Author’s response to reviews

Title: Bridging the Gap between Basic Science and Clinical Practice: A Role for Community Clinicians

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Author’s response to reviews: see over
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Martin Ecceles, MD, and Brian Mittman, MD
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Re: Response to Reviewers for Manuscript by Kahn, et al: Bridging the Gap between Basic Science and Clinical Practice: A Role for Community Clinicians

Dear Drs. Ecceles and Mittman:

I want to begin by thanking you for your understanding regarding the delayed response of my team to the three manuscripts you reviewed. As we discussed by email a few months ago, I was diagnosed with metastatic cancer soon after we received your reviews. It has taken several months for me to receive my treatments and reconvene our team to address your comments. We are now submitting our responses to the three reviews. Thank you for your patience. If your reviewers have any additional comments, we should be able to respond to them promptly as I am now feeling much better and back to work.

Thank you again for the helpful comments

Responses to Reviewer 1:
1. In general the background frames the issues well. However, the representation of the placebo-controlled trial as the gold standard of effectiveness is miscast. The RCT is the gold standard, whether the control is placebo or usual care.

   We appreciate your identifying this text as requiring an edit. You make a great point. We have implemented the edit as you suggested. Text now states the randomized controlled trial is the gold standard for revealing the effectiveness of a new treatment.

2. One major area of clinical epidemiological thought and literature is absent. The authors are basically calling for implementing the RE-AIM model (www.re-aim.org) but do not cite it nor consider the body of literature derived from it.

   The RE-AIM model is certainly applicable to this discussion. We have added text with appropriate citations to the Ee-AIM web site and to associated references in the Discussion Section of the manuscript (paragraph 3).
3. The selection of the starting points (initial key informants) for the snowball analysis should be noted. Whether this may have led to the omission of any significant viewpoints should be addressed in the discussion.

We have added additional detail regarding the selection of the starting points in paragraph 2 of the Methods section. The newly included text is shown here. Additionally, we have noted the potential problem that the selection of the starting point potentially could have led to the omission of any significant viewpoints.

4. Some additional detail on the qualitative analysis is necessary. Was the weekly analysis by informal consensus conference, or was a formal method (e.g., immersion crystallization, coding, and theme abstraction) employed? Was there any member checking with the informants?

Additional detail on the qualitative analysis is now provided in the Methods Section, paragraph 4. For almost one-quarter of the informants a follow-up interview checked with the informants about themes.

Discretionary Revisions by Reviewer 1.

1. Much of what appears under Results, in the form of suggested solutions to the barriers identified, seems better placed in Discussion.

Since the suggested solutions emerged from our interview analyses, we believe they are better placed in this manuscript in the Results Section. We concur that in many similar manuscripts, they would be best placed in a Discussion Section.

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.

Responses to Reviewer 2.

1. This paper represents an important contribution to a growing field of research that recognizes the challenges in translating advances from basic biomedical science to clinical practice. The authors focus understanding the barriers to increasing the participation of community clinicians in clinical research activities. The barriers identified represent a significant contribution through organizing and identifying many anecdotal barriers reported by those familiar with practice-based research networks. However, the discussion of these identified barriers is unclear in describing how their results link back to the growing field of translational research. As defined in the program announcement for the Clinical and Translational Science Awards, “translation research includes two areas of translation. One is the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in human studies. The second area of translation concerns research aimed at enhancing the adoption of best practices in the community.” This paper appears to focus primarily on the first type (e.g., page 8 –
“combining explanatory and participatory trials may be an effective strategy for including community practice settings in research that aims to bridge the gap between basic science and clinical application” and “page 10 – a clinical trial registry would also provide a venue for sharing trial data among participants…” Yet the discussion seems to imply that achieving the first type of translation will automatically achieve the second. (page 14 - Engagement of clinicians in the research enterprise will allow the extraordinary results of the basic, explanatory research conducted in recent decades to be translated into practical applications for responding to the challenges associated with major public health risks, different health care delivery organizations, and different types of clinicians. However, there are extraordinary challenges in translating the extraordinary results of clinical research into clinical practice, ranging from the need to evaluate whether treatments shown to be efficacious in clinical trials continue to be effective in real-world practice to the need to develop a better understanding of the best ways to implement effective treatments across a wide variety of settings. It is important to recognize the distinction and to clarify which type of translational research is being addressed, as each type requires different strategies and infrastructures.

Additional text has been inserted to describe the CTSA Awards as this NIH Roadmap effort substantially informed the development of the CTSA Awards. Within the Background Section paragraph 5 we have added text about the scope of translational research. We additionally have introduced new text focusing, in particular, on the second area of translation concerns aimed at enhancing the adoption of best practices in the community. We agree with your points that the text underemphasized the value of community clinicians and their important role in understanding the best ways to implement effective treatments across a wide variety of settings. We agree it is important to clarify the types of translational research is being addressed, as each type requires different strategies and infrastructures. This is addressed in the Discussion Section, paragraphs 1 and 3.

2. The paper would be greatly strengthened if the discussion were expanded. This depends somewhat on whether the authors would prefer to focus the study entirely on the first type of translational research, leading up to clinical trials, or to discuss the implications of there results for the second type of translational research. Although it represents an extension of their current framing of the issue, many of their results have important implications for the conduct of effectiveness and implementation studies.

We have expanded the discussion of these points in Discussion, paragraphs 1 and 2.

Some issues that might be addressed include:
1) There is an assumption of the need to maintain rigorous quality control, which is very appropriate for clinical trials. It might be helpful to discuss quality control over the research process (e.g. data collection) and quality control over the intervention (which in effectiveness studies is presumed to vary in application according to the setting).
2) The authors note that community clinician participation may depend on the research questions and study design. For the second type of translational research, there is often an explicit tradeoff between internal and external validity and the research questions and design may be very different. Some discussion of the potential link between clinician involvement in clinical trials and in effectiveness/implementation studies may be useful.
3) The need for two-way participation between community clinicians and researchers is critical, as identified by the authors. Perhaps more thought could be given to mechanisms or models that would allow clinician involvement at a very early stage in the process, before research questions and protocols are designed. The proposed clinical trial registry would only allow access to study questions and protocols after they are finalized. Earlier involvement might be particularly useful to ensure adequate representation of a broad array of patients.

We have added text throughout the expanded Discussion Section relevant to these important points. Of note, these exact points are additionally addressed in the related to submitted manuscripts by Beckett, et al, and by Ryan, et al.

3. Some discussion of the types of interviewees might be helpful. It appears that only 37 interviews were conducted with community clinicians and clinician organizations not participating in research and 30 with those who had participated. It would be useful to know a bit more about these clinicians (e.g. solo practice, large group, availability of an electronic medical record system, etc.)

Community clinicians including those practicing in solo offices, in small group offices and in large group offices from each of the large regions of the United States. Clinicians were from urban, suburban, and rural areas. Some clinicians were involved with managed care while others were not. Managed care clinicians were from staff model, from medical groups and from independent practice associations. Only those few from a staff model had a fully automated medical record system. (We did not interview VA physicians). Most physicians had access to some patient data electronically (e.g., laboratory and/or imaging results) but most did not have a complete or nearly complete electronic medical record system.

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.

If you have any questions, please call me at (310) 794-2287 or email me at kahn@rand.org.

Sincerely,

Katherine L. Kahn
Senior Natural Scientist