

# AMWA-EMWA-ISMPP

## Joint Position Statement on Medical Publications, Preprints, and Peer Review



### Background

In medical publications, just as in research and development, quality depends on the expertise and integrity of researchers/authors as well as qualified peer reviewers and journal editors. However, the laborious and time-consuming process of the traditional peer review<sup>1</sup> can be compromised by the pressure to publish quickly – particularly during a health crisis, when timely

distribution of credible medical information can make a substantial difference.<sup>2</sup> Recent examples of negative consequences are two articles on COVID-19 that were hastily published in high-profile medical journals and subsequently retracted.<sup>3,4</sup>

Traditional peer review, although not perfect, remains the most frequently used process for vetting scientific publications. However, it has become more common for manuscripts to be released without prior review, which raises new concerns.

The potential value of rapid publication should be weighed against the potential harm of inadequate validation of the final output. There is a danger that lowering the threshold of publication oversight sets a precedent that cannot be easily reversed, potentially eroding standards and public trust in medical science.<sup>2</sup>

We have joined in a multi-party consortium

among three eminent professional organisations for medical communication professionals – AMWA, EMWA, and ISMPP – to advocate for the adoption of standards by all stakeholders to better ensure the integrity of published scientific and medical information. Thus, the following Joint Position Statement has been developed to provide practical and implementable suggestions to uphold data integrity and quality, and the transparency of medical publications.

Note: We use the term “medical writer” to represent the spectrum of professionals who prepare documents either for submission to regulatory authorities or for publication in peer-reviewed journals.<sup>5</sup>

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## Communication of research: issues and suggested solutions

### Preprints

Preprints are preliminary scientific reports that are made publicly available online for anyone to read, comment on, and discuss before they have been peer reviewed. Some preprint servers scrutinize submissions for scope and for basic quality standards before making them publicly available.<sup>6–8</sup> Once the preprint is posted, most reputable preprint servers assign a unique digital object identifier (DOI) to aid traceability. Authors can revise preprints according to readers' comments and post iterative versions. Preprints are often not indexed on mainstream bibliographic services, although Europe PMC now indexes preprints,<sup>9</sup> and there are standalone tools for searching named preprint servers to improve discoverability.<sup>10</sup>

Preprints have been rapidly adopted by physicians and scientists, their obvious benefits being the immediate availability to their peers and the public, avoiding lengthy peer-review processes prior to release, and the option of readers to leave comments. However, there are issues associated with preprints that ideally should be addressed by standards jointly developed by a convened body of all stakeholders.

#### Issues with preprints:

- While preprints enable rapid release and discussion of data, many are never revised, and only about a third to a half are ever fully published.<sup>11,12</sup>
- “Once the toothpaste is out of the tube, it cannot (easily) be stuffed back in.”<sup>13</sup> Provocative or poor quality research results could be reported by the media, or posted and discussed on social media, with little regard to the preliminary nature of the findings.<sup>14,15</sup> No amount of retrospective “tagging” will have much effect. Misinformation or deliberately misleading or sloppy science can be freely circulated, cited, and believed ad infinitum, regardless of whether it is ultimately debunked and retracted.

#### Our suggested solutions:

- Preprints should not be used as references in any medical publication unless these are cited in the manner of a personal communication, that is, as an in-text reference (using the preprint link, DOI, or both) rather than as

bibliographic references. It should be clearly disclosed that the source is a preprint.

- Clearly distinguishing preprints from peer-reviewed articles might help to reduce the tendency of readers to view the work as fully vetted.<sup>14,15</sup> This should be done by
  - Watermarking the article, as is done, for example, by medRxiv and bioRxiv, with the information that it has not been peer reviewed.
  - Placing a clearly-worded disclosure in the body of the article highlighting that the findings have *not* been formally peer reviewed.
- Pre-publication vetting:
  - Pre-publication checks by server hosts. MedRxiv performs a basic screening process for plagiarism, nonscientific content, and material that might pose a health risk, including material that might compromise existing public health measures.<sup>7</sup> However, these checks should be more extensive and consistent across server hosts, and a comprehensive checklist should be used (Appendix I)
  - Encouraging authors to ensure that preprints that have been subsequently fully published be marked as such on the preprint server and linked via DOI to the fully published article.

