Author's response to reviews

Title: QUERI Series: The Role of Organizational Research in Implementing Evidence-based Practice: VA QUERI Examples and Applications

Authors:

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Author's response to reviews: see over

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Martin Eccles, PhD
Co-Editor-in-Chief, Implementation Science

Ian Graham, PhD
Editorial Board, Implementation Science

Dear Drs. Eccles and Graham:

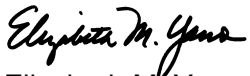
RE: **MS ID: 1056353461127342**
Title: ***The Role of Organizational Research in Implementing Evidence-based Practice: VA QUERI Examples and Applications***
Journal: **Implementation Science**
Author: **Elizabeth M Yano**

Thank you for giving me the opportunity to revise and resubmit the above-referenced manuscript for further consideration in the *QUERI Theme Series* of Implementation Science. I have worked to carefully consider and revise the entire manuscript based on your comments as well as those of Reviewer #1 (Estabrooks). As requested, below you will find a comment-by-comment review and response to each of the issues raised in these reviews, including verbatim changes in the text to facilitate your assessment of the revised paper. Responses are provided in italics to match the requested format as well.

I have also attached two versions of the resulting manuscript, one in revise-mode so that changes are again readily apparent, and another in accept-changes mode so that the paper is readable without observing the changes made. These revised versions include the requested QUERI Series' language, including the paragraph on the Series itself and the new Table 1 summarizing what QUERI is. All tables and references have been renumbered to accommodate the standardized Series' text.

I hope the changes meet with your favorable review, and look forward to hearing whether the paper as revised is acceptable for publication. If additional questions or issues arise, I will be happy to consider further input.

Sincerely,



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Reviewer's Report (Estabrooks)

Major Compulsory Revisions

1. Add a short methods section. [Note: Reviewer #1 recommends addition of a methods section matching the level of detail found in the abstract.]

   I have added a Methods section to the manuscript at the requested level of detail on page 5, paragraph 2. The new text follows:

   "Using the six-step QUERI process as a foundation (Table 1), we designed an organizational research framework to help improve and accelerate implementation of evidence-based practice into routine care. We reviewed organizational research from specific QUERI centers, culling and summarizing the organizational measures they included and the methods used to apply them to different implementation research efforts. We describe these applications in the context of a continuum of organizational research activities to be conducted before, during and after implementation."

2. Page 8—the treatment of culture is somewhat abbreviated, significant literature is not referred to and should be at least as it does or does not have relevance for organizational behaviour (e.g., Schein, Martin, Smirich).

   I have expanded the treatment of culture as recommended, and incorporated core background material and citations from EH Schein, JL Martin and L Smircich. Below is the entire revised paragraph related to organizational culture from pages 8-9:

   "The role of culture and relationships as organizational attributes are also important to health care redesign and implementation of evidence-based practice [44]. Schein has defined culture as a pattern of shared basic assumptions that groups learn as a function of the problems they solve in response to external adaptation and internal integration [45]. When these group assumptions have worked well enough to be considered valid, they are taught to new members as the correct way to think and feel in relation to those problems (i.e., "this is how things are done around here") [45-46]. As is often the case, evidence-based practice is likely to reflect a new way of doing things, and thus may come into conflict with the prevailing culture of a practice.

   There are, however, highly divergent views on how to study culture [46-47]. Culture encompasses a wide range of concepts that capture attitudes, beliefs and feelings about how the organization functions or the role of the individual (or team) within the organization (e.g., leadership, practice autonomy, quality improvement orientation, readiness to change) [48-49]. Culture has been classified as both a structural feature (i.e., some measurable organizational average that characterizes a practice and serves as context or an explicit trait to accommodate) and an organizational process (i.e., symbolic approach for viewing the organizational life of an institution) [44,50]. Integral to the evaluation of and adaptation to local culture is the need to understand and appreciate the dynamics of relationships within and outside health care organizations that influence the adoption and use of innovations [51-52]. These dynamics may include consequences of political and social ideologies that may exert themselves on what is acceptable organizational behaviour [50]. Organizational culture is hypothesized to influence operational effectiveness, readiness to adopt new practices, and professional behaviour

and style, and considered by many to be a critical determinant of organizational performance [31,35]. Culture change is thus commonly treated as an explicit (or implicit) part of efforts to implement evidence-based practice insofar as QI interventions aim to change business as usual [53-55]."

3. There are no examples offered for Step 2 (page 11). Add examples for Step 2 to text and Table 3.

   I have now included examples for Step 2 in the text (now on pages 16-17) and to the new Table 4 (formerly Table 3) (pages 44-45).

