Author’s response to reviews

Title: Ten Recommendations for Using Implementation Frameworks in Research and Practice

Authors:
Joanna Claire Moullin (jcmoullin@gmail.com)
Kelsey Dickson (kdickson@sdsu.edu)
Nicole Stadnick (nstadnick@ucsd.edu)
Bianca Albers (balbers@implementation.eu)
Per Nilsen (per.nilsen@liu.se)
Sarabeth Broder-Fingert (Sarabeth.Broder-Fingert@bmc.org)
Barbara Mukasa (barbara.mukasa@mildmay.or.ug)
Gregory Aarons (gaarons@ucsd.edu)

Version: 1 Date: 23 Jan 2020

Author’s response to reviews:

Associate Editor: This is a very nice paper, which could benefit the field. The reviewers have suggested several important revisions, in particular: providing additional detail on whether/how stakeholders were engaged in developing the tools or whether these tools underwent any user testing and providing additional clarification on what makes a framework a good/bad fit and how to evaluate this, which could strengthen the paper and make it more useful to readers.

Thank you for your comments and those of the reviewers. We have made revisions as suggested, which we believe have greatly strengthened the paper. Of particular note is the additional details about our process of stakeholder engagement in reviewing and testing of the tools. “Specifically, the goal of the stakeholder input was to critically review the paper, making any additions, edits and comments, by concentrating their thinking on, (i) Would they be able to apply these recommendations as they are written to their implementation work (proposals, studies, projects, evaluations, reports etc.)? (ii) Would they as a researcher, intermediary or provider know what to do to use an implementation framework for each recommendation? In addition, we felt one area that needed some extra attention was the two tools, which aim to assist readers apply the recommendations. They were asked to test/trial the tools with any projects that they, or a colleague had to ensure they were functional.” We have also added clarification on assessing framework fit at the conclusion of paragraph 1 or recommendation 1. “Frameworks may be evaluated against these four criteria to see if they fit the implementation effort’s purpose (aims and objectives) and context (setting in which implementation is to occur). If for example a project was aiming to implement an educational program in a school setting a framework that includes factors associated with the healthcare system or patient characteristics would not be a good fit.”
Reviewer #1: enjoyed reading this publication and think it contributes to the implementation literature. Below are my thoughts for how it might be strengthened.

Related to the first sentence "There is great value in effectively using implementation frameworks, models and theories [1, 2]. When used in research, they can guide the design and conduct of studies and inform the theoretical and empirical thinking of research teams." I would add interpretation of findings.

Actioned.

I also would clearly define and distinguish frameworks, models, and theories. We need more theories and use of theories in implementation science, in particular. I think we diminish that goal when we lump these three into the single term "frameworks".

We did deliberate on the terminology and using frameworks as the collective term. For ease of reading we believe a single term is preferable to abbreviating theories, models and frameworks to TMFs, or to using all three throughout. We have however added in definitions of the three terms and the reasoning for our choice of using the term frameworks throughout.

“Theories are generally specific and predictive, with directional relationships between concepts that may guide what may or may not work, and therefore suitable for hypothesis testing and validation. Models are similarly narrow in scope, however are more often prescriptive, for example delineating a series of steps. Frameworks on the other hand tend to organize, explain or describe information and the range and relationships between concepts, including some which delineate processes, and therefore are useful for communication. While we acknowledge the need for greater use of implementation frameworks, models and potentially even more so theories, we use the term frameworks to encompass the broadest organizing structure.”

The opening section on why underuse of theories/frameworks is a problem would benefit from greater specificity. Consistent terms/constructs aid communication and synthesis of findings and therefore is key to replication and to building the evidence base. Frameworks tend to organize information and do not suggest hypotheses for the relationships among constructs - therefore are useful for communication. Theories suggest hypothesis and therefore more explicitly guide what may or may not work.

Thank you for suggestions. We have incorporated them into the introduction.

