Conflict of Interest Disclosure Policies and Practices in Peer-reviewed Biomedical Journals

Richelle J. Cooper, MD, MSHS,¹ Malkeet Gupta, MD, MS,¹ Michael S. Wilkes, MD, PhD,² Jerome R. Hoffman, MA, MD¹

COI disclosures is publicly available.

METHODS: We performed a cross-sectional survey of a convenience sample of 135 editors of peer-reviewed biomedical journals that publish original research. We chose an international selection of general and specialty medical journals that publish in English. Selection was based on journal impact factor, and the recommendations of experts in the field. We developed and pilot tested a 3-part web-based survey. The survey included questions about the presence of specific policies for authors, peer-reviewers, and editors, specific restrictions on authors, peer-reviewers, and editors based on COI, and the public availability of these disclosures. Editors were contacted a minimum of 3 times.

RESULTS: The response rate for the survey was 91 (67%) of 135, and 85 (93%) of 91 journals reported having an author COI policy. Ten (11%) journals reported that they restrict author submissions based on COI (e.g., drug company authors' papers on their products are not accepted). While 77% report collecting COI information on all author submissions, only 57% publish all author disclosures. A minority of journals report having a specific policy on peer-reviewer 46% (42/91) or editor COI 40% (36/91); among these, 25% and 31% of journals state that they require recusal of peer-reviewers and editors if they report a COI. Only 3% of respondents publish COI disclosures of peer-reviewers, and 12% publish editor COI disclosures, while 11% and 24%, respectively, reported that this information is available upon request.

CONCLUSION: Many more journals have a policy regarding COI for authors than they do for peer-reviewers or editors. Even author COI policies are variable, depending on the type of manuscript submitted. The COI information that is collected by journals is often not published; the extent to which such "secret disclosure" may impact the integrity of the journal or the published work is not known.

KEY WORDS: conflict of interest; disclosure; peer-review; editorial policy.

 $\begin{aligned} & \text{DOI: } 10.1111/\text{j.}1525\text{-}1497.2006.0598.x} \\ & \text{J GEN INTERN MED 2006; } 21\text{:}1248\text{-}1252. \end{aligned}$

E ach year, thousands of articles are published in peer-reviewed biomedical journals. Journal publication of authors' disclosure of conflicts of interest (COI) has become quite common. With increased media attention and public scrutiny of reported conflicts, and concerns about the impact

This work was previously reported at the Fifth International Congress on Peer Review and Biomedical Publication held September 16 to 18, 2005, in Chicago, IL.

Address correspondence and requests for reprints to Dr. Cooper: UCLA Emergency Medicine Center, 924 Westwood Blvd, Suite 300, Los Angeles, CA 90024 (e-mail: richelle@ucla.edu).

of industry-sponsorship, journals have stressed the importance of such author disclosures, and in many cases have attempted to make them mandatory. 1,2

Previous studies have focused primarily on the impact that study funding and author COI have on the reporting and conclusions of journal articles. Tonflicts of interest among journal peer-reviewers and editors may be equally important, however, as these groups control decisions about article publication and publication content, and thus have enormous impact on the biomedical literature. It becomes important to understand the extent to which peer-reviewer and editor COI is documented and handled, to begin to understand how these COIs may affect the peer-review processes.

The World Association of Medical Editors (WAME), the International Council of Medical Journal Editors (ICMJE), and Committee on Publication Ethics (COPE) all have guidelines that recommend policies for authors, staff, peer-reviewers, and editors. 12-14 However, little is known about the policies and practices of journals regarding COI among peer-reviewers and editors, and their disclosure to the public. While 1 prior study has examined editor COI policies, it was limited to a small sample of journals, in 1 specialty only. 15 We undertook our investigation in an attempt to characterize the policies of a broad variety of general and specialty medical journals with regard to COIs of not only manuscript authors but also peer-reviewers and editors. While we expected journals to have formal policies on COI for authors, we hypothesized that similar polices for peer-reviewers and editors would be less common, and that public disclosure of such information would be limited.

