Reviewer’s report

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

Version: 0 Date: 20 Jun 2019

Reviewer: Yvonne Yarker

Reviewer's report:

ABSTRACT

Suggest qualifying that the primary focus of this article is on pharmaceutical company-sponsored research (as is GPP3). Add (GPP3) as an abbreviation, similar to your using (ICMJE).

INTRODUCTION

PAGE 3

If you start by saying there are numerous recommendations and guidelines you should cite some of them, eg, those from EQUATOR, CONSORT, WAME, COPE, CSE, AMWA, EMWA, MPIP, etc. Also, as above, recommend qualifying that you are focusing on pharmaceutical company-sponsored research when you talk about scientific and medical publications and the application and interpretation of GPP3.

Rephrase the description of ICMJE guidelines - they are used by major journals as a basis for much more than just authorship criteria - perhaps note their broad scope then say that they are probably the leading source of determining authorship criteria.

Line 17/18 reads "as well as and" - please fix.

For the last line of this para, again suggest expanding the citations as noted above.

re: expanding pharma in AP region and Japan, I believe there are data now that the number of clinical trials and publications in China has eclipsed that of North America - an important point here.

re: "executing regional publication plans" - suggest providing an explanation of what this is, otherwise you are assuming all readers are familiar with this concept.

re: first mention of GPP3, I think you need to introduce to the reader what this is, what it covers, why it was developed, and that is contains specific ethical best practices for pharma-sponsored publications.
re: "lower income countries", I don't think income is necessarily the reason that some countries are not aware of Western guidelines/best practices. Japan, China, Australia/NZ, for example, are not low income countries, but ethical and cultural differences are considerable.

PAGE 4

re: "adherence to ethical publication practices in the Asia-Pacific region" - you mean adherence to Western ethical publication practices - I think you need to say somewhere in the Intro that Western regions have gone to some lengths to set best practice guidelines, which is why you are proposing interpreting them for application in the AP region.

re: authorship practices, it would be helpful here to explain some cultural differences with regard to authorship in different regions. I don't think it's just lack of consistency in applying (Western) guidelines, but there are strong cultural expectations in some regions that are very different.

re: same comment about "globally recognised ethical publication practices" - I don't think the guidelines you focus on are globally recognized (yet).

PAGE 5

"Data should also ultimately be published in a peer-reviewed journal following any conference or informal presentation" - this isn't clear to me. Do you mean every abstract/poster/oral should be published in a peer-reviewed journal? Is this really possible? Perhaps qualify by saying that publication or presentation at international congresses is encouraged for abstracts/posters/orals at regional or country-specific congresses to broaden their accessibility.

PAGE 6

"Data relevant to the Asia-Pacific region is often delayed" - the reason for this delay is not clear to me as written. Do you mean that subanalyses by region/ethnicity of international studies are undertaken and published later because they are subanalyses? It is recommended that the primary analysis of any trial is published first anyway, regardless of any planned subanalyses. And what about studies that are only, for example, conducted in Asian or Japanese patients? These aren't mentioned here. This section seems to be focusing on large international trials only, so I think this needs more explanation.

re: "evidence gaps", again I don't think all readers will be familiar with this concept so it needs explanation and/or the text/statement rewording. Overall, this whole para is confusing - it's not clear how this para relates to ethical best practices statement that "The design and results of all
clinical trials should be reported in a complete, accurate, balanced, transparent, and timely manner." For example: "there is a need to drive awareness of potential differences in clinical study design" - who should be driving this awareness, what are these differences, and how might they be resolved?

re: "stakeholders" - again I think you need to explain what you mean here - these terms/jargon are familiar to people in the West working in industry or agencies, but I am not sure they are generally understood.

Can you provide any examples in this past para of p6 of key laws in AP regions that may also have to be applied by? As you are talking about applying GPP3 in AP regions, might there be laws or regulations that are contrary to what GPP3 proposes? How should this be handled?

PAGE 7

Is it true that ICMJE and GPP3 are "readily accessible" in the AP region? Do all researchers/authors in these countries have access to these websites, for example? If not, what are some ways that these guidelines and resources could be accessed or disseminated?

Case Study 1 needs a bit more explanation - was this a diagnostic test developed in or for the AP region and/or by an AP company, and/or written for an AP audience? It isn't clear as written.

PAGE 8

Again there is reference to "overall publication planning process" - I think this kind of industry-specific language should either be avoided or clearly defined.

"While originality is always preferable" - not sure what this means in this sentence. Overall I think this para needs rewriting as the focus is not clear. Are you trying to say that access to international or overseas congress data is limited in the AP region, so encore presentations at AP regional events should be considered? If so, I think that would be a simpler way to say it.

"data that is of high interest and has not been presented" - data ARE plural - so "data that are of high interest and have not..." (also elsewhere in the manuscript).

"local audiences" - presume you mean researchers in AP countries.

"universal authorship agreement" - I'm not sure this document would be well known outside the pharma/agency field.
"Opportunities may exist to republish articles initially published in English in other languages" - this is confusing as written and should be revised, eg, "Opportunities may exist to republish in other languages articles initially published in English."

"If republishing a translated version of a manuscript" - here I think you mean publication, not manuscript?

Use of "stakeholders" here and throughout - I think this terms should either be avoided or defined - to me it seems like pharma/agency jargon.

