
Harmonizing Financial Disclosures in Biomedical Journals: A Shared Responsibility

SYMPOSIUM SUMMARY

This one day symposium, organized by the American Society of Clinical Oncology, Association of American Medical Colleges, Council of Medical Specialty Societies, JAMA, and Memorial Sloan Kettering Cancer Center, convened leaders representing a diverse collection of organizations from across the biomedical research community, including representatives from academic institutions, journals, publishers, professional associations and societies, government officials, industry, as well as conflicts of interest experts, ethicists, researchers and patient/public representatives.

Through speaker presentations and facilitated table discussions over the course of three sessions, attendees outlined the actions needed to standardize the submission of financial interest disclosures by authors to journals and the need to create greater transparency around journal disclosure requirements to foster a system that is clear and functional. The symposium sessions included the following:

- **Session One: Harmonizing Financial Disclosures across Biomedical Journals** explored the drivers for, impacts of, and practical opportunities for the harmonization of financial disclosure requirements among biomedical journals.
- **Session Two: The Relevance of “Relevant” Financial Interests** discussed the benefits and potential consequences of the requirement that authors disclose “relevant” financial interests or relationships versus a “general” disclosure approach that would ask authors to disclose all financial interests or relationships without consideration as to whether the financial interest is related to the subject of the manuscript.
- **Session Three: Shared Responsibility and Accountability**, sought to identify specific areas of opportunity where institutions, journals, societies, and authors can work together to identify appropriate disclosure that will help our community maintain trust in the biomedical research enterprise, including the actions needed to verify “appropriate” disclosure and how to address situations where appropriate disclosure did not occur.

The issues raised and primary recommendations from each discussion are presented below.

Harmonizing Financial Disclosures across Biomedical Journals

- **Feasibility and desirability of harmonization:** There was complete agreement among symposium attendees that a harmonized set of disclosure requirements or disclosure criteria across journals is both desirable and feasible. However, it was identified that the support from the biomedical research community is critical for the adoption and implementation of harmonized requirements. Defining a group of key stakeholders to lead these efforts and build consensus (“buy-in”), within the research community was identified as a necessary part of the process.

- **Common definitions:** Existing resources and efforts led by organizations such as the International Committee of Medical Journal Editors ([ICJME](#)), [ORCID](#), and the [Convey Global Disclosure System](#), should be leveraged to help determine a single set of common definitions and/or common denominators that meet all stakeholders needs. Ensuring a secure and flexible exchange of information should also be considered in this process. Approaches to defining a common set of definitions include, first identifying the scope of definitions that currently exist and analyzing current data, reviewing relevant regulations, laws, best practices, and institutional policies, as well as understanding international factors.
- **Challenges and concerns:** There was broad agreement that despite challenges, harmonization would create a “single source of truth,” helping to build public trust. Working together, the research community should also address whether the interoperability of data systems and fluidity of data between those systems is feasible, in addition to the exportation of data from a common repository. Privacy and data security issues must also be considered.

The Relevance of “Relevant” Financial Interests

- **Consistency of “relevance” determinations:** Symposium attendees discussed the varied approaches to determining the relevance between a financial interest, the subject matter of a manuscript and how often this may lead to meaningful variation in resulting disclosures. There was general agreement that standardizing relevance determinations across journals posed difficulties. Conversely, there was also optimism that through a multi-stakeholder approach, this was not impossible to achieve. Consistent processes regarding *who* makes the relevance determinations (e.g., author or journal) should be developed. It may also be important to determine whether relevance determinations can be better achieved with the support of artificial intelligence, thereby eliminating personal “judgment calls” by authors and whether those judgments are fair and reasonable.
- **“General” versus “relevant” disclosure:** There were mixed responses regarding whether a “general” or “universal” disclosure process (i.e., the disclosure of all financial interests regardless of their relationship to the research) was more preferable than a “relevant” disclosure approach. While there was more favorability for general disclosure, there were also recommendations for a hybrid approach which included: annotating relevance in the journal manuscript, refining and creating consensus on relatedness standards before moving forward with a general disclosure approach, and requiring authors to select disclosures related to the article or study using a standard form or central repository.
- **Overall impact of general disclosure:** A general disclosure approach would significantly impact the operations and workload of journals institutions, societies, and other organizations. However, this burden falls more on journals and editors since there are not enough copy editors, and many journals do not have the resources to spot, check, and/or verify an author’s disclosures.

