Author’s response to reviews

Title: Framework, principles and recommendations for utilising participatory methodologies in the co-creation and evaluation of public health interventions.

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Author’s response to reviews:

Dear Editor,

Thank you very much for the opportunity to submit a revision of our manuscript. We would be grateful if you could thank the reviewers on our behalf for their cognisant and valuable comments. Below, please find the comments from the reviewers and underneath it, the appropriate changes that have been made to the manuscript. To make this a much more simple process, all references to line numbers and highlighted sections have been uploaded in the updated manuscript.

If you have any more questions please feel free to contact us.

Kind regards.

The authorship team
Reviewer reports:

Reviewer #1 noted his/her interest in the manuscript, however felt that the manuscript was very length in its current format and expressed difficulties concentrating until the end.

Our response: We thank the reviewer for this comment. The authorship team agree that this is a very detailed manuscript, however believe this is necessary given the dearth of literature in the area. Our hope in time is that, using these principles and recommendations as a starting point, they may be further refined and synthesised. We view this manuscript as an overarching foundation upon which further work in the field can be built. However, we would like to acknowledge that the manuscript has been revised to remove any redundant information.

Reviewer #2 described the importance of this paper in the field, however voiced concerns regarding the robustness of the methodology used from which to derive the principles described within.

Our response: We thank the reviewer for his/her understanding of the importance of this work.

Reviewer 2’s comments have highlighted that our methodology was not described with enough clarity and the term “case study” may have, in this circumstance, caused confusion to the readership. Here, case studies are one element of the recursive learning method described within. As such, we have altered the manuscript to highlight the fact that we have used a robust and recognised methodology that is described in detail in the referenced literature. See lines 169-174: “The principles and recommendations described here emerged following multiple discussions of the material and iterative circulation and redrafting of this manuscript. This method has been used previously to develop principles in community participatory intervention implementation [34] and more detailed information regarding recursive learning cycles is available elsewhere [25].”

Reviewer #3 noted his/her interest in the manuscript and provided specific comments for improvement in different sections of the manuscript, each of which have been addressed directly:

* Line 84 you introduce end-users and non-academic stakeholders, later in line 111 you introduce three groups of actors. This is quite confusing. To set the stage relevant groups should be introduced at the beginning.
Our response: “Actors” is the term given to stakeholders who engage with the co-creation process. However, we agree that without definition, this may be confusing to the readership. To clarify, the manuscript has been altered in lines 111-113: “In Table 2 the potential groups of actors (i.e. the stakeholder groups who engage in the process) are illustrated in an example case of co-creating a public health intervention for school-children.”

* Line 101 you write ‘Traditionally, public health intervention….’ Much publications of participatory development of public health intervention come from developing countries, a well known researcher and advocate for participatory research is M. Minkler. You might reconsider this quite statement.

Our response: The authorship team has indeed read the work of M. Minkler et al. and have cited their work within this manuscript (reference 55). We agree that there is a building momentum for participatory development on public health intervention, which is why we are developing these recommendations. However, we acknowledge that it is still very common to develop public health interventions using a top-down approach as this begins the rationale for co-creation, as stated in lines 103-107: “However these traditional public health interventions do not involve end-users in their development. By comparison, utilising end-users in the co-creation of public health interventions is thought to increase adherence and effectiveness due to empowering end-users [20] to develop outcomes tailored to their circumstances [21].”

* Line 106, 127 and several other lines you write about effectiveness but you do not define it. What do you mean by it: the process of co-creation, the impact of co-creation on the intervention itself, increased empowerment of end-users or better health outcomes? Please clarify.

Our response: Principle 5b explains effectiveness in detail with regards to testing a co-created intervention, the outcome of interest being that which is decided within the co-creation workshops. Additionally, the authorship team describes effectiveness with regards to co-created interventions in lines 425-427, however, we agree that it may be useful to provide this earlier within the manuscript. As such, lines 107-110 have been altered: “Indeed, while few studies have yet to investigate the effectiveness of co-created interventions (i.e. do they result in positive change of the targeted public health problem), some report that these are more effective than one size fits all programmes [22] and lead to increased patient satisfaction [23] and a higher quality of service provision [24].”
* Line 114 Table 2. This table describes three groups of actors, and a fourth group. The actors in the fourth group are the same of previous groups. This reads confusing.

