Scientific publishing

Any Ghosts Around?

Ghost writing has been shown to be commonplace in clinical research articles when drug companies are involved. A new study, for example, claims that statisticians were not named in three quarters of the clinical studies examined.

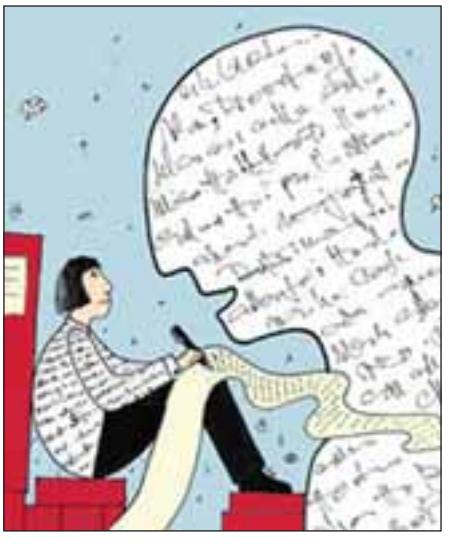
The general public became aware of ghost written clinical studies when the mass media made top stories of cases that have been identified by academic whistleblowers. One such case was brought up in 2005 by Adriane Fugh-Berman, a Professor of Alternative Medicine at Georgetown University (USA). She was invited by Rx Communications, a company based in the UK, to write a review on the potential of medicinal herbs and dietary supplements to interact with a commonly used blood thinner. When she asked for details it turned out that she was not expected to write the review herself but was simply meant to lend her name to an article that had already been prepared. Fugh-Berman said no. Later she was asked by the *Journal of General Internal Medicine* to review a paper on the same topic. It turned out that this paper was exactly the same one as that for which she had been asked to play author but which was now "written" by another person. Fugh-Berman said that AstraZeneca was behind the whole story. The drug company had developed its own blood thinner and wanted to point out some major drawbacks of a competitor's product. AstraZeneca and Rx Communications both denied all charges, claiming misunderstandings and sent out apologies.

No time, poor English,...

Is Fugh-Berman's experience representative of the pharmaceutical companies' marketing strategies? Other cases have been reported where pharmaceutical companies have actively looked around for key opinion leaders to serve as lead authors for manuscripts designed by the drug companies, written by professional in-house or freelance writers and serving the pharmaceutical companies' marketing interests. Nobody knows how many such papers have been produced and published.

There are plenty of drawbacks to this sort of ghost authorship. Despite being named authors, such „ghosts" have no creative input to the papers but receive payment from the companies for lending their names. There is no doubt that this sort of ghost authorship is to be condemned as unethical.

There is also another kind of ghost authorship. Professional writers prepare original research articles for scientists who have produced the data but do not want to write the paper. The reasons for employing professional writers are manyfold: no time, poor English, or the belief that that a well-written, easy-to-read article will better convince a referee than a piece penned by oneself. It's contentious, however, whether this "preparation of the manuscript" can be called ghost writing or not. Adam Jacobs, former president of the European Medical Writers Association (EMWA) and current Head of Dianthus Medical Limited (UK), a company that offers medical writing services, says: "Ghost writing is a confusing term which is best avoided. If they [the professional writers] are mentioned in acknowledgements, then they are not ghosts of any kind."



The hidden statisticians

Data on the prevalence of ghost written scientific articles are scarce. According to a widely cited study by Annette Flanagin *et al.* (*JAMA* 280, pp. 222-4), 11% of 809 articles had ghost authors. Other studies came up with similar numbers. In most of these cases ghost authors were medical writers, free lancers or employees of drug companies who helped in the preparation of the manuscript.

The newest study, however, identified another sort of hidden author: statisticians. A team led by Peter Gotzsche at the Nordic Cochrane Centre in Copenhagen analysed 44 industry-initiated clinical trials approved between 1994 and 1995 by the Scientific-Ethical Committees for Copenhagen and Frederiksberg in Denmark (*PLoS Medicine* 4, S. e19). The scientists compared the author by-lines and acknowledgements of

44 publications with corresponding initial study protocols. The result was surprising: Ghost authorship was detected in 33 trials. In 31 of them ghost authors were identified as being statisticians. This amount increased to 91% when cases were included where a person who qualified for authorship was only acknowledged. That is amazing!

The scientists' definition of ghosts is rather straightforward. Ghost authorship is met "if individuals who wrote the trial protocol, performed the statistical analyses, or who wrote the manuscript, were not listed as authors of the publication, or members of a study group or writing committee, or in an acknowledgement". That directly raises the question: should a statistician be named as an author at any time or is it also acceptable to simply acknowledge his work?

No hard rules

"There are no hard and fast rules", says Chris Palmer, Director of the Centre for Applied Medical Statistics at Cambridge University (UK). He argues that if the statistical work is comprised of simple Chi-square tests or t-tests, it's enough to acknowledge the statisticians' work. Though this is worth little from the scientific point of view it makes who did the work more transparent. "Therefore, a statistician should be named as an author in the by-line if his expertise is needed to do more complicated things like multivariate analyses", says Palmer.

Is an acknowledgment appropriate?

Palmer, himself a statistics referee for medical journals, has identified publications lacking any hint of a statistician despite the paper containing substantial statistical input. Says Palmer: "I have reviewed papers that contained so much statistical work that I asked whether someone else assisted with the statistical aspects and if so whether they should be invited to become a co-author. It would be interesting to do some follow up to see what happened in each of those cases."

