Author’s response to reviews

Title: Requirements of Health Policy And Services journals for authors to disclose financial and non-financial conflicts of interest: a cross-sectional study

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Version: 1 Date: 19 Jul 2017

Author’s response to reviews:

Clinical Research Institute
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July 19, 2017

Rosanna Gonzalez-Mcquire, Editor

Subject: “Requirements of Health Policy and Services journals for authors to disclose financial and non-financial conflicts of interest: a cross-sectional study”
Dear Dr. Gonzalez-Mcquire,

We thank you for the opportunity to revise our manuscript for your consideration for publication in Health Research Policy and Systems. The reviewers’ comments and suggestions were very constructive and helped us improve the quality of our manuscript.

Please find on the following pages our detailed point-by-point responses to the reviewers’ suggestions. We will be happy to address any further comments or suggestions you or the reviewers might have.

With kind regards,

Elie A. Akl, M.D., M.P.H., Ph.D.
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Please note: reviewers’ comments are in bold font, our responses are in regular font and, and extracts from the text are in italic and placed within “quotation marks” with any changes underlined.

Reviewer #1:

Thank you for the opportunity to review this very interesting and relevant study. I hope that my comments will be helpful to the study team.

Response: Thank you for the positive feedback.

Comment 1:

Abstract:
Conclusion seems to be more of a summary of findings. Might be more interesting to include some of the discussion points here instead. The "so what" implications.

Response 1: thank you for bringing up this to our attention and for the helpful suggestion. We have modified the conclusion to include implications as follows:

“A majority of Health Policy and Services journal policies require the disclosure of authors’ financial and non-financial COIs, but few required details on disclosed COIs. Health policy journals should provide specific definitions and instructions for disclosing non-financial COI. A framework providing clear typology and operational definitions of the different types of COIs will facilitate both their disclosure by authors and reviewers and their assessment and management by the editorial team and the readers.”

Comment 2:

Background

Page 4 -Line 10: the authors indicate that the IOM report resulted in a surge of COI policies across health organizations but it would be good to know if the IOM report also resulted in a change or introduction of COI policies across health journals (since this is the focus?) Perhaps knowing when these journals introduced or changed their policies and whether they coincide with an important event or report such as above would strengthen the paper. (if there is a way of finding this information and using it as an indicator or proxy indicator) Else it seems a little tangential.

Response 2: thank you for raising this issue. Unfortunately, we could not find information about when journals introduced or changed their policies and how that coincides with the publication of the International Committee of Medical Journals Editors (ICMJE) COI disclosure requirements. We have edited the text to indicate the date of publication of the ICMJE requirements and to avoid suggesting that the publication of the requirements resulted in a surge of COI policies:

“The Institute of Medicine defines a conflict of interest (COI) as “a set of circumstances that creates a risk that professional judgment or actions, regarding a primary interest, will be unduly influenced by a secondary interest” [1]. In healthcare, the primary interest is to assist in the advancement of health research and generate the useful knowledge for patients, while the secondary interest is personal gains either financial or non-financial [2, 3]. In 1998, the international Committee of Medical Journals Editors (ICMJE) required submitting authors to include a covering letter including “a statement of financial or other relationships that might lead to a conflict of interests” [4]. Since then, it appears that journals and health organizations (e.g., professional societies that produce practice guidelines) have developed or amended their policies
regarding COI [3-5]. These include organizations whose mandate is to deal with issues of health policy.”

Comment 3:

Page 4-Line 22: Examples of COIs affecting policy making is a very important contribution in this paper. However, the authors fail to provide a strong argument. For instance, they mention "a number of reports" but do not cite all the reports, with only reference to the one from China. More examples or references would be helpful here. Furthermore, the China example could probably be made more succinct to get the main point across.

