

## BRIEF REPORT

# The involvement of professional medical writers in medical publications: results of a Delphi study

Adam Jacobs on behalf of the European Medical Writers Association's Ghostwriting Task Force\*

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### ABSTRACT

*Objective:* Using a Delphi consultation process, a group of medical writers established by the European Medical Writers Association (EMWA) set out to determine the current thinking on the problems of ghostwriting in medical publications and what should be done about them. In this context, ghostwriting is where a professional medical writer prepares a manuscript on behalf of a named author, but the writer is not listed as an author.

*Methods:* A 4-round Delphi consultation process was conducted via email to generate statements about the main issues in ghostwriting. Participants rated their agreement with the statements on a scale of 0–10.

*Results and conclusions:* Members of the task force strongly believed that professional medical writers can improve the quality of scientific papers, but that this fact is often not recognised outside the medical writing profession. At least in part, this is because of a perception that ghostwritten papers may have been inappropriately influenced by pharmaceutical companies.

One theme that emerged strongly from the discussions was transparency. Members thought it very important that the existence of a ghostwriter should always be made clear to the reader. Another strong theme was the importance of defining in detail what practices relating to ghostwriting are ethical, and what practices are not. This definition of ethical ghostwriting should be widely known, and unethical ghostwriting should be strongly condemned.

Use of the term 'ghostwriting' itself was questioned. Members of the task force felt that use of a more neutral term should be encouraged.

The task force suggested various activities for ensuring that the above objectives could be met, including discussions with other interested parties, such as journal editors and pharmaceutical companies, educating medical writers about ethical practices, further research into ghostwriting, and developing guidelines for ethical medical writing.

## Introduction

There has been considerable controversy in the medical literature about the practice of 'ghostwriting'; in other words, when a medical writer drafts a paper for publication on behalf of its named author. Concern has

been expressed that this can lead to inappropriate control of the scientific content of papers by pharmaceutical companies or by medical communication agencies working on behalf of pharmaceutical companies<sup>1,2</sup>. The involvement of professional medical writers in medical publications has also been reported in the lay press.

\* Members are listed in the Acknowledgement section

Usually, however, this has not been done in a balanced manner and the general indictment of the process has overlooked the significant value added by professional medical writers.

A recent review of the literature on the effects of professional writing assistance on biomedical publishing identified a number of potential problems associated with the use of professional writers<sup>3</sup>. These included inappropriately influencing the reporting of research, reducing the accountability of a scientific paper, and a lack of openness associated with failure to disclose the contributions of professional writers<sup>3</sup>. Although many concerns are based on opinion rather than research evidence, one recent comparison of industry-linked articles coordinated by a medical writing agency and articles not coordinated in this way on the therapeutic uses of sertraline showed significant differences between the two<sup>4</sup>. Coordinated articles had a higher number of authors and pages per article, a higher citation rate, and a higher literature profile (a measure of impact). Of the 41 independently-generated articles, 20 reported negative findings whereas the coordinated clinical trial articles all reported favourable results.

A study published in 1998 attempted to determine the prevalence of ghostwriting in the literature<sup>5</sup>. Flanagan and others estimated that 93 of 809 (11%) articles (original research reports, reviews, editorials, commentaries, and opinion articles) published in 1996 in 6 peer-reviewed biomedical journals involved ghost authors<sup>5</sup>.

Potential benefits associated with the use of professional medical writers include improving the quality and readability of articles leading to enhanced acceptability, speeding the submission process, and educating researchers in writing, editing, and good publication practices<sup>3</sup>. Comprehensive guidelines on the use of professional medical writers in biomedical publication development were lacking when we started this consultation, although guidelines from the World Association of Medical Editors<sup>6</sup> and the Committee on Publication Ethics<sup>7</sup> endorse disclosing the use of professional writers.

The European Medical Writers Association (EMWA) represents professional medical writers in Europe and has over 500 members, including freelance writers, members of pharmaceutical companies, medical communication agencies and research institutes, and contract research organisations. As a representative organisation, EMWA takes an active interest in all issues that affect medical writers and thus has a duty to take part in the ghostwriting debate. EMWA's ghostwriting task force was therefore set up to discuss the issues relevant to ghostwriting, to ensure that the view of professional medical writers is heard, and to seek solutions to any problems identified. This paper describes the initial discussions of the ghostwriting task force.

## Methods

### Selection of task force

Members of the task force are listed at the end of the paper. Most members of the task force were selected at EMWA's 2003 annual conference during various discussions of ghostwriting. All members have professional experience relevant to ghostwriting. The group was deliberately selected mainly from freelance consultants or those working in communication agencies to ensure that the influence of pharmaceutical company employees was kept to a minimum. The group therefore represented the views of medical writers rather than the views of the pharmaceutical industry. Only one member of the task force (ELN) is currently an employee of a pharmaceutical company although all undertake writing projects for such companies.

