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Title: Assessing the scalability of innovations in primary care: a cross-sectional study	
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Reviewer 1: Dr. C Van Weel	
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Reviewer comments	Author response
<p>This is an innovative study approach in the domain of health reforms. Scalability is often considered implicitly and there is growing evidence of the need to look at this as a factor in its own right in health reforms. That makes this paper in principle worthwhile. However, I have a couple of points for the authors to consider, to make the flow of the paper stronger and more focused on the development of tools/strategies to assess scalability early-on:</p>	<p>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.</p>
<p>1. The paper apparently looks at primary care as a unified, one size fits all. What should be introduced in one place should also be introduced elsewhere. But a core aspect of primary care is its ability to work person- and community centered. It takes into account that due to variation in population, setting etc. scalability is probably depending on setting and not a 'general' standard. This should be included in the assessment and implementation of scalability.</p>	<p>We agree that a big danger in health reforms is the rolling-out of innovations as a population-wide one-size-fits-all, while all the experience in primary care is that implementation should be based on individual and community based needs, as needs may differ substantially, even between geographically near communities (Ben Charif et al. CMAJ Open, 2018; Ben Charif et al. Med Decis Making, 2019). Your question is a critical one in the field of scaling up, essentially the challenge of maintaining both implementation fidelity and adaptability. This is why the current version of the ISSaQ survey includes three questions on Setting Assessment that attempt to keep a balance between a scaled up innovation staying true to the "master" (is it consistent with policy directives?) and adapting it to target settings (has it been implemented in a setting similar to the target setting? Is it compatible with similar innovations in that setting?) (see Additional File 1). Second, survey questions regarding variations in the target population (under the dimension Impact") included "Do you have data on the adaptability of the innovation?" and "Do you have data on the effectiveness of the innovation (i.e., testing in real-world conditions)?" Third, an important scalability</p>

	<p>criteria was the innovation’s acceptability among key stakeholders.</p> <p>Finally, we have also added discussion of this issue to the second point of our Interpretation section, please see response to Editors #18 (above).</p>
<p>2. In the conclusions, the authors come back to their statements in the introduction of the importance of scalability of an innovation, as a preliminary and essential, but often overlooked aspect of innovation. This implies the possibility to predict beforehand the likelihood to scale-up health innovations, and their conclusion is that it is still not possible to predict scalability. However, in the introduction ‘prediction’ was no stated aim. In fact, the presented results contain the project leaders opinion of the likelihood of scaling-up. From this:</p> <p>a. The aim of the study should be better articulated – in particular how this relates to building the possibility to predict scalability. What can the data collected in this study contribute to this?</p> <p>b. In the discussion it might be good to explain what next steps are needed to come to a predictive approach. A first point to consider would be how the views of the project leaders relate to actual scalability. In other words, what would be the external criterion against which to assess this ‘assessed scalability’?</p>	<p>a) We have clarified the aim of this paper throughout. It was not in fact to predict scalability but to explore scalability assessments. The data we collected is on the components of these assessments and their strength and failings. We have rephrased our objective as follows (Page 4): “...As part of the preparation for this symposium, we sought to explore scalability assessment among these primary care innovators in the province of Quebec to evaluate their preparedness for scaling up province-wide.”</p> <p>b) Thank you for this interesting question. In response we have added some information in the Limitations and Conclusion subsections:</p> <ul style="list-style-type: none"> - Limitations (Pages 11-12): “Second, our survey collected data mostly on the presence of information necessary for assessing the scalability of innovations, rather than on the results of these assessments. However, our goal was to encourage innovation teams to improve the scalability of their projects and to target components requiring action. Finally, in our analysis, each criterion contributed equally to the scalability assessment score, while some criteria may be more relevant for some innovations than for others. Future analyses should consistently collect the results of scalability assessments, as well as seek secondary, external, and double-blinded evaluations to support evidence for these scores.” - Conclusion (Page 12):

