Manuscript Writing

Section Editor:

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A guideline for manuscript flow. Part 4 – The discussion

Medical writers with little experience of writing manuscripts can struggle to organise their thoughts. Linking the information within the different sections of a manuscript can be referred to as 'manuscript flow'. This article is the last of a series of four articles on manuscript flow. Article one focused on the introduction,[1] article two on the methods,[2] and article three on the results.[3] The focus here is the discussion, the manuscript section that many find most challenging.

Where to start

A recommended flow for the discussion is shown in Figure 1. Begin by outlining what the study showed, making sure that you explain how the data collected address the study objective(s). It is fine to restate the main objectives as they were presented in the introduction to remind the reader what they were.[4]

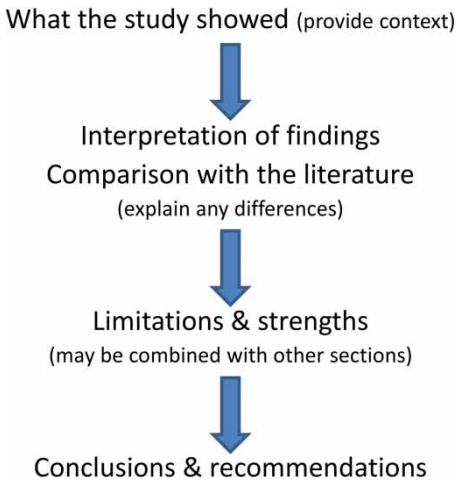

Figure 1: Summary of flow of the discussion.

While it is okay to highlight key findings at the beginning of the discussion, do not simply repeat all the results. The results section is where you should present and describe the results; in the discussion you should interpret them and discuss their implications. A sentence in the results section might read as follows:

> *Child-related stressors were the strongest predictor of membership in the high-stress group (odds ratio = 2.16).*

In the discussion you might interpret this result thus:

> *In this study, we showed that childhood stress is one of the strongest predictors of stress in adulthood.*

The middle part: Comparing your results with the literature

Compare your findings with the literature. Be sure to include references to articles by key people in the research field. This will show that you know the field, and won't do any harm if these key people end up refereeing your manuscript. Report any discrepancies with related studies, and try to provide explanations for them; don't pretend they don't exist.[4] Provide also alternative explanations for your findings.[4] This will again help show that you know your field, and that you have carefully considered the meaning of your results.

Be sure to explain the study's strengths and limitations. Don't forget the strengths! For example:

> *This initial study, which included 37 patients, did not allow us to draw formal conclusions about the efficacy of the malaria treatment. However, it is highly relevant for understanding malaria treatment because it was performed in a region of high transmission.*

Importantly, if particular study limitations didn't affect the results, make this clear. Explain also any steps you took to limit the influence of potential biases and other limitations.

End strongly by presenting your conclusions and recommendations

Finally, present your conclusions and recommendations. Mention unanswered questions and future research by all means, but don't just write 'Further studies are needed.' Be specific: if you think future studies are needed, indicate what it is they should aim to do and how. But make sure future research isn't the very last thing you mention; instead, leave

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your readers with a punchy statement about the importance and implications of your findings.[4]

What do official guidelines say?

This flow is also recommended by the ICMJE (International Committee of Medical Journal Editors) *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals*.[5] The ICMJE recommendations, which were recently updated (see page 107), include the following for the discussion section:

> *'Emphasize the new and important aspects of the study and the conclusions that follow from them in the context of […] the best available evidence. Do not repeat in detail data or other information given in other parts of the manuscript […] briefly summariz[e] the main findings, then explore possible mechanisms or explanations for these findings, compare and contrast the results with other relevant studies, state the limitations of the study, and explore the implications of the findings for future research and for clinical practice.'*

> *'Link the conclusions with the goals of the study but avoid unqualified statements and conclusions not adequately supported by the data. In particular, distinguish between clinical and statistical significance, and avoid making statements on economic benefits and costs unless the manuscript includes the appropriate economic data and analyses. Avoid […] alluding to work that has not been completed. State new hypotheses when warranted […].'*

The guidance on distinguishing between clinical and statistical significance, in the second paragraph above, is particularly important. For example, in an epidemiological study of 4 million people, an odds ratio of 1.05 could easily be statistically significant. But is it necessarily clinically meaningful?

Some information on essential content is included in the CONSORT 2010 Checklist,[6] which has the following specific items for the discussion section:

- Item 20: Trial limitations; addressing sources of potential bias; imprecision; and, if relevant, multiplicity of analyses
- Item 21: Generalizability (external validity, applicability) of the trial findings
- Item 22: Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence

Item 21 is especially noteworthy. *Generalisability* is a relatively young word, first documented only 100 years ago,[7] but it has become a key concept for clinical studies. How generalisable a study's results are to the wider population will help to determine how broadly the tested treatment can be applied. Be realistic when describing the generalisability of your results. Don't make unwarranted claims – journal editors, referees, and readers won't accept them.

Additional points to consider

Use transition words and phrases such as *therefore*, *however*, *thus*, *conversely*, *consistent with*, and *in contrast to*,[4] but make sure you use them appropriately. Don't, for example, start consecutive sentences with *However*.

Do not introduce new data or refer to 'data not shown' in the discussion. Any references to data not shown belong in the results section. Moreover, if the data are important enough to bring up in the discussion, they should be presented in the results section!

A final point

Making sure that the discussion flows logically from one element to another so that it tells a story can be difficult. The flow described in this article is a good place to start, but feel free to adapt these recommendations to your specific needs and writing style.

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ICMJE *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals*: December 2014 update

In December 2014, the ICMJE[1] updated its *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals*.[2] The material changes are listed below. No explanatory notes are provided. This forces users to infer the precise intended meanings of terms such as 'self-interest' (section IV A 3 g) and 'concerns' (IV B). The reasons for the changes are also unclear. However, a number of them seem to reflect ethical issues and dubious practices that journal editors and authors have engaged in or faced in recent years. Indeed, I can confirm that the amendment to section IV A 3 g was introduced to discourage journal editors, peer reviewers, and authors from choosing references in a manner aimed at increasing citations of their own (journal's) papers (Darren Taichman, personal communication, 2015 Feb 3). Elsewhere, the new section on fees (III F) would appear to be a response to hidden charges levied by predatory journals. Sadly, such journals are hardly likely to adopt the ICMJE recommendations.

Section II E. Protection of Research Participants. New guidance:

> *'Approval by a responsible review committee does not preclude editors from forming their own judgment whether the conduct of the research was appropriate.'*

Section III D 2. Duplicate Publication. Change in policy:

> Registration of clinical trial results (not more than 500 words) in an acceptable registry other than the primary trial registry will no longer be considered prior publication.

Section III E. Correspondence. New guidance:

> *'Responsible debate, critique and disagreement are important features of science, and journal editors should encourage such discourse ideally within their own journals about the material they have published.'*

Section III F. Fees. New section:

> *'Journals should be transparent about their types of revenue streams. Any fees or charges that are required for manuscript processing and/or publishing materials in the journal shall be clearly stated in a place that is easy for potential authors to find prior to submitting their manuscripts for review or explained to authors before they begin preparing their manuscript for submission.'*

Section IV A 3 Manuscript Sections. b. Abstract. New guidance:

> *'If the data have been deposited in a public repository, authors should state at the end of the abstract the data set name, repository name and number.'*

Section IV A 3 Manuscript Sections. d. Methods. New guidance:

> *'The Methods section should aim to be sufficiently detailed such that others with access to the data would be able to reproduce the results.'*
>
> *'If an organization was paid or otherwise contracted to help conduct the research (examples include data collection and management), then this should be detailed in the methods.*
>
> *The Methods section should include a statement indicating that the research was approved or exempted from the need for review by the responsible review committee (institutional or national). If no formal ethics committee is available, a statement indicating that the research was conducted according to the principles of the Declaration of Helsinki should be included.'*

Section IV A 3 Manuscript Sections. g. References. New guidance:

> *'References should not be used by authors, editors, or peer reviewers to promote self-interests.'* They should instead be chosen according to relevance and usefulness for the reader (Darren Taichman, personal communication, 2015 Feb 4).

Section IV B. Sending the Manuscript to the Journal. New guidance:

> *'The [cover] letter or [completed journal submission] form should inform editors if concerns have been raised (e.g., via institutional and/or regulatory bodies) regarding the conduct of the research or if corrective action has been recommended.'*

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GPP3 on the way

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In January 2015, an article describing GPP3 (the third iteration of the Good Publication Practice guidelines) was submitted to *Annals of Internal Medicine*.[1] GGP3 builds on GPP2, described in a *BMJ* article from 2009.[2] The original GPP guidelines were published in 2003.[3] GPP2 and GPP3 are the work of members of the International Society for Medical Publication Professionals (ISMPP). New to GGP3 are sections devoted to core publication principles and data sharing. In addition, the persistent problems of plagiarism and self-plagiarism are addressed for the first time. As ISMPP points out, peer reviewers will have some influence as to the final content of the GGP3 paper. Expect a fuller description of GPP3 in *Medical Writing* when the GPP3 paper is published.

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New authorship framework for industry-sponsored publications

Are ICMJE guidelines on authorship[1] too broad to allow valid and consistent assignment of authorship of publications based on clinical trials? Yes, according to members of the Medical Publishing Insights and Practices (MPIP) Initiative, which brings together representatives of pharmaceutical companies and ISMPP.

One of MPIP's 10 recommendations for improving the credibility of industry-sponsored publications is to 'Improve disclosure of authorship contributions and writing assistance and continue education on best publication practices to end ghostwriting and guest authorship'.[2] To address this recommendation and perceived shortcomings in the application of ICMJE and other guidelines, MPIP members worked with other stakeholders to develop a five-point framework for determining authorship.[3]

Key steps in developing the authorship framework were:

(1) Creation of seven case scenarios illustrating difficult decisions regarding assignment of authorship
(2) Creation of an online survey based on these scenarios
(3) Emailing of this survey to four groups of stakeholders: clinical investigators involved in industry-sponsored trials, journal editors, medical writers, and industry-paid publication professionals
(4) Discussion of survey results in two roundtable meetings to identify key themes[3]

498 people completed the survey. Their responses reveal some interesting trends:

(i) A majority of respondents felt that trial site management and a considerable contribution to patient recruitment were sufficient grounds for authorship.
(ii) A majority of respondents felt that a statistician who contributed to data analysis and interpretation, but not trial design or manuscript drafting, should be added as an author of the final manuscript.
(iii) A quarter of journal editors and clinical investigators felt that medical writers should be listed as authors.[3]

The opinions expressed in (i) and (ii) above are potentially valid according to ICMJE guidelines, but only if the potential author fulfills additional authorship criteria. By contrast, medical writers do

not normally qualify for authorship. Several respondents highlighted what they considered to be the conflict between what is permitted by the guidelines and what is fair.

The five-step authorship framework

Based on the survey and their discussions, MPIP suggests the following five steps as a framework for determining authorship in clinical trial publications:[4]

> (1) Establish a working group responsible for steps (2) to (5) below. Members of the working group need not be authors and should not be guaranteed authorship.
> (2) Identify trial-related activities that are to be considered 'substantial'.
> (3) Track and record substantial trial-related activities.
> (4) Assess the recorded substantial activities and invite those responsible for them to be authors.
> (5) Ensure those invited to be authors fulfill all ICMJE criteria.[1] Authors can be added or removed, at the consent of all authors. In the interests of internal transparency, authorship changes and the reasons for them should be documented.

To me, this all seems very sensible. Importantly, it is suggested that the framework be backed up by a 'publication agreement', which defines the procedures in steps (2) and (5) and which should be approved by all trial contributors.[4] The framework has the potential to increase consistency in authorship decisions and reduce disputes over authorship. However, people invited to be authors in step (4) and then removed from the author list in step (5) are unlikely to be overjoyed, irrespective of any publication agreement they might have signed.

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