Author's response to reviews

Title: QUERI Series: A Process for Developing Implementation Interventions

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Author's response to reviews: see over
May 8, 2007

Dr. Martin Eccles
Dr. Ian Graham
Editors-in-Chief
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Dear Drs. Eccles and Graham:

Re: MS ID:
Title: QUERI Series: A Process for Developing Implementation Interventions
Lead Author: Geoffrey M. Curran

Thanks for the opportunity to resubmit a revised manuscript. My co-authors and I very much appreciated the thoughtful comments from you and 2 reviewers. We hope our responses to the concerns raised are satisfactory. A summary of the concerns and our actions taken are provided below. The manuscript has been re-worked considerably, and hopefully improved.

We do raise a couple of questions in our responses. Any guidance would be appreciated. We have not noted in this letter our responses to the general comments on the QUERI Series papers from Dr. Eccles. We have addressed those issues, however.

We look forward to hearing from you.

Sincerely,

Geoffrey M. Curran
Reviewer 1

Major Compulsory Revisions

--“No question is posed or addressed by the article and no data are presented; as currently written, it is therefore not suitable as a journal article.”

While this would most certainly be true in most cases, one goal of the QUERI Series is to present descriptions of implementation tools. While we no longer say this in the paper, future writings from the study will detail the study’s hypotheses and present outcomes data.

--“The articles would be strengthened by more detail about how the empirical and theoretical literature it drew on were used to decide to develop the intervention components.”

We focused this article on our process for developing an intervention; hence, we spent little time referring to the specific elements of the intervention that was developed (and their theoretical and evidentiary roots). This does create some tension for the reader. After reading a detailed description of the process, one is easily left with the question, “Hey, what was the intervention you developed?” To ease this tension, but not to take away the focus from the process, we now include a brief section towards the end of the methods section where we describe the intervention components developed and used in the study. Table 2 also notes these and lists relevant literature. We also note the theoretical background for the intervention components on page 6.

--“Another issue to be addressed is the context and generalisability of the intervention.”

With a common background section provided to the QUERI Series papers about the QUERI process in VA, the question of context has been addressed. Regarding generalisability, Dr. Eccles indicated in his review of the paper that given the article is mainly about process, he indicated that we need not address this point in the revision.

--“The article could be considerably shortened by cutting out repetition and redundancy, and writing in a more concise style.”

The paper has been shortened. The passages about the QUERI program and the Mental Health QUERI group have been deleted. Revisions were also made to tighten the writing.

--“My view is that the description of the current process should be shortened and presented alongside future data about whether or not the intervention improved implementation.”

Given the nature of the QUERI Series, Dr. Eccles suggested that we not address this concern.

--“Typos ‘care’ missing after ‘primary’ on p.7; were should be where on p.12; comment should be commented on p.14.”
These changes have been made.

Reviewer 2

Major Compulsory Revisions

--“The terminology should be consistent. Was this a ‘multisite demonstration project’ of ‘Phase 1’, or organizational efficacy study of ‘Phase 2’, or a ‘Phase 2 implementation study?’”

We now consistently use the term “small scale, multisite implementation trial” throughout the paper to describe the study type. This terminology comes from the QUERI table that will be used in all of the QUERI Series articles. An example of new text is provided below.

First, it should be clearly noted that the process described above was directed at the specific stage of implementation that was called for in this case—a small scale, multisite implementation trial as defined by QUERI. A single site pilot study had already taken place. In the QUERI framework, these small scale multisite trails are intended to be efficacy studies of an organizational intervention. These studies necessitate rigorous site diagnostic analyses, partnerships with key clinic stakeholders in the intervention development process, significant external facilitation by the study team, and extensive formative evaluations to shape the intervention and understand its impacts. (p. 17)

--“It would be useful to summarise the resources used. The study is described as involving ‘significant external facilitation, time, and effort.’ How much staff time was used? A time graph showing the series of steps and the resources used would be very useful. This would help in removing vague expressions, such as “much time had passed.”

We decided to include text in the paper to better inform the reader of the timeline and staff involvement. It seemed better to us to include the information right where it was needed the most, and not have a table or figure to turn back to each time. We added this information as we discussed each component of the development process. We include the time spent on each activity, note if it differed from expected and why, and give an overall sense of investigator and staff support effort across the development process. (See examples below) Unfortunately, we do not have the space to devote to a more detailed explanation of the resources used. We gathered a lot of information about staff time and effort devoted to the project, and we will discuss the relationship between those things and organization changes observed in the main outcomes paper.
The investigators’ plan was to complete these tasks in 8 weeks time. In reality, the time span from the beginning of the development panels to the launch of the intervention at each program was approximately 5 months. Delays were caused by difficulties in scheduling the multi-stakeholder calls, problems with the installation of an electronic clinical reminder, and difficulties associated with human subjects protection reporting and approvals (common to multisite projects). (p.13)

