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Title	Scalability assessment of evidence-based innovations in community-based primary health care: a cross-sectional study
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Reviewer 1	Chris van Weel
Institution	Department of Primary and Community Care, Radboud University Medical Centre, Nijmegen, the Netherlands
General comments (author response in bold)	This paper analyses the scalability of evidence-based innovations in community-based primary care settings. The paper comes from the innovative funding through the Canadian Institutes of Health Research funding, in support of Canadian health reforms. At the same time it is an exciting example of how this linking of health reforms to research also stimulates research methodology. Although there has been growing scientific support for implementation research, 'scalability' of interventions has not yet been addressed in a systematic way. **Thank you very much for your positive comments, for agreeing to review our manuscript, and for your suggestions that have helped us to propose a revised and improved version of it.**

1) In addressing this novel domain the authors have developed a rigorous and in my view convincing methodology. The charm of the paper is that it (i) provides concrete data of the value of innovations for large(r) scale use – important message for funders, professionals and service users – and at the same time (ii) argues for the strength of the methodological innovation. But there is a bit of tension between these two aspects. The authors make the distinction, but I would advise to address this a bit stronger in the discussion section. In the end, the strength and confidence of the practice-relevant message is depending on the strength of the methodology developed. **Thank you for your comments. We have added a phrase in our Conclusion on the value of our data. Regarding "the methodological innovation", we assume you are referring to the difference between methodological innovations and health interventions. We have also strengthened our paragraph on the importance of the methodological innovation in the Interpretation section by adding: "...In addition, the diffusion of methodological innovation often takes a more complex, intuitive and organic path that is more horizontal than top-down (18,53,54). Yet, without a doubt, there is value in assessing, adapting and scaling up methodological innovations (such as theories and frameworks) for wider use by KT and implementation science researchers (53,55–58). However, there are few opportunities for researchers to develop and experiment with methods and to evaluate their effectiveness at addressing social and clinical research questions (53). We concur with arguments about the need for funding to enable the experimentation and evaluation of such innovations (53,59). In the end, the usefulness of all scaled-up EBIs will depend on the strength of the methodology developed" (Page 12). Also, in the Conclusion we added the following sentence regarding the message of our study: "Finally, our study informs stakeholders on how and why scalability assessment needs to be incorporated into project design and grant submission as a reportable outcome measure and then evaluated" (Page 15).**

2) For this, I think it is important to present a bit more on the conceptual basis of 'scalability' and this brings me to my main concern: there is a tension between 'scaling-up' and 'implementation' under community-based primary health care conditions. A big danger in health reforms is the rolling-out of interventions as a population-wide one-size-fits-all, while all the experience in primary health care is that implementation should be based on individual and community based needs (person-centeredness and people-centeredness), as needs may differ substantially, even between geographically near communities. Scalability might then be counterproductive. The authors must be aware of this, as they put 'scalability' in the title, but soon in the paper they rephrase this 'scalability potential'. And this is exactly the essence of primary health care: sometimes needs are relatively general and generally available interventions are relevant, but on other times needs point to distinctly different priorities. At the core of primary health care development is: who is the master of such decisions – federal government, health insurers, or the local stakeholders of service users and professionals? This conceptual aspect deserves a bit more explanation. **Thanks for this comment. Our three criteria for Setting assessment (Table 2) attempted to keep a balance between the "masters" (communities or policy makers): The three criteria are "implemented in setting comparable to target setting", "compatible with similar EBIs in target settings" and "consistency with policy directives" Also, an important scalability assessment criteria is the EBI's acceptability among key stakeholders. We discuss this point further in our discussion (2nd paragraph of the Interpretation section): "...This intervention has already been implemented and assessed in several different settings (e.g., a seniors' centre, the Indigenous Early Intervention Organization, an elementary school) (50), so the team is likely to have collected a variety of data and information relevant to future scale up. A danger in health system reform is the rolling-out of EBIs as population-wide one-size-fits-all solutions, while the experience in CBPHC is that implementation should be based on individual and community-based needs (2). A crucial element of successful scale-up is user-informed assessment of the environment to determine if there is a fit between the target units and the EBI (27,51)" (Pages 11-12).**