   "Organizational attributes have come into play at Step #2 in QUERI when established guidelines assume access to or availability of certain organizational resources to accomplish them (e.g., specialty access, equipment availability). Guidelines do not typically contain recommendations that consider area or organizational factors. For example, for the Colorectal Cancer QUERI, VA and U.S. Department of Defense (DoD) guidelines for colorectal cancer screening were updated with recommendations for direct colonoscopy as the screening test of choice. Implementation of evidence-based practice in these circumstances would require different approaches in VA facilities with adequate in-house gastroenterology staffing compared to those where specialty access required referral to another VA facility or to community resources to accomplish the same goal. Anecdotally, in the face of limited specialty resources, some VA facilities adapted guideline adherence policies by fostering primary care-based sigmoidoscopies. In contrast, the U.S. Public Health Service smoking cessation guidelines relied on by researchers in the Substance Use Disorders QUERI offer a more explicit roadmap that includes adaptive changes to health care settings to promote adherence with options for actions within and outside of primary care [71]. However, even they are limited in terms of their guidance on how best to accommodate different organizational constraints."

4. Discussion section—framework proposed in Figure 1 needs further explanation and reference to study findings. The purpose of this study was to use the context and examples from the US VA QUERI to illustrate a framework (Figure 1) to support inclusion of organizational factors when planning and implementing EBP. There is no reference to this framework till the discussion and very little explanation of it at that point. Further explanation/discussion of Figure 1 and its link to the study findings is needed.

   The reviewer's points are well taken. I have now included more explication of the framework proposed in Figure 1 on page 8, paragraph 2 (having also moved it up in the paper as recommended by the editor). As a result, I have also refined Figure 1 to further clarify the organizational research that may be conducted before, during and after traditional implementation activities are performed.

   "When to introduce organizational research applications as an adjunct to implementation efforts has also not been well-described. Figure 1 suggests possible timing of different organizational research activities in relation to the implementation, evaluation and spread of evidence-based practices.

   First, organizational factors may be broadly applied as a pre-step to the design of QI interventions (e.g., elucidating organizational precursors of high and low performance) [35] or more narrowly in preparation for refining an implementation strategy in one or more specific facilities (needs assessment) [14]. During implementation, attention to local organizational structures and processes enables systematic assessment of their influences

on fidelity to the evidence (e.g., is the care model being deployed in ways consistent with the evidence base?). Such assessments may be accomplished through qualitative methods (e.g., semi-structured interviews of stakeholders at different levels of the organization; ethnographic immersion in the practice; observational site visit checklists of organizational resources) or quantitative methods (e.g., key informant surveys of predetermined organizational attributes; administrative data pulls on utilization patterns, costs, performance in total and for patient subgroups). Such organizational assessments are sometimes used as an integral function of evaluating implementation in real time to enable mid-course corrections through audits, feedback and adjustment of intervention elements (formative evaluation) [36] and other times as post-implementation appraisals.

If done iteratively, as in the Plan-Do-Study-Act (PDSA) cycles of individual quality improvement (QI) projects, local adaptation and resolution of implementation problems at the organizational level may be accelerated (Figure 1). Traditionally applied in continuous quality improvement (CQI), PDSA cycles are generally designed to take a single or few patients or providers through a series of processes underlying a proposed QI activity to iteratively test what works or does not work before investing in widespread policy or practice change [44]. Each process is refined, new elements added or others subtracted until the complete set of actions is found to be effective in a particular setting. In implementation research, PDSA cycles offer the same opportunity to hone implementation strategies in diverse settings. The system level PDSA occurs when the PDSA cycles move from implementation within a single organization to a set of organizations that may or may not be similar in characteristics to the original institution [14]. Though not all QUERI centers have relied on PDSA approaches for their implementation efforts, as more of them move to multi-site implementation trials or are engaged in regional or national spread initiatives, we anticipate that greater appreciation of the details needed to adapt evidence-based practices to different organizational contexts will be helpful.

After implementation ends, traditional process and outcomes evaluations may be augmented with analyses of organizational variations in implementation strategies, outcomes (e.g., system-level effectiveness or costs) and the degree to which organizational factors influence sustainability and spread (Figure 1). Examining the impacts of the newly implemented evidence-based care on the organization as a whole is also an essential evaluation component as they begin to form the foundation for a business case for quality improvement for health care managers (e.g., changes in performance measures, employee satisfaction/retention, evidence for the organizational return-on-investment associated with changes in care) [38-39]. Systematic collection, analysis and reporting of detailed organizational data may then contribute to updated guidelines that integrate effective adaptations for different organizational characteristics."

