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COMMENTARY

Substantial contribution and accountability: best authorship practices for medical writers in biomedical publications

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ABSTRACT

Objective: To provide clarity on the professional medical writer as author or contributor by examining what “a substantial contribution” and “accountability” mean with respect to authorship in a biomedical publication. These terms relate to criteria 1 and 4 of the International Committee of Medical Journal Editors (ICMJE) authorship guidelines.

Methods: We reviewed the ICMJE and Good Publication Practice authorship guidelines, which recommend that individuals not meeting all four authorship criteria should be acknowledged as contributors. We also surveyed and assessed selected journals for published guidance on authorship versus contributorship.

Results: We found that journals often vary in their authorship guidelines for medical writers. Notwithstanding, and to assist in determining the contribution made by the medical writer, we have expanded on current guidelines to develop recommendations for important intellectual contribution to the design of the work (developing the protocol, choosing endpoints) or the interpretation of data for the work (developing the discussion, interpreting new statistical output), which should result in inclusion of the medical writer as an author, as well as when accountability is relevant. If the medical writer does not qualify as an author, then their inclusion in the acknowledgements section is appropriate.

Conclusions: Authors and contributors have a responsibility to create a publication that is accurate and true to the study results, but only authors must provide a substantial contribution and are accountable for that contribution. Contributions made by authors and non-author contributors should be fully described in the publication, to enable the reader to assess credit and responsibility.

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Introduction

Whether the contributions of a professional medical writer connote authorship or contributorship in a biomedical publication continues to evoke controversy. A recent report claimed that any manuscript supported by a medical writer not listed as an author should be considered ghostwritten¹. This claim conflicts with the most widely recognized authorship criteria developed by the International Committee of Medical Journal Editors (ICMJE)². Many journals have adopted these guidelines, and other professional groups such as the International Society for Medical Publication Professionals (ISMPP), the World Association of Medical Editors (WAME) and the International Federation of Pharmaceutical Manufacturers and Associations cite them in their own recommendations^{3–8}. The ICMJE guidelines provide a list of four criteria upon which authorship should be based²:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis or interpretation of data for the work; AND
2. Drafting the article or revising it critically for important intellectual content; AND

3. Final approval of the version to be published; AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

These criteria aim to clarify the roles and responsibilities of authors and contributors. Thus, individuals who do not meet all four authorship criteria but have contributed to the work should be acknowledged as contributors². It is relatively easy to agree on whether an individual has fulfilled criteria 2 and 3; however, criteria 1 and 4 are often more difficult to determine, particularly when considering the role of the medical writer, statistician or sponsor representative⁹.

A recent joint position statement released by the American and European Medical Writers Associations (AMWA and EMWA) together with ISMPP advises that authors should “recognize as a co-author all contributors (including a professional medical writer) who meet the ICMJE authorship criteria”¹⁰. Although the Good Publication Practice (GPP3) guidelines provide some specific guidance with respect to authorship³, guidelines on the role of the medical writer vary by journal and sparse guidance is available regarding other

contributors. In the current article, we aim to provide some clarity on the medical writer as author or contributor by examining more closely what “a substantial contribution” and “accountability” mean with respect to authorship in a biomedical publication.

Rationale for good authorship practices

Ghostwriting is considered a serious ethical concern by ISMPP, ICMJE, WAME and many other professional groups. Definitions of ghostwriting vary^{1,11}. According to ISMPP, “ghostwriters are individuals who contribute substantially to a medical publication but do not appear on the byline and are not acknowledged for their contribution”¹². The Global Alliance of Publication Professionals (GAPP), an advocate of ethical practices, defines ghostwriting as “where a professional medical writer prepares a manuscript on behalf of a named author, but the writer is not listed as an author”¹³. Though slightly different, both definitions in general imply that medical writers should always be included *as a minimum* in the acknowledgement section of a publication. A common fear associated with ghostwriting is that writers hired by the pharmaceutical, medical device or diagnostic industry can influence the content of publications and hide unwelcome results, creating a potential bias that remains obscured if academic experts are credited with authorship¹⁴. The ultimate casualty of such practices is public trust in the healthcare profession¹¹.

