Pressure ulcers: guideline development and economic modelling

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The use of pressure-relieving devices for the prevention of pressure ulcers. In particular, the analysis focused on high-specification foams and standard hospital mattresses (defined as mattresses without pressure-relieving qualities).

Type of intervention
Primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised a hypothetical cohort of patients at risk of developing pressure ulcers. The analysis was carried out for four different patient groups, classified according to different levels of risk of developing pressure ulcers.

Setting
The setting was a hospital and nursing homes. The economic study was carried out in the UK.

Dates to which data relate
The effectiveness evidence came from a study published in 2001. Some costs were derived from studies published between 1997 and 1999, and were expressed in 2000/01 prices.

Source of effectiveness data
The effectiveness evidence was derived from a synthesis of published studies.

Outcomes assessed in the review
The outcomes estimated in the effectiveness review were the efficacy of pressure-relieving devices (in terms of relative risk of developing pressure ulcers in comparison with standard devices) and quality of life.

Study designs and other criteria for inclusion in the review
Only randomised, clinical trials comparing pressure-relieving devices in the prevention of pressure ulcers were included in the review. Studies that only used subjective outcome measures were excluded, as were those that only used intermediate outcome measures such as the pressure on different parts of the body. The recent HTA (Cullum et al. 2001) was updated using the same methods.
Sources searched to identify primary studies
Several databases were considered, for example MEDLINE, CINAHL, EMBASE, the Cochrane Library, PsycINFO, NHS EED and HEED.

Criteria used to ensure the validity of primary studies
The inclusion of clinical trials ensures a high internal validity of the primary estimates of effectiveness.

Methods used to judge relevance and validity, and for extracting data
Not reported.

Number of primary studies included
Only one review of four clinical trials was found. This was the source of the clinical evidence.

Methods of combining primary studies
Pooled estimates were calculated.

Investigation of differences between primary studies
Not reported.

Results of the review
The relative risk of developing a pressure ulcer with a high-specification foam mattress compared with a standard mattress was 0.29 (95% confidence interval, CI: 0.19 to 0.43). Thus, the relative risk reduction of developing a pressure ulcer with a high-specification foam mattress relative to a standard mattress was 71% (95% CI: 57 to 81).

No studies evaluating quality of life using measures such as the EuroQol questionnaire were found.

Measure of benefits used in the economic analysis
The summary benefit measure used was the incidence of pressure ulcers in a hypothetical sample of 100 patients.

Direct costs
The perspective chosen for the cost analysis was unclear, although it was probably that of the UK NHS. The analysis included only the direct medical costs associated with the device and the treatment of pressure ulcers. A partial breakdown of the cost items was provided. The unit costs were presented separately from the quantities of resources only for standard mattress, high-specification foam mattress, high-tech mattress and overlay devices. The cost of treating pressure ulcers was instead presented as a macro-category. The costs of the devices were derived from five published studies. Data on the cost of treating pressure ulcers and the lifespan of the different devices were based on the opinions of the GDG members. Discounting was not relevant as the costs were incurred during a short timeframe. The costs were expressed as 2000/01 prices.

Statistical analysis of costs
The costs were treated deterministically.

Indirect Costs
The indirect costs were not included in the economic analysis.
Currency
UK pounds sterling (£).

Sensitivity analysis
A univariate sensitivity analysis was undertaken to assess the robustness of the cost-effectiveness analysis to variations in the clinical and economic data. Specifically, least favourable estimates for the high-specification foam mattress were used. These included the lowest estimate of the additional cost of treating a pressure ulcer, the smallest reduction in the risk of developing a pressure ulcer, the maximum purchase cost of high-specification foam mattresses, and an estimated lifespan of these mattresses of only 4 years (8 years in the base-case). Alternative values were derived from the literature or fixed by the GDG.