5. The introduction of the term "organizational change" should also be explicitly addressed in the discussion or more care taken earlier in the manuscript to lay out the specific terms used in the paper and their meaning(s). Greater care and precision throughout will make this a more useful contribution to the literature.

   I have reviewed and revised the narrative of the manuscript to remedy the term slippage that the reviewer points out. This point is especially well taken because one of the dilemmas in the organizational research literature is the different terminologies of the various disciplines engaged in related work (e.g., social psychology, organizational sociology, education, economics, health care epidemiology, etc.). In some cases, this required tightening the text by eliminating reference to the organizational change literature in the discussion, which was

too broad for the purposes of describing organizational influences on implementation of evidence-based practice.

Minor Essential Revisions

1. QI not defined in text or on abbreviation page.

   I have now defined QI in the text (spelled out in the abstract and top of pg 4 Introduction; limited its use early in the paper where possible, until it gets defined under the QUERI steps where it is an essential part of what QUERI aims to achieve [page 13 under "Implementing Quality Improvement (QI) Interventions"]). I have now also included it on the abbreviation page (top of page 22).

2. Section: Common measure of health care organizational factors (pages 6-9). This section is organized according to the 3 components of Donabedian's Quality of Care Framework. This should be acknowledged.

   I have added both Donabedian's name in the description as well as linked it to an appropriate reference (bottom of page 7):

   "For the purposes of generally classifying different types of organizational attributes related to quality of care, we delineate them along the lines of Donabedian's structure, process and outcome framework [25]."

3. First sentence under "Organizational Structures" (page 7) needs references.

   I have added references to the first sentence as requested (now page 9, 2nd paragraph).

4. Organizational processes – author suggests these support the actions between doctor and patient, it seems likely that they would in fact support actions of the full range of providers, not just physicians.

   Excellent point—I have replaced the word "doctor" with "provider". The full sentence is shown below from page 8, paragraph 2:

   "Organizational processes may be distinguished from the classical interpretation of Donabedian's process of care measures by virtue of their role in supporting the actions between provider and patient at a given encounter [25]."

5. Bullets on page 9 should have references.

   I have now included references for each bullet (now on pages 6-7 because of the relocation of this section per the editor's recommendation—see Item #5 under Specific Comments from the Editor). The conceptualization of these bulleted issues being central to how we may benefit from integration of health care organizational research in implementation science is one of the contributions of this paper.

6. Referring to point 4 above, material in Table 2 (page 32) should either be reduced or text that correspond to it should be streamlined and focus primarily on examples.

I have reduced the text associated with the explanation of the roles of organizational research in QUERI in the former Table 2 (now Table 3 in response to the request that QUERI Theme Series authors add a new Table 1 summarizing QUERI). To reduce redundancy, I have taken out each statement describing individual steps since they are in the Table, and otherwise tried to focus on explanations and examples. This resulted in the elimination of over 20 lines of text.

Discretionary Revisions

1. The word "measures" on page 6 is problematic. This work implies a specific instrument/scale, number or unit, but the author is referring to characteristics of organizations not specific measures of these characteristics. A more appropriate term would be "concepts" accompanied by rewording of the sentence.

   I have replaced the term "measures" with the term "concepts" as suggested, as well as reworded the sentence in question as shown below (now middle of page 7 under revised heading "Common Concepts Representing Health Care Organizational Factors"):

   "Several common concepts have been used to describe the characteristics of health care organizations (Table 2)."

2. Two or three sentences describing and a reference for PDSA if available (page 10) could be added.

   I have expanded the section describing PDSA (and included an appropriate reference), and also addressed the notion that this is not an automatic step as mentioned under the specific editorial comments below. In the process of reorganizing several sections, bringing them into the paper earlier (organizational theory, etc.), I have also moved the PDSA section up where I more fully discuss Figure 1 as requested. The PDSA cycles are more clearly articulated in the Figure as well.

