

Responsibility of medical writers who draft articles reporting clinical trials

Commentary on: *Authorship—More than just writing, but how much more?*

by Elise Langdon-Neuner

We cannot dismiss the work of a medical writer as being of little importance, can we? Writing is more than mechanically setting words onto paper. The tremendous emphasis on the writing itself is what has given rise to the booming medical writer industry. Medical writers have not clamoured to be named as authors on biomedical papers. Unlike scientists their career progress does not depend on publications. The secrecy generally implicit in ghostwriting, which for centuries had not been viewed as a problem, only became an issue of public concern in the biomedical sciences when cases came to light where the writing did not genuinely interpret the study data, but rather was influenced by a marketing agenda which could cause harm to patients.

Liz Wager [1] and the *BMJ* are certainly not alone in their view that authorship criteria laid down by the ICMJE guidelines have serious flaws. In the main these flaws arise in their interpretation, where authors do not agree with or wish to follow the spirit of the guidelines—although they will sometimes declare compliance to nominally satisfy the requirements for publication. Only 24% of authors surveyed in a large study of pathologists and physicists agreed with the guidelines [2], which were decided and are regularly updated by the Vancouver group comprising 12 editors of general medical journals. While the ICMJE are a standard point of reference for defining authorship in the biomedical sciences, in practice authorship is governed by the rules and customs of authors' institutions and governing bodies. These rules and customs often reflect the ICMJE guidelines but override them where tradition is stronger. The naming of the head of a department as an author on every paper is one such example. Another flaw in the guidelines is that while they have concentrated on criteria for allocating credit within a traditional concept of scientific authorship, responsibility for today's papers, especially those reporting clinical trials or which are part of a pharmaceutical company's planning policy extends to employees of such companies—including statisticians and medical writers—who fit uneasily into the ICMJE's authorship criteria. Nevertheless, even within the current flawed criteria I believe that there is an argument for including medical writers on the byline of reports of clinical trials published in biomedical journals.

Liz's and I part company on her sentence "Professional medical writers are well aware that drafting a publication does not make the writer an author in the same way that, say, writing a poem makes the writer an author." I

think that it can. Let's first take a step back. Medical writers tend to claim that they only provide writing assistance. 'Writing assistance' is different from drafting an article. The first is only worthy of acknowledgement according to the ICMJE guidelines. It's the second that is worthy of authorship: "All contributors who do not meet the criteria for authorship should be listed in an acknowledgements section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a departmental chair who provided only general support" [3]. Note that 'purely *draft* the article' or 'not who only *drafted* the article' is **not** the wording. So what does drafting mean? According to the *Oxford Dictionary* a draft is a preliminary version of a piece of writing. Who produced the draft? If it was the researcher the medical writer is providing writing assistance but if it was the medical writer we are looking at authorship. A recent report provides a vivid illustration of the importance of the first draft and control of the manuscript (see Box on page 24). It has been contended that in any event at present an acknowledgement of writing assistance by a medical writer is taken to mean that the medical writer wrote and controlled the paper [4] as set out in Figure 1.

But wait, you say. According to the ICMJE, to qualify as an author a medical writer also has to analyse or interpret the data. I have two arguments here. One is that if the medical writer is preparing a manuscript from clinical trial data he¹ (personally or under instruction from his employers) may well be selecting which data to present and selecting how it is presented, drawing up tables or graphs. My other argument is that choosing the words and structure that transfer thoughts onto paper is also an interpretation. I subscribe to the notion that writing whether it be a report or a poem invariably involves interpretation and influences readers, "Language is not neutral. It is not merely a vehicle which carries ideas. It is itself a shaper of ideas" (Dale Spender).

This leads to my main quarrel with the GPP2 guidelines. Liz points out that they advise that if a medical writer is willing to take responsibility for relevant portions of the content he may be in a position to meet the remaining ICMJE criteria for authorship. The contention here is that authorship depends on 'willingness'. Surely if a researcher publishes his research he cannot choose, he must accept

¹ As a counterbalance to Adam Jacob's use of 'she' in his commentary see footnote on page 28

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Figure 1. Acknowledging ghostwriters does not accurately reflect their authorship role. This figure is a reprint of Figure 1 in [4], which was modified from Fugh-Berman A, Dodgson S. Ethical considerations of publication planning in the pharmaceutical industry. *Open Medicine* 2008. Available: <http://www.openmedicine.ca/article/view/118/215>. Used under a Creative Commons license which permits the modification and re-use of intellectual content as long as it is properly acknowledged.

responsibility for it. If a writer drafts a paper from material produced in a clinical trial he must take responsibility for the integrity of his presentation. So, although Liz says she might take responsibility for the way the research is reported, I say, I'm afraid she has to if she drafted the manuscript. She might not be able to explain why a particular trial design, statistical method etc. was used but here she would most likely be in good company with the other researcher authors who were only au fait with their part of the trial. Is the statistician responsible for the work done collecting the data in the lab? To be fair Liz does question what the ICMJE guidelines mean by authors taking responsibility for 'relevant portions of the content'. The main purpose of the guidelines as I have already mentioned seems to be to lay down criteria for awarding credit to qualify for authorship but here the guidelines venture into imposing responsibility on the author for the integrity of the paper. However, the logical concept that not all the authors can be responsible for all aspects of the paper is gaining acceptance (See Box about *Science's* policy below). Instead

Guarantors per data set to discourage 'honorary authorship'

Science now requires senior authors to certify that they have personally reviewed the original data generated by their group and the figures and tables are appropriately presented. As most papers result from co-operations between groups this is a move away from one author as guarantor for the paper. *Science* does not accept provision of laboratory space or supplying samples as adequate for authorship, for which the intellectual contribution is of prime importance. The idea that mentoring should be acknowledged is also aired in Bruce Albert's editorial, Promoting Scientific Standards. *Science* 2010;327:12.

someone needs to be responsible for each portion, one of which is the interpretation involved in drafting if the medical writer is selecting what to present, making decisions on graphic representations as well as choosing the words and structure of the paper.

