

# Pressure relieving support surfaces (PRESSURE) trial: cost effectiveness analysis

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## Abstract

**Objective** To assess the cost effectiveness of alternating pressure mattresses compared with alternating pressure overlays for the prevention of pressure ulcers in patients admitted to hospital.

**Design** Cost effectiveness analysis carried out alongside the pressure relieving support surfaces (PRESSURE) trial; a multicentre UK based pragmatic randomised controlled trial.

**Setting** 11 hospitals in six UK NHS trusts.

**Participants** Intention to treat population comprising 1971 participants.

**Main outcome measures** Kaplan Meier estimates of restricted mean time to development of pressure ulcers and total costs for treatment in hospital.

**Results** Alternating pressure mattresses were associated with lower overall costs (£283.6 per patient on average, 95% confidence interval – £377.59 to £976.79) mainly due to reduced length of stay in hospital, and greater benefits (a delay in time to ulceration of 10.64 days on average, –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.

**Conclusion** Alternating pressure mattresses for the prevention of pressure ulcers are more likely to be cost effective and are more acceptable to patients than alternating pressure overlays.

## Introduction

Current National Institute for Health and Clinical Excellence guidelines on the prevention of pressure ulcers recommend the use of high specification foam mattress as the standard in vulnerable patients and surfaces such as alternating pressure mattresses for high risk people.<sup>1</sup> This latter recommendation was based on expert opinion in the absence of research. Alternating pressure surfaces are available as mattress replacements (about £4000, \$7464; €5847) and as overlays (£1000), which are placed on top of a standard hospital mattress. The relative costs and effects of these different systems are uncertain. We carried out an economic evaluation alongside a large multicentre pragmatic randomised controlled trial of alternating pressure mattresses and alternating pressure overlays. The clinical results of the trial are published in the accompanying paper.<sup>2</sup>

## Methods

Eligible people were aged at least 55 years and had been admitted to vascular, orthopaedic, medical, or care of the elderly wards, either as acute or elective admissions, in the previous 24 hours. Inclusion criteria were an expected length of stay of at least seven days, and an expected (if elective) or actual limitation of activities and mobility or an existing pressure ulcer of grade 2, or both. Participants were randomised to an alternating pressure mattress or an alternating pressure overlay within 24 hours of hospital admission.

We carried out an economic evaluation analysis in the intention to treat population of the multicentre randomised controlled trial. We estimated mean health benefits and mean total costs associated with both surfaces.<sup>3 4</sup>

To estimate the number of pressure ulcer free days we recorded the time taken for the development of a new grade 2 pressure ulcer for each patient. The average length of hospital stay was estimated from the dates of entry and discharge from hospital.

See [bmj.com](http://bmj.com) for a description of the unit costs. Patients were assumed to have remained on the allocated surface for their entire hospital stay. For the base case analysis we assumed a two year life span for the surfaces. The pricing year was 2002-3.

We defined health benefit as the difference in the mean time to develop a pressure ulcer between the groups. Survival analysis was used to calculate the restricted Kaplan Meier estimates of mean time to pressure ulcer development in each trial arm.

We carried out a cost effectiveness analysis, from the perspective of the UK NHS and Personal Social Service, on the intention to treat population for the period of hospital stay.<sup>5</sup> The time horizon was shorter than one year, consequently neither costs nor benefits were discounted.

To account for the skewed nature of data for costs and length of stay, we used generalised linear models to estimate the mean difference in overall hospital costs between the groups. We used the Akaike Information criterion and the normal plot of deviance residuals to compare models assuming different distributions functions and link functions.<sup>6</sup> The final model assumed a gamma distribution for the data with an identity link function.<sup>7</sup> The coefficient estimates of a generalised linear model with an identity link function represent the difference between groups using arithmetic means. To preserve the correlation between health benefits and overall hospital cost, we used non-parametric bootstrapping techniques to estimate the bias corrected 95% confidence intervals of the mean



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differences in time to development of pressure ulcers and costs between the groups.<sup>8</sup>

The robustness of the results was explored in three different scenarios: both devices assumed to be rented rather than purchased and a five year or seven year life span for both devices.

## Results

Overall, 1972 participants were randomised. One patient was excluded, leaving an intention to treat population of 1971 participants.

In the base case analysis the generalised linear model which best described overall hospital costs indicated that on average the mattress group resulted in a mean reduction in total hospital cost of £283.60 (95% confidence interval –£377.59 to £976.79,  $P=0.418$ ; table 1). This difference was not statistically significant.

The difference in Kaplan Meier restricted estimates of the mean time to development of pressure ulcers indicated that participants in the mattress group took 10.64 days longer to develop a pressure ulcer than participants in the overlay group (table 2). This difference was not, however, statistically significant (95% bias corrected confidence interval –24.40 to 3.09 days).

The base case economic analysis indicated that mattresses are a dominant strategy when compared with overlays; they are associated with a delay in the development of pressure ulcers and lower hospital costs. The sampling uncertainty associated with this result was investigated in an incremental cost effectiveness plane (see [bmj.com](#)). The location of the point estimates suggest that the overlays are associated with a more rapid development of pressure ulcers than are the mattresses.

