Medical Communications

SECTION EDITOR

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Editorial

Dear all,

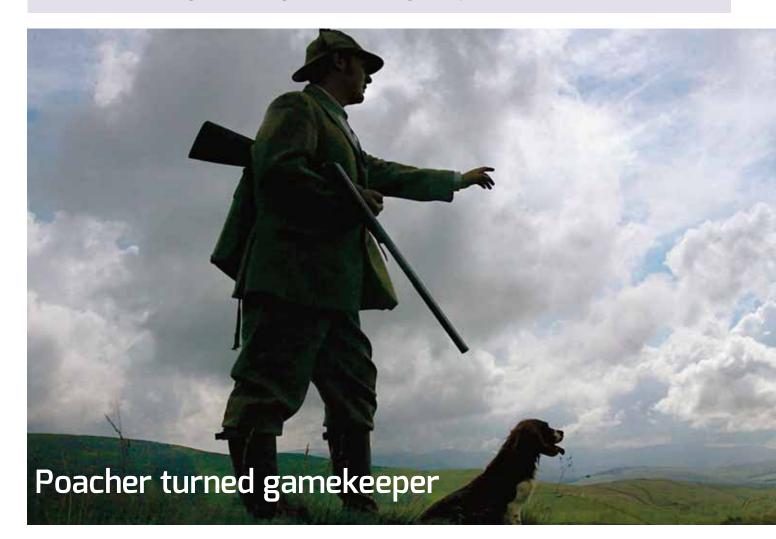A very warm welcome to the first issue of *Medical Writing* in 2016!

This issue is dedicated to authors and authorship, so I'm delighted to have an article for this section from one of EMWA's authorities on all things authoring and ghost writing – Adam Jacobs.

In this issue Adam discusses the roles of reviewers in the collaborative process of producing well-written documents. Adam is now in the role of statistician, but having been an accomplished medical writer himself, he is perfectly placed to give us some excellent insights into the review process from the reviewer's side as well as from the writer's side.

Adam's thoughts and tips are particularly useful for anyone sending out their first document for review, but I think even 'old hands' can learn something from his experiences as a reviewer – particularly as a statistical reviewer. As we all know, so much time and energy can be wasted in poor review cycles, with non-specialists offering their 'wisdom' on sections outside of their remit, and it's in everyone's interest to make review cycles as efficient and useful as possible.

As for whether Adam is now a 'poacher turned gamekeeper' or a 'gamekeeper turned poacher' – I'll leave that for you all to decide!! Bestest.

Lisa

Poacher turned gamekeeper

Medical writing is a collaborative process. Medical writers seldom write about their own research. Typically other people do the research, and the medical writer writes about it. Whether the writing is for a study report for regulatory purposes, a peer-reviewed journal article, a conference abstract, or something intended for a lay audience, the collaborative process is broadly similar. The medical writer must collaborate with researchers to make sure that the end product accurately describes

the research, is suitable for the target audience, and is clearly written.

I have been fortunate enough to have experienced this process from both sides. I used to be a medical writer, and I am now a statistician: one of the researchers with whom medical writers need to collaborate. I'm not entirely sure if that makes me a "poacher turned gamekeeper" or a "gamekeeper turned poacher". Make your own mind up about that.

But either way, I think my experience of medical writing was fantastically useful in helping me to make sure that my collaboration with medical writers is as efficient as possible. Having been a medical writer myself, I know what kinds of contributions medical writers find helpful and what kind of things piss them off.

Probably top of the list of things that piss

medical writers off is gratuitous nitpicking. It is not only annoying, it is a waste of everyone's time. So if I come across a sentence that the medical writer wrote one

way that makes perfect sense, then I will not change it, even if I would have written it differently. That's not my job. It's the medical writer's job to decide how to phrase things. Maybe there was a good reason for writing it that way that I wasn't aware of, such as complying with a client's style guide. Maybe my idea of how it should be phrased is a bit odd and the medical writer's version is clearer anyway. And even if my way of writing it is better, then so what? No drug ever got rejected by the FDA because they didn't like the way a sentence was phrased in a study report.

What I *do* focus on is the sort of thing that was the reason why the medical writer wanted a statistician to review the document in the first place. So, for example, does the statistical methods section accurately describe the analyses that we actually did? Have statistical results described in the results section been properly interpreted? Do the conclusions as written by the medical writer follow from the results?

There can, of course, be a fine line between commenting on what is written and how things are written. Some statistical concepts do require a certain amount of precision in the way they are expressed. I will comment on the way a sentence is written if I feel it is missing some statistical subtlety. For example, if a medical writer were to write (and I'm sure no EMWA members would ever do this!) that treatment A was superior to treatment B when in fact we have just done a non-inferiority analysis that only shows that treatment A is not inferior to treatment B, then I would correct them. And if text is unclear or misleading, then I will comment on that as well.

So what can medical writers do to help their reviewers be efficient in their reviews? First, I think it is always helpful if a medical writer tells me which parts of a document I need to review, or, if I am expected to read the whole thing, then at least which parts I should pay particular attention to. If someone sends me a 150 page clinical study report to review, it is not a good use of time for me to review the whole document in great detail. It is far better that the clinical project manager spends time looking in detail at what was written in the visit schedule part of the methods section than that I do. And if the adverse events section contains substantial discussion of the clinical relevance of the adverse events

observed, then that's a job for the medic more than it is for me.

It is also helpful if I know whereabouts the document is in its quality control process. If I see a typo or misplaced comma in the first draft of a document that I know is going to have a couple of rounds of editing and proofreading before it sees the light of day, then I'm not going to waste everyone's time by telling you about it. If the document is supposedly a final version, then perhaps it would be more helpful to point out things like that.

Often medical writers will have questions for me in a draft document, often inserted as comments. That's great. If there are specific things you need to know from your statistician reviewer, then ask me. And it's helpful if the questions can be made as specific as possible. "What do you think of this?" is less helpful than "Is my interpretation of the relevance of the upper limit of the 95% confidence interval correct here?" If you are not sure what to write about something and need some help, then please be clear about whether you need me to explain to you what's going on so that you can write something appropriate or whether you want me to supply a ready made paragraph of text.

Adam Smith, the influential 18th century Scottish economist, explained at some length the benefits of division of labour. He described the example of pin making, in which some workers drew out the wire, others cut it, others sharpened the point, and so on, and how this was more efficient than single workers making entire pins by themselves, as it allowed for specialisation.

So it is in writing about clinical research. Statisticians have expertise in statistics, medics have expertise in medicine, and medical writers have expertise in communication. If we all stick to our own areas of expertise and recognise the expertise of others, then we will find that research is written up more efficiently.

Disclaimer
This article represents my own personal views and does not necessarily represent the views of Premier Research.

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