodological quality of each of the trials is shown in Table 4. Methodological rigour in randomised controlled trials is essential in order to eliminate bias. Though the majority (90%) of trials discussed the criteria for including patients, only one third of the reports gave information that makes us confident that patients were truly randomly allocated[26].

D8 Synthesizing the evidence.

The review has identified a large range of devices tested on a variety of patients and care settings, therefore a quantitative pooling of the studies is impossible. A narrative description of study findings is provided to give an overall picture of the effectiveness of pressure relieving devices in the prevention and treatment of pressure sores.

TRAIL	CLEAR INCLUSION & EXCLUSION CRITERIA	SAMPLE SIZE Total number (arms)	A PRIORI SAMPLE SIZE CALCULATION?	TRUE RANDOMISATION WITH ALLOCATION CONCEALMENT	BASELINE COMPARABILITY OF TREATMENT GROUPS	BLINDED OUTCOME ASSESSMENT	GRADE I SORES EXCLUDED OR PRESENTED SEPARATELY	ARE THE MAIN INTERVENTIONS WELL-DESCRIBED?	IS THERE ADEQUATE DESCRIPTION OF ASSOCIATED CARE?	APPROPRIATE OUTCOME MEASURES USED?	WITHDRAWALS REPORTED BY TREATMENT GROUP WITH REASONS
Allan et al,1987[52]	✓	65 (2)	✓	✓	✓	✓	✓	✓	✓	✓	✓
Anderson et al,1982[30]	✓	482(3)	✓	×	✓	×	✓	×	✓	×	✓
Bliss et al,1966[27]	✓	341(6)	×	×	✓	✓	✓	✓	✓	✓	✓
Bliss,1995[37]	✓	358(7)	×	×	✓	×	✓	✓	✓	×	✓
Brown et al,1985[28]	✓	15(2)	×	×	×	×	×	✓	×	×	×
Caley et al,1994[51]	×	55(2)	×	×	×	×	×	✓	×	×	×
Conine et al,1990[42]	✓	187(2)	×	×	✓	✓	✓	×	✓	✓	✓
Daechsel & Conine,1985[43]	✓	32 (2)	×	×	✓	×	×	✓	✓	✓	✓
Devine,1995[48]	✓	41 (2)	×	✓	✓	×	✓	✓	✓	×	✓
Economides et al,1995[55]	✓	12 (2)	×	✓	✓	×	✓	✓	×	✓	✓
Ewing et al,1964[31]	×	30 (2)	×	×	×	×	×	✓	✓	×	×
Exton-Smith et al,1987[52]	✓	66 (2)	×	×	✓	×	✓	✓	×	✓	×
Ferrell et al,1993[49]	✓	84(2)	✓	✓	✓	×	✓	✓	✓	✓	✓
Gebhardt et al,in press[41]	✓	43(2)	✓	×	✓	×	✓	✓	×	✓	✓
Gentilello et al,1988[57]	✓	65 (2)	×	✓	✓	×	×	✓	✓	×	✓
Goldstone et al,1982[32]	✓	75 (2)	×	×	✓	×	×	✓	×	×	×
Gray & Campbell,1994[33]	✓	170 (2)	×	✓	✓	×	✓	✓	×	×	×
Hofman et al,1994[34]	✓	44 (2)	✓	×	✓	×	✓	✓	×	✓	✓
Inman et al,1993[50]	✓	100 (2)	✓	×	✓	×	✓	×	✓	✓	✓
Kemp et al,1993[36]	✓	84 (2)	×	✓	✓	✓	×	×	✓	✓	×
Lazzara & Buschnann, 1987[52]	✓	74 (2)	×	✓	×	×	✓	×	×	×	×
Lim et al,1988[38]	✓	62 (2)	×	×	✓	✓	✓	✓	✓	✓	✓
Munro et al,1989[53]	✓	40 (2)	×	×	×	×	✓	✓	×	✓	×
Santy et al,1994[35]	✓	505 (5)	✓	✓	✓	×	×	✓	×	×	✓
Sideranko et al,1992[46]	✓	57 (3)	×	×	✓	×	×	×	✓	×	×
Smith & Malone,1990[29]	✓	19 (2)	×	×	✓	×	×	✓	✓	×	×
Stapleton,1986[44]	✓	100 (3)	×	×	×	×	✓	×	✓	✓	×
Strauss et al,1991[54]	✓	112 (2)	×	×	✓	✓	✓	×	×	×	✓
Summer et al,1989[58]	✓	86 (2)	×	✓	✓	×	×	✓	✓	×	×
Whitney et al,1984[45]	×	51 (2)	×	×	×	×	×	×	✓	×	×

