## INTRODUCTION

### Maintenance of Quality in Publications During Public Health Emergencies

Timely release of data in the form of peer-reviewed publications is crucial in medical research and necessary for productive scientific discourse. However, during public health crises such as a pandemic, the need to communicate science rapidly can lead to abbreviated vetting and substantially increase the risk of compromised quality and accuracy in data analysis and reporting. Indeed, the pressing requirement for speed in tackling a pandemic and the necessary collaboration between academia, industry, and regulatory agencies on an international level creates a significant dilemma: the need to rapidly release data on PubMed Central and other resources, such as the World Health Organization's databases, while upholding the quality of the communication and the data. Maintenance of integrity and accuracy in scientific publications via a thorough vetting process prior to public release requires time and implementation of quality-control measures. Medical communicators have an important role to play in this process.

By way of their speed, some publication modalities, such as preprints, may seem particularly attractive when quick release of information and rapid scientific discourse is desired. However, because such preliminary scientific reports are generally not subject to thorough peer review, there is an inevitable increase in the concomitant risk of lower quality and lack of precision. Thus, full disclosure of whether a publication has been peer-reviewed and transparency about the quality-control process are absolutely required.

In this Joint Position Statement (JPS) from AMWA, EMWA, and ISMPP, we provide suggestions and a structured framework, including a number of practical recommendations that can be implemented to help maintain quality and avoid damaging public trust in scientific and medical communication. The practical recommendations in the current JPS are intended to support quality-control processes in both the acute phase of intense reactions during the course of a public health emergency as well as the longer-term evergreen need to maintain quality in medical publications. The persistent call for rapid sharing of scientific advances against a firm background of insistence on high quality enables acceleration of medical innovation. Safeguards are presented as a clear and concise checklist that can be used by journals, authors, and medical communicators in the preparation and review of manuscripts before submission.


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***Author declaration and disclosures:*** *The authors note no commercial associations that may pose a conflict of interest in relation to this article.*

This joint position statement originally appeared in *Current Medical Research and Opinion*, DOI: 10.1080/03007995.2021.1900365.


# AMWA–EMWA–ISMPP Joint Position Statement on Medical Publications, Preprints, and Peer Review

## 1. 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[1] 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.[2] Recent examples of negative consequences are two articles on COVID-19 that were hastily published in high-profile medical journals and subsequently retracted.[3,4]

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.[2]

We have joined in a multi-party consortium among three eminent professional organizations 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.[5]

## 2. COMMUNICATION OF RESEARCH: ISSUES AND SUGGESTED SOLUTIONS

### 2.1. 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.[6-8] 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,[9] and there are standalone tools for searching named preprint servers to improve discoverability.[10]

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.[11,12]
- "Once the toothpaste is out of the tube, it cannot (easily) be stuffed back in."[13] 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.[14,15] 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.[14,15] 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.[7] 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.

### 2.2. 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,[16] 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 comments 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 for 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.

### 2.3. 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).[17,18]
  - Be more accepting of editor referrals to cascade journals.[19]
- 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, ResearchSquare [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:
  - Standardize formatting requirements to expedite resubmission.[20]
  - Offer fast-track options for potentially practice-changing work.
  - Consider incentives for reviewers.[21]

## 3. SUGGESTED SOLUTIONS FOR ALL FORMATS

### 3.1. Quality control

- Make use of existing publication guidelines[22–24] and available checklists[25] 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, and accept 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.[26]
- Journals should clearly explain the initial quality review that editors perform on newly submitted manuscripts.

### 3.2. 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),[25] 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.

## 4. 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,[27–33] and such assistance has been associated with a reduced risk for retractions due to misconduct.[34] If a qualified medical writer is

part of the team, they should be involved in the process as early as possible.[5] 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,[22,24,35] and the use of appropriate publication checklists.[36] 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 Section 3.2).

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.

## 5. ACKNOWLEDGMENTS

This joint position statement was reviewed and approved by representatives of AMWA, EMWA, and ISMPP. It was also reviewed and approved by representatives of EFSPI (European Federation of Statisticians in the Pharmaceutical Industry). Preparation of this statement was possible thanks to the efforts of the members of the Writing Committee (Slavka Baronikova, Beatrix Doerr, Art Gertel, Andrea Rossi, EMWA; Gail V. Flores and Dikran Toroser, AMWA; Jackie Marchington and Rob Matheis, ISMPP; and Todd Pesavento, The Ohio State University). Also, we thank the independent reviewers, Alison Abritis, Andrea Bucceri, Andrea Cortegiani, Martin Delahunty, Lisa Chamberlain-James, Paolo Morelli, Roger Pickett, Gregory A. Poland, Thomas M. Schindler, and Amy Whereat for their review, insights into further actions, and encouragement.

## 6. APPENDICES

Appendix I: Reviewers' checklist

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## 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 (ie, 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 |
|---|---|---|---|---|---|
| **Source documents (if available and required by journal)** | | | | | |
| Clinical Study Protocol | | | | | |
| Redacted Clinical Study Report Synopsis | | | | | |
| Statistical Analysis Plan | | | | | |
| Tables/Listings/Graphs | | | | | |
| **Attestations** | | | | | |
| Data sharing statement (ICMJE template) | | | | | |
| Author contribution form[a] | | | | | |
| Signed author forms confirming that the authors had full access to the data reported in the article and accept responsibility for submitting the article[b] | | | | | |
| 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 | | | | | |
| **Suggested Checks for Preprint Editorial Review** | | | | | |
| Manuscript contains no offensive or nonscientific content | | | | | |
| No material is plagiarized | | | | | |
| Basics of the statistical methods are sound (eg, adequacy of analysis population, adequate handling of missing data) | | | | | |
| End points and inclusion/exclusion criteria are in alignment with the study registration on a publicly available registry (eg, ClinicalTrials.gov), provided this is required. For primary reports of clinical trials, all end points are mentioned in the results section. | | | | | |
| Content is consistent and clear across each section of the manuscript (eg, information in abstract matches results, hypothesis posed in introduction is addressed in discussion) | | | | | |
| Discussion points and conclusions are supported by the reported data | | | | | |
| Adherence to guidelines (eg, CONSORT, STROBE, PRISMA, SPIRIT, CARE)<br>Specify guideline(s):_____ | | | | | |
| No ethical concerns | | | | | |
| **Additional Checks for Peer Review** | | | | | |
| Further statistical considerations:<br>- adequacy of sample size calculation (eg, adequate comparator)<br>- adequacy of statistical methods<br>- check for random errors<br>- sources of bias addressed | | | | | |
| Methodological quality[c]<br>- confounding influences (eg, concomitant treatments)<br>- inadequate disclosure of information<br>- misinterpretation | | | | | |
| Study design[b]<br>- adequacy and relevance of endpoints<br>- adequacy of inclusion/exclusion criteria<br>- blinding<br>- adequacy of follow-up period<br>- adequacy of reporting complications<br>- adequacy of data presentation | | | | | |

[a]Should include a question if medical writing support was used.
[b]May be merged with author contribution form.
[c]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.

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# CALENDAR OF MEETINGS

***Please confirm with individual meeting hosts***



**DIA**
June 27 to July 1, 2021
Virtual
https://www.diaglobal.org/Flagship/DIA-2021

**Regulatory Affairs Professionals Society**
September 12–15, 2021
Virtual
https://www.raps.org/regulatory-convergence

**National Association of Science Writers**
October 8–11, 2021
Boulder, Colorado, and Virtual
https://www.nasw.org/events/sciencewriters2021

**International Society of Managing and Technical Editors**
October 11–14, 2021
Virtual
https://www.ismte.org/page/Conferences

**International Conference on Communication in Healthcare**
October 17–20, 2021
Virtual
https://achonline.org/ICCH2021

**American Public Health Association**
October 24–27, 2021
Denver, Colorado, and Virtual
https://www.apha.org/events-and-meetings/annual

**AMWA Medical Writing & Communication Conference**
October 27–29, 2021
Virtual
www.amwa.org/conference

**Association of Health Care Journalists**
October 28–31, 2021
Austin, TX
https://healthjournalism.org/calendar-details.php?id=2245

**European Medical Writers Association**
November 4–6, 2021
Cascais, Portugal
https://www.emwa.org/conferences/future-conferences/