The mattresses are associated with an 80% probability of being cost saving (the probability associated with a willingness to pay of zero) compared with the overlays (see [bmj.com](#)). Similarly, a probability of about 15% was associated with overlays being cost effective for a range of willingness to pay from £25 to £30 000 for an extra pressure ulcer free day.

The results from the base case analysis were fairly robust to considering feasible variations in the life span of the surfaces or in changing between rental and purchase. Sensitivity analyses suggest that the overlays are more costly and associated with a more rapid development of new grade 2 pressure ulcers than are the mattresses (table 2).

## Discussion

Alternating pressure mattresses to prevent pressure ulceration in patients admitted to hospital are associated with lower costs and greater benefits and are more likely to be cost saving than alternating pressure overlays.

The health benefits associated with the interventions were captured as pressure ulcer free days. We chose this approach rather than the more usual method of trying to capture a patient's utility through changes in quality of life because concurrent illness would dominate any quality of life measurement.

That the mattress is likely to be economically dominant may initially seem counterintuitive. The mattress has a higher purchase cost and no statistically

**Table 1** Means (standard deviations) of cost estimates (£) of using alternating pressure overlays or alternating pressure mattresses for the prevention of pressure ulcers in patients admitted to hospital

Item	Overlay	Mattress
Resource use:		
Length of stay	20.36 (25.72)	19.14 (21.54)
Hospital costs:		
Base case	6793.33 (8196.52)	6509.73 (7347.56)
Rental	6967.81 (8357.40)	6747.48 (7558.25)
Five year life span of device	6776.43 (8177.07)	6443.49 (7278.95)
Seven year life span of device	6773.38 (8173.56)	6431.62 (7266.67)

significant effect on the proportion of patients developing an ulcer, the time to ulceration, the severity of ulcers, or length of stay. However, the cost of these surfaces is low when viewed over their life span, and the difference in costs between overlays and mattresses is small over this time period. For a two year life span, the average cost per day would be £1.38 for an overlay and £5.71 for a mattress (see [bmj.com](#)). This difference is small in the context of daily inpatient costs of £165-£385 and the reduced length of stay (on average, 1.22 of a day less) for mattress recipients in this trial and translates into an average reduction in costs of £283.6 per patient. The health benefit associated with the interventions was measured as the difference in mean time to develop a pressure ulcer and favoured the mattress (by 10.64 days). The accompanying clinical paper for this trial reports the median (rather than mean) time to ulceration, as is common practice owing to the skewed distribution of time to event data.<sup>2</sup> By contrast, and as recommended for economic analyses, we use the mean time to pressure ulceration since the median would greatly underestimate the costs.<sup>3 4</sup>

The delay in ulceration associated with the mattresses is crucial because the longer a patient avoids ulceration the less likely they are to go on to develop a pressure ulcer.

Total cost is a function of length of hospital stay which itself is mainly a function of overall health status. Patients who are more ill are both more at risk of pressure ulcers<sup>9</sup> and likely to have longer lengths of stay. It is probable that good nursing care will prevent pressure ulcers in a proportion of patients and will delay their appearance in others. The longer length of stay in patients with pressure ulcers is probably a consequence of comorbidities rather than the pressure ulcer itself. We found no effect when we tested to see whether the surfaces had a differential effect on length of stay depending on the presence of a pressure ulcer; overall lengths of stay for patients who developed a pressure ulcer on either surface were similar.

Our results oppose those from the model based cost effectiveness analysis by Fleurence because data in

**Table 2** Economic evaluation of alternating pressure overlays compared with alternating pressure mattresses for the prevention of pressure ulcers in patients admitted to hospital

Overlay-mattress	Mean (95% bias corrected confidence interval)
Base case analysis:	
Differential health benefit (days)	-10.64 (-24.40 to 3.09)
Differential cost (£)	283.60 (-377.59 to 976.79)
Sensitivity analyses:	
Differential rental cost (£)	220.33 (-459.85 to 927.00)
Differential cost for five year life span (£)	332.95 (-325.27 to 1020.77)
Differential cost for seven year life span (£)	341.76 (-315.92 to 1028.63)

**What is already known on this topic**

No previous trial based economic evaluation has compared alternating pressure mattresses with the less costly alternating pressure overlays

**What this study adds**

Alternating pressure mattresses were associated with lower costs and greater benefits and are more likely to be cost saving than alternating pressure overlays

that trial were based on expert opinion whereas we collected our data.<sup>10</sup> The previous model also disregarded that pressure ulcers are rarely the reason for people being admitted to hospital. Thus the marginal cost of treating a pressure ulcer in hospital may be small compared with the overall costs of hospital treatment. In this sense our analysis reflects actual practice. Our assumption that participants remained on the allocated surface over their entire hospital stay is conservative; in reality patients are moved on to standard mattresses or higher specification surfaces if their risk of pressure ulcers changes. Given participants in the overlay group developed pressure ulcers earlier than those on the mattresses, this assumption will have over-estimated the cost of the mattresses, thus strengthening our conclusions.

