Author's response to reviews

Title: EQUIP: Implementing chronic care principles and applying formative evaluation methods to improve care for schizophrenia

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Author's response to reviews: see over
1. Response to Reviewer Roger Paxton

Major compulsory revisions

1.1 The methods section in the abstract should describe the methods used in the paper as well as the methods contained in the interventions described in the paper. The paper reports the background, development, results and implications of EQUIP, and goes on to describe work in progress on EQUIP-2. This should be clear at the start.

The abstract has been revised per the suggestion to describe the paper’s methods and the intervention’s methods, as follows: “This paper reports the background, development, results, and implications of EQUIP, and goes on to describe work in progress in the second phase of the project, EQUIP-2. The EQUIP intervention uses implementation strategies and tools to increase the adoption and implementation of chronic illness care principles. In EQUIP-2, these strategies and tools are conceptually grounded in a stages-of-change model, and include clinical and delivery system interventions and adoption/implementation tools. Formative evaluation (including developmental, progress-focused, implementation-focused, and interpretive evaluation) occurs in conjunction with the intervention.”

1.2 The results section should be clear that EQUIP-2 is in progress and not completed: initial findings are being used to develop a more comprehensive approach, rather than were used to develop…

The results section now reads: “In EQUIP-2, which is currently in progress, these initial findings were used to develop a more comprehensive approach to implementing and evaluating the chronic illness care model.”

The point that EQUIP-2 is currently in progress is reiterated in the main body of the paper, on page 3: “Evaluation of EQUIP led to a more recent project, EQUIP-2, which is a larger-scale trial of chronic care model implementation currently in progress.”

1.3 The conclusions are not justified by the results presented. The last sentence should begin: There is preliminary evidence that QUERI tools are useful…

The discussion has been revised to reflect a more tentative level of support for QUERI tools: “In QUERI, small-scale projects contribute to the development and enhancement of hands-on, action-oriented Service-Directed Projects grounded in current implementation science. This project supports the concept that QUERI tools can be
useful in implementing complex care models oriented toward evidence-based improvement of clinical care.”

1.4 The tables should be clearly introduced and commented on in the text.

*Each table is now clearly introduced and commented on in the text (see revision 1.6 below). The number of tables has been reduced (see revision 2.17 below).*

1.5 Where does the background end and the methods start? The section on EQUIP seems to be the start of the main substance of the work reported, and so the methods section should begin here.

*The methods section now begins with the section on EQUIP, as follows:*

**“Methods”**

This section will describe: (1) the EQUIP project and intervention methods in more detail; and (2) the methods used in the formative evaluation component of EQUIP.

*EQUIP Overview and Specific Aims”*

EQUIP findings are also clearly introduced, followed by a section entitled **EQUIP-2 Methods.**

1.6 Again the tables need to be introduced in the text.

*The tables are introduced in the text:*

“*QUERI is briefly outlined in Table 1 and described in more detail in previous publications [2,3].”*

“The intervention included clinical interventions, delivery system interventions, and adoption/implementation tools. These interventions and tools are presented in Table 2.”

“In addition to the clinical intervention described above, EQUIP involved formative evaluation. Table 3 depicts the methods that were utilized in the evaluation.”

“Evaluation of EQUIP provided an understanding of quality gaps and how to address related problems in schizophrenia. Our findings are summarized in the left column of Table 4.”

“Each of these factors is integrated into the STM, which guides the EQUIP-2 intervention and formative evaluation. Table 5 provides an overview of how we will engage in each phase of the STM.”

“Each VISN involved was asked to choose two evidence-based practices from a list of four practices that EQUIP-2 was prepared to support (Table 6). All four VISNs chose the same two targets: wellness and supported employment.”

1.7 EQUIP is introduced as an RCT but without mention of participants, participant numbers, settings, power calculations etc. Some but not all of the information is in table 3, but it should all be provided and summarized in the text.
The RCT is more thoroughly described as follows:

“The chronic illness care principles were evaluated at two outpatient mental health clinics within two large, urban VA Medical Centers in Southern California. At these two clinics, psychiatrists were randomized to intervention (care model) or control (treatment as usual). Case managers and patients were assigned to the same study arm as the psychiatrists with whom they were associated. At the third clinic within one of the Medical Centers, all the clinicians and patients were assigned to the control group. The chronic illness care model intervention was developed, implemented and fully operational in January 2003 and it was sustained for more than 15 months. The relevant Institutional Review Boards approved all trial procedures.

