Reviewer’s report

Title: Measuring organisational and individual factors thought to influence the success of Quality Improvement in primary care: a systematic review of instruments

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Reviewer: Cara Lewis

Reviewer’s report:

The premise of the submitted manuscript, to conceptualize factors related to CQI in primary care and develop a taxonomy for identification, categorization, and evaluation of associated instruments, is ambitious. This study has the potential to facilitate systematic evaluation of CQI efforts in primary care settings around the globe. However, the major strength of this manuscript--the ambitious nature of the study--simultaneously emerges as the manuscript’s major weakness given the complex nature of the theoretical, conceptual and empirical results reported. Overall, I think the critical issues that have arisen from reviewing this manuscript, which are outlined below, can be addressed by the authors of this manuscript and make a substantive contribution to the literature. I have attempted to provide constructive comments and suggestions that will be helpful in disseminating this research, even if not in Implementation Science.

Major Compulsory Revisions (which the author must respond to before a decision on publication can be reached)

1. The authors refer to a “conceptual framework” in the introduction and provide only a cursory explanation of the framework’s genesis while simultaneously noting the limitations that the framework does not yet have empirical evidence for the relation between constructs. Because this framework is used to organize the entirety of their work thereafter it begs for additional attention. In its current form, introduction to the framework leaves the reader with more questions than answers. First, it appears that this framework was both proposed for and modified by the current study. If this is not the case, please clarify. Regardless, the following points need to also be addressed. Second, how were models of QI, teamwork theory, and preliminary findings merged to create a framework that depicts temporal relations between factors when the “known relationships between variables” and the “magnitude of effect of these variables… is limited” (see first paragraph entitled “Scope of the review-conceptual framework”)? Third, why were previously established frameworks such as the Consolidated Framework for Implementation Research (CFIR; Damschroder et al., 2009) not considered? Similarly, the framework includes factors previously identify by Proctor and colleagues (2010) in their Implementation Outcomes paper (e.g., effectiveness, safety, equity, timeliness, efficiency, cost) or originally articulated by the Institute of Medicine, but the authors do not even refer to these works. At a minimum, it is this reviewer’s opinion that the presentation of this new
framework would be strengthened if existing theoretically or empirically derived frameworks were critiqued and an explanation provided for why they were not used. Fourth, although the conceptual framework provides decent coverage of potential factors implicated in CQI, why were others omitted? For instance, provider attitudes, planning, and compatibility have been identified by other frameworks as factors influencing implementation and likely CQI efforts. More description of the decision regarding how potential factors were and were not included would be helpful. Finally, more background or explanation is necessary to build the case for why the authors focus on only three particular domains (i.e., CQI use, organizational context, and individual level factors) and not others. This may be addressed through a more in-depth explanation of the theoretical underpinnings of their proposed conceptual framework. It is this reviewer’s concern that yet another model actually impedes the evolution of the science as opposed to advancing it. However, if the authors can address these points, their proposed framework in its current form might not only be appropriate, but also necessary for the field of CQI.

2. There is a cyclical process used to identify the taxonomy, which is then used to categorize the instrument content. It might be more appropriate to identify the taxonomy using previous research, review articles, theory, etc and then categorize the instruments within the taxonomy. In addition, no rationale is provided for why 84 instruments were used to construct the taxonomy to organize the 41 instruments. A brief statement regarding the rationale would be helpful. This is another example, similar to the above-mentioned points, where the author’s ambitious efforts were not adequately described in the manuscript.

3. In their conclusion, the authors circle back to their aim of providing “guidance to support decisions around which factors to include in evaluations of CQI”. This, however, was not a main (or even small) component of the discussion. Given the plethora of information presented and communicated in this review, the manuscript may actually be strengthened by removing this aim. It is not clear from the information presented in the manuscript which factors should be included in evaluation of CQI other than those included in their proposed conceptual framework which has the limitations outlined above.

