

Author's response to reviews

Title: Improving eye care for veterans with diabetes: an example of using the QUERI steps to move from evidence to implementation

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Author's response to reviews: see over



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April 27, 2007

Dr Martin Eccles
Dr. Ian Graham
Implementation Science
QUERI Series Editors

Re: MS ID 1943474018110941

Title: QUERI Series: Improving eye care for veterans with diabetes: an example of using the QUERI steps to move from evidence to implementation

Journal: Implementation Science

Authors: Sarah L. Krein, Steven J. Bernstein, Carol E. Fletcher, Fatima Makki, Caroline L. Goldzweig, Brook Watts, Sandeep Vijan and Rodney A. Hayward

Dear Drs. Eccles and Graham:

Thank you for the opportunity to resubmit a revised manuscript, which we are submitting for consideration as part of the QUERI Series. We thank the reviewers and the Editors for their careful review of the manuscript. We appreciate the constructive nature of the reviews and have revised the manuscript in accordance with the suggestions made by the reviewers, including the general comments from the series Editors. Our responses to the reviewer comments and specific revisions are described in detail in the attached document.

On behalf of all the authors, I would like to thank you for your time and consideration.

Sincerely,

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Reviewer 1 Comments (Luciana Ballini)

Minor Essential Revisions

Step 1: Priority Conditions/Issue. I would welcome a broader discussion on Step 1. In particular it is often the case that choice for a specific condition can be supported by adequate statistical data and cost information (as it is done in the paper). However, the issue of establishing a priority does not, in my opinion, relate so much to evidence of morbidity etc. but to how you rate priority in the presence of competing conditions/ issues with equivalent adequate statistical data and cost information. My question is: was the issue “preventing blindness among veterans with diabetes” chosen from list of competing conditions within diabetes or was it chosen from a wider list of conditions including diseases other than diabetes, and on what basis the choice was made.

We certainly agree that prioritization is a much more complicated process than described in this paper and in many cases should be approached from a more comprehensive perspective. Because each QUERI center was by design created to focus on a specific condition (e.g., diabetes, chronic heart failure, stroke), as the diabetes QUERI our decision about what issues/conditions to address was selected from a list of conditions within diabetes. Preventing blindness is actually only one of several priority areas, as noted in our description of the diabetes QUERI priorities areas in the background section. However, we appreciate that the fact that all of our priorities are diabetes related may not be apparent and have clarified this issue in the description provided in paragraph 1, page 6: “Reducing preventable morbidity and mortality among veterans with diabetes is the primary objective of the VA’s diabetes QUERI with specific diabetes-related priority areas that include . . . “

In addition, due to space constraints our discussion of Step 1 was kept very brief. We agree that we should provide more context as to our selection of preventing blindness as an important issue and have revised the last sentence under the step 1 heading, paragraph 1, page 7 to both reiterate our primary goal and refer back to the broader discussion in the background section: “Thus, preventing blindness among veterans with diabetes is a high priority issue for the VA and, as part of our goal to reduce preventable morbidity and mortality among veterans with diabetes as previously described, one of several important issues for the diabetes QUERI.”

Step 2: Evidence-based Practices. Similarly I found I missed some information on the description of Step 2, which as far as I understood, led to the recommendations to be implemented. Were these recommendations simply the result of literature search and appraisal or did they undergo a discussion and consensus process by a multidisciplinary panel?

The recommendation included both evidence from the literature, including the study highlighted, as well as review and discussion by a multidisciplinary panel. We have clarified this issue in sentence 1, paragraph 2 on page 9: “The results of this Step 2 project, along with similar findings by other researchers [31,32], provided some of the evidence for review and discussion by a multidisciplinary panel of a proposed change in

the prevailing quality standard from requiring annual screening for all patients with diabetes to a risk stratified approach.”

Discretionary revisions

The lack of quantitative data on the results of the implementation programs, justified as published elsewhere, is compensated by the interpretation of the problems encountered during implementation. Indeed the discussion/conclusion section seems to refer (though not stated explicitly) to a series of barriers to the actual implementation strategy, thus giving the impression that barriers identification, analysis and removal becomes a sort of Chinese box enterprise, where interventions to remove barriers are hindered by further barriers to the application of the interventions themselves. Although this might seem disconcerting, it nevertheless reflects what actually happens in practice and I think it deserves further emphasis.