* in this trial patients may have experienced more than one intervention, and may be counted in the sample size more than once.

Table 4: Quantity of randomised controlled trials of pressure sore prevention & treatment

E. THE EFFECTIVENESS OF PRESSURE RELIEVING INTERVENTIONS

The effectiveness of different schedules of manual repositioning has not been adequately studied. The standard hospital mattress is less effective at preventing sores than some low pressure foam mattresses. There is some evidence which suggests that large-celled alternating pressure mattresses and certain low-air loss and air-fluidised beds are more effective than foam and silicore-based surfaces in preventing and healing sores. However, there is no evidence as to which of these technologies is the most cost-effective, and under which circumstances.

E.1 Several studies assess the effectiveness of pressure relieving interventions for both the prevention and treatment of pressure sores. The results are summarized according to the type of devices tested. The implications for prevention and treatment are considered separately in the conclusions.

Manual Repositioning

E.2 Manual repositioning, usually achieved by turning patients from side to side, is an established means of preventing pressure sores. At first sight it might appear to be the cheapest technique, however consideration must be given to the cost in terms of staff time and the risk to staff and carers' backs. There is little research demonstrating the effectiveness of manual repositioning and it is unclear what the optimum frequency of repositioning is. Two-hourly changes of position are often recommended but alternatives have not been evaluated. Only one small RCT has evaluated routine manual repositioning compared with the normal ward regime, however only 10 patients actually received regular repositioning, and a regular turning regime was found difficult to implement[27]. Two RCTs have evaluated unscheduled turning[28,29], however in both studies the incidence of pressure sores was extremely low, sample sizes were small and no significant difference was detectable between experimental and control groups. Little is known of the need for manual repositioning when patients are using any of the pressure-relieving surfaces discussed below.

`Low-tech' constant pressure supports

E.3 ***Trials of the standard hospital mattress***

This section considers comparisons of the standard foam hospital mattress with other low-technology, constant pressure supports. Six RCTs comparing 'standard' mattresses/surfaces with low-tech supports for the prevention of pressures sores were identified[30-35]. When compared with standard hospital mattresses, the incidence and severity of pressure sores in `high risk' patients were reduced when patients were put on either the Comfortex DeCube mattress[34], the Beaufort bead bed[32], the Softform mattress[33], or the water-filled mattress[30]. In a recent, unpublished British study of older people with hip fractures admitted to orthopaedic trauma wards, patients allocated to receive a NHS standard foam mattress (manufactured by Relyon) experienced over three times the rate of pressure sores as those using one of a number of foam alternatives (Clinifloat, Therarest, Transfoam and Vaperm - see Table 1)[35]. There was insufficient power to distinguish between the low pressure foam mattresses. These alternatives to the cheaper standard hospital mattress may be cost-effective if their durability is adequate.

E.4 A small trial of the standard hospital mattress with and without sheepskin overlays was inconclusive and of poor quality[31].

E.5 Comparisons between `low-tech' alternative mattresses

Older patients allocated to a convoluted foam overlay had a lower rate of pressure sores than those on a solid foam overlay, however the difference was not statistically significant[36].

E.6 Bliss[37] reported that fewer pressure sores deteriorated in patients on contoured foam overlays than on fibre-filled overlays.

E.7 In the only RCT identified which evaluated wheelchair cushions for pressure sore prevention, polyurethane foam cushions in slab form were compared with a customized contoured foam[38]. After 5 months of follow up, there were no significant differences in the incidence, location, severity, or healing time of the sores that developed.

