Author's response to reviews

Title: Five-Step Authorship Framework to Improve Transparency in Disclosing Contributors to Industry-sponsored Clinical Trial Publications

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Author's response to reviews:

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To: Claire Barnard, PhD
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Re: MS: 1391689452136324

Split, Croatia, September 23, 2014

Dear Claire,

Thank you for providing me and my co-authors with reviewer comments for the
“Five-Step Authorship Framework to Improve Transparency in Disclosing Contributors to Industry-sponsored Clinical Trial Publications” manuscript. We appreciate the positive feedback and opportunity to revise the manuscript based on these helpful suggestions. I have provided below a point by point response to these comments to assist with your review of the resubmitted version.

Beyond these suggestions, we have also reformatted the manuscript based on its reclassification as a correspondence and conforming to the journal style.

We hope the revised manuscript addresses the reviewers’ comments and is ready for publication in BMC Medicine. Should any questions arise, please do not hesitate to contact me.

Sincerely,
Ana

Ana Maruši#, MD, PhD

Reviewer 1

Comment 1: There is value in the proposal for a five step approach to authorship, and it deserves a full discussion in the relevant literature. I am not sure I agree with the resistance against providing more detailed guidance in guidelines or authorship rules of journals with respect to what constitutes substantial contribution, rather than allowing a committee to decide on a more ad hoc basis what will constitute substantial contribution. Committees could be manipulated (e.g. by the sponsor or lead investigators), or there could be a power dynamic in these committees which results in legitimate authors to be excluded and authors who do not deserve it to get authorship status. Yet, as a result of the mere procedural respect of the five step project, there would be no way to challenge authorship decision making. Authorship is very much about providing a reliable public representation of the study and the analysis and drafting process. But if these committees can create their own criteria for ‘substantial contribution’, there is perhaps not more clarity about what exactly happened with respect to the contributions of a study.

Response: This comment is quite important and was discussed at length by the authors and with journal editors during development of the Five-Step Framework. We think that the large number of clinical trials and their complexity, which tends to increase over time, makes it nearly impossible to put together a comprehensive list of substantial contributions that would remain relevant and easy to use. Instead, it was felt that a working group with representation from both the trial sponsor and contributors independent of the sponsor (e.g., academic clinician helping to design/ implement the trial) would prevent “power dynamics” from creating arbitrary authorship criteria. Second, it is already stated noted in the text that these criteria “should align with external guidelines (e.g., ICMJE, GPP2, and journals being considered for submission)” further insulating the process from manipulation. Finally, these criteria are suggested to be
included in agreements clinical investigators sign prior to begin working on a trial. As a result, there should be full clarity from all involved about the authorship criteria.

To address this point, an additional sentence in the Discussion was added to reiterate the alignment with external guidelines - “In addition, these authorship criteria should align with external guidelines, such as ICMJE and GPP2, to avoid potential bias in selection of criteria that exclude legitimate authorship.”

Comment 2: Another comment is that the term transparency is particularly used in the context of access to research data and access to hidden information. Would it not be better to use the term ‘clarity’ with respect to the identification of who did what with respect to authorship?

Response: The reviewer raises an important distinction, and references to “transparency” have been changed throughout the revised manuscript to “clarity” when referring to identification of contributions.

Comment 3: “The most common and frequently referenced authorship guidelines in biomedicine are issued by the International Committee of Medical Journal Editors (ICMJE), with the goal of enhancing transparency in authorship disclosure and ultimately building trust and credibility with the medical literature readership [2-3].” Problem with ‘with the goal’. : structure of sentence unclear. Suggest cut in two sentences. Second one “The goal of the ICMJE is…”

Response: This change has been made. The text now reads, “The most common and frequently referenced authorship guidelines in biomedicine are issued by the International Committee of Medical Journal Editors (ICMJE). The goal of the ICMJE criteria is to enhance transparency in authorship disclosure and ultimately building trust and credibility with the medical literature readership [2-3].”

Comment 4: “erode credibility in industry research” only in industry research?

Response: This change has been made. The text now reads, “Despite implementation of these authorship criteria by journals and trial sponsors, concerns over transparency in disclosure of authorship contributions persist, which ultimately can erode credibility in clinical trial research and related publications [4-9].”

Comment 5: “the diversity unscientific research” Add: “of”?

Response: This change has been made.

Comment 6: “to elevate trust, transparency, and integrity in publishing industry-sponsored studies” should be : ‘a collaboration aimed at…”

Response: This change has been made.

Comment 7: “all respondents selected ICMJE as their top choice, although to a smaller extent by clinical investigators” “by clinical investigators” not correct in
this sentence: perhaps better: ‘although this was less the case among clinical investigators’/

Response: This change has been made.

Comment 8: ICMJE criteria for authorship available at the time of the survey [19] were unclear as to whether patient recruitment was considered to be a substantial contribution as part of data acquisition.” Is this really so? Patient recruitment is not mentioned as an example in ICMJE suggesting it is not sufficient.

