Manuscript Writing

Section Editor:

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A guideline for manuscript flow. Part 3 – The results

New medical writers and medical writing students are often unsure how to start writing a manuscript and need help in organizing their thoughts. This is the third in a series of articles that explain how to link the sections and the information within them together, what I call 'manuscript flow'. The first two articles in this series covered the Introduction[1] and the Methods.[2]

Guidance from the ICMJE recommendations and the CONSORT statement

Manuscript content guidelines (e.g. CONSORT) and the ICMJE recommendations provide some guidance about the content of the Results section[3] but little or no advice on how to organise the content. The journal's instructions for authors may also have some information on what to include, but they do not explain how to organise the flow of information.

The ICMJE guidelines state:[4]

> *Present your results in logical sequence in the text, tables, and figures, giving the main or most important findings first.*

This is a bit vague, but putting the main or most important findings first is good advice. The ICMJE recommendations also state:

> *Do not repeat all the data in the tables or figures in the text; emphasize or summarize only the most important observations. Provide data on all primary and secondary outcomes identified in the Methods Section. Extra or supplementary materials and technical details can be placed in an appendix where they will be accessible but will not interrupt the flow of the text, or they can be published solely in the electronic version of the journal.*

In addition, the CONSORT statement can be used to help guide the reporting of randomized clinical trials, although they can be adapted to other study designs. They require inclusion of the following information in the Results section:[5]

- Participant flow.
- Dates defining recruitment and follow-up.
- The demographic and clinical characteristics of each group.
- For each group, the number of participants included in each analysis and whether the analysis was by the originally assigned groups.
- For each primary and secondary outcome, the results for each group, and the estimated effect size and its precision, and for the binary outcomes, presentation of both the absolute and relative effect sizes is recommended.
- The results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing the pre-specified from the exploratory.
- Adverse events.

Although this does not give specific guidance on the logical flow, following the order of this list can help.

A general structure for the results

Described below and summarized in Figure 1 is a general structure that fulfils the requirements of complete reporting of the Results section for a

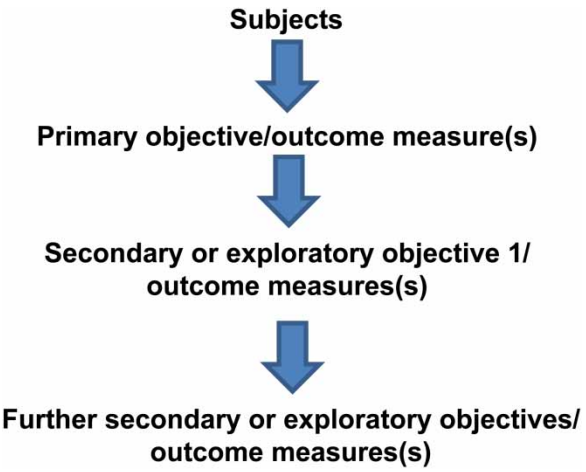

Figure 1: Summary of flow of the results.

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clinical study, although this structure can be adapted to any type of study.

Start with a section describing the subjects

This section gives the reader an overview of the number and the characteristics of the subjects. Give the section a logical title, like 'Subjects' or 'Patients'. Begin the text of this section with a sentence describing how many subjects were included, when they were included, and how they were split up or randomized. Next, explain what happened to them and follow with a description of their baseline characteristics. If the study is complex, include a CONSORT flow diagram[5] showing the flow of the subjects in the study, but if it is a simple study, the flow of the subjects can be summarised in the text. Below is an example:

> *A total of 2001 subjects were enrolled in the study (1001 in the XMD group and 1000 in the YMD group) between October 1, 2008 and March 26, 2009, and the study was completed on April 24, 2009. Ten subjects (6 in the XMD group and 4 in the YMD group) withdrew consent before receiving treatment. An additional 50 subjects (26 in the XMD group and 24 in the YMD group) did not complete the study, mostly due to loss to follow-up (Figure 1). Thus, 1941 subjects completed the study. In both groups, approximately 60% of the subjects were female, average age was approximately 41 years, most were White/Caucasian, and approximately 10% had previously been treated with corticosteroids (Table 1).*

Follow with sections describing the primary outcome(s) and addressing the primary objective

The goal of the study and the main focus of the Results section should be to address the primary objective and therefore to present the primary outcome measure or measures. Present this information first. For example, if this is a study assessing the superiority of a vaccine compared with the current standard vaccine, start with the section on immunogenicity. Such a section might simply be entitled 'Immunogenicity'. Within the section, present the main analysis – in this case superiority analysis – first. Follow with additional related analysis, for example, presentation of antibody titres, cellular immune responses, and analysis of the factors predicting immune responsiveness or lack of response.

Finish with the secondary or exploratory outcomes

The next section or sections should cover the secondary or exploratory objectives and outcome measures. Organise these sections into logical chunks, each with their own title. Within these secondary sections, as in that describing the primary outcomes, organise with the most important assessments first and follow with secondary information or more detailed or exploratory analyses.

For the example of a vaccine study, the next logical step might be to present safety information. This section could simply be called 'Safety' or 'Adverse events'. In such a section, the most important information might be expected or solicited reactions, such as injection-site swelling and itching. This might be followed by unsolicited adverse events and, finally, analyses of the risk factors for adverse events or solicited reactions.

A final note

Keep in mind that each method described in the Methods section should have results. It may help to organise the results in the same order as in the methods, namely, in the order of most to least important.

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