"To ensure that the recommendations are clear, practical and comprehensive, we invited an international stakeholder panel" Would be helpful to provide more information on how many stakeholders and mode of engagement.

We have included that there were four stakeholders in the panel. In addition, the section below.

“Specifically, the goal of the stakeholder input was to critically review the paper making any additions, edits and comments, by concentrating their thinking on, (i) Would they be able to apply these recommendations as they are written to their implementation work (proposals, studies, projects, evaluations, reports etc.)? (ii) Would they as a researcher, administrator, intermediary or provider know what to do to use an implementation framework for each recommendation? In addition, we felt one area that needed some extra attention was the two tools, which aim to assist readers apply the recommendations. They were asked to test/trial the tools with any projects that they, or a colleague had to ensure they were functional. The tools were refined according to their suggestions.”

As an example "For example, researchers may use a framework for understanding and testing
determinants (e.g., EPIS [17]) and another for evaluating outcomes (e.g., Implementation Outcomes Framework, RE-AIM [18] or Proctor's [19])." Provide a citation for the Implementation Outcomes Framework? I suspect is same as Proctor's?"

This has been removed.

In the EPIS application sections (e.g., for step 1) would be helpful to clearly describe how the step was operationalized - how and why did you select EPIS? And don't use the passive tense when doing so. Tell the reader who did what to select.

EPIS was selected as the authors have the most experience with this framework and we believed having one framework across the application sections aids readability. EPIS is also useful for consideration of both determinants and implementation process. We have however incorporated a more examples of other frameworks within the preceding paragraphs describing each recommendation. In addition, EPIS Application has been amended as follows: “A mixed-methods developmental project aimed to systematically adapt and test an EBP for youth with Autism Spectrum Disorder in publicly-funded mental health settings and develop a corresponding implementation plan [20]. EPIS was specifically selected by the research team, given the EPIS framework’s focus on public services settings, that it specifies multilevel inner and outer contextual factors, bridging factors between outer and inner contexts, addresses implementation process, and emphasises innovation fit. EPIS was an apt fit for the project aims and context. In combination with the EPIS framework and as one example of a bridging factor, a community partnership model [21] was also applied to inform the community-academic partnership integrated throughout this study.”

For step 2, you discuss using frameworks to guide how you engage stakeholders and also how you engaged stakeholders in the application of frameworks. I think the second is challenging and worth discussing further - and including in application section. How do we meaningfully engage a diverse stakeholders in applying frameworks?

We have tried to make this clearer in the text: “Stakeholders can be engaged in the application of an implementation framework by, for example, having them involved in defining the local health system needs and selecting EBP(s) and/or implementation strategies in the EPIS implementation phase, as these are important to enhance their collaboration and ownership of the implementation effort [23].”

For step 7, I think it would be helpful to more clearly call out the frameworks that list implementation strategies such as Powell's ERIC and the BCW. Selecting from established taxonomies promotes communication and synthesis across imp sci.

We have added in ERIC and BCW to the section: “Taxonomies of strategies, such as the ERIC or BCT, are useful to promote uniform communication and synthesis across implementation science.”

The manuscript would benefit from editing - For example, minor errors throughout, frequent use of formats like "There are" or "It is" to start sentences, e.g. and i.e. sometimes in parenthesis and sometimes not, and use of passive tense.

The manuscript has been re-edited.

Reviewer #2: This paper outlines 10 recommendations for applying D&I frameworks in the context of "implementation efforts." Overall, the paper is well-written, addresses an important gap in the science and practice of D&I, and recommends concrete tools to guide application of the proposed
recommendations. I have a few general critiques and suggestions:

As noted by the authors, the order and relevance of these 10 steps can vary - and likely depends on the purpose of the study. What guidance might you provide on the order and relevance for different types of implementation science projects? For instance, this order looks right for those who are at the stage of developing and testing implementation strategies - but those who are earlier in the process, perhaps at the point of trying to determine implementation determinants, may not be able to produce process or logic models or articulate mechanisms yet. This doesn't mean a framework isn't very informative at this stage, but the steps and their order would vary. It could be really helpful - especially for more junior D&I scientists - to indicate when each step may be especially relevant. As it stands, I think the list could be overwhelming and it would be difficult for users to know what to use and what not to use.

