Author's response to reviews

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

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Author's response to reviews: see over
Dear Editor,

On behalf of all co-authors, I would like to thank you very much for giving us the opportunity to submit a revised manuscript. We appreciate the thoughtful reviewer comments and we have considered each recommendation very carefully. As you will see in our point-to-point response to the reviewers, we have made every attempt to incorporate these suggestions as thoroughly as possible. We are grateful for the comments that have considerably improved the manuscript.

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: Aaron Leppin

Reviewer’s Report:
“Thank you for the opportunity to review this timely and methodologically sound article. Although limited by the quality and quantity of available evidence, the authors have taken on the difficult task of attempting to answer a key question of interest to many stakeholders. I feel that the manuscript represents a sizable and scientifically guided body of work. A challenge that the authors (and reviewers) must deal with is that there is no completely appropriate “label” (that I’m aware of) for this review as it was undertaken. In truth, this is a systematic review. Although synthesizing the evidence necessitated the use of narrative synthesis principles, the systematic approach and comprehensiveness should make the product of higher value than typical narrative reviews. To maintain the rigor and objectivity expected of a systematic review, however, particular effort must be taken to stay within the bounds of the available data, to adhere to systematic and structured reporting principles, and to caution readers regarding the confidence one can have in conclusions drawn from this work. Given the disclosed conflicts of one author, these matters seem particularly relevant. I ultimately support the manuscript under consideration, but before I can advocate for publication, I feel that more work must be undertaken to present the methods and results more clearly and transparently. I hope and believe my proposed edits will serve the authors well and enhance the value of the final product.”

We thank the reviewers for the positive feedback and very helpful considerations and suggestions. We have endeavored to address all comments fully.

1. Major Compulsory Revisions

1.1. “The Abstract needs improvement. At current, the abstract is poorly organized and does not reflect the substance of the manuscript itself. It also does not adequately report the methods used. Unless required to use current headings by journal policy, I recommend structuring the abstract along PRISMA guidelines. I think the background could be condensed to one brief statement followed by the study aim. Your background statement should be reflective of the contextual imperative for the work (perhaps something like: Many believe that SDM reduces the risk of litigation and some advocate it as a more meaningful way of ensuring the objectives of informed consent are pursued. The aim of this study was….). The methods section is merely a list of databases searched. It tells the reader very little about what you did. (Perhaps try something like: We searched for any articles that had primary data and met such and such criteria within electronic databases. We also hand searched references, contacted study authors, etc. Acting independently and in duplicate, we screened eligible studies and extracted such and such. Due to the number and heterogeneity of included studies, we conducted a narrative synthesis in accordance with such and such guidelines, identifying data topics and outcomes that occurred across studies and commenting on the direction, magnitude, relevance, and context of measured effects.) The results section needs more structure. At current, it reads as a haphazard list of jargon-filled statements. Because you do not currently mention that a narrative analysis was done, the reader is left wondering where this
information came from or if it is anything more than commentary. The results should be structured to reflect the structured nature of the analysis. (Perhaps try something like: the synthesized data suggest that 1) SDM may improve pt satisfaction and reduce the risk of medical litigation, 2) many healthcare providers remain skeptical of SDM, 3) documentation of decision support may offer some level of protection, 4)...., and 5)....). Be certain that the results to not overstep the data and that no results are left out without reason (i.e. either restrict to a priori outcomes or include everything). Please stay away from jargon in the abstract (failure to inform claim, defensive medicine, etc). Also, it is clear to me after reading the paper that establishing SDM as a way to engage in informed consent is a question of interest. This is not mentioned in the abstract background nor is it explored in the methods. Commenting on this matter in the results (is it even a result? Did data guide this determination?) and conclusion is out of context and confusing to the reader.

We have rewritten the abstract entirely and have structured it according to PRISMA guidelines, as suggested by the reviewer (see page 2 and 3 of the revised manuscript).

1.2. “The introduction needs reorganization. I feel that most of the information a reader needs to understand the context and science of this work is found somewhere within the manuscript, but it is not well organized and is rather frustrating to read. For example, I felt that much of the information in the discussion would have been useful to me earlier in the paper. (also, terms like “defensive medicine,” “perfected informed consent,” “failure to inform claim,” “shared decision making” and “informed consent” are thrown around in the paper before they are ever explained or defined—if indeed they ever are) Latter parts of the manuscript are written much more clearly and with better grammar than earlier sections. Indeed, in some cases, information given in the discussion is just a more clear and focused version of that given in the introduction. Most of this information would be more appropriately and usefully placed within the introduction.

