Title: Specialty Mattresses for Prevention of Pressure Ulcers: Guidelines and Clinical Effectiveness

Date: 14 December 2007

Context and policy issues:

Pressure ulcers develop frequently in long term care (LTC) residents. In Canadian non-acute care facilities the ulcer prevalence rate is reported to be 29.9%. Ulcers may be complicated by pain and infection, and in the elderly, are associated with an increased risk of death. Numerous interventions to prevent ulcers from developing 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 (e.g. heels and sacral area), facilitating healthy capillary flow and preventing tissue necrosis leading to ulceration. They may be static (low-tech) or dynamic (high-tech). Static devices include sheepskins, air, foam, fibre, 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.

Research questions:

1. What is the clinical effectiveness of specialty mattresses for prevention of pressure ulcers for patients in long term care?

2. What are the guidelines and / or criteria for use of specialty mattresses in long term 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 2002 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, randomized controlled trials (RCTs) and observational studies. Non-randomized trials without a control group were not included in the summary of findings.

Summary of findings:

Evidence specific to the LTC population was limited to one RCT and one observational study. The search also identified three systematic reviews, and three clinical practice guidelines relevant to a number of settings including LTC.

Three systematic reviews were identified. Patients from all care settings were included. The support surfaces evaluated were specialized mattresses, cushions and overlays, and standard hospital mattresses. One review assessed the prevention of heel ulcers only, the other two assessed the prevention of all pressure ulcers. The authors concluded that pressure-reducing foam mattresses and overlays can reduce the incidence of ulcers compared to standard mattresses. It is unclear if dynamic support surfaces are superior to static surfaces. A summary of the evidence related to LTC can be found 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>
</thead>
<tbody>
<tr>
<td>Cullum 2004</td>
<td>Any patient care setting (41 RCTs) 5 of the trials assessed mattresses or overlays in LTC. These RCTs were published between 1985 and 1998.</td>
<td>Pressure-relieving cushions, beds, mattress overlays and mattress replacements versus standard support surfaces</td>
<td>All 5 LTC studies included in the Reddy et al. report were included in this review (see below for a summary of results).</td>
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<td>Reddy 2006</td>
<td>Any patient care setting (59 RCTs) 6 of the RCTs assessed mattresses or overlays in long term care. All but one was published prior to 2002.</td>
<td>Any intervention to prevent pressure ulcers. The interventions targeting impaired mobility included specialized mattresses, beds and cushions</td>
<td>Of the studies in LTC, only one (Kemp 1993) detected a significant reduction in the incidence of pressure ulcers between two types of foam overlays. Four other studies found no differences comparing different static devices, or static versus dynamic devices. The 6th RCT included in the systematic review (Defloor 2005) is summarized in Table 2.</td>
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<tr>
<td>Nicosia 2007</td>
<td>Adults in any patient care setting (14 RCTs) 1 RCT assessed two types of overlays in a mixed LTC and neurology population (1985).*</td>
<td>Any prevention program, device, mattress or overlay that may alter the incidence of heel ulcers</td>
<td>The one RCT that included LTC patients reported no difference in the incidence of heel ulcers between a silicone overlay and an air overlay.</td>
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</table>
Nicosia et al.⁹ identified one other RCT (Vyhildal 1997) as a LTC population however this same RCT was stated to be acute care or “skilled nursing facility” in the Reddy et al.⁵ and Cullum et al.⁸ systematic reviews. There was also a discrepancy in the comparator intervention. It was reported as a standard hospital mattress by Nicosia et al.⁹ and as a foam overlay in the other two reports.³⁸

The RCT by Defloor et al. is summarized in Table 2.⁶ This study used cluster randomization to allocate each LTC nursing ward to one of four intervention groups. The interventions consisted of repositioning the patient every two to six hours on either a standard mattress or a viscoelastic mattress. Due to the resource intensive nature of the turning schedules, only a portion of eligible patients were then randomized to receive the intervention. The remainder of the patients received standard care (control group). Patients in the control group received preventative measures based on the nurses’ clinical judgment which may have included water mattresses, alternating mattresses, sheepskins and gel cushions, but did not include turning.

Allocation concealment was unclear and the nurses and outcome assessors were un-blinded. No intention to treat analysis was conducted and a total of 77 out of 838 patients were excluded from the analysis (reason for exclusion death, transferred to hospital, missing data).⁶

The study found no difference between groups on the incidence of grade I ulcers (i.e. non-blanchable erythema). The group that was turned every four hours on a viscoelastic foam mattress had a significantly lower incidence of grade II to IV ulcers (i.e. blistering, superficial or deep ulcers).⁶ No significant differences were detected between the other groups on the incidence of grade II to IV ulcers. Considering the methodological issues and the combined nature of the intervention groups (different turning schedules and mattresses) the results of this study are difficult to interpret.