This is a great suggestion. We have added in the section below.

“Depending on the stage in the implementation process it may not be necessary to apply all the recommendations. The full list is suitable for implementation efforts that will progress at least to the implementation stage, whereby implementation strategies are being employed. However, for those who are early in the exploration phase of implementation or perhaps at the point of trying to establish implementation determinants, they may not be able to produce process or logic models or articulate mechanisms yet. This doesn't mean a framework isn't very informative, but the order of the recommendations would vary and the full list may only be applicable as the implementation project progresses in future work.”

I can see the pros and cons of always using EPIS as the exemplar framework for each Step. The consistency does aid in understanding and cognitive processing - and the authors are quite experienced in the application of EPIS. However, there are other types of frameworks that are much better suited for certain steps. Perhaps the exemplar frameworks at each step could extend beyond EPIS to include a determinant and an evaluation framework as well - especially those that pair nicely with EPIS.

We have however incorporated a few more examples of other frameworks within the preceding paragraphs describing each recommendation. EPIS is both a multilevel determinant and multiphasic process framework, the EPIS website includes definitions and measures for each determinant as well as the implementation phases.

Specific critiques and suggestions:
1. Page 5, lines 39-55. This content nicely mirrors the categories of frameworks as described in the D&I frameworks chapter in Brownson et al (process, determinants, and evaluation frameworks), but does not explicitly use that terminology. It would be helpful here to introduce that terminology to describe the various categories of frameworks (with examples of each), and then refer to this terminology later when explaining each of the 10 steps. For instance, you might say, "Process models such as EPIS and REP are particularly well-suited to Step 2, engage stakeholders." Or "Determinant frameworks are particularly well-suited for use in Step 6, determine implementation determinants." (The framework categories are indeed referenced under Step 1, but are not previously defined.)

The categories of frameworks, process, determinant and evaluation, comes from Nilsen et al 2015 and Moullin et al. 2015, which has been adopted across implementation science. We have included in the paragraph the category terms, process, determinant and evaluation, as well as including examples in step 1.

2. How might you address the use of hybrid or custom frameworks - e.g., combining process models
and determinant frameworks - for different aspects of a project?

The introductory section to our recommendations states: “The key is that all recommendations are considered and that ideally, a framework(s) would be applied to each recommendation. This may mean one framework is used across all recommendations or multiple frameworks are employed. We recognize that this may be unrealistic when working under real-world resource constraints and instead strategic selection of frameworks may be necessary (e.g., based on greatest needs or strongest preferences of stakeholders).”

3. Page 6, line 1: Please clarify, what makes use of a framework "suboptimal"?

We have added in our definition: “Recent analyses of implementation science studies show suboptimal use of implementation frameworks [1, 8]. Suboptimal use of a framework is where it is applied conceptually, but not operationalized or incorporated throughout the phases of an implementation effort, such as limited use to guide research methods [1, 9].”

4. Page 6, line 23: Please define what is meant by an "implementation effort."

“Ideally, implementation frameworks are used prior to and throughout an implementation effort, which includes both implementation research and real-world implementation projects.”

5. Page 7, lines 21-25, "the framework's orientation, for example the setting….": This wording is a bit confusing. Please rephrase.

Amended as follows: “the framework’s orientation, which includes the setting and type of intervention (i.e., EBP generally, a specific intervention, a guideline, a public health program being implemented) for which the framework was originally designed”

6. Page 8, EPIS application: In selecting a framework, how might one determine that a framework is NOT a good fit or should be ruled out? How about an example showing how a particular framework would NOT fit a particular context?