PAGE 10
Case 3 - add that this was an AP regional affiliate.

PAGE 11
Could the 4 ICMJE criteria be listed here for those not familiar with them?

PAGE 12
"authors must agree to the writer's involvement" - I think what you mean is that all authors must be asked if they agree to the involvement of a medical writer.

This section discussed what should be done on a practical/process level when implementing ICMJE authorship criteria, but doesn't address how to explain these requirements to investigators/authors who are used to a very different cultural norm with regard to authorship and the roles and responsibilities. Similarly for authorship seniority and order. Can the authors provide some guidance about this here? What approaches have been successful in their experience?

Instead of talking about an author needing to be "removed from a manuscript", this implies that someone else is making this decision. May be better to just stop at "proposed author does not meet the ICMJE criteria". Can you give that author the opportunity to meet these criteria before any discussions about removing them? Perhaps mention also the option to have such an individual listed in an Acknowledgment?
This case is written as a mixture of statements and a case, ie, not a problem and a solution. Recommend rewriting to present as a case, eg. "Employees of a multinational pharmaceutical company were trained on the ICMJE and GPP3 recommendations. However, when working Japanese investigators of a clinical trial, cultural norms made it difficult for study sponsors to explain to the authors why the ICMJE authorship criteria should be followed. This was compounded by professional medical writing support provided in English by an overseas-based agency. To address this problem, local medical writers who were familiar with both cultural norms and ethical publications practices were brought in to..."

This is a bit better as it provides suggestions re: how to implement 'Western' guidelines when working with people in the AP region who are either not familiar with them, or who have different cultural norms re: authorship and seniority. The authors' experiences and practical examples would be very useful here and elsewhere in the manuscript.

"However, the scope of 'drafting the work...' - explain for the readers that this is one of the 4 ICMJE authorship criteria, as not everyone will be familiar with this.

"may need to develop new methods of engaging authors" - can you give some examples that have worked for you? If the intent of this paper is to be a "practical guide", there should be practical examples that the readers can try.

"If an author does not agree with a study's findings, as presented in a manuscript, they may wish to politely decline authorship." - is this their only option? Shouldn't discussions be set up to evaluate everyone's interpretation of the data before this stage is reached?

"Guest or gift authorship" - these terms should be explained/defined. Honorary authorship is another term that could be used/defined here.

Again, can you provide practical guidance on how to implement these authorship guidelines where culture or language is a barrier?
Case study 5 does not seem specific to an AP region situation. Given the title of this paper and its goals, it would be better to provide a case that reflects an AP authorship situation.

PAGE 17

There isn't really a recommendation here about capturing "intellectual contribution" as it relates to working with AP authors. What suggestions/recommendations can you make, eg, authors should be provided with a list of potential contributions (in their native language if necessary) from which to indicate their specific contributions to the research and the reporting of it. And/or work with a local affiliate (familiar with culture, customs, and language) to discuss these requirements with AP authors.

PAGE 18

As above, what recommendations do you have with respect to working with AP authors? Perhaps, as above, provide a list of potential COIs (in their native language if needed) from which they can indicate their specific COIs. And/or work with a local affiliate (familiar with culture, customs, and language) to discuss these COI requirements with AP authors.

Case study 6 - as previously, can you make this more relevant to an AP situation?

PAGE 19

"All authors in the Asia-Pacific are encouraged" - suggest rewording to "All authors in the Asia-Pacific should be encouraged"

"awareness of data-sharing requirements in the Asia-Pacific is low." - if so, what do the authors recommend to address this situation?

PAGE 20

What suggestions or recommendations can the authors provide to address some of these issues?

"a majority of the audience" - there can only be one majority so "the majority of the audience" or "most attendees"

"audience is comprised of" - should be "audience comprises". Better to simplify/reword, eg, "Most attendees at such meetings are industry stakeholders"
Suggest a separate section earlier in the manuscript on predatory journals/congresses if they are particularly prevalent in the AP region, including a better definition of these.

**TABLE 1**

Some of the suggestions/recommendations noted above should be included in this table to provide practical advice for people working within or across the AP region. Many of these recommendations state what "should" be done without providing guidance on "how" to do so, given the cultural, financial, language, and other barriers.

As well as a list of Abbreviations, I think a Glossary would be helpful to explain some of the jargon/terms used throughout the manuscript (eg, stakeholder, publication plan, evidence gaps, etc.).

**Level of interest**

Please indicate how interesting you found the manuscript:

- An article of importance in its field

**Quality of written English**

Please indicate the quality of language in the manuscript:

- Acceptable

**Declaration of competing interests**

Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?
5. Do you have any other financial competing interests?

6. Do you have any non-financial competing interests in relation to this paper?

If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.

I am an author of the Good Publication Practice Guidelines (GPP3), the application and interpretation of which is discussed at length in this manuscript.

I am past Chair of the Board of Trustees of ISMPP, a non-profit professional organization mentioned in this manuscript.

I agree to the open peer review policy of the journal. I understand that my name will be included on my report to the authors and, if the manuscript is accepted for publication, my named report including any attachments I upload will be posted on the website along with the authors' responses. I agree for my report to be made available under an Open Access Creative Commons CC-BY license (http://creativecommons.org/licenses/by/4.0/). I understand that any comments which I do not wish to be included in my named report can be included as confidential comments to the editors, which will not be published.

I agree to the open peer review policy of the journal.