To help orient the reader, I recommend restructuring the Background/Introduction section such that concepts are introduced in a more logical sequence and explained and defined more clearly and that jargon is minimized (this is more likely to require cutting material rather than adding). I will leave it to the authors’ discretion to make these improvements, but consider a variation of the following outline as one potential approach:

1. Introduction to informed consent and its inadequacies (current comparison with other studies paragraph 2, 3)
2. Importance of good communication and its effects on litigation (current background paragraph 3, 5)
3. Introduction to shared decision making, how it differs from good communication, and its claimed effect on litigation (current background paragraph 4, 5, discussion 1)
4. Proposed advantages of shared decision making over informed consent (current paragraph 2)
5. Current medico-legal landscape (current paragraph 1, comparison with other studies paragraph 4)
6. The imagined state of shared decision making as a replacement of informed consent (can you be more explicit about how this would be different and/or what
it might look like?)
7. The objectives of the study”

The introduction has been restructured entirely and partly rewritten in order to address the reviewer’s comment (see page 2 and 3 of the revised manuscript).

1.3 “The inclusion criteria need more specificity. The “outcomes” that studies had to assess to meet inclusion criteria are confusing. The first option was that, to be eligible, studies could assess the effect of SDM on litigation. The second option was that studies could assess the effect of promoting patient participation and/or eliciting patient preferences on litigation (presumably implying that these things are/can be somehow separate from SDM). The third option is to explore the influence of SDM (which is then defined in parentheses as the very thing assessed in the second option) on litigation or on intention to litigate. If SDM and patient involvement/elicitation of preferences are the same thing, then the first two options can be combined. If they are not, then I believe the third.”

The inclusion criteria have been reworded to improve clarity (see page 7 of the revised manuscript).

1.4. “The Results should adhere to a more structured presentation. This review included studies that assessed one of three outcomes (or perhaps 2 or 4). (i.e. the effect of SDM on litigation, the effect of patient participation or preference elicitation on litigation, and the potential influence of SDM on litigation or litigation patient intention to litigate) It would be helpful if results were reported and summarized per outcome (including number of studies contributing and data format, direction, and magnitude of effect, along with an expression of confidence and/or quality). A results table would be the ideal way to present this data, but it may be that the included studies are simply too different to estimate their pooled effects on the outcomes of interest in any way. Still, if the 5 included studies cannot be reliably traced back to their original inclusion criteria, then it raises questions about the particular rationale that guided their inclusion. At minimum, Table 1 should be modified to include some of this information by adding a couple columns; (i.e. one indicating the inclusion criteria/on met based on intervention/outcome). Finally, the results should incorporate the findings of the narrative synthesis process (described below).”

Given the paucity of research in this area, we chose to include all study outcomes in the analysis. However, given the heterogeneity of the included outcomes, we weren’t able to report and summarize the results per outcome. We were forced to summarize the results thematically instead. We have added clearer theme name and numbers, revised the paragraph describing the analysis and added more details.

1.5. The narrative synthesis process should be explained more clearly. I have no objections to the use of narrative synthesis as a method to synthesize the data. However, (especially because this was not the planned approach), the authors should provide more detail regarding the rationale for choosing to do this. The results of the 5 studies could simply be summarized in text and highlighted in a table, for example, along with a comment about the inability to do a meta-analysis. I presume that the goal of the narrative synthesis was to make
overarching conclusions based on a very heterogeneous body of evidence. It would seem to me that, because this synthesis was conducted after a set of studies identified by strict inclusion criteria were selected, the inclusion criteria that guided the accumulation of the studies should direct conduct of the synthesis and the reporting of results. I believe that, given the theoretical model you used to guide the synthesis, this was the case here. If so, the results of the narrative synthesis should attempt to answer one or more of the questions posited as review objectives (i.e. determining the effect of SDM on litigation, etc.). It remains unclear to me the actual steps taken in conducting this synthesis and what occurred within each. The text says that “The preliminary synthesis was undertaken using the extracted data organized in a tabular form. The direction and size of the effect reported as well as study quality were examined and the relationships and patterns in the data were subsequently synthesized. Finally, the robustness of the data trends was assessed against the variable outcomes, study designs, populations, and contexts.” This described approach is not consistent with the presented data. Please provide more detail (ideally through a figure and/or table) of what happened at each stage of this process and report the results of this analysis more transparently. For example, what was the extracted data? What relationships and patterns were identified? How was the data synthesized? What were the determinations of the robustness assessment? At current, the “results” from the narrative synthesis seem nothing more than commentary; it is unclear to the reader what criteria were used in selecting the outcomes and text that are reported from each study and what guided interpretations. If these issues cannot be addressed, perhaps this paper is best split up into a systematic review and a narrative commentary.

The narrative synthesis is now described in more detail and relevant sections have been rewritten.

2. Minor Essential Revisions
The author can be trusted to make these. For example missing labels on figures the wrong use of a term spelling mistakes.

2.1. “I recommend placing inclusion criteria before search methods. This is also more consistent with PRISMA.”

The change has been made on page 6 of the revised manuscript.

