Author's response to reviews

Title: RAMESES Publication standards: realist syntheses

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Author's response to reviews: see over
Dear Sabina,

Re: MS: 2137735952812938 – RAMESES Publication standards: realist synthesis

Thank you for providing us with the peer-reviewers’ comments on our manuscript. We have discussed their comments and provided a point-by-point response to the concerns raised.

I hope that our responses and revisions to our manuscript are satisfactory. All the texts we have amended in our revised manuscript are clearly indicated. Please feel free to contact me if any further changes are needed.

Yours Sincerely

Geoff

On behalf of the authors

Reviewer 1
Point-by-point response and action(s) taken

HAVE THE GUIDELINES BEEN PRESENTED AND EXPLAINED IN A WAY THAT THE COMMUNITY CAN FULLY UNDERSTAND AND IMPLEMENT THESE?

I very much welcome these guidelines. Realist synthesis is an important form of review and there is not always clarity about its methods or standards of reporting. I have come across many cases of people stating that they were undertaking realist syntheses which on inspection did not seem to me to be following realist methods.

Although these guidelines are excellent in many ways I believe that their benefit could be significantly increased if they were further refined before publication. I make some suggestions for this below. These suggestions are based on the draft versions made available to me in October 2012. I have never undertaken a realist synthesis and I apologize for any of my comments that are based on errors in my understanding of the issues.

(i) Lack of context about the realist synthesis compared to other methods
a) Realist synthesis is one of a very many approaches to reviewing literature. The opening of the introduction to the abstract positions realist synthesis in opposition to Cochrane reviews: ‘There is growing interest in realist synthesis as an alternative to (or to extend and supplement) conventional Cochrane-style reviews.’ (page 2). This could be questioned on several grounds: Cochrane reviews are well known but are probably not the most common form of review; some Cochrane reviews do include theory driven approaches; and surely guidelines for realist reviews should contextualize themselves against other
approaches that emphasize theory driven or mixed methods approaches rather than in opposition to Cochrane.

1. Response and action taken
The reviewer has raised an important point in his comment about the context within with realist synthesis exists. We had provided the contrast with Cochrane reviews as a simple polarity, rather than to deny the existence of other review methods. However, we fully accept that there are many other review methods that also deserve mention. We have thus amended the relevant section of text on page 4.

One counter-argument is that the discussion as to the relative merits of the various review methods is beyond the scope and purpose of this manuscript and so we hope that we will be forgiven for not engaging in such a debate. We have however included clear direction for the reader as to where to find such a debate (on page 4).

b) Much of the text on ‘What is realist synthesis’ could apply to other methods of evaluation research and reviews. For example:
Expressions such as “What works for whom under what circumstances, how and why?” (page 4 and 13) and ‘Realist inquiry seeks to unpack the context-mechanism-outcome relationship’ (page 4) are often used in discussing realist synthesis but these ambitions are not limited only to realist synthesis reviewers and may be part of the reason that some people consider they are undertaking realist reviews when they are not.
Similarly, the ‘key tenets’ of realist philosophy (page 5) state that our understanding of social reality is mediated through our brains, that macro and meso and micro levels contexts interact, and that we hypothesize mechanisms to understand how contexts effect outcomes. These are also tenets shared by many other approaches to evaluation research.
The ‘potential for insights that go beyond the narrowly experimental paradigm of the randomised controlled trial’ (page 5) is also shared by many evaluating complex interventions.