We have kept the EPIS application section specific for EPIS, however added to end of paragraph 1 or recommendation 1: “Frameworks may be evaluated against these four criteria to see if they fit the implementation effort’s purpose (aims and objectives) and context (setting in which implementation is to occur). If for example a project was aiming to implement an educational program in a school setting a framework that includes factors associated with the healthcare system or patient characteristics would not be a good fit.”

7. Page 9, step 3: This paragraph is great! I would love to see this step introduced sooner (perhaps even first). I think it helps set the context for the rest of the steps and aids in reader understanding. It also nicely shows that there are many research questions that could be relevant depending on the stage of the research or the state of the evidence around a particular EBP or IS.

Thank you for your comments. We believe engaging stakeholders should be early in the process, so they can be involved in deciding the research questions, and frameworks can assist in this process, hence the order of the recommendations. However, as noted previously, the steps may occur in different order and we appreciate that often research questions are chosen first.
8. Page 10, line 4, "the selection of the BCW as a guiding framework necessitates for a question or issue to be described in behavioral terms and, in many cases, refined to be more specific." This sentence is a bit awkward. Please clarify what it means for a question or issue to be described "in behavioral terms" and what would be entailed in refining an issue to be more specific.

We have added the sentence: “Being specific about the problem to be addressed entails being precise about the behaviors you are trying to change and whose behavior is involved.”

9. Page 10, lines 9-10, "Frameworks also provide guidance for the translation of implementation literature to research or evaluation questions." Please clarify what "translation of implementation literature to research or evaluation questions" means.

Additional clarity has been added: “Frameworks also provide guidance for the translation of implementation literature to research or evaluation questions. For example, it has been written that education used alone as a single implementation strategy is not sufficient for successful implementation. An implementation framework will assist in realizing implementation determinants that remain to be addressed and therefore the selection of an additional implementation(s) strategies.”

10. Page 10, Step 3 EPIS application: Please clarify - it is difficult to tie this example to the "step" in #3.

Now on page 10-11 we have added more detail to this section to broadly describe this study without going into very minute detail.

EPIS Application: Work by Becan and colleagues (2018) [39] provides an example of a comprehensive application the EPIS framework to inform hypothesis development in their US National Institute on Drug Abuse study Translational Research on Interventions for Adolescents in the Legal System (JJ-TRIALS). JJ_TRIALS utilized EPIS to inform, identification of outer and inner context determinants, measures to assess those determinants, predictions based on theory, and tracking progress through the EPIS phases including identifying what constitutes the transition between each phase and the next phase. Specifically, the trial applied EPIS to inform the development of four tiers of questions related to: 1) the differential effect of two implementation strategies; 2) the factors that impacted and supported the transition across implementation phases; and 3) the impact of this process on key implementation outcomes, and 4) tracking progress through the EPIS phases. For example, relevant determinants at the outer context system level and inner context organizational levels were identified. Specific hypotheses were developed to test how determinants (e.g., independent variables) influenced mechanisms (e.g., mediators/moderators) and ultimately “targets” (e.g., dependent variables) that are implementation outcomes and outcomes with clinical relevance.

11. Page 11, Step 4 EPIS application: EPIS may not serve as the best example here. What specific determinant framework was used in this case?

EPIS is both a multilevel determinant and multiphasic process framework, the EPIS website includes definitions and measures for each determinant. As such, EPIS was the determinant framework used.

12. Page 12, lines 27-30, "Beyond identifying and analyzing key implementation determinants, there are frameworks that describe important implementation mechanisms and their associated impacts across the phases of implementation processes": It is unclear how this relates to the research and evaluation method step.