	<p>“...Our findings contribute to important understanding of the strengths and weaknesses of scalability assessments in primary care innovation. Future surveys should include secondary validation of the assessment of scalability components, and seek detailed results of these assessments..”</p> <p>Finally, this study does not so much predict scalability (we did not have data on the results of the scalability assessments) as explore whether and how project leaders assessed scalability and its various components.</p> <p>The next step is to relate the project leaders’ assessments to actual scalability. The next version of our questionnaire will collect data on the results of the scalability assessments (positive or negative), and then, once available, the results of scaling up itself, according to the assessment measures established (or not). This may reveal further gaps in scalability assessment tools and help us refine our own.</p>
<p>3. I am not familiar with the International Classification of Health Interventions, and I do not understand the way the Action axis typing of innovations works. How is, for example, capacity building an exclusive aspect of preventing? If the allocation of type of innovation is important, the classification should be clarified better.</p>	<p>We have revised the Statistical analysis section to better explain our allocation of innovation to the categories. It now reads as follows (Pages 6-7):</p> <p>“...This classification includes three axes: 1) Target (the entity on which the action is carried out), 2) Action (the deed done by an actor to the target), and 3) Means (the processes and methods by which the action is carried out). For this survey, the Action axis was the most appropriate for categorizing innovations that act to change systems or behaviours. Within this axis are six categories of innovation: managing, preventing, therapeutic, diagnostic, other (i.e., not elsewhere classified), and unspecified action...”</p> <p>As suggested, we have removed the terms “mutually exclusive.” We agree that some innovation could include components relating to the management</p>

	category and others components relating to the prevention category.
<p>4. In calculating a sum-score of ISSaQ items, the implicit assumption is that each item contributes equally to the scalability. This looks counter-intuitive, as 'impact' may be more relevant for participants than whether it has a strong theoretical basis or not. Is there sufficient evidence for this?</p>	<p>Thanks for pointing this limitation out. We have discussed this point as a limitation of our analysis (Pages 11-12):</p> <p>“Finally, in our analysis, each criterion contributed equally to the scalability assessment score, while some criteria may be more relevant for some innovations than for others. Future analyses should consistently collect the results of scalability assessments, as well as seek secondary, external, and double-blinded evaluations to support evidence for these scores.”</p>
<p>5. What were the reasons for selected teams to withdraw their participation? And what was the impact of this on the representation of the study participants for the field of primary care innovators?</p>	<p>We have now given the reasons for non-participation in more detail, as follows (Page 8):</p> <p>“The nine other teams did not complete the questionnaire due to lack of time and/or resources (3 teams), lack of results (1 team), and unknown reasons (5 teams).”</p> <p>Also, while nine teams did not respond to our survey, we had a satisfactory rate of response. We discussed our selection bias in the Limitations section as follows (Page 11):</p> <p>“First, our study shares the general limitations of any approach using self-administered questionnaires (e.g., overestimation of evaluated criteria, reduction of objectivity) and cross-sectional studies (e.g. selection bias). One member of each team completed the survey and there was no secondary objective assessment, nor do we know if this respondent consulted other team members. However, we had a satisfactory response rate....”</p>

<p>6. Apparently, the innovations with high scalability potential follow the funding priorities in Canadian health reforms and are in particular related to the change from mono-discipline to multi-disciplinary care. The study was presented as an analysis of innovation potential. But is that what is actually found. To me it looks like it reflects that funding through the health system, rather than the internal strength of the innovation project itself, or its nature ('management', as the authors claim) is decisive.</p>	<p>Thank you for this comment. Our results show that management innovations seem to be most prepared for scaling up. We did not presume to state that this is due to the internal strength of the innovation project independently of any other factors. Indeed, it may well be because Canada's funding opportunities have prioritized management as well as scaling up, and so such projects are more focused on scale-up, better informed and better resourced. This does not change our results, but we have added more discussion of this to our Interpretation section (Page 9-10):</p> <p>"First, our sample of innovations reflects the evolution of primary care philosophy towards patient-oriented approaches to care delivered by multidisciplinary healthcare teams.(4,37–41) It also reflects current health funding priorities in Canada, which promote the scaling up of management and preventive interventions over types that improve health more directly.(7–10) This provides motivation and resources to focus both on management solutions and on scaling up. In addition, Quebec is one of the provinces that has made the most efforts to scale up primary care innovations province-wide.(34,47). In our study, it is therefore no surprise that management innovations predominated, and that they were those that integrated scalability assessments the most. Provincial priorities for healthcare system reform may have made producers more aware of the relevance of generating evidence and the degree of rigour required to qualify these types of innovations as scalable. Thus, our findings capture the evolution of family medicine in Quebec and could catalyze the effective scaling up of management innovations in primary care."</p>
<p>7. It is interesting that 'fidelity' has such a low profile, even though the authors stated in the introduction that it was essential. A critical aspect of successful change and innovation is co-construction between stakeholders who have a vested interest in the outcome of the innovation. One would expect that the trust stakeholders have in innovations they pursue, would be high. The authors might reflect on this:</p>	<p>Thank you for this comment. In response to your query about fidelity we have added to our discussion (Page 10):</p> <p>"...While a strong focus on implementation fidelity may seem to contradict the need for adaptability, some authors have argued that adapting an</p>

