Exploring Diversity and Common Ground in Medical Communication

This article is the last in a series of articles based on interviews with leaders in allied organizations in an effort to explore the diversity of medical communication and the "hot topics" that AMWA and other groups are confronting.

PUBLICATION PLANNERS AND MEDICAL WRITERS: A NATURAL ALLIANCE

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In 2007, a legislative earthquake of 5.1 magnitude hit the US pharmaceutical industry. Congress passed the Food and Drug Administration Amendments Act (FDAAA), which expanded requirements for **ClinicalTrials.gov** such that phase II–IV clinical trials of drugs, biologic agents, and medical devices must now be registered there.[1]

The FDAAA changed clinical trial registration in 2 other vitally important respects. First, it required posting of study *results* at **ClinicalTrials.gov** (an added requirement to the basic trial design and contact information required previously). Second, it set onerous deadlines for doing so.[1] But publication planners (also sometimes referred to as medical publication professionals) were well-poised to respond. Faced with the prospect of having to post trial data even before they could be published, along with the gathering storm about disclosing funding support and medical writing assistance, the medical publication industry created 2 professional societies well before the legislation was passed. Publication planners, the least well-understood participants in medical publishing, were suddenly at the forefront, working with medical writers and other stakeholders to create guidelines for timely and transparent communication of clinical trial results.

AN OVERVIEW OF PUBLICATION PLANNING

A publication plan is a structured approach to disseminating basic research results and clinical trial data for a new product, a new use for an existing product, or a new approach to disease management. In its simplest form, publication planning involves developing timetables and venues for publications and presentations that will come out of a single study. More often, the term refers to managing the complex communications needs of an entire development program, taking into account very early phase I studies through large, multicenter phase III trials that involve many investigators and that are critical to the evidence base that informs health care.

When done without integrity, publication planning has been criticized as "ghost management" of scientific research for marketing purposes.[2] In the current environment, there are published standards, guidelines, and position statements of professional organizations for publication planners and medical writers to follow.[3–11] The most comprehensive of these is "Good Publication Practice for Communicating Company Sponsored Medical Research" (GPP2, published in 2009),[10] which updates "Good Publication Practice for Pharmaceutical Companies" (GPP, published in 2003).[4] There are several key differences between these 2 sets of guidelines (Table 1). Like GPP, the GPP2 guidelines are designed for use by companies that sponsor clinical trials and any companies or individuals who work on industry-sponsored publications (eg, freelance writers, contract research organizations, and medical publications and communications companies). GPP2 guidelines apply to oral/audiovisual presentations at scientific meetings as well as to journal publications (both peer-reviewed and non-peer-reviewed). The AMWA Board

Table 1. Key Differences between GPP and GPP2

Element	GPP (2003)[a]	GPP2 (2009)[b]
Development process	Draft created in 1998 by a working group of what is now CSE; after review by the authors' companies, published in 4 journals in 2000; final version published by 3 authors in their individual capacities	GPP revised/expanded by a 14-member ISMPP steering committee, then submitted to 193 consultants from all areas of medical publishing (including AMWA representatives); 116 blinded sets of comments evaluated by the steering committee; final version published in a peer-reviewed journal
Authorship	Follow ICMJE guidelines where possible or list contributors if the journal requires that. Whatever the criteria, apply them in the same way to both external investigators and company employees.	As in GPP, plus "Before writing begins one author (a lead author, who may also be guarantor) should take the lead for writing and managing each publication or presentation. One author (identified as guarantor) should take overall responsibility for the integrity of a study and its report."
Contributorship	As above	Gives detailed guidance about how contributors, including sponsor companies, should be acknowledged
Acknowledgement of professional medical writers	The medical writer should be acknowledged	"We recommend that authors and professional medical writers working with authors use a published checklist to discourage ghostwriting.[c] We recommend that particular care is taken to ensure appropriate acknowledgment of the contributions made by medical writers and to describe their funding."
Reimbursement	No guidance	Authors should not receive honoraria for peer-reviewed articles or presentations. Reimbursement of travel expense and payment for specialized services such as statistical analysis may be reasonable.
Documentation	No guidance	Companies should develop policies on the types of documentation to be maintained and for how long (eg, retain main versions of the draft to document how comments on previous versions were incorporated)

Abbreviations: CSE = Council of Science Editors; ICMJE = International Committee of Medical Journal Editors; ISMPP = International Society of Medical Publication Professionals.

[a]*Wager E, Field EA, Grossman L. Good publication practice for pharmaceutical companies.* Curr Med Res Opin. *2003;19(3):149-154.*

[b]*Graf C, Battisti WP, Bridges D, et al. Good publication practice for communicating company sponsored medical research: the GPP2 guidelines.* BMJ. *2009;339:b4330. Available at* ***www.gpp-guidelines.org****. Accessed July 24, 2010.*

[c]*The checklist is published as Table 1 in Gøtzsche PC, Kassirer JP, Woolley KL, et al. What should be done to tackle ghostwriting in the medical literature?* PLoS Med. *2009;6(2):e23.*

of Directors endorsed GPP2 in April 2010.

In addition to its emphasis on ethical practices, GPP2 recommends that authors follow established reporting standards, such as the CONSORT guidelines for reporting randomized, controlled trials and the PRISMA guidelines for reporting systemic reviews and meta-analyses. A library of reporting standards can be found at **www.nlm.nih.gov/services/research_report_guide.html**.

Any publication plan should be based on a needs assessment, conducted to determine the current knowledge of each audience (eg, physicians, nurses, and pharmacists) and its informational needs. Publication planners also determine when, and in what format, each audience should get the information. For example, for a late phase III trial of a lung cancer treatment, the publications team might decide to target the following.

- An oncology congress that will be held just after the final data are expected to become available
- An oncology journal whose submission-to-publication lead time is such that it can be expected to publish the primary report within a year of trial completion
- An oncology journal with a higher impact factor, for publication of a secondary analysis
- A journal for oncology nurses, for publication of a review article that helps provide clinical context for the data

For years, publication planning has been done inhouse by the pharmaceutical, biotechnology, or medical device company or has been outsourced to a medical communications or publications company. Before

beginning to implement the plan, a publications team must reach consensus on the roles and responsibilities of the authors; the medical writer; other contributors, such as statisticians; the medical communications or publications company, if any; and the sponsor company. The GPP2 guidelines note that it may be useful to form a publications steering committee that comprises members of the study steering committee and the protocol development team, other investigators involved in the clinical program, and employees of the sponsor company.[10]

According to GPP2, study sponsors also have a responsibility to make all data available to all authors and other publication contributors.[10] Designation of authors versus contributors to be acknowledged should follow the ICMJE criteria.[11] The authors must be involved with the manuscript from inception through publication, and they have ultimate authority over the content and responsibility for it after publication. The roles of all participants in the process—including the professional medical writer—must be transparent, and all contributors to the publication, including the sponsor company, must be acknowledged according to the journal's guidelines. Some journals still do not have requirements for disclosures, but proponents of good publication practice advocate providing the disclosures regardless.

ISMPP

The development of GPP2 was led by the International Society for Medical Publication Professionals (ISMPP), which was founded in 2005. According to its Web site (**www.ismpp.org**), its goals are to "advance the medical publication profession through education and advocacy; drive integrity, excellence, and transparency in medical publications; and lead the establishment and adoption of medical publication standards and best practices." The approximately 1,000 members represent all segments of the medical publication profession, including pharmaceutical, biotechnology, and medical device companies; publishers; medical communications and publication agencies; academicians; investigators; editors; and independent medical writers.

ISMPP describes itself as "the only not-for-profit professional organization dedicated to supporting medical publication professionals." It is member-driven through volunteer committees and a member-elected Board of Trustees. Remarking on the differences between ISMPP and AMWA, ISMPP President Julia Ralston says, "Although there are clear differences between the 2 organizations, certainly in terms of history, scale, and focus of the member functions, there is also overlap where medical writing plays an appropriate role in the publication arena. This provides the basis for our collaboration to maximize the best of both organizations in terms of ensuring transparency and integrity in medical publications."

ISMPP holds an annual conference, open to members and nonmembers; presents monthly educational Webinars on a range of topics relevant to the profession at no charge to members; and provides a member lounge on its Web site, where members can access job postings, a Listserve, news alerts, and other resources. To both members and nonmembers, ISMPP offers the opportunity to sit for the Certified Medical Publication Professional (CMPP) examination, discussed at length in a previous issue of the *AMWA Journal*.[13] According to the January 2011 issue of the ISMPP newsletter, approximately 300 individuals worldwide hold the CMPP credential.

TIPPA

The International Publication Planning Association (TIPPA) is a membership organization run by a group of volunteer board members sponsored by Pharmaceutical Education Associates, LLC (PEA), a division of Financial Research Associates, LLC. Although TIPPA is a for-profit organization, its Web site explains that it "is not and has never been intended to be a revenue-producing 'business' " (**www.publicationplanningassociation.org**). TIPPA was established in 2005 following a conference hosted by PEA on publication planning; the tremendous interest by participants in that meeting led to the development of the more formal group.

Each year, TIPPA sponsors 2 conferences that comprise discussions by industry leaders about ethics, editor/journal views on industry-sponsored publications, current publishing guidelines, and much more. Featured speakers are professionals from the publication planning industry, but no advertising or commercial messages are allowed, in order to maintain the unbiased open exchange of information, ideas, and feedback by TIPPA members. Membership in the organization is free.

TIPPA aims to "foster excellence in the publication planning and communications within the biopharmaceutical industry by providing a foundation from which the industry can stand together to organize thoughts and present recommendations and ethical guidance," its Web site states. "In addition, TIPPA provides practical strategies for developing, implementing, and executing an effective publication and communication plan." According to Art Gertel, a member of the TIPPA advisory board and an AMWA past president, TIPPA does not have a formal organizational goal of advocating for the publication planning industry. However, he notes that, by coming together for dialog with thought leaders and other industry professionals, TIPPA members can raise awareness of issues that affect publication planners. So, although TIPPA does not concentrate on education or advocacy, it does present forums for discussion of current

industry practices, views, and news. Among other offerings, any qualified person who registers at the Web site can tap into a job bank, article archive, and message boards.

WHERE ARE WE HEADED?

At recent meetings of ISMPP and TIPPA, speaker presentations addressed authorship, industry transparency in publishing, and the FDAAA regulations on the posting of clinical study results, among other topics. These regulations deserve particular attention from medical writers. For trials involving approved products, the results must be posted within 1 year of completion, which is defined as "the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome."[1] For new products, and new indications for approved products, clinical trial results must be posted to **ClinicalTrials.gov** within 30 days after initial approval of a drug or new indication. Companies may be fined up to $10,000 per day if they fail to post their data on time.

The ICMJE does not consider posting of trial results on **ClinicalTrials.gov** to constitute prior publication.[11] In general, though, sponsor companies prefer to publish their data before posting it there, to provide clinical context that assists the reader/practitioner with interpretation of the data, reduce the chance for misinterpretation by the public, and avoid other problems that could arise from posting data that have not been peer-reviewed.[13] Therefore, sponsors are trying to have manuscripts written very soon after the data become available, sometimes even before the clinical study report is complete.[13] All aspects of publication planning now have to be decided much earlier in the clinical program, and many companies now have standard operating procedures in place that dictate the sequence of events that must occur for regulatory compliance. Medical writers who understand these constraints will be invaluable to the companies with which they work.

At the Midwest TIPPA meeting in February 2010, publication planners uniformly indicated that there is a very clear delineation between the science and marketing functions of their companies. Although this distinction may be common practice now, convincing critics is another matter entirely. There is still much to do in raising awareness of the medical writing and publication planning professions and how they function, and in ensuring that all stakeholders follow current guidelines such as GPP2. But we are making strides in the right direction. Working together, medical writers and publication planners have created and are upholding ethical standards and best practices that increase our transparency and credibility. TIPPA and ISMPP are 2 organizations that are helping us to do this.

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