METHODS

Study Design

We performed a cross-sectional survey of peer-reviewed, biomedical journals to characterize journal COI policies.

Selection of Participants

We selected a convenience sample of peer-reviewed journals, chosen to reflect a broad range of general and specialty medical topics, with an emphasis on primary care specialties. We included only journals that publish clinical research, while excluding those that publish only review articles. At the same time, we avoided journals that exclusively, or primarily, publish basic science research. We included only English-lan-

¹Emergency Medicine Center, Los Angeles School of Medicine, University of California, Los Angeles, CA, USA; ²University of California, Davis School of Medicine, Davis, CA, USA.

OBJECTIVE: We undertook this investigation to characterize conflict of interest (COI) policies of biomedical journals with respect to authors, peer-reviewers, and editors, and to ascertain what information about

guage publications. We attempted to choose journals that are most prominent in their specialty area, first selecting journals in 29 content areas as rated by their impact factor, ¹⁶ and then cropping the field based on the opinions of practitioners in the relevant content areas. (We excluded journals in which the editor was a pilot tester of our instrument.) While the majority of journals we chose are published in the United States, we also attempted to include internationally published journals for each specialty (Table 1). Our goal was to create a diverse sample that captured the most influential and prominent journals in the various general and specialty areas.

Survey Development

We developed a 19-question, 3-part survey to obtain information about journal COI policies for authors, peer-reviewers, and editors. The only identifying information collected was the name of the journal, used only to determine whether a particular journal editor had responded. For each portion of the survey (authors, peer-reviewers, and editors), we asked general information about any journal COI policy, and whether specific policies required the participant (author, peer-reviewer, or editor) to provide a written attestation of their COI state-

Table 1. Topic Category and Country of Publication of the 135 Journals Sampled

| Medical Specialty | Number of Journals Surveyed |
|---|--------------------------------|
| Primary care and general specialties | |
| General medicine | 16 |
| Family practice | 3 |
| Pediatrics | 8 |
| General surgery | 12 |
| Emergency medicine | 5 |
| Obstetrics and gynecology | 3 |
| Neurology | 4 |
| Psychiatry | 5 |
| Radiology | 2 |
| Ophthalmology | 3 |
| Anesthesiology | 4 |
| Dermatology | 4 |
| Medical subspecialties | |
| Allergy and immunology | 4 |
| Cardiology/cardiovascular | 6 |
| Infectious disease | 4 |
| Gastroenterology/hepatology | 3 |
| Pulmonary/critical care | 3 |
| Nephrology | 3 |
| Endocrinology | 6 |
| Hematology | 4 |
| Oncology | 4 |
| Rheumatology | 4 |
| Gerontology/Geriatrics | 4 |
| Surgical subspecialties | |
| Neurosurgery | 4 |
| Orthopedic surgery | 4 |
| Otolaryngology | 3 |
| Cardiothoracic surgery | 2 |
| Urology | 3 |
| Vascular surgery (and peripheral vascular | 5 |
| disease) | |
| Country of publication sponsor | |
| United States | 83 |
| United Kingdom | 21 |
| International | 17 |
| European | 6 |
| Other (e.g., Sweden, Canada, Australia) | 8 |

ments. We asked about any attempts made by the journal to verify COI statements, and any specific restrictions on peerreview or authorship based on COI. For example, we asked whether review articles regarding specific products could be written by authors with financial COI with regard to the same product. We additionally asked about the availability or publication of disclosure statements. For each portion of the survey, we asked additional specific questions pertinent to each type of contributor. For authors, we asked about differential journal policies on collecting and publishing information based on the type of submission (e.g., original research, review, letters), and any restrictions on authorship based on disclosed COI. For peer-reviewers and editors, we asked how often COI information is collected, and whether the journal has any policy regarding recusal from any defined activities in the presence of a possible or perceived COI. (Survey instrument available online—Appendix A.)

