Author's response to reviews

Title: Conflicts of Interest and Critiques of the use of Systematic Reviews in Policymaking: An Analysis of Opinion Articles

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Author's response to reviews: see over
Response to reviewers and editor:

Thank you very much for your insightful comments on our paper.

Reviewer 1 (Kaelan Moat)

Overall, I think this is a very well written and an extremely interesting paper that will be of broad interest to anyone following and/or contributing to the discussion about the use of systematic reviews in health policymaking. Given the difficulty in assessing and analyzing conflict of interest (and particularly undisclosed conflict of interest), the authors likely had to overcome significant difficulties during the design stages of the study, and I feel that they were able to develop a compelling approach, given these challenges. While I have one major point of feedback which can easily be addressed with some additions to the text, the majority of my concerns outlined below relate to points that require clarification within text.

Response: Thank you

Major Compulsory Revisions:

1) While the authors have provided a very detailed and extensive description of the study design and methods adopted, there isn’t a section that explicitly discusses their analysis approaches. As such, it wasn’t clear whether and how the quantitative data were analyzed (and I believe it was just a simple observation of trends in descriptive statistics), or the approach taken to analyze qualitative data, either. It isn’t until the conclusion section that the authors state why they decided not to use inferential statistical methods (which is a valid point) but this type of information ought to be discussed in the methods section, as well. I think an additional section needs to be added in the methods that clearly outlines the analysis stages.

RESPONSE: The following section was added: Data extraction and coding, (page 8, line 4-14)

“After articles were selected for inclusion, each article was closely read by two authors (SRF and DHO) and a decision was reached about whether the article supportive or critical of the use of systematic reviews in policy making. Discrepancies were resolved by a third author (LAB). Using an author-generated data collection sheet, we coded: full citation and article type, whether the article was supportive or critical of the use of systematic reviews in to inform policy, individual argument types, affiliations of authors, stated conflicts of interest of all authors, funding source of articles, extent of disclosure, as described below. Argument types were then iteratively coded and then categorized into either internal reliability arguments or external reliability arguments as described below. Once all data from the article had been extracted, we then searched for undisclosed industry ties and individual journal disclosure policies. Finally, we identified the number of times each article had been cited in the academic literature.”

To address the second point, the following section was added: Analysis (Page 12, lines 14-16)

“All data were analyzed using descriptive statistics, as use of inferential statistics was inappropriate due to the non-randomness of the sample.”
2) While I believe there is merit in trying to separate out methodologically focused arguments from arguments about the utility of reviews more broadly, I struggled with these particular terms and the definitions used by the authors given there seems to be a lot of overlap between the two (i.e. it wasn’t always clear to me whether and how these two categories of arguments/discussions were mutually exclusive). Two related issues stem from this:

a. Given the focus in this paper on analyzing arguments for/against the use of reviews to inform policymaking processes external to the conduct of the review itself, wouldn’t all included studies, by definition, be relevant to discussions of reviews’ utility as an input into these processes?

b. In papers that currently fall into the authors’ ‘methods arguments’ grouping, is it the case that systematic review methods are discussed in isolation of how they relate to their potential input into the policymaking process? Isn’t it the case that internal validity and methodological rigor was discussed in these papers as they related their utility as an input into the policy process? I find it difficult to parse out how methods-focused papers weren’t also utility-focused papers.

I believe that this is likely a language issue. Perhaps the authors would consider using more appropriate names for these categories to address this conceptual ambiguity (e.g. internal reliability and validity arguments vs. external validity arguments).

Utility and methods arguments:  *We have relabeled the arguments. This section has been rewritten to reflect the reviewer comments and for clarity (pages 8-10 and pages 15-18)*

Minor essential revisions:

• Minor Essential Revisions

1) It would be helpful if the authors provided some additional information to clarify their process for assessing retrieved papers for inclusion. In particular, I struggled on pages 5 and 6 where the authors describe a title review (“Two researchers screened search result titles”), but also state that:
   - “Research articles, including studies, reviews and case examples were included if the authors expressed an opinion on the use of systematic reviews in policymaking within the body of the article” (page 5)
   - “Included articles that contained significant arguments for or against this…We considered arguments to be significant if they did not focus solely on a single systematic review, but rather commented on whether systematic reviews did or did not have a role in policymaking” (page 6)

It strikes me as quite a difficult task to use titles when trying to determine whether “significant arguments” were made. It is important that the authors clarify this.
2) On page 11, the authors mention that “The number of individual articles that a single paper contained ranged from one to twelve”. However, the authors also separated articles into groups that argued in support of reviews from those that criticized reviews. In the case of articles containing more than one argument, isn’t it the case that some would have described arguments for AND arguments against? If so, how did the authors overcome this in order to categorize into the “supportive” and “critical” categories? I think this warrants discussion in either the methods or results section. The issue comes up again on pages 15-16, but the authors haven’t described how these were grouped into two discrete categories, despite having potential relevance to both.

RESPONSE: The sentence “The number of individual articles that a single paper contained ranged from one to twelve” has been removed as it is confusing and doesn’t add to the paper. We have added a sentence to the methods section (page 9, lines 4-6) indicating that multiple types of arguments could be found in an individual article. The issue that the reviewer brings up about whether an article could contain both supportive and critical arguments is addressed under the external validity subheading in the results section where we discuss supportive articles that express concern about generalizability.

3) The use of “off-topic” as an exclusion criterion makes sense, but it would help the reader if the authors could provide a definition of what is meant by this, as well as a brief illustrative example of how this was operationalized during the inclusion/exclusion phase (e.g. could be a bracketed description of the types of articles that were excluded given they were “off-topic”).

RESPONSE: As in the response to reviewer 2, this phrase and been removed and more clarifying text has been added, as well as a study selection flowchart.

4) On page 10 the authors describe a process in which they used their own personal files/databases to identify an additional ten articles. I think that this needs to be included in the methods section in their search strategy as well.

RESPONSE: This information has been placed in the in methods sections (page 7, line 14-15).

5) On page 12 in the results section the authors state “critical articles were twice as likely…”. Given inferential statistics weren’t used, I’d use this type of phrase with caution (particularly in light of the arguments being considered in this manuscript!). Could the authors consider another term?

RESPONSE: This term has been changed to “twice as often.” In addition, these types of phrases have been reworded throughout the paper.

6) On page 18 the authors use the term ‘utility’ (see: “accurately judge an article’s accuracy or utility”) in a slightly different way than in the rest of the paper, where it is used as a conceptual category within the analysis of arguments. As such, I think it would be best, to ensure no confusion arises, to consider a different term here.
RESPONSE: term was changed from utility to relevance (page 18, line 16).

70 On the bottom of page 18, the authors state that “…our findings are important because they demonstrate that industry ties may influence opinions…”. I would encourage the authors to reconsider the use of the term “influence”, given their study design lends itself to assertions of association (although only very loosely), rather than direct influence, which can imply causation to some. Semantics, yes, but something that may jump out at a certain type of reader.

RESPONSE: This term has been changed to “may play a role in.” (page 21, line 3.

Discretionary Comments:

1) On page 4, the authors describe many of the characteristics of reviews, which is likely going to be helpful for readers not entirely familiar with reviews, but for whom this paper is particularly relevant (i.e. policymakers). While it is discussed in the results section to some extent, I was wondering if it would also be helpful to provide readers with some sense of the major arguments in favour of reviews vs. single studies in policymaking—which I would argue are now quite well established in the field and can be found in some of the Lavis papers cited in the study (e.g. can save time, reduce bias, etc.). I don’t think this would interfere with the results, which are much more focused on how COI intersects with the range of arguments, so it could be provided as additional background.

RESPONSE: While this an excellent suggestion, we are considered about article length and have chosen not to include this.

Reviewer 2 (Michael Wilson)

I found this to be an interesting article to read. The role of COI and industry ties and their influence in the literature is important, and this seems to be the first systematic analysis related to their role in arguments for and against using systematic reviews to inform policy. I think this will be a unique contribution to the literature that can certainly help to spur dialogue, reflection and (hopefully) action on several fronts (e.g., addressing the lack of COI and industry ties in commentaries/editorials). I also thought the conclusion section provided a number of important implications. I have provided some feedback below, which are largely minor concerns.