E.8 Similar rates of pressure sores were found in patients on an air-filled overlay compared with a gel mattress in elderly nursing home residents[39].

`High-tech' pressure relief

E.9 ***Alternating pressure supports.***

A variety of alternating pressure air supports are used in hospital and in the community (see example in Figure 3). The depth of the air-cells and the mechanical robustness vary between devices and these factors may be important in determining effectiveness. Eleven RCTs were identified, within which there are thirteen comparisons between alternating pressure and standard hospital mattresses (in two studies); constant low pressure devices (in eight studies); and with other alternating pressure supports (in three studies).

E.10 ***Alternating pressure compared with standard hospital mattress.***

Two RCTs showed that the use of alternating pressure surfaces reduces the incidence of pressure sores as compared with standard hospital mattresses[27,40,30] (Table 3).

E.11 ***Alternating pressure compared with constant low pressure.***

A number of studies have compared alternating pressure devices with constant low pressure, however there is conflicting evidence as to their relative effectiveness. Two studies from the same research group concluded that alternating pressure is more effective. Bliss compared an alternating pressure mattress (the Large Cell Ripple) with similarly-priced constant low pressure supports (Surgicgoods Hollowcore Mattress Pad, Spenco, Ardo Watersoft mattress, Modular Propad, a groove prototype, and the Preventix) in long-stay elderly patients[37]. The incidence of pressure sores on the alternating pressure mattress was approximately one-third of that found on the constant low pressure devices, however there were a number of weaknesses in the study design and outcome measurement (see Table 4). Gebhardt and colleagues[41] reported that eight of the twenty patients allocated to a variety of low pressure supports developed grade II or greater pressure sores, compared with none of the twenty three patients in the alternating pressure group.

E.12 In contrast, six small RCTs comparing different types of alternating pressure supports and a variety of constant low pressure devices such as the Spenco (silicore) overlay[42-44]; a water mattress[30]; a polyurethane convoluted foam pad45, a static air mattress and a water mattress[46] showed no difference in effectiveness.

E.13 ***Comparisons between different alternating pressure devices.***

Alternating pressure devices differ somewhat in structure, including the size of the inflatable air cells. One early study of pressure sore prevention found large-celled alternating pressure mattresses (15cm diameter) were more effective than those with small-cells (3.8cm diameter).

E.14 A second study of prevention[47] compared two large-celled alternating pressure devices (Pegasus Airwave and the Large Cell Ripple - similar except the Airwave has two layers of cells). The authors reported that the Airwave System is significantly more effective than the Large Cell Ripple in preventing and reducing severity of pressure sores in a high risk group of elderly patients. However, the allocation was not truly random, and an intention-to-treat analysis would not have shown a statistically significant difference in the rate of pressure sores (16% vs 34%, P>0.05).

E.15 One small RCT compared the effectiveness of the Nimbus I DFS (composed of rows of figure-of-eight-shaped cells) and the Pegasus Airwave for the treatment of existing pressure sores but found no significant difference[48].

E.16 It is difficult to interpret these studies because different (often poorly described) types of alternating pressure supports were used in the trials. The breakdown rates of these alternating pressure supports were often high, making it difficult to disentangle the impact of efficacy and reliability on effectiveness.

E.17 ***Low-air-loss beds***

There are two trials comparing low-air-loss with low-tech foam alternatives[49,50] and one comparing a low-air-loss bed with a low-air-loss overlay[51]. One trial showed that low-air-loss beds were more cost-effective at decreasing the incidence of pressure sores in critically ill patients than a standard (but poorly described) ICU bed[50]. The other study showed the low-air-loss bed was better at treating pressure sores than a corrugated foam overlay[49].

E.18 Only one trial has compared different types of low-air-loss support surfaces51. This showed no significant differences but was too small and was of questionable quality (see Table 4).