2.2 “Because you report a method for dealing with disagreements, it implies studies were screened in duplicate, yet you do not say this in the search section; I recommend adding this as it attests to the quality of the work.”

This is described on page 6: “three researchers independently screened the title and abstract of retrieved records. Disagreements were resolved by discussion. Two researchers independently screened full-text articles.”

3. Please be more explicit in explaining the confidence one can have in conclusions made based on this review. Similarly, consider pointing out the limitations of the body of evidence related to this issue and the need for future study, etc. Ideally, a formal expression of confidence (i.e. a GRADE rating or
something similar) should accompany any statements or conclusions made from
the review. It should be authors’ discretion on approach taken, but this needs to
occur in some way.

We have added such statement in the discussion and conclusions of the revised manuscript.

4. “Please temper the tone and focus the content of the conclusion section.
Restrict it to conclusions that can actually be drawn based on the conduct of this
review. Currently, it reads as very prescriptive and does not qualify the
conclusions made in light of the very weak and limited evidence. It also includes
background information and a large amount of opinion. This material is better
suited for the discussion section and/or a section on implications or
recommendations for future study or left out completely.”

We agree with the reviewer’s comments and have revised the conclusions.

5. “It is unclear to me how you delineated a distinction between “person-centered
communication and satisfactory provider relationships” (which you claim in the
comparison with other studies section has been extensively evaluated in regards
to its connection with litigation risk and would be ineligible for this review) and
“processes and interventions that go beyond good communication” which
describe study interventions eligible for this review.”

The focus of this review was on shared decision-making and related interventions. It is
indeed very important to make this distinction, and the manuscript (introduction and
discussion) has been revised to this effect.

6. Explain where the topic headings in narrative synthesis come from. If this is
the result of the synthesis (i.e. themes identified), it needs to be explained and
highlighted as such. Some are presented as questions, others as ideas. If they
are truly results, they should be statements. If they are questions and/or ideas,
why are they in the results section?

As explained above, these are indeed the themes that emerged from our analysis. We
have added a paragraph in the results section to clarify the method used and emergence of four
distinct themes. We have also reworded some of the themes in light of the reviewer’s
comments.

7. Beckman should be framed more objectively. It appears that most of what
accounted for litigation could be described as poor communication and care that
was not centered on the patient; arguably, this information is irrelevant as it is not
within your inclusion criteria and a good deal of this information was already
excluded. Matters evaluated that you claim are “specific to SDM” are not well
described, do not all seem specific to SDM, and are actually identified in a very
small minority of cases anyway, seeming to suggest that these factors play a
minor role in litigation. Please clarify this.

We have taken the reviewer’s comment on board and have amended the paragraph
describing Beckman’s study to improve objectivity and avoid extrapolating.
8. Regarding the Um case, it seems quite clear that efforts to further engage patient in decision making could have avoided litigation in this case. On the other hand, the suit was made on the grounds of negligence and the law in place respected the woman’s right to self-determination. From a legal standpoint, then, it seems laws are in place to discourage this sort of behavior. Perhaps you could articulate how SDM promotion might act to prevent these scenarios more effectively?

In order to elaborate on this important point, we have added a paragraph on page 19 (discussion section) of the revised manuscript.

3. Discretionary Revisions
3.1. Please improve the clarity of the writing, avoid jargon, and streamline to essential points. Do not introduce concepts without first defining them. Avoid excessive wordiness.

The entire manuscript has been revised to address those points.

2. You defined SDM interventions as the use of tools or strategies designed to engage patients in medical decision-making and/or facilitate SDM and patient activation or self-determination in the medical encounter. You also state that you excluded studies that exclusively examined the impact of communication skills, provision of information, or informed consent alone, without considering the effect of patient participation and/or elicitation of patient preference. Many “definitions” of SDM exist. Please state more explicitly the definition and criteria used when determining whether SDM was a component. For example, why are flyers and pre-encounter information decision aids considered SDM? Is it purely based on what they are DESIGNED to do? How can this be objectively assessed? How do we know informed consent forms are not DESIGNED to accomplish patient participation and/or elicitation of patient preference? The whole idea of distinguishing SDM from person-centered communication from informed consent seems rather messy to me. I put this in the discretionary section because I think it’s an inherent problem of the field and not much you can do anything about! Perhaps it is worth mentioning in the limitations, however.

The definition appearing in the manuscript was derived from the definition used in the Cochrane systematic review of decision aids for people facing health treatment or screening decisions. We have added a reference and reworded the paragraph.

3. The figures I received are not publication ready and do not display all text. I think more useful figures would describe the narrative synthesis process.

The figures have been revised.
Reviewer 2: Leslie Wolf

1. Major Compulsory Revisions

1.1 A definition of “shared decision-making” should be given early in the paper to ensure that readers have a clear understanding of what the authors mean by that term and how it difference from “traditional means of obtaining informed consent.” This is especially important as some of the US state laws seem to equate “shared decision-making” with the tools used to facilitate shared decision-making.

