Author’s response to reviews

Title: Can Shared Decision-Making Reduce Medical Malpractice Litigation? A Systematic Review

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The letter pasted below is also attached.

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Dear Editor,

On behalf of all co-authors, I would like to thank you very much for giving us the opportunity to submit a second revision. We appreciate the reviewers’ and Editor’s thoughtful comments and have addressed them to the best of our ability. We have worked hard to revise and improve this manuscript, and feel that we have taken the analysis as far as the data justify. Prof Elwyn, who is the senior author on this paper, shares my view, as do other co-authors. As discussed at length in the manuscript, the small sample and heterogeneity of studies included does not warrant further elaboration.

We believe that this manuscript addresses an important research gap, which many have hypothesized about, but one that has never been investigated systematically before. Despite limitations highlighted above, and in the manuscript, this topic is of importance. In our view, the gap in the literature deserves to be brought to the attention of a wide readership. The small number of empirical studies in this area is the mere reflection of methodological challenges in gathering this type of data but does not undermine its importance or relevance.

We hope our revised manuscript is now acceptable for publication in BMC Health Services Research and look forward to your response.
On behalf of all authors,
Yours sincerely,
Marie-Anne Durand
Reviewer 1
1. “Please separate Appendix 1-search strategy from Study protocol.”
   # We have created an additional supplementary file with the search strategy.
2. “Please separate PRISMA checklist as an appendix.”
   # We have created an additional supplementary file with the PRISMA checklist.
3. “Quality ratings are quite unclear. Please avoid using overall score to describe study quality. Please add a separate table to list all quality items you used for each study.”
   # Overall quality scores are commonly used in systematic reviews. The reviewer’s request does not seem justified and would not add a lot of value to the manuscript. Given the heterogeneity of included studies (which is amply described and discussed throughout the manuscript and in the discussion section), we had to use three different scales, two of which are qualitative. What the reviewer suggests isn’t feasible in the context of this narrative synthesis with a very small, and heterogeneous sample of included studies.
4. “Search method, please add Keywords used in the search.”
   # The keywords and MeSH terms are listed in the complete search strategy, which was already provided in the study protocol and is now available, at the reviewer’s request, as a separate supplementary file.
5. “It's still not clear about the study outcomes. "All study outcomes" is such a broad term that can range from patients health outcomes to court decisions. Do you mean outcomes related to litigations? Please be more specific on this.”
   # The detailed list of information and outcomes extracted from all included studies had originally been removed from the manuscript to reduce the word count. We have re-integrated this information on page 7 in order to address the reviewer’s comment. We have also specified on page 6: “We included all study outcomes related to litigations.”
6. “It's unclear how your Narrative Synthesis section can fit in the framework (Figure 1). The themes should be presented in a way that can be a part of the
framework. And also please list any items in the framework was not identified by the literature.”

# All themes, except for theme 4, are aligned with the model represented in Figure 1. In order to facilitate the association between the themes discussed in the results section and Figure 1, we have reworded theme 1: “Respecting patient preferences”.

Theme 4 is not a theme that we had anticipated to find or one that we had identified as prominent when developing the ‘theory of change’ presented in Figure 1. It is a theme that naturally and very strongly emerged from our analysis. We have added the following paragraph on page 10:

‘Three out of four themes are closely aligned with the theory of change, which we had developed before undertaking this analysis and which is represented in Figure 1. However, theme 4 is one that naturally emerged from the data analysis, and which we had not anticipated or identified as prominent.’

7. Some terminologies were not described, such as decision coaching (in figure 1), and self determination. 

# In an attempt to simplify the manuscript and improve its readability and accessibility, we have removed the term self-determination from the manuscript, except on page 12, where it is used to describe the outcome of the lawsuit and is extracted from Um’s case study. In this context, it is not necessary to define this term. Decision coaching is only used once in Figure 1 as an example of one possible type of intervention, which might be used to promote SDM and may thus contribute to reduce litigation. As discussed in our response to comment 6, the model presented in Figure 1 is a theoretical model, and by definition, is hypothetical. In accordance with the ESRC guidance for narrative synthesis, it was developed before starting the data analysis. We expected to find studies that would have evaluated the impact of several types of interventions on litigation. Decision coaching was one of them, but was not featured in any of the studies included in the review. Therefore, defining this term does not seem necessary and would unnecessarily complicate the methods or results sections.

8. I agree with Dr. Wolf’s comments on "standard of care". The response is not adequate. Please consider to address the comment.

# The following paragraph has been added on page 18 of the discussion section:

‘Finally, and in relation to Barry’s study, it is worth noting that, in medical malpractice, the determination of whether or not a ‘standard of care’ is met is typically determined by medical experts, and not by lay people, although the jury would make the final decision. The findings of Barry’s study thus need to be interpreted carefully. In a real case of medical malpractice, the jury’s final decision might have been influenced by the experts’ discussions and opinions as
to whether or not the standard of care had been met, which was not the case in Barry’s study.

9. The difference of study designs, qualitative descriptive case review, case studies, qualitative study, is confusing. These are all qualitative studies to my view. Please consider to group them together.

# We thank the reviewer for this comment. We have removed the term qualitative descriptive case review from the manuscript as it was introducing unnecessary confusion. We have therefore reworded the sentence on page 9 (see below) and revised Table 1.

“They encompass the following study designs: Four qualitative studies (including two case studies) and one quasi-experimental design.” We feel that is it important to make a distinction between the qualitative studies that used a case study approach and those that didn’t. The differences in design, and methods of data collection and analysis are such that it warrants a distinction, particular in the legal context, and justified using a separate quality appraisal tool for the case studies.