Response 3: This is an excellent point. We now provide three examples in sequence to illustrate the potential effect of COI on policy making, all in the field of tobacco control: the examples of China and India where COI had a negative impact on policies; then the newly included example of Thailand where the appropriate management of COI had a positive impact:

“A number of reports highlight how COIs can affect health policy-making [8-11]. One of these reports relates to the implementation of the Framework Convention on Tobacco Control (FCTC) in China. After signing the convention in 2003 and starting 2009, China printed on-pack warnings according to the FCTC agreement [8]. However, the on-pack warnings did not follow global standards [8]. According to Wan et al., the State Tobacco Monopoly Administration (STMA) responsible for implementing the FCTC agreement had a share in the largest tobacco company in the country, an obvious COI [8].

India is another example of how COI may have affected tobacco control health policies. Although, the Indian government signed the FCTC in 2003, tobacco users represented up to 35% of the adults in 2010 according to the Global Adult Tobacco Survey (GATS) [12]. Rao et al. investigated one-hundred public documents addressing the competing interests in tobacco control policies in India [9]. They identified COIs at three levels: individuals, organizations/government and policy plans. Specifically, stakeholders and advocators holding positions in governments and institutions responsible for setting and implementing tobacco policies shared or had ownership in tobacco companies [9]. In one illustrative example, a former minister and the director of a tobacco company, served as a member of the powerful group of ministers deciding on pictorial warnings on tobacco packs.

Thailand succeeded over a 20 yes period in reducing the tobacco use among adults [11]. One of the main success factors was assigning the state-owned Thai Tobacco Monopoly (TTM) to the Ministry of Finance, while the Ministry of Health (MOH) was responsible for tobacco control [10, 11]. The MOH assembled a National Committee for the Control of Tobacco Use (NCCTU) whose members must not be part of other tobacco agencies to exclude any potential COI [10, 11].”
Comment 4:

Page 4 - Line 41: the India example is an interesting one but unlike the China example, we don't see "how" health policies were affected by the identified COIs. This would important as that is the point that the authors are trying to make.

Response 4: Thank you for bringing that to our attention. We clarified the India example and gave an example that is the closest to illustrate the 'how':

“India is another example of how COI may have affected tobacco control health policies. Although, the Indian government signed the FCTC in 2003, tobacco users represented up to 35% of the adults in 2010 according to the Global Adult Tobacco Survey (GATS) [12]. Rao et al. investigated one-hundred public documents addressing the competing interests in tobacco control policies in India [9]. They identified COIs at three levels: individuals, organizations/government and policy plans. Specifically, stakeholders and advocators holding positions in governments and institutions responsible for setting and implementing tobacco policies shared or had ownership in tobacco companies [9]. In one illustrative example, a former minister and the director of a tobacco company, served as a member of the powerful group of ministers deciding on pictorial warnings on tobacco packs.”

Comment 5:

Page 5 - Para 1: The paragraph begins by stating the importance of reviewing evidence impartially for EIPM. But then it goes on to talk about authors and reviewers…there seems to be a disjunction here…the first sentence is relevant to the policymaking community and the second for scientific community. I understand the link that the authors are trying to make but it needs to be clarified.

Response 5: Thanks for this great remark. We have edited that paragraph to make the link between the policy making community and the policy research clearer:

“Evidence-informed health policy making should be based on a disinterested evaluation of the best available evidence [13]. One study found that health policymakers in the Middle East do refer to evidence in their decision-making processes [14, 15]. Several studies, although not in the policy making field, found a positive association between authors reporting COI and increased likelihood of their studies reporting positive results [16, 17]. This highlights the need for policymakers to assess the potential for bias in the evidence they are considering making their decisions. Requiring authors to disclose their COIs, will allow policymakers to better assess the possible bias introduced by those interests.”
Comment 6:
Page 5 - line 12: The context of a previous similar study is helpful and very relevant. It would be interesting to note what impact the study had on the clinical journals (if any) with respect to their COI policies. Given that the authors are interested in research for impact, has there been any impact? This would help justify the reasons for the current study as impetus for change rather than traditional academic research on journal COI policy.

Response 6: We agree with the reviewer that it would be interesting to know more about the impact our previous study had on the clinical journals with respect to their COI policies. Unfortunately, it is too early to see an impact given the study was published in November 2015. Indeed, none of the seven papers citing the study addressing clinical journals aimed to assess its impact on COI policies.

Comment 7:
Methods
Page 7 - line 10-37: It is not immediately obvious why some of these characteristics of the journals were important to note for the study. The study team obviously had reasons for collecting this information. It would therefore be helpful for the authors to include an additional few words explaining the relevance of these characteristics.

Response 7: Thank you for raising this issue. The intention was to give a general profile of what journals were included in this study, and to be able to assess how this profile differs from that of the clinical journals included in our and other previous studies. We did add a clarification about the relevance of some of those characteristics as follows:

• “Journal category other than “Health Policy and Services” category (according to the JCR Science Edition 2015) (to better characterize the profile of journals included in the study);

• Membership of the International Committee of Medical Journal Editors (ICMJE), according to ICMJE website (as this could be potentially associated with adoption of certain COI policies);

• Membership of the Committee on Publication Ethics (COPE) (also, could be potentially associated with adoption of certain COI policies);”
Comment 8:

Page 7 - line 17: wasn't this the journal category you were searching for? Not sure why data on those "other than" this were collected? Clarification here would be helpful.

Response 8: Thank you for the question. As per our answer to the previous question, the intention was to better characterize the profile of included journals. We clarified what is meant by other than “Health Policy and Services”:

“Journal category other than “Health Policy and Services” category (according to the JCR Science Edition 2015) (to better characterize the profile of journals included in the study);”

Comment 9:

Results:

Page 9 - Line 39: This statement is rather unclear "…required it for work outside the submitted work"…

Response 9: Thank you for bringing that to our attention. We clarified this point:

“Although most journals’ policies required COI disclosure for the submitted work (87%), only one (2%) required COI disclosure for work other than the submitted work (e.g., being paid as a consultant by a company with a vested interest in the product being studied, but for issues unrelated to that product).”

Comment 10:

Limitations

Are there any biases that may have been introduced by your processes for selection or interpretation?

Are there any possibilities of bias based on the investigators’ personal experiences with journals?

Response 10: Thank you for raising a valid question. We believe that we followed rigorous processes in the selection, data abstraction, analysis, and interpretation of the evidence. That included duplicate and independent processes, use of standardized and pilot test forms, abd calibration exercises. As an example of our thorough work, the Web of Science (WOS) updated its list of journals that fit the category of Health Policy and Services, shortly after we launched our study. We did go back and adjusted the list of included journals accordingly. by WOS. This
possibly minimizes the bias during the selection process. Regarding the investigators and their potential biases, we have added the following text:

“We do not believe that any of the authors had biases against any of the included journals. Specifically, the team members who abstracted data were naïve to the list of included journals and had no personal experience with any of them.”

Comment 11:

Discussion

Page 12 - Line 15: The phrase" they may suggest that health policy journals are lagging slightly behind" is a bit nebulous. Are they only being compared to the core clinical journals and if so, without a benchmark for what is appropriate COI policy, it would be hard to mark a judgment on what lagging behind means (and to quantify it). Furthermore, its not apparent whether clinical journals are also potentially "lagging behind" other disciplines or further ahead. The relative assessment of what constitutes appropriate COI Policy is unclear and therefore a comparison would be unfair. (Nb: the next two paragraphs that make comparisons with other journals are much more convincing on the relative COI policies)

Response 11: Thanks for your suggestion. We have deleted the sentence implying that health policy journals are behind. Also, we added the findings of two additional studies on journal adoption of COI policies:

“Two other studies found that 87% of Oncology journals and 95% of high impact biomedical journals adopted COI policies [19, 20].”

Comment 12:

The paper is missing the WHY - Ie why is this all important? Why should journals take heed of COI policies? What if they don't? Should there be a oversight "ethics/IRB" for journals? Why should readers take author and editor COI into consideration when reading an article of research? Journals have so far "got away" with vague or incomplete policies - has the impact of this been so damaging that revisions are critical? And what is an ideal benchmark for all the various COI's that have been suggested?