4. The authors at times are vague in their report of methods and results perhaps given the immense task of describing such an elaborate process within the confines of one report. However, there are places in which more information would make the manuscript stronger. For instance, the authors contest that their category development is set within the “broader literature” but they do not provide specific examples of the review articles or conceptual papers used (see paragraph 2 under Stage 1 Taxonomy Development).

5. It is unclear why the authors used the COSMIN and made modifications (e.g., added criteria to assess level of analysis issues) but did not include evaluation of other, potentially useful measures of validity (e.g., concurrent, convergent, divergent, predictive).

6. The authors state that 68 instruments were excluded from further review because the instrument was not “feasible”. This is a difficult criterion to use particularly when their definition does not operationalize a cutoff. To be clear,
when authors state the instrument is “too long” some example of what this means would be helpful to better understand why so many instruments were excluded. Having one author subjectively rate the feasibility of a measure, without a clearly defined and articulated cutoff, runs the risk of reifying opinion rather than communicating objective, empirical support.

7. The authors stress the importance of defining concepts in their discussion, yet I do not see definitions provided for the factors included in their framework. At the minimum it seems important to include definitions for the taxonomy referred to in the report.

8. Although the authors articulate some limitations, they do not include the application of their newly developed framework (which has not been empirically evaluated) as a limitation. And, if they choose to retain as an aim to provide guidance about which factors to include in evaluations of CQI, the limits of their framework should be reiterated in this particular section.

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

1. To provide the reader with greater clarity, it is recommended that the authors either define or provide examples of CQI and how this is different from implementation of an innovation if indeed it is conceptualized as such.

2. The authors write in the third paragraph of the Background section that “measuring these factors as intermediate outcomes permits investigation of the mechanism by which CQI works”. It is perhaps more appropriate to state that this “permits investigation of at least one mechanisms”.

3. The authors might replace the phrase “consistent interpretation” used in “Stage 1 Data extraction” with the term inter-rater reliability. In addition, inter-rater reliability kappas should be reported.

Discretionary Revisions (which are recommendations for improvement but which the author can choose to ignore)

1. It might be helpful to name the proposed conceptual framework. In the Abstract it is unclear what framework the authors are referring to and even in the section entitled “Scope of the review – conceptual framework” it is not entirely clear that this is a new framework being proposed.

2. Tables 1 & 2 might better facilitate consumption if instead of author name/year the instrument name or acronym is included.

3. In the Method section under Stage 3 Data Extraction, the authors state that they extracted information about the development of the instrument, but they do not indicate the method of extraction. That is, did the authors use a software program such as NVivo?

Minor issues not for publication
(spelling, typographical errors, grammatical errors, stylistic suggestions etc)

1. There is an incomplete sentence in “Data extracted” in the Abstract.
2. The authors frequently include very long sentences (with extensive use of semi-colons) in an attempt to make several related points, but in doing so they challenge this reviewer’s ability to identify the main idea and integrate the information. For example, “Consequently, measures that capture the CQI implementation process, and use and modification of the intervention components (i.e. measures of intervention ‘fidelity’) are required to assess whether intervention effects (or the absence thereof) can be attributed to the intervention; the extent to which individual intervention components contribute to effects; and whether changes to the intervention have an important influence on effects [16, 19-20].”

3. Headings and subheadings should capitalize the first letter of each word. There are places in the manuscript where it actually appears the first sentence is cut off as opposed to this actually being a heading.

4. The authors are not consistent in their citation format. At times they include (e.g., [citation numbers]) whereas other times they write (for example, author name, year [citation number]).

5. The authors need to fix the structure of this sentence: “Frameworks for specifying and defining these dimensions exist for health behaviour change interventions; encompassing intervention intensity (e.g. duration, frequency), quality of delivery and adherence to protocols [86-87].”

6. The authors frequently use the word “relationship” to refer to the “relation” of two constructs.

7. In the last sentence of the paragraph on “Measurement of Organizational Context” the authors wrote “use” when they intended to write “used”.

8. In the second to last sentence of paragraph 2 of the “Strengths and Limitations” section, the authors need to pluralize the word “instrument”.

9. TQM needs to be defined before the acronym is used.

**Level of interest:** An article of importance in its field

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests.