

Medical Ethics

Publication ethics during the Covid times: Reflections on research integrity, authorship, peer review and editorial policies

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Most investigators are well aware of research ethics. However, it is not so with regard to publication ethics especially among junior researchers and postgraduate students.¹ Recent circumstances have prompted researchers to re-inform themselves about ethical aspects of not only carrying out scientific investigations in human beings and animals as prescribed in the framework of the institute human and animal ethics committees, but also of reporting the results. However, questions and ambiguities remain about publication ethics. Authors are expected to adhere to the guidelines of the Committee on Publication Ethics (COPE) and recommendations of the International Committee of Medical Journal Editors (ICMJE) on publishing high-quality articles, maintaining public trust in scientific findings and ensuring due credit for their contributions.^{2,3} Fabrication or falsification of data, plagiarism, redundant publications and improper credit sharing are to be avoided. As we witness a publication surge during the Covid-19 pandemic, it is time to consider 'research integrity' in a holistic manner, including publication ethics.

The general public has taken extra interest in medical research during the Covid times. We are experiencing a heightened spirit and vigour of scientific investigations in unravelling the mystery of the pandemic and in developing treatment and prevention strategies. At the same time, some published studies have aroused considerable controversy raising serious questions about research integrity and publication ethics. However, even in the midst of the darkness, there are silver linings of hope. Here, we underscore the substantial impact of the COPE guidelines and its beacon effect in ensuring scientific integrity during this pandemic, which has led to a surge in publications.

Extreme competition, the pressure to publish first, and the desire for publicity and fame prompt researchers to adopt questionable methods to conduct the studies and introduce bias in interpreting the results. During the early phase of the Covid-19 pandemic, a study published in *The Lancet* reported safety issues and increased deaths with chloroquine treatment in Covid-19 patients.⁴ The study was based on data collected

from medical records of 96 000 patients from 671 hospitals from all over the world. This publication prompted the WHO and others to immediately suspend ongoing trials with chloroquine and hydroxychloroquine in patients with Covid-19. However, the paper provoked criticism and concerns were raised by the scientific community about the authenticity of the data and its analysis. This compelled the journal to issue an expression of concern alerting readers that serious scientific questions about the study have been brought to its attention and the readers would be updated about the third-party audit of the data commissioned by the authors.⁵ Meanwhile, some of the authors requested for retraction of the article because Surgisphere Corporation, the US-based company that provided data did not provide full access to the information for the third-party peer review, stating client agreements and confidentiality violation, and the authors were not in a position to assure the veracity of the data.⁶ Subsequently, another paper on the use of angiotensin-converting enzyme (ACE) inhibitors in Covid-19 patients, which used data from the Surgisphere database, and authored by some of the same individuals, was retracted from the *New England Journal of Medicine*.⁷⁻⁹

These are not the first retractions in leading journals and the retraction of a published paper is not so uncommon as well. Most guidelines on retractions are given by COPE, which state when editors should consider retraction of a publication.¹⁰ So, what is peculiar about these two retractions? First, this happened during a pandemic and the study has immediate policy implications for the treatment of the disease causing the pandemic. Second, nowhere in the recent past have papers in leading medical journals aroused such sharp criticism from peers and the wider scientific community. Third, the authors themselves came forward to accept the shortcomings and requested for retraction. Another aspect of concern here is the lack of collective accountability of the authors in the case of *The Lancet* retraction where three of the four authors requested for retraction. Yet another point to note is that the academic researchers in this academia-industry collaborative work did not have access to the data from the company.

Now, what were the effects of these retractions on journal policies? *The Lancet* immediately made changes to its editorial policies and it is now necessary that the author statement form requires a statement that more than one author has directly accessed and verified the reported data.¹¹ The authors who have accessed and verified the data are to be named in the contributor's statement. For articles arising from academic and commercial partnerships, one of the named authors must be from academia. In addition, all authors need to sign and confirm that they have full access to the data reported and accept responsibility for submission for publication. Changes have

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been made in the peer review policies as well. The *Lancet* journals now have additional peer-review requirements for papers based on large, real-world datasets. A review from an expert in data science will be sought; editors will ensure that at least one peer reviewer is knowledgeable about the details of the dataset being reported, and the reviewers are also encouraged to report any concern on research integrity or publication ethics about the manuscript they have reviewed.¹¹

