Author’s response to reviews

Title: What is preventable harm in healthcare? A Systematic Review of definitions

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Author’s response to reviews: see over
Associate Editor's Comments:

ABSTRACT
The abstract is the first (and only!) part of the paper that many readers will see - it is therefore particularly important that this is clear and stands alone as a summary of the work undertaken. The following minor points would make the abstract clearer:
- Please state "English language" rather than "English" [since you included international studies and not just those from England]

Done, Thanks!

- It is not clear what is meant by the "three most common harms" - do you mean that the papers most commonly focused on these three types of harm? [rather than the most prevalent harms in the studies included were these three types...] Please clarify this sentence

We thank the Associate Editor for his comment. We meant the latter (most prevalent). Text revised as suggested.

- Similarly it is not clear what these percentages relate to - 26% of what? As previously requested, please state the number that each percentage relates to, as well as the percentage, either by saying that 26% of 127 focused on medication adverse events, for example, or by saying that X (26%) focused on medication adverse events, etc. The same applies to the data on themes or definitions - 44% of what? 44% of the 127 included studies? or 44% of the seven themes?

We made the requested changes by adding number, percentage and unit, to the abstract.

INTRODUCTION
- Reference 6 is Ferner and Aronson [not Ferner and Jeffery as cited]

This has been corrected. Thank you!

METHODS
- It is not clear how Kappa was calculated for the assignment of a definition for preventable harm (page 8) - was this based on the presence / absence of a definition, or on the domain / theme of the definition, or on details of the definition itself? Please specify.

The kappa was assigned as yes/no (the two reviewers agreed on the theme of definition assigned to a particular study, or not). We edited this paragraph on page 8 to clarify.
- Since data on interventions are not now presented in the paper, the authors may wish to remove the phrase relating to extracting data on definitions in the section on "data synthesis and analysis"

Done, thank you!

- Top of page 9 - please clarify whether you were extracting data on the minimum level of harm specified in the paper to constitute "harm", or whether you were extracting data on how harm was classified in the included studies. I assume the former, but this is not very clear.

It is the former. Text is revised accordingly.

- Page 9 second paragraph, I would suggested specifying "defintions of preventability reported" [rather than just "definitions reported"] as the previous section is about severity, and so it is slightly ambiguous as to which definition is being considered here.

Done, thanks!

RESULTS
- Under "type of harm", I feel that the phrase "The three most common harms cited..." is misleading. I think you mean "The papers most commonly focused on the following three types of harm" [rather than the three most common harms identified in the studied...]

We corrected this in a similar fashion to what we did in the abstract. Thank you.

- Definitions of preventable harm - I think you are saying that there were 132 definitions analysed in total. Please state this explicitly.

Done, thank you!

- Again, many of the percentages need to refer back to either the relevant denominator or to the number concerned. eg you state that 53% of definitions were author derived - it would be much clearer to state that 53% of 132 definitions were author derived.

Done, thank you!

- Page 11, second paragraph, second sentence - do you mean three previous definitions [rather than three publications]?

We appreciate the Associate Editor’s comment. This means that three published article were cited commonly as a source for the definition of preventable harm. We have edited the paragraph to make this clearer and it now reads (page 9):
“Most of these definitions were author derived (67/127, 53%) and did not cite a specific source of the definition of preventable harm. In the remaining articles, three publications were cited the most as a source for the definition of preventability.[10-12] Notably, the definition used in these three articles was “the presence of an identifiable modifiable cause”.

- Page 11, second paragraph, the section starting "The definitions were described in observational studies...." - I wondered if this would be better earlier in the results section, where you refer to 127 publications and 132 definitions?

We moved that section to follow the first paragraph in the results section. This makes the reading flow better.

- The section on severity of harm - again it's not very clear whether you are talking about describing the level of harm required for a harm to be included in the studies concerned, or whether you are talking about studies including a separate classification of separate levels of harm.

It is the former; we clarified this in the text. Thank you.

- Page 12, section on "validity and operational characteristics" - the kappa statistics - would it be clearer to state that kappa statistics were for each "type of definition", or "definition domain" [rather than "each definition"]

Done, thank you!

- Figure 1 - the numbers still do not add up. Of 460 papers, 116 were excluded. This leaves 344 [not 333 as stated].

This is now corrected. We thank the Associate Editor for pointing this out.

- Figure 2, as previously requested, please specify what the key relates to (ie level of agreement).

Done, thank you!

- Supplemental table 2 is a helpful addition, but would be even clearer with the addition of row and column totals.

Changes to supplemental table 2 are done as suggested.
DISCUSSION
- Bottom of page 13 - please specify "UK" National Patient Safety Agency

Done, thank you!

- Top of page 14 - do you mean "definition domains" or "types of definition" [rather than "definition"]?

We added “domains” to make this clear.

- It may be useful to briefly discuss whether a standardised definition of preventability is desirable or possible. Might definitions of preventability depend on the purpose for which they are intended?

We added a sentence to reflect the need for a definition but also the need for it to be purpose/scope specific.

- It may be useful to briefly discuss reference 7 in relation to the point about hindsight bias

This is done. Thank you for the suggestion.

- Page 16 - only one study cited a Kappa - please reference the study concerned

Done, thank you!

- Page 21 - limitations - it is stated that "... providing more specific estimates was not feasible...". Please specify - estimates of what?

We thank the Associate Editor for his comment. We have revised made this clearer in our revised manuscript. It now reads (page 21):

“The analysis in this systematic review was meta-narrative, i.e., non-quantitative; hence, providing more specific estimates of the operational characteristics of definitions was not feasible”

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We thank the Associate Editor for the valuable comments and the opportunity to review our work to make it more useful for BMC HSR readers.