When Disclosures Are More Interesting Than the Evidence

To the Editor:

The recent update to the American Heart Association/American Stroke Association (AHA/ASA) Recommendations for the Prevention of Stroke in Patients with Stroke and Transient Ischemic Attacks incorporates new evidence for antiplatelet agents and statins. The most interesting aspect of the update is not its content but the author disclosures. Of the 16 authors, 7 have personal financial ties to companies that own and market Plavix or Aggrenox, and 8 have financial ties to one of 7 companies that own and market brand name statin agents (including 5 authors with ties to Pfizer, the maker of Lipitor). The overlap of interests and hence conflicts is unambiguous. Four questions should be asked:

First, did the industry relationships of the authorship panel influence the decision to update the guideline, select the topics, grade the evidence, or formulate the recommendations? Levels, Classes, numbers and letters may look objective, but the process of translating evidence to recommendations remains largely subjective. One wonders if a less conflicted panel would have interpreted differently the risk and benefits of Aggrenox compared to aspirin, including the limitations of the ESPRIT trial. It is also unclear how and why the evidence level for Aggrenox can be downgraded (from Level A to B), yet the recommendation upgraded (from Class IIa to I).

Second, must it be so? Although complete elimination of author conflicts may not be desirable or possible, should there be less conflict and more balance to panels that impart recommendations, which, in turn, will increasingly guide practice and inform performance measurement? Although more conflicts may exist in authors with more expertise, should greater attempts be made to find authors without a direct overlap of interests with the industry whose products they evaluate? The lead author in this update reports “significant” financial interests in Boehringer Ingelheim and “modest” financial interest in Bristol-Myers Squibb and Sanofi-Synthelabo. The breadth of these disclosures is a distraction. Even if there is no conflict of interest bias, one is left wondering more about if and how bias exists rather than scrutiny of the evidence itself.

Third, are the current transparent and complex disclosure practices sufficient? When should a guideline development organization use other management strategies such as reducing one’s interest, restricting one’s activity as an author, and recusal for unmanageable conflicts? Only one author recused himself from any discussion or recommendations on statins because of a potential conflict of interest (COI). The management of COIs in authors, therefore, appears haphazard and based on self-identification of one’s own conflicts. This may not be a prudent management strategy because there are considerable psychological barriers that prevent individuals from recognizing visible and otherwise obvious COIs.

Fourth, should guideline development organizations be more lenient of COIs in authors than universities are of their faculty in conducting research? The Association of American Medical College’s report on COI in research recommends that faculty with a COI should not participate in human subjects research unless “compelling circumstances” exist.

Although institutions vary in how they operationalize “compelling circumstances” most do not allow faculty to participate above certain interest thresholds (eg, patents, ＄10 000, ＞1% equity). Clinical practice guideline development is not human subjects research, but its potential effect on global health is likely much larger than any one clinical trial.

The AHA/ASA has not been immune to scrutiny of its guideline development procedures in the past. This skepticism should be expected when big money is involved and will increase as the maturing field of performance measurement homes in on each recommendation with laser-like focus. The AHA/ASA should consider developing more transparent and detailed COI management procedures for authors of its clinical practice guidelines. Until then, they risk their guideline being judged more by the content of its conflicts, rather than the content of its evidence.

Disclosures

R.G.H. is on the Advisory Board for NINDS Data Safety Monitoring Boards; and C.B. is on the Advisory Board for the New York State Department of Health.

Robert G. Holloway, MD, MPH
Curtis Benesch, MD, MPH
Department of Neurology
University of Rochester Medical Center
Rochester, NY, US

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Robert G. Holloway and Curtis Benesch MD

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