Response: The 2008 Uniform Requirements state that “Authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.

In addition, supporting text for the above also notes that “Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship.” The updated 2013 version, published more than a year after our survey was fielded, extends this point to say “Examples of activities that alone (without other contributions) do not qualify a contributor for authorship are acquisition of funding; general supervision of a research group or general administrative support; and writing assistance, technical editing, language editing, and proofreading.” As a result, the ICMJE criteria overall do not provide an exhaustive list of what would be considered substantial contribution. Therefore, the lack of inclusion for patient recruitment as an example of substantial contribution from our perspective does not mean it does not meet the standard.

During our research to create the authorship scenarios, the idea that patient recruitment should be considered a substantial contribution was repeatedly mentioned since it was not clear from the ICMJE criteria if patient recruitment could be considered “data acquisition” and thus substantial or as “data collection” and thus not substantial.

Based on the above, we feel our statement as currently written accurately reflects the 2008 Uniform Requirements.

Comment 9: It is not clear to me why this case represents a case of prioritizing ‘transparency’ over proprietary information. This should be clarified.

Response: This case presents the scenario where an individual who made a substantial contribution is not provided an opportunity to serve as an author (Step 2-4 of the ICMJE criteria). Therefore, this was characterized as prioritizing proprietary information to the trial sponsor over allowing all who made a substantial contribution to have the opportunity to serve as authors, providing transparency to a reader that all the views have been represented in the manuscript. While not part of the 2008 Uniform Requirements, this point was seen as important enough to be explicitly addressed in the 2013 Uniform
Requirements, “All those designated as authors should meet all four criteria for authorship, and all who meet the four criteria should be identified as authors.

Since this description is potentially confusing, it has been changed to: “Finally, Case 7 tests whether providing those who make a significant contribution the opportunity to serve as an author takes precedence over protection of proprietary information”.

Comment 10: and develop: suggest to add ‘to’ before develop
Response: This change has been made.

Comment 11: structure of following sentence is not ok: “are more often concerned with the importance or significance of the contribution rather than following..”[ are concerned… rather than following : following not correct here] The sentence is also not clear.
Response: This change has been made. The text now reads, “Finally, clinical investigators, who make up a significant percentage of authors on manuscripts from clinical trials, appear to be concerned with the importance or significance of the contribution rather than following external guidelines to determine authorship. This perspective is exemplified by clinical investigators ranking lowest among the groups surveyed for awareness of authorship criteria.”

Comment 12: “with respondents potentially having a special interest in authorship and therefore not representative.” Structure sentence: ‘not being representative’…
Response: This change has been made.

Reviewer 2

Comment 1: It would be helpful in the introduction to discuss what authorship is and what the implications / responsibilities of authorship are. An explanation of the difference between an author and a writer would be useful.
Response: This point is a very helpful suggestion. Additional perspective has been added to the Abstract and Introduction section to address this suggestion.

The definition for a writer was included in the Methods section as those “…employed or contracted by trial sponsors who collaborate with authors in drafting, revising, and editing medical information for peer-reviewed journals and congresses”.

Comment 2: Authorship is one way to acknowledge “significant” contributions made to the piece of work that is being reported in a manuscript. Less significant contributions can be acknowledged in other ways and it would be helpful to discuss these other options (eg what types of contributions should be in the Acknowledgements section)
Response: We have included a more detailed description of the idea of contributorship in the Introduction, also a request of Reviewer 3 (see below).

In addition, Step 4 of the Five-Step Framework in the Results section has been updated to note that contributions which are not considered substantial still should be included in the acknowledgements. The added text reads, “Contributions which do not meet the standard for “substantial” should be agreed to by all authors and noted in the acknowledgements.”

Comment 3: Case study 1 refers to patient recruitment, the clinical investigator and day-to-day management. The credit is given to the investigator but in many cases the work of recruiting and following the participants, ensuring compliance with the protocol, etc is not done by the clinician but by the data manager or research nurse. Is this a contribution that merits authorship?

Response: As mentioned above, the 2008 Uniform Requirements also note that “Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship.” This definition was reiterated and extended in the 2013 Uniform Requirements. During our preparation of the case scenarios, our research suggested an interesting aspect to test in the larger survey was the contribution of the clinical investigator rather than the data manager or research nurse given the language included in the 2008 Uniform Requirements. Therefore, the scope of our case was limited to the clinical investigator question of substantial contribution.

Comment 4: My understanding is that in larger, multi-centre trials (and as an incentive to recruit) that authorship will depend on recruitment of a minimum number (or percentage) of participants. This could be mentioned in the discussion.

Response: This point is an important one. The discussion has been updated to include the following text when discussing Case 1, “This adaptable format will help facilitate the continued movement away from patient recruitment as sole criteria for substantial contribution and place greater emphasis on intellectual contributions, thus better aligning with the evolving concept of authorship”.

