A comparison of cost and efficacy of three incontinence skin barrier products

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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 study examined the use of a polymer-based barrier cream, applied either once daily or three times a week, to prevent incontinence dermatitis (ID). The film used was 3M Cavilon No Sting Barrier Film.

Type of intervention
Prevention.

Economic study type
Cost-effectiveness analysis.

Study population
Initially, nursing homes were selected for inclusion if they used one of three barrier ointments to prevent ID, or if they used a non-alcohol barrier film in an ID treatment protocol. The nursing homes had to have at least 100 beds and approximately 40 residents with incontinence and intact perineal skin. The residents included in the study had to be incontinent (urine or faeces or both). Residents were excluded if they had existing ID, a history of allergies or sensitivities to skin care products, or required catheterisation. They were also excluded if, for any other reason, they were thought to be unsuitable for participation.

Setting
The setting was nursing homes. The economic study was carried out in the USA.

Dates to which data relate
The effectiveness and resource data were obtained from 2002 to 2003. The price year was 2003.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
A sub-set of the patients (three out of four nursing homes) that provided the cost data also provided the effectiveness data. The nursing homes that provided the cost data used a sample of patients for some of their calculations. It would appear that some of the cost data were collected prospectively and some retrospectively.

Study sample
No power calculations were reported. The first four nursing homes that qualified for inclusion in the study were enrolled. These provided 521 residents who were screened for enrolment. Of these, 250 residents satisfied the inclusion criteria and were enrolled in the study. There were 67 patients in the ointment #1 group, 38 in the ointment #2 group,
78 in the once-daily barrier film group and 67 in the thrice-weekly barrier film group. No effectiveness data were provided by the ointment #1 group, which withdrew from the study. Each nursing home used one treatment for all their patients, generally the treatment they were using before the study.

**Study design**
This was a prospective, multi-centre, non-randomised trial with concurrent controls in which the patients were followed up for 90 days.

**Analysis of effectiveness**
The patients were studied on an intention to treat basis. The patients' skin damage was assessed according to four categories (normal, mild, moderate or severe). No information on the comparability of the patient groups was given. Daily incontinence episodes in the three groups were clearly different. For the purpose of the economic analysis, an average incontinence rate was used.

**Effectiveness results**
The nursing home using ointment #1 withdrew from the study and provided no effectiveness data.

During the 90-day follow-up, there were 3 new cases of ID in the once-daily barrier film group, 2 cases in the thrice-weekly barrier film group and 1 case of mild ID in the ointment #2 group.

The incidence was not significantly different between the protocols (Fisher's exact test, p=0.4448).

**Clinical conclusions**
The authors suggested that barrier films provide an acceptable alternative to ointments for ID prevention in nursing homes.

**Measure of benefits used in the economic analysis**
No summary measure of benefits was produced. In effect, a cost-consequences analysis was performed.

**Direct costs**
The direct costs measured were those for the materials (barrier film and ointment) and for the labour time to apply the treatment. The costs were estimated from actual data. The materials costs came from published distributor list prices, while labour costs were obtained from the Bureau of Labour Statistics and the Consumer Price Index. No discounting was carried out as the costs were incurred during less than one year. The quantities and the costs were analysed separately. The price year was 2003.

**Statistical analysis of costs**
When there was more than one distributor list price, an average price was used.

**Indirect Costs**
No indirect costs were estimated.

**Currency**
US dollars ($).
Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The annual cost was $16,425 for the barrier film once daily, $7,118 for the barrier film three times weekly, $37,504 for petrolatum ointment #1, and $38,325 for petrolatum ointment #2.

Synthesis of costs and benefits
Not relevant as no summary measure of benefit was derived.

Authors’ conclusions
The use of barrier films is less expensive than petrolatum ointments for the prevention of incontinence dermatitis (ID) in nursing home residents.

CRD COMMENTARY - Selection of comparators
The choice of the comparator (petrolatum ointments) was justified as it represented the current practice in many US settings. You should decide if this represents a valid comparator in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness data were derived from a single study. The study design, a non-randomised trial with concurrent controls, was not ideal in that it was unclear that the patient groups in the different treatment groups were comparable. Also, the different nursing homes would probably differ in several ways and not simply in their choice of treatment for preventing ID. The study gave information on the demographics and health status of the study sample, thus the reader can judge whether the study sample appears representative of the relevant population in their own setting. The nursing home giving the once-daily barrier film switched to the thrice-weekly film application after 6 weeks of follow-up, which meant that the two kinds of barrier film application were not properly assessed. The internal validity of the effectiveness estimates is likely to be low given the limitation in the study design. However, it is worth noting that the authors’ main objective was to assess the costs.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The health benefits are therefore those associated with the effectiveness outcomes. The reader is referred to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

Validity of estimate of costs
From the cost perspective adopted, all the relevant categories of costs were included. In addition, the costs were reported separately from the quantities. The resource use quantities were taken from a single study. The frequency of application was obtained by the study protocol in the case of barrier films, and from the number of incontinent episodes per day (i.e. the average across all the residents in the study sample) for the ointments. No other sources were used for resource quantities, and no other analysis of the quantities was conducted. The prices were taken from published sources, and no statistical, sensitivity or any other kind of analysis was performed. The price year was reported and this will aid any future reflation exercise.
Other issues
The authors did not compare their results with the findings from other studies. In addition, the issue of generalisability to other settings was not addressed. The results obtained were presented in full. However, the conclusions may not truly reflect the scope of the analysis since each treatment was given in a different institution, the patients were not shown to be comparable, and the cost comparisons were not based on the actual costs incurred in that particular institution. The authors reported several limitations of their study. For example, the small sample size and the fact that the nursing homes were all in one geographical location.

Implications of the study
The authors recommended a larger, more tightly controlled cohort clinical trial to verify the findings of their study. Any such study should take the drawbacks of the current study into consideration.

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