DOI: 10.1111/j.1475-6773.2006.00656.x

New Policy at HSR

New Policy on Disclosures at Health Services Research

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The appropriate role of scientific journals is to disseminate the best science available to the public and the research community. Two principal mechanisms to fulfill this role are peer review and open disclosure of potential biases in conducting and reporting results. Peer review primarily focuses on what is presented in the submitted manuscript—reviewers cannot easily assess what has been omitted or whether the authors made choices in the design or execution of the study that may have biased their results. For example, it appears some key adverse data were omitted from the Vioxx Gastrointestinal Outcomes Research (VIGOR) trial reported in the *New England Journal of Medicine* (Curfman, Morrissey, and Drazen 2005a, b). Some authors claimed to have been unaware of the problems, raising questions about what are the roles and responsibilities of all authors in ensuring "the best science available" is published in scientific journals. Increasingly, journals have adopted more explicit policies about what to disclose and who should be informed during the process of review and publication.

There are also studies showing that a project's sponsorship may be related to the findings reported. Most of these have focused on trials reporting use of drugs and devices, comparing studies sponsored by the for-profit manufacturers with those sponsored by not-for-profit and government entities (Lexchin et al. 2003; Ridker and Torres 2006), or on studies relating to tobacco use (Barnes and Bero 1996). Publication of biased studies is an insidious problem because the submitted findings may not be incorrect per se and thus are unlikely to be caught by peer reviewers. Absent or incomplete disclosure, however, prevents the consumer of such published information from applying the appropriate skepticism.

POTENTIAL BIAS IN HEALTH SERVICES RESEARCH STUDIES

Bias in clinical studies is not rare in biomedical journals. It can also be found in health services research, but for several reasons may be problematic in more types of arenas and even less readily detected. Double-blind randomized controlled clinical trials typically have detailed protocols and tight, reproducible study designs, often with independent external review prior to submitting for peer-reviewed publication. While still subject to manipulation (the VIGOR results were apparently truncated to exclude some deaths), the process and methods used in clinical trials are expected to be well-documented and open to audit. In contrast, randomized clinical trials are rare in health services research. Consequently, peer-reviewed evaluation *of the appropriateness and quality of the methods* used in health services research is far more important; findings may crucially depend on decisions by investigators interpreting either quantitative analyses applied to large data sets or qualitative findings derived from case study observations. Users of health services research are thus arguably more dependent on the openness and integrity of the authors to disclose their methods and potential biases.

Health services research also frequently addresses questions involving policy issues and value judgments, at least with respect to the implications of the findings. Although most research manuscripts do not explicitly advocate for a particular policy or strategy, the findings often support one policy perspective rather than another. Research should be used to inform policy, but it is important that the findings can be understood in context and that any roles that sponsors or organizations have played and any relationships of the authors to advocacy groups be fully disclosed.

What potential biases should be disclosed? Ideally, researchers are drawn to specific research foci and study designs by the presence of important, unanswered questions or the availability of data. Some, however, may be drawn to a topic by their own discomfort with the policy implications of the existing research base or by the willingness of sponsors to fund specific types of research. Consider, for example, a hypothetical set of studies comparing the quality of care for people in health maintenance organization (HMO) and fee-for-service (FFS) settings. Suppose the studies vary markedly in terms of specific questions, settings, populations, data, and methods and that findings appear to favor HMOs in some studies and to be unfavorable in other studies. Each study is internally consistent and well-executed and has passed successfully through the peer-review process. Would it matter to a reader if the pattern

of findings reported depended upon the sponsorship of the studies? Or if authors consistently finding results unfavorable toward HMOs also served as experts in legal suits against HMOs or in legislative hearings on HMOs? Or if the sponsors or providers of data for some studies had the right to review the manuscripts before publication? We argue that if the answer to such questions is "yes," or even "maybe," disclosure of such information for the reader is important. The challenge is to find a mechanism without undue burdens on the peer review process or hampering the publication of good research.