   "If done iteratively, as in the Plan-Do-Study-Act (PDSA) cycles of individual quality improvement (QI) projects, local adaptation and resolution of implementation problems at the organizational level may be accelerated. Traditionally applied in continuous quality improvement (CQI), PDSA cycles are designed to take a single or few patients or providers through a series of processes underlying a proposed QI activity to iteratively test what works or does not work before investing in widespread policy or practice change [44]. Each process is refined, new elements added or others subtracted until the complete set of actions are found to be effective in a particular setting. In implementation research, PDSA cycles offer the same opportunity to hone implementation strategies in diverse settings. The system level PDSA occurs when the PDSA cycles move from implementation within a single organization to a set of organizations that may or may not be similar in characteristics to the original institution [14]. Though not all QUERI centers have relied on PDSA approaches for their implementation efforts, as more of them move to multi-site implementation trials or are engaged in regional or national spread initiatives, greater appreciation of the details needed to adapt evidence-based practices to different organizational contexts will be helpful."

Specific Comments from the Editor

1. The article is based on the fact that, at a system level, it is necessary to understand organisational attributes because [1] these vary and [2] they can be successfully modified

to good effect. The conduct of a pragmatic randomised controlled trial within which the known and unknown variables are randomly distributed between intervention and control sites and within which sites can modify the intervention to a degree can produce a policy relevant evaluation of effectiveness. The pragmatic nature of the trial allows for the fact that the same degree of modification would happen under subsequent implementation and the same overall effect should be seen. The approach doesn't open the black box but side steps it. It represents another way to deal with the problem of varying attributes of participating sites.

I agree that pragmatic randomized trials offer one possible solution and now integrate their discussion in the paper (see below). I also agree theoretically that the known and unknown variables ought to be randomly distributed. However, our own work suggests that, to the contrary, some key organizational variables are not randomly distributed and one may sidestep them at some risk. Our key example related to QUERI is the Quality Improvement Trial for Smoking Cessation (or QUITS). In this group randomized trial of 18 intervention and control practices, matched on region, size and academic affiliation, we identified substantial variations in a host of organizational attributes (both structures and processes) associated with implementation effectiveness (revised manuscript summarizing main trial results still under review). Because our work in this area is still underway and component articles are in various stages of preparation for publication, I cannot offer more than a conceptual "think piece" treatment in the current paper. Thus, I hope that the more explicit treatment of pragmatic trials addresses your main concern.

Within the paper, these issues seem to best fit within the section laying out the key considerations for dealing with organizational issues in implementation research as a 4th bullet ("The nature of the study designs and evaluation methods needed to demonstrate implementation effectiveness and foster sustainability and spread at the organizational level") under the "Role of Organizational Factors in Implementation Research" that starts on page 5. Below is a new paragraph added (middle of page 10) that presents the value of pragmatic trials (integrating some of your language above):

"Study Designs and Evaluation Methods Supporting Implementation Effectiveness

Achieving study designs and methods that produce credible evidence with relevance to "real world" settings is challenging, especially when aiming to evaluate population-based or practice-level interventions [40-41]. Balancing the needs of internal and external validity, pragmatic clinical trials offer participating sites an opportunity to modify the intervention to a degree that is likely to mirror what would happen under routine-care implementation [42-43]. Rather than open the "black box," these trials assume that the known (and unknown) variables are randomly distributed between intervention and control sites. Systematically assessing organizational factors through qualitative or quantitative methods may nonetheless provide a useful empirical complement to our use of pragmatic clinical trials. This is especially true in circumstances when researchers have reason to believe the variables of interest are not in fact randomly distributed. These types of data are also likely to improve our understanding of factors which influence provider or site participation [44-45] and the nature of modifications that worked in different organizational contexts [46].

Ensuring integration of rigorously designed and well-conducted organizational research to the mix will require not only broader recognition of its contribution to the goals of implementation science but also an organizational research framework, like the one proposed here, that guides researchers to the types of organizational research they ought to be considering each

step along the way. We posit that collecting and using organizational data will increase what we are able to learn about what settings, arrangements and resources foster or hinder adoption, penetration, sustainability and spread beyond the trial or implementation process. As Green and Glasgow suggest, "if we want more evidence-based practice, we need more practice-based evidence [46]."

These issues are also partially dealt with at the top of page 20 within the context of the QUERI steps:

"Few large-scale experimental trials of the effects of specific adaptations to local organizational context that may be incorporated in Step #4 implementation efforts have been conducted. Recruitment of a sufficient number of organizations with the characteristics of interest typically requires dozens of health care settings, adding to the size, expense and complexity of cluster randomized trials [50]. Adaptations to local organizational context therefore commonly occur as extrapolations from associations identified in quantitative cross-sectional analyses or through application of qualitative data. It is important that the level of evidence supporting on-the-ground changes in implementation protocols and procedures from site-to-site be clearly described."