Survey Administration

We developed a web-based version of the survey for data collection, which was pilot tested by a small group of journal editors, after which final revisions to the content were made, for clarity and convenience.

We used the website of each journal chosen to identify the journal editor, and contact information. We then contacted each journal editor, or members of the editorial staff office, by email, asking editors either to answer the survey themselves, or to appoint a responsible staff representative (e.g., managing editor) who would have accurate knowledge of journal policies. Nonresponders were recontacted every 3 to 4 weeks, up to 3 times. We provided the URL for the web-based survey in our letter request to allow editors to link directly to the survey web page, or allowed editors to print the web survey and fax responses. For the minority of editors who could not access the website or preferred not to enter data on the website, we faxed a print version of the survey and manually entered their responses.

Analysis and Outcomes of Interest

Our planned analysis was descriptive. We present estimates for the frequency of disclosure policies, the manner of editorial and peer-review conflict management, and the public acknowledgment (published) of these disclosures with simple descriptive percentages.

RESULTS

We contacted 135 journals, including 29 categories of general medical journals, primary care journals, and various medical and surgical specialties or subspecialties and received a response from 91 journals (response rate 67%). Most (92%) directly entered responses on the website, while the remaining 8% faxed responses on a printed version of the survey; in these cases, data were manually entered on the website by a research assistant. The majority of responders reported a journal policy pertaining to author COI disclosure (93.4%), although not all journals with such a policy require a written attestation (Table 2). Policies to verify authors' disclosures were infrequently reported (8.8%), although the majority of journal editors (61.5%) reported instances or particular

circumstances under which they made special efforts to clarify or confirm the accuracy of an author's COI statement.

The majority of responding journals reported having an author COI policy, although these policies only require disclosure on certain (76.9%) types of submissions (Table 2). The 21 journals that do not always require author disclosure reported that it is collected for original research (16/21), systematic reviews (15/21), narrative reviews (10/21), guidelines (9/21), policy statements (10/21), editorial (10/21), letters to the editor (4/21), and other (e.g., case report, book review, 3/21) contributions. Journals even less frequently (57.1%) publish the collected author disclosures for all types of manuscripts (Table 1).

According to respondents, peer-reviewer (46.1%) and editor COI (39.6%) policies are far less common than author COI policies (Tables 2 and 3). For journals with one of these policies, peer-reviewers are most commonly asked about COI with each paper reviewed, while editors are more likely to be asked to disclose COI on a yearly basis. Approximately a quarter of the journals responding stated that they ask peer-reviewers with a COI to recuse themselves from reviewing, and approximately 30% of journals have a policy of editor recusal if a COI exists. Peer-reviewer (3%) and editor (11%) COI disclosure statements are rarely published. In the "comments" section of our survey, several editors stated that their journal is currently addressing the question of peer-reviewer and editor COI, and new policies may be elucidated.

DISCUSSION

Almost all the journals that responded to our survey stated that they have written COI policies for authors, although the extent to which this applies universally to all submissions or is publicly disclosed is more variable. While the majority of journals (76.9%) require author COI for all submissions, almost a

Table 2. Reported COI Policies and Disclosures for the 91 Responding Journals

| Author COI Policies | Reported Yes, N (%) |
|--|------------------------|
| Journal has a written policy on author COI | 85 (93.4%) |
| Authors must submit written attestation of potential COI | 75 (82.4%) |
| Specific mechanism or procedure to verify authors' COI disclosures are accurate | 8 (8.8%) |
| No specific policy of verification, but under some circumstances specific efforts made to contact the authors due to concerns about disclosed or undisclosed COI | 56 (61.5%) |
| Policy to deal with authors who fail to disclose a COI for a paper that was published | 42 (46.2%) |
| Author COI disclosure applies to all types of articles submitted | 70 (76.9%) |
| Specific policy restricting author publication of articles with a stated COI? (e.g., Review articles on a specific drug will not be accepted if the author has a financial COI with regard to the drug or therapy) | 10 (11%) |
| Publishes the authors' COI disclosures for all submissions | 52 (57.1%) |
| If authors' COI are not published is the information | |
| available: | |
| On the web | 2 (2.2%) |
| Upon request only | 20 (22%) |
| Not available | 7 (7.7%) |

COI, conflict of interest.

