

The Ghostwriting Controversy: Time for a Proper Burial?

Moderator:

Devora Mitrany
Caremark
Scottsdale, Arizona

Presenters:

Annette Flanagin
Journal of the American Medical Association
Chicago, Illinois

Laurence J Hirsch
Merck Research Laboratories
Rahway, New Jersey

Cindy W Hamilton
Hamilton House
Virginia Beach, Virginia

Reporter:

Rita M Washko
Arizona State University
Tempe, Arizona

Three speakers with different perspectives presented their views of the medical ghostwriting controversy, an issue in which paid professional medical writers craft reports for a study's sponsor—for example, a pharmaceutical company—but their role is not publicly acknowledged. Annette Flanagin, managing deputy editor, *Journal of the American Medical Association (JAMA)*, gave an editorial perspective; Laurence J Hirsch, of Merck Research Laboratories, presented a pharmaceutical research company perspective; and Cindy W Hamilton, a freelance medical writer, spoke on the issue from her point of view.

An author must meet all three conditions set forth by the International Committee of Medical Journal Editors (ICMJE), Flanagin said. (The criteria can be accessed at www.icmje.org/#autho.) To be considered an author, a person should have

- Made a substantial contribution to the conception and design of the study, or to

the acquisition of data, or data analysis and interpretation.

- Substantially contributed to the drafting of the manuscript or its revision for important intellectual content.
- Given final approval of the version to be published.

Everyone who qualifies for authorship should be listed, Flanagin said. She added that ghostwriting raises serious ethical concerns and can result in a loss of trust because of the lack of transparency. It also poses problems for editors. For example, potential biases and conflicts of interest remain hidden when ghostwriters are involved in the manuscript process.

Because of the problems posed by ghostwriters, processes are in place to promote transparency. *JAMA* published its criteria for authorship in 1997 and also has an acknowledgment statement that the corresponding author must sign in an effort “to make all ghosts visible”, said Flanagin. Input by nonauthor contributors, such as those who provide outlines or drafts, should be disclosed.

Hirsch reiterated some of Flanagin's points and then provided an industry perspective. Multiple guidelines now exist to address the ghostwriting issue, and all have similar recommendations, he said. Central to the guidelines is that medical writers can make valuable contributions, that they should be acknowledged for their contributions, and that compensation made to these writers should be disclosed.

“In industry-sponsored trials in the past, oftentimes those who contributed the most patients to a trial would be listed as authors. We at Merck steer away from this”, Hirsch said. Authorship should be based only on a substantial contribution to a manuscript as put forth by ICMJE, for example. But despite the publication and wide availability of the criteria, not everyone is familiar with their existence or agrees with them, Hirsch noted. A single-center study among

faculty at a British medical facility showed that among 66 interviewed faculty, only 16 (24%) were aware of the ICMJE criteria, only one respondent knew that all three criteria needed to be met, and 62% disagreed with the criteria.¹

Hamilton, a former ghostwriter, said that freelancers are in a good position to influence the ghostwriting controversy and transparency in publication. To look more closely at the issue from freelancers' perspective, she conducted a survey that was sent electronically to American Medical Writers Association (AMWA) members with listings in the AMWA freelance directory.

Among 221 freelance writers with valid e-mail addresses, 73 (33%) participated. Of those, 80% responded that they had “ever written a manuscript in which the writer's contribution was not identified”. Nearly half—49%—of survey participants said they were familiar with ICMJE's guidelines; 75% were familiar with AMWA's position statement on authorship. Some 70% at one time or another had to write or request their own acknowledgments; this led Hamilton to point out that they would welcome help from journal editors who encourage acknowledgments. Roughly half the participants responded that they encouraged authors and other contributors to follow ICMJE's and AMWA's guidelines. That last issue “goes directly to my hypothesis that freelance writers and editors are in a position to influence this process”, offered Hamilton.

Hamilton concluded the session by recommending that everyone work together to solve the ghostwriting controversy and educate their peer groups about guidelines. 

Reference

1. Bhopal RS, Rankin JM, McCol E, et al. The vexed question of authorship: views of researchers in a British medical faculty. *BMJ* 1997;314:1009-12.