Reviewer's report

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

**Version:** 2  **Date:** 16 September 2014

**Reviewer:** Aaron Leppin

**Reviewer's report:**

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.

- **Major Compulsory Revisions**

The author must respond to these before a decision on publication can be reached. For example additional necessary experiments or controls statistical mistakes errors in interpretation.

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.

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

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 option needs to be split up. Perhaps I am misinterpreting. Please clarify.

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).
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.

- 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.

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

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

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.

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.

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.

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?

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.

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?

- Discretionary Revisions

These are recommendations for improvement which the author can choose to ignore. For example clarifications data that would be useful but not essential.

Please note that both the comments entered here and answers to the questions below constitute the report bearing your name that will be forwarded to the authors and published on the site if the article is accepted.

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.

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.

3. Please consider adding primary empirical data as an inclusion criteria.

4. 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.

Again, thank you for the opportunity to review your work. I truly hope you find this feedback useful and that it helps you structure a more clear and valuable research product.

**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 declare that I have no competing interests