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: Richard Thomson

Reviewer's report:

This paper describes the results of a randomised controlled trial comparing a decision aid (two versions: one with and one without audio content) with “normal care”. The decision aid was designed in a robust fashion to support women in making prior decisions about pain relief in labour and this is, in itself, interesting in that the decision aid and support is being used well in advance of the time when the actual treatment (pain relief in labour) is implemented. It also differs from other decisions since the options are not exclusive and women may progress from one form of pain relief to another.

There is also considerable evidence that there is a disparity between women's expectations and experience (see Lally JE, Thomson RG, Murtagh MJ, Burges-Watson D, MacPhail S. More in hope than expectation: Women’s expectations and experience of pain relief in labour: A systematic review. BMC Medicine 2008 6:7 doi:10.1186/1741-7015-6-7). This paper is therefore an important contribution to the literature on decision support for shared decision making in an area that has some unique elements to it.

Major Compulsory revisions

It would help the reader to understand the results better if more detail could be given about both the decision aids and the pamphlet provided for the control group. The previously published protocol gives much detail on the development processes, but still leaves the reader with a number of questions. It would help if the authors could expand upon those details. It might be possible to provide at least the written decision aid on the web as an attachment to this paper or on their own website with a link. I think it is also important that the paper says a bit more about the type of information that was provided in both the decision aid and in the pamphlet. One of the key comparisons between the study arms was related to knowledge. The significantly increased knowledge in the decision aid arm might reflect a difference in content between the decision aid and the pamphlet of the control arm, rather than an inherent increase in knowledge as a result of engagement in shared decision making and use of the decision aid. This is an important issue that needs explanation and discussion.

It would also be helpful to understand how patient values were elicited and incorporated in the decision aid and the worksheet. Again it might be that some boxed examples of this would help to explain this to the reader.
I think that the authors rather overstate and over interpret the findings. When looking at the primary outcomes, there was no change in decision conflict, there was no increase in satisfaction, there was no reduction in anxiety but there was some increase in knowledge. How important this is depends at least in part on the above comments about the content of the decision aid compared to the pamphlet.

In terms of secondary outcome measures, there was a significant increase in those who felt they had enough information to make a decision, but this is not a large increase - and in both intervention and control the proportion feeling that they had enough information was high.

It was also interesting that in terms of their perception of engagement in decision making there was no difference between the intervention and control arms. If this was truly a decision aid supporting shared decision making one might expect that those using the decision aid would feel that they were more engaged in their decisions. This needs discussion.

It is stated that the decision aid group were more likely to consider their provider opinion and that there was a significant difference. However, this is problematic from two counts. First, it is not clear why one would expect a group who are using a shared decision making approach to be more likely to consider their provider opinion than those who are not. It raises a question to what is actually being measured here. Furthermore, there was no difference in the response to their perceived engagement between the groups - it would help to understand better how this difference in considering their provider opinion was measured. On the second point, perhaps more important, the P value for this is quoted as 0.14; i.e. not significant. Unfortunately the paper doesn’t include the actual numbers or percentages for this measure so it is difficult to see what is being measured here.

The authors might like to consider their results in the light of recent discussions about decision quality. For example see Sepucha, K. R., J. Floyd, et al. (2004). "Policy Support For Patient-Centred Care: The Need For Measurable Improvements In Decision Quality." Health Affairs Web Exclusive. In this conceptualisation of decision quality associated with shared decision making there are three elements. The first is that the patient should be well informed. Arguably (see comments above) the women in the decision aid arm were more knowledgeable. Secondly, their decisions should be consistent with their values. This is not discussed or addressed, but is worthy of comment if the authors have any data on this. An example of this might be a correlation between women who have a choice of mastectomy or breast conserving surgery for breast cancer and who express a desire to retain their breast ought to choose breast conserving surgery. Finally, the third element of decision quality is that their choice is followed through with. This is often not the case in this study, and the authors to be fair do discuss this in the light of the particular decision making processes, and the temporal nature of decision support and decision making in pain relief in labour.
In the discussion, the first paragraph rather overstates the findings.

Minor Compulsory revisions

- Reference 10 has been updated since the reference given.

- In the published protocol it states that the decision aid takes about 30 minutes to complete. In the present study it states that the audio guide itself is a 40 minute compact disc and the booklet 55 pages with a 4 page A3 worksheet. Is this really manageable in 30 minutes?

- In the text it states that the significant difference in knowledge “were consistent for all subscales within the knowledge questionnaire (table 2)”. These data did not appear to be in table 2.

- Satisfaction is stated as a secondary outcome in this paper, but was included as a primary outcome in the published protocol.

- The discussion suggests that there is a positive finding in “including care providers in decision making contrary to antenatal plans does not reduce satisfaction”. I am not clear what this means, nor why one would expect or highlight this as an issue. This needs clarification.

- In the discussion there is a statement that “labour staff preference and medical labour factors, other than the maternal preference have also been shown to have a significant effect on analgesic choice and these variables cannot be incorporated into an antenatal labour analgesia decision aid”. Once again it is not clear what this means; one of the functions of a decision aid to support shared decision making ought to be to enable that sort of discussion between women and labour staff/clinical staff in order to bring their perspective to bear alongside that of the pregnant women.

- With reference to the comments above about decision quality, I think the observation that in this setting it may preclude the appropriateness of decision follow through as a measure of effectiveness is an interesting one.

- There is a statement that “labour analgesia decision making may be driven more by values and norms than by risks and benefits”. I am not sure I see any evidence for this in the study, but this might be clearer is there were data available from the study on of alignment between values and decisions if that is possible.

Discretionary Revisions

- The introduction could be shortened.

- The MIDIRS leaflets quoted in references 12 does not really fit the Cochrane definition of a decision aid.
• Perhaps the authors could discuss a bit more the finding that those in the pamphlet group reported using other sources more frequently than the decision aid group. This seems to be a big difference (20% compared to 58%) and yet has a P value of 0.09. This seems odd given the significant findings for much smaller differences between groups, may be the authors should check their data.

• The poor follow through between analgesia intentions and use is an important observation, is consistent with other literature (see Lally et al above) and should perhaps also be included in the abstract.

• Is there any evidence that there was any impact on the utilisation of care in terms of appointments or length of appointments as a result of the decision aid implementation?

Level of interest: An article of importance in its field

Quality of written English: Acceptable

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

Declaration of competing interests:

I am involved in supervising a PhD fellowship that is focused on decision making in pain relief in labour