A definition of shared decision-making is provided on page 5 of the revised manuscript.

1.2. On page 5, lines 90-93, given the impact of shared decision-making on patient decision-making (supported by studies), it was not clear why reducing litigation was “important,” especially as some studies have suggested that fewer patients sue than are injured by malpractice. But two possibilities for reframing came to mind: 1) demonstrating reduction of litigation could increase uptake of shared decision-making (with the additional benefits indicated) or 2) shared decision-making presents a relatively easy tool to reducing “preventable litigation” (to borrow from the medical error literature).

We agree with the reviewer’s comment and have reframed the aim of the study as suggested above, using the term preventable litigation.

1.3. The case on page 11, lines 211-221, is both fascinating and distressing. However, I was not sure whether it advanced the authors’ arguments regarding shared decision-making since the patient expressed her preferences, which were overridden. This doctor did not seem likely to engage in shared decision-making, no matter what the incentive. Perhaps the authors could make it clearer what this case adds.

This study met our inclusion criteria and was thus included in the systematic review. The implications of this case study in the context of shared decision making are now discussed on page 19 of the revised manuscript.

1.4. There is a problem with discussing “standard of care” in the context of what lay people think (e.g., lines 330-338, p. 16). I recognize this comes from the interventional study. However, the issue of “standard of care” in malpractice is typically determined by the practice in the profession – i.e., by experts. Granted, a jury makes the final determination (based on what they’ve heard). It is at least worth putting this issue into context.

The discussion of standard of care was part of Barry’s paper. We are reporting it as part of this review and are thus not responsible for the association between this term and the involvement of lay people in the study.

1.5. In the results (p. 19, line 422-424), there is the statement “Most legal-systems, and some health care providers, are slow to view that respecting information patient preferences should be the new standard of care.” This (without more) seems like an overstatement to me. My own view is that there are many ways
that the legal system (at least in the United States) recognizes the obligation to respect patient preferences, even if there are exceptions to this. For example, while certainly imperfect (especially in practice), the informed consent doctrine embraces this. I don’t think I’m alone in my view, so I would encourage the authors to provide a little more explanation as to why they reach that conclusion.

We agree with the reviewer and have removed this sentence from the discussion.

1.6. Page 2, line 24, “Introducing” should not be capitalized.

The abstract has been entirely written and the word “introducing” has been removed.

1.7. Page 16, line 330 – delete “from” after “beyond”

The manuscript has been substantially revised throughout and these words have been deleted.

1.8. Page 17, lines 367. This sentence needs to be clarified. Filing a “complaint” is typically the start of “litigation,” unless the authors do not mean the filing of the formal pleading (complaint) to initiate a lawsuit. I have an idea what is mean, but I could be misinterpreting it.

This sentence has been reworded to address the other reviewer’s comments and these words have been deleted.

1.9. Page 18, lines 397-399 – The discussion of Kerry O’Connell is not helpful. This is not a case that has been previously introduced, and there is insufficient information included to understand the significance.

We agree with the reviewer. The entire paragraph about Kerry O’Connell has been removed.

1.10. The figures seem to have had some text cut-off (esp. 3rd level). This needs to be corrected.

The figures have been corrected.

2. Discretionary Revisions

2.1. Although I am not qualified to evaluate the quality of the systemic review, the limited number of studies for inclusion does seem to limit what can be concluded from the systematic review. I will comment that I found the description of how the systematic review was conducted quite clear. I do seem some concerns with including studies from different legal environments (US, UK, and Korea), especially given the small universe of studies. However, I’m not sure this can be avoided with any evaluation of laws (even within the United States). I do think it is important to highlight that none of the studies tested directly whether litigation was in fact reduced, even though those are studies that likely cannot be done.
We agree with the reviewer and have made it even more explicit in the abstract, results and discussion sections that none of the studies provided empirical data to determine whether or not litigation can be reduced.

2.2 Page 5, line 85, “Nonetheless” doesn’t seem to be the right opener. It felt more like “an additional benefit” of shared decision-making.

“Nonetheless” has been removed.

2.3. Page 10, lines 205-6, the quote does not seem connected to the rest of text. Some commentary to set it up would be helpful, if you keep it.

We agree with the reviewer’s comment. The quote has been removed.

2.4. In introducing the case on pages 11-12, lines 228-251, I would suggest making clear that this set up one of the studies in the systematic review. As it stands, it was a bit confusing how it fit (as the MD seemed to engage in at least some form of shared decision-making).

The sentence has been reworded (see page 12 of the revised manuscript).

2.5. Page 16, line 347 – is “global” used to mean “internationally” or “broadly”?

This term has been removed.