We have clarified this by identifying issues of determinants, mechanisms, and mechanisms that would
jointly invoke using frameworks along with theories of action or change.
“Beyond identifying and analyzing key implementation determinants, theory should be applied along
with frameworks in order to describe important determinants (e.g., independent variables),
implementation mechanisms (e.g. mediators), and their associated impacts on implementation targets
(e.g., dependent variables) across the phases of implementation processes”

13. Pages 14-15, Step 8: This section is really strong. I really appreciate the citations from a variety
of published studies representing this step. It seems the evidence here is much stronger than for other
steps. Is that the case? If other steps have a weaker evidence base, please comment on this as an
opportunity. If not, then it would be really helpful for the other steps to have a similar discussion of
(non-EPIS) examples from the literature.

We have now incorporated more non-EPIS examples and citations into the recommendations prior to
EPIS application sections.

14. The tools (Tables 1 and 2) appear to be useful worksheets for study planning. Some of the
questions appear to be redundant or overlapping, and may be somewhat confusing. While it was noted
on page 6 that stakeholders were engaged in reviewing the recommendations, it does not explicitly state
that the tools underwent review by stakeholders. Was any user testing done on the tools? Methods and
results of user testing, and demonstrating refinement of the tools based on that user testing, would
significantly strengthen this paper.

The section describing our stakeholder engagement has been amended to explain the review of the
tools.
“Specifically, the goal of the stakeholder input was to critically review the paper, making any additions,
edits and comments, by concentrating their thinking on, (i) Would they be able to apply these
recommendations as they are written to their implementation work (proposals, studies, projects,
evaluations, reports etc.)? (ii) Would they as a researcher, intermediary or provider know what to do to
use an implementation framework for each recommendation? In addition, we felt one area that needed
some extra attention was the two tools, which aim to assist readers apply the recommendations. They
were asked to test/trial the tools with any projects that they, or a colleague had to ensure they were
functional. The tools were refined according to their suggestions.”

15. There are a few questions in Table 1 that are confusing or need to be more specific, which would
likely be discovered in user testing. For example, Step 2, "How can the selected implementation
framework(s) be used as a tool in engaging stakeholders in this implementation project? (i.e., as a
simplified and therefore appealing and intuitive representation of the implementation process)" and
"How can the selected implementation framework(s) be used to determine the roles and activities of
stakeholders within and across the implementation phase(s)?" - this is confusing. In what sense would a
D&I framework guide stakeholder roles and activities? Same for the questions in Step 5 - in what sense
would a framework guide study design, etc? In Step 8 - "Given the framework(s) and determinants
selected, what evaluation method and measures are being employed to measure determinants and
changes in determinants over time?" - this seems to fit better with Step 6. (Minor detail in step 9, "How
can the selected implementation framework(s) inform tailoring and adaption…" should say adaptation,
not adaption.

The tool is a summary and should be used concurrently with the detailed information in the article. For
example, from the article in Step 5 it states: “In the design of an evaluation, frameworks should be used
to inform decisions about what constructs to assess, data to collect and which measures to use.” For
step 2 to describe how an implementation framework may guide stakeholder roles and activities: “For example, stakeholders being involved in defining the local health system needs and selecting EBP(s) and/or implementation strategies, are important to enhance their ownership of the implementation effort.”

For Step 6: the determinants are selected, while in Step 8 how those determinants are to be evaluated is chosen.

Thank you for picking up the error in step 9, we have amended. We have also made the instructions clearer.

16. For Table 2, what is the purpose of the ratings? How would they be used? For instance, is more always better or does the extent to which the framework is used for each specified domain depend on the needs of the project? How might the scale responses capture this?

We considered and deliberated ways in which the ratings could be most useful. In the introduction to the tools we tried to capture the purpose of the tools, however did not explicitly include the ratings. Together with the questions, the ratings are to assist users to thoroughly think through the ways in which the framework(s) are used. We believe for those questions that are applicable for a project, a higher rating is preferable, as we encourage where necessary use of multiple frameworks or modifying/enhancing a framework to ensure utilization across the implementation effort.