2. Response and action taken
We agree with the reviewer that there are many similarities between realist synthesis and other review methods. We had provided the section in question to provide a potted history of realist synthesis is – as an attempt to orientate readers.
We do not, however, believe that the purpose of this manuscript is to provide a detailed description and justification of realist synthesis. This is a vast undertaking that we believe is beyond the scope of this manuscript and other resources already exist that have addressed these issues. We have covered this question in previous papers and publications and referenced selected publications on this topic in the manuscript (page 6).
c) In addition, some of the text could also apply to other forms of review. For example:
‘.. review may generate a large number of avenues that might be explored and explained, and because resources and timescale are invariably finite, the expectation is that the review must be contained by progressively focusing both its breadth (how wide an area?) and depth (how much detail?). This important process may involve discussion and negotiation with (for example) content experts, funders and/or users.’ (page 13)
And:
‘Realist reviews do not exclude sources solely on the basis of their study design’ (page 16)
Recent references which discuss the differences between approaches to systematic reviews include papers by myself and by Sandelowski:

3. Response
We agree with the reviewer that some of the text in the list of items might also apply to other review methods. This is not unexpected, but a discussion of methods is (as we have mentioned above) not the purpose of our manuscript and a robust discussion of this theme would make our manuscript significantly longer. We have developed publication guidance based on the input of a Delphi panel. Our panel was drawn from experts in the field of evidence synthesis. It is thus likely that when they fed in their expertise, there would be a degree of overlap with what has already been published on methodological issues in evidence synthesis.

We agree there is much more that needs to be debated and developed in the field of evidence synthesis and we ask the editor and reviewer to note that a further publication on this theme is in preparation by our team.

(ii) Lack of clarity about the distinctive features of the realist synthesis method
The authors of the guidelines could quite reasonably argue that they need to specify what realist reviews do even if other reviews do the same. The difficulty is that the guidelines do not aim to provide a detailed account of the method, so the reader may not be clear about the defining characteristics of a realist review compared to other forms of theory driven evaluation reviews. Some of this specificity of realist reviews is revealed as you read through the progressive sections of the guidelines but I believe that it would be more helpful if there were
clearer statements about the specific methods of realist synthesis at the start of the guidelines. I understand that the philosophical approach is key and drives everything else, but without clear statements about the interpretative method, it is more likely that people will misunderstand the approach. My understanding is that a realist review undertakes an iterative interpretative synthesis of theories or mechanisms followed by empirical testing of those theories. The same could be said of other theory-driven approaches to reviewing. What seems to be distinctive (due to the particular orientation of realist methods) is that the empirical testing stage is also iterative (in contrast to a priori empirical testing of other approaches). This iterative approach in the second stage of a review does become evident as you read through the guidelines (e.g. page 13 on the evolving questions, page 16 on iterative searching, page 19 on selection and appraisal and synthesis,) though some sections give a bit of a mixed message – see section (iii) below). I believe the guidelines would be much clearer if this fundamental difference about iteration in empirical testing was spelt out at the very start of the guidelines. If however I am wrong about the approach to empirical testing, then maybe this whole issue could be made clearer in the guidelines.

4. Response
We would agree with the reviewer that any review method needs to be clear about what its methods are. However, the purpose of this manuscript is to provide publication guidance on realist syntheses and not to act as a methodological ‘how to’ manual. A further paper on the ‘how’ of realist review is in preparation by our team. We have modeled this publication standards paper on CONSORT, PRISMA and other statements in this genre.

We appreciate his comments that some researchers may be confused as to how they might undertake a realist review if they only read these publication guidelines. However it does not follow that we should cover all aspects of the topic in this paper. We would hope that any researcher seeking to undertake a realist synthesis would not just read publication standards and then expect to be able to undertake a review. In the same vein, would it be reasonable to expect the PRISMA publication standards to teach a researcher to undertake a systematic review? Researchers should surely first direct their attention to the Cochrane Handbook?

(iii) Text might be interpreted as inconsistent or accurate in terms of describing the method

a) Qualitative or quantitative methods?
The example for Item 2 of the Abstract (page 11) states: ‘Realist review - a qualitative systematic review method whose goal is ..’. Is realist synthesis a qualitative method? It seems to me that it uses quantitative
approaches in empirical testing and so uses both quantitative and qualitative methods. This seems to be confirmed by later text in the same example with empirical statements of likelihood: ‘Learners were more likely to accept a course if ….‘ and ‘Interactivity led to effective learning only if…’. I would suggest not using the terms quantitative and qualitative as they create a very confusing and imprecise distinction (see Gough et al (20112) and Sandelowski et al, (2012).

