



## Authorship and review articles: Multiple shades of grey...

by Elizabeth Crane

### The current environment

As evidenced by recent headlines in major newspapers, review articles have been of particular interest to the media and United States Congress [1-3]. Review articles relating to clinical trials and pharmaceutical products seem to possess an aura of mystery to the general public because their origins often lie within a ‘strategic publication plan’, thereby amplifying the potential for bias and product promotion. In particular, the roles of the authors and the sponsoring company are central to the public’s suspicion. A leading perception is that the content of review articles is largely dictated by the sponsoring company rather than by the authors. The term ‘guest authorship’ is used to describe cases in which an individual listed in the byline did not actually contribute to the article and merely approved a draft manuscript prior to submission. The content of such a paper may have been written with assistance from a professional medical writer whose role is undisclosed, also referred to as ‘ghostwriting’. Finally, ‘ghost authorship’ describes cases where someone’s, perhaps a medical writer’s, contributions to the paper are substantial and intellectual enough to qualify for authorship, though the individual is absent from the byline.

While it is very clear how *not* to determine authorship of review articles, identifying individuals who do qualify as authors is not always easy. Existing guidance published by editorial [4, 5] and professional writing organizations [6-8] are an essential reference to provide clear expectations and requirements for ethical publication practices. While these guidance documents quite clearly apply to publication of original research papers, there is significantly less instruction regarding publication and determining authorship of review articles. Additionally, lessons can be learned from cases and resulting media coverage on how to interpret and apply current guidelines to formulate, or update, ethical policies and practices.

As the vast majority of authors, medical writers and publication planners have no aspirations of achieving public infamy, this paper will review the current guidelines for determining authorship and how they do, or do not, apply to review articles, and discuss the implications for publication policies and practices.

### Guidelines for authorship

The International Committee of Medical Journal Editors (ICMJE) Uniform Requirements [4] is the standard by which many journals and industry-related entities set their

authorship policies. ICMJE states that authorship criteria are met when an individual fulfils all three of the following requirements:

- Substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data
- Drafting the article or revising it critically for important intellectual content
- Final approval of the version to be published

While these criteria do not directly refer to review articles, they can be stretched and extrapolated to fit reviews and other types of non-research publications. The third condition—approval of the final version—is straightforward and applies to any type of publication. The second condition—drafting the article or providing intellectual contributions—is also clear and applicable, though the question of what qualifies as an important intellectual contribution could be the basis of its own supplement. Nonetheless, the vagueness applies equally to research and non-research publications.

In systematic reviews, publications in which there is a methodology by which searches were conducted and literature included for evaluation, the first condition could translate to conception of the review article, determination of search parameters and inclusion criteria, execution of literature searches, or evaluation and interpretation of qualifying literature. Non-systematic or narrative reviews, those that describe a topic and have softer methodology and criteria for article inclusion, are more difficult to apply to current authorship criteria. The initial, broad idea for a review article may originate from numerous sources: an individual, discussions during a sponsored advisory board, a hallway conversation, or frequently received questions to a sponsor’s Medical Information Call Centre, to name a few. Additional research and discussion are needed to transform a very general idea (for example, a review of nighttime heartburn) into a concept that can be developed into a review manuscript (for example, a review of the physiology and available pharmacological and non-pharmacological treatments for nighttime heartburn in adults). In the cases where a scientific expert formulates the initial concept and continues forward to develop the concept into a full-fledged publication, the qualification for potential authorship is clear. In the other cases where an agency, a team or a committee identifies the initial, general idea and brings it forth to one or more scientific experts for further discussion, the experts need to be accountable for

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- > transforming the rough concept to a point where an outline can be developed. Then they should be able to confidently demonstrate their contribution, assume responsibility for the work and fulfil the first criterion for authorship.

Some journals are addressing the unique authorship requirements of non-research papers. The *Annals of Internal Medicine* has modified the first ICMJE criterion by stating that the author must have “conceived and planned the work that led to the article or played an important role in interpreting the results, or both” [9]. Additionally, the *British Medical Journal* specifically approaches the roles of those contributing to non-research articles, as author or otherwise, by requiring transparency in declaring which individuals conceived of the paper, performed literature searches and wrote the paper [10]. However, the *BMJ* model for contributorship does not further stipulate any specific criteria for distinguishing byline authors of non-research articles.

It is also worth noting that the ICMJE Uniform Requirements [4], and other guidelines that reference it, state that authors listed in the byline must be able to take public responsibility for the work. This includes being able to explain and defend the work to peers in the scientific and publication fields. However, in an environment where authors are not only criticised in print by journal editors, but can be subpoenaed to testify about their knowledge of study data and contributions to a manuscript, public responsibility takes on deeper significance. While sorting out specific roles and significant contributions, those involved in creation of review articles must remember that their inclusion in the paper, regardless of whether this be in the byline or the acknowledgements, is a public endorsement of the work.

With a lack of specific authorship criteria for review articles, editors, authors and publication professionals are left to their own devices in interpreting the current guidelines, and interpretation is notoriously variable when done on a case-by-case basis. Inconsistent interpretation can also lead to a spectrum of strict-to-lenient application of authorship criteria, which will further confuse and frustrate all stakeholders.