2. You assume that greater understanding of factors leads to greater success of interventions. I accept that the QUERI framework (which is, after all, what you have been asked to write about) takes you down this route. However, I would be interested to know what evidence you can cite to support the underlying contention. The only attempt I know to try and address this issue (B Shaw, F Cheater, R Baker, C Gillies, H Hearnshaw, S Flottorp, N Robertson. Tailored interventions to overcome identified barriers to change: effects on professional practice and health care outcomes.) did include some studies that could have been regarded as evaluations of interventions that had organizational elements – and it came to very ambivalent conclusions about the effectiveness of tailored interventions. If you know of other robust attempts to look at this it would be valuable to include them.

   I agree that the published literature in this regard is modest and the Shaw et al. example is probably the best citation for the effectiveness of tailored interventions. In light of their systematic review, I have modified the sentence as follows:

   "Practice individuation or tailoring has also had variable success [33-35]."

3. Having read the paper I was left uncertain about what it was that was unique about "organizational research." Many of the things that you include in your examples are the sorts of things that I would expect thoughtful "health services researchers" to do within implementation studies. The other way of dealing with this would be to say something about how research teams could organize themselves as multi-disciplinary teams and cast organizational research as one of several lenses through which the situation can be viewed. The reviewers encourage you to use terminology consistently. Part of what I perceive as the reason that you slip between terms is related to this point. On page 17 you say "Applying organizational research methods, theory and thinking to implementation science…" without ever defining how you distinguish these. Hopefully dealing with the general issues can help with this.

   I agree that one would hope that thoughtful health services researchers would incorporate such organizational constructs in their work, but there is little evidence in the literature that

this is broadly done at this juncture with the exception of basic measures such as size or area factors like urban/rural location. Integration of organizational theory is also woefully inadequate. The best way to deal with these issues is to do exactly what you describe and that is to "cast organizational research as one of several lenses through which" implementation research may be viewed. The notion of "lenses" is consistent with the extant sociological literature as well. I have significantly revised the first paragraph of the discussion with this and other issues you have raised in mind (top of page 23) (below) in addition to dealing with the terminology issue throughout:

"We posit that a better understanding of the organizational factors related to implementation of evidence-based practice is a critical adjunct to efforts to systematically improve quality across a system of care, especially when the evidence must be translated to increasingly diverse practice settings. Specifically, more explicit accommodation of organizational inquiry into implementation research agendas has helped QUERI researchers to better frame and extend their work as they move toward regional and national spread activities. While some QUERI researchers have used traditional or pragmatic randomized trials, they have also worked to integrate complementary evaluation methods that capture organizational attributes in ways that enable them to open the "black box" of implementation, and in turn help inform and accelerate adoption and spread of evidence-based practice in each successive wave of practices. We argue for the value of casting organizational research as one of several lenses through which implementation research may be viewed."

4. It would be helpful if, throughout the article, you hold onto the distinction between description and prediction. QUERI as an enterprise is about changing things. Therefore it needs to understand attributes in terms of their changeability or fixed attributes that are effect modifiers. There are places within the manuscript where you are dealing with this but to have it consistently enforced throughout would be helpful for the reader. This is highlighted by your section on organizational culture on page 8. My understanding of this area is that there is no widely agreed definition of culture, no agreed instrument to measure it and problems with analysis. If I am wrong it would be most helpful to say what is the current state of play. However, if I am correct I think that you have to be much more cautious. I take the implication of the section on theory that you have written on page 19 to lend some support to my position. I agree with what you have written on p19 and wonder if you shouldn't move it to the start of the paper as it forms an important backdrop for the whole paper. This also applies to the bottom half of page 18.

   I agree with the importance of the distinction between description and prediction, and the need to understand organizational attributes in terms of fixed and mutable characteristics. I have gone through the text, working to make this point more consistently and explicitly reinforced. For example, I have added the following statement to the introduction of "The Role of Organizational Research in the QUERI Model" (starting on the bottom of page 14) (the new sentence appears at the end of the 1st paragraph on the top of page 15):

   "The role of organizational research is therefore both to understand the changeability of organizational attributes, and when fixed, to integrate them as effect modifiers in analyses of the effectiveness and impact of implementation efforts."

   Again in the Discussion section, I emphasize the VA's contribution in this area from this perspective (bottom of page 23):

   "Because of its size, diversity and national data systems, the VA provides a useful venue for

developing transferable insights regarding the effects of fixed and mutable organizational factors on routine care implementation."