Current authorship recommendations

The World Medical Association states in its Declaration of Helsinki that all parties should adhere to accepted reporting guidelines, without mentioning those guidelines specifically¹⁵. Although the ICMJE guidelines are the most widely accepted authorship guidelines^{3–8}, it has been suggested that they should be revised^{1,16,17}; one criticism is that they attempt to exclude medical writers from co-authorship and thus support the commercial development of ghostwritten manuscripts. The WAME Publication Ethics Committee states that “journals should publish guidance about what constitutes authorship”, indirectly suggesting that the ICMJE criteria are not always adequate⁸. The Committee on Publication Ethics (COPE) notes that “editors should provide guidance about criteria for authorship and/or who should be listed as a contributor following the standards within the relevant field”⁷.

More than 1000 journals follow the ICMJE guidelines², and many have their own additional instructions. However, these journals do not always provide consistent recommendations on the role of the medical writer, and guidance for other contributors, such as statisticians, is lacking. In Table 1, we have provided examples of differing journal recommendations: those which state that the medical writer should be included as an author or contributor, as appropriate; those which require medical writers to be authors; and those which propose that medical writers be included in the acknowledgements section of a manuscript.

Medical writers as authors or contributors

Professional medical writers often have a background in scientific research with an extensive peer-reviewed publication record and many have an advanced degree^{18,19}. Medical writers also improve the quality of publications through their language, communication and formatting skills, project management abilities, and knowledge of publication ethics and guidelines^{3,4,10,20–22}. Whilst it is agreed that medical writers sometimes qualify as authors¹⁰, examples of non-author contributions, according to the ICMJE, include “writing assistance, technical editing, language editing and proofreading”². These are presumably non-substantial contributions, but exactly what constitutes writing assistance is unclear.

The GPP3 guidelines define a substantial contribution to a publication or presentation as “an important intellectual contribution, rather than technical assistance, without which the work, or an important part of the work, could not have been completed or the manuscript could not have been written and submitted for publication”^{3,23}. Some examples include “actively guiding the scientific or medical content of the publication or presentation, statistical analysis and interpretation, crafting of the discussion, and developing the protocol”, which provides additional guidance not only to medical writers, but also to other contributors³. However, the GPP3 and EMWA guidelines also state that medical writers generally do not meet authorship criteria unless “they contribute substantially to a review article”^{3,4}. When considered against the claim that any contribution made by a medical writer has the possibility to influence content¹⁶ and should be considered ghostwriting if they are not listed as an author¹, it appears that some ambiguity remains.

Substantial and non-substantial contributions

Due to the above discrepancies, we developed Table 2. We propose that the following activities should be classified as non-substantial contributions to the interpretation of data for the work, which would permit inclusion of the medical writer as a contributor to the publication (here we focus on manuscripts): performing technical editing, language editing or proofreading, collating author comments, and making minor corrections for grammar, language, formatting or layout. Furthermore, if an author drafted the introduction and discussion sections of the manuscript, then the medical writer likely would not have contributed to the interpretation of the data. Finally, if the medical writer developed the manuscript from a clinical trial report written by another writer as well as substantial input from the authors and did not do a literature review or elaborate on the discussion, then he or she should be acknowledged as a contributor. In each of these cases, we would argue that the acknowledged medical writer has not influenced the content of the work substantially and, hence, should not be considered a ghostwriter. Under many scenarios, the medical writer is unlikely to have provided a substantial contribution to the conception of the work, or the acquisition or analysis of data.

Table 1. Journal opinions on the role of the medical writer as author or contributor. Examples are provided of journals' views on medical writers as authors or contributors, the relationship of the respective journal to the ICMJE, and a statement taken directly from the journal's author guidelines or editorial policies*.