### Post-publication peer review

In post-publication peer review, an article is published in its original form, then subjected to informal (as with preprints) as well as invited peer review. For instance, with the model used by the F1000 publishing platform,<sup>16</sup> articles are posted online after passing pre-publication checks and after an article processing charge (APC) is paid. When posted, articles are assigned a DOI and opened to comment from registered users. Expert peer reviewers are invited to review in the usual way. All comments, peer review reports, and article revisions are available with the article, and once the article receives two favorable peer review reports, the final, peer-reviewed version is indexed in external bibliographic databases and becomes fully discoverable. The benefits of this model are similar to those of preprints – rapid access to the readers and the option for readers to comment.

#### Issues with post-publication peer review:

- The issues with post-publication peer review are basically identical to those of preprints, but it should be noted that the requirement for an APC would potentially discourage casual or low-quality submissions. Articles are clearly marked as “under peer review,” and the progress of that review is accessible to readers.
- As with preprints, articles undergoing post-publication peer review should not be used as references in any medical publication until the peer review process is completed and the article is approved for publication. If the article is cited, we suggest the citation be made in the same manner suggested for preprints.
- Issues associated with traditional peer review also apply and are addressed in Section 2.3, below.

#### Our suggested solutions:

- Our suggested solutions include those proposed for preprints; however, we suggest that the publication be indexed by mainstream bibliographic databases (if applicable) once it has been fully peer reviewed, as is done on the F1000 platform.

### Traditional peer review

Traditional peer review occurs after a submitted article is accepted for consideration by a journal, then passed to expert peer reviewers. The reviewers' comments are sent to the authors to use in revising their article, or else the article is rejected after review. For rejected articles, authors can start the process again with another journal. If an article is revised to the peer reviewers' satisfaction, the article is published and assigned a DOI, after which the article is indexed in mainstream bibliographic databases. Peer review reports and revisions may or may not be available with the final article, depending on the peer review model the journal uses. The benefit of traditional peer review is that information is released to the readers only after there has been quality control applied by subject matter experts.

#### Issues with traditional peer review

- Lengthy review process, which may impede the timely release of valuable information – particularly in a pandemic or public health crisis
- Inadequate time for high-quality peer review
- Inconsistency among reviewers

- Difficulty in “recruiting” qualified reviewers, given time commitment, particularly in times of health crises when the most appropriate reviewers are likely to have a high clinical workload

#### Our suggested solutions:

- Authors:
  - Submit rejection comments to second-choice journals, with itemized rebuttals and updates to the manuscript (portable peer-review).<sup>17,18</sup>
  - Be more accepting of editor referrals to cascade journals.<sup>19</sup>
- Journal editors:
  - Accept, request, or require portable peer review as described above, thereby reducing the need for additional review cycles.
  - Consider commercial back-end services that expedite peer review (eg, Research-Square [<https://www.researchsquare.com/>], as used by the BMC journals and others).
  - Form a rapid response team of reviewers, with appropriate expertise, who can provide peer review with a quick turnaround time.
- Publishers:
  - Standardise formatting requirements to expedite resubmission.<sup>20</sup>
  - Offer fast-track options for potentially practice-changing work.
  - Consider incentives for reviewers.<sup>21</sup>

#### Suggested solutions for all formats

##### Quality control

- Make use of existing publication guidelines<sup>22–24</sup> and available checklists<sup>25</sup> to ensure high-quality publication development.
- Include Clinical Trial Protocols and Statistical Analysis Plans (SAPs) as supplementary material.
- Ask all authors to sign an author form confirming that they had full access to the relevant data reported in their article, along with acceptance of responsibility for submitting the article for publication. Furthermore, the contributor statement should name the authors (at least 2) who have accessed and verified the underlying data, as suggested in the revised *Lancet* publication guidelines.<sup>26</sup>
- Journals should clearly explain the initial quality review that editors perform on newly submitted manuscripts.

#### Training in peer review

- Authors, peer reviewers, and editors should be adequately trained in the nature and technical aspects of peer review.
- Guidelines should be used, such as those created by the Committee on Publication Ethics (COPE),<sup>25</sup> along with the reviewers’ checklist in Appendix I.
- Medical journalists and the public should be educated on how preprints and pre-publications differ from peer-reviewed literature.
- The role of professional medical writers and scientific communicators in expediting the publication process
- Evidence suggests that the use of professional medical writers enhances publication quality and speed,<sup>27–33</sup> and such assistance has been associated with a reduced risk for retractions due to misconduct.<sup>34</sup> If a qualified medical writer is part of the team, they should be involved in the process as early as possible.<sup>5</sup> The medical writer should have access to the clinical study report (if available), source data, and related documents, including statistical outputs and patient narratives, to the extent that data-protection regulations allow.
- Professional medical writers should have an active role in ensuring the high quality of publications, including their development, editing, and referencing,<sup>22,24,35</sup> and the use of appropriate publication checklists.<sup>36</sup> Medical writers and statisticians should be actively involved in peer review, during which the medical writer will critically assess the quality of the manuscript according to common appraisal criteria, thereby augmenting the traditional subject-matter-expert review (Appendix I).
- Medical writers could also be involved in pre-publication vetting, act as trainers, or both (see Training in Peer Review section).