3) In this, the end-users' opinions of 'scalability' should have a place in its assessment. The current data (page 7) were based on research teams' opinions. For this paper as a first exploration this is acceptable (but should be mentioned), In a more definitive version of the instrument their opinions should be included. **We agree. Our third point of the Limitations subsection now reads as follows: "Third, the questionnaires were completed by 12-Teams stakeholders who, although best qualified to answer detailed questions about their projects, were also researchers in the study. This may have reduced objectivity. Also, all teams had end-user partners, and if these partners had completed questionnaires as well they would have added an important perspective on the project's scalability" (Page 14). Also, in the Interpretation section, we highlighted that: "...A crucial element of successful scale-up is user-informed assessment of the environment to determine if there is a fit between the target units and the EBI (27,51)" (Page 12).**

4) Under the results the authors present a diversity of 'evidence-based interventions' varying from health interventions to analytical methods to surveys to conceptual frameworks. This reflects in my view in a very concrete way the inherent complexity of community based primary health care, and this is at the core of the tension between large-scale rolling-out and community/social determined health needs. Most policy makers are not very familiar with this complex nature and often assume a simplicity in terms of applying available interventions. It would be important to clarify and explain the complexity of primary health care and illustrate this with the nature of the various innovations that were developed through funding by the Canadian Institutes of Health Research. **We agree and we added more emphasis to this point in our Interpretation section: "Second, the diversity of EBIs developed by the teams (from health interventions to methodological innovations) reflects the inherent** |

complexity of CBPHC research, not all of which can be appropriately or easily scaled up. EBIs that were not health interventions were overall ranked lower in scalability than health interventions. Teams whose EBIs consisted of a conceptual framework or an analytical method, for example, were less concerned about widespread implementation of their EBIs as they were not necessarily designed to directly improve health functioning or conditions (52). In addition, the diffusion of methodological innovation often takes a more complex, intuitive and organic path that is more horizontal than top-down (18,53,54). Yet, without a doubt, there is value in assessing, adapting and scaling up methodological innovations (such as theories and frameworks) for wider use by KT and implementation science researchers (53,55–58). However, there are few opportunities for researchers to develop and experiment with methods and to evaluate their effectiveness at addressing social and clinical research questions (53). We concur with arguments about the need for funding to enable the experimentation and evaluation of such innovations (53,59). In the end, the usefulness of all scaled-up EBIs will depend on the strength of the methodology developed" (Page 12).

5) Under 'limitations' the authors mention the difficulties they encountered – even within their researchers group! – of terminology and mutual understanding. In terms of research methodology development this must be of great interest, probably referring to the above mentioned points of how complex the actual study setting is, and how full of tensions (f.e between scalability and community needs. It is a strength of the paper, that this came forward and I would encourage the authors to explain a bit more: what were the concrete problems of understanding they encountered?

As suggested, we added more details about terminology difficulties encountered by the teams in our Discussion (fourth point), as follows: "...some of the concepts relating to the science of scale up (such as adoption, adaptation, maintenance, spread, and scale up itself) are as yet ill-defined and under-theorized in KT and implementation science (62). For example, many of these concepts were unfamiliar to some of the stakeholders responding to our questionnaire, and this was reflected in their reactions to the questionnaire. This highlights the need to refine and standardize terminology relating to scale-up science (11). As a first exercise to rank EBIs in CBPHC in Canada for their scalability, these findings will enable us to refine the language of scaling up, adapt the scalability assessment criteria, improve our scalability assessment form and validate it for future studies" (Pages 13-14).