Journal guidance for medical writers as authors or contributors

BioMed Central journals (refer to ICMJE guidelines ²)	The involvement of scientific (medical) writers or anyone else who assisted with the preparation of the manuscript content should be acknowledged, along with their source of funding, as described in the European Medical Writers Association (EMWA) guidelines. The role of medical writers should be acknowledged explicitly in the "Acknowledgements" or "Authors' contributions" section as appropriate.
Blood (member of ICMJE journal list ²)	Any involvement by pharmaceutical or medical device company employees or medical writers supported by a pharmaceutical or medical device company in the writing of an article must be clearly defined and disclosed in the Conflict-of-interest Disclosure section of the manuscript (if the individual is an author) or the Acknowledgments section (if the individual is not an author).
Journal of Antimicrobial Chemotherapy (refers to ICMJE guidelines ²)	Professional medical writers and other forms of writing assistance have an important role to play in the clear communication of scientific results. However, unless this role is openly explained and acknowledged unfounded suspicions about this role will continue. JAC encourages the open and precise description of any such assistance received by authors in relation to any article. It is possible that writers may qualify for authorship of a manuscript, we recommend that authors review the ICMJE criteria for authorship before submission.
Journal of Managed Care & Specialty Pharmacy (refers to ICMJE guidelines ²)	A medical writer who interprets the data and writes the manuscript, for example, should generally be a listed author. Failure to recognize a writer who meets authorship criteria is known as "ghost writing" and is unethical. On the other hand, a person who primarily reviews a manuscript and makes minor editorial changes does not generally qualify as a listed author. This latter situation has occurred when experts were solicited to serve as authors because of their position or recognition in a field of study. Thus, it is important that solicited authors' consultative roles are assessed for congruency with authorship criteria.
The Lancet (signatory member of ICMJE journal list ²)	We require signed statements from any medical writers or editors declaring that they have given permission to be named as an author, as a contributor, or in the Acknowledgments section.

Journals requiring medical writers to be authors and their authorship definition

Dermatologic Surgery (refers to ICMJE guidelines ²)	Authorship practices such as "ghost" authorship (individuals who qualify for authorship or who have made a contribution but who are not listed either as authors or as contributors) are inappropriate. This includes professional medical writers and their names, affiliations, and conflicts of interest must be included among the authors.
Neurology (member of ICMJE journal list ²)	Neurology defines an author as a person who has made a substantive intellectual contribution to the submitted manuscript. A substantive contribution includes one or more of the following: Design or conceptualization of the study; OR analysis or interpretation of the data; OR drafting or revising the manuscript for intellectual content. Professional writers employed by pharmaceutical companies or other academic, governmental, or commercial entities who have drafted or revised the intellectual content of the paper must be included as authors. <i>Neurology</i> defines a Contributor as a person who does not meet the criteria for authorship of the study, but who has contributed in other ways, such as collection of data; technical assistance; acquisition of funding; supervision of personnel; contribution of drugs, reagents, equipment, or participants; or editing the manuscript for nonintellectual content.
Health Services Research and Managerial Epidemiology; Translational Epigenomics (SAGE publications) (refer to ICMJE guidelines ²)	Manuscripts submitted for publication must list all authors, including the person who drafted the original manuscript. This includes paid or unpaid medical writers ("ghost writers"). If medical writers are to be involved in the preparation of manuscripts then they must co-author with a clinician (or other medical professional) and their name and full affiliation must appear on the article. The work of any medical writer must not be passed off as that of a clinician or other medical professional.

Journals proposing that medical writers are included in the acknowledgements

European Journal of Pain; International Journal of Laboratory Hematology (Wiley publications) (refer to EMWA and COPE guidelines ^{4,7})	Please name any professional medical writer among the list of contributors to any article for the journal (not only original research papers), and specify in the acknowledgments and statement of competing interests for the article who paid the writer.
The Oncologist (member of ICMJE journal list ²)	If an article has been substantially written by a contracted writer not named in the byline, this fact needs to be noted in the Acknowledgments section of the manuscript. In addition, all other contributors who do not meet sufficient criteria for authorship should also be noted in the Acknowledgments section.

*Selection of journals was by manual searching using keywords "authorship guidelines" and "medical writer"; search performed 28 January 2018.

Abbreviations. COPE, Committee on Publication Ethics; EMWA, European Medical Writers Association; ICMJE, International Committee of Medical Journal Editors; JAC, Journal of Antimicrobial Chemotherapy.

Table 2 also provides additional guidance on what might constitute an important intellectual contribution to the design of the work or the interpretation of data (criterion 1 of the ICMJE recommendations), and thus should result in inclusion of the medical writer as an author. Substantial contribution to the design of the work may occur when the medical writer is asked to provide input to or actually write the study protocol, including development of the introduction and benefit-risk assessment and suggestions for clinical endpoints. Defining a substantial contribution to interpretation of data for the work is more difficult due to the nature of collaboration between the medical writer and the larger team of contributors and authors. Ideally, the medical writer

should combine the authors' input, knowledge and expertise into a well written and correctly formatted publication. Unfortunately, in practice, authoring teams vary in their level of contribution. The medical writer may develop a basic manuscript outline based on early discussions with the authors and receive only a handful of references and a clinical trial report that includes minimal discussion. Thus, the medical writer may perform a literature search and develop the introduction and several discussion points, identifying material not already suggested by the authors who designed the study. In some cases, medical writers are asked to interpret the data in light of these new references and, therefore, warrant authorship.

Table 2. Recommendations for designation of substantial contribution for the medical writer to qualify for authorship.

Substantial contributions ^{a,b}	Non-substantial contributions
Interpreted the data and wrote the first full draft of the manuscript, including outline.	Edited the manuscript for grammatical mistakes or data errors.
Developed discussion points based on review of the data and published literature.	Reformatted an outline or manuscript provided by an authoring team for a new journal.
Performed a literature review that facilitated the data interpretation and wrote the first draft of the manuscript, including interpretation of literature for the introduction and interpretation of the trial data for the discussion.	Performed technical editing, language editing and proofreading, and collated comments from authors.
Developed the (primary) publication from a clinical trial report written by another writer and developed it further, including performing and interpreting a literature review and interpretation of the data.	Developed the (primary) publication with input from the authors, and did not perform a literature review or provide additional interpretation of data in the introduction or discussion.
Developed the (primary) publication from a clinical trial report that the medical writer wrote and in which their own interpretation was applied to the discussion.	Drafted the methods and results sections of the manuscript while an author or authors drafted the introduction and discussion sections.
Contributed to trial design by choosing endpoints or clarifying specifics of trial intervention.	Reviewed the manuscript or protocol for consistency between sections without finding or addressing major errors.
Provided intellectual input to or interpretation of statistical output developed for a secondary manuscript, which the medical writer then drafted.	Summarized a literature review performed by a scientist or medical expert ^c .
Wrote substantial portions of the protocol or data analysis plan or trial report and manuscript.	Composed the draft methods and results based on primary outcomes in a trial report.
Designed tables and figures and provided intellectual input/decisions for the selection of specific noteworthy data to enable correct interpretation of meaningful results.	Copied and pasted tables from a trial report under direction from a trial investigator. Reformatted tables for a specific journal style.
Contributed to a search-term or meta-analysis design and composed the first full draft of a manuscript.	Made a table of bibliographic information from papers derived from a literature search.

^aIt is assumed that the additional authors on the paper each qualify as such according to the ICMJE criteria and are actively engaged in the manuscript development process.

^bIn each of these cases, the medical writer has provided a substantial contribution to the design of the work, or the interpretation of data for the work.

^cAuthors should be provided with full access to data from the study, while maintaining subject confidentiality. Full access would mean access to sponsor documents such as the protocol, clinical trial report, including tables and figures, statistical analysis plan and any additional statistical output.

Accountability

All authors must agree to be accountable for the work². Thus, each author should be able to identify how each other author contributed to the development of the manuscript³. One author, usually the corresponding author, is generally designated the guarantor for the integrity of the whole work. However, and partly as a result of well publicized cases of scientific misconduct, the need for all authors to accept responsibility for the work and not just enjoy the credit, ultimately led to the addition of criterion 4 of the ICMJE recommendations in 2013.

Some medical writers may not wish to be held accountable, because they do not want to act as a guarantor for results or conclusions they did not collect or provide²⁴. Others may be happy to accept this responsibility, and consider themselves perfectly placed to account for the integrity of the work and the contributions made by each author. In accordance with ICMJE and GPP3 recommendations and to support full transparency^{2,3}, we propose that the contributions made by authors and by those who do not qualify for authorship be accurately and fully listed in the acknowledgements. Table 2 could be used to assist in determining the contribution made by the medical writer, and the examples used or adapted accordingly. Contributions to both the research and the manuscript will enable readers to assess both credit and responsibility²⁵.