In this context, it is apt to point out the debates related to another published study as well. We refer to the first report on the possible beneficial effect of chloroquine and azithromycin for treating patients with Covid-19.¹² This publication raised an unrealistic hope of treatment for Covid-19 infection. The study elicited sharp disapprovals from the scientific community for methodological and ethical reasons, and a rapid peer review with potential violation of publication ethics. The editor-in-chief of the journal was a co-author of the publication. This paper was not retracted; however, statements were issued by the International Society of Antimicrobial Chemotherapy (ISAC) and by the publisher Elsevier.^{13,14} The ISAC stated that the ‘article does not meet the Society’s expected standard, especially relating to the lack of better explanations of the inclusion criteria and the triage of patients to ensure patient safety’. It went on to state that the editor-in-chief was not involved in peer review and best practices were followed. Thus, it became clear that the pandemic necessitated a review of the authorship criteria through the COPE guidelines. Notably, the lack of benefit of chloroquine during the interim analysis of the SOLIDARITY trial by WHO underscored the doubts raised by the critiques on the results of a small preliminary study.¹⁵ The role of chloroquine for the treatment or prophylaxis of Covid-19 infection was debated and has been discarded after scientific scrutiny. The preliminary study results need to be treated cautiously and there is a need for restraint and show of maturity by the authors, reviewers, editors, publishers, policy-makers, media and the general public.

The authorship criteria also developed faultlines during the pandemic, with author non-responsiveness becoming an issue. Due to multiple reasons, all the authors could not contribute to the scholarly work till the completion of the manuscript and its approval by all authors (criteria 4 by ICMJE). In this scenario, The International Society for Medical Publication Professionals (ISMPP) proposed recommendations to preserve proper attribution of researchers to scholarly work in instances where the pandemic has resulted in author non-responsiveness.¹⁶ The recommendation is: ‘For situations in which there is a candidate for authorship who has previously met ICMJE Criteria 1 and 2, and there is a reasonable rationale to believe that coronavirus disease has contributed to a state of non-responsiveness or inability to complete authorship duties with respect to Criteria 3 and 4, the remaining panel of authors may elect the following course of action in order for the scientific journal or congress to render a final decision.

1. ‘Following a reasonable period of documented attempts to reach the author, proceed with submission to the peer-review journal or congress, including the affected individual as a by-line author who has previously achieved ICMJE Criteria 1 and ICMJE Criteria 2. It is understood that the inclusion of the individual as an author shall be agreed upon by all authors who have fully met the four ICMJE Criteria. It is further understood that the work can be submitted provided that other authors approve the

publication and accept responsibility for the work, as is required by ICMJE Criteria 4.

2. ‘As a matter of full disclosure, provide an accompanying statement to the journal or congress to transparently represent that ICMJE Criteria 3 and/or Criteria 4 were not fully achieved by the affected author.’

Most national and international journals and publishing houses have remained diligent and sensitive about publication ethics during the Covid-19 pandemic, strictly adhering to the COPE guidelines and maintained the sanctity of truthful enquiry, which is vital for public trust in the scientific establishment. Within India, research integrity is crucial during the Covid-19 crisis, given the need for robust, evidence-based conclusions, urging the research community to respect the highest integrity standards in performing and reporting research. It is desirable to have a research integrity office in every organization or institute conducting health research especially medical colleges to provide a formal forum to address and resolve issues related to research integrity and publication ethics and to promote awareness among young researchers, in accordance with the guidelines set forth by the national research organizations and funding bodies such as the Indian Council of Medical Research (ICMR), Council for Scientific and Industrial Research (CSIR) and the University Grants Commission (UGC).¹⁷⁻¹⁹

In short, strict adherence to COPE and ICMJE guidelines by the authors, reviewers and editors, close monitoring by the Research Integrity Office of the institutions and the independent critical scientific evaluation by the vigilant readers are essential for upholding public trust in the scientific establishment. Though rapid decisions are desirable especially during situations such as pandemics, editors should stay true to journal policies, maintain high standards of peer review and transparency.

Conflicts of interest. None declared

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