

Book review

## Review of: *Interpreting and Reporting Clinical Trials – A guide to the CONSORT statement and the principles of randomised controlled trials* by Anthony Keech, Val Gebski and Rhana Pike

Stephen JW Evans

Address: Medical Statistics Unit, London School of Hygiene & Tropical Medicine, Keppel Street, London WC1E 7HT

Email: Stephen JW Evans - [Stephen.Evans@lshtm.ac.uk](mailto:Stephen.Evans@lshtm.ac.uk)

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### Book details

Keech A, Gebski V, Pike R:

*Interpreting and Reporting Clinical Trials. A guide to the CONSORT statement and the principles of randomised controlled trials.*

Sydney, MJA books, Australasian Medical Publishing Company; 2007.

This book is based on a series of articles in the *Medical Journal of Australia* "Trials on Trial"; I did not read the original articles, but this edited book is of high quality. Its structure has 22 short chapters essentially based on the 22 item checklist used in the CONSORT statement. The chapters read well generally, although each is written by a different combination of about 2 to 4 of the 22 different authors, with at least one of the editors. The original CONSORT statement authors have provided a full paper explaining and elaborating the reasons for the items in the checklist, but this book goes further. It is not only a guide for authors of trial reports but also a very useful book for anyone studying the science of clinical trials or taking a course about them.

Standard textbooks on trials give a great deal on how to plan, design analyse trials but usually have only a limited amount on how to report them. This book remedies that, and while there is mention of design issues it concentrates on how to report a trial clearly.

Each chapter has a brief description of what is required for the CONSORT item, with some details of how to set these out and the rationale for ensuring that the information is included in a report. There are text boxes with a shaded background in each chapter giving the relevant CONSORT

items, together with pithy quotes, often from the 19<sup>th</sup> century, to illustrate points. One that appealed to me was "to calculate is not in itself to analyse", Edgar Allan Poe, 1831.

There are a number of boxes containing short items giving the history of particular early events that relate to trial methodology. The 16<sup>th</sup> century, almost accidental, trial comparing alternative poultices to the standard boiling oil led to Ambrose Paré being criticised but a powerful reputation in later life is one example. These help keep a reader's interest, but many chapters also have a more detailed, modern, case study which illustrates the key points being made in a chapter. These are very helpful.

This book does have a few minor problems. It has web references, which inevitably fall out of date. The European Medicines Agency has modified its web addresses so those quoted in the book are now incorrect, but it is not too difficult to find the correct ones (usually just changing "eu.int" to "europa.eu" works). This may well apply to other web addresses but it is more helpful to give some reference than not to include web-based material. The discussion of post-hoc adjustment for baseline imbalance is not a universally agreed approach and the authors might consider noting this for a future edition. The statistical section is limited and perhaps not always sufficient (handling of missing data is very weak), but the section on sample size calculation is very clear. Whether their example of a bimodal distribution is simply chance variation and their treatment of non-parametric tests is questionable. Non-normality is rarely important but inequality of variance is much more important. It is also not true to say that para-

metric tests are more powerful – this is generally only true if parametric assumptions hold.

The chapter on adverse effects takes the relatively recent CONSORT paper updating the Statement into account and is another of the excellent chapters. The book closes with a helpful Glossary and an Index that includes the historical references (though not all the pithy aphorisms).

Overall this book is to be highly recommended to anyone doing a course in randomised trials, and is very helpful to anyone writing up a trial report. Since many journals use CONSORT criteria (though not all enforce them, as noted in the Foreword by Moher and Rennie) they would be well advised to recommend the book to their authors. Many of the papers on trials I have reviewed, particularly for the *British Medical Journal*, over the years would be notably improved if the authors followed the suggestions given here.

### Competing interests

The author declares that they have no competing interests.

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