Estimated benefits used in the economic analysis
In the low- to high-risk groups (A, B, C, D, where group A was at lowest risk and group D at highest risk), the numbers of patients developing pressure ulcers in a hypothetical sample of 100 individuals were, respectively:

0.5 (A), 5 (B), 10 (C) and 20 (D) with a standard hospital mattress; and

0.15 (A), 1.5 (B), 3 (C) and 6 (D) with a high-specification foam mattress.

The difference in the number of patients developing pressure ulcers between the standard versus high-specification foam mattresses was 0.35 in risk group A, 3.5 in group B, 7 in group C and 14 in group D.

Cost results
The total costs associated with the standard and high-specification foam mattresses were, respectively:

386 and 170 (difference -216) in group A;
3,761 and 1,182 (difference -2,579) in group B;
7,511 and 2,307 (difference -5,204) in group C; and
15,011 and 4,557 (difference -10,454) in group D.

The extra purchase costs of high-specification foam mattress were more than offset by the reduction in the costs of treating pressure ulcers.

Synthesis of costs and benefits
An incremental analysis was carried out to combine the costs and benefits of the alternative devices. However, incremental cost-effectiveness ratios did not need to be calculated as high-specification foam mattresses represented a dominant strategy (i.e. more effective and less expensive than standard devices).

The dominance of high-specification foam mattresses was confirmed in the sensitivity analysis in which worst-case estimates were used.

Authors' conclusions
High-specification foam mattresses were a cost-effective alternative to standard devices for the prevention of pressure ulcers in the UK. The extensive review of the clinical and economic literature on other pressure-relieving devices (high-tech mattress, overlay devices) demonstrated the shortage of published evidence.

CRD COMMENTARY - Selection of comparators
The authors provided a justification for the choice of the comparators, which were appropriate for the study question. High-tech devices were not considered, as the merits of recent technologies were unclear. Pressure-relieving overlays on operating tables and in the postoperative period were not considered because there was very little published evidence on their effectiveness and cost-effectiveness. You should decide whether they are valid comparators in your own setting.

**Validity of estimate of measure of effectiveness**
The effectiveness data were derived from a systematic review of the literature, and some search methods and inclusion criteria were reported. The inclusion of only clinical trials represents a strong feature of the analysis. The method and conduct of the review were the same as those for a recent HTA, which was used as the main source of data as more recent studies could not be found. The HTA pooled the results from four clinical trials and is likely to have been robust. A sensitivity analysis was carried out by varying the clinical end points found in the literature.

**Validity of estimate of measure of benefit**
The summary benefit measure was specific to the disease considered in the study. It is not comparable with the benefits of other health care interventions. The authors stated that the impact of the intervention on quality of life could not be assessed given the lack of reliable evidence in the literature.

**Validity of estimate of costs**
The analysis of the costs was mainly based on published evidence and on the opinions of a panel of experts. For this reason, some costs were presented as macro-categories and information on the unit costs and quantities of resources used was provided only for the interventions under analysis. This might limit the possibility of replicating the analysis in other countries. Some assumptions about resource consumption were also made, and the impact of these estimates on the total costs was then tested in the sensitivity analysis. The costs were treated deterministically and no statistical tests were carried out. The price year was reported, which will facilitate reflation exercises in other time periods.

**Other issues**
The authors did not compare their findings with those from other studies. They also did not explicitly address the issue of the generalisability of the study results to other settings. However, the use of sensitivity analysis enhances to some extent the external validity of the study, as alternative estimates of costs and effectiveness were used. The study referred to patients at risk of developing pressure ulcers and this was reflected in the authors’ conclusions. A strong feature of the analysis was the fact that the study considered different patients grouped according to their risk of developing pressure ulcers.

**Implications of the study**
The GDG recommended that all patients at risk of developing pressure ulcers be placed on high-specification foam mattresses. The GDG also suggested that future studies should provide reliable estimates on the cost per patient of supplying different pressure-relieving mattresses and treating pressure ulcers. Further research on quality of life data is also required.

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