Although there was considerable uncertainty around the point estimates of mean health benefits and costs (table 2), this should not result in large uncertainty for decision makers since even for large willingness to pay values (see [bmj.com](http://bmj.com)) the probability of the overlays being cost effective is only between 10% and 20%.<sup>11</sup>

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Ethical approval: This study was approved by the North West multicentre research ethics committee and local ethics committees.

- 1 National Institute for Health and Clinical Excellence. Pressure ulcer prevention: pressure ulcer risk assessment and prevention, including the use of pressure-relieving devices (beds, mattresses and overlays) for the prevention of pressure ulcers in primary and secondary care. *NICE clinical guideline*. 2003;7.
- 2 Nixon J, Cranney G, Iglesias C, Nelson EA, Hawkins K, Phillips A, et al. Randomised, controlled trial of alternating pressure mattresses compared with alternating pressure overlays for the prevention of pressure ulcers: PRESSURE (pressure relieving support surfaces) trial. *BMJ* 2006;332:1413-5.
- 3 Thompson SG, Barber JA. How should cost data in pragmatic randomised trials be analysed? *BMJ* 2000;320:1197-200.
- 4 Claxton K. The irrelevance of inference: a decision-making approach to the stochastic evaluation of health care technologies. *J Health Econ* 1999;18:341-64.
- 5 National Institute for Health and Clinical Excellence. *Technical guidance for manufacturers and sponsors on making a submission to a technology appraisal*. London: NICE, 2004.
- 6 Lindsey JK, Jones B. Choosing among generalized linear models applied to medical data. *Stat Med* 1998;17:59-68.
- 7 Barber JA, Thomson SG. Multiple regression of cost data: use of generalized linear models. *J Health Serv Res Policy* 2004;9:197-204.
- 8 Mihaylova B, Briggs A, Armitage J, Parish S, Gray A, Collins R. Cost-effectiveness of simvastatin in people at different levels of vascular disease risk: economic analysis of a randomised trial in 20,536 individuals. *Lancet* 2005;365:1779-85.
- 9 Baumgarten M, Margolis D, Berlin JA, Strom BL, Garino J, Kagan SH, et al. Risk factors for pressure ulcers among elderly hip fracture patients. *Wound Repair Regen* 2003;11:96-103.
- 10 Fleurence RL. Cost-effectiveness of pressure-relieving devices for the prevention and treatment of pressure ulcers. *Int J Technol Assess Health Care* 2005;21:334-41.
- 11 Fenwick E, O'Brien BJ, Briggs A. Cost-effectiveness acceptability curves—facts, fallacies and frequently asked questions. *Health Econ* 2004;13: 405-15.

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**Corrections and clarifications**

*An international standard for disclosure of clinical trial information*  
A couple of errors cropped up in this editorial by Fiona Godlee (*BMJ* 2006;332:1107-8, 13 May). In discussing the setting up of trial registries, Fiona mentioned the metaRegister of Clinical Trials, but this should have been the ISRCTN Register (<http://isrctn.org>) since this is where trials are uniquely registered in accordance with international requirements. In addition, the meeting convened by WHO to determine what information must be disclosed at registration was in April 2005 (not 2004 as written).

*Short cuts: Two antiplatelet agents work better than one after stroke*  
In the final item of these Short Cuts by Alison Tonks (*BMJ* 2006;332:1264-5, 27 May), the number needed to treat for a combination of aspirin and dipyridamole should have been 33. The value of 104 that we gave (and which is given in the *Lancet* paper cited) refers to the number needed to treat per year.

*Effect of patient completed agenda forms and doctors' education about the agenda on the outcome of consultations: randomised controlled trial*  
We inadvertently used the wrong terminology in one of the figures of this research article by J F Middleton and colleagues (*BMJ* 2006;332:1238-41, 27 May). The cluster of boxes in figure 2

of the full version on [bmj.com](http://bmj.com) that state "data not available" should have read "did not attend appointment." In addition, a column heading in table 2 of the full version (the table of the print version) is incorrect: the heading spanning the last three columns should read "Change in means (95% CI) (intervention group-reference group)" [not "(reference group-intervention group)"].

*Randomised controlled trial of four commercial weight loss programmes in the UK: initial findings from the BBC "diet trials"*

During the writing, rewriting, and editing of this research paper by Helen Truby and colleagues (*BMJ* 2006;332:1309-11, 3 June), some small errors crept into table 3 of the full version on [bmj.com](http://bmj.com) (table 2 of the print version). In the control group the mean (SD) fall in cholesterol during 2-6 months should be 0.24 (0.6) (not 0.24 (0.24) as written) and during 0-6 months should be 0.18 (0.5) (not 0.5 (0.18)). The table footnote should have stated that the fall in total cholesterol at 2 months in the Weight Watchers, Rosemary Conley, and Slim-Fast groups was significantly different from that in the control group. However, the text is correct in explaining these differences, and the conclusions drawn are not affected by the errors.