Author’s response to reviews

Title: Essential items for reporting of scaling studies of health interventions (SUCCEED): protocol for a systematic review and Delphi process

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Version: 1 Date: 27 Nov 2019

Author’s response to reviews:

Prof. Marijn de Bruin,
Sr. Editor Systematic Reviews

RE: Submission of the revised version of the manuscript ID: SYSR-D-19-00416

Dear Professor Marijn de Bruin,

Thank you for your response to our paper “Essential items for reporting of scaling studies of health interventions (SUCCEED): protocol for a systematic review and Delphi process”, and for the thoughtful comments of the reviewers.

We appreciate your constructive feedback and we took great care to address your concerns. We
provided our detailed point-by-point responses to your comments in the submission system and attached two copies of the manuscript, one with track changes and one clean copy. We hope that this current version meets your approval.

As mentioned in the cover letter, the protocol of the systematic review has been submitted for registration in PROSPERO on August 20, 2019 and we will provide you with an update when it becomes available.

Please do not hesitate to contact us for any questions or further comments.

Your sincerely,
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BACKGROUND
Reviewer’s comment: For readability, please write out knowledge translation throughout, instead of abbreviating to KT
Authors’ response:
Thank you for pointing this out. We replaced KT by knowledge translation throughout the manuscript.

Reviewer’s comment: Line 226: please give examples of gaps identified in reference 8
Authors’ response:
Thank you for this suggestion. Some of the gaps identified in reference 8 were mentioned in lines 229-231 so we edited the section as follows:
“The lack of a specific reporting guideline for scaling studies and the identification of several gaps[10] have prompted the registration of the Standards for reporting trials assessing the impact of scaling up strategies of EBPs (SUCCEED) with EQUATOR.[3] These gaps include a) poor description of scaling strategies; b) lack of mention of the type of scaling strategy (e.g. vertical, horizontal); c) unclear distinction between the EBP and the strategies used to scale the EBP; d) inconsistent reporting (e.g. no information on assessing the scalability of the EBPs, lack of a clear measure of the scaling outcome). Our goal for proposing the new reporting guideline is to help address these gaps in reporting and in knowledge translation related to scaling of EBPs, including lack of assessment of potential harms; little information on sex and gender issues and absence of patients and public engagement in designing the scaling strategies.[3, 20]”p8-9

Reviewer’s comment: Line 237: explain why sex/gender is particularly important to take into account (more so than other factors) and how that might affect the guideline
Authors’ response:
Thank you for mentioning this important point. We provided the rationale for taking into account sex/gender and potential impacts on the guidelines as follow:
“In addition, the project will also contribute to the science of reporting guidelines as it will be among
the first to integrate sex and gender considerations. The rationale of taking into account sex and gender in the development of the reporting guideline stems from several elements: a) while their importance in the manifestation and management of health conditions and in health outcomes is now getting better established, their considerations are rarely integrated in research design and reporting guidelines;[22, 23] importance of appropriate use of the terms sex and gender based on documentation that they are often misused, misunderstood, confused or conflated in health research,[24] unlike other health determinants such as education, employment and income; fulfilment of the role of a reporting guideline that is to help reduce waste in health research by addressing the deficiency in the quality of its reporting and better inform practice, policy and programs. Moreover, the success of implementation and scaling is highly context-dependent, particularly for complex interventions. Thus, sex and gender considerations will be integrated in the literature review and in the development of the guideline (e.g. mention of appropriate use of sex and gender, extent to which both sexes were represented in the panel group and in each trial, presentation of disaggregated data). We will include a few items in our reporting guideline. For example, a) the stakeholders involved in the process of scaling have to be described according to their sex/gender; b) all outcomes have to be reported by sex/gender; c) data analyses have to be sex/gender-based.”

Reviewer’s comment: Line 219: it is useful for the general readership to more clearly position in the background a) the concept of scaling interventions amongst the other often-used terms in the domain of implementation science / knowledge translation; and b) the added value of this reporting guideline to already available guidelines. The potential added value of the work is currently insufficiently clear. From Table 2 it seems the domain includes implementation studies. Suggestions: for a) Include and explain something similar to Figure 1 from Pinnock et al., BMJ. 2017;356:i6795. b) give several concrete examples of key items on which the available reporting guidelines are inadequate for the reporting of scaling interventions.

Authors’ response:
“Background
The scaling of evidence-based practices (EBPs) can be considered as one of the ultimate phases of knowledge translation. Whereas ‘knowledge translation’ in general is concerned with the conversion of research into action; ‘scaling’ is how we optimize the magnitude, variety, equity, and sustainability of research informed actions. Among the diverse concepts used in knowledge translation and implementation science and defined elsewhere[1] such as adoption, adaptation, dissemination, spread, sustainability, scaling is “often used in the context of international, national and regional health programs”.[2]

Figure 1 depicts the place of scaling in the context of knowledge translation and the incremental contribution of SUCCEED reporting guideline. SUCCEED will be informed by elements addressed in existing reporting guidelines such as the clear distinction between the implementation strategies and the intervention being implemented in StaRI. Examples of items that will be specific to our reporting guideline include a) description of the scalability assessment of the EBP in the introduction; b) ethical and technical justification of the scaling; c) justification of the scaling unit; d) description of stakeholders; e) sex and gender considerations (objectives, measures of outcomes and effects, analyses, discussion”).