5. Response and action taken
Thank you for pointing out these inconsistencies. We have selected a different example for Item 2 (pages 12-13) to avoid any confusion.

b) Are the screening examples iterative?
The example for Item 9 on the Selection and appraisal of documents (page 17) reads like the application of a priori inclusion criteria tool for screening rather than an iterative process. Similarly, Figure 1 of the flow chart of search (Item 12 on page 22, 35 and 40) looks similar to those using a priori methods. This might unintentionally give the impression that this was the approach to searching, rather than the more iterative strategies of realist reviews.

6. Response and action taken
Thank you for pointing out the issue with the example for item 9. In our attempts to try to keep the examples as brief as possible, we have not been able to include all the relevant details that might be found within the manuscript from which we had drawn the example. We make clear in our paper (page 10 – first paragraph) that those seeking to fully understand our examples must go to the original sources and read the full paper. Note however, when we reviewed the methods section of this example from Jackson et al. it was clear that they did not apply a priori inclusion criteria tool for screening (see ‘Search process’ page 963 reference 26 in our manuscript).

The reviewer is correct to point out the inconsistency within Figure 1 in our original manuscript. We have replaced this with a different figure in our revised manuscript.

(iv) Other unclear text
a) Repetition of rational for realist reviews
The examples for Item 3 rationale for review (page 12) seem to focus on why a realist review was used rather than the need for a review of some sort. This is a bit repetitive as it is also dealt with in example for Item 6 on the rationale for using realist synthesis (page 14).

7. Response and action taken
Thank you for pointing this out. We have addressed this issue by providing a different example.

b) Clarity about scoping the literature
The example for Item 7 on scoping the literature (page 15) states ‘we started out by conducting a rapid review’ but this term is not explained – what type of rapid review is it?. This followed by the explanation which starts ‘This step ..’ without a very clear explanation about what this step is or involves.

8. Response
As we have stated in response number 6 above, we have tried to keep the examples brief. This example is from an open access journal and so is accessible free of charge.

c) Technical terms
Does the word ‘demi-regularity add anything in ‘recurrent patterns (or demi-regularities) of outcomes ‘ (page 21)?

9. Response and action taken
Thank you for pointing out this error, we have moved the parenthesis that contains the term demi-regularity so that we now hope it more accurately explains what we mean. Recurrent patterns of outcomes are demi-regularities.

(v) Possible implicit criticisms of other methods
A few words in the text might be interpreted as a critique of other approaches or positioning of realist synthesis as the only review method examining complexity. This might be over sensitive on my part but little would be lost by removing words such as ‘merely’ from ‘Realist review is not a technical process – i.e. merely following a set protocol’ (page 18). Research that uses a priori methods undertakes conceptual work in advance and after the study rather than during (as is done in iterative methods such as realist reviews) and their methods are not ‘merely’.

10. Response and action taken
We agree and have removed the offending word (page 18).

(vi) Reporting of detail of methods used
The draft guidelines clearly state the importance of transparency in reporting and that this may be problematic with publication in journals with word limits (page 30).

I believe that it would also be useful to even more explicitly warn against the dangers of a lack of detail existing in the methods of a specific review. A realist review can be a very large undertaking involving an interpretative review of the theories/mechanisms being examined and then a number of sub-reviews checking the empirical evidence supporting different aspects of those mechanisms. It would not be surprising if a review team found that it did not have the resources to examine all the details of this process yet submit a paper for publication that seemingly covered all of these areas. I have come across such realist reviews that were fascinating and well executed in many ways, but which on examination had very little detail of the empirical testing stage of the many sub areas of the review.

