Author's response to reviews

Title: Methods and Metrics Challenges of Delivery System Research

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Author's response to reviews: see over
Reviewer 1: Luciana Ballini

This is a very well written paper that addresses in a clear and constructive way major problems of delivery system research – and of research on complex interventions in general. The authors present in a nicely organized way the “challenges” and offer a range of pragmatic suggestions (methods and techniques) to overcome them. In doing so they successfully attempt to bridge the gap between the rigour needed to ascertain effectiveness of interventions and the richness of data and analyses necessary to understand the “when”, the “why”, and the “under which conditions” interventions work/don’t work.

The writing is clear and smooth, although at times burdened by some repetitions especially when emphasizing role/importance of context.

A typo at page 21, second line from the top: trails instead – I presume – trials.

“Trails” has been changed to “trials” on p. 22.

Reviewer 2: Nick Sevdalis

The paper presents 5 challenges that researchers dealing with what is termed “delivery system research” – i.e., research on the delivery and evaluation of organisation-wide interventions. Each challenge is described and some recommendations follow. The article is generally well written and should be of interest to the audience of the Journal.

MAJOR REVISIONS

First of all, although I empathise with most of the challenges that the authors identified, I was often unclear regarding the contribution of this manuscript to the wider discussion of these challenges. I think a better structure is required to ensure that the work does not look like a simple list of problems – otherwise there is a risk that many readers will find the paper just common sense. I would advise the authors to present their work as a systems-based framework to interventions evaluation (or something similar) and also use a pictorial representation of their proposed framework (i.e. some sort of figure). Table 1 is not very useful, in my view.

We appreciate the suggestion to make our contribution to the broader literature clearer by linking these issues to a systems framework. We have made several additions to the paper to do that. First, we now discuss some of the defining features of a systems perspective and why such a perspective would be helpful in evaluating delivery system interventions (pp. 4-5):

“In this paper we discuss the research challenges posed by five key methods and metrics issues in delivery system research: (1) modeling intervention context, (2) measuring readiness for change, (3) assessing intervention fidelity and sustainability, (4) assessing complex, multicomponent interventions; and (5) incorporating time in delivery system models. We focus on these particular issues because, from a systems perspective, they are related to a core set of interdependent components that contribute to or compromise the effectiveness of
health care interventions [6]. According to this perspective, systems behave according to a number of key properties: 1. Each component can affect the behavior or properties of the whole system; 2. Each component is necessary but is not sufficient to achieve the objectives or functions of the system; 3. Behavior and properties of one component depend on the behavior of other parts of the system. Health care organizations and the implementation of delivery system interventions within them exhibit these properties [2,3]. Figure 1 provides an overview of the methodological and metric issues associated with studying delivery system interventions implemented in complex social systems.”

Second, we now include a figure that displays how the methods and metrics issues that we discuss are interrelated within this systems framework.

We were less certain, however, about whether to remove Table 1 as suggested by the reviewer, especially given that reviewer 3 found it “extremely helpful”. Therefore, we followed reviewer 3’s suggestion to modify the table by including examples of studies for each issue. We believe that this change makes the table more useful.

Secondly, although the authors claim that they offer recommendations, some of them are only present in the summary section. In other parts of the manuscript, the writing seems more aimed at increasing awareness of issues rather than offering solutions – for example, the discussion of what to do about the fidelity challenge (p 11) does not really answer the question, other than to say that researchers ought to be aware of it (which I am sure is something that most researcher would agree with anyway).

The reviewer is correct that some of the recommendations we make are only presented in the concluding parts of the manuscript; however, we have structured the manuscript that way intentionally to distinguish between recommendations that may pertain to specific challenges or issues and more general recommendations that may pertain to multiple or even all of the issues described in the manuscript. We felt that such a structure was necessary to provide specific, concrete recommendations while avoiding redundancy in our discussion.

With respect to the reviewer’s comment about increasing awareness, we agree with one of the other reviewers that many of the issues discussed in the manuscript may not be broadly recognized, especially beyond those who study implementation. Thus, we think that raising awareness of these methods and metrics challenges is an important issue and one that we intentionally included as an objective of the paper. However, we have also tried to go beyond simply raising awareness of these issues and believe that each section does include specific, tangible recommendations that could potentially be employed by researchers. For instance, on pp. 14-15 we describe three recommendations with respect to improving understanding of implementation fidelity and sustainability:

“Three related recommendations are noted. First, approaches to measuring implementation should focus on group, organizational, or external factors—in addition to the more commonly studied individual attributes and attitudes. This requirement includes
adequately accounting for organizational context as a key variable in implementation efforts rather than simply as descriptions of study settings. Second, research design and measurement approaches to implementation need to go beyond assessing the elements of the intervention/program itself and attempt to account for multiple integrative factors that may influence implementation of delivery system change. These factors might include, for example, resources, leadership, and prior experience with similar changes. Finally, evaluating sustainability of a delivery system change will require assessment of intervention fidelity over time. Specifically, it cannot be assumed that measuring implementation of a delivery system change at a single point in time indicates that it will remain stable and/or that reversals will not subsequently occur. Longitudinal assessments of the key program elements are essential to explaining the extent to which a particular delivery system change has been incorporated into the standard operating practice of a system and, therefore, its potential for ongoing impact on patient outcomes. Assessments of treatment fidelity over time also allow for the possibility of organizational learning, a process by which organizations draw on their experience with the intervention to make adaptive modifications that improve the fit of the intervention to the local context in which it operates.”

Although some of the recommendations are more specific and actionable than others, we believe that more attention to all of the issues will improve the quality of research and our knowledge of intervention implementation.

Thirdly, related to the point above, I feel the authors ought to expand and slightly change the Conclusion section. They are offering very useful recommendations here in relation to research funding and also research design – these are truly useful for researchers, policy makers and funders alike. I therefore feel the section should be called Recommendations and Conclusions and the recommendations element of it beefed up. The problems that arise from short-term funding and lack of integration of qualitative with quantitative approaches could be fleshed out in this section in some more detail – I think if the authors think of their work as a framework and present it like one the paper would be very useful in informing not only the design of the research but the scope and scale of such projects.

We have retitled the conclusion section as “General Recommendations and Conclusions” to distinguish it from the specific recommendations suggested for each issue. We have also revised the discussion in this section in several places to more clearly underscore the consequences of not addressing these issues. In doing so, we have tried to better highlight the importance of our recommendations. For instance, on p. 22 we note the importance of using multifaceted research approaches such as mixed methods, to better reflect the systems frameworks that are increasingly used by implementation and health delivery system researchers.

“Indeed, given the systems perspective that is increasingly advanced by implementation and delivery system researchers, failure to draw upon the rich set of research tools available will likely continue to impede our understanding of how and why interventions affect outcomes, and thus, how these interventions can be leveraged in the most effective ways in different settings. However, such multifaceted, systems-oriented approaches will challenge
our current linear thinking about how systems of care delivery work and the traditional “internal validity at all costs” frameworks for designing and conducting research on delivery system change.”

Likewise, on pp. 22-23, we extend our discussion of the implications of short-term funding and inadequate funding for studies that address the issues identified in our manuscript.

“The burden for implementing these recommendations, however, does not fall solely on investigators. Funding agencies should consider supporting studies with larger organizational sample sizes to allow appropriate modeling of contextual effects and assess the generalizability of interventions. Also, studies of longer duration should be funded to permit assessment of fidelity and sustainability of delivery system change, as well as growth trajectories in individual patient outcomes. Such studies are important for improving our knowledge about the intermediate and long-term effectiveness of interventions and whether resources should be dedicated to disseminating these interventions more broadly. Consideration should also be given to funding retrospective assessments of previously funded interventions to assess these issues. Finally, funding agencies should encourage applications that employ more non-traditional, mixed methods designs to advance understanding of the “why” and “how” questions of delivery system changes and their effects. Answers to such questions speak to issues of how to improve interventions as well how widely they might be disseminated. In sum, without the support and direction from these funding agencies, our knowledge about health service interventions and delivery system change, much like the quality of the research itself, seems poised to improve only marginally.”

MINOR REVISIONS

Fourthly, the authors offer a good discussion of various statistical and modeling approaches in relation to intervention context, but much less in way of qualitative analysis (pp 7-8). The assumption that organisational context can be measured and quantified is quite a stringent one – and I would argue that even if this is true sometimes it is not practical or feasible. More therefore should be said regarding qualitative approaches to context analysis and how to integrate it with quantitative data.

We have revised our discussion on p. 8 to more thoroughly describe the qualitative approaches to measuring context and the conditions that might require the use of these techniques.

“Whereas direct measurement and analysis of individual or bundled contextual effects are probably the most intuitive to most delivery system researchers, other approaches may also contribute to understanding the role of context. Indeed, in some cases qualitative methods such as participant observation and archival document analysis may provide insights into context that simply are not possible or practically feasible via direct measurement methods such as surveys. Likewise, key informant interviews can provide detailed description and informed reflection on the role that context plays in influencing the meaning, variation, and relationship among variables under study. Such approaches may be appropriate when
contextual variation is limited by the sample and/or when measuring key contextual factors (e.g., history) cannot be quantified.”

We discuss mixed methods in some depth on pp. 16-17, including how quantitative and qualitative data might be integrated, therefore, we did not discuss this issue at length in this section as suggested by the reviewer.

“Despite advances in quantitative methods such as hierarchical linear modeling, there are important questions and concepts in delivery system research that are not well suited to quantification and which call for a combination of qualitative and quantitative data analysis. For example, among hospital CEOs, organizational processes—such as effective communications, strong leadership, and trust building—appear to play a prominent role in improving quality and other patient outcomes [25]. However, many studies of delivery systems tend to emphasize structural properties (such as size, system affiliation, and ownership), rather than management and team processes, and existing databases usually lack measures or indicators of these complex processes. To the extent that nonlinear and interactive processes and system dynamics are, in fact, important drivers of patient outcomes, delivery system researchers may be well served by complementing the traditional focus on structural correlates of outcomes with intensive, qualitative research on management processes conducted in smaller samples of organizations.

Despite their intuitive appeal and potential utility in delivery system research, mixed methods designs are often misunderstood and difficult to implement in a manner that creates synergistic benefits from the use of different forms of data collection and analysis. Researchers who choose to conduct mixed methods explanatory studies must consider issues such as the priority or weight given to the quantitative and qualitative data collection and analysis in the study, the sequence of the data collection and analysis, and the stages in the research process at which the quantitative and qualitative phases are connected and the results are integrated [26-28].

If the goal of a mixed methods approach is to enhance explanation, research designs can take several forms, including but not restricted to: (1) connecting quantitative and qualitative phases of the study through selecting participants for the second data gathering phase based on the findings from the first phase, (2) developing qualitative data collection protocols grounded in the results of the statistical tests (or vice versa), or (3) integrating quantitative and qualitative results for purposes of interpreting study results and drawing implications for policy or practice. An integrative strategy for combining quantitative and qualitative methods will likely result in higher quality inferences than if the two forms of data analysis are distinct, unintegrated components of the research [29].”

Finally, I think the sustainability issues (pp 9-12) fit in better with the time aspect discussed by the authors (pp 12-16). The issue of intervention fidelity, which I think is of paramount importance, can stand alone, whereas sustainability really reflects a time dimension to the intervention and also its evaluation (which the authors introduce and describe as the time element).
We appreciate the reviewer’s suggestion regarding incorporating sustainability within the discussion of time. While we agree that an important factor influencing sustainability is time, we also believe that issues of sustainability are broader than just time (e.g., organizational support, work process redesign). Furthermore, we intentionally framed sustainability and fidelity as separate but related issues to highlight their unique contributions to the implementation of interventions and subsequent outcomes. More specifically, we wanted to draw attention to the fact that one without the other will likely mitigate the effectiveness of an intervention. We believe that such a framing is consistent with a systems framework that we now use more explicitly to organize the discussion.