These activities fall under what Stetler [10] refers to as “external facilitation,” meaning activities supportive of implementation that are provided by persons external to the clinical setting. External facilitation is itself an implementation intervention that is getting more attention in the literature, and the investigators explicitly included it in the study as an important part of the implementation strategy. However, questions about “what kind of” and “how much” external facilitation to provide and under what circumstances (i.e., moving from a small to a large scale implementation project) remain unanswered. The current study measured closely the extent of external facilitation so as to facilitate analyses of linkages between facilitation and intended clinical change. While detailed descriptions of the resources devoted are beyond the goals of this article, we can state here that the principal investigator spent at least 16 hours per week, and the project coordinator, 40+ hours, on these facilitation efforts in the development phase of the project. (p.16)

--“Not all of the many acronyms are explained when they first occur in the text. Please clarify and consider a separate terminology list…”

We decided to keep the acronyms to a minimum. When we deleted references to the VA funding mechanisms and other VA-related material, a number of the acronyms were deleted then. Most others have been deleted as well. I’m afraid that in the VA we get immune to them. It was good to step back and realize how tiring it is to read acronym-filled papers.

--“The abstract is not consistent with the article; its conclusions… are not based on what the authors did.”

The abstract has been revised completely.

Minor Essential Revisions

--“Brief description of VA is needed in the Background.”

We hope that the paragraph written by Mittman that will be included in all QUERI Series articles will suffice here. While no specific data are noted on size of VA system, number of facilities, etc., he does cite 4 papers with background on VA. Please let us know if this will suffice. If not, we can add a section with characteristics of the VA system.

--“Please check the references for lacking data and consistency in style.”
The references have been fixed.

--“/ is not a word. Please use a comma, and, or or instead.”

We have replaced all such instances except for one: barriers/facilitators. If we changed this instance, we would have to write “barriers to and facilitators of,” which seemed overly lengthy. We will, of course, change this if asked by the editors.

--“References to other studies in this series should be systematically made throughout the set…”

We use the paragraph provided by Mittman in the background and do not reference other papers in the Series elsewhere.

Discretionary Revisions

--“The style is quite voluminous. Be brief, cut the text by 20% and help the reader stay awake.”

Guilty as charged. We have cut several passages and gone through the text and removed phrases like “it is important to note” and “as noted earlier.”

--“Table 1 has too much text.”

We deleted the table. The text gives enough of the necessary background of the study.

--“Table 3 seems to provide a quite complete list instead of just examples as the heading suggests. Which one was intended?”

We have removed “Outline of…” from the title of the table to avoid the impression that what follows is brief. (We’re not good at brief.)

--“Some of the language is jargony.”

Very guilty as charged. We’ve read through closely and tried to remove as much implementation science jargon as possible.

Specific comments from Dr. Eccles

--“Both reviewers felt that the paper could be written more concisely. I agree. There are a number of initial comments to help with this. You should make the focus of the paper the process and content of intervention development only. You should not mention articles yet unwritten. Delete detailed description of QUERI. Delete the section describing the activities of the MHQ Centre. Not refer to the to the QUERI series of
articles. Delete the sections describing the funding dimensions of the project. Detail the context (SUDS) once only and then do not use the acronym again. Frame the article according to the QUERI framework. Make greater use of subheadings.”

**Done. Thanks very much for the very helpful suggestions.**

--- “I think you could reverse the order of the title…”

We followed the instruction recently provide by Mittman and put “QUERI Series” before the colon. Afterwards, we shortened the rest of the title to “Process for Developing Implementation Interventions.” We hope this works for everyone.

--- “The paper would be enriched enormously by linking your description of your process to the example of the intervention that you ended up delivering.”

While Table 2 does include some of this information, we have added a new section in the paper which describes the intervention in more detail. The beginning of the section is provided below. The full section is on pages 16-17.

<table>
<thead>
<tr>
<th><strong>Intervention Components Developed and Used in Implementation</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>The intervention produced from this process was composed of 1) support tools for the staff and patients and 2) a group of activities or strategies for both program staff and study stuff to support implementation. These tools were developed to facilitate the clinical practices being adopted, namely assessment for non-substance-induced depression and a quick referral to a program psychiatrist.</td>
</tr>
<tr>
<td>The following support tools were developed for the depression management intervention—evidence summaries for staff members concerning depression management, educational materials for patients, a sample depression screener, a computerized clinical reminder to facilitate screening and referral, and template progress note language for medical records. The study team was responsible for developing the tools, making and delivering the necessary number of copies of materials, and supervising the installation and testing of the computerized clinical reminders.</td>
</tr>
<tr>
<td>These activities fall under what Stetler [19] refers to as “external facilitation,” meaning activities supportive of implementation that are provided by persons external to the clinical setting. … (p.16)</td>
</tr>
</tbody>
</table>

--- “If you were able to say a little more about the link between theory and your work it would be of considerable interest to our readers. For instance, if you were measuring constructs dictated by a particular theory…”

We have made more explicit the specific theories we used to help us choose which constructs to measure in the formative evaluation. Here is the reworked section which follows the description of the PRECEDE model of provider behavior change:
This model of healthcare provider change is consistent with several individual-level and organizational change theories, namely the Theory of Planned Behavior [27] (addressing underlying perceptions and beliefs), Social Learning Theory [28] (addressing self-efficacy), and Rogers’ [3] model of diffusion (focusing on leadership support and removing barriers to action). These theories were helpful to the investigators in deciding which macro-and micro-level determinants of behavior change would be included in the diagnostic assessments (See Table 2). (p.7)

--“I don’t find the term “Developmental Evaluation” informative. Could you come up with a more informative term?”

We got the term from the Stetler paper. It breaks down formative evaluation into 4 different sub-steps. It’s too jargony for this paper I think. To avoid confusion, we now just use the term “formative evaluation,” and state that the process described in the paper is best considered a method of formative evaluation. Her definition is: “A rigorous assessment process designed to identify potential and actual influences on the progress and effectiveness of implementation efforts” [9, p.S1]. I am making the assumption that the term is used frequently in the QUERI Series papers. If not, and you’d prefer we use another term, we’d be glad to explore it.

--“I would like more on the roles of the principal investigator. Can you say more about the problems caused by experiencing the two roles [implementation researcher and facilitator]?”

We have included a more thorough discussion of the roles and potential tensions or hazards associated with attempting them together, as follows:

Combining data gathering and marketing in the same interview has the potential for creating tension, however, and it could “backfire” in terms of building rapport. To minimize tension, the interviewers (i.e., the principal investigators or select co-investigators) would be up front about the dual-nature of the interview. Before the interview started, they would frame the interviews with the staff participants as “a chance to learn more about current practices here, hear your thoughts and feelings about them, and for you to provide feedback on some clinical options being considered in the program.” These points were also explicit in the informed consent process and forms used prior to the interviews. During the interview, the interviewers would transition to the “feedback on the clinical practices under consideration” activity by outlining the evidence base in the area and noting the strength of the evidence a motivator for the program to participate in the project. The interviewer would also state that the program’s participation was voluntary. During the feedback section, the interviewer would take very much of a “motivational interviewing” approach to eliciting feedback and ambivalence about adopting new practices. Every barrier raised was affirmed and restated by the interviewer, and ideas for solutions were encouraged. These approaches seemed to help avoid difficult situations; however, more discussion and research is necessary to understand how best to collect diagnostic data from programs and generate positive reactions concerning their involvement in change activities. (pgs. 19-20)
More discussion about the observations. What is the method for identifying culture?

The introductory paragraph was re-structured to lay out the “nuts and bolts” of the observations. The second paragraph was completely re-written to include more specific information about the goals of the observations, the method for compiling the notes, and what was done with them. This new paragraph is included here:

A primary goal of the observations was to come away from the site visits with a good understanding of each program’s common and accepted ways of doing things, their structures for decision-making, and their favored modes of communicating information. The team also needed to have a sense of staff cohesion, evidence of staff conflict, and which individual staff members might be experiencing burnout. Based on this information, the study team would then begin to see how the clinical practices to be implemented (screening, scoring, rapid referrals) might fit into the daily structure of activity, including especially which staff positions or individuals at each site would likely need to be targets of the intervention. The study team met periodically during the site visits to share notes and observations, and the principal investigator compiled the observations after the site visits were over. These data were used (along with data from the key informant interviews) to generate written summaries of program characteristics and pictorial descriptions of clinic processes. (p. 9)

Data on whether or not the intervention worked or not would add another layer of interest.

Our hesitation for not including such data was based on two thoughts: 1) We knew that another paper would report these data in full, and we were not sure how to put in “a little” without trumping the other paper. 2) Describing the fidelity measures would take a good deal space. The screening algorithm adopted by the programs was 2-tiered and complex. Some patients had to be screened twice over 2-3 weeks time. There are different fidelity scores based upon which screen we are talking about, and we also have referral data, satisfaction data, etc. Would we say a little about each one; chose one process measure; or give an overall picture of how well or not the programs did with little or no data included? We still are not sure what to do. I’d say that our thoughts are leaning towards leaving these data out; however, if the editors feel strongly about including this information, we’d ask for more specific guidance on what to include and what is OK to leave out. We would respond very quickly to any request.

The discussion needs tightening up and the conclusion needs to be re-written completely.

These sections have been re-written. The conclusion still feels somewhat awkward to us. Any suggestion on improvements would be appreciated.

Table 1—what does citation list mean in the 2nd column last row?

This table has been deleted because it was largely redundant with the text.