E.19 ***Air-fluidised beds***

Air-fluidised beds are another type of `high-tech' pressure relief system, comprising a deep bed of ceramic beads through which warmed air is circulated. Four RCTs have evaluated the use of air-fluidised beds in the treatment of people with existing pressure sores compared with a range of "conventional therapies". Two studies showed enhanced healing associated with air-fluidised beds used in hospital[52,53]. A home-based study showed no statistically significant difference[54]. One small trial in patients after plastic surgical repair of pressure sores, showed no difference between an air-fluidised bed and the Roho dry flotation mattress[55].

Turning beds (kinetic therapy)

E.20 Turning beds contain motors which constantly turn and tilt the patient, and are used in critical care settings primarily to prevent pneumonia and atelectasis. Four RCTs were identified in a meta-analysis of kinetic therapy56. Only two of the trials were obtainable[57,58]. Sample sizes in all the trials was small, and no beneficial effect of kinetic therapy on pressure sore incidence was detected.

E.21 No RCTs evaluating other forms of pressure-relieving equipment, such as special operating theatre tables, were identified.

Summary of effectiveness of pressure relieving supports

E.22 The clearest conclusion one can draw is that the standard hospital mattress is outperformed by a range of foam-based, low pressure mattresses and overlays, and also by `higher-tech' pressure-relieving beds and mattresses, both in the prevention and treatment of pressure sores.

E.23 Some types of large-cell alternating pressure devices (cell diameter 10cm or greater) may be more effective than simple, low-pressure mattresses but further research is needed.

E.24 It appears that low-air-loss beds are effective in preventing and treating pressure sores compared with foam mattresses, but there are no studies comparing low-air-loss therapy with alternating pressure surfaces and other `high tech' low pressure supports.

E.25 There is no evidence to indicate the degree to which manual repositioning is effective, or what would be an optimum turning regime. Little is known about the degree to which manual repositioning of patients on pressure-relieving surfaces provides additional benefit.

F. ADVICE TO COMMISSIONERS AND PROVIDERS OF SERVICES AND RESEARCH

Most of the equipment available for the prevention and treatment of pressure sores has not been reliably evaluated, and no `best buy' can be recommended. Patients at raised risk should be provided either with an evaluated low pressure foam mattress, or if at higher risk, with a large-celled alternating pressure mattress or a proven low-air loss or air-fluidised bed. However there is insufficient research evidence on clinical- or cost-effectiveness to guide equipment choice. A co-ordinated programme of randomised controlled trials could provide decision-makers with reliable evidence on the relative cost-effectiveness of different interventions and strategies within a relatively short time.

F.1 There are many expensive, `high-tech' pressure-relieving devices in use (see Table 1), however there is insufficient evidence to identify the best-buy. Therefore, investment in the more expensive, `high-tech' pressure-relieving equipment should only take place within the context of randomised controlled trials.

F.2 Patients at raised risk of developing pressure sores should at least be placed on one of the foam mattress alternatives shown to be better than the standard hospital mattress (eg. Comfortex DeCube, Softform, Clinifloat, Vaperm, Transfoam, Therarest).

F.3 In the absence of clear evidence for the optimal strategy, patients at very high risk of developing sores (such as those in intensive care, orthopaedic units or with neurological deficits) and people with established sores, should probably be placed on alternating pressure mattresses with large cells, or one of the other devices shown to be effective in RCTs in such patients (eg. Clinitron, KinAir).

F.4 The effectiveness of pressure-relieving equipment is undermined if high-risk patients sit out in ordinary hospital chairs for long periods of time.

F.5 Given current knowledge, the most cost-effective strategies for meeting prevalence targets are unclear.

F.6 Measures of the incidence of pressure sores may only be used to compare the quality of care over time and between units if they are adjusted for patients' risk of developing pressure sores. The prevalence of pressure sores should not be used as a measure of quality because it is affected by so many factors unrelated to the quality of care (Appendix 1).

F.7 Whenever a pressure sore occurs, thought should be given as to whether and how it could have been avoided, for example was a patient obviously at high risk not provided with a suitable pressure-relieving intervention?

F.8 Since equipment sometimes deteriorates or breaks down, all pressure-relieving equipment should be regularly checked and maintained in good working order, and staff should be properly trained in its use.

