Reviewer’s report

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

**Version:** 1  **Date:** 30 March 2013

**Reviewer:** CLAIRE LEATHEM

**Reviewer’s report:**

Thank you to the researchers for submitting their paper entitled 'Lesson learned from the conduct of a multisite cluster-randomized practical trial of decision aids in rural and suburban primary care practices'. Researchers who submit papers for publication describing the lessons they have gained whilst carrying out their research can be of benefit to others who can utilise this knowledge in their own research.

All comments are: Major Compulsory Revisions.

1. Firstly I believe the title is mispelt and should be 'Lessons learned from the conduct of a multisite cluster-randomized practical trial of decision aids in rural and suburban primary care practices'.

2. In the 'Methods section' the researchers state that patient lists of the clinicians who opted into the trial were reviewed for inclusion and eligible patients contacted. Due to the recruitment target not being reached the next method of recruitment is described as approaching both clinician and patient at the clinic just before the patient appointment (the 'opt-out' approach). In my experience clinicians and patients are recruited into a trial by firstly ensuring they have all the information about the study that they require to make an informed decision, followed by time to think over what involvement will mean for them before giving their decision. Clinicians need to know as precisely as possible for example how participation will affect the day to day running of the practice. Those who are fully informed and supported will not only be more likely to be retained in the trial, they are more likely to comply with the study process and very importantly consider participation in future studies. The terms opt in and opt out are unnecessary and even appear to be used inappropriately.

3. Results

Lesson number one: is already universally known by researchers working with primary care practices.

Lesson number two: should be a lesson to others to avoid and not a recommendation. The opt-out approach was entirely flawed leading to lower retention rates. Patients agreed but had second thoughts most likely due to not having time to consider the trial (or discuss with for example a partner or family member) prior to their visit - this omission is also unethical.
Lesson number three: regarding approaches that improve recruitment being associated with reduced retention - see comment on lesson number 2

Lesson number four: ”Procedures that improve recruitment by working closely with the practice also affects the quality of the implementation of the study”- is the wrong way around. It is working closely with the practice (also providing support and expertise which is not mentioned) leading to improvement in recruitment and the quality of the implementation of the intervention. However this phenomenon of entering into a collaborative relationship with practices (assessing individual practice/clinician need and ensuring they receive the necessary practical support) has been fully documented previously in published literature.

4. Figure 1: There is no figure 1. On page 20 this is labelled as Table 1

5. Identification and selection for recruitment

A purposive sample of practices were initially approached. The line 'clinicians were offered to participate in the study (opt in) and consented during the meeting' is a strange use of English.

6. Background paragraph 2

Researchers continually pay lip service to the very great challenges of patient recruitment without taking on board that they also will fall into the same traps and come up against similar barriers unless they take steps to be as prepared as possible. One lesson which surprisingly the researchers did not learn was how many of their problems could have been lessened/avoided by firstly carrying out a small feasibility/pilot study. By seeking clinicians advice on the suggested trial methodology at the outset valuable information can be gained on the barriers which may lie ahead. Involving the target audience by use of focus groups/interviews can give vital insights into the acceptability of the intervention, talking to practice staff responsible for carrying out database searches can confirm that the screening/data collection being prosposed is possible or problematic. This could have proved very useful as the coordinators eventually removed Aspirin Choice DA due to the considerable time determining whether patients were on aspirin, it turned out that most where.

7. Comment regarding Patient recruitment methods.

I am unsure of the method described which recruited patients who were unable to participate because their clinician did not give consent. I was unaware that patients could be contacted by researchers without the knowledge/consent of their clinician. Apart from the negative effect on patient recruitment this caused, it throws up an ethical issue regarding access to patient personal information without clinician consent. Perhaps I have misunderstood. However another issue which concerns me is regarding recruiting patients in the last 4 practices on the day of their visit. It's unclear if the patient was contacted prior to the visit and provided with a copy of the study information sheet or if they were only spoken to in the reception area prior to seeing their clinician. It is good clinical practice to ensure that patients have time to consider study information, including talking
over the pros and cons and formulating questions they would like to have answered prior to taking part in a study. This 'cooling off period' ensures that patients can provide informed consent and will also lead to higher retention rates. The fact that the researchers improved recruitment rates with this method but had higher rates of withdrawal bears this out. Patients will drop out if they have been inadequately recruited.

8. The recruitment figures quoted in the text are confusing and unclear, table 2 is inadequate. Figures need to be clear and precise at each stage of the process, tables should contain the patient numbers contacted and responding or alternatively a flow chart could be utilised to describe:

The number of diabetic patients screened for the study (deemed eligible/ineligible)
The number of potentially eligible patients contacted, the number who responded and were interested, the number who responded and declined, the number who did not respond. The number of patients who responded but were missed by the researchers.
The number of patients who attended the study visit and were enrolled in the study, the number who were found to be ineligible at the visit and not enrolled, the number who did not attend.
The five patients who attended and wished to participate but could not be enrolled as their clinician declined cannot be included in 'responded' as they were ineligible and should not have been contacted. This would include the patient recruited in error.

9. Discussion
This trial was not designed to compare two methods of recruitment and the 2nd set of practices were brought on board to boost recruitment only. The researches state these limitations by acknowledging their inability to link the recruitment approaches with the outcomes. However this paper also fails to provide 'new' insight into the issues of practice, clinician & patient recruitment in primary care and indeed has been unable to identify lessons that they should have learnt from this study including the value of a thorough literature review to identify that which is already known on the subject.

Thank you to the researchers for their efforts and I wish them well in all their future endeavors

**Level of interest:** Reject as not of sufficient priority to merit publishing in this journal

**Quality of written English:** Not suitable for publication unless extensively edited

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.
Declaration of competing interests:

'I declare that I have no competing interests'