Response 12: Thank you for raising the important question of “why”. Per our response to a previous comment, we made edited a paragraph in the introduction section to explain why COI disclosure by study authors is important for policy makers:
“Evidence-informed health policy making should be based on a disinterested evaluation of the best available evidence [13]. One study found that health policymakers in the Middle East do refer to evidence in their decision-making processes [14, 15]. Several studies, although not in the policy making field, found a positive association between authors reporting COI and increased likelihood of their studies reporting positive results [16, 17]. This highlights the need for policymakers to assess the potential for bias in the evidence they are considering making their decisions. Requiring authors to disclose their COIs, will allow policymakers to better assess the possible bias introduced by those interests.”

As for a benchmark, we have included in the manuscript a table with suggestions for items that journals could include in their policies for authors’ disclosure of COI.

**Describe the COI:**

**Specify the level of COI: individual vs. institutional**

**Specify the type of COI: financial vs. non-financial**

If financial COI, specify:

- The subtype: grant; serving as an advisor, consultant, or public advocate; stock ownership; indirect financial support (examples include paid by the entity, writing assistance, administrative support); personal fees; direct employment; honoraria for speaking, writing, or reviewing on the topic discussed in the manuscript; speaker bureaus or board membership; royalties; patents

- The monetary value

- Date

- Source and source type (e.g., private for profit, private not for profit, governmental, institution, medical professional society, inter-governmental)

If non-financial COI, specify:

- The subtype: (e.g., participation in guideline panel, public expression of opinion, religious beliefs, political affiliation)

- Date
Please note that we have taken out the findings related to the COI of editors and reviewers given this was not part of the objective of the study, and valid assessment of the COI of editors and reviewers would require abstracting information from sections of the journal website other than the instructions for authors.

How do the authors suggest that the changes being suggested are implemented? How will the various journals be reached with these results? Besides this being interesting information, what are the plans for this research to have the intended impact?

In terms of implementation, we are working on the following:

• Sharing the results coming out of the different studies in our project with relevant stakeholders at major scientific meetings, including: 2016 Cochrane Colloquium, 2017 International Peer Review Congress, 2017 Global Evidence Summit, the 2017 8th International Conference of Evidence Based Health Care for Teachers and Developers

• Disseminating the results of publications through social media

• Contributing initiatives related to the subject of COI, including the Cochrane initiative to develop a tool for addressing funding and conflicts of interest in randomized clinical trials

• Once the paper is published, we will share it with editors of the included journals.

Comment 13:

Conclusion

The conclusion is rather weak and should be revisited.

Response 13: We have addressed the issue as suggested.

“The objective of this study was to assess the policies of health policy and services journals for authors to disclose financial and non-financial COIs. While the majority of the policies required the disclosure of financial and non-financial COIs of authors, few required details on disclosed COIs. We also found that a small minority of policies specified how the disclosed COIs would impact the editorial process or required COI disclosure for reviewers and editors. This may jeopardize the published evidence to bias which may be reflected on the health policies. Our findings should assist journals in improving their COI disclosure policies. Detailed COI disclosures will help researchers and policymakers in building unbiased evidence-informed decisions taking into account the possibilities of competing interests imposed on their policy plans.”
Comment 14:
Minor edits
Background
Line 12: use COI acronym since its already been introduced
Line 17: Replace "the mandate of which" to "whose mandate is"
Response 14:
“Since then, it appears that journals and health organizations (e.g., professional societies that produce practice guidelines) have developed or amended their policies regarding COI [5-7]. These include organizations whose mandate is to deal with issues of health policy.”

Comment 15:
Page 6 - Line 56: there seems to be a word missing after standardized? The sentence seems fragmented
A copy-edit read through of the grammar throughout the paper for word order etc…
Response 15: Thanks for pointing this out. We addressed those issues as suggested.
“After conducting calibration exercises, we abstracted data using a standardized and pilot tested data abstraction form.”