RESPONSE: Thank you

Major Compulsory Revisions:

1. There is currently no flow diagram for study selection, which should be included.

RESPONSE: A flowchart has been included as Figure 1.
2. At first it seemed as though this was a systematic review given that the methods are structured around the typical steps taken by a systematic review. In reading the results and reviewing the supplementary file that contained the included articles I was able to quickly note several articles that should have been included (e.g., Lavis JN. Towards systematic reviews that inform health care management and policy-making. PLoS Med 2009 & the SUPPORT Tools for evidence-informed health Policymaking series led by John Lavis and Andy Oxman in Health Research Policy and Systems…among others that would also be indexed in PubMed). Once I got to the strengths and limitations in the conclusion, the authors do acknowledge that the list of included papers was not comprehensive. I think the lack of comprehensiveness needs to be addressed more explicitly in the objective and/or methods by saying that this cannot be taken as a systematic review but rather an analysis of a representative sample of articles.

RESPONSE: Our search was not focused on identifying tools to improve the uptake of evidence (including systematic reviews) in the policy process. As we note, we searched for opinions which is a difficult task. We have added a sentence added after objectives in the background section (page 6, lines 6-8), “This study was not intended to be a systematic review, as we did not undertake a comprehensive search with multiple databases, nor did we contact authors for unpublished paper. This is an analysis of a representative sample of available opinion articles.”

3. p.6: the list of articles excluded because of language should either be cited or listed in the supplementary file.

RESPONSE: An additional file labeled “Additional File 1- Articles not in English has been created and contains the articles that were excluded because they were not in English. It is referenced in the text (page 12, line 20).

Minor Essential Revisions:

1. “While some authors argue that systematic reviews...” needs citations: Citations added (page 4, lines 10-11).

2. Note that systematic reviews include both qualitative and quantitative primary studies: The phrase both “qualitative and quantitative” was added (page 4, lines 16).

3. Content too focused on quantitative research: Sentence added. "Qualitative systematic reviews summarize and narratively synthesize results using a range of methods {Greenhalgh, 2009 #175}[Thomas, 2008 #176][Barnett-Page, 2009 #177], (page 4, lines 17-18).

4. Page 4- second to last sentence needs citation: citation added (page 5, line 5).

5. Remove “off-topic” from exclusion criteria: removed.

6. Utility arguments seem to be methods arguments: section has been rewritten (page 16, line 11 through page 18, line 20.)

Discretionary Comments:

1. Change “coding...” with “to inform policy.”: wording changed (page 8, line 15-16)
Consider moving the descriptions of methods and utility arguments up to follow the 1st sentence of the previous paragraph.

2. This section has been revised.

RESPONSE to Handling Editor’s comments:

1. Time frames have been added to the literature search.
2. A section on search strategy has been added, along with details of the strategy.
3. A data extraction and coding and section was added, as well as a separate analysis section.
4. A clearer statement regarding primary and secondary outcomes has been added.
5. We did not see where a synthesis section was requested by the reviewers. We did, however, address all of the reviewers concerns regarding addition of an analysis section.
6. We added language in the COI section delineating that we considered funding separate from COI data. We did collect data on specific journal requirements regarding COI and funding statements, however we did not collect data on the clarity of these statements. We did add the word “currently” to further clarify. We did add the range of dates that the articles were published in first paragraph of the results section.
7. We coded the “no-funding” articles as “self-funding.” We have clarified this.
8. We added the three year criterion to the discussion of ISS in the methods section.
9. We have changed the terms method and utility to internal reliability and external validity which are universally understood.
10. Double coding changed to “coded in duplicate.”
11. PRISMA flowchart added.
12. Will report percentages with ns in parentheses.
13. Redundant numbers were removed.
14. A discussion heading was added.
15. The next to the last paragraph has been moved to the conclusion section.

Editorial requests:

1. We have added a page break to the abstract page.
2. The sentence was added.
3. We have added a competing interests statement to the end of the manuscript.