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COMMENTARY

European Medical Writers Association (EMWA) guidelines on the role of medical writers in developing peer-reviewed publications

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ABSTRACT

Background: Many papers in biomedical journals are drafted not by the named authors, but by professional medical writers working under the direction of those authors, usually funded by pharmaceutical companies. Although this practice can improve both the quality and speed of publications, it has attracted controversy as a result of concerns about the inappropriate influence of pharmaceutical companies.

Objectives: To define ethical standards for professional medical writers who prepare papers for publication in medical journals.

Consensus methods: Guidelines were drafted after a 4-round Delphi consultation among a group of experienced medical writers. The guidelines were then further refined by seeking comments on

the draft from a range of interested parties.

Findings and conclusions: The guidelines stress the importance of respecting widely recognised authorship criteria, and in particular of ensuring that those listed as named authors have full control of the content of papers. The role of medical writers must be transparent, which normally means a mention in the acknowledgements section, together with a statement about funding. Writers and authors must have access to relevant data while writing papers. Medical writers have professional responsibilities to ensure that the papers they write are scientifically valid and are written in accordance with generally accepted ethical standards.

Background to the guidelines

The need for guidelines

Medical journal editors have expressed concern about the role of commercial sponsors in publishing research relating to their products and, in particular, about the use of professional medical writers (who were not involved with the research) to develop publications.

The issues about involving medical writers and the appropriate role of sponsors are separate but sometimes overlap. Although many guidelines already exist that cover the preparation of manuscripts for peer-reviewed publications, none specifically provides guidance to medical writers who prepare publications on behalf of named authors. The European Medical Writers Association (EMWA) has developed this document to

provide guidance for medical writers and to outline the legitimate role of professional writers in developing publications.

Scope of the position statement and guidelines

These guidelines are intended for medical writers who develop papers for publication in biomedical journals or presentations for scientific conferences, on behalf of named authors. The guidelines may also apply to authors' editors and others who perform substantive editing in preparing publications for submission.

They are intended to apply to any writers who work on peer-reviewed biomedical publications, regardless of who employs or hires them, i.e. they apply to writers who are directly employed by pharmaceutical companies or other sponsoring agencies, those working for contract research organisations and communication agencies, and those who are self-employed.

Development of the guidelines

The development of these guidelines has not followed a strict evidence-based approach, primarily because of a lack of published evidence on how medical writing practices affect outcomes. The guidelines were drafted following a Delphi consultation process among the members of EMWA's ghostwriting task force¹. They were refined after consultation with journal editors, academic investigators, and medical writers working for pharmaceutical companies and communication agencies.

The use of writers who have not participated in research to help the named authors to develop publications is sometimes referred to as 'ghostwriting'. This term implies that the writer is invisible because their work is not acknowledged or because it is purposely concealed. Similarly, the practice of omitting deserving individuals from authorship lists is sometimes termed 'ghost authorship'. We have avoided using these terms in these guidelines, partly because we believe that medical writers can have a legitimate role in developing papers and we therefore want to avoid these slightly pejorative terms, and also because we feel they are misleading if the writer's contribution is properly acknowledged. However, the term was used for the EMWA task force.

The question of authorship

Many journals have endorsed the Uniform Requirements of the International Committee of Medical Journal Editors (ICMJE)² (sometimes called the Vancouver Group). These include a section on authorship which

may be helpful in determining who qualifies to be listed as an author. The Uniform Requirements state that named authors should have made a substantial contribution to: (1) study conception and design, or data acquisition, or data analysis and interpretation; (2) drafting the article or revising it critically for important intellectual content; and (3) final approval of the version to be published. Authors must fulfil all three criteria and everyone who meets the criteria should be listed. Named authors should also be prepared to take public responsibility for at least one aspect of the research.

In most publications reporting clinical trials, a medical writer who has not been involved in study design, data analysis, or interpretation will not qualify to be listed as an author according to the Vancouver criteria. However, so long as they work closely with the named authors, there is no ethical reason why such writers should not prepare drafts of publications.

Financial interests and funding

The issues of involving professional writers and the interests of commercial sponsors often arise together, but should not be confused. EMWA encourages pharmaceutical companies to follow Good Publication Practice for Pharmaceutical Companies³. Research sponsors (whether they are commercial companies, charities, or public bodies) have a legitimate interest in the publication of the research they fund. Medical writers employed or hired by sponsoring companies may be involved in developing publications; their contribution and relationship to the sponsor should be acknowledged alongside other relevant acknowledgements about the funding and organisation of the research.