Table 2. RCT by Defloor et al.⁶

<table>
<thead>
<tr>
<th>Setting, number of patients enrolled (completed), follow-up</th>
<th>Interventions</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>LTC setting</td>
<td>1. turning q2h on standard mattress (n=65)</td>
<td>Grade I ulcers *</td>
</tr>
<tr>
<td>838 patients (761 completed)</td>
<td>2. turning q3h on standard mattress (n=65)</td>
<td>1: 48%</td>
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<td></td>
<td>3. turning q4h on viscoelastic foam mattress (n=67)</td>
<td>2: 45%</td>
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<td></td>
<td>4. turning q6h on viscoelastic foam mattress (n=65)</td>
<td>3: 42%</td>
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<td></td>
<td>5. standard care based on clinical judgment (n=579)</td>
<td>4: 46%</td>
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<td></td>
<td></td>
<td>5: 43%, p=0.95</td>
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<td></td>
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<td>Incidence of grade II to IV ulcers was lower in group 3 (3%) compared to other groups (p=0.002)</td>
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<tr>
<td></td>
<td></td>
<td>Grade II to IV ulcers</td>
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<tr>
<td></td>
<td></td>
<td>1: 14%</td>
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<td></td>
<td></td>
<td>2: 24%</td>
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<td></td>
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<td>3: 3%</td>
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<td>4: 16%</td>
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<td></td>
<td></td>
<td>5: 20%</td>
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* Grade of pressure ulcers: [I] non-blanchable erythema: redness which cannot be pressed away with the thumb and which lasts longer than one day; [II] blistersing pressure ulcer; [III] superficial ulcer; [IV] deep ulcer as described by the Agency for Health Care Policy and Research, US.
One industry sponsored non-randomized trial evaluated two alternating pressure devices in LTC residents at moderate to high risk of pressure ulcers. A total of 22 residents participated; 11 used the Sidhil Plus mattress replacement and 11 used the Sidhil Solo mattress overlay. Ten of the 22 patients completed the full six weeks of the study; the others discontinued the study early (nine died, two were discharged and one did not like the mattress). Two patients using the overlay and none using the mattress developed new pressure ulcers (ulcer grade not specified). In this study, no attempt was made to match the patients between groups and the outcome assessor was not blinded.  

Guidelines:

Three clinical practice guidelines were available that included patients in LTC. The recommendations relevant to the research questions are summarized in Table 3. No recommendations specific to LTC were stated. The recommendations stated below in two of the guidelines were either based on expert opinion, or on trials conducted in acute care. One guideline did not provide any details on the development process or the level of evidence to support their recommendations.

Table 3. Clinical practice guidelines on the prevention of pressure ulcers

<table>
<thead>
<tr>
<th>Guideline</th>
<th>National Institute for Clinical Excellence (NICE) 2003&lt;sup&gt;5&lt;/sup&gt;</th>
<th>Queensland Health 2004&lt;sup&gt;10&lt;/sup&gt;</th>
<th>Registered Nurses Association of Ontario (RNAO) 2005&lt;sup&gt;4&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population, setting or scope of guidelines</td>
<td>Persons of all ages who are vulnerable to developing pressure ulcers and are being cared for in hospital, nursing home, supported accommodation or at home. Scope limited to the evaluation of beds, mattresses and overlays in terms of clinical and cost effectiveness.</td>
<td>Patients at risk of pressure ulcers in the healthcare setting. Guidelines were developed to standardize and streamline pressure ulcer diagnosis, prevention and treatment in Queensland state.</td>
<td>Adults who are at risk of pressure ulcers receiving nursing care in “diverse practice settings”. The guideline provides direction to nurses in early prevention interventions and management of stage I ulcers.</td>
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<td>Assessment of risk</td>
<td>“Decisions about which pressure relieving device to use should be based on cost considerations and an overall assessment of the individual. Holistic assessment should include all of the following points, and should not be based solely on scores from risk assessment scales: • Identified levels of risk • skin assessment • comfort • general health state • lifestyle and abilities • critical care needs • acceptability of the proposed pressure-</td>
<td>Recommends using the Waterlow Pressure Ulcer Risk Assessment Tool in addition to clinical judgment. Patients with a score &gt;10 are considered ‘at risk’, &gt;15 is at ‘high risk’ and &gt;20 is at ‘very high risk’.</td>
<td>“The nurse uses clinical judgment to interpret risk in the context of the entire client profile, including the client’s goals.”[level of evidence, IV]</td>
</tr>
</tbody>
</table>