We like the reviewer’s analogy of a “Chinese box enterprise”, which we think is a rather accurate summary of what we encountered and tried to convey in this article. And, while it can be disconcerting we also believe that many of the obstacles we experienced are not insurmountable and with additional planning and foresight can to some degree be overcome or incorporated as part of the implementation process. We have attempted to convey this message within the confines of the space and format constraints of a journal article but to really do justice to these complex issues would likely result in an entire book.

Finally authors might like to comment more on the “adverse side-effect” of an implementation programme, such as the raising of expectations, which then fail to be met, both for patients (page 16 – “300 patients expressed an interest in having an appointment scheduled. Unfortunately, fiscal constraints preclude scheduling exams for these patients . . .”) and for health professionals (page 19 – “Moreover, as time passed any momentum or enthusiasm that may have been generated among clinic staff was soon diminished as the “promise” of a better system did not materialize”). Possible adverse reactions to future proposals of change may in fact arise from this past experience.

We appreciate the reviewer bringing this issue to our attention and agree that it should be acknowledged. Therefore, we have added a sentence in the conclusion section, paragraph 2 page 23: “Finally, despite the importance of learning by doing we must also be cognizant of the potential adverse consequences of unsuccessful implementation efforts, which for this project included not meeting the expectations or needs of both providers and patients, as we do not want to jeopardize future initiatives that could lead to significant improvements in patient care and outcomes. “

Reviewer 2 Comments (Gordon Mosser)

Minor Essential Revisions

At the top of page 9, the sentence that reads “In addition, this study helped identify close follow-up as a possible quality gap . . .” is a bit confusing. Perhaps a word or phrase is missing. I would suggest: “In addition, this study helped identify lack of close follow-up as a possible quality gap . . .”

The sentence has been changed as recommended: "In addition, this study helped identify lack of close follow-up as a possible quality gap that could result in preventable visual loss among patients with diabetes thus leading to Step 3 in the QUERI process."

Discretionary Revisions

In the results section (p. 15-16), it is reported that 708 (actually 780) checkout forms were completed. If possible reporting the success rate here would have some value, i.e., the rate of completion of forms for all patients for which a form would have been appropriate during the time period in question (November 2004 through June 2005). This would provide at least some measure of how well the ophthalmology residents and others were engaged in the project (on p. 17, the author say that this point cannot be fully assessed, but can any quantitative estimate be provided?)

We agree this would be useful information and regret that our tracking system was not structured for this purpose. Thus, we do not have the denominator information required to calculate the completion rate.

The comment, previously on page 17 refers to the use of the check out forms at 2 study sites, not just site A and cannot be determined as we do not have complete denominator data. This point is now clarified on page 18 as follows: " In addition, the extent to which the check-out forms were used at the two sites cannot be fully assessed due to incomplete information about the number of patients or patient visits while the forms were in use."

Also, I wonder whether it might be useful to discuss whether “building infrastructure” and “creating tension” are out of order in the model. The authors are clear that they had various difficulties in engaging eye clinic physicians and staff in using the checkout form and other parts of the system devised. Were these people engaged in devising the solution? If not, perhaps their motivation for using it might have been higher if they had been involved in building the system that was intended to solve the problem. But perhaps this would have been impractical because staff rotate through the clinics. Or perhaps this would be undesirable because a single system is desired for the whole VHA. Some discussion of these issues might be valuable.

Although our discussion is structured with “building infrastructure” first, followed by “creating tension” these activities were for the most part taking place at the same time so it is difficult to know what sort of order might be best. However, we certainly agree that engaging the physicians and staff in devising a solution would be ideal and to some extent tried to make them part of the process. This effort is described in more detail in paragraph 1 in the discussion on page 19: “Two prototypes were created and plans were

being made for testing and refinement of the electronic template in collaboration with the eye clinic staff and physicians. However, neither prototype was implemented due in part to staff turnover and a lack of active support from the eye clinic's clinical leadership at the main development site. "

Reviewer Comments (Martin Eccles)

Major Compulsory Revisions

On page 4 you refer to the QUERI approach, programme and process model – these all seem to refer to the same thing. If this is the case it would be best to take a single term and stay with it.

