Reviewer's report

**Title:** Tool for evaluating research implementation challenges: A sense-making protocol for addressing implementation challenges in complex research settings

**Version:** 2 **Date:** 23 June 2012

**Reviewer:** ian graham

**Reviewer's report:**

1. Is the question posed by the authors new and well defined?
   The authors clearly state the purpose of the paper and the development of a sense making tool is novel.

2. Are the methods appropriate and well described, and are sufficient details provided to replicate the work?
   The paper presents a tool that is theory and experience-based. The process by which the tool originated and was developed is well described.

3. Are the data sound and well controlled?
   Not applicable

4. Does the manuscript adhere to the relevant standards for reporting and data deposition?
   Yes for reporting- not applicable for data deposition

5. Are the discussion and conclusions well balanced and adequately supported by the data?
   Yes, for the most part. A section of limitations of both the tool and its development would be appropriate

6. Do the title and abstract accurately convey what has been found?
   Yes

7. Is the writing acceptable?
   Yes

The paper is interesting and relevant to readers of IS. I have only 3 minor essential revisions.

1. The paper would benefit from a short epistemological discussion placing in context the varied approaches to implementation trials that range from one extreme representing the traditional medical approach to the other extreme representing a participatory approach to trials. The paper is particularly relevant for those adopting the medical approach to implementation trials where the researcher, typically in isolation, develops the intervention and then executes the
design by enrolling ‘subjects’. Great care is taken to avoid modifying the study protocol for fear of contaminating the process. What may result from this sort of approach is a perfectly designed and well executed trial that may produce evidence for an intervention that will never be feasible to implement in the real world or fail to provide evidence for the intervention because it may not have been adequately delivered. The authors’ description of their protocol shows how challenges arising from the study design and execution of the intervention may threaten the trial and offer a systematic process for making trial course corrections while maintaining the fidelity of the intervention and study design. Basing the tool on complexity theory provides a strong rational that supports to view that practice settings are delicate ecosystems that can be easily put into disequilibrium by the introduction of implementation research (unless it is sensitively and carefully managed as the authors propose).

At the other end of the continuum there are implementation researchers who do conduct trials using a participatory approach with the intended users of the findings, be they clinicians, managers, policy makers, etc. (also referred to by such terms as collaborative research, co-production of knowledge, mode 2 knowledge production, integrated KT and even community based research) (ie doing the trial with rather than to trial participants). A truly collaborative approach that meaningfully engages the field often has the advantage of anticipating some of the challenges noted in the manuscript during the development of the study protocol and intervention and finding the solutions before the trial goes live. This is not to say that challenges may not emerge conducting trials using a participatory approach, and the proposed protocol would still be of use to those researchers from this paradigm. The only adaptation required would be to expand the research team to include the site investigators and create essentially a community of practice among the researchers and site investigators/knowledge users on the team to help solve the emerging challenges together. I may incorrectly be assuming this was not the case here because the site investigators appear not to have warrent authorship on this paper and the it is not clear if they are included in figure1 - apologies if i am mistaken. The advice about creating a culture of trust and equality among team members applies equally well here. An acknowledgement that there are different philosophical approaches to conducting trials and engagement of trial participants/site investigators would be helpful as would explaining how the tool would be of use to those in the traditional medical paradigm through to the participatory paradigm.

2. Appreciating that this is a theory paper, and realizing there may not be any relevant data, could the authors provide any indication of whether (and how) site investigators (or study participants) perceived the usefulness of the protocol and the resulting solutions. Do they believe the trial is better, or their participation facilitated because of the adjustments that were made from using this process.

3. The conclusion section would benefit from a discussion of the limitations in how the tool was developed and any limitations specific to the tool (ie that it has not been used by others yet or has it? which goes to its validity). A discussion about how the tool might be validated is also warranted.
Thank you for the opportunity to review this paper. It is important that we share from our experiences doing implementation science and your paper is an excellent example of codifying tacit knowledge so that others can benefit from it. thank you.

**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.