There is also a circular argument which highlights the inadequacy of the ICMJE guidelines. 'Authors' have to be involved with the study. Yes, but they also have to be involved with the drafting of the manuscript. If we argue that medical writers cannot be authors because they are not involved with interpretation of the study then those who did interpret the study cannot be authors if they were not involved with the drafting. Ah, you say, but they only need to have approved the drafts. Not quite. The guidelines actually say to be an author the researcher should be involved in "drafting the article or revising it critically for important intellectual content." Do all the academic authors make this contribution when a medical writer drafts the manuscript or a statistician makes an analysis? According to the ICMJE they should, but can they and do they? Here I can do no better than to quote from a recent paper on industry-sponsored ghostwriting "Physicians may rationalize their participation in the publication of ghostwritten articles because they read and agreed with the manuscript, or even because they made a number of editorial changes they believed qualified the authorship. However, this fails to address the main problem that key marketing messages have already been incorporated into the manuscript [by the medical writer]" [5]. The article goes on to consider that more seriously the author might not have analysed the raw study data, which is another requirement of the ICMJE guidelines.

Liz deals with access to data. It's very important and the Eastell case is a good illustration. Eastell has since been cleared of misconduct by the GMC but the very fact that the GMC saw fit to investigate the matter shows how seriously they view authors' claims of having access to data [6]. Eastell did not

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- have access to all the data—only one author, the sponsor’s statistician, had this access—but the GMC found that he never said he did, the medical writer is believed to have added this statement and it would appear Eastell did not critically revise the statement but, remember, he was cleared of misconduct. Liz omits to mention that this paper did contain errors, e.g. one graph had been trimmed to exclude some of the more extreme values. Who drew the graph? It might have been a coauthor, the statistician or the medical writer.

The ICMJE’s ‘decision to publish’ and ‘final approval’ provisions also fail to reflect the real life situation. Quite apart from the finding that ‘final approval’ is the ICMJE authorship criteria where authors are least compliant [7], if an article is part of a publication planning policy, who is making the decision to publish and who gives the final approval? One person at least is probably the manager of the publication planning department or the medical writer’s boss. Does the name of this individual appear in the byline?

At the end of the day my question is this: if each of the researcher authors and the statistician is taking responsibility for his part of the work what is it that is stopping medical writers from taking responsibility for their part, i.e. the drafting, if they have done this? If it is solely that they do not feel they deserve the credit of authorship according to the ICMJE’s criteria, the Vancouver group should make provision for a declaration that a paper has been produced as part of a company’s publication planning policy. If individuals employed by the company selected and analysed the data to be presented, drafted the article, or approved the paper they could then be named in the declaration and accept responsibility for their contribution. In this way transparency would be achieved and any fear that medical writers might have of carrying the whole weight of the sponsor’s internal decisions solely on their shoulders would be avoided—a fear that possibly plays a greater role in their shying away from authorship than the debates on meeting authorship criteria laid down by the ICMJE reveal.

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Who produced the draft and controlled its revision?

McHenry and Jureidini examined documents produced in court proceedings against SmithKline Beecham (SKB) relating to their antidepressant drug paroxetine (Paxil/Seroxat)¹. The 3 studies conducted by SKB to obtain regulatory approval for the paroxetine for adolescents had failed to show superiority of the drug over placebo on the primary outcomes. Prescription of Paxil to adolescents therefore was only possible off-label. SKB contracted Scientific Therapeutics Information (STI) to prepare a based on one of the studies, Study 329. STI was to be paid \$17,250 for production of the paper. Sally Laden, the medical writer at STI, testified that she prepared the first draft without input from any of the authors. She relied on the final clinical report of study 329 provided by SKB. Although her writing assistance was acknowledged in the paper her role in writing the first draft and guiding the process as well as her relationship with the sponsor was not revealed.

When questioned why her first draft failed to distinguish between primary and secondary efficacy variables, Laden replied “this may have been my interpretation of the data” but she did not know why there were 8 primary efficacy variables in the draft whereas there had only been 2 in the report. McHenry and Jureidini found that in contrast to the clinical report Laden’s draft gave a systematic misleading impression of efficacy and safety. The published paper’s claim that paroxetine is “generally well-tolerated and effective for major depression in adolescents” was not supported by the data. The substance of the published paper did not differ from the first draft. From McHenry and Jureidini’s analysis of the documents they concluded that at least 10 of the 22 named authors made no contribution to the article content and those who did mostly provided only minor text editing. Several undeclared SKB employees made greater contributions. One of the authors submitted an amendment to correct the inaccurate account of serious adverse events but his amendment was tempered, apparently from the SKB/STI side, prior to publication. McHenry and Jureidini found difficulty in deciphering who was responsible for the distortions in the final paper but concluded that the sponsor retained control of the manuscript and “the fact that the article was ghost-written meant that individuals unknown, presumably from within SKB, could intervene without the named authors being encouraged to step in to correct any manipulation of the data.”

¹ McHenry LB, Jureidini JN. Industry-sponsored ghostwriting in clinical trial reporting: A case study. *Accountability in Research* 2008;15(3):152-167