I have also specifically added cautions to the use of organizational culture as suggested (bottom of pg 13 and top of page 14):

"Despite substantial interest in the potential of culture as an organizational attribute, there is no widely agreed upon instrument to measure culture and no consensus on how best to analyze or apply findings from these data to improve implementation of evidence-based practice. Also, organizational culture as measured among VA employees has been fairly consistent over time, raising issues about its mutability and the measures' sensitivity to change."

In responding to Reviewer #1's comments asking me to expand the culture section, I have now also added material on the "current state of play" (see response to Reviewer #1's Item #2 under Major Compulsory Revisions above).

I agree with your recommendation to move the theory section to an earlier part of the paper. Review and discussion of Figure 1 have been moved up as well. The changes are significant enough that I have not replicated the paragraphs here but instead would point you to pages 7 through 10 of the revised manuscript.

5. Role of Organizational Factors in Implementation Research. I'm not sure what you mean by a "structure-quality" linkage – could you clarify?

   I have clarified what I meant by "structure-quality" linkage by revising the sentence as follows (top of page 6): "As a result, relatively few linkages between organizational structure and quality (either processes or outcomes of care) have been demonstrated [12]."

6. I have some problems with your sub-section Organizational outcomes. What I think that you are describing are measures of the process or outcome of clinical care being applied within the context of the evaluation of an organization. This doesn't, in my book, make them organizational outcomes but illustrates the inter-relatedness of the nature of the evaluations that are needed.

   I have revised the "organizational outcomes" section further by refining one of the examples (e.g., "glycemic control among all diabetics in the entire practice" on top of page 13) and working to make the distinction between typical outcomes among those "enrolled" in a particular trial and what the results of implementation may be for the entire practice or organization. As you point out, if implementation of an evidence-based care model is designed to improve care for diabetics, then some part of the evaluation of that intervention should also be at the practice or population level. To that end, I have added the following two sentences to this section (middle of page 13):

   "Many trials and observational studies of the implementation of evidence-based practice continue to focus on "enrolled" populations rather than the entire practice that would be likely to experience the new care model or practice intervention under routine conditions. Organizational outcomes are distinct only insofar as they represent what the entire practice or institution would experience as a whole once implementation is complete, and are thus inter-related to other evaluation activities."

7. I think the section starting "The diversity of how…" on page 9 is important and could again be usefully placed earlier in the manuscript. I think you could add to it a bullet point relating to the question being posed and could link it to the paragraph about the limitations of theory.

   I agree and have moved this section up to page 6, paragraph 2. I have also added a bullet point as suggested, linking it then to the paragraph that I have already moved about the limitation to theory. Thank you for helping recommend this improved order, which is actually consistent with the order from one of my earlier drafts. You can see the revised flow on page 6 starting on paragraph 2 through page 10. I have used the bullets to organize the relocated paragraphs under new subheadings: Organizational Theory and Conceptual Frameworks, What is Known about Organizational Structures and Processes Underlying Evidence-based Practice, and Timing of Organizational Research Applications Before, During and After Implementation. This has also helped me address Reviewer #1's concern about the lateness with which Figure 1 (timing of integration of organizational research) was originally introduced (in the Discussion) (see response to Reviewer #1's Item #4 under Major Compulsory Revisions).

8. The section about QUERI on page 10 is now redundant and could be largely removed.

   I have removed much of this section about QUERI (almost 9 lines' worth) now that the standardized material has been included (top of current page 11).

9. You imply in page 10 that the use of PDSA cycles is some sort of automatic step – I don't think it is. It seems more to be a tool (one of a number that are available) that QUERI has chosen to use. Is this correct?

   Point well made—I agree that use of PDSA cycles is not an automatic step and did not mean to imply such. I have revised this section in addition to adding definition and reference per Reviewer #1 (see above). I have also clarified that this is a tool or approach to implementing evidence-based practice in organizations just like you would apply it to patient or provider level QI interventions. Not all QUERI centers have chosen to use PDSA cycles, so that point is made more clearly now as well.

   See response and accompanying text for Reviewer #1 comments above (Item #2 under Discretionary Revisions).

10. On pages 10 and 11 you talk about steps 1 and 2 in a way that seems a bit artificial – almost that you are saying something because steps 1 and 2 are how you get to steps 3 to 6 where I think you have much more to say. I would be quite happy for you to deal with steps 1 and 2 in a much more cursory way identifying that it is at step 3 that the major impact of "organizational research" begins. Unless you wish to make the case that it is important to have an organizational focus when conducting the prevalence/environmental scan studies in step 1 and identifying variation by organization/setting, etc. Also, re:step two EBP – adaptation of guidelines that take into account organizational factors set ups is also important and could be highlighted better.