- **Actions to advance progress:** While a general disclosure process was identified as the best approach, there were remaining questions regarding how this process could be successfully applied. There was overall agreement there should be consensus within the research community on what specifically should be included in a general disclosure process—e.g., key words, company sponsor name, agreement on the disclosure period(s). Consideration should also be given to the development of a central disclosure repository and/or universal form in addition to defining the scope of the general disclosure process. As discussed in the previous session on relevance, it was re-emphasized here that technical algorithms or artificial intelligence solutions may help navigate disclosure policies and assist with relevance determinations. This included recommendations for developing a type of system or database that could support both a general or hybrid disclosure approach.

Shared Responsibility and Accountability

- **Standards for accountability:** To facilitate complete and accurate disclosure, the research community should begin by developing clear and consistent standards or criteria for disclosure (e.g., relevance, terms, definitions). This will help inform best practices and set expectations. However, there was broad consensus that the responsibility for complete and accurate disclosure falls on the author not the institution, journal, or organization. Furthermore, there should be systems or processes in place to eliminate errors and increase accuracy. It is important to acknowledge the institutional role in this process with some suggestions for including the institution in the process well in advance of publication (e.g., establishing a single database or system with author information reviewed and audited by institutions – this pre-vetted information would then be sent to journals).
- **Additional considerations for future action:** In addition to the approaches discussed previously, the challenges and issues related to the Centers for Medicare and Medicaid Services’ Open Payments data should also be addressed (e.g., delayed publication of data on the Open Payments website, data discrepancies). Creating accountability and ensuring complete and accurate disclosure also requires open and “coordinated communication” between institutions and journals, helping to break current “communication silos” and encouraging consistent information flow between institutions and journals. It was suggested that journals could alert the institution if a conflict of interest discrepancy was brought to their attention.
- **Consequences:** As a general principle, it was broadly agreed that the research community should develop a common understanding of the consequences for incomplete or inaccurate disclosure. However, recommendations on the actions that could be taken to address this issue varied. There was some consensus that keeping track of repeated offenders (“bad actors”) was important with a recommendation for including this information in a central database. Yet, questions remained regarding the consequences for honest error, misinterpretation, and/or intentional misrepresentation. Ultimately, developing a formal process across journals and institutions for dealing with individuals who serially retract manuscripts is important. Public naming and/or “black listing” was suggested, but with the caveat that this may not be the best approach considering its impact on other authors.

Symposium Outcomes and Next Steps

The symposium concluded with attendees reflecting on the discussions that took place throughout the day; agreeing on common themes, additional issues that need to be addressed, and next steps. Based on this feedback and the key themes presented above, the symposium's planning committee will take immediate steps to engage journals, institutions, organizations, and other key stakeholders to move this conversation forward. Accordingly, the following efforts will be undertaken:

- **Broad Dissemination of Principles and Key Discussions:** Given the level of interest in the general public on issues of transparency and conflicts of interest in biomedical journals and research, the planning committee will be sharing outcomes from the symposium and other efforts in news and scholarly publications.
- **Working Group on Harmonization:** The planning committee will establish a working group comprised of a broad representation of individuals across the biomedical research community to build on the issues discussed at the symposium and presented in this summary. To inform their recommendations, the group will: review current disclosure systems and models, evaluate existing harmonization efforts, and analyze relevant research and data. In addition, the working group will develop practical strategies to guide implementation.
- **Publication of Working Group Outcomes:** The working group members will disseminate a public statement that will include the finalized principles and recommendations. This statement will be broadly distributed and may provide the biomedical community opportunity for endorsement or statement of adoption.

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