Reviewer 2	Terrence McDonald
Institution	Department of Family Medicine, University of Calgary, Calgary, Alta.
General comments (author response in bold)	This is an important topic particularly in the Canadian context given the provincial jurisdictional nature of delivering health care, sharing information and breaking down silos is critical. Similarly, developing a standardized framework for evaluating scalability for funded EBM projects is essential. **Thank you very much for your positive comments, for agreeing to review our manuscript, and for your suggestions that have helped us to propose a revised and improved version of it.** 1) The main theme of the paper needs to be enhanced and introduced more effectively and placed front-and-centre into the Canadian context. Readers might benefit from additional details on key terms (for scalability) such as 'coverage', as well as improved organization and presentation of project themes. For example, Table 1 offers potential to provide a concise overview of the projects examined, and might be enhanced by changing the focus from simple 'ranking' (high to low), to being organized first into themes to draw more attention to the content topics (and then their scalability). Its message appears otherwise lost while reading as it lacks important context. **Thanks for this comment. Our new Introduction locates our study more clearly in the Canadian context: "Development and implementation of innovations (i.e., ideas, practices, or products that are new or perceived as new in terms of knowledge, persuasion or a decision to adopt (9,10)) have been strongly incentivized as part of primary care reform in Canada. This has resulted in an extensive array of programs, models, approaches, tools, instruments, indicators, algorithms, services, and policies for which an evidence base has been established. Focus has been placed primarily on generating evidence and determining the degree of rigour required to qualify innovations as "evidence-based" (11–13). However, such evidence is typically generated under experimental or quasi-experimental conditions (efficacy trials). For an innovation to be integrated into standard care, it needs to be tested not only under optimal conditions, but also in real-world conditions (effectiveness trials) (10). There is a growing gap between development of evidence-based innovations (EBIs) as research projects and their widespread implementation as standard care (14–16)" (Page 4).** **It also introduces the project themes more clearly: "...The teams have taken on a diverse array of CBPHC projects, including clinical trials, community-based participatory research projects, surveys and qualitative research, health information technology, and innovative care models for underserved communities or communities with specific diseases such as HIV or diabetes..." (Page 5).** **In addition, beyond the examples provided for each type of EBIs (page 9), we also added the following result: "As shown in Table 1, over half of the EBIs focused on chronic diseases and/or access to resources (e.g., healthcare services, social services and complex care needs)" (Page 9).** **We have also further defined the concept of coverage in our the Introduction section as follows: "...To be scalable, an EBI should meet certain minimum criteria, such as effectiveness and cost-effectiveness (23,24,26). Rigorous evaluation of scale up includes measuring "coverage". This refers to number of the units (individuals, organizations, or systems) that adopt the EBI over the number of units targeted (11,29)...." (Page 5).** **Finally, as suggested, we reorganized Table 1 according to type of innovations (and ranking on scalability of innovations).** 2) (a) It is unclear why the authors chose only a 'self-reported' questionnaire, as opposed to, or in addition to telephone interviews with a set of validated questions that might offer the ability to gather additional and more meaningful information such as: "Do you understand what the concept of coverage entails and why it is important to scalability?". (b) Second, the questionnaire uses language that is vague and difficult to understand in places, depending on who responded to the survey and their level of knowledge, the responses are likely to vary. (c) It is also unclear how and if the questionnaire was validated, was it constructed through general opinion (from the guidelines referenced), consider additional detail on this. **Our project was a first exercise in evaluating scalability in a limited number of EBIs and we believe it offers several lessons about future evaluations. We agree that there is added value to validating the instrument, and we mention this as follows in the Interpretation: "...some of the concepts relating to the science of scale up (such as adoption, adaptation, maintenance, spread, and scale up itself) are as yet ill-defined and under-theorized in KT and implementation science (62). For example, many of these concepts were unfamiliar to some of the stakeholders responding to our questionnaire, and this was reflected in their reactions to the questionnaire. This highlights the**

need to refine and standardize terminology relating to scale-up science (11). As a first exercise to rank EBIs in CBPHC in Canada for their scalability, these findings will enable us to refine the language of scaling up, adapt the scalability assessment criteria, improve our scalability assessment form and validate it for future studies" (Pages 13-14).