METHODS LITERATURE REVIEW
Reviewer’s comment: Suggest to describe the systematic literature review search/selection before extraction (i.e., including 2.1, which is now described before the search is explained). Table 1* does not appear very informative, as it includes some items (not further) explained and then a simple summary statistic. Consider excluding or make this more informative.
Authors’ response:
Thank you for the suggestion. There are two components in the literature review and 2.1 is different from the systematic review described at 2.2. to document the absence of reporting guideline for scaling studies and to identify relevant items. As such, we reorganized the section and excluded table 1.

“2. Literature review
This includes the documentation of the quality of reporting scaling interventions and identification of relevant items in SUCCEED.

2.1. Evidence of poor reporting
To inform the quality of reporting in scaling studies will conduct a secondary analysis of the articles included in the previous systematic review of our team [10]. A list of key elements of scaling up will be compiled using reference documents in scaling up (e.g. Milat et al., WHO-ExpandNet) and validated by scaling experts. We will report the proportion of that did not report these keys elements. The deficiencies identified will be considered for inclusion in SUCCEED.’p12

METHODS DELPHI
Reviewer’s comment: Please check that all the Delphi protocol adequately covers all all relevant items from CREDES https://www.equator-network.org/reporting-guidelines/credes/
Authors’ response:
“The method is widely used … It will be conducted and reporting using the guidance on Conducting and Reporting Delphi Studies[36].

Recruitment of experts
Panelists will be selected to capture the multiple perspectives of those that influence the design, implementation, evaluation and reporting of scaling of health interventions. A list of expert panelists will be compiled by the research team and include: authors of the articles included in the literature review; authors of relevant reporting guidelines; methodologists (experts in systematic review and reporting guideline development); content experts (healthcare professionals, and scaling up experts); patient and the public representatives; implementers, e.g. The Evidence Project; editors from journals that publish to implementation science and scaling-up and from varied countries including low- and middle-income countries, e.g. Implementation Science, Bull. World Health Organization, PloS One, Am J Trop Med Hyg; funders, e.g. FRQS, CIHR, NIH, EU, WHO, IDRC, Grand Challenges Canada, Melinda and Bill Gates, Charities that fund primary care research. An invitation will be sent to all the identified panelists and an active list and a backup list will be compiled based on their response and availability to participate in the e-Delphi and/or the face-to-face meeting. All the invitees will be asked to indicate their willingness to participate in the evaluation of the guideline and in a semi-structured interview. Prior to the start process, we will assess any conflict of interest among the members of the research team.

Procedure
We anticipated that three rounds of web-based Delphi consensus will be needed for an acceptable degree of agreement; if not a final round will be undertaken. Summaries of previous rounds will be compiled for subsequent rounds. We will use the REDCap[37] platform to administer the survey. The full questionnaire will be pre-tested prior to administration.”p16-17
Reviewer’s comment: The purpose and activities of the face to face meeting is currently to general. What are the objectives, methods, and anticipated outcomes (any further item selection and voting? Drafting definitions and Examples?).
Authors’ response:
Thank you. While referencing the ‘Guidance for Developers of Health Research Reporting Guidelines’, we revised and added text to the section.
“The objectives of the meeting are to a) produce the final list of items for SUCCEED reporting guideline; b) discuss strategy for producing the documents of the reporting guideline and their dissemination; c) distribute the post-meeting tasks such as draft of the guideline documents, obtention of endorsement, website development. [13]. Steps to produce the final list of items are: i) present the results of Delphi exercise (name, rationale and score of each item); ii) discuss the rationale and relevance for including the items in the checklist; iii) vote on non-consensual items. We will invite around 20 expert panelists 1.5 to 2 days meeting. We will record all the sessions and use note-taking services to report the discussions. At the end of the meeting, the final list of items for SUCCEED reporting guideline will be defined.”p18-19

METHODS GUIDELINE VALIDATION
Reviewer’s comment: 429 this sentence confused me: if participants use SUCCEED to code how they had previously reported their study (basically, a data extraction exercise), how can they evaluate the checklist as it is designed for prospective reporting? It seems more logical to ask them to report their studies again but now using SUCCEED and then evaluate it.
Authors’ response:
We agreed and rewrote the whole section 3. to make it clearer.
“Study design
To pilot test the SUCCEED checklist, we will use cross-sectional and qualitative approaches.
Participants
All the authors of the identified studies at 2.1 and additional studies identified by updating the searches will be invited (less than 50 studies are expected).

Data collection
We will collect general characteristics of the participants (e.g. country, sex, field of expertise). For the quantitative component, participants will be asked to use the SUCCEED checklist to report their study and provide comments on the items. A brief semi-structured interview of 15-30 minutes on the form (layout, wording and structure) and barriers and facilitators of using the guideline will be conducted with each participant. The interviews will be conducted in person, by telephone or video conference (e.g. gotowebinar), recorded and transcribed verbatim.

Analyses
Descriptive analyses will be conducted on quantitative data: number and percentages of items reported; interview data and comments will be analyzed using constant comparative techniques and thematically synthetized by one researcher and validated by the other members of the research team. The results will inform how the guideline improve the quality of reporting and provide information and examples to enrich the elaboration of the statement of the SUCCEED and the accompanied explanatory paper.”p19-20

Reviewer’s comment: Analyses: this lacks detail, it is unclear how what type of information will be used to answer which research questions. Please advance detail these methods further so that it includes a level of detail comparable to the other studies (review, Delphi).

Authors’ response:
Thank you. We provided more details while rewriting the section 3. Please see above.