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Maramba-Lazarte CC. Improving Quality of Medical Writing of Trials

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EDITORIAL

IMPROVING THE QUALITY OF MEDICAL WRITING OF TRIALS IN THE PIDSP JOURNAL: ADAPTING THE CONSORT STATEMENT

The PIDSP Journal Editorial Team strives to make improvements in order to uplift its own standards and be at par with International Journals. One quick fix which did not require any additional budget, but would significantly improve the quality of manuscripts was to adopt standard reporting guidelines, in particular the CONSORT Statement.

We all want our articles to have complete information and fully reflect what procedures were undertaken. This is especially true in the reporting of randomized clinical trials. When reporting these clinical trials, we also want to be aware of what measures were performed to reduce bias so we could assess the metholodological quality of the research. Also, standardized reporting makes it easy for us to compare different trials on the same therapy, intervention or device to each other. It would also make us more confident to combine data, as in meta-analyses, when the research presented are of high quality.

Thirty experts who included medical journal editors, clinical trialists, epidemiologists and methodologists have made it easier for us by creating the CONSORT statement in 1993, which has been revised twice, with the latest version in 2010. The CONSORT Statement can be found at http://www.consort-statement.org/ including the Explanation, Extensions, checklist, flow diagrams and other important information.

CONSORT stands for the Consolidated Standards of Reporting Trials. This is a minimum set of recommendations for reporting clinical trials. This makes possible for authors to be guided on all the necessary elements to make a complete presentation of their procedures, as well as other important aspects of the trial. The CONSORT Statement includes a 25 item checklist and a flow diagram. The Checklist includes the 6 major sections (Title and Abstract, Introduction, Methods, Results, Discussion) with specific checklist items for each section. These items were selected because evidence have shown incomplete reporting of these information is associated with biased estimates of treatment effect. Also many of the items are needed to critique the research or because the information is essential to judge the reliability or importance of the results. In the 2010 revision, 3 more items were deemed necessary information to be included in the report. These include the registration number of the trial

registry, where the full trial protocol can be accessed, if available and the sources of funding. This is to allow full transparency by the author.

The flow diagram presents the progress of all participants during the trial. Thus how many patients were enrolled, allocated, dropped out , followed-up as well as how many patients were included in the data analysis are seen in the flow diagram. There are also translations of the Consort Statement, Checklist and Flow Diagram in several languages including Chinese, French, Vietnamese, Japanese, Italian and Greek.

The CONSORT group in 2010 also developed other important documents to compliment the statement which includes the CONSORT 2010 Explanation and Elaboration (E&E) Document. This article offers an explanation of every item in the Checklist as well as examples of how it can be written. This 32-page document provides an explanation of each of the CONSORT Checklist items, and how to apply them in your reporting.

There are also CONSORT Extensions which have either checklists or explanations for different trial designs (ex. Cluster trials, non-inferiority and equivalence trials), and interventions (ex. Herbal medicine trials, non-pharmacologic intervention trials, acupuncture trials).

There has been a massive support as well as uptake of the CONSORT reporting guideline. More than 600 journals have endorsed the CONSORT Statement, while major editorial groups have also given their support. These groups include the Council Science of Editors, the World Association of Medical Journal Editors as well as the International Committee of Medical Journal Editors.

Thus, all completed trials, whether with positive or negative results should be published. Not publishing a trial is a disservice to those who took risks in participating in the trial. The CONSORT Guidelines should be used in reporting these trials as a minimum requirement in order to ensure unbiased and quality reporting. This would also allow other authors who wish to make systematic reviews to have the necessary data and information if they want to include the research.

So if you are submitting a manuscript of a clinical trial, please check the CONSORT reporting guidelines first and comply with them to ensure publication of your research.

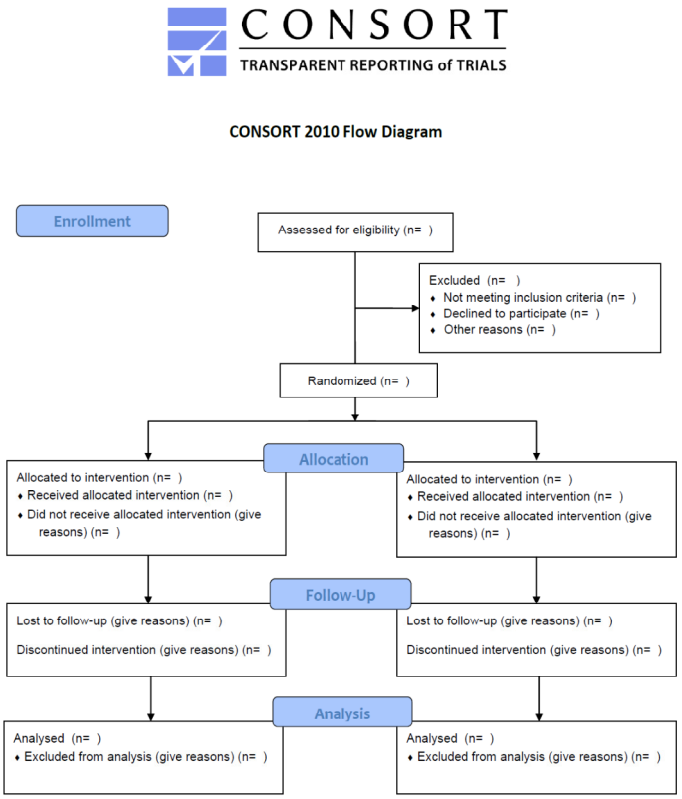

Figure 1. Consort Flow Diagram

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