As professional medical writers and communicators, we have identified areas that could benefit from increased quality assurance. We have suggested some processes that we believe would better ensure effective oversight of scientific and medical publications, whether in the context of a health emergency or not. To maintain confidence in published science, each involved party (including the reader) must take responsibility for exercising their best judgment and selecting information from sources with good publishing practices that are rigorous and transparent.

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#### References

1. Rennie D, Flanagan A. Three decades of peer review congresses. *JAMA* 2018;319(4):350-353. doi:10.1001/jama.2017.20606
2. Palayew A, Norgaard O, Safreed-Harmon K, Andersen TH, Rasmussen LN, Lazarus JV. Pandemic publishing poses a new COVID-19 challenge. *Nat Hum Behav*. 2020;4(7):666–9. doi:10.1038/s41562-020-0911-0
3. Mehra MR, Desai SS, Ruschitzka F, Patel AN. RETRACTED: Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis. *Lancet*. 2020. doi:10.1016/S0140-6736(20)31180-6.
4. Mehra MR, Desai SS, Kuy S, Henry TD, Patel AN. Cardiovascular disease, drug therapy, and mortality in Covid-19. *Retracted in: N Engl J Med*. 2020;382(25):e102. doi:10.1056/NEJMoa2007621
5. AMWA-EMWA-ISMPP Joint Position Statement on the Role of Professional Medical Writers. 2017. [cited 2017 Nov 17]. Available from: <http://journal.emwa.org/writing-better/amwa-emwa-ismpp-joint-position-statement-on-the-role-of-professional-medical-writers/>.

