Reviewer's report

Title: Lesson learned from the conduct of a multisite cluster-randomized practical trial of decision aids in rural and suburban primary cares practices

Version: 1 Date: 24 May 2013

Reviewer: Moyez Jiwa

Reviewer's report:

Major Compulsory Revisions

I struggled with the notion of 'opt-in' and opt-out'. Perhaps it means different things in different parts of the world- in this part of the world- 'opt out' would imply that patients had agreed to participate in a study unless they specifically decline. In your study it appears to means that the patient was recruited at the time of their appointment. This makes it confusing for an international reader and perhaps your manuscript could make it much more explicit- my inclination would be to find some other name for what you did. e.g. recruitment 'at appointment' compared to recruitment 'before appointment'.

It is also not clear whether you were breaching patient confidentiality by accessing their records before they had consented to participate in the study. That would be frowned upon in the UK and Australia- I'm surprised you could do that in the US. And what makes it even worse from our perspective is that your reearchers were contacting patients who similarly had not consented- how did they explain who was telephoning them and how they obtained the numbers?

It is also possible that your 'opt-out' approach was coercive and that patients and practitioners were unwilling participants as was noted in the low retention rate. this possibility needs to be explored as a limitation. There is no evidence from your data that researchers being more present in the clinic led to improved relationships- that is speculation. You could equally speculate as above.

It is very important to explain how the approaches your describe in this study satisfy the principles of medical ethics.

Please explain the statement in your background: ....'exposing study participants to risk despite a diminished ability to answer the study question'....In my view research, especially of the kind described in this study, should not expose patients to additional risk than is the case in normal practice- otherwise research can harm the participant and is therefore unethical.

Minor Essential Revisions

It would be helpful to understand how your decision aid works. That is almost secondary to the thrust of your paper but a screen shot or some such illustration of the decision aid would help bring the study to life.
The eligibility criteria included inadequate glucose control - please explain explicitly.

Your sample size needs to be explained - what was the outcome measure and the estimate of effect size? How was clustering taking into account?

Discretionary Revisions

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

Nil