Author's response to reviews

Title: The sustainability of new programs and innovations: A review of the empirical literature and recommendations for future research

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Author's response to reviews: see over
Dear Dr. Kent,

My co-authors and I would like to thank you and the reviewers for the considerable time and effort devoted to reviewing our manuscript entitled “The sustainability of new programs and innovations: A review of the empirical literature and recommendations for future research” (ms # 1838421577543607). We appreciate the opportunity to submit a revised version of the manuscript. The reviews have led us to think carefully about our own work, to expand our discussion to integrate the reviewers’ observations and feedback as well as other models and literatures, and to be more precise about what we intended to investigate in our review. Below, we address the concerns that Dr. Greenhalgh reiterated in this review. The strength and persistence of her reactions to our work have helped us sharpen our thinking, and we have given careful consideration to the ecological perspective.

Our understanding of one of Dr. Greenhalgh’s central concerns was that our paper did not engage with the limitation of the “logic model”, and that it will promote the viewpoint that sustainability should be equated with maintenance of the intervention as originally developed or implemented. It is certainly not our intention to equate sustainability with rigid adherence to an intervention as originally developed or implemented, and we hope that this point comes through clearly in our revision. In response to Dr. Greenhalgh’s concerns, we have made a number of additional modifications. We have indicated significant changes in “track changes” format throughout the manuscript, and also quoted longer sections of the manuscript in different font below.

First, we have specified more clearly in our introduction the approach that we have taken in our review in order to allow readers to draw conclusions regarding the usefulness of our approach and the relevance of our review to their own goals and interests:

To better understand the state of research on sustainability to date, we reviewed studies that investigated whether or to what extent programs or interventions that had previously been implemented were sustained, and those that sought to understand factors that influence their sustainment. We present an overview of the ways that some key research considerations have been addressed from this perspective in a variety of fields, and we allow what we found using this approach to guide our synthesis of the results and recommendations. For the purposes of this review, we consider relevant studies to be those that identified interventions, procedures, or programs that were implemented to achieve specific program, patient, or population-level benefits. We reviewed studies that examined 1) sustainability outcomes[23] (such as the continuation of some or all components [16], or the desired recipient-level outcomes beyond initial efforts to implement, fund or study a new practice) or 2) influences on the sustainment of these programs or innovations.(page 6)

We acknowledge that this is a very different approach from a “nested systems”, or ecological approach, and that we asked different questions than one might ask if approaching the topic from an ecological perspective. We reinforce this in the “limitations” section of the paper on page 25: In this project, we reviewed studies that identified specific programs or interventions and investigated either the extent to which those interventions and/or the desired benefits were sustained, or factors that influenced their sustainability. Information generated from this review can inform researchers about what has not yet been sufficiently explored and stakeholders about what
may be important to consider when monitoring specific programs or interventions that they have chosen to implement. We did not specifically seek studies that examined the adaptive capacity of systems, and we did not take an ecological or developmental perspective in our review[20, 84]. Such perspectives are valuable for future research and much can be learned by broadening the research questions beyond whether or not an intervention continued as originally implemented. However, from a number of stakeholder perspectives, and given the substantial resources that have been devoted to implementing effective practices to date, there is also value to understanding the findings and limitations of the existing body of research that has investigated whether and how interventions and their health benefits have been sustained[17]. Thus, in this review, the ways in which we presented our findings, conclusions that we drew, and recommendations that we made were shaped by an effort to understand more about sustainment or discontinuation from this perspective, and by the state of the existing literature that has addressed sustainability in this manner.

We also attempted to clarify our view (which is consistent with a number of other authors) that sustainability is not a static state, and that it is quite common for adaptations to be made to programs and interventions. For example, on page 4-5, we state:

> The results of program evaluation and research to date suggest that sustainability must be studied as a distinct and dynamic phenomenon [4, 5]. Although a variety of factors may create conditions that facilitate initial implementation, their presence or influence may diminish over time [6-8]. Even when initial implementation efforts are successful, interventions or programs do not necessarily continue as originally implemented. At times, discontinuation of a particular intervention may be the result of development or discovery of more effective, efficient, or compatible practices [9]. Adaptations, partial continuation of a program or intervention, or integration of new practices may occur in response to new evidence, changes in priorities or resource availability, or other contextual influences.

Dr. Greenhalgh’s review stated, “the reproduction of flawed assumptions is in places very subtle, e.g. page 5 they say: ‘Challenges in drawing conclusions…’ but actually, this omits the biggest challenge of all – that there is an inherent tension between sustaining an intervention as originally conceptualised and adapting it to fit a changing context”. In the previous draft, we had intended the entire paragraph that followed the sentence that was quoted to further delineate and discuss challenges (including the tension between fidelity and adaption), but we agree that a stronger statement is necessary to highlight this central challenge. We have made the following revision on page 4:

> Many factors make it difficult to study the sustainment of innovative programs and interventions and draw conclusions the current literature. A fundamental challenge is the tension that exists between the continuation of interventions as originally designed and the need to adapt them for use in contexts that may differ in important ways from those in which they were originally developed and tested [5, 17, 18]. A number of conceptualizations of sustainability have been proposed that reflect differing priorities and perspectives on this issue [19]. In some models, the intervention, rather than the system into which it is introduced, is the focal point of interest. Such models tend to identify a set of factors or conditions that increase the likelihood of sustainability of a specific intervention [18]. This approach is very different from models and studies that examine sustainability from an ecological, or complex systems perspective and emphasize the interconnection between broader environmental forces, contextual influences, and the program or intervention itself [20, 21]. These
differing approaches have important implications for the way that research is conducted and the conclusions that can be drawn. For example, the former perspective may reflect an emphasis on determinants of the preservation, fidelity to, or discontinuation of a program or intervention. In contrast, research conducted from an ecological perspective would seek to understand the ways in which the intervention and the local context mutually adapt and evolve [22] and how this process impacts sustainability. Additional challenges to the study of sustainability and interpretation of the literature include the numerous definitions and related but not entirely equivalent terms that have been used in differing fields, and variation in the timing and method of assessment employed across studies. Furthermore, the assessment of programs, practices, and interventions as varied as community-level prevention programs, medical records systems, psychotherapies and quality improvement programs will necessarily limit the extent to which assessment can be standardized.

We believe that the paragraph above also addresses the concern that the review gives the impression that there is only one way (the use of “logic models”) to study sustainability, as we include discussion of the ecological perspective. Further, we discuss some limitations that our review revealed that are consistent with Dr. Greenhalgh’s concerns about “logic models” on page 16:

Studies with quantitative designs were less likely to identify processes and interactions of this nature, perhaps due to their design and research questions, as well as the models and measures that were employed. Important processes may have been subsumed, identified, or obscured under related and more readily measured constructs. The process-related findings highlight the importance of investigating the ways in which influences at multiple levels may interact to impact sustainability [20]. For example, some processes that were identified in our review suggest mutual adaption between the intervention and the organization or system (e.g., adaptation of the intervention to improve fit, alignment of the organizational goals or procedures with the intervention), or important interactions between stakeholders in various roles (e.g., negotiation, navigating competing demands). Such findings suggest that interplay between contextual factors and the innovation itself is to be expected given the dynamic nature of the complex systems into which innovations are introduced [20, 56].

In response to Dr. Greenhalgh’s feedback on our comment that “partial sustainability may be more easily achieved than full sustainability”, we have removed this from our discussion. We have also looked for parts of the paper that imply a “pro sustainability bias” or the superiority of one approach over the other and we have modified our discussion in several places, including removing the text that she quoted.