Guidelines for medical writers involved in preparing peer-reviewed publications

Authorship status of medical writers

Medical writers should not agree to be listed as authors on publications if they do not fulfil the authorship criteria of the target journal. To qualify as an author, according to the Vancouver criteria, the writer would need to have made a substantial contribution to the analysis or interpretation of the data and feel able to take public responsibility for the research. In practice this means that professional writers are unlikely to be named as authors on primary research publications. However, they may qualify for authorship of review

articles, for example if they have conducted an extensive literature search. It is important to note that by agreeing to be listed as an author, the medical writer takes public responsibility for the research.

Although the Vancouver criteria have been widely adopted, some journals supplement the traditional author by-line with a contributor list indicating each individual's contribution to the research and the publication. In such cases, it might be appropriate to list a medical writer who had prepared a first draft or made some other significant contribution to the publication. Any specific requirements of the journal in this respect should be followed.

Relationship between medical writers and named authors

Medical writers and study sponsors must recognise that the named authors are responsible for all stages of the publication. They should therefore ensure that authors are involved at the earliest possible stage, ideally when an outline is drawn up, or the key points of the publication (or presentation) are discussed. In the case of studies involving many investigators, writers should encourage sponsoring companies to form a writing group or identify the named authors at an early stage and involve them in the process of developing the publication or presentation in collaboration with the writer.

While it is understandable that sponsoring organisations will want to contribute to or comment on a publication, this should not prevent the involvement of authors at the early stages. It is unethical to invite investigators to be authors if they have seen only a pre-final version of a paper. Writers should therefore request that sponsors involve authors at an early stage in publication planning and should resist attempts to do detailed work on a publication before the authors have been confirmed and the content of the proposed publication discussed with them.

Medical writers should discuss and agree the content of a publication or presentation with the named author(s) before preparing a detailed draft. Getting the named author(s) to approve a publication outline and key messages is usually the best way to achieve this.

The medical writer is a facilitator in developing the manuscript, but the named author(s) must take responsibility for the content. If disagreements arise over the content of the paper, the named author(s) must always have the final say. If disagreements arise between authors they should be resolved by discussion – all authors must see and approve the submitted version and any subsequent revisions. Many journals now require confirmation that the submitted manuscript has been approved by all authors.

To qualify as authors, investigators (or others involved with a trial such as statisticians) need to have an opportunity to make a substantial contribution to the publication. This will usually involve commenting on an outline, or discussing key points before a first draft is prepared, then having sufficient time to comment on draft versions, and will always involve review and approval of the final version. Medical writers are often well placed to ensure that this process is properly carried out, by advising on timetables for review and ensuring that named authors have the materials required to perform a proper review (e.g. data tables and background literature).

Acknowledgement of medical writers

The involvement of medical writers and their source of funding should be acknowledged. Identifying the writer, either as an author or contributor or in the acknowledgements section, helps readers, reviewers, and journal editors to understand how the manuscript was developed, and recognises the writer's involvement. Identifying the writer's funding source ensures transparency and makes readers aware of any potential conflicts of interest. Medical writers should therefore ensure that the relevant journal's or meeting's requirements for financial disclosure, or other statements of competing interest, are met.

If writers are not listed among the authors or contributors, it is important that their role be acknowledged explicitly. Vague acknowledgements of the medical writer's role, such as 'providing editorial assistance' should be avoided as they are open to a wide variety of interpretations. We suggest wording such as 'We thank Dr Jane Doe who provided medical writing services on behalf of XYZ Pharmaceuticals Ltd'.

Although EMWA encourages transparency about writers' involvement with publications, because it believes that this usually serves readers and reviewers best, it also acknowledges that writers retain the right to withdraw their names from publications in exceptional circumstances (just as researchers who qualify for authorship may sometimes withdraw their name from a paper if they disagree with the way in which the research is presented or interpreted). Such a situation might occur if the writer prepares an outline or initial draft which is so substantially altered or replaced by material from the named author that the writer no longer feels that acknowledgement is appropriate.

Access to data

Some confusion has arisen over the specifications in the Uniform Requirements² concerning access to the data.

It is not usually necessary or desirable for authors to have access to individual patient data listings, as results become meaningful only after the raw data have been analysed, and tables and graphs produced. This analysis should usually be done by a statistician rather than by a clinician. However, there will be occasions where access to anonymised individual patient data is useful (for example when reporting details of serious adverse events), and in those cases medical writers should ensure that the data are made available both to themselves and to the named author(s).

Both the medical writer and the named author(s) must have access to the relevant study data, for example a clinical study report or set of statistical tables, before starting work on the publication. In addition, the writer must have access to the study protocol in order to identify secondary endpoints and analyses. Authors should not be expected to comment on a publication if they have not had access to the underlying data.