Table 3. Peer-Reviewer COI Policies for the 91 Responding Journals

| Peer-Reviewer COI Policies | Reported yes, N (%) |
|--|------------------------|
| Journal has a specific policy regarding peer-reviewers' COI | 42 (46.1%) |
| Require peer-reviewers to provide written attestation of COI | 30 (33%) |
| How often must peer-reviewer disclose COI | |
| With each submission reviewed | 32 (35.2%) |
| Yearly | 3 (3.3%) |
| With first appointment as a peer-reviewer | 0 |
| Specific procedure or mechanism in place to verify the accuracy of peer-reviewers' COI disclosure | 0 |
| Specific policy of recusal exists if there are reported conflicts of interest | 23 (25.2%) |
| Peer-reviewer COI are published | 3 (3.3%) |
| Peer-reviewers' COI disclosures not published but available upon request | 10 (11%) |

COI, conflict of interest.

quarter of the journals do not require universal author disclosure. Absence of disclosure appears to be most common for narrative reviews, editorials, policy statements, and guidelines. This seems striking, given that all of these types of publications reflect the opinions of their authors, and that unlike research papers, most do not have any "Methods" sections that can be scrutinized by readers to determine the presence of bias. In addition, as these types of papers may in many cases be even more influential to the clinician reader than is original research, it would seem particularly critical for journals to mandate author disclosure, and public reporting, of authors' COIs for all such submissions.

To date, the study of editors and peer-reviewers in the production of biomedical research has been largely ignored. One prior survey of 37 general medical journals found that only 30% had a policy to deal with editor's financial COI despite most editors believing that the issue was important. ¹⁶ Similarly, we found that less than half of the responding journals stated they have a written policy to manage peer-reviewer and editor COI, despite the fact that it is precisely people in these positions who have the power to decide what is or is not published.

Journals are dependent on the pharmaceutical industry for both advertising dollars and for the sponsored research studies that are their life-blood (and that provide further substantial revenues through the sale of reprints). Transparency in reporting, policies to handle potential COIs, and editorial independence are essential to the perception of the credibility of the information presented. As Richard Smith, the former editor-in-chief of the *British Medical Journal*, stated "the quality of the journal will bless the quality of the drug," and the economic well-being of a drug or product is tied to the "stamp of approval" provided by publication in prestigious journals. ¹⁷ Recent increased public scrutiny of author COI should make journal publishers equally concerned about the public's perception and potential scrutiny of peer-reviewer and editor COI.

We found that almost no journal has a formal policy of verification of COI disclosures by all journal contributors (authors, peer-reviewers, and editors). Such verification would

Table 4. Editor COI Policies for the 91 Responding Journals

| Editor COI Policies | Reported Yes N (%) |
|---|-----------------------|
| Journal has a specific policy regarding editors' COI | 36 (39.6%) |
| Require editors to provide written attestation of COI | 32 (35.2%) |
| How often must editors disclose COI | |
| With each submission refereed | 5 (5.5%) |
| Yearly | 30 (33%) |
| Only with initial editorial appointment | 8 (8.8%) |
| Other | 3 (3.3%) |
| Specific procedure or mechanism in place to verify the accuracy of editors' COI disclosure | 4 (4.4%) |
| Specific policy of recusal exists if there are reported conflicts of interest | 28 (30.8%) |
| Editors' COI are published | 11 (12.1%) |
| Editors' COI are not published but available upon request | 22 (24.2%) |

COI, conflict of interest.

be cumbersome, and journals appear to rely on the professionalism of the authors, peer-reviewers, and editors.