Comment 16:
line 27: on-pack warnings, "they examined for any relevant emails" etc)
The authors alternate between the first person (our study) and the third person (the investigators). Suggest choosing one or the other to maintain flow and consistency.
Response 16:
“The simulated submission consisted of the following. First, we logged into the journal online submission system and submitted an empty manuscript under the manuscript category ‘original research’, or its equivalent, on the journal online submission system. We also submitted a cover letter explaining the objective and methods of the current study. We included in the submission
one email address for the ‘submitting author’ and another for a ‘co-author’. Then, we examined for any relevant email sent to the author and co-author email addresses.

After conducting calibration exercises, we abstracted data using a standardized and pilot tested the data abstraction form. We abstracted data in a duplicate and independent manner and resolved discrepancies through discussion or through the help of a third reviewer.”

Reviewer #2:

An interesting, descriptive article on the state of COI disclosure requirements for Health Policy & Services journals. It would be interesting to report future follow-up as to whether any of the Health Policy & Services journals strengthened their COI disclosure policies and procedures on the basis of having been included in this study.

Response: Thank you for the very positive feedback and valuable evaluation.

Reviewer #3:

Thank you for the opportunity to review this manuscript. The authors have examined a set of policy and services journals listed in Web of Science to examine the requirements for disclosing competing interests. The strengths of the work include the detail of the examination, the comparison to core clinical journals, and the transparent presentation of the results. The weaknesses of the work include potential limits of the journals that were selected, and that compliance was not examined as part of the work or examined in comparisons with other literature (journal policy may be very different from journal practice!). In what follows, I have described some comments and suggestions in chronological order.

Response: Thank you for your valuable feedback. We chose Web of Science list as it updates on a periodic base and it happened while doing our study. We consulted with experts in health policy research and with an experienced librarian who confirmed that the Web of Science list was more comprehensive than the one provided by Embase. Regarding compliance, the main scope of our study to assess the COI requirements of Health Policy and systems journals. Assessing compliance would need a separate study with a different study design.

Comment 1:

Major comments:
1. I felt that for a study on primary research, the use of anecdotes in the background didn't match the type of research. The background could have done more to explain why it is important that conflicts of interest are reported in a complete, standardised, and transparent manner.

Response 1: Thank you for pointing this out. We used anecdotes to illustrate the potential impact of conflicts of interest in real life health policy. In addition, and as noted above, we have added text to the background section to explain the importance of COI reporting:

“Evidence-informed health policy making should be based on a disinterested evaluation of the best available evidence [13]. One study found that health policymakers in the Middle East do refer to evidence in their decision-making processes [14, 15]. Several studies, although not in the policy making field, found a positive association between authors reporting COI and increased likelihood of their studies reporting positive results [16, 17]. This highlights the need for policymakers to assess the potential for bias in the evidence they are considering making their decisions. Requiring authors to disclose their COIs, will allow policymakers to better assess the possible bias introduced by those interests.”

Comment 2:

2. Are there health policy and services journals listed in PubMed and signed up to ICMJE that are not included in Web of Science? If there are, I think PubMed (and perhaps Embase) should have been considered, or this should be listed as a limitation. If the authors are confident that the set of journals is complete, then I could be convinced that this is not a limitation.

Response 2: Thank you for raising an important question. Per the reviewer’s suggestions, we have included this as a limitation:

“Another limitation of our study is that we included journals listed under the category of “Health Policy and Services” by the Web of Science (WOS). This list might not have included journals listed under similar categories in other databases such as PubMed. However, we don’t have a reason to suspect that this might have affected the representativeness of our sample.”

Comment 3:

3. How did the journals differentiate between funding disclosures (who paid for the work represented in the articles) and declarations of competing interests (do the authors have relationships that could influence their work outside of the work represented in the article)?
Response 3: Thank you for raising the question. It was not part of our objectives to study journals' requirements for inclusion of funding statement (nor how these were differentiated from the COI declarations). However, and in order to avoid any confusion during data abstraction, the instructions document provided guidance to distinguish between the COI disclosures (being specific to the authors) and funding statements (being specific to the study). We have clarified this as follows:

“In the instructions document, we provided guidance to distinguish between the COI disclosures (being specific to the authors) and funding statements (being specific to the study).”

Comment 4:

4. I might have missed this, but were there results on how the journals handle editor's conflicts of interests and if this policy was public?

Response 4: This is an excellent point. We did contemplate investigating journals’ requirements for both editors and peer reviewers to disclose COIs. However, we realized that these requirements will not necessarily be made publically available, neither in the instructions for the authors, nor in the online system for submission of manuscripts. Although we found relevant information in the website of few journals, there are probably many journals who do not provide such information on their website, in the instructions for authors, or in the online submission system.

Comment 5:

5. Did the authors consider examining the relationships between the different characteristics of the journals and the completeness and characteristics of the policies? Are they related to impact factor? Belonging to ICMJE/COPE? If this is not appropriate for a statistical analysis, can you think of a way to visualise the raw differences in a useful way so readers can quickly see where the main issues are and who is doing it better than others?

Response 5: Thank you for this suggestion. We did not find a significant relationship between existence of a COI disclosure policy, and the explicit requirement for disclosure of financial and non-financial COI respectively, and the following independent variables: COPE, ICMJE and impact factor.

Table 1: Multiple logistic regression of existence of a COI disclosure policy

<table>
<thead>
<tr>
<th></th>
<th>Unadjusted OR</th>
<th>95%CI</th>
<th>Adjusted OR</th>
<th>95%CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impact factor</td>
<td>2.60</td>
<td>0.66 – 10.30</td>
<td>2.89</td>
<td>0.58 – 14.42</td>
</tr>
<tr>
<td>ICMJE</td>
<td>0.25</td>
<td>0.02 – 2.83</td>
<td>0.16</td>
<td>0.02 – 2.33</td>
</tr>
</tbody>
</table>
We have added the following text to the analysis section of the paper:

“We conducted regression analyses to identify relationships between (1) existence of a COI disclosure policy, (2) explicit requirement for disclosure of financial COI, and (3) explicit requirement for disclosure of non-financial COI, and the following independent variables: COPE, ICMJE and impact factor. None of these analyses was significant.”

If the Reviewer and Editor prefer, we would be happy to include the above table in an appendix.
Comment 6:

Minor comments:

1. Background: The definition of a conflict of interest is fine but I think it would be problematic to use it without explaining what the primary interest of a researcher might be. In some cases, the primary interest is one’s own career or the profits of the company they run. We typically assume that the primary interest is set and it relates to the welfare of patients and society but never explicitly state this. When discussing non-financial conflicts of interest, this distinction becomes more important.

Response 6: thank you for bringing up this to our attention. We have added an explanation to what is considered as primary and secondary interests as follows:

“The primary interest is to assist in the advancement of health research and generate the useful knowledge for patients, while the secondary interest is personal gains either financial or non-financial [2, 3].”

Comment 7:

2. Results: Out of interest, I would want to know the level of agreement between investigators when extracting information from the journals. Having looked at a large number of actual disclosures recently, I suspect the ambiguity might have made the level of agreement quite low. It would be worth including information about this somewhere.

Response 7: This is a good point. While, we did not formally measure agreements, the impression of the team is that the level of agreement was high. We think this is expected for abstracting data form policies, as opposed to abstracting data from actual disclosures, which was not part of this project. However, our experience with abstracting data from actual disclosures as part of another project, confirms that this could be a very challenging task.

Comment 8:

3. Discussion: As a suggestion only, how does the research relate to any surveys that have examined either (a) the difference between policy and disclosure, and (b) adherence to ICMJE standards by the journals in their disclosures and lack of disclosure by authors?

Response 8: We have searched, but unfortunately did not find any study assessing ‘the difference between policy and disclosure’. On the other hand, we identified a paper in which the editor of a
German journal describes the impact of introducing a COI disclosure policy on disclosures by authors of their financial COI:

“Indeed, the editor of a German journal reported that the introduction in 2005 of a policy requiring all authors to disclose their COI increased disclosures from none in 2002 to 30% of the published articles in 2006 [21].”