<sup>5</sup> Guidelines:

Three clinical practice guidelines were available that included patients in LTC. The recommendations relevant to the research questions are summarized in Table 3. No recommendations specific to LTC were stated. The recommendations stated below in two of the guidelines were either based on expert opinion, or on trials conducted in acute care. One guideline did not provide any details on the development process or the level of evidence to support their recommendations.
| Support surfaces for 'at risk' patients | “Individuals assess as being vulnerable to pressure ulcers should, as a minimum provision, be placed on a high-specification foam mattress with pressure relieving properties.” [B] | Pressure reducing foam mattresses should replace the standard hospital vinyl mattress for patients considered ‘at risk’, and those with a Waterlow score less than 10 (not at risk). | “Clients at risk of developing a pressure ulcer should not remain on a standard mattress. A replacement mattress with low interface pressure, such as high-density foam, should be used.” [Ia] |
| Support surfaces for 'high risk' patients | “Although there is no research evidence that high-tech pressure-relieving mattresses and overlays are more effective than high-specification (low-tech) foam mattresses and overlays, professional consensus recommends that consideration should be given to the use of alternating pressure or other high-tech pressure relieving systems:  
  - As first-line preventative strategy for people at elevated risk, as identified by holistic assessment  
  - When the individual's previous history of pressure ulcer prevention and/or clinical condition indicates they are best cared for on a high-tech device  
  - When a low-tech device has failed.” [D] | Patients at ‘high risk’ with intact skin should be placed on an alternating air overlay or static air mattress. Those with a stage I or II ulcer should have an alternating air overlay or mattress. Patients at ‘very high risk’ should be placed on a low air loss or alternating air mattress. | No recommendations provided related to support surfaces for high risk patients |
| Grade/level of evidence | [B] evidence from non-randomized controlled trial(s) or quasi-experimental type study; evidence extrapolated from RCT(s) or meta-analysis of RCTs.  
[D] expert opinion or extrapolated from level A, B or C evidence | Not reported for any recommendation | [Ia] evidence from meta-analyses or systematic review(s) of RCTs  
[IV] expert opinion |
In assessing patient risk, the NICE guidelines state there is little evidence that using a pressure ulcer risk scale is better than clinical judgment, or that these scales improve outcomes. Routine use of scales may lead to inefficient use of preventative measures as the diagnostic accuracy of these tools is low. Scales may be used as a memory aide but should not replace clinical judgment.

In two systematic reviews the authors reported that the methodology for pressure ulcer trials was suboptimal. In the Reddy et al. review only three of 59 trials met all the criteria for methodological quality. Due to the nature of the intervention it was difficult to blind the study participants. Un-blinded study designs have been associated with exaggerated treatment effects. The potential for bias may be of particular concern in trials with subjective outcomes.

Due to lack of empirical evidence, many of the recommendations from the clinical practice guidelines were based on expert opinion. The majority of RCTs published are in the acute care setting and studies specific to the LTC population are lacking. Our search identified only one recent RCT in LTC. It is not clear if the efficacy of support surfaces in acute care can be generalized to other populations and settings. Some older studies in LTC (published in the 1980’s or 1990’s) were described in the systematic reviews however the devices assessed may be different than the ones available today. In some trials, the devices used were poorly described. The ‘standard’ hospital mattress may vary from country to country and over time.

**Conclusions and implications for decision or policy making:**

The data available specific to LTC was limited to one observational study and one recent RCT. The RCT reported that repositioning the patient every four hours on a viscoelastic foam mattresses reduced the risk of grade II to IV ulcers compared to standard care or to other turning schedules on either a standard or viscoelastic mattress.

Three systematic reviews that included trials from acute and LTC were also identified. It was not possible to draw any conclusions from these reviews on the efficacy of pressure relieving devices in LTC.

Three guidelines were identified that made recommendations on the use of pressure-relieving mattresses and overlays for the prevention of ulcers. None of the recommendations were specific to LTC, but included patients from a broad healthcare setting. Two of the guidelines endorsed a holistic assessment of the individual patient to determine their risk of pressure ulcers and to determine the appropriate support surface. One of these guidelines suggested that the cost of the device should also be considered when making this decision. The guidelines recommended that patients at risk of ulceration be placed on pressure-relieving foam mattresses or overlays. Based on expert opinion the guidelines suggested that patients at high risk be placed on a high-tech (dynamic) mattress or overlay.

The methodology of pressure ulcer prevention trials in suboptimal and well conducted RCTs are lacking, particularly in LTC. There is difficulty in identifying patients at risk of developing pressure ulcers and further research is required in this area.

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References:


Appendix:

Other relevant clinical practice guidelines


