Author’s response to reviews

Title: Shared decision making when patients consider surgery for lumbar herniated disc: Development and test of a patient decision aid

Authors:

Stina Andersen (stina.brogard.andersen@rsyd.dk)
Mikkel Andersen (mikkel.andersen2@rsyd.dk)
Leah Carreon (leah.carreon@rsyd.dk)
Angela Coulter (angela@angelacoulter.com)
Karina Steffensen (karina.dahl.steffensen@rsyd.dk)

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Author’s response to reviews:

Dear Peter Schulz,

BMC Medical Informatics and Decision Making

Thank you for considering our paper for publication and for both reviewers very constructive comments. In the following I have tried to address/answer every concern raised by them.

Best regards,

Stina B. Andersen

Reviewer reports:

Tim Benson (Reviewer 1):

This is a useful paper. I liked the way that this paper shows that introducing SDM is by no means simple.
Major Points

1) The discussion on page 12 is about differences between CollaboRATE and DQW-HD. DCS is not mentioned at all in the Discussion, but it should be.

You are right, that DCS is not mentioned. The discussion is now changed, so that DCS is part of it. We have also chosen to focus the discussion of our findings on the fact that SDM could be optimized instead of the differences between the questionnaires.

“The baseline study showed us the need for additional support for SDM in the surgical clinic. We are aware of the dissimilar findings concerning the extent of SDM when we compared the different ways to score or analyze the questionnaires.. This becomes clear for instance when we look at the DCS score. The mean score is 18 and therefore below the threshold of 25, which is associated with implementation of SDM21. However, when we look at the score of each individual patient one third scored above 25. This indicates that the principles of SDM were not fully integrated in routine practice21. The CollaboRATE and the DQW-knowledge score supported this finding. The CollaboRATE topscore showed that one third of the patients did not reach gold standard of SDM and the mean DQW-knowledge score told us that on average patients only answered two out of five questions correctly. Information to the patients about the options could therefore be improved. Compared to Sepucha’s study 30 the mean DQW-process score found in our study seems to be fairly good.”

2) Table1 is confusing, especially the use of commas. For example, on line 3, does 85,7 mean 85.7. if so, it would be better to round up to 86, given relatively low n.

We have changed the table and presented mean and SD instead of medians (please see table 1) This makes it more comparable to findings from other studies, even though presentations of medians are more statistical correct. We have also dealt with the threshold of DCS, and presented the number of individual patients who are above and below the threshold score of 25.
3) It is not clear from Table 1, taken in isolation whether this refers to Before or After use of the PtDA.

We have added a line under the table saying that: The numbers presented in this table indicates the level of SDM before testing a PTDA in the current clinic.

4) It is clear from the text that Table 1 refers to Before. However, I had confidently expected to see a comparable After table. Why is it not here?

The idea of the baseline study was to confirm whether SDM was integrated in the clinical encounter when patients with LDH chose between surgical or non-surgical treatment.

A randomized controlled trial is being performed separately to study the effect of the PtDA. Results from the RCT will be published separately. At the end of the paper, in the last two lines, it is also stated: “What still needs to be confirmed is evidence of the tool’s ability to optimize the SDM-process. A randomized controlled trial is planned to test the effectiveness of the current LDH PtDA”.

5) I appreciated the supplemental material. I think that the references should be repeated in the supplemental material.

The references on each questionnaire are added in the appendix.

6) It was good to see the copyright notes included too.

We are not quite sure, what is meant by this comment. The word BESLUTNINGSHJÆLPER has a Trademark. If relevant we can add the approval from the Danish Patent and Trademark Office. If so please let us know and we will add it as an appendix.

Collaborate is really about the patient’s view of their doctor at a specific encounter. DCS is about the patient. DQC-HD is also about the patient but is more like a knowledge test.
We assume that this comment is a prolongation of point 1?

Minor points

7) P5 L120 I think DCS is "Decisional Conflict Scale", not "Decision Conflict Scale"

You are right; it has been changed to decisional (Page 5, line 126).

8) P6 L130 The PtDA is generic, not specific to LHD. It may be useful to say that the adaptation is discussed below. The references (22-24) do not appear to cover a full description of the generic PtDA. It might be useful to clarify that reference 25 does this and to move it above 22-24.

This is a very good point. Nov ref. 25 is changed to ref 23, and is added right after the generic template is mentioned (Page 6, line 136). We have also added a sentence at page 6, line 140: “as described by Olling et al”.

9) P6 L133 I am not sure that a paper leaflet can consist of a frame and a set of cards. Please clarify.

The sentence has been changed from: “The BESLUTNINGSHJÆLPERTM is a folder containing loose-leaf cards, called option cards (Figure 2)” to “The BESLUTNINGSHJÆLPERTM is a folder containing loose-leaf cards, called option cards (Figure 2)” (Page 6, line 137-138).