Dr. Greenhalgh suggests that we give more consideration to ‘ecological’ adaptation of innovations. While we acknowledge the importance of adaptation in several places throughout the paper, we are also concerned about the implications of neglecting attention to program or intervention fidelity when some evidence has emerged in some fields that adherence to a set of procedures is necessary to promote desired health benefits in routine medical practice (c.f., McGlynn et al., Woolf, 2005), prevention programs (e.g., Domitro维奇 & Greenberg, 2000; Dane & Schneider, 1998), and mental health interventions (e.g., McHugo et al., 1999). Low fidelity in some of these cases cannot be attributed to identification of more effective practices or reinvention and may be inconsistent with some of the goals of the stakeholders who selected and implemented a specific intervention. At the same time, we acknowledge that adaptation does not always appear to negatively impact desired health benefits. Some of the discussions on fidelity and adaptation acknowledge that adaptation will naturally occur, and that “flexible” fidelity may
be an appropriate goal (Mazzucchelli & Sanders, 2010). Thus, while Dr. Greenhalgh indicated that she is unconvinced that innovations can be divided into “core” and “modifiable” components, we believe that some evidence has emerged for the notions of core and adaptable elements, but that further study is warranted. We discuss these issues on pages 19-21 and recommend that both fidelity and adaptation be studied further:

Consistent with discussions of sustainability that suggest that adaptation and evolution of the practices and innovations are to be expected[25, 32, 59, 60], a number of studies that we reviewed indicated that some form of modification had occurred. While such changes may be made to interventions or programs in response to contextual influences such as shifting priorities or availability of resources, the process and nature of adaptations may vary considerably between projects. Most studies that we reviewed did not describe adaptations or examine their impact on health-related outcomes. To facilitate a greater understanding through future research, some clarity regarding adaptation and fidelity is necessary. Additional research is needed to assess the conditions under which fidelity, or different types and degrees of adaptations are important for the achievement of specific health benefits. While it is important to differentiate sustainment from entrenchment, which may prevent further innovation or adoption of more effective practices [17, 31, 32], it is also critical to understand when, and to what components of a particular program or intervention, fidelity is necessary. Fidelity has been conceptualized in the mental health literature as a combination of adherence to a prescribed set of practices at adequate dose or intensity, competence in delivery, and differentiation from other interventions [46, 61], with judgments of competence taking response to certain contextual factors into account [23]. In the medical literature, it has been defined as “the extent to which the system provides patients the precise interventions they need, delivered properly, precisely when they need them” [58]. Evidence has emerged that for some interventions, a higher level of fidelity or intensity may be required to produce desired health benefits [11, 49, 61]. In these cases, insufficient levels of fidelity may in fact indicate that a program was not sustained at the level necessary to promote these outcomes. On the other hand, the success of some programs (e.g., community-based health promotion programs) may be less dependent on the implementation of a set of procedures with fidelity than on the flexibility and adaptive capacity of the system or organization that implements the program. In such cases, the range of possible or even necessary adaptations within the program might be quite broad [62, 63], and may reflect new priorities or response to local conditions[64]. This type of ongoing evaluation, modification, and replacement of elements or procedures as necessary is an approach advocated in organizational learning and continuous quality improvement literatures [65-67]. Theory in this area suggests that an appropriate balance between exploration of new methods while exploiting existing knowledge regarding effective strategies may in fact result in more sustainable and successful programs[68, 69]. Simply measuring fidelity and characterizing modifications as deviations may obscure the very refinements that facilitate the continued use of some innovations. A period of mutual adaptation[70] is probably common between initial implementation and institutionalization, and some innovations may continually evolve[63]. To advance the field, subsequent research should include further attention to the nature of the modifications that occur and the process by which modifications are made [71, 72]. Even for those interventions for which there is evidence that fidelity is important, there may be aspects that can be adapted and modified while preserving desired outcomes [16, 73, 74], provided that the critical elements are conducted or delivered at adequate levels of fidelity. Several types of modification, at either a molecular or molar level [61, 75], may occur as practitioners, communities, and systems implement specific programs and interventions. For example, tailored adaptation may be guided by available evidence and remain faithful to identified core elements [16], with an eye towards facilitating desired health benefits. Evolution may occur if
procedures are modified in light of the emergence of new evidence [76]. Replacement may occur if more compatible or effective interventions or procedures are identified[9]. Adaptations which result in reversion or erosion fail to preserve the core elements of an intervention, which may in turn result in a failure to preserve desired health outcomes. In such cases, if the intervention that was originally introduced becomes unrecognizable[13], it may be considered to have been discontinued. We therefore recommend that when the intervention is the focal unit of interest, in addition to identifying methods of assessing fidelity, researchers study periods of adaptation [77] and characterize the nature of modifications made to interventions. It will also be important to understand more about the nature of possible tradeoffs that are made between fidelity and sustainability and how stakeholders make such decisions.