Reviewer 3

Comment 1: There is no mention of ‘contributorship’ a perspective introduced by Rennie and colleagues (e.g., Rennie D, Yank V, Emanuel L. When authorship fails. A proposal to make contributors accountable. JAMA. 1997 Aug 20;278(7):579-85) which has gained some traction and credibility. I think the authors need to address this issue in their revision

Response: We thank the reviewer for the excellent suggestion to include additional approaches beyond authorship. Reference to contributorship has been added to the Introduction. The text reads, “Another authorship model, referred to as contributorship, lists each person’s contributions to the research and manuscript, even for those who are not authors. One or more of these contributors will fulfill the role as guarantors of the paper [4].” A new reference
was added to the list of references – the change in reference order was made accordingly, but was not indicated as a change in the revised manuscript to make it easier to follow.

Comment 2: The authors have proposed a five-step approach – what I perceive to be an intervention for handling clinical trial authorship in industry-sponsored research. That said there is nothing discussed about endorsement of the framework or its implementation across any stakeholder groups, most obviously, the pharmaceutical industry. I see little merit in proposing something without a more detailed action plan for change. It would be similar to developing a reporting guideline without giving adequate attention to how journals and editorial groups might endorse and implement them. I think the authors need to include issues pertaining to endorsement and implementation of the five-step framework.

Response: This point is quite important and was the focus of many conversations by the authors during development of the manuscript. We feel that it is important for other clinical trial sponsors to see this manuscript as providing a relevant tool which is not merely an abstract concept but being used in practice.

As a result, the MPIP co-sponsor companies are currently in discussions for how to best utilize the Five-Step Framework as a means to supplement best practice for their future clinical trials activities. In addition, given the involvement of journal editors, MPIP will be reaching out to those entities to reference this tool in their “For Authors” section to provide another resource to increase transparency for authorship decisions. Other organizations could also provide assistance as well, potentially including CONSORT, EQUATOR, and COPE (as a means to deter unethical authorship practices).

We have also updated the text at the end of the Discussion section to address this point. The text now reads, “The companies included in this publication will support implementation of this tool in their clinical trials to supplement best practice and would encourage other industry members to do so as well to ensure this framework is broadly embedded for maximum impact. Given the contribution from other stakeholders, such as journal editors, the authors will be reaching out to them and other organizations to ask for their help to foster awareness and uptake for the Five-Step Framework.”

Comment 3: The discussion is almost solely focused on industry-sponsored trials. Does the five-step framework not have any generalizability for all clinical research authorship or are industry-sponsored trials so unique the proposed plan is of no use?

Response: Both the Abstract and Conclusion have been revised to include this suggestion.

Comment 4: Introduction - Towards the end of the first paragraph I think the authors have a typo when they state “….the diversity of unscientific research…” I assume they mean “scientific”?

Response: This change has been made.
Comment 5: In the methods there is no mention of involving COPE. Was COPE one of the respondent groups?

Response: COPE was not included as a respondent group given they are more focused on publication ethics and how to handle cases of research misconduct. Since the Five-Step Framework seeks to increase transparency for how authorship determinations are made, it hopefully will help to avoid instances of inappropriate conduct. Liz Wager, the former head of COPE, was consulted when developing the cases and helped to represent these perspectives when designed the survey. Her contribution is noted in the Acknowledgements.

Comment 6: There is no mention of response rates. I assume this is because the authors did not have access to the denominators from each group they surveyed?

Response: Given the methodology employed, we were not able to calculate denominators from each group surveyed. This point was included in the Results section: “Given the various methods used to contact potential respondents and collection of survey data, it was not possible to calculate a response rate or determine any differences between respondents and those who did not take the survey.”

Comment 7: On page 10 the authors state “answer rate”. I assume they mean the response rate? There is no mention of the completion rates (by question and/or cumulatively) by respondent group. Do the authors have this information?

Response: Since this phrase refers to the qualitative answers filled in by survey respondents, response rate would be a more accurate description. This change has been made.

Comment 8: I think the section “development of five-step authorship framework” should come towards the end of the results section rather than where it is now.

Response: We agree that the current description includes results in the methods section. As a result, we shortened this text to focus more purely on the methodology while making additional edits in the results section which refers to development of the Five-Step Framework.

Comment 9: From Table 1 it looks like approximately a third of the respondents were inexperienced as authors (in industry-sponsored trial publications). Did the authors conduct any sensitivity analyses? For example, were these respondents different from the more experienced ones?

Response: After running the sensitivity analysis, the only significant difference occurred in Case 1 with less experienced clinical investigators (i.e., with two or less clinical trial publications) being less likely to invite a clinical investigator who enrolled the most patients to help draft/revise the manuscript compared to more experienced investigators (i.e., with three or more clinical trial publications). There were no differences in confidence or perceived frequency of the case
scenarios.

As a result, text describing the result has been included in the Results and Discussion section. Importantly, it points out that publication experience is unlikely to provide the basis for these opinions from clinical investigators, and therefore it becomes even more important to establish a multi-party authorship working group to help set reasonable criteria that align with external guidelines that clinical investigators are less likely to be aware of and experience does not change this perception.