Reviewer’s report

Title: A guide to applying the Good Publication Practice 3 Guidelines in the Asia-Pacific Region

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Reviewer: Lisa M. DeTora

Reviewer's report:

General:

I really agree with the authors that some leadership is needed for biomedical publication collaborations with industry in the AP region, but this paper is not doing that job well enough. I feel like the paper needs to start out with the idea that these authors see a need for leadership in the region and then specifically map out what that would mean.

I can see the work that went into the revision, but I am sad to say that the paper still does not seem publishable. In fact, the writing in the responses to the comments does a much better job explaining the purpose of the paper than the paper does—so the authors clearly have an important point to make, but it is not coming through in the paper. So, once again, while it seems like a good idea to have AP-specific guidance, this paper does not provide that guidance clearly enough for a reader who does not already know the area very well. It seems like a matter of experts talking to experts and not quite understanding how to address people who are naive to the area.

As a peer reviewer, I am confused by the new material included as a response to my comments. If the goal of the paper is to define how GPP3 works in the AP region, why is there an ICMJE authorship table? And if the goal of the paper is to explain both ICJME and GPP3, then why is ICMJE not discussed more specifically? I still think it would be clearer to organize the text around unique situations in the AP region rather than repeating the GPP3 text (especially since GPP4 is already underway). In my opinion, it should be relatively easy to concentrate on the areas needing specific attention in the AP region instead of duplicating material already published elsewhere. In other words, the paper should have been fundamentally reorganized around specific areas of interest in the AP region and should not serve as basically a repetition of GPP3 with a few added notes.

While I still generally like the idea of providing specific advice for the AP region, this paper does a somewhat poor job at building a case for the need for such guidance and also in giving the specific guidance needed. (Again, the response to reviewers does a better job than the paper itself.) In fact, the local laws mentioned are from the US and UK, which undercuts the value of this publication as a document by and for AP colleagues. Furthermore, the advice given is rather bland and could have been presented on a member web site in a series of blog posts or some
other format that would be more easily accessible. In other words, this paper (as written) provides no new or useful information for an AP audience that warrants peer-reviewed publication in this format.

In addition, the information presented is distributed across text and the long table in such a way as to prevent readers from finding it easily. The case studies are only tangentially related to the rest of the text and would be better placed elsewhere so that they can function in the way the authors explain in their response to reviewers. Personally think they should be incorporated into the ISMPP main site because they are valuable for that membership.

In addition, I am somewhat taken aback that the authors refused to look at the long list of ISMPP-sponsored publications on more granular practices for authors. It seems somewhat irresponsible in a paper by ISMPP members that mentions regional work by ISMPP to neither consult nor cite this work. For example, A Stocks and colleagues recently published an ISMPP-sponsored paper on the very authorship questions these authors find confusing—this paper should be cited instead of trying to reinvent the material.

This brings me to another problem, which is that the reference citations seem wrong. The very first citation is incorrect, which affects the entire paper, and makes me think the authors have not really taken enough time to carefully review their article before resubmission. Or perhaps the submission program picked up a penultimate version in error?

Specific:

Introduction:

* The authors need to make one clear claim to support the need for this paper. So, either there is some problem with the existing guidelines (as stated in the introduction and abstract) or people in the AP region are unfamiliar with the global guidelines and having trouble implementing them based on local practices (as stated in the conclusion). I believe the latter is true, given the comments the authors made in their peer review responses.

* The references supporting claims about the AP region seem to conflate all scientific publishing with publishing in biomedicine. For example, the Science paper is not specifically about biomedicine. Also, a heavy proportion of this work is grey literature, including opinion pieces, or specifically about China. So, if the authors want to make a claim about the whole AP region in the context of GPP3 (which is a guidance for biomedical publication collaborations with industry), I would want to see some citations that specifically address problematic collaborations with industry in the region -OR- some interesting information about local regulatory or other practices that present challenges in the AP region in this setting.
I still fail to believe that working in Australia, New Zealand, or Japan (a founding ICH region) presents huge barriers to biomedical publishing. It might help to explain what those barriers are, exactly. For example, there seems to me to be a space for debunking vague generalities about "poor practice" in the AP region by being more specific about the high-quality work already being done there.

Requirements for reporting research

GPP Principle 1:

* The authors note that information and guidelines are not available in AP-regional languages (although I am unclear as to where Persian is spoken in the AP region, given that most of its native speakers reside in Iran and Afghanistan?) and then recommend that all local data be published in English. I'm not sure this makes sense, and it seems to counter to the idea that local physicians need access to this data. It's also inconsistent with recent EU requirements for Lay Summaries…. companies that market products in the EU will already need to have data in local languages.

* I do not think, given the problems in the Science article the authors cite, that the authors should be recommending editing services instead of noting the value of professional medical writers with specific experience in the AP region. It also might be more helpful to address the idea of translation (with back translation), and how to go about doing that for local and global audiences.

* I don't understand what kind of data are not suitable for peer-reviewed publication. Can the authors give an example that is specific to the AP region? And explain why can't such data be added to a review?

* Why are publications delayed for subgroup analyses in this region but not others? And how might one address this problem? An ISMPP group, for example, published on using publication planning as a means of guiding study design and data analysis planning. That could be a helpful reference that will put this paper in conversation with ongoing ISMPP work.

* The authors could address where to publish local subgroup analyses and how to find journals or conferences that meet needs across a subgroup.

GPP2 Principle 2:
* None of the laws mentioned are pertinent to the AP region specifically. Please list some local laws that impact publications

* Recommending the use of EQUATOR guidelines is not new, and the comments on translations do not make very much sense in the context of the recommendation in the previous section that all publishing be in English. I feel like these sections were handled by different authors and that the last read-through wasn't quite finished. (Maybe the submission program picked up the wrong version?)

GPP Principle 3:

* Nothing in this section looks that different compared with the recent paper by Foster and colleagues. What is specific to the AP region? What is new?

GPP Principle 4:

* Nothing in this section seems original or targeted to the AP region. What is new? What is specific to the AP region?

GPP Principles 5-7:

* This paper opens by criticizing the very guidelines you cite here (unless the problem is just that the abstract needs updating), but this section just says to follow the guidelines and offers little to no specific advice about working in the AP region.

* Stocks and colleagues just published a paper about the specific nature of authorship criteria and many (many) publications exist that give this type of general advice, much of which seems to parallel GPP3. Some of that literature should be cited.

GPP Principle 8:

* Relies too heavily on US guidance and does not explain the unique situation in the AP region.

GPP Principles 9-10:
Also feel heavily derivative of the GPP3 guidelines

... The next sections on ORCID ID's and predatory journals would also benefit from information specific to the AP region. None of this information feels new.

Leadership on Publication Ethics in the AP Region

This is really the most interesting section of the paper, but it does not go far enough. The authors need to define the AP region and its concerns for the reader and then and explain how to balance the concerns of different constituencies across the region. The idea is to explain this information to naive (but intelligent) readers. Personally, I would really welcome such a paper because it could highlight some of the really important work already being done by the authors.

Level of interest

Please indicate how interesting you found the manuscript:

An article of limited interest

Quality of written English

Please indicate the quality of language in the manuscript:

Not suitable for publication unless extensively edited

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