Author's response to reviews

Title: An economic appraisal of the Australian Medical Sheepskin for the prevention of sacral pressure ulcers from a nursing home perspective

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Author's response to reviews: see over
Dear Miss Hewitt, dear editor,

Thanks to you and the referees for reviewing our manuscript. Below you find a point-by-point response to the comments made. Attached to this e-mail you find a file in which all changes to the revised manuscript are colour marked. The revised manuscript (without colour marks) has been uploaded on the manuscript-website. We hope you will find our responses and the new version satisfactory.

Sincerely,

Dr. Patriek Mistiaen
POINT-BY-POINT RESPONSE
Our response is in blue and italic

Referee 1:
http://www.biomedcentral.com/imedia/1809728966362040_comment.pdf
Reviewer: Murray Krahn
Reviewer's report:
This is a simple but quite nice assessment of the cost effectiveness of Australian sheepskins to prevent pressure ulcers. The authors use an RCT of this intervention, and apply some costs to a fictional Dutch nursing home to obtain estimates of cost effectiveness.
Major issues:
-authors do not specifically indicate design of the analysis (cost comparison, and CEA)

*In the introduction and method section, a sentence has been added that a CEA design has been applied.*

-should be a section in methods in which the design of the analysis, time horizon, currency, discount rate etc etc...all of the standard economic evaluation methods parameters are laid out

*A short paragraph has been added to the beginning of the method section, where it is clearly stated that we used a CEA design, a time horizon of 1 year, the applied currency is € at year 2008, the perspective for the analysis is from the perspective of a nursing home operating in the Dutch health care system and a discount rate was not necessary except for one input variable from the literature.*

-choice of NH perspective is interesting , though a bit odd. Why not also estimate costs averted due to local and systemic infection caused by PU?

*This comment is not very clear for us. We can imagine that this reviewer would have preferred a societal perspective, but that doesn’t imply that another perspective, such as a nursing home perspective would not be interesting, since these organisations have to make the decisions whether or not buy sheepskins. Moreover, in our RCT in nursing home patients, there are no societal costs such as production loss or travel costs; this makes the institutional level the appropriate one for the analyses. Also we do not understand what is conflicting between a nursing home perspective and taking costs for infections into account. In our analysis we did not exclude other costs such as costs due to infection caused by pressure ulcers, but since we only looked at grade 1 and 2 pressure ulcers, these types of infection did not occur and are not to be expected. Mostly local and systemic infections occur only in grade 3 and 4 pressure ulcers and indeed can cause then great costs. However, as already stated in the text we confined the treatment costs of pressure ulcers to grade 1 and 2 since we have no data on which we can base that the Australian Medical Sheepskin is also able to prevent grade 3 or 4 pressure ulcers.*

-interpretation is a bit muddy, as is to be expected of a cost effectiveness analysis. The authors show that the sheepskin costs money over all, but then do not help the reader interpret the ICER. Is it worth paying for or not? What's the WTP of a pressure ulcer? Are there other analyses in which WTP for pressure ulcer has been estimated? The authors place the burden of interpretation on the readers, many of whom will be ill equipped to perform this task. The authors
themselves, I suspect, will have difficulty with this task, which is why they have sidestepped it.

Interpretation of cost-effectiveness analyses is indeed always a bit muddy, because of the mostly unavoidable uncertainty that is involved in the calculations. In this study we found that the intervention is more effective than the control condition, and that the costs related to the intervention outweigh the savings obtained through the intervention. At that point we had two choices, which we will call ‘the cost-effectiveness solution’ or ‘the cost-utility solution’. The cost-effectiveness solution defines the unit of effect; in this case as an avoided case of pressure ulcer. This is what we actually did. The result can be interpreted as the additional costs of preventing one extra case of pressure ulcer are 2,974.