### Delphi consultation process

To explore the issues surrounding ghostwriting, a 4-round Delphi consultation process was used, with communication by email.

In round 1, I asked participants to write down initial ideas about ghostwriting, in 3 categories:

- What are the major issues in ghostwriting?
- What should be the objectives of the process, or how would we like ghostwriting to operate in an ideal world?
- What activities should we undertake to reach our objectives?

In round 2, I asked participants to elaborate on the ideas generated in round 1.

In round 3, I collated the ideas generated in rounds 1 and 2 into various statements about ghostwriting (Tables 1 and 2), and asked participants to rate their agreement with each statement on a scale from 0 to 10.

In round 4, I asked participants to re-rate items that had not achieved a consensus view in round 3. A consensus was arbitrarily defined as a standard deviation of 2 or less for the scores from round 3. Participants were shown the mean score from the previous round and asked to justify any responses that differed markedly from the mean score.

### Analysis of results

Final scores were generated by counting round-4 responses where they existed and by counting round-3 responses where a round-4 response did not exist (either because consensus had been reached in round 3, or because a particular member did not provide a response in round 4).

*Table 1. Final ratings of issue statements from the Delphi process*

Statement	Mean	SD	Min	Max
Skilled medical writers are an important resource and can improve the quality of scientific papers	9.64	0.67	8	10
Ghostwriting is not intrinsically unethical	9.27	1.56	5	10
The involvement of ghostwriters often lacks transparency	9.00	1.56	5	10
Ghost authorship (the ghost controlling the content) is unethical	8.91	1.58	5	10
EMWA has a duty to represent the views of medical writers in any discussions of ghostwriting	8.82	1.89	4	10
There is a need to define whether medical writers should be listed as authors, as contributors, or in the acknowledgements	8.73	1.10	7	10
The professional skills of medical writers are not widely recognised outside our own profession	8.73	1.27	6	10
Medical writers can help to improve the readability of research and thus make it more accessible to readers outside the specialist discipline	8.64	1.50	5	10
Ghostwriters are put in a difficult position if their client asks them to do something they think is unethical, and lack support in this situation	8.45	1.97	4	10
There is an important distinction between ghost authorship (the ghost controlling the content) and ghost writership (the ghost drafting the paper under the direction of the named author)	8.36	1.69	5	10
Currently accepted authorship guidelines are inadequate for guiding how ghostwriters should be acknowledged	8.20	1.55	5	10
The term 'ghostwriter' has unsavoury connotations	8.18	1.40	5	10
Who controls a paper is more important than who writes it	8.18	1.54	5	10
It is important that ghostwriters should be well versed in publication ethics	8.09	2.30	2	10
Ghostwriting is widely perceived as intrinsically unethical	8.00	1.18	6	10
Ghostwriters speed the publication process	7.55	1.81	4	10
Drug companies discourage acknowledgement of ghostwriters because they are afraid that it could diminish the credibility of their papers	7.40	1.84	5	10
Journal editors assume that any paper written by a ghostwriter has been unduly influenced by the pharmaceutical industry	7.00	1.41	5	10
Medical writers have a responsibility for ensuring that pharmaceutical companies do not bias the reporting of research	6.91	2.51	2	10
Journals' instructions to authors are widely ignored as regards conflicts of interest and authorship criteria	6.90	1.79	3	9
Drug companies try to discourage acknowledgement of ghostwriters	6.64	1.57	4	9
The issue of the corrupting influence of drug companies is beyond the scope of EMWA's ghostwriting initiative	6.55	2.77	2	10
Journals are getting better about encouraging acknowledgement of ghostwriters	6.36	2.46	2	10
Many investigators would be insulted by the suggestion that a professional medical writer would write their papers better than they would	6.36	1.96	4	10
Communication agencies try to discourage acknowledgement of ghostwriters	6.30	1.70	3	8
Journals discourage acknowledgement of ghostwriters	6.27	2.45	1	10
It is important that ghostwriters should have a thorough knowledge of the subject area of any manuscripts they write	5.91	1.76	2	8
Drug companies are usually careful to present data in an unbiased way, but sometimes distort research for commercial gain	5.90	1.52	2	7
Ghostwriting is frequently done unethically	5.09	2.34	2	8

Scores are on a scale from 0 to 10, with 0 indicating complete disagreement and 10 indicating complete agreement  
*N* = 12 for most statements. This is a subset of the full list, which is available in the full report at [www.emwa.org](http://www.emwa.org)

## Results and discussion

The main findings are reported below under the two headings: 'issues and objectives', which describes the views of the group about what the main issues are in ghostwriting and what we would like to happen in a perfect world; and 'activities', which describes suggested activities for how we can move towards that perfect world. A list of the main issue and objective statements generated in rounds 2 and 3 of the Delphi process are shown in Tables 1 and 2 respectively with summary statistics of the scores generated in rounds 3 and 4. A full list of all the ideas generated is available in the full report of the process on the EMWA website at [www.emwa.org](http://www.emwa.org).