    You are right that the impact of organizational research is more clearly seen in steps 3-6. However, there are anticipatory activities for steps 1-2 that are useful in gearing up to steps 3-6. I try to make the case more clearly that an organizational focus is useful even at these early stages—the results of organizational work at these early stages

provide an early window to the issues implementers may face in adapting to local variations in key organizational characteristics. I have dealt with steps 1 and 2 by focusing on their contribution toward preparing for subsequent steps, while also highlighting the importance of adapting guidelines to take into account organizational factors. Hopefully, these changes have made the steps seem more robust and less artificial, especially with the addition of examples per Reviewer #1. Below is the text that has been revised to accommodate these changes:

REVISED MATERIAL UNDER QUERI STEP #1 (from pages 15-16):

"Evaluate Disease Burden and Set Organizational Priorities (Step #1)

In a national health care system like the VA, conditions have been chosen on the basis of nationally prevalent conditions (e.g., diabetics, depression) or those associated with high treatment costs (e.g., HIV/AIDS, schizophrenia). Target conditions have also been updated periodically to accommodate changes over time (e.g., additional focus on hepatitis C added to the QUERI HIV center mission and scope).

On a national level, all facilities have commonly been held to the same performance standards regardless of organizational variations in caseload or resources. In smaller systems or independent health care facilities, organizational priorities should be established based on ascertainment of disease burden at the appropriate target level (e.g., individual practices or clusters of practices). At this step, it is important to determine how salient target conditions are among member organizations or individual practices by evaluating the range or variation in disease burden or performance. Modified Delphi expert panel techniques have been useful in establishing consensus among various organizational stakeholders in order to set institutional priorities [67]. These techniques entail advance presentation of the evidence base for a particular condition or setting (e.g., a compendium of effective interventions based on systematic reviews) [68-69] and stakeholders' pre-ratings of their perceptions of organizational needs and resources, followed by an in-person meeting where summary pre-ratings are reviewed and discussed. Participants then re-rate and prioritize planned actions with help of a trained moderator.

Many QUERI efforts have benefited from inclusion of QUERI-relevant measures in the national VA performance measurement system (e.g., glycemic control, colorectal cancer screening); this alignment of QUERI and national VA patient care goals fosters research/clinical partnerships in support of implementing evidence-based practice. For those QUERI centers whose conditions fall outside the national performance measurement system (e.g., HIV/AIDS), alternate strategies, such as business case modelling (i.e., spreadsheet-type models summarizing operational impacts of deploying a new care model or type of practice), have anecdotally met with some success."

REVISED MATERIAL UNDER QUERI STEP #2 (from pages 16-17):

"Identify Evidence-based Practice Guidelines and Clinical Recommendations (Step #2)

Organizational attributes have come into play at Step #2 in QUERI when established guidelines assume access to or availability of certain organizational resources to accomplish them (e.g., specialty access, equipment availability). Many guidelines do not contain recommendations that consider organizational factors. It is thus essential to begin to consider the implications of the differences between the characteristics of the health care organizations in which efficacy and effectiveness have been established vs. those in which

the evidence-based practices will subsequently be applied in order to improve their reach and adoption [70].

For example, for the Colorectal Cancer QUERI, VA and U.S. Department of Defense (DoD) guidelines for colorectal cancer screening were updated with recommendations for direct colonoscopy as the screening test of choice. Implementation of evidence-based practice in these circumstances would require different approaches in VA facilities with adequate in-house gastroenterology staffing compared to those where specialty access required referral to another VA facility or to community resources to accomplish the same goal. Anecdotally, in the face of limited specialty resources, some VA facilities adapted guideline adherence policies by fostering primary care-based sigmoidoscopies. In contrast, the U.S. Public Health Service smoking cessation guidelines relied on by researchers in the Substance Use Disorders QUERI offer a more explicit roadmap that includes adaptive changes to health care settings to promote adherence with options for actions within and outside of primary care [71]. However, even they are limited in terms of their guidance on how best to accommodate different organizational constraints."

11. You shouldn't underline in text.

    I have removed the underlining within the text (originally used to highlight which QUERI Center a particular finding was related to).

12. page 10: need description of how priorities are actually set in step one which is a separate issue from collecting data on the prevalence or burden of the condition – what are the criteria for identifying condition that needs attention?

