



### Journal watch:

## Publication practices survey, advice on using medical writers, advertorials, new GPP guidelines, and ghost management of medical publications

by Nancy Milligan

### Authorship, writing, and publication planning practices survey

Surveys on publication practices tend to be based on author responses or acknowledgements in published articles; Stephanie Phillips has carried out a survey with a different approach: of writers within healthcare companies [1]. A 16-item questionnaire was emailed to over 700 American Medical Writers Association (AMWA) members involved in, or knowledgeable about, their company's authorship, writing, and publication planning practices. 61 members responded (53% worked for a pharmaceutical company and 28% worked for service companies, e.g. medical communications agencies, contract research organisations). The major findings of the survey were:

- Use of medical writers: research articles were more likely to be drafted by medical writers than review articles; a third of responders said that their companies were more likely to use medical writers now than 5 years ago, although 63% felt that there had been no change; speed and quality were the main reasons for companies using medical writers
- Publication planning: 66% said that their company developed publication planning strategies (21% suggested they sometimes did), this was higher for pharmaceutical company employees (75% yes, 19% sometimes)
- Role of author and writer: for research articles, 70% said that authors were not involved until after data tables were developed, 5% said authors were not involved until a first draft of the article had been prepared; for review articles, 75% said that authors were involved before an outline was written; responders estimated that when drafting an article, 51% of content was controlled by the author, 32% by the writer, and 19% by the company
- Acknowledgement of medical writers: 49% said that their company always acknowledges medical writers (this was less common in medical communications companies [18%] than in pharmaceutical companies [67%]); 64% felt that writers are more likely to be acknowledged now than 5 years ago (35% felt that there was no change); 88% did not feel that acknowledgement made acceptance less likely

The author commented that the survey seems to suggest that companies are using medical writers more, involving authors earlier in the writing process, and are more likely

now than previously to acknowledge medical writers, which helps to make the process more transparent.

### Advice for authors using professional writers

Writing recently in the *Clinical Journal of Oncology Nursing (CJON)*, Mayer et al suggest that the journal "needs to provide more guidance to authors to ensure *CJON* articles are unbiased as well as to help develop the publication skills of oncology nurses" [2]. To avoid ghostwriting, *CJON* previously had an editorial policy banning articles written by medical writers; however, in this article Mayer et al recognise that ghostwriting does not occur if writing support is clearly described in published articles. Mayer et al suggest that authors should think about several key points when considering hiring a professional writer; these were, in brief: ask questions about how and why a potential author is approached to write the paper, retain ownership of the work by determining the flow and direction of the paper, review and approve the amount and type of editing before submission, and upload the article files or request a copy of the final uploaded version if the writer/company submits to ensure version control (they suggest the author should also be in charge of editing queries and review of the final proofs). Mayer et al argue that transparency is essential to maintain editorial integrity and therefore the published article must honestly acknowledge the use of a professional writer, the funding source of the support, and the extent to which the author claims ownership of the paper.

### Journals and 'advertorials'

In a series of letters to *The Lancet*, the topic of journals publishing 'advertorials' (advertisements disguised as editorial content) was discussed [3]. In the first letter, Meilof and Hylkema criticised a *Lancet*-published research article by Ho et al [4], which they considered an advertorial because 8 of the 12 authors (including the first and corresponding author) were employed by Merck, the funding sponsor of the study. They also pointed out that data were analysed and the process supervised by employees of Merck, and that 3 employees drafted the first version of the paper. Meilof and Hylkema argued that this raises the question of who, independent of the sponsor, can vouch for the integrity of the data and the presentation of the results. They went on to suggest that a paper should not be accepted for publication if the first and last authors are employees

## Publication practices survey...

of the funding sponsor. In response letters, academic authors (Ferrari, Dodick, Winner, and Koppen) and industry authors (Ho, Michelson, and Gertz) agreed that whether conflicts of interest should disqualify researchers from participating in scientific discourse was an important issue, but suggested that they had been completely transparent and honest about the people involved in the design, conduct, analysis, and interpretation of the study in full compliance with the guidelines for authorship (which they suggest is a good deal better than using ghostwriters and fake first authors). They went on to argue that just because a researcher works for a pharmaceutical company doesn't mean that they don't have adequate professional training and an allegiance to scientific principles, as do other researchers. They also pointed out that many journals, including *The Lancet*, have developed policies and practices to reduce bias from potential conflicts (i.e. by requesting to see the protocol or analysis plan that was finalised before unblinding data). They suggested that "rather than simply criticising pharmaceutical industry involvement, the real challenge should be to come up with a realistic solution to prevent industry-biased publications".