F.9 Guidelines for the prevention and management of pressure sores may be useful to improve the cost-effectiveness of care, but they must be based on rigorous, comprehensive, systematic reviews of the research evidence and kept up-to-date[59].

F.10 Rather than the supply and evaluation of beds being determined principally by the manufacturers, the NHS might wish to consider commissioning the development and evaluation of a bed which is cost-effective, durable, reliable and acceptable to patients and staff.

F.11 Independent, well-designed, multi-centre RCTs need to be carried out in order to compare the cost-effectiveness of different types of pressure-relieving devices for patients at different levels of risk in a variety of settings. In particular, this research should aim to compare (i) alternating pressure devices with other `high-tech' equipment (such as low-air-loss and air fluidised) and (ii) alternating pressure devices with lower tech' alternatives (such as

different types of foam mattresses). Patients must be truly randomised (with concealed allocation), trials should be of sufficient size, have clear criteria for measuring outcomes which should be assessed without knowledge of the intervention received (blinded). The studies should also have adequate follow-up and appropriate statistical analysis.

F.12 Given better evidence of the relative cost-effectiveness of different interventions, research will also be needed to compare the cost-effectiveness of alternative strategies for the prevention and treatment of pressure sores in hospital and community.

F.13 If interventions are to be targeted on patients at highest risk, or if the incidence of pressure sores between units is to be compared, then methods of accurately grading and adjusting for the risk of patients will be needed.

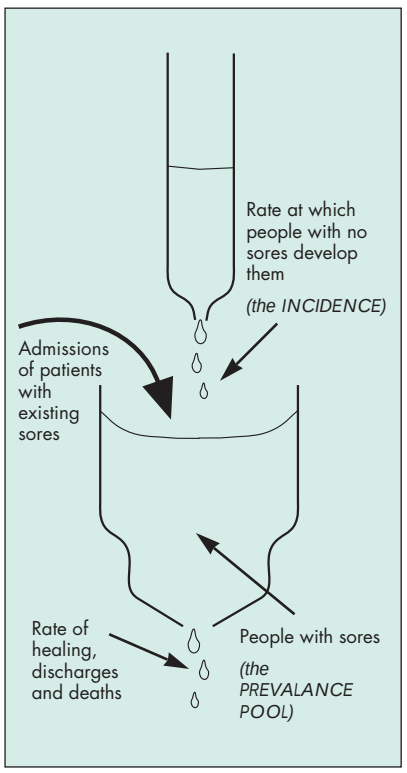

Figure 5 Relationship between the incidence and prevalance of pressure sores.

APPENDIX 1

Using the frequency of pressure sores as a measure of quality of care.

Since pressure sores are common, relatively easily measured and often avoidable, their frequency on a hospital ward/unit is often seen as a convenient measure for comparing quality of care3. Targets have also been set for reducing the frequency of pressure sores5.

There are two ways of measuring pressure sore frequency - incidence and prevalence. The incidence rate measures the rate at which people admitted without a sore develop one during a specific period of time. The prevalence rate on the other hand simply describes the number of people on the ward who have a pressure sore at a given point in time.

The relationship between the two is shown in Figure 5. Incidence is determined by the type of patients admitted (those at high risk have a high incidence), and the effectiveness of the preventive care administered.

The prevalence rate is affected by the rate of new sores (incident cases plus people admitted with a sore) and the rate at which people with sores leave the ward (deaths and discharges) or are successfully treated.

Comparison of incidence rates over time, or between units, will only accurately compare the effectiveness of prevention policies if suitable adjustment is made for differences in the risk of developing a sore in the patients admitted.

Comparisons between units' prevalence rates, because they are affected by incidence rates, healing rates, admission and discharge policies, are very difficult to interpret.

APPENDIX 2

Searching strategy

MEDLINE was searched from 1966 to February 1995 by using the MESH term DECUBITUS (which covers bedsores, pressure sores and pressure ulcers) combined with text words bedsores, pressure sores, pressure ulcers, decubitus, and the names of known assessment scales. A similar search was undertaken in CINAHL. The search was limited to English language articles and human studies.