We also added to the Limitations as follows: "...in seeking a balance between brevity and science, our short questionnaire may not have covered every dimension of assessing scalability, and its brevity made it difficult to fully explain the intricacies of scalability assessment criteria. Two teams contacted us for more guidance as to how to respond to the survey. However, our questionnaire was created using a group process (with three teams) and questions were pretested with at least three EBIs before being administered...

Third, the questionnaires were completed by 12-Teams stakeholders who, although best qualified to answer detailed questions about their projects, were also researchers in the study. This may have reduced objectivity. Also, all teams had end-user partners, and if these partners had completed questionnaires as well they would have added an important perspective on the project's scalability. Fourth, this scalability assessment form is novel and not yet validated. Therefore scores obtained with the hierarchical cluster analysis are specific to the EBIs used, which does not allow for generalization of results" (Page 14).

Additional Comments:
3) Abstract/Methods (Study Question): Consider highlighting the content of projects such as chronic disease management, as well as 'themes' to provide context, it will assist in making this paper more tangible for readers and how it might be important.
Thanks for this comment. See answer to your comment 1. In our Introduction we give more detail on the project content: "...The teams have taken on a diverse array of CBPHC projects, including clinical trials, community-based participatory research projects, surveys and qualitative research, health information technology, and innovative care models for underserved communities or communities with specific diseases such as HIV or diabetes. Their work has been programmatic, incorporating several sub-projects and innovations within one or a few general themes..." (Page 5).

Typos and Grammar:
4) Missing words 'have' lines 39-41.
Thanks for pointing this out. The manuscript has undergone a comprehensive revision to make the linguistic corrections.

Typos and Grammar:
5) 'Awkward' sentence structure lines 22-24.
Thanks for pointing this out. The manuscript has undergone a comprehensive revision to make the linguistic corrections.

Suggestions for Authors:
6) What might enhance this manuscript and its message, is to identify and highlight projects within the cohort of projects who participated in the survey that have varying levels of potential scalability and why? Then, highlight the themes of those project, their details and then illustrate the concepts of scalability (from the questionnaire), for example, within the projects to highlight why they are important – and why these projects might succeed and be scaled-up. The authors indicate case studies might be of value in further work or to add to this current work, this is an excellent idea.
Thanks for this relevant point. In our Interpretation section, we expanded our analysis of levels of scalability: "....EBIs that were not health interventions were overall ranked lower in scalability than health interventions. Teams whose EBIs consisted of a conceptual framework or an analytical method, for example, were less concerned about widespread implementation of their EBIs as they were not necessarily designed to directly improve health functioning or conditions (52). In addition, the diffusion of methodological innovation often takes a more complex, intuitive and organic path that is more horizontal than top-down (18,53,54)..." (Page 12).
Finally, although our questionnaire did not allow to collect more information on each EBI, in terms of projects that are a good illustration of the concepts of scalability (from the questionnaire), we mentioned this in the Interpretation: "...Future investigation is needed to learn from the EBIs that ranked highest within this cohort of EBIs, and to explore the details of in what way these EBIs were best prepared for scale up. For example, the Pop-up Health and Community Service Event (50) met all of the scalability assessment criteria, and a case study on this health intervention could inform us further about scalability. This intervention has already been implemented and assessed in several different settings (e.g., a seniors' centre, the Indigenous Early Intervention Organization, an elementary school) (50), so the team is likely to have collected a variety of data and information relevant to future scale up..." (Pages 11-12).

Suggestions for Authors:
7) This paper identifies the need for enhanced KT – this might be an opportunity to inform the readership on how scalability fits and needs to be incorporated into project-design, grant-submission (as a reportable outcome measure), then evaluated particularly when local factors may influence the scalability of projects that offer such potential.
Thanks for this comment, we used this suggestion in the last sentence of our conclusion: "Finally, our study informs stakeholders on how and why scalability assessment needs to be incorporated into project design and grant submission as a reportable outcome measure and then evaluated" (Page 15).