6. bioRxiv. Advancing the sharing of research results for the life sciences. [cited 21 Sep 2020] Available from: <https://www.biorxiv.org/about-biorxiv>.
7. medRxiv. Submit your article to bioRxiv, an online archive and distribution service for preprints in the life sciences. [cited 21 Sep 2020] Available from: <https://www.biorxiv.org/submit-a-manuscript>.
8. Preprints.org. How it works. preprints.org. 2020. [cited 21 Sep 2020] Available from: [https://www.preprints.org/how\\_it\\_works#screen](https://www.preprints.org/how_it_works#screen).
9. Levchenko M. Preprints in Europe PMC: Reducing friction for discoverability. Europe PMC. [cited 21 Sep 2020] Available from: <http://blog.europepmc.org/2018/07/preprints.html>.
10. Iwema CL, LaDue J, Zack A, Chattopadhyay A. search.bioPreprint: A discovery tool for cutting edge, preprint biomedical research articles [version 2; referees: 2 approved]. F1000Research. 2016;5. doi:10.12688/F1000RESEARCH.8798.2
11. Abdill RJ, Blekman R. Tracking the popularity and outcomes of all bioRxiv preprints. Elife. 2019;8. doi:10.7554/eLife.45133
12. Fraser N, Momeni F, Mayr P, Peters I. The relationship between bioRxiv Preprints, citations and altmetrics. Quant Sci Stud. April 2020:1-21. doi:10.1162/qss\_a\_00043
13. Gertel A. The Data economy | Rush to publication – what do we have to lose? Med Writ. 2020;29(2).
14. Maslove DM. Medical preprints – a debate worth having. JAMA – J Am Med Assoc. 2018;319(5):443–4. doi:10.1001/jama.2017.17566
15. Penfold NC, Polka JK. Technical and social issues influencing the adoption of preprints in the life sciences. Shafee T, ed. PLOS Genet. 2020;16(4):e1008565. doi:10.1371/journal.pgen.1008565
16. F1000Research. About F1000Research | how it works | beyond a research journal. F1000Research. 2020. [cited 21 Sep 2020] Available from: <https://f1000research.com/about>.
17. Wiley. Catheterization and cardiovascular interventions. Author Guidelines. Wiley. [cited 21 Sep 2020] Available from: <https://onlinelibrary.wiley.com/page/journal/1522726x/homepage/forauthors.html>.
18. Bell GP, Kvajo M. Tackling waste in publishing through portable peer review. BMC Biol. 2018;16(1):146. doi:10.1186/s12915-018-0619-z
19. Taylor & Francis. Article transfers – author services. Taylor & Francis. [cited 21 Sep 2020] Available from: <https://authorservices.taylorandfrancis.com/peer-review/transfers/>.
20. Wiley. Free Format Submission. Wiley. [cited 21 Sep 2020] Available from: <https://authorservices.wiley.com/author-resources/Journal-Authors/Prepare/free-format-submission.html>.
21. Tennant JP, Ross-Hellauer T. The limitations to our understanding of peer review. Res Integr Peer Rev. 2020;5(1):6. doi:10.1186/s41073-020-00092-1
22. Battisti WP, Wager E, Baltzer L, et al. Good publication practice for communicating company-sponsored medical research: GPP3. Ann Intern Med. 2015;163(6):461–4. doi:10.7326/M15-0288
23. ICMJE. Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals. ICMJE. 2020. [cited 21 Sep 2020] Available from: <http://www.icmje.org/recommendations/>.
24. Matcham J, Julious S, Pyke S, et al. Proposed best practice for statisticians in the reporting and publication of pharmaceutical industry-sponsored clinical trials. Pharm Stat. 10(1):70-73. doi:10.1002/pst.417
25. COPE: Committee on Publication Ethics. Ethical guidelines for peer reviewers. 2017. doi:10.24318/cope.2019.1.9.
26. The Editors of the Lancet Group. Learning from a retraction. Lancet. 2020;396(10257):1056. doi:10.1016/S0140-6736(20)31958-9.
27. Jacobs A. Adherence to the CONSORT guideline in papers written by professional medical writers. Med Writ. 2010;19(3):196–200.
28. Gattrell WT, Hopewell S, Young K, et al. Professional medical writing support and the quality of randomised controlled trial reporting: a cross-sectional study. BMJ Open. 2016;6(2):e010329. doi:10.1136/bmjopen-2015-010329
29. Bailey M. Science Editing and its effect on manuscript acceptance time. J Am Med Writ Assoc. 2011;26:147–52.
30. Hamilton CW, Gertel A, Jacobs A, Marchington J, Weaver S, Woolley K. Mythbusting medical writing: Goodbye ghosts, hello help. Account Res. 2016;23(3):178–94. doi:10.1080/08989621.2015.1088788.
31. Woolley KL, Ely JA, Woolley MJ, et al. Declaration of medical writing assistance in international, peer-reviewed publications and effect of pharmaceutical sponsorship. Fifth Int Congr Peer Rev Biomed Publ Chicago. 2006;296(8):932–934. doi:10.1001/jama.296.8.932-b.
32. Breugelmans R, Barron JP. The role of in-house medical communications centers in medical institutions in nonnative english-speaking countries. Chest. 2008; 134(4):883–5. doi:10.1378/chest.08-1068
33. Manring MMM, Panzo JA, Mayerson JL. A framework for improving resident research participation and scholarly output. J Surg Educ. 2014;71(1):8–13. doi:10.1016/j.j Surg.2013.07.011
34. Woolley KL, Lew RA, Stretton S, et al. Lack of involvement of medical writers and the pharmaceutical industry in publications retracted for misconduct: a systematic, controlled, retrospective study. Curr Med Res Opin. 2011;27(6):1175–82. doi:10.1185/03007995.2011.573546
35. Chipperfield L, Citrome L, Clark J, et al. Authors' submission toolkit: a practical guide to getting your research published. Curr Med Res Opin. 2010;26(8):1967–82. doi:10.1185/03007995.2010.499344
36. The EQUATOR Network | Enhancing the QUALity and Transparency Of Health Research. [cited 21 Sep 2020] Available from: <https://www.equator-network.org/>.



## Appendix I. Reviewers' checklist

This checklist is intended to be used by journals. However, it can also guide authors and medical writers in their review of manuscripts before submission.

The checks should be performed by a suitably qualified team, preferably consisting of editors, subject matter experts (i.e., peer reviewers; not required for preprints), medical writers, statisticians, and trained researchers. The review team should comprise at least two reviewers.

