Author's response to reviews

Title: Shared decision making for patients with type 2 patients: a randomized trial in primary care

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Author's response to reviews: see over
Dear Editors

Enclosed please find our revised manuscript entitled Shared decision making for patients with type 2 diabetes. A pilot, clustered randomized trial in primary care for consideration of publication in PlosOne,

This original manuscript reports on clinical trial results of the impact of decision aids use with type 2 diabetic patients and primary care clinicians compared to usual care in the discussion of medication management. The results come from patient and clinician reported outcomes, medical records and pharmacy records that were obtained from the randomized trial of decision aids (Diabetes Medication Choice and Statin Choice). This work builds on the body of evidence that evaluates decision aids and the role of shared decision making within the clinical encounter, evaluating the outcomes and experience from both the patient and clinician perspective.

This is the second submission of this manuscript. Below is a list of modifications that were made after addressing the reviewers’ comments, these changes were also highlighted in the text for ease of review. We have also provided point by point responses to the reviewers addressing each of their concerns below.

Sincerely,

Victor M. Montori, MD, MSc
Professor of Medicine
Mayo Clinic
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Changes to manuscript:

1. Formatted section headings throughout paper
2. Under ‘Participants’ added the line ‘Minimal training was provided to clinicians that consented to participate [10].’ (page 4)
3. Added reference to decision aids in appendix (Appendix A). (Page 5)
4. Changed ‘post-visit’ under ‘Decisional outcomes’ to ‘after the clinical encounter with their clinician’. (page 5)
5. Added ‘Knowledge Transfer’ and ‘Knowledge of Risk’ for references to analysis under ‘Decisional outcomes’. (Page 5)
6. Added ‘created by our team’ the fidelity checklist description under ‘Decisional Outcomes’. (Page 6)
7. Changed Appendix reference for patient results from ‘A’ to ‘B’ under ‘Results’. (Page 9)
8. Added ‘at baseline’ to knowledge transfer results under ‘Decisional outcomes – patient outcomes’. (Page 10).
9. Removed text from ‘Implications for Policy, Practice and Research’:
10. Added text to ‘Implications for Policy, Practice and Research’: “We have been able to conduct trials of decision aids for use during the consultations of people with diabetes in academic subspecialty and primary care and, in this study, in nonacademic primary care settings. In these contexts, the decision aids have been well received by patients and clinicians, have improved decisional outcomes, and have not had favorable impact on adherence or clinical outcomes. Research to select patients most likely to benefit from SDM and to explore ways to improve high-fidelity delivery of the tools may improve their clinical utility. Yet, their value as promoters of patient-centered practice and patient engagement remains, in our view, the most important justification for their use. We do not think these results will satisfy those pursuing legislation of SDM seeking reductions in healthcare utilization and costs [18].” (Page 14)
11. Replaced ‘Thankfully, it’ with ‘The act also’ under ‘Implications for Policy, Practice and Research’ for the sentence addressing PCORI. (Page 14)
12. Replaced ‘with a focus on informed decision making’ with ‘and communication of evidence through SDM’ to the end of the sentence addressing PCORI. (Page 14)
13. Revised the sentence ‘Thus, current federal policy strikes the right balance, supporting more research before rushing to implementation’ to ‘In our view, current federal policy strikes the right balance, supporting additional research rather than mandating implementation’. (Page 14)
15. Table 2a, changed number of responses in knowledge at 3 and 6 months. Responses from statin patients were included in error. Added, reference for the sample size included
16. Table 2b, added number of missing values
17. Table 3, added “OPTION) to ‘level of patient engagement’ for clarification.
Response to reviewers (receipt of review 3/17/2013)
Reviewer 1:

METHODS
1. Add - earlier in the paper, in the methods section - information about your tactic to provide minimal training to clinicians: What training was provided to clinicians on how to use the decision aids to create shared decision-making? Why was it "minimal"? Was the checklist referred to in the Results section provided to them? What did the checklist consist of?
(Research has shown the importance of clinician training to the successful implementation of an innovation to their workflow.)
"Patient-centered decision making means a process that involves directed interaction between a health care professional and the patient or the patient's legal representative to assist the patient in understanding the patient's health condition, available treatment options, and the benefits and harms of each option, and in deciding what treatment is best for the patient based on the patient's circumstances, values, and preferences. The interaction may be conducted by a health care provider or through the use of patient decision aids, or both.” (Definition from Journal of the Senate, State of Minnesota, May 11th, 2011.)

