

An editorial perspective on the infamous COVID-19 studies retracted by Lancet and NEJM

Over the past 1 month, a story of extreme deceit, data fabrication and publication fraud has emerged from some of the very top journals in medicine. I am certain that by now, most of you have heard about the retracted papers on hydroxychloroquine (HCQ) by Lancet,^[1,2] and on cardiovascular disease, drug therapy and mortality related to COVID-19 by the New England Journal of Medicine.^[3,4] Incidentally, both these papers were written by the same authors and data were derived from the same international registry, the validity of which could not be confirmed by independent review teams. The paper claiming that HCQ lead to serious cardiovascular side effects caused ripple effects throughout the scientific community,^[1] and prompted the World Health Organization (WHO) to temporarily halt recruitment of the international Solidarity trial, evaluating the role of HCQ in COVID-19.^[5]

With the retractions, one might believe that justice has been done. However, credit must still be given to the journals, their editors who expressed concern,^[6] and above all, the lead author who has swallowed his ego and done the right thing by publicly apologizing and asking for a retraction himself.^[2] It takes a lot of courage to admit a mistake, and in my opinion, these retractions should restore faith in the peer review process once again. The fact that these papers were caught red-handed almost instantaneously means that the retractions were timely and not much scientific damage was done. However, I wonder whether psychological damage is done in the minds of physicians who believed in these journals as gospels. In the wake of these events, we seem to be suddenly questioning the very foundations of evidence-based medicine and trying to find reasons to discredit decades of honestly done scientific research that has influenced our practice patterns. An even more dangerous precedent is also emerging amongst many elite and senior physicians who once again recommend falling back on clinical acumen and personal experience and not on data-driven recommendations. This is an impression that is difficult to reverse, can spread very quickly and impact impressionable young minds, which represent the future of healthcare. The real question is, can you trust yourself and your acumen all the time, and on what basis? It's hard to see trends and see what is working and what is not until you analyze your results critically and your findings are accepted by your peers. I think there is still a lot of merit in data-driven recommendations rather than anecdotes and personal experience. I appeal to you to still believe in these fundamentals.

The journey of a research paper from concept to fruition goes through many sieves and faces many checks and balances before it is in print. In these retracted papers, a lot of these balances seem to have been missed. The author's misconduct of using potentially fabricated data (or at least some of it) notwithstanding, the journal review process missed the fact that the source of the data might be fraudulent. But if you review the published papers carefully, you will notice that everything looks perfectly in place to the naked eye,

even to expertly trained eyes of the reviewers who might have reviewed it. The study design looked impeccable, the statistics were good, and the results were expertly presented and discussed beautifully. But the reviewers failed to see the fact that it is next to impossible to have an international registry of the sort mentioned in the paper due to data protection laws, different data formats, de-identification issues and many more hurdles. One must also remember that when the rewards of publishing in the apex journals are huge, the risks taken to commit and then hide misconduct are also huge. The owner of the registry, who was highly likely to have financial interests in publishing such a paper and claim credit and publicity for his database, was the second author in both the Lancet and NEJM papers. Ironically, he has authored papers on ethics and fraud in research himself.^[7] It is easy to point these out in retrospect but it is a major lapse on the part of the reviewers to have missed this. But let's face it, most journal editors and reviewers do not ask for the datasheet in 99.99% of cases. However, after this fiasco, this might change. We will now see more and more journals asking authors to submit their datasheets along with their manuscript submissions. For journals who don't, it may be prudent for the authors to themselves upload their datasheets on online repositories such as research gate or research square and mention this in their manuscript cover letters.

Retractions are extremely serious events for any journal and taken very seriously by the editorial board, the parent scientific organization the journal represents, the publisher, and the indexing authorities. At the beginning of the tenure of the current editorial board of the Indian journal of ophthalmology, we had published an editorial on publication ethics covering all these topics including data fabrication, publication fraud, plagiarism and retractions.^[8] Most guidelines on retractions are given by the committee of publication ethics (COPE), which state that "editors should consider retracting a publication if they have clear evidence that the findings are unreliable, either as a result of major error (e.g., miscalculation or experimental error), or as a result of fabrication (e.g., of data) or falsification (e.g., image manipulation), it constitutes plagiarism, the findings have previously been published elsewhere without proper attribution to previous sources or disclosure to the editor, permission to republish, or justification (i.e., cases of redundant publication), it contains material or data without authorization for use, copyright has been infringed or there is some other serious legal issue (e.g., libel, privacy), it reports unethical research, it has been published solely based on a compromised or manipulated peer review process, the author(s) failed to disclose a major competing interest (a.k.a. conflict of interest) that, in the view of the editor, would have unduly affected interpretations of the work or recommendations by editors and peer reviewers.^[9] The notice of retraction should be published with the link to the retracted paper and with clear reasons for retraction. The retracting authority should also be declared. In the current case, the authors themselves asked for a retraction and furnished an apology which was published online.^[2,3] We follow the same guidelines given by the COPE at IJO and the editorial board is ever vigilant so that papers with major deficiencies do not slip through the sieves of our review process.

In conclusion, the past month has possibly witnessed the biggest attempted heist in the history of scientific publications, akin to the Cambridge Analytica fiasco during the American presidential elections in 2016. This attempt at maligning the entire fundamentals of clinical research is worthy of protests and black armbands. But lets not vilify honest attempts at clinical research and data-driven recommendations for patient care, which ultimately supplement your acumen and help you get better results for your patients. Research needs to be meaningful and have clinical applications impacting our practices. Publishing for other motivations might lead you to cut corners and dodge scientific inquiry methods, which is never desirable. When the rewards are large, chances of misconduct are high; hence the editors, reviewers and the readership should have a high index of suspicion to weed these out. The application of clinical research to practice requires you to critically analyze papers, and question its validity before adopting the treatment guidelines.

Before parting, I would like to emphasize that the onus of treating patients is ultimately on us. Let us all tighten up and learn some basic techniques of research so that we can make the best decision for patients and perform the best possible research going forwards.

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