Not every reviewer is required to complete all fields, but all items need to be checked by at least one accountable reviewer.

| Item                                                                                                                                                                  | Medical Writer Reviewer | Clinical Reviewer | Biostatistical Reviewer | Peer Reviewer A | Peer Reviewer B |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|-------------------|-------------------------|-----------------|-----------------|
| <b>Source documents (if available and required by journal)</b>                                                                                                        |                         |                   |                         |                 |                 |
| Clinical Study Protocol                                                                                                                                               |                         |                   |                         |                 |                 |
| Redacted Clinical Study Report Synopsis                                                                                                                               |                         |                   |                         |                 |                 |
| Statistical Analysis Plan                                                                                                                                             |                         |                   |                         |                 |                 |
| Tables/Listings/Graphs                                                                                                                                                |                         |                   |                         |                 |                 |
| <b>Attestations</b>                                                                                                                                                   |                         |                   |                         |                 |                 |
| Data sharing statement (ICMJE template)                                                                                                                               |                         |                   |                         |                 |                 |
| Author contribution form <sup>a</sup>                                                                                                                                 |                         |                   |                         |                 |                 |
| Signed author forms confirming that the authors had full access to the data reported in the article and accept responsibility for submitting the article <sup>b</sup> |                         |                   |                         |                 |                 |
| Author confirmation that verified data were used to develop the manuscript                                                                                            |                         |                   |                         |                 |                 |
| Conflict of interest statement (ICMJE template recommended)                                                                                                           |                         |                   |                         |                 |                 |
| List of sources of funding for the study and any supporting activities                                                                                                |                         |                   |                         |                 |                 |

| Item                                                                                                                                                                                                                                                                                        | Medical<br>Writer<br>Reviewer | Clinical<br>Reviewer | Biostatistical<br>Reviewer | Peer<br>Reviewer A | Peer<br>Reviewer B |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|----------------------|----------------------------|--------------------|--------------------|
| <b>Suggested Checks for Preprint Editorial Review</b>                                                                                                                                                                                                                                       |                               |                      |                            |                    |                    |
| Manuscript contains no offensive or nonscientific content                                                                                                                                                                                                                                   |                               |                      |                            |                    |                    |
| No material is plagiarised                                                                                                                                                                                                                                                                  |                               |                      |                            |                    |                    |
| Basics of the statistical methods are sound<br>(e.g., adequacy of analysis population,<br>adequate handling of missing data)                                                                                                                                                                |                               |                      |                            |                    |                    |
| Endpoints and inclusion/exclusion criteria are in<br>alignment with the study registration on a publicly<br>available registry (e.g., ClinicalTrials.gov),<br>provided this is required. For primary reports<br>of clinical trials, all end points are mentioned<br>in the results section. |                               |                      |                            |                    |                    |
| Content is consistent and clear across each section<br>of the manuscript (e.g., information in abstract<br>matches results, hypothesis posed in introduction<br>is addressed in discussion)                                                                                                 |                               |                      |                            |                    |                    |
| Discussion points and conclusions are supported by<br>the reported data                                                                                                                                                                                                                     |                               |                      |                            |                    |                    |
| Adherence to guidelines (e.g., CONSORT, STROBE,<br>PRISMA, SPIRIT, CARE)<br>Specify guideline(s): _____                                                                                                                                                                                     |                               |                      |                            |                    |                    |
| No ethical concerns                                                                                                                                                                                                                                                                         |                               |                      |                            |                    |                    |

|                                                                                                                                                                                                                                                                                                                        |  |  |  |  |  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|--|--|
| <b>Additional Checks for Peer Review</b>                                                                                                                                                                                                                                                                               |  |  |  |  |  |
| <b>Further statistical considerations:</b> <ul style="list-style-type: none"> <li>adequacy of sample size calculation (e.g., adequate comparator)</li> <li>adequacy of statistical methods</li> <li>check for random errors</li> <li>sources of bias addressed</li> </ul>                                              |  |  |  |  |  |
| <b>Methodological quality<sup>c</sup></b> <ul style="list-style-type: none"> <li>confounding influences (e.g., concomitant treatments)</li> <li>inadequate disclosure of information</li> <li>misinterpretation</li> </ul>                                                                                             |  |  |  |  |  |
| <b>Study design<sup>b</sup></b> <ul style="list-style-type: none"> <li>adequacy and relevance of endpoints</li> <li>adequacy of inclusion/exclusion criteria</li> <li>blinding</li> <li>adequacy of follow-up period</li> <li>adequacy of reporting of complications</li> <li>adequacy of data presentation</li> </ul> |  |  |  |  |  |

<sup>a</sup> Should include a question if medical writing support was used.

<sup>b</sup> May be merged with author contribution form.

<sup>c</sup> Adapted from MEDDEV 2.7/1; alternatively, other criteria can be used to appraise the manuscript (eg, <https://libguides.napier.ac.uk/litrev/critapp>).

Additional columns and signature lines can be added as needed.

|                 |                  |
|-----------------|------------------|
| Reviewer: _____ | Signature: _____ |
| Reviewer: _____ | Signature: _____ |