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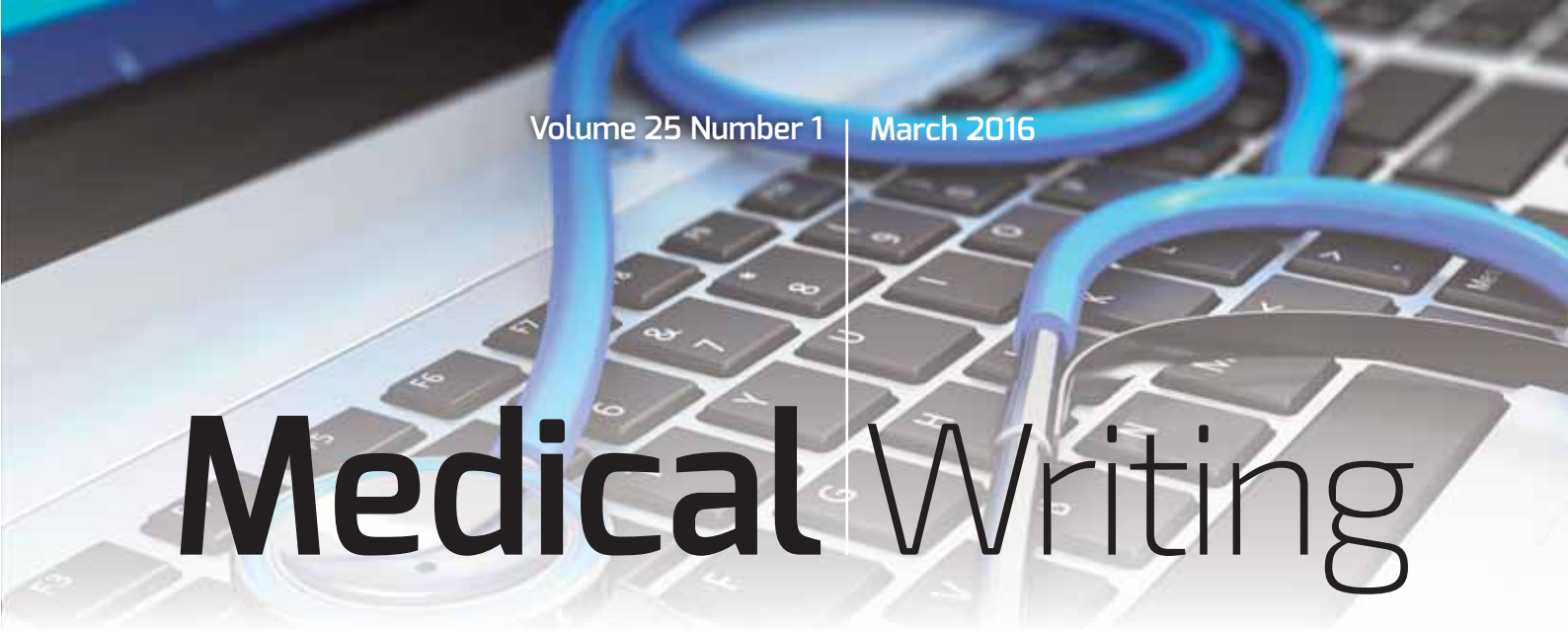

Medical Writing

Authors and Authorship

Phil Leventhal, Editor-in-Chief

Authorship of medical journal articles has been and continues to be a complicated subject. The unethical practices of guest, honorary, and ghost authorship and incomplete or biased disclosure of clinical trial data have led to guidelines meant to eliminate these practices. The International Committee of Medical Journal Editors (ICMJE) Recommendations,[1] first published in 1979, and Good Publication Practice (GPP) guidelines, first published in 2003,[2] have led the way.

The current ICMJE guidelines[1] stipulate that authors of medical journal articles should make substantial contributions to:

- The conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

These authorship criteria mean that adding an author after the fact – a guest or honorary author – is not acceptable. The third and fourth criteria are meant to prevent authors from denying responsibility for any of the article's content. In their current state, the ICMJE authorship criteria also generally preclude medical writers from being authors because they usually cannot (or are unwilling to) satisfy criteria 3 and 4. Finally, the ICMJE guidelines state, "Contributors who meet fewer than all 4 of the above criteria for authorship should not be listed as authors, but they should be acknowledged." This means that the contributions of medical writers and editors should be transparently and clearly stated in the acknowledgments.