Few journals (about 10%) reported having written policies regarding recusal of authors, editors, or peer-reviewers in the event of a specific COI (e.g., writing a review on a specific treatment of a disease produced by a biotechnology firm that the author has a financial stake in). There may be reasons why limited COI can, under certain circumstances, actually be beneficial. It may be advantageous to have authors with competing COI provide commentary in a pro and con debate of a topic. Similarly, it may be advantageous to have rival researchers serve as peer-reviewers of each other's work, as their expertise might provide additional insight into the research. These advantages come with potential hazards when rival researchers peer-review each other's works. Authors may be concerned that competitors would appropriate ideas or use the review process to delay a competitor's research publication. With full disclosure of COIs, the editor adjudicating the publication decision can make a fair and informed decision. A policy of editor recusal or peer-reviewer recusal seems warranted in cases in which the COI may be perceived to affect adversely the honest appraisal and decision to publish a manuscript.

Finally, our study highlights the relative lack of public acknowledgment of the COI that is disclosed to journals. Although author COI is frequently collected, almost a quarter of journals do not collect this information for all submissions. More importantly, more than 40% of journals do not publicly disclose author COI statements for all submissions. This is far more true of the few peer-reviewer and editor COI data that are less frequently collected and only rarely published. We agree with the ICMJE, WAME, and COPE recommendations that journals have policies and procedures for disclosure and management of COI for all who participate in the peer-review proc- $\ensuremath{\mathsf{ess.}}^{12\text{-}14}$ International Council of Medical Journal Editors and WAME both recommend public disclosure of editor ${\rm COI.}^{12,13}$ We believe that editors and peer-reviewers should be held to the same professional standard as authors, given their ability to influence biomedical publications. The failure of journals to publicly disclose author COI for all contributions, and/or failure to disclose COI for those most influential in the publication of scientific articles is of concern. The credibility of the medical literature requires greater transparency, not secrecy. We question the concept of COI "disclosure" that remains hidden from public scrutiny.

Limitations

As we surveyed a convenience sample of journals, and because the response rate was 67%, we cannot estimate the prevalence of COI policies among all journals, nor can we make meaningful comparisons based on impact factor or country of publication. We do not believe that this greatly limits the value of our findings, as it clear from this sample that there are substantial gaps in journal COI policies, even among high-impact journals, and with regard to all 3 categories of journal contributors (authors, peer-reviewers, and editors). The implications of our results would not change whether this was even truer of journals with smaller readership or impact in the field, as we suspect is likely, or if it was limited to the journals we sampled.

We relied on self-report of journal editors, and did not attempt to verify the accuracy of their statements. Surveys were completed by individuals who we believe are reliable (editors in chief, or their designates), and knowledgeable about their journal's policies; furthermore, given the anonymous nature of the survey, we do not believe there is any reason to doubt the accuracy of their reports. To the extent that these self-reports may have been incomplete or less than perfectly accurate, we suspect that it would likely be in the direction of overstating the nature and rigor of COI disclosure policies.

Finally, we chose not to specify or define COI, or ask editors how their policies define COI (financial, nonfinancial, or both), for a number of reasons. First, we wanted to increase our capture of journals with any COI policy whatsoever; narrowing the definition of COI would have risked misclassifying journals as having no policy any time their definition did not match ours. Second, we wanted to decrease responder burden in order to insure a good survey response rate. Finally, although many journals reported COI policies, it is unclear to what extent these COI policies are consistent in their definitions across journals. It may be important in future research to ascertain the types of COI disclosure that journals require, and to evaluate whether and to what extent variations in such policies limit them from achieving their intended goals.

