Reviewer's report

Title: Cost-minimization analysis in a blind randomized trial on small-incision versus laparoscopic cholecystectomy from a societal perspective. Sick leave outweighs efforts in hospital savings.

Version: 1 Date: 20 April 2009

Reviewer: Anthony Delaney

Reviewer's report:

Thank you for the opportunity to review this manuscript. The authors present the results of a randomised controlled trial to compare the costs of laparoscopic cholecystectomy compared to small-incision cholecystectomy for patients with symptomatic gall-stones and reasonably good health.

1. Is the question posed by the authors new and well defined?
- The question is not well defined in the manuscript, and could be explicitly stated at the end of the introduction.

2. Are the methods appropriate and well described, and are sufficient details provided to replicate the work?
- The methods for performing the RCT are reasonably well described. The methods for performing the cost minimisation component of the study are reasonably well described.

3. Are the data sound and well controlled?
- There is one issue with regards to the data that is of concern. There appears to have been a differential calculation of costs in the two groups. The costs of the laparoscopic equipment is costed separately from the standard operating theatre costs, while for the small incision cholecystectomy the costs of the relevant instruments are not calculated separately. Both sets of instruments require cleaning and sterilisation, both have capital costs for acquisition and thus for depreciation. Given that the conclusion that small incision is the preferred method is based upon these data, it is important that costs are ascertained in both groups in an identical fashion. The authors should justify why they have identified the additional costs in the laparoscopic group and not the small incision group.

- There is data missing from Table 4. The direct costs related to complications appear to be a lot greater in the small incision group compared to the
laparoscopic group, although a per patient value is not given and p-value is not
given for this comparison. The fact that the complication related costs are higher
is in the small incision group, and subsequently the overall direct costs are higher
in the small incision group, makes the conclusion that the small incision group
preferable somewhat harder to believe. The justification given for this in the
discussion would be more convincing if it had been specified a-priori.

4. Does the manuscript adhere to the relevant standards for reporting and data
deposition?
- The reporting of the study could be enhanced by reference to the following
paper outlining a guideline for reporting of economic analyses
- Guidelines for authors and peer reviewers of economic submissions to the BMJ.

5. Are the discussion and conclusions well balanced and adequately supported
by the data?
- The conclusion that small incision cholecystectomy is the preferred method for
performing cholecystectomy in reasonably well patients with symptomatic gall
stones is not supported by the evidence found in the study. The total direct costs
are greater in the small incision group, and the only advantage for small incision
cholecystectomy appears to be in a post hoc analysis performed with the most
costly patients excluded. I think a more balanced conclusion is indicated given
the all the data available.

6. Do the title and abstract accurately convey what has been found?
- The title could probably do without the second sentence. The abstract could be
more balanced as noted above.

7. Is the writing acceptable?
- The style could be tightened a little in accordance with the guidelines referred to
above.

Major compulsory revisions
- The question is not well defined in the manuscript, and could be explicitly stated
at the end of the introduction.
- The authors should justify why they have identified the additional costs in the
laparoscopic group and not the small incision group.
- The conclusions should be more balanced. I don’t think there is sufficient
evidence presented to warrant the conclusion that small incision cholecystectomy
is definitively cheaper than laparoscopic cholecystectomy
- The finding that there are significant costs associated with loss of employment
is interesting, but was not the focus of the study. References to this should be
taken out of the title and not given such importance in the abstract, and in the
conclusion.
- The authors should explicitly state that results from this study have been previously published twice.
The paper in Archives of surgery is referred to in the introduction, and the quality of life paper is referred to only obliquely in the methods section.
- The authors should provide justification for the use of costs for the sample size calculation. This is an unusual way of looking at sample size, which would more commonly be calculated looking for a clinically meaningful difference in a patient oriented outcome.

Minor essential revisions
- Some of the language in the manuscript is inappropriate. Examples include:
o References to laparoscopic cholecystectomy conquering the world
o The statement that no differences were found in clinical outcome measures between small incision cholecystectomy and laparoscopic cholecystectomy should specify that this was based on the results of a meta-analysis performed by the authors. In fact this section might be better placed in the introduction, to make the argument that a cost-minimisation study needed to be performed.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**
I declare that I have no competing interests.