## Issues and objectives

The idea that had the strongest support in this section was that 'skilled medical writers are an important resource and can improve the quality of scientific papers'. There was a high level of agreement in support of this. We felt that benefits of involving professional medical writers included speeding the publication process, improving readability of papers, thus potentially making them accessible to a wider audience than just specialists, and improving the quality of papers by providing critical appraisal and assuring that reporting guidelines are met.

However, there was also a consensus that the benefits of involving professional medical writers are not widely

*Table 2. Final ratings of objective statements from the Delphi process*

Statement, objectives	Mean	SD	Min	Max
Unethical behaviours should be avoided	9.73	0.65	8	10
We should ensure that ghostwriting is fully transparent	9.70	0.95	7	10
We should raise awareness that medical writers make substantial contributions beyond simply improving grammar	9.27	0.90	8	10
There should be no such thing as 'marketing writing' as distinct from scientific writing: all journal articles should be scientifically valid	9.00	1.76	5	10
A medical writer who disagrees with a paper should have the right to refuse to be acknowledged in the paper	8.82	1.78	5	10
We should reach agreement with journal editors on authorship policies	8.73	2.37	2	10
We should define ethical ghostwriting in detail	8.64	2.16	3	10
We should ensure that journal editors, medical writers and pharmaceutical companies are all aware of what is acceptable practice and what is not	8.45	2.58	1	10
Investigators should acknowledge that appropriate involvement of professional medical writers can raise the standard of publications	8.36	1.80	5	10
The term 'ghostwriter' should be replaced by something more neutral	7.45	2.11	5	10
Scientific writing and marketing writing must always be clearly distinguished	7.18	2.40	5	10
Medical writers should be listed as authors, rather than simply acknowledged, under some circumstances, such as if they have made a substantial contribution to a review article	5.82	3.31	0	10
We should develop a licensing or accreditation system that gives a status to ethical and competent medical writers, and encourage journals to reject papers written by unlicensed ghosts	3.91	3.02	0	10
Journal editors should actively encourage ghostwritten manuscripts	2.82	1.54	0	5
Medical writers should usually be listed as authors	2.73	2.05	1	8

Scores are on a scale from 0 to 10, with 0 indicating complete disagreement and 10 indicating complete agreement  
*N* = 12 for most statements. This is a subset of the full list, which is available in the full report at [www.emwa.org](http://www.emwa.org)

recognised outside of our own profession. Indeed, we felt that substantial hostility exists towards ghostwriting. We would like the skills of professional medical writers to be more widely recognised. In particular, there was strong support for raising awareness that medical writers make substantial contributions to manuscripts beyond simply improving grammar.

Some journal editors are hostile to the concept of ghostwritten manuscripts, and we would like that hostility to disappear. However, we did not feel it necessary that journal editors should go so far as to actively encourage manuscripts written by medical writers. We also desire greater recognition by named authors of the part that medical writers can play, although we recognised that there is a danger that some authors might feel insulted by the idea that medical writers could improve their papers.

Another theme to feature strongly in the discussions was the way in which the involvement of medical writers is made clear to the reader. There was a strong consensus that involvement of medical writers should be fully transparent, which is often not true currently. We felt that there was a need to define exactly how medical writers should be mentioned, and that current authorship guidelines were inadequate to address this issue. Moreover, we noted that the authorship guidelines that do exist are in any case often ignored. In theory, medical writers could be listed as authors, as

contributors, or mentioned in acknowledgements, and there was a strong consensus that it was important to define which of these was most appropriate. There was little support for the idea that medical writers should usually be listed as authors, although more support for the idea that they should be under some circumstances. We felt that it was important to reach agreement with journal editors on policies for how medical writers are acknowledged.

In whatever way medical writers are mentioned in papers, we felt that it is very important that they are mentioned somehow. However, we noted that pharmaceutical companies, communication agencies, and journals sometimes discourage acknowledgement of medical writers, although we felt that journals were generally improving in this regard. We thought that it was possible that pharmaceutical companies were reluctant to allow the acknowledgement of a medical writer as they might believe it would diminish the credibility of the paper.

We also generally agreed that a medical writer who disagrees with the final version of a paper should have the right not to be acknowledged.

