Title: Mattresses for Decubitus Ulcer Prevention in Acute and Critical Care: Clinical and Cost-Effectiveness

Date: 14 December 2007

Context and policy issues:

In Canadian acute care facilities and in critical care units the pressure ulcer (PU) prevalence rate is reported to be 25.1%. Ulcers may be complicated by pain and infection, and in the elderly are associated with an increased risk of death. Numerous interventions to prevent the development of ulcers are available. These include nutritional support, skin care and management of incontinence, frequent repositioning, and specialized support surfaces. These surfaces are designed to reduce the pressure on bony sites, facilitating healthy capillary flow and preventing tissue necrosis leading to ulceration. They may be static (low-tech) or dynamic (high-tech). Static devices include sheepskin, air, foam, fiber, gel and fluid-filled overlays or mattresses. Different types of foam mattresses are available including high-specification foam, viscoelastic, convoluted foam or cubed foam. Dynamic devices mechanically vary the pressure on parts of the body. Examples of these include alternating pressure mattresses, low air loss beds or air-fluidized mattresses.

There are a growing number of new devices to prevent PUs. Moreover, the clinical and cost-effectiveness of well-known devices such as foam mattresses, foam overlays, air filled sacs and low air loss surfaces remains unclear. A review of more recent evidence may shed light on the current clinical and cost-effectiveness of these devices.

Research questions:

1. What is the clinical effectiveness of foam mattresses, foam overlays, air filled sacs and low air loss surfaces for prevention of decubitus ulcers for patients in acute care and critical care?
2. What is the cost-effectiveness of foam mattresses, foam overlays, air filled sacs and low air loss surfaces for prevention of decubitus ulcers for patients in acute care and critical care?

Methods:

A limited literature search was conducted on key health technology assessment (HTA) resources, including PubMed, The Cochrane Library (Issue 4, 2007), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international HTA agencies, and a focused Internet search. Results include articles published between 2000 and the present, and are limited to English language publications only. Filters were applied to limit the retrieval to systematic reviews, meta-analyses, health technology assessments and randomized controlled trials (RCTs). Guidelines, observational studies and non-randomized trials (with or without a control group) were not included in the summary of findings.

Summary of findings:

Systematic reviews

Three systematic reviews have been retrieved\textsuperscript{3,6,7}, including a total of 12 RCTs published from 2000 and onward.\textsuperscript{8-18} For the studies that compared support surfaces, Reddy et al.\textsuperscript{3} concluded that they were appropriate strategies to prevent PUs (no specific percentages, relative risk (RR) or other types of results were available in the report). The Cochrane systematic review\textsuperscript{7} had only 5 recent studies. Cullum et al. found that foam alternatives to the standard hospital foam mattresses can reduce the incidence of PUs in people at risk. Pressure relieving overlays on the operating table have been shown to reduce postoperative PU incidence. The reviewers concluded that consideration should be given to the use of higher specification foam mattresses rather than standard hospital foam mattresses. The last systematic review completed by Nicosia et al.\textsuperscript{6} concluded that pressure-reducing/relieving surfaces were associated with a significantly lower incidence of heel ulcers compared with standard hospital mattresses (RR = 0.50, 95% CI = 0.26-0.93, P < 0.03). Foam mattresses also significantly reduced the risk of developing heel ulcers. There was evidence to support the use of certain air or foam mattresses/overlays in the prevention of heel PUs when compared with a standard hospital mattress. The information pertaining to studies published from 2000 and forward in these systematic reviews is summarized in Table 1.

