Reviewer's report

Title: Assisting informed decision making for labour analgesia: A randomised controlled trial of a decision aid for labour analgesia versus a pamphlet.

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Reviewer: Allison Shorten

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General Comments:

This is a well written paper describing a systematic evaluation of two interventions designed to support women’s decision making about pain relief options for labour. The decision-aid interventions (booklet +/- audio plus worksheet) were developed using the Ottawa decision support format for decision-aids. The control group or ‘standard care’ comparison group received an evidence-based pamphlet designed to provide information and risk data about options for pain relief during labour titled “Pain relief during childbirth-a guide for women”.

Although the study has been systematically conducted and is carefully described, there are severe limitations in design and analysis. The major limitation of this study is that in supplying the pamphlet intervention as a proxy for standard care without including a true ‘standard care’ control group in the design, the study is unable to inform clinicians about the actual benefit for women who used the decision-aid when compared to the ‘usual’ care they would have otherwise received during pregnancy. The study is therefore totally unable to answer the key question of whether the intervention is worth administering, in that no information is provided on what, if any, benefits it provides compared to the current status quo.

The authors proposed that actual ‘standard care’ in the two hospitals studied would be too variable for control purposes and therefore another intervention was required to bring a type of uniformity to the comparison group. However one could argue that the best approach to discover whether a pregnancy decision-aid is an effective and useful addition to current pregnancy care is to examine what occurs when a decision-aid is provided in addition to whatever currently constitutes ‘routine’ pregnancy care in the participating hospitals.

All that can be concluded from the current experiment is that the decision-aid when supplied to a group of well educated women in the last trimester of pregnancy was statistically more effective than the pamphlet in improving knowledge for women. Women who received the decision-aid were also more likely to consider their care provider’s opinion when making decisions about pain relief. For most other outcomes, including decisional conflict, there was little obvious difference between the decision-aid and the pamphlet groups. It would
therefore be important to address issues of cost-effectiveness when deciding whether either intervention should be introduced into clinical practice. Discussion about the potential costs associated with implementation of this decision-aid in practice would be a useful and important element for discussion in the paper and contribute to the evidence to inform clinical practice.

The following additional issues are also discussed in order to help improve the paper.

Major Compulsory
1. The sample size is calculated according to anticipated reduction in decisional conflict. This means that the major assumption of the study is that women are highly conflicted in their decisions about pain relief for labour. The results indicate that this was not the case for the women studied. The authors should provide more information about the basis for the assumption that DCS would be high and need to be reduced. If this was discovered during pilot work it should be included in the methods section. If the assumption has come from the literature then the relevant evidence should be provided by the authors to justify their DCS assumptions.

In addition it would be useful to see the sample size justified according to anticipated change in knowledge levels.

2. The women participating in the study were clearly atypical when compared to the broader Australian birthing population. The fact that the majority of women had achieved university level education needs to be addressed to a greater degree in the analysis as well as the discussion. At a minimum, the results should be reported taking into account the level of education held by women.

The degree to which knowledge scores improved may have differed according to a range of factors and this is important and useful information. Logistic regression analysis should be conducted to examine the possible effects of exogenous factors and maternal characteristics such as education, hospital site, model of care etc.

3. There are potentially important study site effects that may have impacted on the results. Given that one hospital was private and the other public there may have been important differences in the characteristics of participants as well as hospital practices. At a minimum this could have been addressed using logistic regression analysis. The authors should refer to Shorten et al (2005) regarding the results of an Australian multi-site RCT of a decision-aid where site effects were anticipated, analysed and proved to be quite important.

4. The complexity of the decision-aid in terms of length (55 pages plus worksheet) and reading level (grade 9.9) brings to question whether this would be usable for a broad spectrum of women and cost effective to implement in practice. Previous work by the NHMRC (2000) recommends a Flesch reading ease score of between 60 and 70 and Flesch-Kincaid Grade level between 7 and 8 (reading age 12-13 yrs). Although this decision-aid and its information appears
to have been accessible for women involved in this study group, it may not have been as successful in a healthcare environment where the education levels were lower. This is why it would be useful to explore the range of education levels within the analysis and identify the extent to which level of education has impacted upon results.

5. The tables provide limited information and need further work. Table 1 adds little to the paper and could either be summarized within the text or expanded to provide more information. Table 2 should provide statistical information for differences between the groups. Table 4 provides little useful information – it is unclear why baby sex and weight is included as an outcome of interest. There are many results reported in the text that do not appear in tables and should. For example intentions to use analgesia. Table 2 is referred to in terms of knowledge subscales (primary outcomes, paragraph 1) but this does not appear in the table.

6. Figure 1 highlights the fact that although there were 1065 eligible women only 627 were approached for recruitment. The process for selecting these women and not the remaining 438 eligible women should be provided. One assumes that it was a matter of stopping recruitment when the sample was achieved, but this should be stated if it is the case.

Minor Essential

The research question for this study is not posed specifically and really should be otherwise the reader is left to make assumptions about the research questions.

Reference 1 contains a spelling error for the word ‘experiences’

Discretionary Revisions:

The issue of cost associated with producing and implementing the decision-aid in practice should probably be mentioned given that the pamphlet may be a more cost-effective alternative for hospitals. Although the decision-aid was somewhat more effective than the pamphlet overall, the extent of the benefit may not be enough to justify the cost.

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

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests.