Author’s response to reviews

Title: How do researchers conceptualize and plan for the sustainability of their NIH R01 implementation projects?

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Author’s response to reviews:

Dear Colleagues,

Re: IMPS-D-18-00330R1: How do researchers conceptualise and plan for sustainability of their NIH ROI implementation projects?

Thank you very much for considering the revised version of our Short Report. We appreciate the thoughtful comments from the peer reviewers and the editor. We have reviewed their suggestions and have modified our manuscript accordingly. We have provided details on our responses below. Because of the request for additional detail from the reviewers and editors, we are slightly over the word limit at 2612.

Please note that the corresponding author has been changed to from Alekhya Mascarenhas Johnson to me as Ms. Johnson no longer works at our institution. This change has been made with her permission.

Sincerely,

Sharon Straus MD, MSc, FRCPC
Interim Physician-in-Chief, St. Michael’s Hospital
Professor, Department of Medicine
Director Knowledge Translation Program
Reviewer 1

Comment

Response

The paper draws attention to the limited focus on sustainability planning in NIH trials. The paper as many limitations as stated, so I believe is suitable as a brief report.

Thank you for this feedback.

You have labelled Tables, Figures and Appendices also as Additional Files, which is very confusing. Please label Tables starting from 1, Figures starting from 1 and Appendices as Additional Files starting from 1. Therefore Appendix A becomes Additional File 1. Include only one form in the brackets.

We have made these changes to the manuscript and the attachments.

The first sentence - is it true? If so, please reference the statement, if not I suggest changing to "Despite progress in research to narrow the research to practice gaps"

Thank you. This change has been made to line 58, page 5:

‘Despite research advances to narrow the research to practice gaps, the sustainability of evidence-based health interventions in clinical and community settings remains a significant challenge [1-2].’

Line 53 add in NIH so it reads: "We explored: how do USA National Institutes of Health (NIH) funded researchers"

Thank you. We have made relevant edits to the abstract on lines 69, page 5:

‘As such, we conducted a sequential, mixed methods study to explore how implementation researchers funded by the United States (US) National Institutes of Health (NIH) conceptualized and planned for intervention sustainability as this has not been reported previously. We explored: how do the US NIH-funded implementation researchers 1) define sustainability 2) use sustainability frameworks in their implementation projects 3) plan for sustainability of interventions; and, 4) what influences these implementation researchers to plan for sustainability?’
Please include the inclusion criteria in the article. It is not clear why 193 articles were excluded.

Phase 1: (any) inclusion vs. exclusion criteria of documents applied?

We have added more information on the inclusion and exclusion criteria in Figure 1. Due to word limitations for the Short Report, we were not able to include these details in the primary publication.

‘Between September 19 and October 05, 2016, we exported data from all R01 Grants and Equivalent project profiles listed in the NIH RePORTER Database reviewed by the DIRH study section. We removed duplicate project profiles with the same grant identification number. Two analysts independently screened project profiles and excluded profiles that did not have primary outcomes related to implementation. We defined implementation as the use of strategies to adopt and integrate evidence into practice within specific settings [16]. We only included projects with an implementation focus for further data abstraction and excluded those that had primary outcomes focused on dissemination. We defined dissemination as the targeted distribution of evidence to a specific public health or clinical practice audience (e.g., the comparative the effectiveness of two modes of delivering information to target audiences) [17].’

I’m not sure the word purposive is required in the sentence “We used purposive sampling and sent email invitations to all Phase 1 PIs”, as all PIs were emailed not a selection.

We have removed the word purposive from line 97.

Second sentence doesn't appear accurate, the NIH funded 277 projects and 76 met the inclusion criteria for your study.

We revised this sentence on line 115, page 8:

‘The NIH funded 277 projects reviewed by the DIRH study section between 2004 and 2016, and 76 met the inclusion criteria for our study (i.e., they were implementation projects).’

Check formatting of headings: line 92 needs a new line and line 117

These changes have been made on page 8.

The switching of the terms projects and profiles in the second paragraph is confusing. This may be clear for US readers, but would be useful for non-US audience to have the terms defined or if accurate use only projects.

