Reviewer’s report

Title: Human Subjects Protection Issues in QUERI Implementation Research

Version: 1 Date: 25 January 2007

Reviewer: Martin Eccles

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These are combined comments from series Editors Martin Eccles and Ian Graham. This is an interesting article that tackles an important topic. We are sorry for the delay in getting back to you but, in order to deal with the series of articles as a whole the pace has been dictated by the getting the last reviews of the series.

General comments
1] Please remember that you are writing for an international audience. In some cases it seems the papers make comments that seem directed at the VHA and these should be deleted - you need to be thinking much more globally and presenting lessons learned and perhaps recommendations for how best to do implementation research regardless of what your own system is like. The DETAIL of VHA structures and funding are of no interest to an international audience. If you wish to make reference to funding it should only appear in the acknowledgements section and not in the body of the text.
2] Related to [1], all articles have a plethora of abbreviations, many of which relate to VHA specific structures functions or procedures. In general these should be described in generic terms and the number of abbreviations kept to a minimum.
3] You need to be clear about who will be the main audience for both these and the rest of the papers- if it is seasoned implementation researchers then sometimes the information seems rather simplistic; if it novel implementation researchers/facilitators then sometimes more clarity is needed- either way the papers need a more similar pitch to the intended audience. We think that the readership is the interested implementation researcher or policy maker.
4] You should use a standard description of the QUERI process both in the text and Table. However, the Journal web system will not retain the formatting so I will send you the preferred version as a separate email attachment. Could you then refer to this as appropriate throughout the paper.

Overall could you ensure that the article conforms to the journal style as specified in the instructions for authors (http://www.implementationscience.com/info/instructions/default.asp).

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

Specific Comments
Throughout the article it would be helpful if you could think about the issues that are specific to implementation research (lack of IRB understanding) and those that are specific to your IRB system (workload from multiple IRBs). This will allow the reader to place what you describe within their own national context. You use such a structure in Table 2 but not in the text or as a framework for the background, experiences or discussion. Table 2 offers a helpful structure to guide the reader through the paper and I would suggest that you use a common structure for both the text and Table.

Throughout you tend to assert that your studies are typical of all implementation research – the example of PDSA cycles and being unable to foresee all changes. You should, as appropriate link the issues back to your studies as there are studies of other interventions where the intervention is much more stable.

Prior to the section “THE IRB EXPERIENCE FOR TIDES-RELATED PROJECTS” it would be helpful for the reader if you could include two sections.
The first should describe the principles of the IRB process that you had to contend with. This would be informative because it has influenced some (but not all) of the issues that you faced. Implementation Science has an international readership and other countries have different systems which would reduce some of the problems you faced. For example in the UK whilst there are local ethics committees that deal with research proposals conducted solely on their site, there are also Multiple Site Research Ethics Committees (operating through a central web-based system) set up to deal with studies that need to enrol three or more sites. What is the IRB system? Does each institution has its own IRB or is there a regional one? Do they need a university IRB as well?
The second should detail the overall activity from which your experiences are drawn. You begin to talk about these data on page 11 linked to Table 3 but it would be useful to the reader to have had the information earlier to inform their reading of the rest of the paper.

A discussion of the differing role of implementation researcher from clinical (more detached) researcher (including the mixing of the role of implementation researcher and facilitator) could be expanded and linked back the QUERI steps and phases and the different roles of implementation researchers throughout the framework.

Many of the IRB issues relate specifically to action research methodology (the research becoming a facilitator) as opposed to other implementation research generally (i.e. trials of effectiveness of different implementation/KT interventions) and this might be highlighted.

In the discussion, when you discuss the RE-AIM framework could you define the components at the start of the section, capitalise them when you describe them and don’t use underlining.

In the discussion, given that you are writing for an international audience the final part of the discussion is less relevant and could usefully be deleted.

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

Discretionary Revisions (which the author can choose to ignore)

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory 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.