Guest Editorial

Reporting of Clinical Trials in the JO—the CONSORT Guidelines

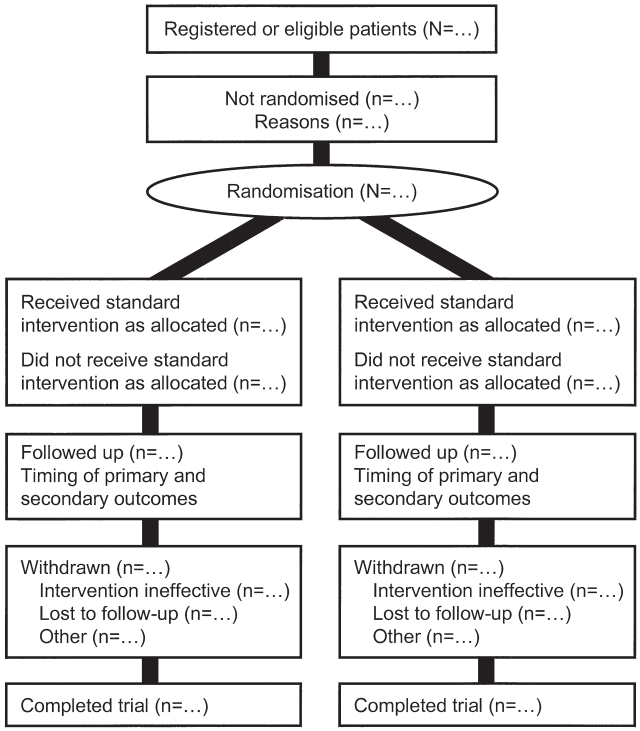
By now many readers will be aware that comprehensive guidelines for reporting clinical trials have been developed. At an editorial board meeting in February 1999, it was agreed that papers reporting randomized controlled trials submitted to the journal will, in future, be required to conform to the CONSORT guidelines. What are these guidelines, and why are they important? How will they help readers to interpret clinical research findings?

The CONSORT (Consolidated Standards of Reporting Trials) guidelines were developed by a team including journal editors, clinical epidemiologists, and statisticians. They set out standards that should be adhered to by those reporting clinical trials. Most of the recommendations are based on published evidence from the literature on the quality of clinical research. The guidelines were originally published in the *Journal of the American Medical Association* (Begg *et al*., 1996; Rennie, 1996) and are now in force for many journals including the *British Medical Journal* (Altman, 1996) and the *British Dental Journal* (Needleman, 1999)—they are just as relevant to dentistry as to medicine.

The key elements are a checklist and a flow diagram, which are available at *http://www.bdj.co.uk/about/consort.shtml* or on page 258 of the *BDJ* issue cited above. They embody information which is essential for the refereeing process. The completed flow diagram should appear as a figure within the manuscript. The completed checklist should accompany the manuscript and identify on which page each item is addressed. One of the issues in the checklist is the use of a structured abstract. This has been a requirement of our journal for some time, see the instructions to authors at the back of this issue for an updated specification. Further information on the CONSORT guidelines may be found in the references and at the websites listed below.

The guidelines are important because every clinician's practice should be based on sound evidence (Harrison, page 71). The key principle is that studies in which eligible, consenting individuals are *randomly* allocated between the treatments of interest are the ones that yield the most reliable conclusions. Nevertheless, there are many other issues relating to the conduct and interpretation of a study which greatly affect its validity. The CONSORT guidelines are designed to ensure that, in all these respects, it is clear that the study has been carried out satisfactorily. Accordingly, they affect the conduct of a study as well as how it is reported. Furthermore, systematic reviews—which fit together the findings of several studies bearing on the same issue—are much more satisfactory when it is clear that each of the individual studies was conducted properly and reported clearly.

What kinds of studies come within the ambit of the CONSORT guidelines? Questions of this sort are often vexing ones; for example, researchers are often perplexed about whether it is necessary to seek LREC approval for their proposed study. For the CONSORT guidelines, the answer is, basically, controlled clinical trials. Nevertheless, we strongly recommend that in other related kinds of experimental studies—cross-over and split-unit studies, *ex vivo* studies, and cluster randomized health services research studies—authors should consider the guidelines carefully and seek to conform as closely as possible to the principles they enshrine. We certainly do not want to deter researchers from doing the randomized study that is appropriate to address a real question about the efficacy of a treatment, just because the reporting requirements are more stringent than for a far less informative observational study (Farthing and Newcombe, 1997).



From August 2000 the Editorial Board would request that all submitted papers reporting clinical trails should conform to the CONSORT guidelines. They should include a flowchart and be accompanied by a completed checklist. We anticipate that this should result in improvements in the conduct as well as the reporting of research, and in due course, to better patient care.

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Further relevant information is available at:

http://www.bdj.co.uk/about/consort.shtml
http://www.ama-assn.org/public/journals/jama/jtrial.htm
http://www.cochrane.co.uk