Identifying core elements, or components that are critical for the achievement of desired outcomes, is also a critical area for future study. Developers of many complex interventions have not yet pursued these questions. Isolating elements of innovative practices and examining their relative contributions to the overall impact of the practice can be challenging and may not be feasible or desirable in some situations. However, when available, this information can facilitate a streamlined or pragmatic implementation effort that retains the aspects found to be most effective and successful in everyday practice[17]. As a positive impact on intended recipients is the ultimate goal of implementation, we recommend that researchers include a consideration of these important matters in their efforts to study sustainability.

In the most recent review, Dr. Greenhalgh stated, “You can’t have it both ways—either you have to agree with me that there’s a problem with the way most people have approached this topic (and you need to say that boldly in the paper) or you have to stand your ground and argue that most other authors and the other two reviewers had it right. I can see that in order to apply a ‘logic model’ to the study of sustainability you would have to specify desired outcomes and measure success against whether these were achieved, but I profoundly disagree that this is the only way to broaden our understanding of sustainability. I think that until we loosen up on what we mean by sustainability – both by building in the study of adaptation and embedding and by zooming out from the measurable within-project variables to consider the wider social, environmental and political context in which these ‘factors’ are playing out – we won’t ever get our heads round this topic.”

We agree that the use of what Dr. Greenhalgh describes as a logic model is not the only way to broaden our understanding of sustainability, and we believe that the sections of the paper that we have quoted above, as well as additional revisions, make this clear. We do wish to note that because so few studies that we reviewed appeared to be explicitly guided by theories or models of sustainability (and thus may have failed to assess key constructs appropriately), we do not believe that our speak to the relative superiority of these perspectives or approaches. They do lead us to agree with Dr. Greenhalgh and other authors that an ecological perspective can advance understanding of sustainability, and we acknowledge this in this revision on pages 16 and 25 as well as in our discussion of adaptation and fidelity on pages 19-21. However, while ecological models have emerged more recently, neither they nor many “logic models” (some of which do include consideration of the broader context) have been evaluated very extensively. As both the Gruen paper and Dr. Greenhalgh’s review acknowledge, we do not yet know whether, and under what circumstances the models of sustainability put forth to date are valid and useful. Thus, while we acknowledge problems with and limitations to the research that has been conducted to date, we feel it is premature to make the assertion in this paper that Dr. Greenhalgh
advocates as boldly as she suggests above. Instead, we believe that further investigation of what can be learned from both perspectives is warranted.

In conclusion, we believe that our revised manuscript engages with and addresses Dr. Greenhalgh’s central concerns. While her review stated that “the goal of (relatively uncritically) summarising previous conceptually-flawed research is just going to reproduce and legitimise this approach”, we believe that our revised conclusions and recommendations highlight some limitations to the research to date. We have discussed the merits of employing alternative approaches and asking additional questions in future research to complement and extend the work that has been done thus far in the field. Further, we believe our conclusions are consistent with the empirical literature that we reviewed. Thus, we believe that this paper will contribute to the ongoing dialogue on sustainability. We also very much look forward to reading Dr. Greenhalgh’s recent work, which she mentioned in her previous review, as it sounds as though it will contribute additional research findings and further articulate the important perspective that she has advocated in her review of our work. Although we may not have drawn some of the conclusions that she advocated in her feedback based on the current review, we have greatly appreciated her perspective as we have worked on this and other projects.

In closing, we would again like to again thank the Editor and the reviewers for their thoughtful comments and for the opportunity to submit a revised version of the manuscript. We believe we have produced a much-improved manuscript in response to the reviewers’ feedback and hope that you find it suitable for publication in Implementation Science.

Sincerely,

[Signature]

Shannon Wiltsey Stirman