Writers' professional and ethical responsibilities

All medical writers, whether they are directly employed by a sponsoring body, or work for an agency, or as a freelancer hired by the sponsor, should endeavour to ensure that publications are produced in a responsible and ethical manner and that relevant guidelines are met.

Medical writers should be aware of any guidelines that apply to the publication they are producing (e.g. the ICMJE Uniform Requirements², CONSORT for randomised trials⁴, GPP for industry-sponsored research³, and individual journal and conference requirements). It is the writer's responsibility to advise customers, colleagues, and named authors if such guidelines are not being followed.

Medical writers should also advise customers and colleagues about the conventions of peer-reviewed publications. For example, they should encourage clear trial identification by including an ISRCTN⁵ (International Standard Randomised Controlled Trial Number), protocol or trial registry number, and discourage redundant/duplicate and fragmented publications.

Medical writers must strive to ensure that the publications they develop are accurate and scientifically valid. However, the named authors must take final responsibility for the content of any publication appearing under their names.

Writers must be aware of the extent of their expertise on the subject on which they are writing, and should ask for guidance from the named author(s) for any parts of the paper that are beyond their own expertise.

Writers and authors should ensure that results are presented in a responsible and balanced fashion. This is particularly important when developing publications

sponsored by a company with a financial interest in their content, e.g. when a publication is sponsored by the company that markets a product described in it. The writer and named authors should have access to all relevant information and should ensure that all such data, e.g. full safety data, are included in the publication rather than selectively reported. The writer should also ensure that conclusions are fully supported by the data and that publications do not contain unjustified claims. Secondary publications and post-hoc analyses must be clearly identified as such. Medical writers should also draw attention to any limitations of the study in the discussion section.

When preparing review articles (whether systematic or non-systematic), writers should ensure that the search criteria are stated. Even in non-systematic reviews, all relevant major studies should be included and not only those that support the key message of the review.

If a writer is aware of good quality evidence that contradicts a point being made in a review, or in the discussion section of a primary publication, the writer should attempt to ensure that this research is cited.

Implementation of these guidelines

This document is intended to provide a framework for professional medical writers in developing publications. We encourage companies who employ or hire medical writers to develop detailed procedures based on these guidelines, for example giving standard wording to be used in acknowledgements sections or contributor lists.

EMWA affirms that professional medical writers have a legitimate role in developing publications and their involvement should not be equated with sponsors' attempting to exert undue influence over publications. In fact, medical writers can raise the quality of publications by bringing to the process language and communication skills, expertise in presenting data, understanding of publication guidelines and conventions, or time which investigators may lack. This position is set out in the accompanying position statement (see Appendix).

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Appendix: EMWA position statement on the role of medical writers in developing peer-reviewed publications

The European Medical Writers Association (EMWA):

- A Affirms that medical writers have a legitimate role in assisting named authors in developing manuscripts for peer-reviewed journals and material for presentation at peer-reviewed scientific meetings.
- B Believes that such contributions and relevant information about funding should be openly acknowledged.
- C Discourages use of the term 'ghostwriter' to describe professional medical writers, as this term implies that there is something secretive about the involvement of the writer. Rather, the involvement of professional medical writers should always be transparent.

D Believes that properly trained medical writers can make a positive contribution to manuscript preparation. Such writers bring expertise about the requirements of journals and congresses and the ethics and conventions of peer-reviewed biomedical publications. They also offer skills in language, scientific communication, and data presentation. Such skills and knowledge enable professional writers to prepare drafts that are clearly written and follow the relevant guidelines. Involving medical writers may therefore raise the standard of publications and accelerate the writing and publication process.

E Encourages medical writers to ensure that publications are developed in a responsible and ethical manner, as specified in the guidelines that accompany this position statement; in practice this means:

- keeping up-to-date with relevant guidelines (e.g. CONSORT, ICMJE, GPP) and journal or conference requirements for financial disclosures or statements about competing interests
- advising colleagues and customers about these guidelines and/or conventions on responsible publication or authorship and alerting them if they are not being followed
- involving the named author(s) early in the publication process
- refusing requests to develop publications without sufficient involvement of the named author(s)
- making their best efforts to ensure that publications are accurate, balanced, and scientifically valid, acknowledging the limitations of their expertise and seeking guidance where needed
- taking particular care to present results relating to the sponsor's product in a fair and balanced fashion
- endeavouring to ensure that the named author(s) has access to the necessary data and adequate time to contribute to a publication
- endeavouring to ensure that all named authors approve the final version before submission to a journal or conference
- refusing requests to develop publications in an unethical or irresponsible manner.

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