Clinicians were eligible for the study if they practiced at one of the clinics. Eligible clinicians were given information about the study and the opportunity to enroll. Patients were eligible if they were at least 18 years old, had a diagnosis of schizophrenia or schizoaffective disorder, had at least one visit with an enrolled psychiatrist during a four-month sampling period immediately before the enrollment period (i.e., “visit-based sampling”; Young et al. 1998), and then had at least one clinic visit during a five-month enrollment period. When an eligible patient came into the clinic during the enrollment period, he or she was provided with information about the study and was given the opportunity to enroll. The intervention included 32 psychiatrists, 1 nurse practitioner, 3 nurse case managers and 173 patients. The control group included 43 psychiatrists, 1 psychiatric pharmacist, 3 nurse case managers, and 225 patients. Informed consent was obtained from all patients or their legal conservators and all clinicians.”

1.8 The aims of EQUIP are first described as to investigate the effects of a particular care model by means of an RCT. Later on the same page we are told that EQUIP was less about that and more about evaluating whether the model could be applied to schizophrenia. What were the aims?

The specific aims are laid out as follows:

“The specific aims of EQUIP were 1) to assess, in a randomized, controlled trial, the effect of a chronic illness care model for schizophrenia relative to usual care on: a) clinician attitudes regarding controlling symptoms and side-effects, and regarding family/caregiver involvement in care; b) clinician practice patterns and adherence to guideline recommendations; c) patient compliance with treatment recommendations; d) patient clinical outcomes (symptoms, side-effects, quality of life, and satisfaction); and e) patient utilization of treatment services; and 2) assess, using mixed qualitative and quantitative methods, the success of the implementation strategy’s impact on uptake of the model.”

Furthermore, the original bullet points about evaluating the model have now been deleted.
1.9 The results are not clearly presented, and this is particularly difficult and surprising as they form the basis for EQUIP-2, which the paper goes on to discuss.

The results have been substantially revised to be more clearly presented. Additionally, the EQUIP results are demarcated by the heading EQUIP Results, and the EQUIP-2 Methods are now found in a separate section, distinct from the EQUIP Results.

1.10 This page moves from the description of methods and tables of results on the previous page to a discussion of results and implications, with no heading signaling the changes. These sections should be separated and clear.

As noted above (1.9), section headings have now been added to differentiate between the description of methods and the discussion of results.

1.11 Here the results of EQUIP are belatedly presented in table 7 together with the lessons drawn from them. This is a disjointed presentation of results and again the tables are not introduced or summarized.

The results are now found in Table 4, which appears earlier in the manuscript and which is revisited later in the manuscript with regard to changes that were made in the design of EQUIP-2. More attention is now given to a textual description of the material in the table. For example, the description begins:

“EQUIP revealed that solutions to quality problems in schizophrenia differ by treatment domain. For example, challenges to implementing family services proved to be very different from challenges to implementing weight management using wellness groups. Improving family services required assessment of each patient-caregiver relationship, intensive negotiation with patients and caregivers, major care reorganization to accommodate family involvement, and attention to clinician competencies (knowledge, attitude, and skills). Improving weight and wellness required assessment of the problem in each patient, the establishment of therapeutic groups, involvement of nutrition and recreational services, and help with referrals and follow-ups.”

The description continues on to explicate each component of the left column of the table.

1.12 The discussion is clear, well ordered and concise.

2. Response to combined comments from series Editors Martin Eccles and Ian Graham.

General comments for authors of all articles

2.1 Please remember that you are writing for an international audience. In some cases it seems the papers make comments that seem directed at the VHA and these should be deleted - you need to be thinking much more globally and presenting lessons learned and perhaps recommendations for how best to do implementation research regardless of what
your own system is like. The DETAIL of VHA structures and funding are of no interest to an international audience. If you wish to make reference to funding it should only appear in the acknowledgements section and not in the body of the text.