11. Response and action
We agree that a more explicit warning was needed and we have done this briefly on page 31.

HOW WELL HAVE REPORTING STANDARDS BEEN ADHERED TO?
They have not been published so we do not yet know but I have witnessed much confusion over what a realist review is and so these guidelines would be very helpful.

12. Response
Thank you for your comment of support. We too hope that this guidance will help rather than hinder.

ARE ALL CLAIMS AND STATEMENTS FULLY SUPPORTED WITH EITHER NEW DATA OR REFERENCES TO PREVIOUS PUBLICATIONS?
I believe so – but see comments under the first section above.

13. Response
We hope that any concerns have now been addressed.

HOW USEFUL WILL THESE GUIDELINES BE TO AUTHORS AND EDITORS?
They will be very useful. They will be even more useful when accompanied by the planned ‘quality standards and training materials’ (page 9). It might have been preferable if the quality standards had been published with or before the reporting guidelines.

14. Response
Thank you for your comment of support. We too agree that quality standards and training materials are needed and are ‘in production’ as part of the RAMESES project.

HAVE SIMILAR GUIDELINES BEEN PUBLISHED PREVIOUSLY?
Not that I am aware.

15. Response
We would agree that there are no similar guidelines at present.

DO THE AUTHORS HAVE THE REQUIRED EXPERTISE AND KNOWLEDGE TO DESIGN THESE GUIDELINES?
Yes, they are leaders in the field of realist synthesis methods.

16. Response
Thank you.

Reviewer 2
Point-by-point response and action(s) taken

This paper presents a realist synthesis reporting guideline. It should be of interest to a wide audience.
I used the following guidance for assessing these reporting guidelines: Moher D, Schulz KF, Simera I, Altman DG. Guidance for developers of health research reporting guidelines. PLoS Med. 2010 Feb 16;7(2):e1000217. Steps 1 and 2 only have been partly followed, or at least I can’t see the relevant information in the manuscript. Some of the comments below reflect this further.

17. Response
In producing our publication guidelines we had examined the paper mentioned by the reviewer. We agree that we have not described every detail of the entire guideline production process since these were provided in a separate open-access methods paper, which is clearly referenced on page 8 (reference 20) of our manuscript.

However, we have undertaken the necessary steps as described in Moher et al.’s paper. For example, Point 3 – we sought funding from the UK’s HS&DR programme. For points 4 to 9, we undertook an online Delphi process and would be happy to share any ‘raw’ data we have with the editors or reviewers if
evidence is required. Point 10 relates to developing an E&E document, which we have undertaken and is now being presented to in the form of this manuscript. Point 11 relates to a publication strategy, which we are now pursuing with the help of BMC Medicine, the Journal of Advanced Nursing and CMAJ.

A range of guidelines for reporting of qualitative research exist, see http://www.equator-network.org/resource-centre/library-of-health-research-reporting/reporting-guidelines/. It would be useful if the authors explain how their publication standard fits in. It would also be useful to make clear whether the authors searched for any existing reporting standards and whether any were found. If none exist, please state so. I am a bit surprised that the Equator network is not mentioned at all.

18. Response and action
Realist reviews includes data from both qualitative, quantitative and mixed-method studies and so any existing qualitative review method reporting standards will not fully apply to realist methods. On page 9 of our revised manuscript we have referred to the Equator network’s website. We have indicated that at present, within the resources available within this organization, none are specific to realist syntheses. Please see: http://www.equator-network.org/resource-centre/library-of-health-research-reporting/reporting-guidelines/systematic-reviews-and-meta-analysis/ and http://www.equator-network.org/resource-centre/library-of-health-research-reporting/reporting-guidelines/qualitative-research/

We agree with the reviewer that the Equator network is an important organization of reporting guidelines and will be approaching them to ask if they would kindly include our reporting standards in their database once it has been published.