Table 1: Summary of systematic reviews

<table>
<thead>
<tr>
<th>Study</th>
<th>Population (number of trials)</th>
<th>Intervention/ Comparator</th>
<th>Results</th>
</tr>
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<tbody>
<tr>
<td>Reddy 2006\textsuperscript{3}</td>
<td>Any patient care setting (59 RCTs) 43 RCTs assessed mattresses or overlays in acute or critical care. 8 studies were published from year 2000 and forward.</td>
<td>Any intervention to prevent PUs. The interventions targeting impaired mobility included specialized mattresses, beds and cushions.</td>
<td>Of the studies in acute care, only two (Jolley et al. 2004\textsuperscript{12} and Theaker et al. 2005\textsuperscript{10}) detected a significant reduction in the incidence of PUs. Jolley et al.\textsuperscript{12} compared specialized sheepskin overlay and standard hospital mattress. (N=441) Theaker et al.\textsuperscript{10} compared low-air-loss mattress versus alternating-pressure mattress (N=62)</td>
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</table>
Nixon et al. (2006)\(^9\) in the PRESSURE trial found no statistically significant difference between alternating pressure mattress replacements and overlays in terms of proportion of patients \([10.7\%\text{ overlay patients, } 10.3\%\text{ mattress replacement patients, a difference of }0.4\%,\text{ 95\% confidence interval (CI) }-2.3\text{ to }3.1\%, p = 0.75]\); but found a delay in time to ulceration of 10.64 days on average \(95\%\text{ CI -24.40 to 3.09}\) \(\text{(N=1971)}\)

Three other studies found no differences comparing static versus standard devices. (Feuchtinger et al. 2006\(^8\), Russel et al. 2003\(^{13}\); and, Gunningberg et al. 2000\(^{17}\))

Two other trials found no differences in the incidence of PUs comparing dynamic 1 (devices with an alternative motion) versus static devices (Vanderwee et al. 2005\(^{11}\) and Russell and Lichtenstein et al. 2000\(^{15}\))

### Cullum 2004\(^7\)

- **Any patient care setting**
  - (41 RCTs)
  - 32 of the trials assessed mattresses or overlays in acute or critical care.
  - These RCTs were published between 1982 and 2002.
  - Only 5 studies were published from the year 2000 and forward.

- One study (McGowan et al. 2000) looked at other interventions in addition to mattresses and is not targeted by this request.

### Pressure-relieving cushions, beds, mattress replacements and mattress overlays versus standard support surfaces

- 2 studies were already included in the Reddy report (Russell and Lichtenstein et al. 2000\(^{15}\), and Gunningberg et al. 2000\(^{17}\))

- One study (Russell et al. 2002\(^{13}\)) compared the CONFOR-Med foam mattress and cushion combination to the standard mattress and cushion combination in an elderly acute population, the results were not significant.

- One study (Keogh & Dealey 2001\(^{16}\)) found no difference when comparing a profiling bed with a pressure reducing foam mattress/cushion with a flat-based bed with a pressure relieving/redistributing mattress/cushion in patients from a surgical ward and two medical wards over 18 years of age.
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Adults in any patient care setting (14 RCTs)

12 RCTs assessed two types of overlays in a mixed, neurology, ICU and Cardiology population* (from 1985 to 2005)

4 studies were done from 2000 and forward.

One study (Gilcreast et al. 2005) reported on other devices not included in this HTIS report.

Any prevention program, devices, mattress or overlay that may alter the incidence of heel ulcers

2 studies were already included in the Reddy report (Russell and Lichtenstein et al. 200015, and Gunningberg et al. 200017)

One study (Gray and Smith, 200018) found no difference in comparing foam mattresses to standard hospital mattresses in a surgical orthopedic ward and medical ward population.

Another study (Sanada et al., 200314) found no difference in heel ulcer occurrence rates in a mixed population comparing air overlays to standard hospital mattresses

* Nicosia et al.6 identified one other RCT (Vyhidal 1997) as a LTC population however this same RCT was stated to be acute care or “skilled nursing facility” in the Reddy et al.3 and Cullum et al.7 systematic reviews. There was also a discrepancy in the comparator intervention. It was reported as a standard hospital mattress by Nicosia et al.6 and as a foam overlay in the other two reports.3,7

