PUBLICATION ETHICS: EDITORS' PERSPECTIVES

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The medical literature serves a critical role in the translation of evidence into practice. Although the ethics of research conduct receive considerable attention, much less attention has been focused on the ethics of the publication process. Given how important the process is to the advancement of medicine, this oversight seems unfortunate. This article reviews several salient ethical challenges from the perspective of two editors of a pediatric journal. (*J Pediatr 2006*;149:S39-S42)

he publication process serves an essential role in assessing the validity of science and disseminating information to frontline providers. It is a critical nexus in the chain that translates research into practice, an essential means by which the multibillion dollar medical research enterprise ultimately benefits patients. However, the ethical challenges of the publication process, though recognized as important, have received much less attention than the ethical practice of medicine. This oversight seems unjustifiable given how critical publication of science actually is to the care of patients.

Publication is the final step in the peer review process and represents a formal stamp of approval of any scientific endeavor. Absent it, many are loathe to accept findings, and rightly so. Fewer than 50% of studies presented at academic meetings (including some heralded by the popular press) are ever ultimately published. As journal editors, we are not only the guardians of the peer review process but also the managers of a business, for in fact, that is what journals are. They have subscribers, they have sponsors, and they have advertisers, all of which contribute to the bottom line and keep them in business. What raises the profile of the journal and what constitutes good science can be aligned or can be at least in partial opposition.

There are three ethical imperatives to editing a research journal: maintaining the integrity of science, ensuring the protection of human subjects, and helping science benefit the public. In the day-to-day operation of a journal, however, these imperatives can be at odds with one another as well as in conflict with the business aspects of running a medical journal. This article will review some of the salient ethical aspects of research publication from the perspective of a journal editor including: rejection and the ethics of nonpublication, duplicate publication, Institutional Review Board (IRB) approval, and the integrity of data analyses. We will not discuss the issue of conflict of interest as that topic is discussed elsewhere.²

REJECTION AND NONPUBLICATION

From an ethical standpoint, research that does not get published is, in many ways, as important as research that does. Recent examples of unpublished research demonstrating lack of benefit and manifest harm in the case of selective serotonin reuptake inhibitors in children highlight one way in which the public is put at risk by the failure to communicate findings. Such unethical and deliberate attempts to suppress results may be rare, but there is an ethical imperative to disseminate the results of all well-conducted science, particularly when human subjects have been involved. It is often stated explicitly as part of the informed consent process to prospective research subjects that their participation may help advance science. Advancement of science in no small measure is contingent on the review and dissemination of research findings. Although the principal investigators might gain knowledge as the result of data that they never publish, no other researcher can benefit from this knowledge and hence the value added is greatly diminished.

Recently, a clinical trials registry (www.clinicaltrials.gov) was created. Its purpose is to ensure that all trials being conducted are publicized, thereby increasing transparency and making suppression of data more difficult. But the principal incentive to register is that leading journals will not consider publishing results from unregistered trials, leaving companies that are not necessarily interested in publishing findings largely unaffected. Moreover, this registry only applies to randomized controlled trials, so the results of other studies, including those that show harm (eg, case-control studies), may never be known if authors choose to suppress results.

Besides conscious suppression of results, why does some sound science never get

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Institutional Review Board

IRB

Table.			
		Topic Notable	
		Yes	No
Science Rigorous	Yes	Accept	????
	No	????	Reject

published? The decision to submit an article for publication resides with the researchers and they should be ethically bound to pursue publication, but the decision to accept it or not resides with the editors.

In passing final editorial judgment on an article, we frequently ask ourselves, "Are the findings notable?" Notability comes in at least two varieties. There is research that is scientifically notable, that is, a study is important in terms of its contribution to a scientific field of inquiry and will be of interest to other scientists in that field. It may even provide invaluable insight to other investigators and one day prove to be a critical step in a multi-step process of discovery. Rarer still, it may have direct implications for patient care or public health policy. But there is another type of notability that has to do with the inherent public interest of a manuscript, sometimes referred to as the "New York Times test." This type of notability is not to be dismissed out of hand. Sensationalism notwithstanding, one can well imagine that the public interest in findings has at least some correlation with the inherent value of the science to society. Stem cell research for example, which, in its infancy, has failed to deliver any tangible benefit, has gained enormous public support, bespeaking the public's deep desire for progress in many diseases for which it is purported to hold promise. The media attention it has received suggests that there is at least the perception that the area is important, and early studies of stem cell research are certain to be heralded by the press (and welcomed by journal editors).

Most journal editors will say on the record that public interest does not drive their editorial decision making. Those that say this are being, at least partially, disingenuous. Each month, we receive a listing of all of the press coverage that our articles have generated. At our annual editorial meeting, we review which articles garnered the most attention in the popular press in the past year. Publicly, we state that we are looking for impeccable science that is also of keen interest to consumers—and we are—but this represents a fraction of the articles we review. Epidemiologists (myself included) make their living thinking of 2×2 tables. The Table illustrates one that relates to these trade-offs.

If the topic is notable and the science is rigorous, the editorial decision to accept is easy. Conversely, if the topic is not notable and the science is flawed, the decision to reject is also easy. The ethical quandaries in the review process arise in the cross corners. How should we deal with a manuscript that is scientifically sound, and might even be of interest to other researchers, but that our readership (mostly practicing physicians) and the general public would view as ho hum? Or how do we handle a manuscript that is likely to be of extreme interest to the lay press and to practicing pediatricians but that is less than perfectly robust scientifically? These are the editorial decisions that we struggle with and they, in fact, have ethical implications.

As editors (and for that matter as authors), we often take solace in the adage that "there is a journal for every manuscript," so that when we reject something that may be good science but is not of interest to us, the authors have alternative avenues to pursue publication. The avenues are indeed plentiful. There are more than 32,000 journals indexed on Medline alone. But authors frequently lose interest in pursuing publication. More than 80% of the abstracts presented at scientific meetings and subsequently not published are not even submitted for publication.⁴ In following up on the reasons why findings presented at academic meetings were not published, the leading reason cited by authors was lack of time. At least theoretically then, the decision on our part to reject a manuscript should be viewed as possibly determinative of whether or not the findings are ever disseminated, and what we reject may never benefit patients.

DUPLICATE PUBLICATION

In analyzing 141 systematic reviews, von Elm and colleagues found that 40% of them identified what they deemed to be duplicate publication.⁵ The precise definition of what constitutes duplicate publication is frankly murky. 6 Rarely are two identical articles submitted to or published in different journals. The more common scenario is for articles that have significant overlap in terms of data, findings, and implications to be published separately. Authors typically believe—rightly or wrongly—that they are substantively different. From an editor's perspective, in determining if a manuscript is duplicative or not, we find ourselves reminded of Potter Stewart's famous definition of pornography: "I know it when I see it." Authors are obligated to make editors aware of any pending or published manuscripts that may overlap with one they are currently submitting for review. There are two principal ethical implications of duplicate publication. The first is that multiple publications on what amounts to the same data can serve to exaggerate the findings. It can lend the appearance of enhanced credibility, as subsequent authors and readers find multiple citations in support of a statement when, in fact, they represent a single study. The second ethical implication of duplicate publication is that it can displace other worthy science from journals, and perhaps, given lack of persistence on the part of investigators, keep it out of the literature entirely. Journal space, though plentiful, is ultimately a finite resource and should be used judiciously and ethically.

IRB APPROVAL

In their review of articles published in the five leading research journals, Bauchner and Sharfstein noted that 40% failed to report having received IRB approval. Most journals require explicit reference to having received IRB approval. But the statement of approval—or its absence—does little to

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