I feel the in the first parts of the paper the authors mix up reporting guidance and quality assessment checklists, for example in the introduction of the Abstract: “However, the quality of realist syntheses can be difficult to assess. This publication standard was developed as part of the RAMESES (Realist And MEta-narrative Evidence Syntheses: Evolving Standards) Project. And in the section “Why are publication standards needed?” the authors state that “Publication standards have two main (and overlapping) purposes: they can help researchers design and undertake more robust studies; and they can also help reviewers and potential users to assess the quality and rigour of research outputs.” I suggest the authors should make very clear what the purpose of this guidance is: how to report realist synthesis is not the same as a quality
assessment tool of realist syntheses. Having looked at the proposed reporting standards I conclude that these are certainly not suitable as a quality assessment (risk of bias) tool. In the section “Scope of the publication standards” and also in the “Discussion” this seems to be much better represented.

19. Response and action
Thank you for pointing out this inconsistency in our manuscript. We agree that we need to be clearer as to the purpose of our reporting guidelines and have changed the relevant texts in our manuscript (pages 2 and 7).

The guidance items themselves and their supporting texts read well, and they largely make good sense. I have refrained from giving my opinion about these items, given that they come from a Delphi process, I think they should not be changed because this peer reviewer has different opinions. However, it would have been good if the authors gave an indication which items of PRISMA do apply and which ones don’t.

20. Response and action
Because realist reviews are very different in many respects to the types of reviews that are covered by the PRISMA statement, we felt that we needed to produce a distinctive set of reporting guidelines. This does not mean there is no overlap between the two guidelines. We hope that when reviewers undertake a realist synthesis, they would use the tailor-made RAMESES publication standards. However for sake for clarity, on pages 10 to 11 of our manuscript, we have briefly highlighted which PRISMA items are comparable to the RAMESES guidelines and which are not applicable or need to be modified.

Questions by the journal to be answered by the peer reviewer:
- Have the guidelines been presented and explained in a way that the community can fully understand and implement these?
  I think they are clearly presented.
- How well have reporting standards been adhered to?
  Not sure what is meant here; the guidance by Moher et al mentioned above has only been partly followed.

21. Response
Please see Response 17 above.

- Are all claims and statements fully supported with either new data or references to previous publications?
This is a weak point of this manuscript. The explanations of the items have not been referenced, references would give a further scientific justification, now it is purely the Delphi panel that we have to put our trust in.

22. Response
The explanation of the items has been derived from a series of sources that include; the Delphi panel, the literature review we undertook, our online email list (www.jiscmail.ac.uk/RAMESES), existing texts on methodology and the collective experience of the RAMESES project team. With regards to the Delphi panel data, we are happy to share this data (anonymised) with the editors and reviewers if this is deemed necessary. We respectfully point out that the outputs of a robustly conducted Delphi panel are ‘data’.

Realist synthesis is a relatively new review method and so it is likely that as more synthesises and methodological research takes place, new knowledge will be generated. As we state in our manuscript (page 32), this publication standard is intended as the first step in what we hope is an evolving process of methodological development. Indeed, the second ‘E’ in RAMESES is for ‘evolving’.

Methodological standards, by their very nature, are in a constant state of evolution. There are drawn in an attempt to formalise what goes on in the conduct of exemplary research but they cannot anticipate every new challenge faced by that method. It is thus useful to ‘harden’ and ‘collectivise’ standards periodically whilst recognizing that the scientific method is adaptive. Our task is to cover standards appropriate to realist synthesis at its present stage of development.

- How useful will these guidelines be to authors and editors?
  They should be very useful, and hopefully result in better reported studies.
- Have similar guidelines been published previously?
  Not that I am aware of, however as commented above, their place within reporting guidance of qualitative studies should be discussed.

21. Response
Please see Responses 18 and 20 above.

- Do the authors have the required expertise and knowledge to design these guidelines?
  Yes, an excellent group of authors and Delphi panel members.

22. Response
Thank you.