

## **Good Publication Practice...**

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If you work in or for the pharmaceutical industry you can hardly fail to have noticed the criticism published in major medical journals about publication practices. Editors and academics have criticised companies for selective reporting of clinical trials, duplicate publication and various other misdemeanours [1]. Yet ironically, attempts to raise publication standards by using professional medical writers have also met with displeasure and there seems to be much misunderstanding among journal editors and academics about the role of medical writers. The reaction of David Sharp, deputy editor of *the Lancet*, to information from a communications agency at the 1998 EMWA conference is a good example of such views [2]. We clearly need to educate journal editors about the importance of medical writers and one initiative is a set of guidelines developed from within the industry to address this problem and related issues.

### ***Where did the idea come from?***

Getting clinical trials published requires collaboration between company employees, external investigators and journal editors. The complexities and difficulties of this three-way relationship formed the subject for a retreat sponsored by the Council of Biology Editors in November 1998. Lack of understanding of how and why pharmaceutical companies handle publications as they do emerged as a source of many of the problems. After the meeting, participants from publication and medical writing departments within Astra Zeneca, Glaxo Wellcome, Merck, Eli Lilly and Hoechst Marion Roussel (now Aventis) were inspired to develop common publication guidelines for pharmaceutical companies. The aim was to encourage high standards of publication by pharmaceutical companies, to reduce editors' misunderstandings about the industry, to raise awareness within the companies themselves, and, ultimately, to improve relations with journal editors and investigators. The guidelines are entitled Good Publication Practice (GPP).

### ***Do we need yet more guidelines?***

The guidelines are designed to supplement documents such as the ICMJE Uniform Requirements [3] and the CONSORT statement [4]. As you might expect, they cover some similar ground, but they add detail designed specifically to aid those working in or for the industry. The GPP guidelines also break new ground in recognising the important role of professional medical writers.

### ***Role of professional medical writers***

The existence of professional medical writers is not acknowledged in journals' instructions to authors or standard texts about writing, yet many companies use them to assist with writing, editing and preparing manuscripts. Although professional writers can raise the quality of manuscripts, ensure that guidelines such as CONSORT are adhered to, increase the chance of acceptance and accelerate publication, many journal editors view them as 'ghost writers', exerting a hidden, shadowy and malign influence[2]. The GPP guidelines therefore provide detailed recommendations on this topic with particular emphasis on the relationship between the writer and the named

## ***The Write Stuff***

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authors. Some of the recommendations will seem obvious to EMWA members but they have been included because of concerns expressed by editors.

The GPP guidelines state that the named authors must determine the content of the publication and retain responsibility for it. All authors should have access to the statistical reports and tables and should be given adequate time to comment on both early and final drafts of the manuscript. The guidelines emphasise the need for named authors to be closely involved with the development of the paper, from agreeing on an outline before the first draft is prepared to submitting the final version to the journal.

At the original three-way meeting, many journal editors accepted that medical writers could play a legitimate role in publishing results from clinical trials, especially in coordinating publications from large, multicentre studies. However they remained adamant that they did not wish to publish editorials or opinion pieces which had been ghost-written. They felt strongly that an article purporting to represent the views of an opinion leader must originate from the named author, although it would be acceptable for a professional writer or author's editor to assist non-native English speakers to polish an article for publication. These views are therefore reflected in the guidelines.

#### **Commitment to publication**

The GPP guidelines state that companies should endeavour to publish the results from all of their clinical trials. Getting papers published takes time and resources and, perhaps understandably, companies have often been unwilling to spend money and time on publications that they fear may damage sales or aid competitors. However, pressure is increasing on companies to take responsibility to endeavour to publish results from all clinical trials, and many now feel that this is an ethical imperative for any research involving patients. This commitment should therefore improve relationships with investigators and opinion leaders. Publications should present results accurately, objectively and in a balanced fashion and should follow the ICMJE Uniform Requirements and CONSORT guidelines.

