

Manuscript Writing

Section Editor:

Phillip Leventhal
pleventhal@4clinics.com

As a medical writer, can or should I be listed as an author of an article?

For manuscripts, medical writers often go far beyond providing basic services and therefore may feel entitled to authorship. Medical writers are often the main force behind an article and may provide much more intellectual input than simply putting the client's ideas into words, including interpretation and sometimes analysis of data, production of graphs and tables, and intellectual input into the presentation of the data and ideas. The medical writer often has much more input than some of the listed co-authors. Accordingly, many medical writers feel that they should qualify for authorship, perhaps even first authorship. Should they? And is it a good idea?

This touches on the sensitive issues of ghostwriting and ghost authorship, which are not discussed here but are discussed in EMWA's guidelines on the role of medical writers in developing peer-reviewed publications,¹ as well as in EMWA's position statement on ghostwriting, which is published on EMWA's website and on page 3 of this issue.

What ethical guidelines have to say on authorship

The main guidelines for determining who should receive authorship are those published by the International Committee of Medical Journal Editors (ICMJE).² Good Publication Practice 2 (GPP2) guidelines also refer to the ICMJE guidelines on the subject of authorship.³ The ICMJE guidelines on authorship and contributorship include the following statements:

An 'author' is generally considered to be someone who has made substantive intellectual contributions to a published study, and biomedical authorship continues to have important academic, social, and financial implications. An author must take responsibility for at least one component of the work, should be able to identify who is responsible for each other component, and should ideally be confident in their co-authors' ability and integrity.

And further down in the text:

Authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.

Although a medical writer may make 'substantive intellectual contributions' to an article, including 'analysis and interpretation of data' and is obviously responsible for 'drafting the article', a medical writer probably cannot 'identify who is responsible for each other component' or their 'co-authors ability and integrity', or have any role in 'final approval of the version to be published'. To paraphrase these guidelines, authorship implies accepting liability for what is published. This is very likely something a medical writer does not want and could imply purchasing expensive liability insurance.

EMWA's guidelines on the role of medical writers in developing peer-reviewed publications provide further guidance:¹

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 [ICMJE guidelines], 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 [ICMJE guidelines] 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.

To summarise, medical writers should not be listed as authors unless they are willing to take public responsibility – and therefore accept liability – for the article and its contents.

So, how should a medical writer's efforts be acknowledged?

Here's what the ICMJE recommends:²

All contributors who do not meet the criteria for authorship should be listed in an acknowledgments section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a department chairperson who provided only general support.

Furthermore, EMWA's guidelines on the role of medical writers in developing peer-reviewed publications recommend that:¹

The involvement of medical writers and their source of funding should be acknowledged.... 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.'

Conclusion

Although medical writers might feel that they deserve authorship, they should not be listed as authors unless they are willing to take public responsibility – and therefore accept liability – for the article and its contents. Instead, a meaningful acknowledgment of the medical writer's work and the source of funding for that work should be made in the Acknowledgment section of the article.

References

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Phillip Leventhal

4Clinics

pleventhal@4clinics.com

A guideline for manuscript flow Part 1 – The introduction

New medical writers and students of medical writing are often unfamiliar or unsure of the sort of information that should go into each section of a manuscript. But even when writers are familiar with the appropriate contents for each section, they are frequently unsure of how to link it all together so that it flows smoothly from one idea to the next.

A scientific or medical manuscript essentially tells a story about what happened. That story includes

why the study was done (introduction), how it was done (methods), what was learned (results), and what the findings mean (discussion). Unlike clinical documents or technical reports, which may contain every detail of a study and hundreds of tables or figures, a manuscript only needs to describe the highlights. Also, unlike a clinical study report, a manuscript must put the outcome in the context of the current literature.

When you are writing an article, keep in mind that you are essentially telling a story. Imagine that you are guiding the reader through a presentation

about what was done and what was found. Thinking in this way will help you create a logical flow of information within each section as the manuscript moves from one section to the next.

This article is the first in a series and focuses on structuring the flow of the introduction. Subsequent articles in this series will focus on the flow of the methods, results, and discussion sections and how to tie them all together.

The flow in the introduction

The introduction is the beginning of your story and introduces why the study was done. In the first sentence, put the main topic up front. The reader should know right away where you are headed. For example:

Herpes zoster, also known as shingles, is a common and often debilitating disease that occurs primarily in older or immunocompromised individuals.

In this case, the reader knows immediately that the subject is herpes zoster.

This approach is relevant not only for clinical studies but also for basic research. For example:

Activation of the epidermal growth factor receptor stimulates the growth of many cell types and is implicated in some forms of breast and other cancers.

In this case, the reader knows immediately that you are going to talk about the epidermal growth factor receptor.

Continue developing the first paragraph with a general background of the area. This is the place to describe, for example, the incidence and prevalence of a disease, its specific effects on the patient, and the economic impact; or for basic research, the essential characteristics of the system. What information you include depends on the journal's audience. For an expert audience, you do not need to provide basic information, but for a more general audience, you might need to present fundamental information about the research area or the disease. For example, if publishing in a journal about infectious diseases, you might not need to explain what streptococcal bacteria are, but you might need to furnish some of this information for an article destined for a molecular biology journal. Generally, this type of background information should be limited to a single paragraph.

Once you have established the general background, describe where things stand now for your

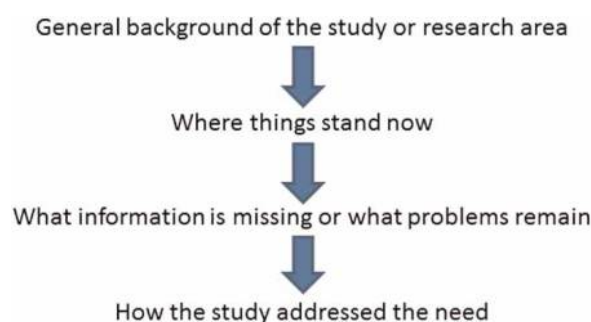


Figure 1: Summary of flow of the introduction.

topic. For example, how is the disease currently treated, or what is the current level of understanding? If discussing a disease, what treatment options or solutions are there? Have improvements been made? Are there new developments in the field? Where are things headed? If you used a special technique or method in your study, this is a good place to establish its validity.

Now you have brought your audience up to the current state of affairs, but what information is missing or what problems remain to be solved? Explain what the study or group of experiments tried to solve. And make sure that you explain why this question is important.

At the end of the introduction, talk briefly about what was done in this study. For a clinical study, what kind of study was it and what were the principal objectives? For basic research, what did you set out to determine? If you had a specific hypothesis, state it here.

In the old days, the introduction in some articles would end with a summary of what was found in the study. If you are working for a crusty old professor, he might insist that this is appropriate. However, I recommend that you don't do this; the abstract includes a summary of the results, and the goal of the introduction is to explain why the study was done, not what was found.

Conclusion

The introduction is the place to explain why a study or set of experiments was done. As summarised in Fig. 1, it should flow smoothly from a general background through to what was done. Finally, the introduction should be approximately 500 to 600 words. Any more than that and you will bore your readers and lead them astray.

Phillip Leventhal
pleventhal@4clinics.com