<p>is co-creation less important for innovations to stand the chance of being up-scaled? Or does it lead to successful local innovations with less appeal for others outside the directly involved group?</p>	<p>innovation too drastically may actually decrease innovation effectiveness.(55) Our scalability assessment tool reflected the goal of achieving a balance between implementation fidelity and adaptation to reliably reproduce the intended outcomes.(56)..”</p> <p>Second, the innovation’s acceptability among key stakeholders is an important criteria included in our scalability assessment tool. However, we’re not sure we understand what your question is. The issue of stakeholder involvement is very important, such as how to transfer stakeholder trust and ownership from the original innovation to the target communities, but we feel it is beyond the scope of this paper.</p>
<p>Reviewer 2: Dr. Terrence McDonald</p>	
<p>Affiliation: University of Calgary, Family Medicine</p>	
<p>Reviewer comments</p>	<p>Author response</p>
<p>This is very important work. Here are some feedback and suggestions.</p>	<p>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.</p>
<p>1. From the discussion, the point(s) made re: CIHR funding priorities, really needs to highlighted much earlier and how this ultimately influences current innovation projects and future investment and scalability. This is a critical point and should be a highlight in the abstract, background and again as it relates to your findings.</p>	<p>Thanks for this suggestion. We have highlighted this point about health funding priorities in the Abstract, Introduction and Interpretation sections.</p> <ul style="list-style-type: none"> - In the Abstract section (Page 2): “Background: Canadian health funding currently prioritizes scaling up for evidence-based primary care innovations...” - In the Introduction section (Page 3): “...Canadian health funding currently prioritizes the large-scale implementation of practices or products perceived as new in terms of a decision to adopt (“innovation”(5,6)), i.e. the scaling up of effective primary care initiatives nationwide.(4,7–11)...”

	<p>- In the Interpretation section (Page 9): “...It also reflects current health funding priorities in Canada, which promote the scaling up of management and preventive innovations over types that improve health more directly.(7–10)...”</p>
<p>2. The Methods sections (specifically data collection and data analysis) might be enhanced by shortening it and wordsmithing it further (for flow, to allow the reader to follow your approach. With the data collection and data analysis suggest created 'sub-headings' for each of the points outlined the details otherwise crowd out your valuable work. Nuances of scalability definitions might benefit from it's own small 'section' as it is relevant, but shortening things might add to the direction you wish to draw the reader's attention to.</p>	<p>Thanks for these suggestions, also brought up by Editors. We have substantially rewritten every section of the paper to improve flow and conciseness as well as reorganized the sections as you suggest.</p> <p>We have revised the Methods section and reorganized it using the CHERRIES checklist. One section has been refocused on the development of tools as suggested by Reviewer 1.</p> <p>Also, we have organized the Introduction section into 3 small paragraphs, including the following one paragraph focused on the nuances of scaling-up definitions and the concept of scalability (Pages 3-4): “In knowledge translation (KT) or implementation science (both hereafter referred to as KT), the differences between “scaling up,” “scaling out,” “scaling deep,” “scaling,” and “spread” are nuanced.(14–16) Here, we define the process of “scaling up” or “scale up” as “deliberate efforts to increase the impact of successfully tested health innovations so as to benefit more people and to foster policy and program development on a lasting basis.”(6) To be successful, scaling up should follow a number of steps.(6,8,17–20) The scalability assessment is the preliminary step, or the evaluation of the “ability of a health innovation shown to be efficacious on a small scale and/or under controlled conditions to be expanded under real world conditions to reach a greater proportion of the eligible population, while retaining effectiveness.”(21) Scalability assessments are often overlooked,(14,22) with unfortunate results such as the replicating of harms at scale.(8,14,23) To be scalable, an</p>