Randomized controlled trials

Two additional RCTs were retrieved that were not included in the systematic reviews.19,20 In a prospective randomized controlled 7-month clinical trial, Berthe et al.19 compared the Kliniplot® mattress with the standard hospital mattress in the prevention of PUs (N=1729). Two groups were monitored for the prevention of pressure sores. The patients were evaluated on a daily basis from their admission until the eventual occurrence of a bed-sore. Forty-two of the 1729 patients (2.4%) who entered the study developed at least one pressure sore. Twenty-one of the 657 patients (3.2%) nursed on the Kliniplot® mattress, and 21 of the 1072 patients (1.9%) on the standard mattress developed bed-sores (p = 0.154). The median time for the occurrence of pressure sores was 31 days (range 6-87) with the Kliniplot® mattress and 18 days (range 2 to 38) with the standard mattress (p < 0.001). The risk categories for developing bed-sores using the modified EK's scale were no different at the baseline between both groups (p = 0.764). The severity of the pressure sores was no different between both groups (p = 0.918). The authors concluded that the occurrence of PUs is not reduced but is delayed when patients are nursed on Kliniplot® pressure-decreasing mattresses.19

Russell et al.20 conducted a randomized trial to compare patient outcomes with the RIK mattress (KCI) and the Nimbus 3 mattress (Hunleigh Healthcare). Patients (N=158) were assessed for their risk to develop pressure ulcers during the trial. There were no statistically significant differences. They authors concluded that for a significant proportion of patients, a static (RIK) mattress can be as effective as an active (Nimbus 3) mattress for management of pressure ulcers.
Health economic analyses

Seven economic papers were retrieved. One was a commentary on a cost-effectiveness model and another was a review paper on the importance of the economic modeling in establishing guidelines. The five health economic analysis studies are summarized below.

Iglesias et al. assessed the cost-effectiveness of alternating pressure mattresses compared with alternating pressure overlays for the prevention of PUs in patients admitted to hospital. This analysis was carried out alongside the pressure relieving support surfaces PRESSURE trial; 11 hospitals in the UK participated (N=1971). The main outcomes were Kaplan Meier estimates of restricted mean time to development of PUs and total costs for treatment in hospital. Alternating pressure mattresses were associated with lower overall costs (£283.6 per patient on average, 95% CI -£377.59 to £976.79). These results were mainly due to reduced length of stay in hospital, and greater benefits (a delay in time to ulceration of 10.64 days on average, 95% CI-24.40 to 3.09). The differences in health benefits and total costs for hospital stay between alternating pressure mattresses and alternating pressure overlays were not statistically significant; however, a cost-effectiveness acceptability curve indicated that on average, alternating pressure mattresses compared with alternating pressure overlays were associated with an 80% probability of being cost saving. The authors concluded that alternating pressure mattresses for the prevention of PUs were more likely to be cost-effective and were more acceptable to patients than alternating pressure overlays.

Catz et al. evaluated the economic profitability of a new computerized mattress system (Matrix 200) in patients with spinal cord injuries (SCI) and as an example of the use of a quantitative approach for decision-making in choosing between alternatives for sore prevention. They compared the new system to two other alternatives: a foam egg carton mattress positioned on a regular foam mattress and the low air loss bed system. In this analysis the cost of achieving one day without signs of impending pressure sore was compared between the alternative options using cost minimization analysis. Savings in nursing costs for the three options were calculated for cost-benefit analysis. The authors found that a foam mattress system is significantly cheaper than the other examined alternatives, and if the nursing manpower cost is constant and the nursing staff is capable of performing sufficient repositioning, this system would achieve the desired medical outcome at a minimal cost. However, if the nursing staff cannot perform sufficient repositioning, or if the use of nursing manpower can be adjusted to the actual need, then it is the computerized mattress system that achieves the desired outcome at the minimal cost (costs are not reported here because they are in 1999 New Israeli Shekels - NIS). This economic evaluation indicated that the computerized mattress system is advisable for patients with SCI who require assistance for repositioning, but its profitability depends on the employment terms of the nursing manpower.

Gebhardt et al. reported on an approach initiated at a large teaching trust (approximately 1000 beds) which pertained to a pressure area care equipment service. Over 200 mattress overlays and replacements were purchased and a mattress coordinator was appointed to manage the stock, and at night, the nursing service was in charge of supplying the wards. The type of equipment (mattress, overlay and others) that was purchased were evidence-based driven (guided by the interpretation of published clinical trials) and by the hospital internal data on equipment reliability. The project was associated with a reduction in cost and a consistent reduction in PU incidence in areas where the beds were provided. The cost of approximately £157,000 per annum compared favourably with expenditures reported in the past for some other
(generally smaller) trust or large hospitals on the order of £500,000 to £900,000 for rental of pressure-relieving equipment alone.\textsuperscript{27}