There should be early agreement by all authors on those individuals who will be invited to fulfill authorship criteria as well as the order of authors and on who should be listed as contributors to the work, preferably before the work

begins^{2,3}. It is important that authors are aware of their roles and responsibilities; they are the experts, and their substantial intellectual contribution to the work is crucial. The GPP3 guidelines propose that the author order may be decided after the work is complete according to the level of contribution, which could also be a useful way of obtaining an appropriate level of input³. Taken one step further, and to improve transparency, a five-step authorship framework has been suggested, which we also support. This framework recommends the early establishment of a working authorship group but also the need to reconvene the group later in the process to assess actual contributions made and make decisions regarding the substantiveness of each²⁶. Thus, individuals could change from contributor to author and vice versa. Whether authors or contributors, medical writers have a responsibility to ensure that manuscripts are scientifically valid, written impartially and prepared in accordance with generally accepted guidelines and ethical standards^{4,20–22}.

Barriers to authorship

In practice, medical writers may not be offered authorship on a biomedical publication due to company policy. Journal authorship guidelines, possibly including a limit on author numbers, also sometimes preclude medical writer authorship. Another potential barrier to medical writer authorship is related to author payment. Companies may pay for medical writing services, but payment to authors must be fully disclosed and comply with relevant policies and rules³, which suggests a potential difficulty of offering authorship to some external medical writers. Lastly, the statement that medical

writers generally do not meet authorship criteria^{3,4} may have created the greatest barrier to authorship when medical writers, as we have stated earlier, may meet authorship criteria and it is a requirement of some journals that the medical writers are authors. Our examples of substantial versus non-substantial contributions may assist in determining whether or not medical writing support should be credited with authorship in a specific situation.

Additional authorship recommendations

Opinions vary about the appropriateness of allowing the medical writer to submit a manuscript on behalf of the corresponding author; for example, the ICMJE finds this practice unacceptable². Others argue that medical writers who serve as authors are ideally suited to act as corresponding author and perform the submission tasks that a lead author often prefers not to do²⁴.

More recently, it has been proposed that the companies who paid for the study should be credited with authorship^{16,27}. We agree that those company representatives who provide a substantial contribution to the work should be included as authors, but individual contributions need to be described in the manuscript and individuals should be named. Common authorship issues are further addressed in Appendix Table 2 of the GPP3 guidelines³. A method for quantifying the individual contributions made to a manuscript, based on the ICMJE guidelines, has also been suggested²⁸. This method used a matrix model to estimate and rank the contributions made by each potential author to four elements (ideas, work, writing and stewardship), and stressed the role of a guarantor having a legal and moral overall responsibility for the work²⁸. While we appreciate the potential value of a quantitative approach, such methods have not gained widespread acceptance and may prove difficult to oversee. We have rather focused on a qualitative means of determining authorship as published by other groups^{3,26}.

The recent AMWA-EMWA-ISMP joint position statement provides an example of a disclosure statement for medical writing support, should the medical writer not qualify as an author, which should be used in all publication types (e.g. manuscripts, posters, oral presentations), whenever possible:

"The authors thank [name and qualifications] of [company, city, country] for providing medical writing support/editorial support [specify and/or expand as appropriate], which was funded by [sponsor, city, country] in accordance with Good Publication Practice (GPP3) guidelines¹⁰."

Conclusions

Both authors and contributors have a responsibility to create a biomedical publication that is accurate and true to the results of the study, but only authors must provide a substantial contribution to the work and are accountable for that contribution. This distinction between contributor and author seems reasonable but is often difficult to determine. We have thus provided suggestions on what kind of substantial contribution by a professional medical writer would

qualify them for authorship, which could be considered when describing the contribution made by the medical writer in the manuscript. We focused here on the ICMJE authorship criteria, and on the role of the medical writer. A transparent and honest description of the contribution made by each individual to a publication would help to determine the eligibility of each individual for authorship. Nevertheless, we would welcome a continuing exchange of ideas between professional groups, academia, authors and journal editors to more clearly define authorship versus contributorship as we have attempted to do in this paper.

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Declaration of financial/other relationships

A.S. has disclosed that she provides publication and regulatory medical writing services to various pharmaceutical companies. D.S. has disclosed that she is principal at and holds shares in Simcoe Consultants Inc., and provides publication consulting and medical writing services to various pharmaceutical companies. D.T. has disclosed that he is employed by and holds shares in Amgen Inc. L.D. has disclosed that she has been employed by various corporate entities, including Merck & Co. Inc., Sanofi Pasteur, Novartis Vaccines and EMD Serono.

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