The Surgical Materials Testing Laboratory Database (part of the Wound Management Research Centre, Wales) was searched using the key words 'pressure' or 'decubitus', 'trial' and 'study'.

The following journals were handsearched: *Decubitus, Advances in the Treatment and Management of Wound Care, CARE - Science and Practice, Journal of Tissue Viability, Journal of Wound Care.* The developing database of the Cochrane Wounds Group was searched to locate randomised controlled trials. The reference lists of relevant publications were checked. Researchers in the field were asked about further studies of interventions and risk scales.

REFERENCES

1 Clark M, Watts S. The incidence of pressure sores within a National Health Service Trust Hospital during 1991. Journal of Advanced Nursing 1994; 20, 33-36.
2 Touche Ross & Co. The costs of pressure sores. Report to the Department of Health, 1993.
3 Department of Health. Pressure sores: a key quality indicator. London: Department of Health. 1993.
4 NHS Executive. Pressure sores - a preventable problem. VFM Update No. 12, 1994.
5 NHS Management Executive. Priorities and Planning Guidance 1994 - 95. Leeds: Department of Health. (EL (93) 54).
6 Clark M, Cullum N. Matching patient need for pressure sore prevention with the supply of pressure redistributing mattresses. Journal of Advanced Nursing 1992; 17, 310-316.
7 Flanagan M. Predicting pressure sore risk: a guide to the risk factors identified in the most common pressure sore risk assessment scales in use. Journal of Wound Care 1993; 2(4): 215-218.
8 Norton D, McLaren R, Exton-Smith AN. An investigation of geriatric nursing problems in hospitals. London : National Corporation for the Care of Old People. 1962.
9 Bergstrom N, Braden B. A prospective study of pressure sore risk among institutional elderly. Journal of the American Geriatrics Society 1992; 40(8):747-58.
10 Waterlow J. The Waterlow card for the prevention and management of pressure sores: towards a pocket policy. CARE - Science and Practice 1988; 6: 8-12.
11 Williams C. A comparative study of pressure sore prevention scores. Journal of Tissue Viability 1992; 2: 64-66.
12 Lowthian P. Identifying and protecting patients who may get pressure sores. Nursing Times 1989; 4, 26-29.
13 Towey AP, Erland SM. Validity and Reliability of an assessment tool for pressure ulcer risk. Decubitus 1988; 1: 40-48.
14 Gosnell DJ. An assessment tool to identify pressure sores. Nursing Research 1973; 22: 55-59.
15 Pritchard V. Calculating the risk. Nursing Times 1986; 82:(59): 61.
16 Kemp MG, Keithley JK, Smith DW, Morreale B. Factors that contribute to pressure sores in surgical patients. Research in Nursing and Health 1990; 13: 293-301.
17 Braden BJ, Bergstrom N. Predictive validity of the Braden scale for pressure risk in a nursing home population. Research in Nursing and Health 1994; 17: 459-470.
18 Hergenroeder P, Mosher C, Sevo D. Pressure ulcer risk assessment- simple or complex? Decubitus 1992; 5: 47-52.
19 Sackett DL, Haynes RB, Guyatt GH, Tugwell P. Clinical epidemiology: a basic science for clinical medicine. Boston: Little Brown & Co, 1991.
20 Jones R. Scoring the risk scores [letter]. Journal of Tissue Viability 1994; 4 (2):65-67.
21 Clark M, Farrar S. Comparison of pressure sore risk calculators. In: Harding KG, Leaper DL, Tuner TD (eds) Proceedings of the 1st European Conference on Advances in Wound Management 1992, Macmillan: London.
22 Smith I. Waterlow/Norton scoring system: a ward view. CARE - Science and Practice 1989; 7 (4); 93-95.
23 Bliss MR, Thomas JM. Clinical trials with budgetary implications: establishing randomised trials of pressure-relieving aids. Professional Nurse, February 1993; 292-296.
