



**Journal watch:**

## Improving the reporting of pragmatic trials and more on ghostwriting

by Nancy Milligan

### New guidance for reporting pragmatic trials

Pragmatic trials, designed to inform decisions about clinical practice, can be distinguished from explanatory trials which are designed to test causal research hypotheses [1, 2]. Pragmatic trials use design features that maximise the applicability of the trial's results to the usual care setting, and calls have been made for more pragmatic trials to be undertaken to inform real world choices. Poor reporting can reduce the usefulness of findings from these studies, but until now there have been no accepted guidelines on the reporting of pragmatic trials. In a recently published specific extension to the CONSORT (consolidated standards of reporting trials) statement, Zwarenstein et al have proposed guidance for reporting pragmatic trials to make explicit the important attributes of these trials with the aim of helping users to determine whether the results are applicable to their own situation [1, 3]. In developing the extension, two two-day meetings were held in Toronto, Canada in January 2005 and March 2008 to discuss ways to increase the contribution of randomised controlled trials to health care decision making, with a focus on pragmatic trials. 66 participants attended the two meetings including people with experience in clinical care, commissioning research, health care financing, developing clinical practice guidelines, and trial methodology and reporting. After the first meeting in 2005, a draft revised checklist and summary paper for the extension was drafted and circulated to a writing group who produced a draft summary paper. The draft was discussed and modified at the 2008 meeting then circulated to the CONSORT group for feedback before submitting it for publication. The meeting participants agreed that the CONSORT checklist and flow diagram did not need modification. However, they felt that eight items on the checklist needed additional text specific to the reporting of pragmatic trials: item 2 (background), item 3 (participants), item 4 (interventions), item 6 (outcomes), item 7 (sample size), item 11 (blinding/masking), item 13 (participant flow), and item 21 (generalisability). For each item, additional guidance was presented along with the standard CONSORT text, as well as an example of good reporting for the item and an explanation of the issues. Zwarenstein et al. hope that the new guidelines will "help editors, reviewers, trialists, and policy makers in reporting, reviewing, and using pragmatic trials", and encourage journals who have endorsed the CONSORT statement to also support CONSORT for pragmatic trials by including a reference to it in their instructions to authors [1].

### 'Ghostbusting' at Blood

In a recent editorial, the editor-in-chief and associate editor of *Blood* journal discuss ghost authorship based on a review article received, and rejected, by the journal in which a pharmaceutical company employee listed in the acknowledgements section was claimed to meet the criteria of a ghost author, i.e. the journal felt that the person had made a substantial contribution to the research or writing of the article, but had not been listed as an author [4]. It should be noted that this person does not meet the standard definition of ghost author as they were mentioned in the acknowledgements section; however, the failure to disclose that the employee worked for a pharmaceutical company and clarify the role this employee played in the submission would be considered bad practice according to most guidelines. All authors are asked to complete a detailed conflict-of-interest disclosure at the time of submission to *Blood*, but the editors suggest that ghost authors, who by definition are not listed as authors, present a real and major problem for journals. The editors are particularly concerned about primary research articles because of the potentially large number of people involved in designing, carrying out, and reporting clinical trials. They offered that if a professional writer or researcher is used then the EMWA principles should be adhered to: are the authors guarantors of the article; was the professional writer advised by the authors before starting the writing assignment; was there transparency, that is, were the writers and researchers identified appropriately on the authorship line or in the acknowledgements section; does the professional writer have the appropriate expertise and background to provide substantive input to the background research or writing of the article [5]? The *Blood* editors also emphasised the importance of first and senior academic authors taking full responsibility for the material. They finished with an assurance that the editors and staff at *Blood* "will do everything possible to ensure that our readers receive information from *Blood* articles that is as unbiased as possible, with full disclosure of possible conflicts and acknowledgement of the participation of all writers and researchers", and invite *Blood* readers to join them in their 'ghostbusting' mission [4].

### Three perspectives on tackling ghostwriting

Ghostwriting is considered bad publication practice in the medical sciences, and some argue that it is scientific misconduct. In a recent debate, this issue was considered by three differing perspectives: a researcher (Peter C