The alternative way, what we also have considered, was the cost-utility solution. In such an analysis is sought for the amount of health improvement associated with avoiding an case of pressure ulcer (in this case a grade 1 or grade 2 pressure ulcer). An essential part of such a calculation is the QALY-weight as utility measure. However, such QALY-weights for grade 1 or grade 2 pressure ulcers in nursing home patients are not available to our knowledge (see also reply to the next point). Therefore, we used to the cost-effectiveness solution only.

We intentionally decided not to calculate a cost effectiveness acceptability curve (CEAC) that supposes a variety of willingness to pay (WTP) thresholds. Such curves depend largely on the WTP-thresholds you put into it. We considered it much more informative to present what additional costs are involved in using the Australian Medical Sheepskin and to relate these in the discussion section to the amount of money a nursing home receives for caring for one patient. We think that the mentioned monetary value of approximately 2€ per day has more clinical relevance than an expression such as ‘with a WTP-threshold of 10000€ there is an 80% certainty that the Australian Medical sheepskin is a cost-effective intervention’.

And indeed we have not clearly answered in the manuscript if the extra money is worth paying for. But we did not sidestepped it. We have done so, because we could not take changes in quality of life into account and these are necessary to make such a statement. We realize that readers would prefer a clear cut conclusion from the study-authors rather than still have to weigh themselves the presented uncertainty. We really think that the task of the researcher is to provide the best available information, leaving the decision making to the policy makers.

-incidentally, I suspect it would have been quite easy to assign a qaly weight to the PU’s averted, and therefore perform a cost utility analysis. Look up the utility penalty associated with a PU (cf Thein et. al QOL research 2009) and multiply by mean duration and that’s the qaly loss associated with a PU.

Of course it is appealing, also to us, to add a QALY weight and perform a costs-utility analysis. However this is not quite easy. Although it is known that pressure ulcers relate negatively to quality of life, the research done in this area and known to us also shows that the lower Quality of Life found in patients with pressure ulcers can also be attributed to factors other than the pressure ulcers themselves. To our knowledge there are no studies yet that clearly states how much the influence is of pressure ulcers solely on Quality of Life. For instance, the study of Thein et al. [1], suggested by the referee, shows that many factors are associated with the lower quality of life score found in patients with pressure ulcers and that the combination of all factors only explained 38% of the variance in quality of life; and these authors could also not state what exactly was the influence of pressure ulcers only on quality of life. And indeed
this suggested Thein et al. publication is very interesting, but because of mentioned reason not useful for our study. Moreover, the Thein et al. study groups grade 1 pressure ulcers into the group ‘no pressure ulcer’ and grade 2 into the group ‘grade 2-4 pressure ulcer’, making it impossible to have separate quality of life scores for no pressure ulcer, grade 1, grade 2, grade 3 and grade 4 pressure ulcer. Are Thein et al. right that the Qol of grade 1 PU is the same as having no pressure ulcer at all? And it is known that there is a large difference between the impact of a grade 2 versus grade 4 pressure ulcer, making it not reasonable to group grade 2, 3 and 4 pressure ulcers into one group. Finally, the study of Thein et al. is not useful because our analysis was confined to grade 1 and 2 pressure ulcers only: so what value did we have to use? Therefore we decided it was better not to take Qol into account because of the too large uncertainty, rather than to put into some imaginary values into the model. Much more research is needed in this area, especially research that differentiates between different grades of pressure ulcers and the impact it has on Qol. However, in the discussion section we added a reference to the Thein et al. study and text wherein it is explained why we haven’t used these data.

Other issues-
-in the RCT, what surface was the sheepskin placed on. Does it work when used with pressure reducing (foam) mattresses? These should be used in all LTC facilities. I suspect the marginal benefits of sheepskins when used with foam mattresses are small.

Eight institutions participated in the trial; there was a variety of standard mattresses across the institutions and even across the different nursing wards of each institution. Nurses were in general not aware of the type of mattress that was on a bed. Consequently, the patients randomized to the sheepskin group laid on an equally diverse range of mattresses as the patients that were randomized to the control group. The trial showed that the AMS was effective across this range of mattresses and we do not have data that the AMS is more effective on one type of mattress than another. In another manuscript [2] about the effectiveness applied types of mattresses are described.