	<p>innovation should meet certain minimum criteria responding to the essential components of scalability,(6,8,17,21,24,25) such as implementation fidelity.(26,27) In Canada, there are few systematic guides to assessing scalability and policy-makers face a predicament when choosing between innovations to scale up in primary care.(8,13)”</p>
<p>3. Results: Table 1, might be better for an Appendix, and create a Figure or Pictogram to highlight the themes, it might allow the reader to further appreciate the 'flavor' of the innovations.</p>	<p>Thanks for this comment. As suggested by Editors, we have moved Table 1 to Appendix 2 and included a summary table (Table 1) showing the types of innovations and their frequencies.</p>
<p>4. Figure 1. Appears clear, but consider additional detail on the project - such that the reader understands the cross-sectional, thematic/descriptive and calculations undertaken as components of the methodology.</p>	<p>Thank you for this comment. As suggested by the Editors, we have removed Figure 1. Readers can find the essential information about the innovations in the Table 1.</p>
<p>5. From the discussion: it currently reads in parts similar to a literature review, although important to highlight in existing work, your own results will benefit from further highlighting. Local Quebec healthcare context and history seems to be missing, a stronger for your findings will benefit from highlighting more in this area, as the readership have much to gain from this work, particularly they are not from Quebec, but can relate.</p>	<p>Thanks for this suggestion. As suggested, we have revised and restructured the Interpretation section to further highlight our own results. For example, we have included our main results in the 1st paragraph (Page 9):</p> <p>“Our study explored scalability assessments of 24 primary care innovations in the province of Quebec. Management innovations, mostly focused on patient navigation and interprofessional collaboration, were those that ranked highest for scalability assessment and thus appear to be most prepared for scale-up. While about half of all innovations addressed all scalability dimensions, implementation fidelity is a critical component that remained largely unaddressed...”</p> <p>In the 2nd paragraph, we have described the Quebec healthcare context as follows (Page 10):</p> <p>“...Quebec is one of the provinces that has made the most efforts to scale up primary care innovations province-wide.(34,47). In our study, it is therefore no surprise that management innovations predominated, and that they were those that integrated scalability assessments the most. Provincial priorities for healthcare system reform may</p>

	<p>have made producers more aware of the relevance of generating evidence and the degree of rigour required to qualify these types of innovations as scalable. Thus, our findings capture the evolution of family medicine in Quebec and could catalyze the effective scaling up of management innovations in primary care.”</p>
<p>6. Similarly, the overall work could be further enhanced, if the context of the local issues and how they relate the Canadian Patient Medical Home evolution and the experience of other provinces-jurisdictions, particularly if limited work has been done to assess.</p>	<p>Thanks for this suggestion. In the 2nd paragraph of the Interpretation section, we have added more information about the context of Quebec local issues. Indeed, since the original Canadian Patient Medical Home vision was launched in 2011, there are increasing calls for coordination and integration of health services to improve the work environments of primary care providers. Quebec has shown progress in adopting the team-based and patient-centred vision for primary care aligned with the Patient Medical Home. It appears to be one of the provinces to have made the most efforts to implement and scale up primary care innovations province-wide over the past years. Please see answer to your question #5 (above).</p> <p>Finally, in a future study we agree it will be important to relate our findings to work done in other provinces that are attempting to scale up primary care innovations.</p>
<p>7. The discussion, will benefit from further highlighting (in sections) the main findings and how it differs or adds to the current literature, it reads now like a literature review and local context is lost.</p>	<p>Thank you for this comment. We have reorganized the Interpretation section to include five main categories: 1) Main results of the study, 2) Comparison of findings with other related studies in the literature, 3) Future directions, 4) Limitations, and 5) Conclusion. Please see answer to Editors question #18 (above).</p>
<p>8. Management scalability is highlighted as a key mechanism for national uptake, this really needs an example of how it might applied to further draw attention to its importance.</p>	<p>Thank you for this suggestion. In our Results section, we now give an example of a management innovation that is ready for scale-up to national level, as follows (Page 9):</p>

	<p>“...The 10 high-ranking management innovations included eight in patient navigation, one in interprofessional collaboration, and one in prescription. Already implemented in communities in Ontario, Alberta, New Brunswick, and Saskatchewan, the latter is a collaborative electronic prescription service that protects patient data (<i>PrescribeIT</i>).(40,41) It had assessed the 16 scalability criteria and seemed ready for roll-out to additional provinces such as Quebec.”</p>
<p>9. The term 'fidelity' although common to this line of research topic, when used in the discussion, it may be very helpful to use a more common descriptive synonym to help the reader again relate to the work and its message.</p>	<p>We used the term “implementation fidelity” as it seems be the term most frequently used in KT (<u>Breitenstein, et al. Nurs Res. 2010; 59(3): 158–165</u>). We now briefly redefine fidelity in the Discussion, to remind the reader, as follows (Page 10):</p> <p>“...In spite of little attention paid to implementation fidelity among our participants, when an innovation is not implemented as was originally intended, it is less likely to be effective, potentially leading to faulty conclusions about its potential for scale up.(27,48,49) Achievement of high implementation fidelity is one of the best ways of replicating the success of the original research and is associated with better health outcomes.(50–53)...”</p>