Our response: the authors have removed the “co-creators” group from the table for clarity.

* Line 141, you write about the evaluation of public health interventions. What is the difference with effectiveness? Or do you mean the same?

Our response: the authorship team refers the reviewer to both the abstract and plain English summary of this manuscript whereby evaluation, as a key principle, is discussed as assessing the validity of the co-created outcome and the effectiveness of the developed intervention.

* You used an iterative reflective process but do not refer to an author.

Our response: We have altered the manuscript and signposted readers to an author of interest, please view lines 171-174: “This method has been used previously to develop principles in community participatory intervention implementation [34] and more detailed information regarding recursive learning cycles is available elsewhere [25].”

* The method of iterative reflection is little worked out. Please add a description of what methods you used in all phases of reflection.

Our response: Reviewer 2 responded with the same query, to which we replied: Reviewer 2’s comments have highlighted that our methodology was not described with enough clarity and the term “case study” may have, in this circumstance, caused confusion to the readership. Here, case studies are one element of the recursive learning method described within. As such, we have altered the manuscript to highlight the fact that we have used a robust and recognised methodology that is described in detail in the referenced literature. See lines 169-174: “The principles and recommendations described here emerged following multiple discussions of the material and iterative circulation and redrafting of this manuscript. This method has been used previously to develop principles in community participatory intervention implementation [34] and more detailed information regarding recursive learning cycles is available elsewhere [25].”

* From line 182 on, in the phase Planning I miss the way all stakeholder groups are involved. Please describe. Now it reads as if the researchers determine the aim and sampling. I miss a substantial first activity of co-creation that of agenda-setting - where it all starts.
Our response: The “agenda-setting” activity highlighted above is encapsulated within our principle of “Framing the aim of the study”, whereby the purpose of the co-creation and the tasks within are collectively defined by the group.

Line 184 articulates that it is the academic researchers that initiate the planning process of co-creation. This is due to the fact that this paper is specifically focusing on the development of public health interventions, as opposed to a community-engagement programme that may result spontaneously in a bottom-up way, such as in a social enterprise. The authorship team has been mindful of the power-sharing implications that this may cause during the co-creation process and have been careful to articulate this within the manuscript, for example lines 307-9: “End-user co-creators also have the right to be trusted by the academic researchers and require power-sharing governance arrangements in order to exercise empowered participation [28].” It is also important to note that the manuscript highlights that, even though this process may be initiated by academics, non-academic stakeholders are heavily involved in the framing of the study (lines 213-217): “Therefore, when framing the aim of the study, it is important to express the specific objective of the process, i.e. the WHAT. However the non-academic co-creators will influence what the intervention actually looks like, i.e. the HOW. When addressing a complex problem, end-users and other stakeholders may collaborate with academic researchers to define the objective.”

* Line 256, 258, 260 and 265 you write about representativeness but you do not specify what do you mean by it. There are quite different notions about representativeness in the literature. Do you define it as epidemiological (descriptive) representation, or substantive (those who have a stake) or symbolic (democratic) representation for example.

Our response: Interestingly, the authorship team had included a definition of this in a previous version of the manuscript but had removed it due to word count. This has now been re-incorporated on lines 229-232: “A representative sample from the end-user group should be recruited as co-creators during the development process. This may include sampling across age, gender, severity of condition (if appropriate) and socio-economic status to create a heterogeneous group with diverse experiences.”

* Line 207 you explain sample size for focus group discussions, however, interviews are often used in PAR, please also add information about sample size concerning interviews.

Our response: whilst the reviewer makes a valid point, the authorship team felt that it was not appropriate to discuss interview sample sizes and this contradicts the essence of co-creation, which should be done as a group (eg, see Janamian et al. 2016 Med J Aust.
* Line 300, I wonder why collectively defining the public health problems are in this step and not in the first. Isn't this late because the aims are already determined by the researchers. Please explain.

Our response: The authorship team has written in the planning section, lines 216-217, that: “When addressing a complex problem, end-users and other stakeholders may collaborate with academic researchers to define the objective.” This is simply re-affirmed in the ownership step as a strategy to increase the likelihood of its manifestation. We have clarified this in lines 303-305: “The co-creators have the right to the knowledge required in order to exercise meaningful participation [54], such as collectively defining the specific aims necessary to address in order to achieve the overall objective [55].”