As explained by **Keith Veitch** in this issue of *Medical Writing*, GPP, first published in 2003, was designed to reinforce the ICMJE guidelines and "establish clear guidelines and standards for industry-sponsored biomedical research publications." GPP2, in 2009,[3] and GPP3, just published in 2015,[4] were designed to further clarify some of the grey areas. They also introduced the contributorship model of authorship, where authors need to specifically state how they satisfied the criteria for authorship. A main goal of GPP3 is to eliminate the practices of guest authorship and ghostwriting. It also discusses in detail the valid role of medical writers and provides recommendations on how authors of publications should work with a medical writer.

By the way, EMWA's position on ghostwriting is articulated in its Ghostwriting Position Statement.[5] It insists that "medical writers have a legitimate role in assisting named authors" and should not be referred to as ghostwriters because our contributions, and funding for our work, should not be secret and should instead be openly acknowledged. The American Medical Writers Association (AMWA) takes a similar stance in their position statement.[6]

Most journals now require that authors meet at least the first three of the ICMJE authorship criteria, and most companies require their employees to follow GPP guidelines, but that does not necessarily mean that the practice of ghost authorship has disappeared. Based on the results of surveys of EMWA and AMWA members conducted between 2005 and 2014, **Cindy Hamilton** and **Adam Jacobs** report in this issue that although the practice has decreased, approximately one-third of respondents were aware of ghostwriting as a continuing problem. Clearly, unethical authorship practices continue and more work needs to be done to wipe them out.

Alastair Matheson argues that even if these guidelines, recommendations, and position statements were followed perfectly, they do not go far enough – that we should be discussing not just authorship but *attribution*, which he defines as "what the article communicates to readers about its stakeholders, origins, and development." In particular, he says that

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in industry-sponsored publications, there is a systematic over-emphasis on academic recruits and downplaying of the sponsoring companies, with the specific intent of using "key opinion leaders" that had nothing to do with the study as product advocates. He says that this unethical practice should be eliminated but that it is consistent with existing guidelines and recommendations. In his article, he suggests specific steps to ensure that companies are assigned the "dominant authorial role" in industry-financed publications.

Thanks to increasing awareness of the potential for unethical advocacy practices and bias, the US enacted the Sunshine Act in 2010. The Sunshine Act, and its European equivalents, require disclosure of transactions or "transfers of value" between industry and healthcare practitioners. **Kim Pepitone** writes about the effects of this legislation on medical writers and authors. She explains that, unfortunately, whether industry support for medical writing and editorial services should be reported remains unclear. She says that requiring authors to report it may scare away potential study investigators or result in refusal of authorship by someone who should receive it, surely not the intent of the legislation.

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Although most conversation about authorship focuses on publications, **Raquel Billiones** explains that authorship of clinical trial documents also deserves scrutiny. It turns out that authorship of these documents is far less well defined for clinical trial documents than for publications. Little guidance is available in current ICH (International Committee for Harmonization) guidelines. This will hopefully change following publication of the recommendations of the CORE (Clarity and Openness in Reporting: E3 based) Reference project,[7] which is led by EMWA President Sam Hamilton and will be co-published this spring here in *Medical Writing* and in the journal *Implementation Science.*

Finally, two articles in this issue of *Medical Writing* provide practical advice on how medical writers can best work with authors on publications. In the first of these, **Andrew Walker** interviews Professor Ruth Roberts, who has published over 130 peer-reviewed research articles and reviews. In the interview, Professor Roberts describes some of the main challenges when working with co-authors including determining who will and will not be listed as a byline author. In the second of these two articles**, Prashant Auti and colleagues** discuss project management in publications writing. Their article describes a specific project management approach that can simplify and speed the delivery of publication writing projects.

Also in this issue

Last but not least, long-time EMWA member **Alison McIntosh** talks about her return from freelancing to full-time employment. This should be interesting to the many full-time medical writers who fantasize about the independence of freelancing, as well as the many freelancers who are considering sacrificing self-determination for stability.

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