We have revised the wording in this paragraph to make it clear that we are referring to content in the NIH RePORTER profiles. We have removed the word ‘project’ where possible. Line 126, page 8:

‘Of the 76 implementation projects, 51 (67.1 %) included sustainability synonyms or variants in their NIH RePORTER profiles. The words sustainability (n= 22, 22.9%), sustained (n= 9, 9%), and maintenance (n= 14, 14.5%) were the most commonly used terms (Appendix C, Additional
References to sustainability (Table 2) included descriptions of their intent to evaluate the impact of a strategy on the sustainability of evidence-based programs (EBP) or practices (n=11, 18.3%); measure the sustainability of EBPs, strategies, practices or health outcomes (n=10, 16.6%); examine factors associated with sustainability of interventions during or after implementation (n=13, 21.6%); estimate intervention sustainability costs and benefits (n=1, 1.7%); and determine elements of EBPs to enhance sustainability (n=1, 1.7%). Only three NIH RePORTER profiles (3.9%) described the intent to study sustainability exclusively. A few profiles referred specifically to the sustainability of their research study efforts by describing the potential large-scale impact or public health relevance of their work (n=7, 11.7%) or describing their intent to disseminate results to promote sustainability (n=3, 5.0%). Profiles referred to implementation frameworks with sustainability constructs but none mentioned sustainability frameworks. The Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) framework (n= 11, 14.5%) was the most frequently referenced framework. One profile (1.3%) referenced the Exploration, Preparation, Implementation, Sustainment (EPIS) framework and one (1.3%) referred to the Replicating Effective Programs (REP) framework.

‘References to sustainability (Table 2) included descriptions of their intent to evaluate the impact of a strategy on the sustainability of evidence-based programs (EBP) or practices (n=11, 18.3%); measure the sustainability of EBPs, strategies, practices or health outcomes (n=10, 16.6%); examine factors associated with sustainability of interventions during or after implementation (n=13, 21.6%); estimate intervention sustainability costs and benefits (n=1, 1.7%); and determine elements of EBPs to enhance sustainability (n=1, 1.7%).’

Profiles referred to frameworks with sustainability constructs, however, none mentioned sustainability frameworks.

‘Profiles referred to implementation frameworks with sustainability constructs, however, none mentioned sustainability frameworks.’

Interviewees described varied sustainability definitions (Table 4); although, nearly all defined sustainability as the continued delivery of evidence-based intervention implementation within an organization or system.
I was surprised that nearly all participants described sustainability as the continued delivery of evidence-based intervention implementation efforts. I thought it would have been continued delivery of an evidence-based intervention. Implementation strategies/efforts are often for a defined period of time e.g. 6 to 12 months, and sustainability is if the intervention then continues after this time (along with the other sustainability components). Please ensure this is what was meant…

We agree that this highlights the lack of clarity in the field around the definition of sustainability. We have added this to the discussion on line 239, page 13, namely:

‘This result highlights the lack of clarity around sustainability definitions as researchers and implementers must consider if they are sustaining the evidence-based intervention, the implementation strategy, the behaviour change, and/or the outcomes of these behaviour changes.’

Check grammar of lines 146-147 and in lines 148-150. In addition, be consistent with "constructs" and "factors", and "barriers"

We have made edits to use the term “constructs” instead of “factors” and “barriers”.

Lines 163 page 10, and 181 on page 10 respectively, were revised as follows:

‘Three interviewees described maintaining improved intervention outcomes as a key sustainability definition construct. In addition to the 5 constructs from the definition, one interviewee included the development of organizational infrastructure to deliver the implementation strategy as a sustainability definition construct.’

‘One approach was to develop a stakeholder interview guide using sustainability constructs from a framework. These interviews then provided information on how the sustainability constructs were present in a given setting; these data were then used to inform sustainability-related decisions at project onset. A second approach was to use the framework to brainstorm what challenges might hinder sustainability, and then use conjoint analysis to determine what challenges were most important or feasible to address. The top-ranked challenges were then mapped to implementation strategies; the strategies may not have been specific to sustainability. In both of these approaches, stakeholders and implementation teams were consulted. The third approach used frameworks to develop surveys or interviews for sustainability evaluations. Research teams reviewed the constructs in each framework and then selected, by consensus, what constructs would be measured in their project.’

Lines 171-172. The majority of strategies appear to be directed at all levels of context, where were the others directed? I'm not sure what this sentence is adding.

There were no strategies targeted to individuals. We have revised the sentence to reflect this.
Line 208, page 11 was revised as follows:

‘The majority of these strategies were targeted towards the sustainability of evidence-based interventions within organizations, communities, or systems and not individuals.’

Line 178 "interviewees who had an interest in sustainability research" How was this assessed? Was it only those with an interest that said their motivation came from…if not remove this part of the sentence.

The sentence has been revised to indicate that it was the participants who self-identified as having a special interest in sustainability research.

Line 216, page 12 was modified as follows:

‘Interviewees who self-identified as having a special interest in sustainability research said that their motivation came from observing the harm that research personnel can do if they leave a setting without making any sustainability plans.’