* Line 335-339, as it is written now one gets the impression here that the end-users are the needy and not-haves and the academics as those who know and are the haves. This might lead to misinterpretation. You might rephrase this.

Our response: this has now been altered, please see lines 339-343: “When developing a new public health intervention, two essential pieces of information are required: 1) the preferences and experience of the end-user (which initially, the end-users (and in some cases, other non-academic stakeholders) have the most knowledge of) and 2) potentially effective strategies (which initially, the academic researchers may have the most knowledge of) [58].”

* Line 349 - 358. You write about up-skill non-academic. I am wondering if there does not happen any up-skill of academics. Please add what academics can learn.

Our response: lines 339-346 show that academics learn about the preferences of non-academic co-creators when co-creating an intervention: “When developing a new public health intervention, two essential pieces of information are required: 1) the preferences and experience of the end-user (which initially, the end-users (and in some cases, other non-academic stakeholders) have the most knowledge of) and 2) potentially effective strategies (which initially, the academic researchers have the most knowledge of) [58]. As co-creation should engage academic and non-academic stakeholders on an even distribution of power and knowledge, it is necessary for all co-creators to share their knowledge to create equality.”

However, we agree with the reviewer that more explicit mention of this will aid the readership and have adjusted lines 362-364 accordingly: “It is important to highlight that mutual learning will occur across stakeholders and academic co-creators can expect to be up-skilled in numerous areas, including the needs and preferences of end-users.”
* Line 376-385 reads like structuring a meeting. Might fit better to the subheading Procedural method - Structure.

Our response: whilst we agree that this could indeed fit under the proposed section, the purpose of the examples provided is to give practical instances of iteration manifesting. This is a non-exhaustive list of examples. Our fear is that if we move it under the structure section, form and function will be confused.

* Line 60 in table 5 What do you mean by 'may increase generalisibility of findings' As it is written now it somehow reads more like commitment for implementation?

Our response: the wider the stakeholder interaction with the co-creation process, the more likely that the outcome developed can be utilised by that group. This dovetails well with the changes made in lines 229-232: “This may include sampling across age, gender, severity of condition (if appropriate) and socio-economic status to create a heterogeneous group with diverse experiences.”

* Line 421-426. Here you describe the evaluation of the co-creation process and the effectiveness of intervention. However, what about a process evaluation of the intervention itself like proportion of reach, components of intervention delivered, recruitment, barriers and facilitators to implementation etc. You also might include some information in principle 5b about this.

Our response: The authorship team concurs and has adapted lines 478-481 to reflect the above recommendations: “A process evaluation of the intervention may also be conducted, with key components including fidelity, proportion of reach, facilitators and barriers to implementation being areas of interest to explore [89].”

* Line 470, her a nationwide RCT is recommended. Somehow, I am not sure if one can get results where there might be many (unidentified) interfering variable. In public health intervention research quasi-experimental design might be an option.

Our response: the authorship team does not dispute that quasi-experimental design may be an option – RCT is provided as an example of one way to test it. It is felt that academic researchers involved in the co-creation process will have the expertise to judge which trial design will be best for the developed intervention and that providing too many examples of different trial designs could begin to convolute the manuscript. The crucial point is to embed the co-creation within an effectiveness evaluation trial, a point which we agree with above and have highlighted
in the text, lines 475-476: “The design of this trial will depend on the research question, population and context.”

* Line 473-477 reporting refers only to scientific publishing. How are results reported back to stakeholders, the end-users and the public? Somehow, it seems that they are not involved here anymore. And, I wonder why are end-users not involved as co-authors in this manuscript. You might want to reflect in the discussion about this. They are not even mentioned in the acknowledgements. You might even take it a step further and think about advising academics adding a paragraph in the method section and discussion about end-user and stakeholder participation. In this paragraph you also mention reporting guidelines. There is a reference for best practice of reporting participatory action research at the Equator website see Smith L, Rosenzweig L, Schmidt M. Best practices in the reporting of participatory action research: Embracing both the forest and the trees. The Counselling Psychologist. 2010;38(8):1115-1138. There is also a guideline for reporting patient and public involvement. It might be worth including them in this manuscript. Staniszewska S, Simera I, Seers K, Mockford C, Goodlad S, Altman DG, Moher D, Barber R, Denegri S, Entwistle A, Littlejohns P, Morris C, Suleman R. GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research. BMJ. 2017;358:j3453 or Research Involvement and Engagement. 2017;3:13.