We have made revisions throughout the manuscript, including page 4, to ensure more consistency in our use of terminology so that we now refer to the QUERI process or process model when talking about the approach that was used. However, we do still use the term QUERI program when we are talking more globally about QUERI, which includes not only the QUERI process but certain resources.

On page 5 you say “The information provided in this paper is intended to help inform the continuing evolution of the VA QUERI program but perhaps more importantly assist anyone charged with the crucial task of implementing research into practice.” The focus of Implementation Science and this series of articles is more to inform those who research the implementation of clinical research into practice. I suggest that the text is edited to reflect this.

We agree that we need to be more explicit about the target audience and have revised the text on page on pages 4 and 5 as suggested. However, in addition to researchers, we believe that our results are also important for policy-makers and managers so have revised the sentence accordingly. The last sentence of paragraph 2, on page5, now reads “ The information provided in this paper is intended to help inform researchers, policy-makers and managers who might be studying or engaged in implementing research into practice. “

My understanding of the QUERI phases is that what you describe for steps 4, 5, & 6 is closer to Phase 2 (Small scale, multiple site quasi-experiment) rather than Phase 1 (Single site pilot) – in that you were working across multiple sites; but you did not use a quasi experimental design. Could you clarify this? Throughout, I didn't have a clear idea of where you were in the overall process from producing scientific evidence to the routinising of such evidence within clinical care. You were involved in an incremental scientific process – not an end point attempt to implement a change. The general frame of writing should be edited to reflect this throughout the manuscript.

We understand the confusion about whether this was a phase 1 or phase 2 project and provide additional clarification on page 11. Essentially the eye care implementation project described under steps 4, 5, & 6 was designed as a Phase 2 study with a quasi-experimental design. Specifically, “The proposed implementation project was a small scale multi-site study (or phase 2 project as described in Table 1) with a quasi-

experimental design. However, because of difficulty with implementation the design was changed to a single site pilot (or phase 1 project as described in Table 1)."

The issue of where we were in the overall process is a bit more difficult to address since we essentially moved through all steps (from producing scientific evidence to an attempt at routinizing the use of this evidence in clinical care). The paper is structured to demonstrate this progression albeit most of the discussion is focused on the implementation aspect. This proposed structure is described on pages 6 and 7. If the question is more specific to the implementation section and where we were in the overall process during that project, that too is difficult to describe given that implementation is not a linear process and we were producing evidence, learning, and trying to enact a change all at the same time.

Could you also, within the discussion say something about the role of a Phase 1 or 2 study in relation to the underlying science. My reading of what you have done is to develop and pilot an intervention – a type of proof of concept study. Would the next steps be to evaluate this within a wider range of settings in order to establish both effectiveness and generalisability?

As requested we have added additional discussion of this issue on page 18: "In retrospect we also now appreciate the potential value of the four phases within the QUERI implementation framework (Table 1). We ambitiously proposed a small scale, multi-site implementation project before completing a single site pilot. Ideally, having conducted the pilot work as just described and with a more functional scheduling intervention we would now move on to the multi-site study. Plans for this next phase may have to wait until certain technological issues are resolved."

When describing work you should do this in a standard way, rather than naming lead authors. There is also no need to repeatedly identify QUERI funding as this can be assumed. After the initial part of the paper funding sources should only be mentioned if they are NOT QUERI related. E.g., at the top of page 8 "To address this issue, Sandeep Vijan and colleagues, with support from the diabetes QUERI, conducted a cost-utility study to examine the marginal cost-effectiveness of different screening intervals for patients with type 2 diabetes." Should be written as "to address this issue, a cost-utility study was conducted to examine the marginal cost-effectiveness of different screening intervals for patients with type 2 diabetes." On page 9 "To better understand the circumstances surrounding preventable visual loss among patients with diabetes a second study, also supported by the diabetes QUERI, was undertaken. This research by Rod Hayward and colleagues, focused specifically on the timing of retinal photocoagulation as a key issue in preventable visual loss." Should be written as "To better understand the circumstances surrounding preventable visual loss among patients with diabetes a second study was undertaken [20], focused specifically on the timing of retinal photocoagulation as a key issue in preventable visual loss."

