

# Rush to publication – What do we have to lose?

Just as the research and development of new drugs requires careful, often painstaking, adherence to empirical processes, the peer-review process and, indeed, the manuscript preparation process, are likewise laborious and time-consuming. The benefits of these are obvious and important, given how critical peer review serves as a “gatekeeper” for the disclosure of new scientific and medical information. However, we must consider weighing the potential value of rapid publication against the potential harm of inadequate vetting (both internal and external) of the final product.

In this time of global great peril where countless lives are held in the balance, are we willing to lower the threshold of scientific integrity for the sake of accelerating the availability of speculative medicinal products? This raises the topic of “situational ethics”. Do desperate times require desperate measures? Added to the traditional dynamic tension between determining what is best for an individual vs. what is best for society at large, is the imminent threat of global pandemic for which there are few, if any, effective measures. Is “No Science” worse than “Bad Science”?

There is no question that bad science does not deserve a forum. However, good science needs to be heard even if some people will twist its meaning. Hopefully, scientists desire the safest and most effective treatment or vaccine and the most reliable diagnostic possible, but these cannot be refined if researchers ignore inconvenient data. Moreover, scientists will earn a lot more public trust, and overcome a lot more unfounded fear, if they choose transparency over censorship.

However, without an appropriate level of pre-publication vetting, how does one determine whether the article is based on good science? Do we have to wait until a more rigorous assessment after the genie is out of the bottle? I would argue that, at that point, the damage is done and no amount of retroactive “tagging” will have much effect. In a rush to “publish” studies that have not undergone traditional levels of scrutiny, unnecessary harm could easily result. Once “the toothpaste is out of the tube”, it cannot easily (if, at all) be stuffed back in. Thus, in an online era, the misinformation is free to be circulated, cited, and believed *ad infinitum*, regardless of whether

it is ultimately debunked and retracted. It should be noted that, at the time of this writing, Retraction Watch reports that 15 COVID-19 articles have been retracted, two temporarily retracted, and one has generated an expression of concern.<sup>1</sup>

The “poster child” example of the dissemination of fraudulent research findings is *The Lancet’s* 1998 publication of Andrew Wakefield’s article linking the MMR (Measles-Mumps-Rubella) vaccine to autism – which, it should be noted, wasn’t retracted until 12 years post-publication – and that was in the pre-open access, on-line era. Anti-vaxxers have taken to treating any attempts to discredit the Wakefield data as part of a conspiracy among a cabal, including the pharmaceutical industry, Bill Gates, and the “Deep State”, intent on reaping huge financial gain at the expense of innocent children. Refusal to vaccinate results in a degradation of one of the founding principles of immunology – that of herd immunity. For example, if 80% of a population is immune to a virus, four out of every five people who encounter someone with the disease won’t get sick (and won’t spread the disease any further). In this way, the spread of infectious diseases is kept under control. Depending on how contagious an infection is, usually 70% to 90% of a population needs immunity to achieve herd immunity.

Should researchers handle findings differently when there is a chance they might frighten the public? Perhaps small, inconclusive, worrying studies should not be published because they could do more harm than good. Dr Paul Offit, director of the Vaccine Education Center at the Children’s Hospital of Philadelphia states: “Knowing that you’re going to scare people, I think you have to have far more data.”<sup>2</sup>

One could argue that even an inconclusive paper can be important, as it can spur the larger, more definitive studies that are needed. It should be “put out there for the scientific community, to look at it, see it, know about it, refine study design and go and look again,” says Gregory Poland, a Mayo Clinic vaccinologist and the Editor-in-Chief of *Vaccine*. It is crucial, though, for researchers to carefully explain such results in their papers to prevent misinterpretation. Even with appropriate disclaimers and cautions, however, nothing can prevent the “cherry-picking” of

data to support one’s particular *cause célèbre*.

*The New York Times* recently published an essay<sup>3</sup> in which the author noted:

*As scientists race to understand the coronavirus, the process of designing experiments, collecting data and submitting studies to journals for expert review is being compressed drastically. What typically takes many months is happening in weeks, even as some journals are receiving double their normal number of submissions.*

The author brings into high relief how we should view the role of the medical/scientific journal:

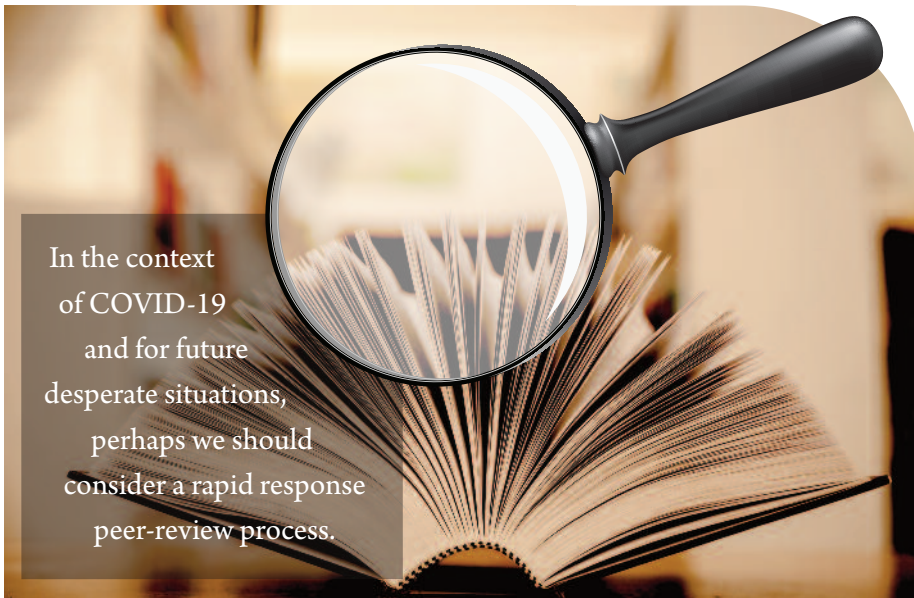
*Should it be an arbiter of facts or a generator of new ideas? A keeper of the historical record or a predictor of the future? A private channel for scientists to communicate with one another or a megaphone with which they can reach the public? Or all of the above?*

In a world in which what is published today may strongly influence the practice of medicine, governmental policy decisions, and individual choices about social behaviour (e.g., mask-wearing, social distancing, resuming “normal” activities), releasing information that may be flawed, disingenuous, fraudulent, or politically influenced can have grave consequences. This is particularly true in an era fraught with conspiracy theorists who command huge audiences through on-line social media platforms.

Of course, there are even more egregious, and less-controlled pathways, of data release. Examples include the irresponsible (and unethical) Gilead teleconference, during which single-site data were shared and discussed among investigators, thereby undermining the principles and protections of Good Clinical Practice. I will not even delve into the promotion of completely unfounded claims from the podium by certain heads of state.

## Improving the process

In the context of COVID-19 (and for future desperate situations), perhaps we should consider a “rapid response peer-review” process, comprising experts in applicable fields (virology, immunology, epidemiology etc.) who volunteer to drop everything at a moment’s notice to give



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at least a “cursory” peer review of any COVID-19 manuscript submitted to a journal. A 24-hour review deadline could be imposed and, there would at least be *some* assessment of the merits, pre-publication.

The post-publication peer-review process, adopted by F1000,<sup>4</sup> provides a pathway for peer-reviewed publication in as few as 14 days, with an in-house editorial team conducting a comprehensive set of prepublication checks to ensure that all policies and ethical guidelines are adhered to. Once the authors have finalised the manuscript, the article is published within a week, enabling immediate viewing and citation. However, a caveat is clearly communicated with a stamp noting that the article had not been peer-reviewed by the time of publication. The process next entails a phase of open peer review and user commenting (similar to Wikipedia). Expert reviewers are selected and invited, and their reports and names are published alongside the article, together with the authors’ responses and comments from registered users. Authors are encouraged to publish revised versions of their articles. All versions of an article are linked and independently citable. Articles that pass peer review are indexed in external databases such as PubMed, Scopus, and Google Scholar. This process is sensible; however, it does not address a number of challenges associated with the urgency of the COVID-19 environment: insufficient speed of publication – most authors/institutions would be unwilling to delay publication by at least 14 days; and insufficient prestige – most authors/institutions would want to pre-publish/publish their findings in a prestigious journal. There may also be some issues regarding journal prior publication policies, potentially precluding publication in a journal if the manuscript was pre-published

outside of that journal’s auspices.

During health crises like COVID-19, the urgency of rapid publication may cause pre-publication in scientific journals, with post-publication peer review, to become the predominant pathway for medical researchers. However, we should be wary lest it become the norm under circumstances that may not warrant the relaxation of standard critical vetting processes. It is here that professional medical writers can serve as advisors and remind colleagues that there are well-established processes that should be followed.<sup>5</sup> These usually entail independent critical review, which will go a long way toward better ensuring the scientific quality and integrity of published research.<sup>6</sup>

Checking sources is also important: perhaps more credence can be given to information that comes from respected journals. But it is equally important to remember that even the best peer-reviewed advice is likely to change – and change again – particularly given the “black box” nature of this virus.

Ultimately, it is incumbent upon all of us who are intimately involved in the process of communicating science and medicine to caution

against “first-blush” credibility. At the same time, we must not undermine the integrity of quality research findings, even if rapidly published. With some chagrin, I quote Ronald Reagan: “Trust but verify”. Hopefully, in the final analysis, more good quality will prevail, and we will instill the place of value in a world of facts.

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