We noted that there is an important distinction between ghostwriting and ghost authorship. The first occurs when a medical writer drafts a paper under the direction of a named author, and the second occurs when the unnamed ghostwriter not only writes the

paper but also has control over its intellectual content. The first is ethical, the second is not. We felt that the important thing was not who writes the paper, but who takes responsibility for its content.

There was very strong agreement that unethical ghostwriting practices should be avoided. While we noted that ghostwriting is widely perceived as unethical, we believed strongly that it is not intrinsically unethical. However, there was a lack of consensus on whether ghostwriting is, in practice, frequently done in an unethical way. Nonetheless, we thought it important to define in detail what is ethical and what is not, and to ensure that all interested parties (journal editors, medical writers, and pharmaceutical companies) are aware of what is acceptable and what is unacceptable practice.

We noted that medical writers may often be put in a difficult position if their client asks them to do something unethical, as they can lack power and support in that situation.

There was moderate support for the idea that the reason that journal editors may be hostile to ghostwritten papers is that they may assume that they have been subject to inappropriate influence by the pharmaceutical industry, and indeed that ghostwriting was even perceived to be synonymous with industry involvement in the publication or research. There was some concern that pharmaceutical companies do indeed sometimes publish papers for purely marketing, and not scientific purposes. We felt that it was important to ensure that all papers are scientifically valid, and that marketing messages never take precedence over what can be justified from the data. There was some support for the idea that marketing and scientific writing should always be clearly distinguished, although the level of consensus on this point was poor. There was also a lack of consensus on whether the whole issue of industry involvement in publishing research was in fact beyond the scope of the EMWA ghostwriting initiative, and whether medical writers have a responsibility to ensure that pharmaceutical companies do not bias the reporting of research.

We thought it was more important that medical writers should have a thorough understanding of publication ethics than of the subject matter of any manuscripts they write: writers usually work with named authors who are experts in the subject of the manuscript and should be in a position to offer advice. Although the idea of developing a licensing or accreditation system for medical writers was suggested, it was generally felt to be unworkable for the time being.

Finally, there was reasonable support for the idea that the term 'ghostwriting' itself was an unfortunate description of what medical writers do, and that it would

be better if a more neutral term were used. However, concerns were also expressed that merely changing the term would be of little use without also ensuring that high ethical standards were maintained.

## Activities

A number of activities proposed to meet the ghostwriting objectives were discussed. Activities that gained the most support included initiating meetings with people who object to ghostwriting, such as journal editors, to explore their objections and how we could tackle them, providing opportunities to discuss medical writing with all interested parties, and involving the pharmaceutical industry in the initiative. There was also strong support for educating medical writers about ethical ghostwriting standards and publicising the ghostwriting initiative.

There was good support for developing an EMWA position statement on ghostwriting with input from the wider membership of EMWA, and for developing guidelines on ethical conduct and appropriate means of acknowledging ghostwriters that would be widely accepted by relevant organisations. The position statement and guidelines have since been written and approved by EMWA<sup>8</sup>. We also identified a need for further research on our part into the issues surrounding ghostwriting.

## Conclusions

This group, which consisted largely of professional medical writers, strongly supported the idea that medical writers have an important part to play in preparing medical papers for publication in peer reviewed journals and can often improve both the quality and speed of publications. We believe that it is important to be aware of the ethical pitfalls that professional medical writers can face in this situation and to maintain high ethical standards. One of the most important steps towards achieving those high ethical standards is transparency about the writer's involvement. Following this discussion, we have since developed guidelines for medical writers involved in peer-reviewed publications. We hope that adherence to those guidelines will help to ensure that medical writers can prepare papers in an ethical and responsible manner.

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## Members of EMWA's ghostwriting task force

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## References

1. Sharp D. A ghostly crew. *Lancet* 1998;351:1076
2. Bodenheimer T. Uneasy alliance. Clinical investigators and the pharmaceutical industry. *New Engl J Med* 2000;342:1539-44
3. Lagnado M. Professional writing assistance: effects on biomedical publishing. *Learned Publishing* 2003;16:21-7
4. Healy D, Cattell D. Interface between authorship, industry and science in the domain of therapeutics. *Br J Psychiatry* 2003;183:22-7
5. Flanagan A, Carey LA, Fontanarosa PB, et al. Prevalence of articles with honorary authors and ghost authors in peer-reviewed medical journals. *J Am Med Assoc* 1998;280:222-4
6. World Association of Medical Editors. WAME recommendations on publication ethics policies for medical journals. 2004. <http://www.wame.org/pubethicrecom.htm> [accessed 5 December 2004]
7. White C, Williamson A, editors. The COPE report. Annual report for the Committee on Publication Ethics 2001. London: BMJ Books; 2001
8. 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(2): 317-21

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