    I have added a description of how priorities may be set in step one (middle of page 14), and worked to clarify the criteria for identifying conditions that need attention as well. Since this required revising this section, I have provided the entire Step #1 section below:

    "Evaluate Disease Burden and Set Organizational Priorities (Step #1)

    Step #1 in the QUERI process focuses on identifying high-risk and/or high-burden clinical conditions or high-priority practices and then setting organizational priorities. In a national health care system like the VA, conditions have been chosen on the basis of nationally prevalent conditions (e.g., diabetics, depression) or those associated with high treatment costs (e.g., HIV/AIDS, schizophrenia). Target conditions have also been updated periodically to accommodate changes over time (e.g., additional focus on hepatitis C added to the QUERI HIV center mission and scope).

    On a national level, all facilities have commonly been held to the same performance standards regardless of area variations in caseload or resources. In smaller systems or independent health care facilities, organizational priorities should be established based on ascertainment of disease burden at the appropriate target level (e.g., individual practices or clusters of practices). At this step, it is important to determine how salient target conditions are among member organizations or individual practices by evaluating the range or variation in disease burden or performance. Modified Delphi expert panel techniques have been useful in establishing consensus among various organizational stakeholders in order to set institutional priorities [60]. These techniques entail advance presentation of the evidence base for a particular condition or setting (e.g., a compendium of effective interventions based on systematic reviews) [61-62] and stakeholders' pre-ratings of their perceptions of organizational

needs and resources, followed by an in-person meeting where summary pre-ratings are reviewed and discussed. Participants then re-rate and prioritize planned actions with help of a trained moderator.

Many QUERI efforts have benefited from inclusion of QUERI-relevant measures in the national VA performance measurement system (e.g., glycemic control, colorectal cancer screening); this alignment of QUERI and national VA patient care goals fosters research/clinical partnerships in support of implementing evidence-based practice. For those QUERI centers whose conditions fall outside the national performance measurement system (e.g., HIV/AIDS), alternate strategies, such as business case modelling (i.e., spreadsheet-type models summarizing operational impacts of deploying a new care model or type of practice), have anecdotally met with some success. "

13. page 12: it would help if the org factors/characteristics associated with adoption of HIV guidelines and glycaemic control were actually stated.

    The organizational factors/characteristics associated with adoption of HIV guidelines and glycaemic control have now been included in the text as shown below (and on page 17, paragraph 1):

    "For example, QUERI-HIV researchers fielded a national provider survey to assess the structure and processes underlying HIV care delivery [66], and used that information to elucidate the organizational factors associated with adoption of HIV guidelines (e.g., urban, complex, larger HIV caseloads, use HIV case managers, report fewer barriers to antiretroviral therapy and opportunistic infection prophylaxis guideline implementation) and HIV-specific QI activities (e.g., larger, more complex facilities) [67]. Diabetes QUERI researchers have used general and QUERI-focused organizational surveys to benchmark practices with a system outside the VA [68], appraise the contribution of practice variations at the patient, provider and facility levels [69], and identify organizational characteristics associated with better glycaemic control (e.g., greater primary care authority over establishing clinical policies, greater staffing authority, greater use of computerized diabetes reminders, special teams or protocols to respond to clinical issues, weekly meetings of multidisciplinary clinical teams) [70]."

14. page 13: are the tools to assess organizational readiness and organizational diagnosis of system barriers available to readers?

    These tools are available from their originators in different QUERI Centers. I do not have authority to distribute them or to make them directly available to others. However, I would be happy to direct requestors to the leaders of some of these projects at different QUERI centers. Another alternative would be to include the QUERI weblink.

15. page 18: virtually no other health care systems can accomplish this to the same degree…except NHS and Kaiser—is this true? What about Australia or some of the western European countries?

    Point well made – the sentence overstates the uniqueness of the VA in international terms, whereas within the US, it is accurate. I have revised the sentence as follows (page 22, bottom of 1st paragraph):

"Virtually no other U.S. health care system can accomplish this to the same degree, with important exceptions of regional systems such as Kaiser Permanente. In many respects, the VA is more akin to national health systems outside the U.S., such as those in the UK and Australia, suggesting natural opportunities for cross-national comparisons and collaboration."

16. In Table 1, I don't understand the distinction between the two bullet points:
    - Knowledge, attitudes, beliefs of managers, providers, staff
    - Organizational readiness to change (conversely provider/staff resistance to change)

    when you have effectively defined the latter as negative attributes of the former.

    You are correct that the 2nd bullet is really a subset of the 1st bullet. I have revised the bullet to be clearer (retaining the 1st bullet and using the 2nd one as an example):

    - *Knowledge, attitudes, beliefs of managers, providers, staff (e.g., organizational readiness to change)*