Disclosure as a Strategy

One approach to potential bias is refusal to publish studies of any authors who reveal a conflict of interest. In its instructions to authors, the *New England Journal of Medicine* states that "[b]ecause the essence of review articles is selection and interpretation of the literature, the Journal expects that the authors of such articles will not have significant financial associations with a company (or its competitor) that makes a product discussed in the article" (http://authors.nejm.org/Misc/MsSubInstr.asp, accessed July 22, 2006). As "significant financial relationship" includes most consultations, contracts and other support, this is a rather broad exclusion, especially if one were to expand it, by analogy, to all health services research involving "selection and interpretation" of data or methods. Furthermore, limiting the prohibition to the assessment of products or to review articles ignores the potential for bias in other areas. We believe that refusing to publish all manuscripts where conflicts of interest are disclosed is too restrictive and punishes those who would disclose subtleties of conflicts that other authors do not.

An alternative approach is simultaneously more expansive and less restrictive than that used by the *NEJM*. Potential conflicts in health services research may reflect not just financial, but political and ideological interests as well. Rather than assuming such potential sources of bias either invalidate the research or are irrelevant and not needing disclosure, we recognize that policymakers live in a world that is neither black nor white, but almost always gray and that policy-relevant research appropriately seeks to influence and inform policy. Thus, we expand the notion of disclosures used by biomedical journals to include disclosures on advocacy roles and sponsorship.

JAMA has just announced a change in its requirements for financial disclosure. It tries to make explicit what should be disclosed and requires such disclosure for every type of manuscript from letters to the editor to editorials to

research reports (Flanagin, Fontanarosa, and DeAngelis 2006). Our approach builds on and extends *JAMA*'s new policy.

Policies for disclosure of peer-reviewed scientific publication should intrude minimally on the free flow of research, yet help readers consider the work in context. Furthermore, if most journals join in requiring disclosure and make more explicit what should be disclosed, those with "something to hide" would have few good places to publish. Sponsors value the credibility provided by publication in peer-reviewed journals, so such collective action may lead to better behavior by sponsors and organizations. Disclosure policies, however, cannot preclude authors from making false or misleading statements or engaging in other forms of behavior that may be considered scientific misconduct (2006).

Honest and complete disclosures are principally to help readers understand potential sources of biases. To that end, we intend to work toward making disclosure statements in health services research (i.e., the field *and* the Journal) serve to create a "level playing field" for all authors and readers. To help readers and authors understand this new policy, we describe the problems we face, the types of information we seek to acquire, and what we will do with it.

Problems we Face

The major focus of biomedical journals has been financial conflicts of interest of researchers who have relationships with companies (or their competitors) producing the interventions being assessed. Studies of bias suggest that firms are unusually expert at funding trials of successful drugs, manage to reduce the likelihood that negative findings are published, or place the "best face" on the results reported; or that there are other forms of bias. The first explanation (good a priori selection of projects) would not truly be a bias if it simply reflected abandoning lines of inquiry with weak or unpromising preliminary findings. There is, however, some evidence of ghost writing by undisclosed authors with conflicts of interest, as well as direct efforts to preclude the publication of research with unfavorable findings. Disclosure statements could help reveal these threats to scientific inquiry.

In response to concerns about potential bias, the AcademyHealth Board established an Exploratory Committee to Assess the Impact of Funders' Restrictions on Publishing Research. The Committee has had preliminary discussions with researchers that indicate such restrictions are imposed (or have

been attempted to be imposed) by various types of funders, including the Federal government, and extend to assessments of policies as well as drugs and devices. (In the spirit of full disclosure, HSL is a member of the Committee, but is not speaking for it or its Co-Chairs, Arnold Epstein and Sara Rosenbaum.)

Restrictions on publications can take many forms. In some instances, clauses included in contracts give the funder the right to review and approve the products of the study—allowing the funder to preclude publication of findings it deems undesirable. Less restrictive are clauses that give funders the right to review and comment on the study. These both allow funders to offer valuable input improving the study but, if there are no limits on how long the study may be held up for comments, such clauses may serve in effect to censor publication.

Influence over the content of published work may occur in other ways. For example, documents disclosed in the tobacco companies' settlement exposed instances in which a researcher affiliated with the industry was a legitimate co-author on a published study, but had undisclosed obligations to receive approval from his supervisors that the study should reflect "positively on the image of RJRT [RJ Reynolds Tobacco Company] and its R&D groups" (Hong and Bero 2006).