Response to the reviewer: We agree with the reviewer that details of the training are important. The reason this is not described in detail in this paper is that we published a protocol paper in which we provided details about this training. Since this paper is in the public domain in an open access journal, we believe it might not be adequate use of resources to reproduce those details here. To better guide the reader of this report, we have added a statement in the methods section (page 4 under Participants) about clinician training and directing the reader to reference 10, the protocol paper, for further detail.

Training in the use of the decision aid that seemed necessary at the time of designing this trial was deemed minimal given that the design process we used to produce the decision aid resulted in a tool that fit the flow of the consultation, since it was designed within it with active participation of clinicians and patients. The training included demonstration, videos, storyboards, and feedback.

The checklist was not provided to the clinicians. Rather it was created to review the video recordings to note which of the aspects considered important in delivering the tool were covered during the visit. The design of the tool is flexible enough to accommodate visits in the real world; providing the checklist might have given the impression to clinicians that they should “cover” all the aspects considered in the checklist with all patients, reducing the fit the tool might have in certain encounters with certain clinicians and patients.

2. Knowledge transfer at baseline is reported in Table 2a, but not easily found in the methods. Was this the video data? Or was there a survey immediately after the clinic visit?
Response to reviewer: A survey was provided to the patients immediately after the encounter where patients in the diabetes group answered questions about antihyperglycemic agents, and patients in the statin group answered questions about their 10-year risk of having a cardiac event and about statins. This has been clarified in the outcomes section (page 5, decisional outcomes).

Minor Essential Revisions
1. Appendix: Add the decision aids (pamphlets) to the Appendix. I did review them from the link provided.

Response to reviewer: The tools have been added to the appendix. However, we prefer that the hyperlinks remain as they will provide ongoing access to the latest version of the tools.

Discretionary Revisions
1. Did you use the demographic data for any statistical analyses?

Response to reviewer: All factors were explored for differences between the arms at baseline; the only factor that had a significant difference was the group discussion (diabetes or statin). All models were adjusted for this difference.

Quality of written English
Section: Implications for Policy, Practice and Research
1. Suggest deleting “Thankfully” and improving sentence structure regarding PCORI.
2. The following sentence beginning “Thus, ….” I suggest leaving out a conclusive statement about “the right balance” because that is an opinion, yet to be proven.
3. Correct/improve sub-headings so they are uniform in format (some sub-headings contain caps for all words; some do not)
Response to reviewer: Each item has been addressed. Thank you. The revised text now reads: “The act created the Patient-Centered Outcomes Research Institute (PCORI) that funds comparative effectiveness research with a focus on informed decision making [9]. In our view, current federal policy strikes the right balance, supporting more research before rushing to implementation. State legislatures, however, have been more sanguine in their approach [8].”

Reviewer 2:
1. The feasibility issues are potentially very interesting and instructive. However, there are no data and no description about feasibility. In “Limitations and strengths” (p 12), the authors indicate some of the challenges, and make reference to some unpublished observations. These are not helpful to the reader. They need to be described in some detail. If these are qualitative data, they may potentially be instructive. If the authors have interviewed site personnel about the approach to integration of the DAs into
practice, or can describe the protocols or clinical processes, the data may be instructive and allow description that would substantiate the comments in the manuscript.

Response to reviewer: We thank you for your insights into our work. After much discussion it was decided that separate papers would be constructed for the feasibility issues and the qualitative work that was done, as the audiences of these papers were likely different (i.e., the paper about the feasibility of the trial procedures in rural clinics will be of interest to trialists and thus has been submitted to the open-access journal Trials). The items in the feasibility paper are not quantitative in nature and address directly the recruitment issues we were faced with and the results of different actions taken to address them. We therefore agree with you that the insights found within both of these papers are important and would be helpful. The qualitative paper has been accepted for publication in Patient Education and Counseling. The paper about lessons learned is under review. We have attached both to aid the reviewer in their suggestions. Because of these other papers, we think the present paper should remain focused on the main results, keeping its length reasonable and its content cogent.

2. Likewise, the section on implications for policy is interesting, but not well substantiated by the data. On page 14, the authors say, “One has to be careful not to draw overenthusiastic inferences from a small trial”. However, the actual data reported actually favor the control group most frequently as reported, so there does not appear to be any reason to be optimistic.