### GPP guidelines for medical communications agencies

Published guidelines and recommendations for publication practices are available to strengthen and uphold ethical standards in biomedical communications. Various guidelines have been developed that reflect the perspective of medical journals, medical writers, publishing professionals, and the pharmaceutical/biotechnology industry. A recent article provides the first publication of good publication practice (GPP) guidelines specifically focusing on the perspective of a medical communication agency [5]. A task force of staff members from the AXIS group of companies in the US reviewed current guidelines and agreed that a GPP document specific to medical communications agencies was needed. Accordingly, the guidelines, provided in full in the article, were developed collaboratively over the course of a year by a working group of employees within the AXIS group of medical communications agencies. The goal of the guidelines is "to provide guidance for medical communications agencies supporting the development of medical publications in collaboration with both the research sponsors and the authors/researchers responsible for the design of the study and the collection of the data". The resulting guidelines are aligned with existing publication guidelines and cover several key issues such as authorship, transparency and acknowledgements, potential conflicts of interest, and financial disclosures. They also provide guidance on topics perhaps unique to agencies, such as interactions among medical writers and editors as part of an agency, authors, journals/congresses, and the sponsoring company; submission processes; data security and confidentiality; and training. The guidelines were developed for the use of agencies in the US, but should be of interest to agencies in other countries as well.

### Publication planning: ghosts in the machine

And finally, in a recent article in *Social Studies of Science*, Sergio Sismondo, associate professor of philosophy at Queen's University in Canada, discusses pharmaceutical company publication planning [6]. In general, Sismondo is quite critical of publication plans saying they "extract the maximum amount of scientific and commercial value of data and analyses through carefully constructed and placed papers" and argues that it reflects "a new kind of corporate science, designed to look like traditional academic work, but performed largely to market products". He suggests that most pharmaceutical company-sponsored research is now carried out by contract research organisations (CROs), analysed by pharmaceutical company statisticians, written up by medical writers, approved and edited by academic researchers who then serve as authors, and the whole process is guided by publication planners. He argues the work of these people behind the scenes is rarely acknowledged, and for this reason suggests we should see publication planning as the "ghost management" of medical research and publication. The bulk of the article reports on a conference of an international association of publication planners (the third annual meeting of the International Society of Medical Planning Professionals, the ISMP), during which Sismondo relays some of the main points made by speakers during the conference and uses examples to liken publication planning to marketing and public relations. There is also a section on authorship and ghostwriting, which was also a topic covered at the conference, in which the author talks about the role of key opinion leaders as authors and the distinction between ghostwriting and medical writing. He acknowledges that both publication planners and pharmaceutical companies want formal guidelines and standardised procedures and formats for clinical trials and journal papers, even though, he points out, that publication planning "runs directly against the goals behind those guidelines and standards".

### Nancy Milligan

Dianthus Medical Limited  
nmilligan@dianthus.co.uk

### References:

1. Phillips SG. Authorship and writing practices in the health care industry. *AMWA Journal* 2009;24(1):4-8.
2. Mayer DK, Mahon SM, Eaby B. Writing for hire: advice for authors (and readers). *Clin J Oncol Nurs* 2009;13(2):131-2.
3. Meilof JF, Hylkema MN. The Lancet and advertorials. *Lancet* 2009;373(9668):1004; author reply 1004-5.
4. Ho TW, Ferrari MD, Dodick DW, Galet V, Fan X, Leibensperger H, Froman S, Assaid C, Lines C, Koppen H, Winner PK. Efficacy and tolerability of MK-0974 (telcagepant), a new oral antagonist of calcitonin gene-related peptide receptor, compared with zolmitriptan for acute migraine: a randomised, placebo-controlled, parallel-treatment trial. *Lancet* 2008;372(9656):2115-23.
5. Bareket-Samish A, Denny M, Ruzicka B, Bogush M, Flynn K, Glinka K, McMahon-Wise B, Schiller S, Sjostedt P, Matheson N. Good publication practice guidelines for medical communications agencies: a MedComm perspective. *Curr Med Res Opin* 2009;25(2):453-61.
6. Sismondo S. Ghosts in the machine: publication planning in the medical sciences. *Social Studies of Science* 2009;39(2):171-98.