People working for sponsors, be they government, health plan, or industry, may provide crucial scientific insights, but their involvement must be disclosed as well as the role of employers in overseeing the design or report of the study. Just as we want authors to approve and take responsibility for the science in a manuscript, we need to know if such approvals might reflect political or other interests—including proprietary concerns for intellectual property, rather than "just" the science.

Funders are not the only involved parties whose interests should be disclosed and understood. Health services research studies often require access to specific data from interviewees or organizations. Authors may want to ensure they are interpreting the data correctly and thus invite their "sources" to review their interpretations. It is certainly appropriate that those providing such access know about how their data are being used and what findings are to be made public in advance of reading the results in the morning newspaper. They may also have legitimate concerns about confidential or proprietary information that can be addressed without compromising the research. Our concern is whether the providers of data or access have the ability to censor the research and our intent is to ask all to openly disclose the nature of the review.

The biomedical field has concerns about "ghost authorship" or the practice of an unnamed person preparing a manuscript for submission by someone else, as well as "guest authorship" or the inclusion as an author of a

senior person who had little to do with the study. Such practices are probably less common in our field, but could become problematic if used as means of control over publication of sensitive studies. More generally, we believe there is a minimum set of roles to be fulfilled to be considered "an author"; all authors should be asked to disclose potential conflicts of interest; and all should reveal non-authors who contributed to the research or its report.

Requesting Information

As future policy for HSR, we first seek to identify who is an author on a specific manuscript and who else contributed to the study. Health services research is increasingly a team effort. It may be impossible for one person to be fully responsible for a manuscript, but we cannot allow many to claim authorship or be rewarded for a small role and yet feel free to deny responsibility for errors and fraud or failure to disclose their real or potential conflicts. To be considered an author, HSR requires one must make a substantial intellectual contribution (1) in (a) conception and design, (b) acquisition of the data, or (c) analysis and interpretation of the data *and* (2) in (a) drafting the manuscript or (b) critical revision of the manuscript for important intellectual content. Those meeting the criteria for authorship must approve the final manuscript and take public responsibility for it.

Although we propose explicit criteria for who should receive the credit for (and accept the responsibility of) authorship, we also want to facilitate the formal recognition of those playing other critical roles in the research process. Examples may be providing statistical analysis, programming, administrative technical or material support (including data), supervision, obtaining funding, initiating the study or through other means. Thus, we will publish electronically a *contributorship matrix* identifying who did what in the research—listing both the authors *and* other contributors (Rennie, Yank, and Emanuel 1997). On the behalf of all the authors, the corresponding author will certify that all who have contributed to the study are appropriately identified in an acknowledgement of contributorship and that all agree to such listing. Over time, analysis of such information may lead to more formal recognition of the "idea people," "statisticians," "commentators," or "graphics experts" who helped create many great manuscripts, yet were the authors of none.

In addition, authors will be asked to disclose all financial and material support (including the provision of, or access to, data) for the research and to disclose to the editors all affiliations and financial involvements with organizations with a financial or policy interest in the subject matter discussed in the

manuscript. The biomedical journals require such disclosures of financial conflicts, but their experience suggests that is not sufficient. In 2005 an important study of fetal pain was published in *JAMA*. When it was "revealed" a few days later that the lead author "once worked for NARAL Pro Choice America," the focus unfortunately shifted from the science to this "non-disclosure" and the potential for bias (Bazar 2005). Given the policy focus of much health services research, we feel it important to expand our request for disclosures. Authors are therefore requested to also disclose public stands they have taken (in print, media, testimony, or other venues) that are identified with a particular advocacy position relevant to the manuscript and whether their current (or at the time of writing) organization is identified with such an advocacy position.

We also ask whether sponsors and/or supporters of the research (including employers and providers of data) have contractual rights to (a) review and approve or (b) review and comment on the manuscript within a reasonable number of days. If a sponsor, employer, or data source has the ability to review and prevent publication, or delay it by requiring interminable revisions, that creates the potential for censorship. Review and approval clauses may have legitimate purposes; they are often presented as allowing the reviewer to assure the work is of high quality. If merely for quality improvement, however, reviews need not have the "approve" clause—we assume authors will voluntarily accept valid suggestions. Work subject to "review and approval" reaching our Journal implicitly has been approved by someone, but there is no way for us to know whether the approval would have been withheld had the study findings or interpretations been different, i.e., subject to true censorship. Although the methods, analysis, and interpretation may be appropriate, science cannot advance if subject to censorship, and the community will not benefit if researchers are not able to freely submit their work.

If the manuscript is subject to censorship by a sponsor, employer, or anyone other than the authors taking responsibility for it, we consider it a "work for hire" and in general will not publish it as research, regardless of its inherent quality. One possible exception would be a manuscript illustrating new methods or approaches, in which the specific findings are irrelevant and the potential censorship of results is revealed.

How Such Disclosures will be Used

Although one may hope that disclosures will eventually be straightforward, until there is a common policy across journals, implementation is not simple.

Differences across journals exist in the types of information requested, when and how it will be used, and in its presentation. Too much information can be as problematic as too little and too many standards set by different journals can create confusion and misunderstandings. We hope our sister journals will adopt the same (or very similar) standards for submission, as we all cooperated in producing a policy statement about disclosing prior dissemination that nonetheless allows for flexibility in implementation (http://www.academyhealth.org/publications/journals.htm). HSR has decided to implement its policy and issue a challenge to the field to help us all improve the scientific basis of our peer-reviewed publications by openly disclosing roles of contributors, potential conflicts of interest and biases, and prior dissemination.

At HSR, we emphasize *disclosure*. With the exception of disclosure of "censorship/works for hire," such information will not enter into our decisions to accept or reject a manuscript. Roughly 40 percent of new submissions are rejected by the co-editors-in-chief and never sent for external review; about half of the remainder are rejected after the first round of reviews. While not all manuscripts invited to revise and resubmit are accepted, the majority are, and we believe that this is the optimal time to require disclosure, i.e., with few authors of manuscripts ultimately to be rejected required to complete the forms. Thus, we will not require disclosure statements until a manuscript has been resubmitted; in most, if not all cases, external reviewers will never be informed about the disclosures except via publication. The editors of HSR will take responsibility for how disclosures are to be made and whether the manuscript requires revisions based on the disclosures. Bottom line: before submitting a manuscript to HSR all authors should be aware of our requirements for disclosure, but they need not submit disclosure statements until invited to revise and resubmit.

To understand our process, it is best to work backwards from what readers will see. For each accepted manuscript we will publish a *contributorship matrix* listing each person involved in the project and what he or she did, clearly identifying those undertaking the tasks needed to be considered an author and those who made other contributions. This will be an appendix in the permanent electronic record for each published article in HSR. We will also publish a one to three paragraph acknowledgement/disclosure statement recognizing the various forms of support that made possible the project and summarizing the real or potential financial and other conflicts about which readers may be concerned. Each author is expected to prepare his or her own disclosure statement and the corresponding author needs to combine these into a joint statement that also acknowledges and reflects project support. This

brief disclosure will appear electronically and in print. The various forms and instructions may be accessed at http://mc.manuscriptcentral.com/society images/hsr/Author%20Responsibility%20Form-Draft-8-29.doc.

We expect that individual disclosures may go into more detail than needs to be published. The editors will work with the corresponding author to determine how much detail is necessary in the acknowledgement/disclosure statement. For example, some employers require that senior people review the work of junior staff—this should be disclosed to us. If the author with a required review is in an academic context, it need not be mentioned in the public statement because we presume the goal of the academic department is open publication. If the author is in a public agency with required review by a political appointee, we may ask that the review requirement be included in the summary statement. Contracts may not have "review and approve" clauses, but if employers impose self-censorship by requiring supervisor review, that too needs to be disclosed.

While the editors and authors become familiar with these issues of disclosure and learn how to write succinct summary statements including all the necessary information, we anticipate a few "rounds" of revisions to make sure the statements are necessary and sufficient, but not overdone. To prevent manuscript publication from being delayed during this process, we encourage all authors to submit drafts of their disclosures and the corresponding author to submit a draft of the joint statement as early in the peer review process as possible. These can be submitted at any time on our electronic peer review system (http://mc.manuscriptcentral.com/hsr) and will be reviewed for consistency and completeness in parallel to the manuscript moving through our normal process.

The publishing "pipeline" is a long one, so these new requirements will be phased in. Authors of all manuscripts submitted after October 1, 2006, the publication of this editorial will be subject to these requirements, as will those whose manuscripts are undergoing an initial review and have not yet received an "R" appended to the manuscript number. We encourage authors whose revised manuscripts have already been submitted to submit the forms and will recognize them as "voluntary disclosers."