### Considerations for applying authorship criteria

Authorship qualifications are generally not an issue when the individual who conceived of the review topic also drafts, revises and approves the manuscript, as all criteria are elegantly met. However, the more prevalent, and complicated, scenario is when a scientific expert agrees to develop a concept to publication and have writing or editing assistance provided by a medical writer and funded by an industry sponsor, as discussed earlier. This scenario becomes further complicated when the medical writer possesses the credentials and scientific expertise to lend important intellectual contributions to the concept, design of literature searches, and evaluation and interpretation of the literature. In this complex scenario, a number of effects and implications should be considered.

First, if one agrees with the extrapolation of the first ICMJE condition for authorship—contribution to manuscript concept development, design and execution of literature searches, and literature evaluation—it is then very important to ensure that the scientific experts invited as potential authors are actually engaged in designing the literature searches and evaluating the literature for inclusion/exclusion, as well as interpreting the research. On occasion, the author actively or passively (through lack of responsiveness) delegates to the medical writer the lead in designing and executing the searches. The medical writer may also conduct the preliminary sorting and prioritization of results. The result can be two-fold: the author is excluded from the process, thereby missing an opportunity to qualify, and the writer is potentially meeting the first criterion for authorship. As described in the EMWA guidelines [6], conduct of an extensive literature search could qualify a medical writer for authorship. Non-responsive authors should be reminded of the responsibilities of authorship and importance of their contributions. If they fail to seize the opportunity and provide significant input, then they should be removed as an author. Conversely, medical writers should remember to solicit direction from potential authors and refrain from filling in the gaps on behalf of the non-responders. In fact, during the project initiation phase, it may be worthwhile for the medical writer and sponsor to discuss expectations of authors (e.g. does an e-mail stating that a draft “looks good” constitute acceptable input?) and a plan of action for whom will contact non-responsive authors at what time points. All stakeholders, including authors, benefit from having clear expectations at the onset of the project.

The role of a medical writer as potential author has been controversial. If an individual, professional medical writer or not, fulfils the conditions for authorship, then guidelines [4-8] agree that the individual must be included in the author byline. Additionally, if the writer or his/her employing agency received funding from the manuscript’s sponsor, this fact should be clearly disclosed. This case becomes complex for those sponsoring companies with written, or unwritten, policies explicitly prohibiting compensation (e.g. honoraria, consulting fees) for authorship activities. If a professional medical writer, who is paid a fee for service under such a policy, becomes an author, the sponsor is left in a quandary—violate their policy or request that the writer return payment or decline authorship. None of these options are attractive, and declining authorship when one qualifies only perpetuates the unacceptable practice of ghost authorship. For companies with strict payment policies, all stakeholders need to discuss roles and expectations during the project planning stage. It must be very clear as to whether a medical writer possessing appropriate scientific qualifications will have an opportunity to qualify as an author, or whether the expectation is for the writer to act in a purely supportive role. Writers and agencies should, in turn, determine if they are comfortable entering

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into business agreements with stipulations that the medical writer will remain in a disclosed contributorship role.

Another aspect of review article authorship is the role of the sponsor's employees. Many industry medical directors and scientists are recognised for their academic research achievements made prior to embarking on a career in the pharmaceutical industry. Some industry scientists are well-known for their notable research achievements made during their industry tenure. As a result, these individuals are often invited, or solicited, to author reviews on a topic or product in their area of expertise. Clearly, there is a potential conflict of interest that requires detailed disclosure, particularly if the sponsor had a role in funding or reviewing the publication. However, someone with relevant expertise should not be prevented from accepting an invitation to author a review paper solely on the basis of being employed by industry. An employer's internal policies may further detail the steps necessary to review and approve such projects, as well as disclosures and disclaimers needed for the resulting publication. Medical writers should solicit details of the scope of the internal review (e.g. limited to legal and intellectual property, or were content and the decision to publish directly influenced?) and gain agreement on a brief and accurate disclosure of such activity in an effort to provide transparency to the journal and public.

Due to their credentials and expertise with a product or therapeutic area, industry employees may be able to make important contributions to an unsolicited review manuscript and potentially serve as authors. In fact, these individuals are likely part of the sponsor's internal publication review process, even if they are not authors. Therefore, the definition of roles and expectations at the initiation of the publication is very important. Some product teams prefer employees *not* to author sponsored non-research papers. This practice may be an effort to reduce potential bias and, hopefully, increase likelihood of acceptance of the review. Aside from anecdotes of rejections, the true efficacy of this approach is not known because sponsorship of the paper is already a potential source of bias, regardless of the presence of a sponsor-author. For sponsors who do allow employees to qualify for authorship of sponsored review papers, it is essential to offer a complete, detailed disclosure statement describing the pertinent financial and personal relationships, as well as if the sponsor provided other means of support, reviewed the article or participated in the decision of whether or not to publish.

As authors, writers, editors and publication planners continue to share and debate current review article policies and practice, establishment of best practices grows closer on the horizon. In lieu of a defined best practice, those involved in development of review articles should document their current procedures so that, if questioned by editors or attorneys, they are prepared to explain and defend the selection and roles of authors and contributors.

## Conclusion

In the absence of guidelines that specifically address authorship of review articles, transparency in disclosing the roles and potential conflicts of interests of authors and contributors is an ethical and appropriate course of action. Additional consultation with journal editors to confirm which individuals meet authorship requirements can also be helpful to ensure that criteria are applied in a manner that is compliant with the journal's policies. Professional organisations and journal editors should consider developing authorship criteria for non-research papers.

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## Answer to quiz on page 11

There are 6 'F's. You counted 4? Usually people can only count 4 'F's in the text because most brains cannot process 'OF'.