Response to reviewer: The reviewer is not correct in terms of the decision making results, which favored the intervention group in all aspects, but is absolutely right in that the results of clinical lab tests and adherence tended to favor the control group. Our sense of enthusiasm comes from the ability of point-of-care decision aids to improve measures of decision quality. Yet, we see the reviewer’s point and we have eliminated the offending line.

3. They also say, “Conservatively, this trial supports the feasibility of SDM in nonacademic primary care clinics when designed for use during the consultation…” No data are presented about feasibility. This must be addressed convincingly to support such a statement.

Response to reviewer: We present data about the fidelity with which clinicians were able to use the decision aid with their patients, the effectiveness of that action, and the extent to which clinicians and patients reported satisfaction with the implementation. Because these data accrued in the context of a trial, no matter how practical the trial, it is indirect evidence of feasibility in practice (without the support of research personnel). Given this point, we have softened the statement as follows: “This trial indirectly supports the feasibility of SDM in nonacademic primary care clinics and adds to the consistent evidence accruing about the impact of point-of-care decision aids in promoting SDM.”
4. The authors then go on to suggest that SDM, while supported in policies they cite, should not be legislated. That is an important and provocative statement. However, the data to support it must be presented in detail, and connected more clearly. Why not? What about your data suggest that SDM with decision aids is not ready for full implementation? The authors cite recruitment challenges and low fidelity. These need to have accompanying data and discussed more directly. The authors further articulate a concern that clinicians should not be held accountable for implementing patient-centered care. Why not? What have they learned that they can share based on their research with the research community?

Response to reviewer: This is indeed a challenging paragraph to write without seeing all the findings of our study, some of which are reported elsewhere. Here we wanted to present our final word on this experience, but we see, thanks to the reviewer, that, as is, the statements quoted appear largely unsubstantiated. We have rewritten the paragraph to stay close to the data presented here, as follows:

We have been able to conduct trials of decision aids for use during the consultations of people with diabetes in academic subspecialty and primary care and, in this study, in nonacademic primary care settings. In these contexts, the decision aids have been well received by patients and clinicians, have improved decisional outcomes, and have not had favorable impact on adherence or clinical outcomes. Research to select patients most likely to benefit from SDM and to explore ways to improve high-fidelity delivery of the tools may improve their clinical utility. Yet, their value as promoters of patient-centered practice and patient engagement remains, in our view, the most important justification for their use. We do not think these results will satisfy those pursuing legislation of SDM seeking reductions in healthcare utilization and costs [18]. To this extent, the Patient Protection and Affordable Care Act of 2010 did not fund, but promoted the establishment of SDM Resource Centers. The act also created the Patient-Centered Outcomes Research Institute (PCORI) that funds comparative effectiveness research and communication of evidence through SDM [9]. In our view, current federal policy strikes the right balance, supporting additional research rather than mandating implementation. State legislatures, however, have been more sanguine in their approach [8]. Clearly large studies outside of academia will be needed to know the full extent of intended and unintended consequences of SDM.

5. The empirical results, as the authors indicate, do not contribute substantially, due to the problems with lack of power that resulted from recruitment problems. In addition, as presented, they are difficult to follow. For example, on page 6, it is not clear whether the fidelity checklist is the same as the OPTION score, etc. Throughout the paper, there is no indication of the frequency of missing data. Other similar conventions of full reporting of trials are also not followed. Until the study is fully described, the contribution of even the low-power results cannot be evaluated. If the study is a failed experiment, due to problems with feasibility, lack of physician ability to implement SDM as indicated from OPTION results, then this should be reported clearly. Failed experiments are very important and instructive to the field. However, a full description needs to be provided.
The authors may be in an excellent position to indicate next steps to fully answer the question about whether SDM with DAs is feasible outside academic settings.

Response to reviewer: The reviewer considers we have not followed conventions of full reporting of trials. We now submit a completed CONSORT checklist to ensure that we fully report the trial methods and results. We believe full reporting is important and as such we have produced a protocol paper, the present results paper, a qualitative study of the experience of patients and clinicians (now accepted at Patient Education and Counseling) and a manuscript about the challenges in conducting the trial (under review at Trials). This level of transparency and full reporting is consistent with our commitment to these values in research and we thank the reviewer for pointing this out. We have also made clarifications to improve the clarity of the paper. For instance in page 6 we have clarified that the fidelity checklist is not the same as the OPTION scale. We also use footnotes in our table to indicate missing data.