In this manuscript reference is made to funding only insofar as the RFP to which we refer in the introduction sets the stage for the evolution of our project. No additional references are made, except in the acknowledgements section.

2.2 Related to [1], all articles have a plethora of abbreviations, many of which relate to VHA specific structures functions or procedures. In general these should be described in generic terms and the number of abbreviations kept to a minimum.

Abbreviations are now minimal.

2.3 You need to be clear about who will be the main audience for both these and the rest of the papers- if it is seasoned implementation researchers then sometimes the information seems rather simplistic; if it novel implementation researchers/facilitators then sometimes more clarity is needed- either way the papers need a more similar pitch to the intended audience. We think that the readership is the interested implementation researcher or policy maker.

We believe that we have directed the manuscript toward the interested implementation researcher or policy maker. For example, in the introduction, we state:

“In describing the evolution of the EQUIP project, we illustrate the value of the QUERI expectation that study development and refinement should occur in implementation research within and across phased, improvement-focused projects. We hope the paper will stimulate additional scientific discussion about the challenges of implementation.”

2.4 You should use a standard description of the QUERI process both in the text and Table. However, the Journal web system will not retain the formatting so I will send you the preferred version as a separate email attachment. Ideally, this should be introduced early on in the article and then referred to as appropriate throughout.

The standard, recommended description of the QUERI process is included both in the text in the introduction and Table 1. It is referred to as appropriate throughout.

Specific comments on this paper

2.5 Overall, the paper needs to be better structured (linked clearly to the QUERI structures at all times) and, where possible, needs to link data to the text.

Several efforts have been made to better structure the paper and QUERI structure is used throughout. For example, in the beginning of the methods section, we state:
“Funded in 2001, the goals of EQUIP were to develop, implement, and evaluate an intervention designed to apply the chronic illness care model to the outpatient treatment of schizophrenia in a Step 4, Phase 1 QUERI project (see Table 1).”

In the beginning of the EQUIP-2 Overview, we state:

“As noted above, the next phase of work building toward national roll-out of the EQUIP intervention is EQUIP-2, a Step 4, Phase 2 multi-site evaluation (see Table 1).”

2.6 At present the background is too discursive, I suggest that you place this text between the second and third paragraphs on page 2, orientate the third paragraph (and the rest of the paper) using the structure of the table and amalgamate and shorten the third and fourth paragraphs. The first paragraph on page 4 (plus Table 1) is now redundant and I don’t think that the overall aims of the Mental Health QUERI are necessary and so would not use Table 2.

The background has been shortened. The aims of the MHQ are briefly described and Table 2 has been deleted.

2.7 Though I am not a mental health specialist I find it surprising that the providers “lack the competencies” to deliver clozapine (bottom paragraph on page 4). Is this worth saying a little more about?

We now provide more information about providers’ lack of competency in delivering clozapine:

“For example, we found clinician competency problems in the use of clozapine. This clozapine competency problem is well established anecdotally, although there is little empirical evidence of it. The main competency problems that we encountered in at least a subset of clinicians were: 1) clinicians were not trained in the use of clozapine or had not used it despite training; 2) clinicians were not credentialed to use clozapine in their settings; 3) clinicians were discouraged by the possibility that having patients on clozapine would necessitate longer clinical visits with more clinical effort; and/or 4) clinicians did not believe clozapine would be helpful.”

2.8 At the top of page 5 you should place EQUIP within the QUERI structure (presumably something like steps 4 and 5, phase 1 or 2).

EQUIP has now been placed within the QUERI structure:

“Funded in 2001, the goals of EQUIP were to develop, implement, and evaluate an intervention designed to apply the chronic illness care model to the outpatient treatment of schizophrenia in a Step 4, Phase 1 QUERI project (see Table 1).”

2.9 I’d suggest deleting the final sentence of the first paragraph on page 5. P5 discussion of implementation evaluation should go by the VA term formative evaluation.
The sentence has been deleted and the discussion of implementation evaluation has been changed to use the phrase “formative evaluation.”

2.10 On page 6 you say “Since prevailing quality was frequently poor and providers often did change treatments in response to clinical data, getting more treatment was of limited value.” I don’t understand the point that you are trying to make. Could you try clarifying further?

This statement inadvertently omitted the word “not” in that it should have read “providers often did not change treatments…” The statement now reads:

“Clinicians typically did not change treatments in response to clinical data. Therefore, additional treatment visits were of limited value because they were not likely to lead to appropriate changes in treatment in response to psychosis or medication side-effects.”

Also on p6 you say - it became apparent - how/why did it become apparent and to whom?

This sentence has been revised as follows:

“During the course of implementation, it became apparent to the research team that increasing the intensity of follow-up (e.g., adding clinic visits) for severely ill patients was of limited use. Clinicians typically did not change treatments in response to clinical data. Therefore, additional treatment visits were of limited value because they were not likely to lead to appropriate changes in treatment in response to psychosis or medication side-effects.”

2.11 On page 7 you should place EQUIP-2 within the QUERI framework (you do this later but it should be done at the outset). From what you say it is possible to deduce that some of what you describe you have already done and that some of it is yet to happen. It would be helpful to the reader to clarify this.

EQUIP-2 has now been placed within the QUERI framework as follows:

“As noted above, the next phase of work building toward national roll-out of the EQUIP intervention is EQUIP-2, a Step 4, Phase 2 multi-site evaluation (see Table 1).”

We have also clarified throughout what has been done and what has yet to happen.

2.12 P7- 2nd para- discuss data collection methods for the diagnostic analysis

These methods are now further discussed:

“These authors recommend diagnostic analysis of organizational readiness (utilizing relevant surveys, for example) and interviews regarding attitudes and beliefs; implementation-focused evaluation examining the context where change is taking place,
maintenance and optimization of research implementation strategies, and provision of feedback. They also recommend collecting data from experts, representative clinicians/administrators, and other key informants regarding both pre-implementation barriers and facilitators and post-implementation perceptions of the evidence-based practice and implementation strategy. All of these elements of diagnostic analysis are being utilized in EQUIP-2 and are described further below with regard to the formative evaluation.”

2.13 Despite mention of an RCT in the text and in Table 3- there is no discussion about it. How does it figure in all of this?

As noted in revision 1.7 above, the RCT is now more thoroughly described.

2.14 At the bottom of page 9 you introduce the formative evaluation but for neither study do you say much if anything about the summative evaluation. Given that the two are intimately linked – and there’s not much point being able to understand a lot about the process of an ineffective intervention, it would be good to clearly link the two elements of your evaluation.

The majority of the EQUIP findings that we present are findings from the summative evaluation component of the project, i.e., the analysis that was done on the evaluation data once the project was completed. We found that our evidence regarding the process of ineffective components of the intervention was critical in the development of EQUIP-2. Thus, while the summative evaluation did not (and could not) change the course of EQUIP, it was essential for the next phase of the project. In the event that the term “Main formative evaluation findings” was confusing as a header for those findings, we changed the header to read “Main evaluation findings.”

2.15 P11 says multi-pronged evaluation is needed in order to develop understanding of the barriers… reiterate what these were

The barriers are now reiterated:

“Clearly a multi-faceted evaluation is needed to develop a comprehensive understanding of barriers to and facilitators of implementation of the chronic illness care model in schizophrenia. In this disorder, barriers to improving care varied by evidence-based practice, and included underdeveloped clinician competencies, burn-out among clinicians, limited availability of psychosocial treatments, inadequate attention to medication side-effects, and organization of care that was not consistent with high quality practice.”

2.16 The last para needs editing since there are no data on success yet- should be fairly careful making sweeping generalizations of the benefits of the approach used in this case

The final paragraph has now been edited to be more tentative about the benefits of the EQUIP approach:
“Research such as EQUIP-2 should help to determine the relative importance of each component, providing direction as to when one component needs more attention than another during the course of a quality improvement implementation project [32]. Scientifically-based qualitative evaluations of quality improvement in schizophrenia may guide project development, strengthen future stages of intervention development (as illustrated in the development of EQUIP-2), and inform future mixed methods evaluation within the field of implementation science.”

2.17 There are quite a few tables – could these be reduced?

*The tables have been reduced from 8 to 6, including the mandatory QUERI table.*