CONCLUSIONS

Conflicts of interest exist for authors, peer-reviewers, and editors, and can take many forms. The integrity and professionalism in all aspects of health care are increasingly under scrutiny. The importance of medical research and peer-review publication to both medical professionals and the public requires us to consider ways in which the perception of COI does not overshadow or distort the message. Although it may be feasible to attempt to limit certain obvious types of COI (and especially financial ones), such an approach is much more likely to have value if it is based on consistent and well-thought principles that are formalized in policy documents.

We would like to thank Guy Merchant for help in website management and data collection and the specialists who provided their ranking of the leading journals in the field. We are also grateful for the assistance of the journal editors who pilot

tested the survey and those journal editors who provided responses to our survey.

Funding: There was no funding source for this study.

Declaration of potential COI: Richelle Cooper is on the Editorial Board of Annals of Emergency Medicine and receives a stipend for providing editorial services. All other authors report no COI to declare.

REFERENCES

- Fontanarosa PB, Flanagin A, DeAngelis CD. Reporting conflicts of interest, financial aspects of research, and role of sponsors in funded studies. JAMA. 2005;294:110-1.
- Davidoff F, DeAngelis CD, Drazen JM, et al. Sponsorship, authorship, and accountability. N Engl J Med. 2001;345:825–6; discussion 826–7.
- Stelfox HT, Chua G, O'Rourke K, Detsky AS. Conflict of interest in the debate over calcium-channel antagonists. N Engl J Med. 1998;338:101–6.
- Krimsky S, Rothenberg LS, Stott P, Kyle G. Financial interests of authors in scientific journals: a pilot study of 14 publications. Sci Eng Ethics. 1996;2:395–410.
- Friedman LS, Richter ED. Relationship between conflicts of interest and research results. J Gen Intern Med. 2004;19:51–6.
- Bhandari M, Busse JW, Jackowski D, et al. Association between industry funding and statistically significant pro-industry findings in medical and surgical randomized trials. Can Med Assoc J. 2004;170: 477–80
- Lexchin J, Bero LA, Djulbegovic B, Clark O. Pharmaceutical industry sponsorship and research outcome and quality: systematic review. BMJ. 2003;326:1167–70.

Supplementary Material

The following supplementary material is available for this article online at www.blackwell-synergy.com

Appendix A: Survey Instrument

- Als-Nielsen B, Chen W, Gluud C, Kjaergard LL. Association of funding and conclusions in randomized drug trials. A reflection of treatment effect or adverse events? JAMA. 2003:290:921–8.
- Choudhry NK, Stelfox HT, Detsky AS. Relationships between authors of clinical practice guidelines and the pharmaceutical industry. JAMA. 2002;287:612–7.
- Kjaergard LL, Als-Nielsen B. Association between competing interests and author's conclusions: epidemiological study of randomized clinical trials published in the BMJ. BMJ. 2002;325:249–52.
- Yaphe J, Edman R, Knishkowy B, Herman J. The association between funding by commercial interests and study outcome in randomized controlled drug trials. Fam Pract. 2001;18:565–8.
- World Association of Medical Editors (WAME). WAME recommendations on publication ethics policies for medical journals. Available at http:// wame.org/pubethicrecom.htm#conflicts. Accessed August 22, 2005.
- 13. International Council of Medical Journal Editors (ICMJE). Uniform requirements for manuscripts submitted to biomedical journals: writing and editing for biomedical publication. Available at http://www. icmje.org/#conflicts. Accessed August 22, 2005.
- Committee on Publication Ethics (COPE). A code of conduct for editors
 of biomedical journals. Available at http://www.bmjpg.com/cope/
 guidelines/. Accessed August 22, 2005.
- Haivas I, Schroter S, Waechter F, Smith R. Editors declaration of their own conflicts of interest. Can Med Assoc J. 2004;171:475-6.
- ISI Web of Knowledge Journal Database Version 2005. Available at http://www.thomsonisi.com/. Accessed January 27, 2005.
- Smith R. Medical journals are an extension of the marketing arm of pharmaceutical companies. [PLoS Med 2005 May 2:e138, DOI: 10.1371/ journal.pmed.0020138].