Line 200 use the word "implementation strategies" while in results "implementation efforts". Check throughout and be consistent.

We have removed the word “efforts” and kept the term “implementation strategies” throughout the manuscript.

Line 231 - Reference 30 is not in the reference list.

We noted that this reference was included but in error had not been numbered in the references and this edit has been made. Because of the addition of another reference, this reference now becomes reference 31.

Add full-stop after NIH in line 235.

We have made this change to line 279. Thank you for catching this error.

Line 237: beginning of sentence would read better with "For this reason we decided"

We have made this change to line 280, page 14:

‘For this reason, we decided to conduct interviews with funded researchers.’

Line 244: "insights are missing" rather than "insights ware missing"

We have made this change to line 287, page 15. Thank you for catching this error.
‘however, it is possible that key insights are missing and that there was a bias in those participating in interviews, especially since most interviewees had mentioned sustainability in their project profiles.’

Line 245: this should be reported in the results.

Thank you we have added this under interviewee demographics. Line 150, page 9 reads:

Two (18.1%) of the 11 interviewees included references to sustainability in their NIH RePORTER profiles.’

The current wording in conclusion appears more as a summary than a conclusion. I would change the heading or reword.

We have used Conclusions as the title as per journal requirements for Short Reports; however, we have made revisions to the text to provide clarity to the conclusions on page 15, line 302:

‘Implementation researchers varied in their conceptualization and planning for sustainability within their funded implementation projects. Our results identified the need to provide guidance on how to identify, select, and use sustainability frameworks, and, to develop strategies on how funders and researchers can advance sustainability research.’

Reviewer 2

For non-US readership it needs online research to understand and figure out that NIH grants are (mostly) US-based. NIH (National Institutes of Health) could stand for any country in the World, so the Abstract & Introduction lacks focus and should explicitly name that this paper is about an US context.

We have added the country to the Abstract (page 3) and ensured that we have provided this context throughout the manuscript including the Discussion. It is also outlined as a limitation in the generalizability of the results to other settings (page 14).

the need of this study/report ("why do we need this study/report?") and the existing state of art ("what do we know about ?") are poorly elaborated in the Introduction part. e.g., lines 45/46: "interventions are either partially sustained or not sustained"…What does that mean? What kind of (health) intervention (there may be differing barriers and challenges) are sustained or not sustained and why? Are NIH R01 interventions already studied? If yes, what do we know about it? If not, why is it even important?

We have clarified the statement around the lack of evidence on sustainability of evidence-based interventions but are unable to provide details on the results of the reviews we and others have conducted since this is a brief research report. We are happy to provide these details in an appendix if the editors would like these details to be included. Line 60, page 5 now states:
‘Knowledge syntheses show that sustainability of evidence-based interventions is often ignored and this gap has been identified as one of the most critical gaps in implementation science [2-7].’

We have also highlighted that this has not previously been explored in NIH-funded projects.

Line 66, page 5:

‘There have been calls for research on how sustainability can be defined, planned for and considered in implementation research[2, 9]. In particular, it is unclear whether implementation researchers consider sustainability when planning or executing their projects. As such, we conducted a sequential, mixed methods study to explore how implementation researchers funded by the United States (US) National Institutes of Health (NIH) conceptualized and planned for intervention sustainability as this has not been reported previously.’

The study focusses "implementation researchers" (PIs). PIs are "experts" in their fields. If expert knowledge/perceptions and a qualitative assessment of it is a research gap in the field of NIH-granted interventions, this should be stated more clearly.

As described above, we changed the lines on page 5 as follows:

‘As such, we conducted a sequential, mixed methods study to explore how implementation researchers funded by the National Institutes of Health (NIH) conceptualized and planned for intervention sustainability as this has not been reported previously. We explored: how do the United States (US) National Institutes of Health (NIH)-funded implementation researchers 1) define sustainability 2) use sustainability frameworks in their implementation projects 3) plan for sustainability of interventions; and, 4) what influences these implementation researchers to plan for sustainability? We perceived these successfully-funded implementation researchers to be experts in this field and would provide insights into the state of the science.’

Given the research questions, it could be even sufficient to report only these (qualitative) expert perceptions in the whole report. This raises also the question why a MM design is needed? Are there either qualitative | quantitative studies on this issue? Why wouldn't be a qualitative assessment of researchers’ perceptions on "defining, using, and planning sustainability" sufficient? Why do we need 1st a document review of an online database next to the qualitative (2nd) analysis? What is the added benefit? See above, one should reconsider if a MM design is really needed. A purely qualitative study would be sufficient, given the research interest ("defining", "using", "planning", "influencing" sustainability).