24 Clark M. Problems associated with the measurement of interface (or contact) pressure. Journal of Tissue Viability 1994;4:37-42.
25 Medical Devices Directorate: Foam Mattresses. Evaluation PS1 August 1993 p1-24.
26 Shultz KF, Chalmers I, Haynes RJ, Altman DG. Empirical evidence of bias: dimensions of methodological quality associated with estimates of treatment effects in controlled trials. Journal of the American Medical Association 1995; 273:408-12.
27 Bliss MR, McLaren R, Exton-Smith AN. Mattresses for preventing pressure sores in geriatric patients. Medical Bulletin of the Ministry of Health 1966; 25: 238-267.
28 Brown MM, Boosinger J, Black J, Gaspar T (1985) Nursing innovation for prevention of decubitus ulcers in long term care facilities. Plastic Surgical Nursing 5, 2, 57-64.
29 Smith AM, Malone JA. Preventing pressure ulcers in institutionalized elders: assessing the effects of small, unscheduled shifts in body position. Decubitus 1990; 3, 4, 20-22, 24.
30 Andersen KE, Jensen O, Kvorning SA, Bach E. Decubitus prophylaxis: a prospective trial on the efficiency of alternating-pressure air-mattresses and water-mattresses. Acta Dermatovener (Stockholm) 1982; 63:227-230.
31 Ewing MR, Garrow C, Presley TA, Ashley C, Kinsella NM. Further experiences in the use of sheep skins as an aid in nursing. The Australian Nurses' Journal 1964; Sept: 215-219.
32 Goldstone L, Norris M, O'Reilly M, White J. A clinical trial of a bead bed system for the prevention of pressure sores in elderly orthopaedic patients. Journal of Advanced Nursing 1982; 7:545-548.
33 Gray DG, Campbell M. A randomized clinical trial of two types of foam mattresses. Journal of Tissue Viability 1994; 4:128-132.
34 Hofman A, Geelkerken RH, Hamming JJ, et al. Pressure sores and pressure-decreasing mattresses: controlled clinical trial. Lancet 1994; 343:568-71.
35 Santy JE, Butler MK, Whyman JD. A comparison study of 6 types of hosital mattress to determine which most effectively reduces the incidence of pressure sores in elderly patients with hip fractures in a District General Hospital. Report to Northern & Yorkshire Regional Health Authority, 1994.
36 Kemp MG, Kopanke D, Tordecilla L, et al. The role of support surfaces and patient attributes in preventing pressure ulcers in elderly patients. Research in Nursing and Health 1993; 16:89-96.
37 Bliss MR. Preventing pressure sores in elderly patients - a comparison of seven mattress overlays. Age and Ageing, 1995; 24:297-302.
38 Lim R, Sirett R, Conine TA, et al. Clinical trial of foam cushions in the prevention of decubitis ulcers in elderly patients. Journal of Rehabilitation Research 1988; 25:19-26.
39 Lazzara DJ, Buschmann MBT. Prevention of pressure ulcers in elderly nursing home residents: are special support surfaces the answer? Decubitus 1991; 4:42-46.
40 Bliss MR, McLaren R, Exton-Smith AN. Preventing pressure sores in hospital: controlled trial of a large-celled ripple mattress. British Medical Journal 1967; 1:394-397.
41 Gebhardt K, Bliss M, Winwright P. A randomised controlled trial to compare the efficacy of alternating and constant low pressure supports for preventing pressure sores in an intensive care unit. Submitted for publication.
42 Conine TA, Daechsel D, Lau MS. The role of alternating air and silicore overlays in preventing decubitus ulcers. International Journal of Rehabilitation Research 1990; 13:57-65.
43 Daechsel D, Conine TA. Special mattresses: effectiveness in preventing decubitus ulcers in chronic neurologic patients. Archives of Physical Medicine and Rehabilitation 1985; 66:246-248.
44 Stapleton M. Preventing pressure sores - an evaluation of three products. Geriatric Nursing 1986; 6:23-25.
45 Whitney JD, Fellows BJ, Larson E. Do mattresses make a difference? Journal of Gerontological Nursing 1984; 10:20-25.
46 Sideranko S, Quinn A, Burns K, Froman RD. Effects of position and mattress overlay on sacral and heel pressures in a clinical population. Research in Nursing & Health 1992; 15:245-251.
47 Exton-Smith AN, Overstall PW, Wedgewood J, Wallace G. Use of the 'air wave system' to prevent pressure sores in hospital. Lancet 1982; ii:1288-1290.
48 Devine B. Alternating pressure air mattresses in the management of established pressure sores. Journal of Tissue Viability 1995; 5 (3): 94-98.
49 Ferrell BA, Osterweil D, Christenson P. A randomized trial of low-air-loss beds for treatment of pressure ulcers. Journal of the American Medical Association 1993; 269:494-497.
50 Inman KJ, Sibbald WJ, Rutledge FS, et al. Clinical utility and cost-effectiveness of an air suspension bed in the prevention of pressure ulcers. Journal of the American Medical Association 1993; 269:1139-1143.
51 Caley L, Jones S, Freer J, et al. Randomized prospective trial of two types of low-air-loss therapy. (1994, Conference paper).
52 Allman RM, Walker JM, Hart MK, et al. Air-fluidized beds or conventional therapy for pressure sores. Annals of Internal Medicine 1987; 107:641-648.
53 Munro BH, Brown L, Heitman BB. Pressure ulcers: one bed or another? Geriatric Nursing 1989; 10:190-2.
54 Strauss MJ, Gong J, Gary BD, et al. The cost of home air-fluidized therapy for pressure sores. A randomized controlled trial. Journal of Family Practice 1991; 33:52-59.
55 Economides NG, Skoutakis VA, Carter CA, Smith VH. Evaluation of the effectiveness of two support surfaces following myocutaneous flap surgery. Advances in Wound Care 1995; 8(1):49-53.
56 Choi SC, Nelson LD. Kinetic therapy in critically ill patients: combined results based on meta-analysis. Journal of Critical Care 1992; 7 (1):57-62.
57 Gentilello L, Thompson DA, Tonnesen AS, Hernandez D, Kapadia AS, Allen SJ, Houtchens BA, Miner ME. Effect of a rotating bed on the incidence of pulmonary complications in critically ill patients. Critical Care Medicine 1988; 16:783-
58 Summer WR, Curry P, Haponik EF, Nelson S, Elston R. Continuous mechanical turning of intensive care unit patients shortens length of stay in some diagnostic-related groups. Journal of Critical Care 1989; 4(1):45-53.
59 Effective Health Care. Implementing Clinical Practice Guidelines. Bulletin No. 8. Leeds: University of Leeds, 1994.
60 Bergstrom N, Demuth PJ, Braden BJ. A clinical trial of the Braden scale on an acute care medical unit. Journal of Enterostomal Nursing 1992; 19:160-65.
61 Bergstrom N, Demuth PJ, Braden BJ. A clinical trial of the Braden scale for predicting pressure sore risk. Nursing Clinics of North America 1987; 22(2):417-428.
62 Langemo DK, Olson B, Hunter S, Hanson D, Burd, Carthcart-Silberberg T. Incidence and prediction of pressure ulcers in five patient care settings. Decubitus 1991; 4(3):25-36.
63 Salvandalena GD, Snyder ML, Brogdon KE. Clinical trial of the Braden scale on an acute care medical unit. Journal of Enterostomal Nursing 1992; 19:160-65.
64 Barnes D, Payton RG. Clinical application of the Braden scale in the acute care setting. Dermatology Nursing 1993; 5 (5):386-388.
65 Goldstone LA, Goldstone J. The Norton score: an early warning of pressure sores? Journal of Advanced Nursing 1982; 7:419-426.
66 Lincoln R, Roberts R, Maddox A, Levine S, Patterson C. Use of the Norton pressure sore risk assessment scoring system with elderly patients in acute care. Journal of Enterstomal Therapy 1986; 13:132-38.
67 Stotts NA. Predicting pressure ulcer development in surgical patients. Heart and Lung 1988: 17; 641-7.
68 Andersen KE, Jensen O, Kvorning SA, Bach E. Prevention of pressure sores by identifying patients at risk. British Medical Journal 1982; 284:1370-71.

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