## Improving the reporting of pragmatic trials and more on ghostwriting

Götzsche), an editor (Jerome P Kassirer), and a group of professional medical writers (Karen L Woolley, Elizabeth Wager, Adam Jacobs, Art Gertel, and Cindy Hamilton) [6]. The article started with the views of Peter C Götzsche who argued that because scientific communication depends on trust, then ghostwriting should be considered scientific misconduct and handled accordingly. He put forward some suggestions that might reduce the prevalence of misappropriated authorship: 1) all journal articles should list the contributions of the authors; 2) editors should explain in their instructions to authors that ghostwriting is scientific misconduct and will be exposed if detected; 3) editors should ask authors to specify who wrote the first draft of the paper, and should contact these people to confirm their contribution if they are not authors; 4) editors should not accept meaningless statements in the acknowledgements, such as 'We thank XX' or 'XX provided editorial assistance'; 5) guidelines on good publication practices should be followed; 6) authors should retain copies of drafts to facilitate investigations of possible misconduct; 7) ethical review committees and drug agencies should not accept protocols without named authors to ensure accountability; 8) journals and PubMed should use the term 'misappropriated authorship' to properly document misconduct; and finally, 9) editors should insist that medical writers be authors as it is not possible to write a paper without judgement and interpretation of data. This last point is particularly interesting as it is not the mainstream view held by organisations such as EMWA and the International Committee of Medical Journal Editors (ICMJE) [5, 7]. These groups favour the position that professional medical writers should be acknowledged but do not usually qualify for authorship. Journal editor Jerome P Kassirer argued that ghostwriting is difficult to define and that we need more evidence of its frequency and impact. Kassirer suggested that overtly biased ghostwritten articles can jeopardise medical knowledge and patient care, and damage the public's trust in both the pharmaceutical industry and the medical profession. After discussing various definitions and cases of ghostwriting, he suggested that editors of medical journals should devote more effort to defining what constitutes appropriate and inappropriate participation in studies and manuscript preparation. He suggested that at the very least, editors can demand transparency by asking: who were the trial designers, conductors, researchers, data managers, and statisticians; and who wrote the manuscript and signed off on the final draft? Kassirer ended by suggesting that we should 'just say no' to ghostwriting. Finally, the group of medical writers argued that professional medical writers can be legitimate contributors to manuscripts, but that ghostwriting is dishonest and unacceptable. They suggested that professional medical writers have health care knowledge and communication expertise, and abide by ethical guidelines for medical writers. They also suggested that although medical writers assist in the preparation of documents, they should ensure that the authors control the content and that appropriate disclosures of funding and involvement are made.

They offered the medical writer's perspective on three ghostwriting questions: 1) Why don't we ban medical writers? The writers suggested that this strategy has not been embraced by many journal editors, because of the huge contribution of professional writers to the medical literature; and EMWA support disclosure rather than prohibition. 2) Why don't we develop more guidelines? The writers suggested that we already have sufficient existing guidelines and the focus should be on adherence to these guidelines rather than development of new ones. 3) Is there anything practical we can do? The writers proposed a mandatory checklist to help detect and avoid ghostwriting. They suggest that the checklist could be included in journals' instructions to authors as an extension of the journal editors' 'gatekeeping role'. The checklist prompts authors to acknowledge professional medical writers and their funding source; to confirm that the authors controlled the main points, outcomes, and data reported in the manuscript; and to verify that medical writers could provide evidence that guidelines on ethical writing practices were followed [6].

### Nancy Milligan

*Dianthus Medical Limited*  
nmilligan@dianthus.co.uk

#### References:

- Zwarenstein M, Treweek S, Gagnier JJ, Altman DG, Tunis S, Haynes B, Oxman AD, Moher D; CONSORT group; Pragmatic Trials in Healthcare (Practihc) group. Improving the reporting of pragmatic trials: an extension of the CONSORT statement. *BMJ* 2008;337:a2390. doi: 10.1136/bmj.a2390.
- Schwartz D, Lellouch J. Explanatory and pragmatic attitudes in therapeutic trials. *J Chronic Dis* 1967;20:637-48.
- CONSORT group. CONSORT statement 2007. [www.consort-statement.org](http://www.consort-statement.org).
- Dunbar CE, Tallman MS. "Ghostbusting" at Blood. *Blood* 2009;113(3):502-3.
- Jacobs A, Wager E. European Medical Writers Association (EMWA) guidelines on the role of medical writers in developing peer-reviewed publications. *Curr Med Res Opin* 2005;21: 317-21.
- Götzsche PC, Kassirer JP, Woolley KL, Wager E, Jacobs A, Gertel A, Hamilton C. What should be done to tackle ghostwriting in the medical literature? *PLoS Med* 2009;6(2):e1000023. doi: 10.1371/journal.pmed.1000023.
- International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals: Writing and editing for biomedical publication. 2006. Available: <http://www.icmje.org>.

## Themes of upcoming issues of TWS

The June issue will have a writing style theme and will also introduce a new **Linguist's corner** featuring abstracts on research relevant to medical writing.

The September 2009 issue, which will be guest edited by Adam Jacobs ([ajacobs@dianthus.co.uk](mailto:ajacobs@dianthus.co.uk)), will have a statistics theme.

Articles (up to 2500 words) and boxes (up to 1000 words) in line with these themes or on any topics of interest to medical writers or of interest to editors, translators, language teachers and linguists working in the medical field are very welcome.

### Elise Langdon-Neuner

[langdoe@baxter.com](mailto:langdoe@baxter.com)