Response: in lines 607-608 the research groups are specifically acknowledged: “We would like to acknowledge all members of the GrandStand, Safe Step and Teenage Girls on the Move research groups for their continued involvement and enthusiasm.” Additionally, the plain English summary states that this was written from collaboration with end users and the authorship team has written to the editors separately, as there was no option when submitting the manuscript to include the members from each research group in the authorship list. This will be addressed should our manuscript progress.

The authorship team acknowledge that dissemination of findings to the public is indeed an important point and the reporting checklist (Table 6) has been updated to specifically ask respondents to report on: “How are results reported back to stakeholders and the public?”, with examples of written reports and presenting at national conferences being provided.

Discussion

* Line 559 you mention the limitation of including only two stakeholder groups. However, then it might strengthen the introduction if you provide a full description of stakeholder groups there. A publication that might help is Preskill H, Jones N. A practical guide for

Our response: The authorship team recognises the value of the above paper and has incorporated it into the sampling section. Please view lines 262-274: “Whilst end-user co-creators should always be representative of the end-user population, the representation of relevant stakeholder groups is dynamic and may involve recruiting additional stakeholders throughout the process, known as opportunistic sampling [40]. Convenience sampling is commonly adopted when utilising participatory methodologies [41] and is valuable to ensure the recruited co-creators are committed and will actively engage in the process. To ensure a representative sample of end-user and relevant stakeholder co-creators are recruited, purposeful sampling may be advantageous [42]. This may include stratified sampling across characteristics of interest to create a heterogeneous group with diverse experiences. Finding end-users who cover the spectrum of perspectives, including typical and extreme cases, is known as maximum variation sampling [43]. Prioritising potential co-creators based upon their motivations for participation has also been cited previously as factors to consider when sampling [44].”

* It might strengthen the manuscript if you add some information what is new about this manuscript when positioning to other literature.

Our response: the novel elements of this manuscript are described in lines 130-137: “Crucial concepts required in intervention research that PHR does not currently consider include: 1) developing a generalised protocol to ensure that the process of co-creating interventions is systematic and reproducible; 2) the formal testing of the effectiveness of co-created, locally developed interventions; 3) the creation of conceptual and pragmatic principles for scaling up locally developed interventions to address public health problems at a population level. Nevertheless, this gap can be addressed by merging the key elements of PHR within a classical intervention research paradigm.”

Reviewer #4 felt the subject of co-creation was important, however queried why only two groups of actors were used within the described case studies.

Our response: lines 570-574 have been updated: “As a result, there may be other principles beneficial to implement in the co-creation process, particularly when engaging multiple groups of actors, which have not been cited here. However, given the dearth of information regarding best practice when co-creating public health interventions, utilising two actor groups was agreed as a pragmatic first step on which to derive key learning.”
At line 468 reference is made to evaluation of co-created interventions by using RCTs. Would this not be an appropriate situation to consider utilising pragmatic trials instead of (or at least as well as) RCTs which usually don't include/reflect the real world population (due to their strict inclusion and exclusion criteria). Nor do they usually test how the interventions will actually work in a real life situation within a health care system etc. Pragmatic trials will also assist to gather a real world evidence base which is relevant in evaluating effectiveness and the effect of treatment in routine clinical practice. Pragmatic trials could test the co-created interventions in everyday situations and enable randomization at the point of care.

Our response: the authorship team does not dispute that different trial designs may be an option – RCT is provided as an example of one way to test it. It is felt that academic researchers involved in the co-creation process will have the expertise to judge which trial design will be best for the developed intervention and that providing too many examples of different trial designs could begin to convolute the manuscript. The crucial point is to embed the co-creation within an effectiveness evaluation trial, a point which we agree with above and have highlighted in the text, lines 475-476: “The design of this trial will depend on the research question, population and context.”