An economic evaluation was performed evaluating the implementation of new bed mattresses in a 650-bed hospital.\textsuperscript{24} The existing mattresses were all replaced for low-pressure foam mattresses. The evaluation consisted of calculating the cost after one year of implementation and calculating incidence and prevalence data. This change resulted in cost savings of £100,000 in the first year after implementation. Incidence and prevalence data were recorded but due to the lack of robust data collection methodologies and no case-mix adjustment and given the challenges of interpreting apparent trends in the data these data were not included. There remains considerable confusion regarding the effect on the prevention of PUs in this evaluation.\textsuperscript{24}

Finally, a cost-effectiveness analysis on pressure-relieving devices was performed in the United Kingdom.\textsuperscript{25} A decision-analytic model was constructed to evaluate different strategies to prevent or treat PUs. The strategies consisted of alternating pressure-relieving devices, mattress replacements, and mattress overlays compared with a standard hospital mattress (high-specification foam mattress) for the prevention and treatment of PUs in hospital patients. Three scenarios were evaluated: the prevention of PUs, the treatment of superficial ulcers, and the treatment of severe ulcers. Costs of the devices were obtained from manufacturers, whereas costs of treatment were obtained from the literature. The authors evaluated the results using £30,000/QALY (quality-adjusted life year) as the decision-maker's cut off point (the current UK standard). In scenario 1 (prevention of PUs), the cost-effective strategy was the mattress overlay at 1, 4, and 12 weeks. In scenarios 2 and 3, the cost-effective strategy was the mattress replacement at 1, 4, and 12 weeks. Standard care was a dominated intervention in all scenarios. The authors concluded that alternating pressure mattress overlays may be cost-effective for the prevention of PUs, whereas alternating pressure mattress replacements appears to be cost-effective for the treatment of superficial and severe PUs.\textsuperscript{25}

Conclusions and implications for decision or policy making:

The data available specific to the acute and critical care population in the prevention of PUs is widely available. A total of 14 RCTs and 5 health economic analyses were published since 2000. Only two RCTs were not included in the 3 systematic reviews retrieved. Because the RCTs included in the systematic reviews were not evaluated as a whole, and because the comparison of the technologies or devices in each trial is often different than the other trials; it is not possible to draw sound conclusions at this time. Moreover, most of the RCTs have methodological issues such as low powered analysis due to small sample size and epidemiological bias. Overall only 2 recent RCTs (Jolley et al. and Theaker et al.) included in the Reddy report detected a significant reduction in the incidence of PUs; one was comparing specialized sheepskin overlay and standard hospital mattress, the other compared low-air-loss mattress versus alternating-pressure mattress, respectively. Another trial performed by Berthe et al. found a statistically significant difference between the median time for the occurrence of pressure sores between Kliniplot® mattress with the standard hospital mattress (p < 0.001). All the other RCTs showed no statistically significant difference in the incidence of PUs between foam mattresses, foam overlays, air filled sacs and low air loss surfaces.

On the other hand, the overall results from the systematic reviews which include RCTs going as far back as 1982 favor foam alternatives to the standard hospital foam mattress in reducing the incidence of PUs and favor the use of overlays in the operating room for reducing post-surgery PUs. There also seems to be evidence to support foam mattresses over standard hospital
mattress although no overall specific data (RR, percentages or others) to support these conclusions were reported.

On the economic side, two studies concluded that alternating pressure mattress overlays were associated with lower costs management and was a cost-effective strategy. Another study found that using low-pressure foam mattresses as a standard were associated with lower hospital costs.

In conclusion, there seems to be some advantages for using any type of overlay to reduce the incidence of PUs. These alternatives were also associated with lower hospital costs. Unfortunately, evidence-based information of other devices such as foam mattresses, low air loss surfaces and air-filled sacs still remains unclear.

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References:


21. Hoskins A. Alternating pressure mattresses were more cost effective than alternating pressure overlays for preventing pressure ulcers. *Evid Based Nurs* 2007;10(1):23.


Appendix:

Other relevant clinical practice guidelines