The Results of the document review raise again the question, if this quantitative part of the study is really needed and innovative. The Results is - not very surprising - that a majority of programs (67%) makes reference to "sustainability", but none referred to "sustainability planning." Again, the presented qualitative Results entail findings which may be a sufficient data source and need no prior document review of an online database.
We thank the reviewer for these reflections on the rationale for use of mixed methods. We believed it was important to use mixed methods to allow for richer detail on the current state of consideration of sustainability (including gaps) in funded implementation research. We concur with the editor’s opinion that mixed methods should be retained in the manuscript. To our knowledge, there are no previous studies on this topic, and thus we believe that the details provided in the manuscript are unique and important as they identify gaps for implementation researchers and funders to consider. The document analysis was used to guide the interviews and as such, we feel it is important to include both components. As outlined above, we have strengthened the rationale for this study above. We have provided additional details on the methods used in Figure 1 and in the Appendices.

The authors aim to answer 4 research questions in 1 paper. Might lack focus for a brief report. Why these 4? This was not anticipated when reading the prior paragraphs. "Defining", "using", "planning", "influencing" sustainability were not derived from existing evidence. Why are these 4 stages/dimensions important? One option to get a better focus for the whole study would be to pay more attention to "influencing". See last bullet point in Results comments (below).

These 4 questions were some of those identified from Proctor’s paper[2], which outlined a research agenda in sustainability. In particular, we identified that these issues could be explored through an examination of funded implementation research and how successfully funded implementation researchers (whom we considered experts in the field) understand and consider sustainability in their planning. We have clarified this in the introduction to the manuscript (page 5)

‘Despite research advances to narrow the research to practice gaps, the sustainability of evidence-based health interventions in clinical and community settings remains a significant challenge [1-2]. Knowledge syntheses show that sustainability of evidence-based interventions is often ignored and this gap has been identified as one of the most critical gaps in implementation science[2-7]. Little is known about how to sustain effective interventions, and the failure to sustain has implications for health system costs, patient outcomes, and support for future implementation work [8].

There have been calls for research on how sustainability can be defined, planned for and considered in implementation research[2, 9]. In particular, it is unclear whether implementation researchers consider sustainability when planning or executing their projects. As such, we conducted a sequential, mixed methods study to explore how implementation researchers funded by the National Institutes of Health (NIH) conceptualized and planned for intervention sustainability as this has not been reported previously. We explored: how do the United States (US) National Institutes of Health (NIH)-funded implementation researchers 1) define sustainability 2) use sustainability frameworks in their implementation projects 3) plan for sustainability of interventions; and, 4) what influences these implementation researchers to plan for sustainability? We perceived these successfully-funded implementation researchers to be experts in this field and would provide insights into the state of the science.’
Phase 2: the authors refer to many supplementary files, but words like "topic guide" or information on the response rate should be stated in the original manuscript and should not to be found only in Supplementary files.

The response rates have been moved to the methods as per the editor’s suggestion (line 99, page 7). Unfortunately, we are not able to include details on the topic guide in the manuscript due to word limits in this brief report.

Appendix B: Why were kappa coefficients calculated to compare codings between coders? There is a serious debate if Kappa is even in content analysis a useful tool to resolve interpretative disagreements, which is more relevant for qualitative research than a measure of distant or near codes. What does Kappa really add to qualitative analysis of expert perceptions? This must be added in the Supplementary file.

We agree that not all qualitative researchers assess agreement, however, formally assessing agreement using the kappa statistic has been used by many qualitative researchers and we have provided a reference (reference 23, Thompson et al) to support its use in the manuscript.

Data integration: Qualitative and quantitative evidence are synthesized by a "contiguous approach" which is reasonable, but how? What kind of steps/stages were applied? One misses 1-2 sentences where the authors describe "1st we did this, 2nd this, etc.".

The contiguous approach to integration means that we chose to gather data, analyze it, review findings, and present results within a single manuscript, but the qualitative and quantitative findings are reported in different sections. This is different from the weaving approach where both qualitative and quantitative data are collected, analyzed, and presented together on a theme-by-theme or concept-by-concept basis. Due to word count restrictions for a Short Report, we were unable to elaborate on the steps for this, however, we have provided a reference (24).

-Information on recruitment, sample, demographics, analysis, response rate, coding/Kappa are not really qualitative "Results", it is part of the methodological chapter and should be moved to Methods ("Sample/Sampling")

We have made this change as noted in our response to reviewer 1.

a qualitative Results part entails usually more quotes/citations, in the current manuscript there is only 1

Unfortunately we had to remove quotes to reduce the word count for a Short Report submission; they are included in the Tables.