These new requirements will add burdens, but we hope they will also add value. The new *contributorship matrix* will help recognize all who are involved in a project, while limiting public responsibility and disclosures to authors. Disclosure of both non-financial and financial interests will help readers and policymakers place research findings in context and avoid people feeling "blind-sided." Although research and advocacy work may use the

same data and methods, the former has credence because of the expectation that the findings would be published regardless of their implications while the latter may be censored. By disclosing the roles of sponsors and others, and by refusing to publish potentially censored findings, we hope sponsors will find it in their interest to support uncensored research leading to peer-reviewed manuscripts in credible journals.

. . . AND A PERSONAL DISCLOSURE ABOUT HAL LUFT'S ROLE IN THIS POLICY AND AT HSR

Hal Luft has been the principal driving force behind the various types of disclosures and the details of the process that HSR is now adopting. In his role as a Board member for AcademyHealth, he actively participated in several AH efforts to promote strong professional norms of ethical behavior and excellent science in health services research. In his role as Professor and Director of the Institute for Health Policy Studies at UCSF, he has been a champion in training future researchers in these values and standards. He has spent many hours with editors of biomedical journals as well as our sister journals in health services research trying to create a fair and effective policy that [we hope] will in the long run protect authors as well as readers and policymakers from biases and misinterpretations. We also hope that having this policy will improve the field and discourage processes that impair or constrain research. This policy is deservedly called "Hal's baby"—"Hal's legacy" when we are being more formal. He has made many important contributions to HSR (the Journal and the field) in addition, for which we gratefully acknowledge his leadership and express our admiration and thanks. (ABF and JJE) And now a parting word from him:

This is my last editorial as Co-Editor-in-Chief of HSR. When asked to take on this role over four years ago, I saw it as both a challenge and an opportunity to give back to the field that has nurtured and supported me over the last third of a century. My predecessors at HSR, Gordon DeFriese and Steve Shortell, had enhanced the breadth and quality of the Journal—that momentum needed to be maintained. Increased quality, however, leads to increased submissions, creating administrative logjams and backlogs. If not addressed proactively, these problems unfortunately self-correct by discouraging the better authors and eventually reducing quality.

One of my major agenda items was to streamline our processes. We now rely entirely on electronic submissions and management tools (a new version came on-line in July) that allow us to handle over twice the number of man-

uscripts with improved turn-around time. This would not have been possible without the support of HSR's owner, the Health Research and Educational Trust and its President, Mary Pittman and her staff, Blackwell, our publisher and its many staff, and Dartmouth and UCSF. Electronics speed getting things from one place to another, but help little if the correct decisions are not made. Meighan Schreiber has been our wonderful Managing Editor, making the system work as well as it does.

A second major agenda item for me was to help make HSR more open, vibrant, and policy relevant. We expanded our publication of manuscripts using a variety of quantitative and qualitative methods, focused on various health and health care topics, as well as manuscripts on how research is undertaken. With this new policy on disclosures, we hope to enhance confidence in the research we publish and eventually encourage broader support for open science and policy debates.

My first (and best) decision occurred when presented with the opportunity to be Editor-in-Chief. It was to argue that this was not a one-person job, but needed to be split, preferably between two people who could complement one another. Working with Ann Flood has proven that collaboration across gender, discipline, and distance can be both highly successful and fun. Our Senior Associate Editor team actually does much of the work in reviewing and making recommendations on the manuscripts. Each SAE has his or her style and expertise, and I will miss working with them all. And my thanks also go to our authors and reviewers. One recent e-mail summarizes the experience:

> I just wanted to let you all know that the referees for our paper were superlative. They rejected the paper for all the right reasons, which, regrettably, we had not fully anticipated or understood upon submission. I have never had a rejection that made me feel that I should have written a much better paper, but this one did. Now to roll up the sleeves and start anew.

José Escarce, M.D., Ph.D., one of our experienced Senior Associate Editors with expertise in both medicine and economics, has agreed to be Co-Editor-in-Chief with Ann Flood, Ph.D. Meighan Schreiber will stay on as Managing Editor. I will continue to oversee my current, but shrinking, "portfolio" of manuscripts. HSR will be in good hands in the future.

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