The University of Cambridge's Centre for Applied Medical Statistics was founded in 1996. Members of the Centre provide statistical consulting. Palmer and colleagues generally discuss authorship issues at the first meeting at the beginning of the collaboration, to avoid awkward discussions later on after the paper has been written. The statistical aspects of most research papers require specialist input to perform the most appropriate analyses. "That comes too late for many medical scientists", says Palmer. "Too often we are approached for advice only after a paper has been rejected by the statistical referee of the journal. On the other hand, some doctors are only too happy to have statisticians as co-authors because they expect a more favourable peer review by having a designated statistician on board. However, I may not always feel happy about that if I consider that our contribution is not really substantial, in which case I might suggest an acknowledgement as being more appropriate."

Sugar-coated data

Palmer has noticed a change in the use of professional statisticians since the mid 90s, when evidence-based medicine was

put on the agenda. "There are still clinical researchers who view statisticians in the same way they view computer technicians, and who regard research wrongly as a chase to get a p-value below 0.05. Things are getting better now that awareness of the need for timely statistical expertise and the number of journals relying on statisticians as part of their peer review processes have both increased", says Palmer. After the media unmasked a number of publications on drugs and therapeutics that relied on data sugar-coated by companies' in-house data management and statistics departments, journals' editors now believe in the value of independent statisticians. Some journals demand that all data be analysed by an academic statistician if the study was initiated and/or funded by a pharmaceutical company. That immediately offended

Peter Kapper

statisticians employed by drug companies and caused them to stand up and argue that they would never falsify any data. However, believe it or not, experience shows that the one who pays the piper calls the tune.

The piper calls the tune

Pathologist and osteoporosis specialist Aubrey Blumsohn, for example, reports exactly that experience. With a grant from Procter and Gamble (P&G) he studied the effectiveness of Actonel, P&G's anti-osteoporosis drug, on bone density and fracture incidence. At that time Blumsohn was a Senior Lecturer in Metabolic Bone Medicine at the University of Sheffield (UK). He collected the clinical data in a blinded study, but when it came to publication there was a surprise. He found out that P&G had already prepared papers and conference abstracts with Blumsohn as a senior author. He was convinced that P&G sugar-coated the effect of the drug by excluding unfavourable data and he asked for full access to the original, un-blinded data to do an independent re-analysis. However P&G would not allow him to see the results. Blumsohn made the case public and that was the start of a lot of trouble (you can follow the story on his blog at *http://scientific-misconduct.blogspot.com*). In the end Blumsohn was suspended from his job, then he left the University – but the trouble with P&G is far from being over.

Steps towards transparency

Let us return to the issue of authorship. Authorship is an elastic word. There is controversy about distinguishing between an author and a contributor to a publication. That discussion has resulted in guidelines being defined for what is required of an author. Many journals now request and publish in detail the contributions of each named person: who took part in the study; who had the idea for the study or article; who collected the data; who carried out the statistical analyses; who had access to the data; who participated in the interpretation of the data; who led the study and who is the guarantor taking responsibility for the correctness and interpretation of the scientific data. It also goes without saying that any potential or actual alliances including financial should be stated in detail.

Such declarations are clearly a great step towards transparency. However, if somebody's help is acknowledged as "assistance in preparing the manuscript" – what on earth does that mean? Did these "somebodies" do secretarial work? Did they take part in discussions? Or did they draft the manuscript? That is hard to say, because "preparing the manuscript" is an ambiguous expression. When we asked some authors to explain it we got answers such as "... typed some handwritten changes to one of the drafts of the manuscript" and, more elaborately, "It's a very interesting question and one that I am sure has many varied answers depending on the context in which it was written. In the article you refer to, I acknowledged my wife [a medical doctor, the editor] for her general help in the process of talking through the ideas related to the article".

After medical journal editors expressed concerns about the role of commercial sponsors in publishing research related to their drugs and, in particular, about the use of professional medical writers, EMWA as well as the American Medical Writers Association (AMWA) developed guidelines regarding the role of medical writers in peer-reviewed publications with the expectation of full transparency. That means mentioning the writer in the acknowledgements together with a statement about funding. Most free lance writers, Jacobs says, demand to be acknowledged with their full name in the papers they drafted. However, there are also writers who explicitly refuse to be named.

The EMWA guidelines envisage that named authors of ghost written studies must have full access to all of the data as well as control of the content of the paper because they are expected to edit the draft, and control presentation and interpretation of the data. Says medical writer Julia Forjanic-Klapproth, vice-president of EMWA and head of the medical writing company Trilogy (Germany): "I write the publication but I'm not responsible for its content. That's the duty of the author. He has to check the data, edit the manuscript and be accountable for its accuracy."

Refusals to be named

What proportion of professional writers follow the rules of EMWA or AMWA and demand to be acknowledged with their full name in the papers they drafted is not known. In any case, there are writers who explicitly refuse to be named.

The EMWA guidelines were published two years ago. Asked if he has recognized any change in publishing behaviour since then, Jacobs states: "I cannot tell yet. We are doing some scientific projects on that issue but we're still in the process of evaluating the data. We will be able to tell more in half a year or so." Let's look out for the results of these projects.

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