#### **Relationships with investigators**

The GPP guidelines recommend that companies have written agreements with investigators that set out policies about publication and ownership of the data. Companies should take responsibility for preventing misleading or duplicate publications of data subsets from multicentre trials but they must not suppress or veto legitimate publications prepared by investigators.

#### **Authorship**

Many editors recognise that the so-called 'Vancouver criteria' for authorship [1] no longer reflect the complex organisation of institutional studies, and some journals therefore list contributors stating who did what. Since journals operate a variety of authorship listing systems, the GPP guidelines recommend that the individual requirements of the selected journal be respected. They go on to state, however, that whatever criteria for authorship are used, they must be applied in the same way to both external investigators and company employees. It seems only fair that scientists, whoever their employer, should be on equal terms when it comes to recognition. This recommendation may result in more company personnel being named on publications and, in the long -term, may perhaps increase awareness of scientists working within industry and appreciation for the calibre of their work. When medical writers are involved, the guidelines recommend that their contribution should be stated in the acknowledgements.

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#### ***Release of results***

Before a paper is published, abstracts, posters or lectures at conferences are useful and well-accepted ways of informing the scientific community about new results and generating discussion about their significance. However, most peer-reviewed journals will not consider papers that have already appeared in, are under consideration by, or have been accepted by, other journals. Similarly, they may impose embargoes preventing media contact such as press releases before full publication. The GPP guidelines recognise these standards and encourage companies to adhere to them.

The guidelines recommend that all publications should include a unique study identifier (e.g. a protocol number) so that abstracts can be linked with full papers, and the relationship between primary papers and secondary publications such as interim analyses or long-term follow-ups is apparent. This is a simple, but important measure to reduce the effects of publication bias on systematic reviews and to increase confidence that companies are not attempting covert duplicate publication.

#### ***Where do we go from here?***

It took almost a year to agree to the wording and obtain approval from senior management in our five companies. Because the GPP Working Group was self-appointed, we considered it only fair to share our efforts with others before we published the document, and have therefore sent copies to over 50 pharmaceutical companies encouraging them to sign up. So far we have received eight endorsements (from 3M Pharmaceuticals, Astra Zeneca, Aventis, Eli Lilly, Glaxo Wellcome, Merck, Otsuka America and Serono). If you would like to receive a copy of the GPP guidelines, please do get in touch. Once we have a list of endorsing companies we will submit the guidelines, together with the list of signatories, to a major medical journal for publication [5].

After this, we will continue to spread the word about GPP and hope that the guidelines will become as well accepted as GCP. Ultimately, we hope they will serve to raise publication standards for clinical trials and increase respect for the role of professional medical writers working in or for the pharmaceutical industry.

#### **References**

- 1 Angell M. Is academic medicine for sale? *New Engl J Med* 2000; 342: 1516-1518.
- 2 Sharp D. A ghostly crew. *Lancet* 1998; 351: 1076 and responses from Wager E and Grossman L. *Lancet* 1998; 351: 1741.\*reprinted in *The Write Stuff* 1998; 7, (2 and 3).
- 3 Uniform requirements for manuscripts submitted to biomedical journals and separate statements from the International Committee of Medical Journal Editors. American College of Physicians, Philadelphia 1997.
- 4 Begg C, Cho M, Eastwood S, Horton R, Moher D, Olkin I, et al. Improving the quality of reporting of randomized controlled trials. The CONSORT statement. *JAMA* 1996; 276: 637-639.
- 5 Sharp D. Drug industry code proposed on "ghost" writing. *Lancet* 2000; 355: 1084

#### **Acknowledgement / contact details**

The GPP Working Group comprises Liz Wager & Betts Field (Glaxo Wellcome), Leni Grossman (Merck), John Tumas (Astra Zeneca) and Brad Glazer (Takeda). For more information or a copy of the GPP guidelines, please contact Liz Wager ([ew33645@glaxowellcome.co.uk](mailto:ew33645@glaxowellcome.co.uk), fax (+44-208-966-4117). A longer version of this article will appear in *Clinical Research Focus* (vol. 11, no. 5). We thank Guy Moody for agreeing to the publication of this version.