Navigating the Bermuda Triangle: Dodgy Journal-Author-Industry Relationships

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Speakers:
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The Lancet, Elsevier
New York, NY

Cynthia E Dunbar
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Preventing bias in industry-sponsored publications is challenging and yet essential in avoiding lawsuits and adverse press.

Maja Zecevic began her presentation at the CSE annual meeting with a full disclosure, explaining she is both the North American senior editor of The Lancet and a full-time employee of Elsevier, the journal’s publisher. She also explained the differences between conducting versus reporting on clinical research and the ethical aspects of each.

Zecevic explained several ethical standards in conducting clinical research, such as fair recruitment of participants, having a favorable risk-to-benefit ratio, an external review process to ensure adherence to ethical guidelines, and obtaining written informed consent from each participant. To ignore this protocol—for instance, by not utilizing an ethics review committee or having informed consent of suboptimal quality—could lead to questioning or even investigation later in the reporting and publication stages of the research.

She also explained the globalization of clinical research (one-third of trials from the top 20 US pharmaceutical companies are conducted offshore) has several benefits to those who sponsor the trials, primarily an increase in profits, and when a pharmaceutical company is sponsoring the research, it is involved in the reporting and dissemination of the results. Thus, at the very least, full disclosure is a must.

The Lancet, she continued, employs such practices as providing conflict-of-interest statements for researchers and their sponsors as well as information about the source and role of a study’s funders. It also is the journal’s policy not to allow submissions from authors who are industry employees, not to publish commercially sponsored supplements, and not to allow editorial travel expenses to be covered by for-profit organizations.

The Lancet helps ensure its credibility by using the Standard Protocol Items for Randomized Trials (SPIRIT), a set of 33 standards for scientific, ethical, and organizational matters; and the Medical Publishing Insights and Practices (MPIP), a collaborative effort between industry publication planners and journal editors who have documented ways of enhancing transparency and efficiency of industry-sponsored research.

Her wish list? It’s long and it features

- Scientific communities and the public, as opposed to only study sponsors, should have input into study protocol development.
- Sponsors should perform more clinically meaningful (not regulatory) research.
- Trials should detail the relevance of trial data to the participants’ communities and whether they will have access to the treatment under investigation after the trial has ended.
- Study titles should reflect the type of research.
- Adverse events should be more stringently reported.
- Members of the data safety monitoring boards should be transparent.
- Author education should be implemented in institutions.

Cynthia Dunbar, editor-in-chief of Blood, said that an undisclosed conflict of interest she recently encountered led, after publication of an article, to new journal standards. She also discussed the prevalence of ghost authorship and the importance of requesting full disclosure of authorship.

Dunbar recounted a case in which an author, an expert in the pharmaceutical field, contacted the editor of Blood about a proposed review article. The article was submitted a month later with a cover letter that made no mention of any involvement with the pharmaceutical industry. The editor deemed the submission acceptable for review.

One reviewer recognized the name of an individual mentioned in the acknowledgments as a medical writer at the pharmaceutical company that developed the primary drug class discussed in the paper.

The corresponding author was contacted and admitted the company had encouraged the author to submit the paper to Blood. Dunbar said that the author emphasized the medical writer had “only” prepared the initial outline, supplied tables and figures, and performed literature searches, but the author had written the draft of the paper. The editor ultimately rejected the submission and implemented a new set of rules requiring authors to identify all associations and provide complete disclosure at the time of initial submission.
The Story of the Journal in Two Parts

Moderator and Speaker: Barbara Meyers Ford
President
Meyers Consulting Services
Mount Airy, MD

Reporter: Kenneth F Heideman
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This session was held in one of the larger rooms, which turned out to be a good thing, as it was filled nearly to capacity. A scheduled co-speak was unable to attend, and Barbara Meyers Ford, president of Meyers Consulting Services, had to deliver the entire presentation herself. No disrespect to the second speaker, but I’m not sure it could have gone any better. This was less a session and more an extremely thought-provoking lecture on the history of the journal as an entity unto itself and practical instructions for piecing together the story, or history, of our own current journals.

I was shocked to learn that the roots of making journals go back more than 5,000 years. It was not until 1665 that the first journal was formally published. In that 4,000+-year interim, major milestones—such as moving from papyrus to paper—occurred at several hundred-year or longer intervals, whereas now they seem to come upon us every couple of years. Meyers Ford suggested visiting the University of Waterloo Web site and clicking on “The Scholarly Society Project,” which tracks societies and their publications from the 1300s forward.

Of course, historical data become much more plentiful as we move to the latter half of the second millennium, and a number of critically important milestones were achieved from the 18th century forward, such as the first modern Copyright Act in 1709, establishment of the American Philosophical Society as the first learned society in 1743, the founding of the Library of Congress in 1800, and the first formal peer-reviewed journal appearing in 1838 (before then, editors made accept/reject decisions unilaterally). As for our own collective heritage at CSE, the IMRAD (Introduction, Method, Results and Discussion) method for STM journal articles was initiated in the late 1880s (we haven’t been around all that long!).

Meyers Ford concluded the first portion of her talk by discussing the dizzying array of printing advancements and journal publishing taking place in the past 30 years, including the advent of the Internet. Had she stopped there, this would have been a very complete presentation. But she deftly shifted gears to discuss the value and practical aspects of developing and preserving histories of our own individual journals. Some points to consider include the following:

- Why was your journal started?
- Provide a profile of the founder(s) of the journal.
- Identify the major turning points in the journal’s development.
- Provide energizing images and informative/entertaining anecdotes.

This session was successful on many levels, but in my mind it succeeded most importantly because those attending would definitely respond in the affirmative if asked “Do you have more useful knowledge now than before you attended this presentation?”

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Journal–Author–Industry, continued

The challenge, Dunbar said, is getting the message out. Journals must request conflict-of-interest disclosures as often as possible: in the official instructions for authors, in the instructions on the submission Web site, and in correspondence with authors. Dunbar suggested that journal staff provide editorial assistance themselves and not allow authors to use their own editors; authors need to be educated early and often about the need for disclosure and consequences of evading it; and academicians should exert peer pressure and adopt formal policies discouraging ghost writing.

Alfred Weigel is an employee of Boehringer-Ingelheim Pharmaceuticals, but as the past president of the International Society for Medical Publication Professionals (ISMPP) he provided an overview of what ISMPP has done to increase transparency and to encourage a favorable relationship among authors, journals, and industry. He commented that there seems to be an increasingly adverse perception of articles written or sponsored by pharmaceutical companies and the journals in which they are published, and the mass media only exacerbates that view.

ISMPP was founded in 2005 as an international nonprofit society to focus on educating everyone involved in the publication process. The creators implemented a formal certification process for medical publication planning professionals and established a code of ethics.

Weigel said ISMPP took on a couple of initiatives: it spearheaded the development of the Good Publication Process (GPP2, as the revised document is called), a set of guidelines that now consists of 25 recommendations for authors, sponsors, and contributors; and cosponsored the creation of MPIP. Currently in the works is the development of a standards and best practices handbook and a code of conduct for publication planners.

ISMPP provides education and advocacy support to its members, Weigel added. Pharmaceutical companies are continuing to raise standards for best practices.