10) P8 L176 It would be good to know how long each interview took

This is a very good point. Unfortunately we did not record the time spent on the interviews.
11) It would be useful to include both a word count and reading age calculation in the results. For reading age The Flesch-Kincaid Grade might be used to measure reading age as it is a core part of Microsoft Word. It is not clear how health literacy has affected the results.

Thank you for your comment on the reading age calculation and you are right that health literacy is an important factor in decision aids. Our PtDA is primarily a visual aid, made by designers, with very little text and short sentences, and therefore a low readability index (LIX=32), which can be interpreted as an easy text to read. What also needs to be taken into account is that the PtDA is used in the consultation, so the content is also explained to the patient by the clinician.

A short paragraph about this is added at page 12 lines, 287-291:

4.3 Readability index

The PtDA designed in this study is primarily a visual aid, made by designers, with very little text and short sentences (Figure 2). The readability index of the overall text, can be interpreted as an easy text to read (LIX=32). What also needs to be taken into account is that the PtDA is used in the consultation, so the content is also explained to the patient by the clinician.

Collaborate is really about the patient's view of their doctor at a specific encounter. DCS is about the patient. DQC-HD is also about the patient but is more like a knowledge test.

Is this perhaps part of point 1?

Chen Liang, PhD (Reviewer 2): This paper described the development of a decision aid tool (leaflet) with the goal of improving the shared decision making process in Lumbar Disc Herniation (LHD). The lack of decision support on surgery for LHD is an unaddressed problem. Overall the study is well conducted. The methods used in this paper is valid in general but with a few major concerns detailed below. The data can support research questions and conclusion. In addition to the strength, please find my major concerns for authors' reference.
1) A major concern is that the proposed decision aid tool may be less compatible with the fast-growing health information technology, therefore may have reduced potential to inform the state-of-the-art studies in health informatics and clinical decision support. For example, how would the proposed tool be incorporated with electronic health information and integrated health data?

Your concern is very understandable. It is important though to point out that patients actually preferred a paper version of a PtDA, rather than an electronic-based app or web-system; (please see ref 22, Olling et al). The PtDA has a date for print and an update date is also stated. A name for who is responsible for the tool is also specified.

In our following RCT study this PtDA is actually supplemented by a prognostic it-tool. During the decision making process electronic information can easily be incorporated in the consultation. The PtDA serves as a guide in the communication, in order to aim for making shared decisions.

2) The rationale between step 1 and the other steps seems not clear. The result of step 1 suggested that a certain proportion of patients are not engaged in shared decision making. But this finding does not necessarily serve as a strong reason for the following steps (development and testing for the decision aid tool) because the finding didn't suggest that the lack of engagement in shared decision making is caused by the missing decision aid tool. Please justify.

Thank you for pointing out the unclear link between step 1 and 2. We have changed the beginning of the method paragraph from:

This current study was conducted in four steps (Figure 1). Step one was to evaluate if SDM was already implemented in the decision making process. The second step was to develop a PtDA to support SDM. In step three the usability and acceptability of the PtDA was tested systematically among potential users (patients) and finally in step four the usability was tested in the clinical setting.

To:

This paper describes four steps (Figure 1). In the initial step, we did a baseline study, to evaluate to what degree SDM was implemented in the decision making process. The result of the baseline study showed a need to optimize SDM in the clinic. Knowing that PtDA’s can be useful to
support SDM we decided to develop a PtDA to support SDM as the next step. In step three the usability and acceptability of the PtDA was tested systematically among potential users (patients) and finally in step four the usability was tested in the clinical setting.

(Please see page 5 – line 114-117)

3) There are several mentions of "literature review/search" as part of methods in the manuscript. However, the procedure of literature review is missing. Without a description of how literature review is done, it is inappropriate to discuss what has been found in by the literature review. For example, Line 225, "The literature review helped to assess the effects of surgery versus non-surgery treatment." In Line 302, "In the literature search we were not able to find evidence based exact numbers to present how often symptoms would decrease spontaneously, the risk of permanent nerve-damage with no surgery or how long pain could be expected to last."

We understand the concern about the literature search. We initially decided to leave it out due to the limited word count in the paper. We have now made an appendix describing the search string and strategy briefly. Please see appendix II. We have also added a reference to the appendix in the text page 7, line 160).

4) Since there are multiple steps participants are engaged, it is suggested to clarify whether these participants are repeatedly recruited. This is important information for evaluating the design of studies.

Thank you for this relevant comment. We have added two lines at page 5, line 120-122 saying:

Each of the different steps involved different clinicians and patients to ensure input and feedback from as many potential users as possible and thereby, development of a more applicable PtDA.