Reviewer 3: Charles Vincent

This paper addresses a number of important issues in the evaluation of interventions to improve the delivery of healthcare. The paper is based on a report commissioned by the US Agency for Healthcare Research and Quality and is therefore presumably a condensed summary of a longer document. The authors set out five core challenges and make a number of recommendations for future research, both conducting and commissioning. One particularly important conclusion is that funders should consider much more substantial evaluations that are able to address the various facets of complex interventions as they unfold over time.

While the content of the paper is valuable it is not very accessible to readers who are not already expert in the field. The paper also gives little information about how these conclusions were derived or why these particular issues were prioritised.

We now include an endnote that describes the purpose of the original report, some of the steps involved in developing that report, and how the issues were identified and prioritized. We also now include a description of an organizing framework on pp. 4-5 that explains why these particular five issues were prioritized.

“We focus on these particular issues because, from a systems perspective, they are related to a core set of interdependent components that contribute to or compromise the effectiveness of health care interventions [6].”

It appears that the Discussion of the report has simply been grafted onto a short introduction, leaving aside the central core of the report which presumably addresses these issues. While I appreciate that the paper must inevitably not cover all the material contained in the report I think that the authors could do more to provide the background to their conclusions and to help readers not well versed in implementation science to gain an understanding of these important issues.

As noted in the previous comment, we now include in the manuscript a framework and description that helps explain how the issues discussed in this paper may influence intervention implementation and subsequent outcomes.

Specific suggestions
The authors should add a section summarising the process of writing the main report explaining how the literature was addressed, the methods they employed and the reasons for highlighting these particular areas. Clearly all are important, but why do these five stand out? Surely there is also a more natural order to the presentation of these themes?

As noted above, we now include an endnote that describes the purpose of the original report, some of the steps involved in developing that report, and how the issues were identified. We have also revised the ordering of the themes to more closely match the systems framework that we used to organize the themes.

The authors have helpfully given a common structure to each theme considering challenges and recommendations in turn. However the content of these sections does not always mirror the heading. For instance ‘recommendations’ under context (p 7) begins with a helpful section defining what contextualisation actually is, but only after the challenges have been outlined. I suggest that, particularly for less expert readers, that each of the five themes could usefully begin with an additional sections called ‘Definitions and background’ or something similar. A short paragraph summarising the key issues and definitions would help enormously. This would then be followed by challenges and recommendations.

We appreciate the suggestion to include an additional section for each issue that defines terms and summarizes the key issues. However, because the challenges that are described in the initial sections are essentially the background issues, we did not think that separating the challenges from the background was feasible and would likely add redundancy to the paper. To address the reviewer’s suggestion, we have revised the manuscript so that the issues now begin with a section titled “Background and Challenges” and where appropriate, the sections begin with definitions of key terms.

I would also suggest that some examples might be provided of studies that have managed to address these challenges, at least in part. Table 1 is extremely helpful summary. I suggest that if five short boxes were added, one per theme, with a brief example of a relevant study, this would greatly help readers to understand and appreciate the recommendations being made.

We think this is very good suggestion and we have revised Table 1 to include references to example samples that have incorporated the recommendations that we are suggesting.

I realise that these suggestions on their own would increase the length of the paper. However I believe the current content could be reduced, particularly if readers could have access to the main report (presumably available from AHRQ?) to follow up particular issues. Overall I would favour a more accessible paper with more explanation and examples even if it does end up a little longer. I believe this would be make best use of this valuable material and the paper would be more influential as a result.