-what are the implications of looking only at stage 1-2 pressure ulcers, and only on the sacrum with respect to the analysis? Discussion should indicate whether this is a conservative or non-conservative assumption.

We took only grade 1 and 2 pressure ulcers into account since there is no evidence (yet) that the AMS is also capable of preventing grade 3 or 4 pressure ulcers. And only sacral pressure ulcers were taken into account since pressure ulcers on the sacrum are the most frequent and since in our trial the AMS was positioned in the middle of the bed (so under the sacrum when the patient was in laying on his back), so mainly preventing sacral pressure ulcers. So taking only grade 1 and 2 ulcers and only sacral pressure ulcers are both conservative approaches, since there is no reason to believe that an AMS would not be able to helpful in preventing in stage 3 and 4 pressure ulcers and would not be helpful to prevent pressure ulcers on other locations, as was demonstrated in the two Australian trials [3,4]. However, we can not quantify the possible preventive effect of the AMS on grade 3 or 4 pressure ulcers and taking other locations into account would complicate the analysis because this implies that additional sheepskins (and intervention costs) would be necessary.
In the discussion there is already the sentence ‘It must, however, be stressed that conservative approaches have been used, meaning that input values for the model were never chosen in a way that clearly favoured the AMS.’ stressing the conservative approach.

-cost of a pressure ulcer seems pretty low to me, notwithstanding the fact that only early stage ulcers were costed. Were the authors' cost estimates in line with those of Bennett, whom they cite? They do a good job of triangulating estimates from the Dutch experience.

As stated in the paper, we were confronted with rather large uncertainty in the treatment costs of pressure ulcers. To reduce this uncertainty we applied triangulation by estimating the treatment costs on four different sources. And, given the chosen perspective for the analysis of a Dutch nursing home, we only used sources that gave approximates for the situation in Dutch nursing homes, because charges and prices vary a lot between health care settings and between countries. In the discussion we now added a comparison to a recent study [5] on pressure ulcer treatment costs in a Dutch hospital situation, clearly showing that these are considerably higher than the estimates we found for a Dutch nursing home. Comparisons to foreign figures, such as that of Bennett [6], are in our opinion not so useful because the large differences in health care costing system. Moreover this would also suppose that these foreign studies apply the same perspective (nursing home), what is clearly not the case with the study of Bennett, who applies a societal perspective and only valid for the UK health care system.

-a stronger design would have been to take the utilization estimates directly from the trial, rather than taking only efficacy estimates. Looking at guidelines/protocols etc. is not really an ideal way to estimate costs.

We agree that the analysis would have had more strength if we had more cases of pressure ulcers in the trial for which cost diaries were kept. However this was unfortunately not the case and we only could make costs calculations for a limited amount of trial patients. Therefore we used also other sources, among which the treatment as registered in a large national dataset of nursing home patients with a N of 2,772 applicable patients. The guideline approach we used as well may not be ideal, but it is not an uncommon approach and was for example also applied by the aforementioned study of Bennett [6]. Moreover, we found that the results of the guideline approach did not much differ from the result we found in the empirical cost diary approach.

Referee 2:
http://www.biomedcentral.com/imedia/1441300101382438_comment.pdf

Version: 1 Date: 21 April 2010
Reviewer: Roger Chafe

Reviewer's report:
-Pressure ulcers are clearly an important issue for the health care sector, from both the nursing home and acute care perspectives. Given that many decision makers look at such problems from a cost-saving perspective, I find the general approach taken by the authors to be reasonable, but the work needs to be put in a clearer context of previous work on this topic.
There are indeed more studies [5,7-11] on cost-effectiveness of preventative approaches for pressure ulcers, but there is no study yet known to us about the cost-effectiveness of specifically the Australian Medical Sheepskin. We have added a sentence in the introduction about this.

A short description needs to be included about how the Australian Medical Sheepskin (AMS) work, for those who are not familiar with this intervention.

*Following sentences have been added to the introduction: ‘The Australian Medical Sheepskin is a real genuine sheepskin, coming from the Australian Merino sheep. The sheepskin has a wool pile length of 30 mm, and a high density of wool piles, and reduces pressure and friction making it a possible good intervention for the prevention of pressure ulcers. The sheepskin is tanned and processed in such a way that it has an increased resistance to urine and can withstand up to 100 washes at 80°C to achieve high-level thermal disinfection, without losing its moisture absorbing and pressure relieving properties.’*

-There is also the issue of the role of AMS in treatment of pressure ulcers, rather than just in their prevention which should be discussed.

*As far as we know, there is only one (non comparative) study [12], and that has not been published in a journal, in which the Australian Medical Sheepskin has been applied as therapeutic intervention for pressure ulcers. Therefore it is not known yet what the therapeutic capability is of the AMS and adding this perspective to our analysis could only be very speculative.*

-One area of concern which the authors need to further discuss is the discrepancy between their costs for treating a pressure ulcer with the cost estimates used in other studies, e.g., Bennett. This is partly related to increased costs associated with transfers to acute care or the longer stays in hospital for patients with pressure ulcers. Although not a direct cost to the nursing home, these costs may be of relevance to payers that are responsible for a patients’ nursing home and acute care costs. The possible implications of these additional costs should be discussed. Defending the author’s calculation of the cost of preventing a pressure ulcer is important, because I think it is likely the point which will be initially noticed by readers with knowledge of this area.

*As mentioned in our reply to referee 1, we come to different cost estimates than other studies, but these can easily be explained by the perspective other studies have chosen (e.g. hospital versus nursing home perspective, provider versus societal perspective) or by the country health care system to which those other studies related (e.g. UK versus USA etc..). In the discussion section of the manuscript we have clearly stated that our results can not be easily transferred to other health care institutions or to other countries.*

- With regard to the calculation of the cost of treatment, while it is acceptable to use €15 / €17 per day as the mean treatment cost, I think the high and low inputs for the sensitivity analysis should reflect the high and low values identified in Table 4.

*We used 15€/17€ as the base values and then in the sensitivity analysis we varied these with plus or minus 5€. We have done this to avoid extreme outcomes that would be the case if e.g. a value of 54€ would be put into the model. This is in line with the input values we used for other variables as lined out in Table 8. Choosing for an
The model described in the article relies on one RCT. The authors should provide more details about that trial and its possible weaknesses. The results of the other two trials on AMS referenced by the authors should also be discussed, and if possible, incorporated into the sensitivity analysis.

A few extra sentences about the Dutch trial have been added. With regard to using the effectiveness values of the Australian trials in the sensitivity analyses, we feel some restraints because these were obtained in hospital patients and we don’t know if these are also plausible for nursing home patients.

**Associate Editor comments:**
- In the revision the authors should add a section in their methods on the time horizon, discount rate, and lay out the economic parameters more clearly. There is sufficient commentary from the reviewers to suggest revisions with respect to both estimating the ICER and to specify what is to be said of willingness to pay to avoid a pressure ulcer. Perhaps some comment on why other costs would not be considered associated with pressure ulcers apart from the nursing home perspective taken in the paper. In addition they might comment on the merit of a cost utility analysis using a published qaly estimate for pressure ulcers, as suggested by one of the reviewers.

  See reply above to referees and changes in the text

- Ethics - Experimental research that is reported in the manuscript must have been performed with the approval of an appropriate ethics committee. Research carried out on humans must be in compliance with the Helsinki Declaration (http://www.wma.net/e/policy/b3.htm), and any experimental research on animals must follow internationally recognized guidelines. A statement to this effect must appear in the Methods section of the manuscript, including the name of the body which gave approval, with a reference number where appropriate.

A paragraph has been added to the methods section

- Informed consent must also be documented. Manuscripts may be rejected if the editorial office considers that the research has not been carried out within an ethical framework, e.g. if the severity of the experimental procedure is not justified by the value of the knowledge gained.

A paragraph has been added to the methods section
References