The authors present at the end of the Results "individual" and "environmental" factors that influence sustainability planning, here comes also the 1st and only quote. This part entails important and interesting findings. Maybe these 2 factors should be described more in-depth in order to get a better understanding, whereas the quantitative part of the whole study could be removed completely.
The editor has recommended that we keep the quantitative portion of the study; as such, we do not have space in the manuscript to include additional quotes. Instead, we have included them in the Tables.

Editor

Although some of the review comments suggest abandoning the mixed methods approach, it is suggested that the mixed method design be retained, and respond to reviewer concerns.

We thank the editor for this suggestion, which we have implemented.

The tension between sustainment and adaptation should be clearly identified. If an intervention is sustained, how will adaptation be accommodated? Is adaptation addressed, or only sustainment?

We noted in the results that 3 interviewees mentioned adaptation. We have added this to the discussion on page 13, line 242:

‘Adaptation was not substantively described in the interviews.’

We also added the following to page 15, line 297:

‘There is also a tension between sustainability and adaptation. Our study does not expound on this debate.’

The authors state that none of the projects mentioned sustainment frameworks, however some of the implementation frameworks and models explicitly include sustainment as an important part of the implementation process. Is it possible that the search strategy would miss that fact that sustainment is a critical aspect of some frameworks, implementation strategies, and scale-up strategies? For example, sustainment is an inherent and integral part of some scale-up strategies. For example, the Interagency Collaborative Team strategy (NIMH R01 supported) has the goal of sustainment from the outset. In that model and in the funded study, relevant stakeholders and collaborators are engaged and involved in the implementation process from the outset of the project and the ICT model has led to effective and sustained use of evidence-based practice in one of the largest child welfare systems in the US.

We did not include sustainability as a search term for the RePorter database and thus would not have missed reports on this basis. We outlined in the manuscript that the profiles referred to frameworks with sustainability constructs as the editor notes, but none mentioned explicitly the use of a sustainability framework.

There is concern that the search strategy was not adequate. First, the review of only information available for non NIH users of RePorter may have missed other NIH R01 grants that didn’t turn up given the search approach described in the manuscript. In RePORTER it is only the project descriptions and abstracts that can be searched. However the authors did not provide
sufficient detail on exactly what was searched within RePORTER. Were subprojects and results (e.g., published papers) also searched?

We identified all grants funded by the Dissemination and Implementation Research Study section. We note in our limitations that we would have missed studies funded by other study sections (page 14). We have provided further details on the methods in Figure 1 (study flow) to clarify the approach.

Second, for a document review, the most detailed documents available would be most appropriate. The search strategy was extremely limited because the full proposals are not easily available for non NIH staff through RePORTER. Thus the extent to which these projects truly addressed sustainment and sustainability is not thoroughly captured by the document reviews. However, it may be possible for NIH staff to search entire proposals for relevant terms, rather than just the abstracts. Was this approach considered? If it was considered what were the reasons for rejecting the approach?

We agree that the profiled details in the database are limited and have outlined this in the limitations to the study, described on page 14. To supplement this, we also conducted a Pubmed search (page 6) using the investigators’ names to identify research protocols related to these funded projects and identified 47 manuscripts describing 44 unique projects (page 8, line 122). Two people abstracted data from these protocols on whether sustainability was planned for (38) or measured (32) and these details were added to Figure 1 of our Short Report and page 8.

Third, all of the grant proposals could have been accrued either through contacting the Principal Investigator or, failing that, through the Freedom of Information Act. This would have provided much more data for the document review.

We completed a PubMed search as above but did not request additional detail through the Freedom of Information Act, which we agree could be considered in future if funding were available to conduct this additional data collection; additional data sources were mentioned in the limitations section.

Fourth, the authors could also determine whether there is a study protocol paper for the funded grants that provides more detail or could be searched for relevant search terms. The use of just the information in RePORTER resulted in an extremely cursory approach to document review and subsequent examination of the issue of sustainment.

We have done this as noted above.

How could the setting of an implementation project (Table 1) not be reported? Is this an artifact of the use of limited information in RePORTER?

In these cases, this information was not reported in the database and we agree it is a limitation and have mentioned it on page 14 of the manuscript.
For the interviews the response rate of only 14.5% is very low and not acceptable. The authors provide limited information about the representativeness of the sample and what settings and health conditions were addressed from those who participated in the interviews.

We have highlighted this as a limitation in the manuscript on page 14.

‘Third, due to our small sample size and poor interview response rate, the interview findings may not be generalizable to all implementation researchers.’