We have standardized our descriptions and revised the specified sentences (now on pages 8 and 9) as indicated.

Re step one- more discussion of how priorities are determined would be helpful (currently it just presents the data supporting the importance of eye care) not why eye care was selected by QUERI for attention – on what basis are conditions prioritized?

As discussed in our response to reviewer 1, the primary objective of the diabetes QUERI is to reduce preventable morbidity and mortality among veterans with diabetes and to address that objective focus on multiple diabetes-related priority areas. These priority areas are described in the background section. As such, we have also revised the last sentence under the Step 1 heading, paragraph 1, page 7 to both reiterate our primary goal and refer back to the broader discussion in the background section: “Thus, preventing blindness among veterans with diabetes is a high priority issue for the VA and, as part of our goal to reduce preventable morbidity and mortality among veterans with diabetes as previously described, one of several important issues for the diabetes QUERI.”

Not sure it should fall under step 2 or not but acknowledging the existing guidelines that were actually at odds with their research should be mentioned to contextualize the research phase and prime the reader for this being an important barrier to implementation later on.

We agree that this issue requires more attention and have made several changes. In response to comments from reviewer 1 we have provided additional clarification in our Step 2 discussion about how the evidence was being used in the policy arena: sentence 1 on page 9: “The results of this Step 2 project, along with similar findings by other researchers [31,32], provided some of the evidence for review and discussion by a multidisciplinary panel of a proposed change in the prevailing quality standard from requiring annual screening for all patients with diabetes to a risk stratified approach.”

In addition, we have added a sentence to our Step 4/5/6 discussion to reiterate the relevance of the quality measures, with a more detailed description provided in the results section (e.g., pages 15 and 17). Specifically we have added this sentence on page 10. “First, as mentioned in our discussion of QUERI step 2, changing the diabetes eye care quality measure used in HEDIS® and the VA’s quality monitoring system was actively being debated. Efforts directed toward changing the current measurement policies began well before the eye care implementation project and continued throughout much of the study period as described in more detail in the next section.”

Explain what retinal photocoagulation is for non clinicians

We have added a definition of retinal photocoagulation (i.e., laser eye surgery) on page 9.

P11 gustafson et al is referenced to citation 32 and 33 – is this correct?

Reference 32 is the citation for the work described prior to Gustafson et al. and the reference has been moved accordingly.

P15 mentions creating tension also requires becoming more actively involved in the policy arena – I would like to know more about this as this is another role IS researchers engage in which falls under change agent.

We have added a sentence to further explain how researchers were involved in the policy process. Page 15, paragraph 2, sentence 2: “Not only were researchers involved by producing evidence (as described in Step 2 above) but also served as technical experts while policy discussions about changing the diabetes eye care performance measure were in progress. “

P16 I would like more discussion about the ethical implications of identifying patients needing eye exams (they now know these patients are at hi risk), collecting info from them that they want exams (the patients now know they should be tested and indicate they want testing) and then not being able to provide the exams – the IRB did not have problems with this? I would have.

We agree that this was a difficult situation but moved from a research to a clinical or administrative issue after the data were collected and provided to the clinical leadership, thus no longer an issue for the IRB. We have revised the description of how this issue was handled through administrative channels on pages 16 and 17: “Unfortunately, fiscal constraints precluded scheduling exams for many of these patients. This was a difficult situation for both the involved researchers and the facility administrative and clinical leaders who had to employ a VA-wide prioritization strategy to determine who would be seen immediately and who would have to be accommodated as resources allowed. However, as of April 2006 less than 15% of the patients who expressed interest in scheduling an appointment had been seen in the eye care clinic.”

We would also like to note that those patients without exams were not necessarily high-risk, as defined in the paper, but of unknown risk status and so getting even 15% of them screened is an improvement.

The hybrid nature of this type of research and the operations enterprise (p23) – while they note this is particularly relevant to QUERI, I think the issues they raise are trying for typical implementation research that involves changing the organization of clinical work so I would suggestion that the discussion might reflect a broader perspective than the VA.

We very much agree and have removed references that suggest these lessons are specific to VA or to QUERI.