GUEST EDITORIAL

Reporting of clinical trials in the *International Endodontic Journal* – 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 October 2003, it was agreed that papers reporting randomized controlled trials submitted to the journal will in future be required to conform to the CONSORT guidelines (CONSORT stands for 'CONsolidated Standards Of Reporting Trials'). What are these guidelines, and why are they important? How will they help readers to interpret clinical research findings?

Concern has often been expressed that the statistical content of medical and dental journals remains highly variable. The issue goes far beyond the niceties of presentation, and can lead to widespread use of inferior treatments. It goes deeper than the choice of statistical analysis for the data collected; the design and conduct of the study are crucial.

The randomized controlled trial (RCT) is now recognized as the cornerstone of evidence-based clinical practice in medicine and dentistry. In recognition of this, leading journal editors and statisticians became persuaded of the need to ensure the highest quality for the reporting of RCTs, and developed the CONSORT guidelines. Most of the recommendations are based on published evidence from the literature on the quality of clinical research. The guidelines primarily relate to the reporting of trials, but clearly have substantial implications for study design and conduct also. They are just as relevant to dentistry as to medicine.

The key elements of CONSORT include a flowchart accounting for all subjects considered for recruitment, and a checklist of items that require to be clear in the report. These embody information essential for the refereeing process. The completed flow diagram should appear as a figure within the manuscript. The completed checklist is not for publication but should accompany the manuscript and identify on which page each item is addressed. One particularly important issue is a clear rationale for the sample size used – a major defect of much current research is the use of sample sizes that are too small to be adequately informative.

The original guidelines were published in 1996, followed by a revised, strengthened version in 2001. They have been reproduced in several journals and are freely available from the World Wide Web. Many leading journals have adopted them. Further information on the CONSORT guidelines is available at the website listed below.

The guidelines are important because every clinician's practice should be based on sound evidence. 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 Local Research Ethics Committee approval for their proposed study, and about the line of demarcation between research and audit. For the CONSORT guidelines, the answer is, basically, controlled clinical trials. Similar issues apply to other related kinds of experimental studies – cross-over and split-unit studies, *ex vivo* studies and cluster randomized health services research studies – and cognate guidelines are being developed for these. Meanwhile, we strongly recommend that investigators who carry out any kind of study should consider the

Full information on the CONSORT guidelines, including the rationale for their development, is available at: http://www.consort-statement.org/revisedstatement.htm (accessed 23/9/2003).

guidelines carefully and seek to conform as closely as possible to the principles they enshrine. The purpose of the guidelines is certainly not 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 & Newcombe 1997).

An accompanying article (Newcombe 2004) illustrates the CONSORT guidelines by applying them (retrospectively) to an article published in the *IEJ* a few years ago (Weiger *et al.* 2000).

We give authors notice that with effect from January 2005 we require submitted papers reporting clinical trials to conform to the CONSORT guidelines. After this date, submitted papers describing RCTs will be assessed according to CONSORT standards. We would urge that as from the date of this editorial, investigators should seek to ensure that new studies conform to CONSORT, and reports include a flowchart and are accompanied by a completed checklist. We are well aware that studies of this kind are often long term in nature, and we will of course use editorial discretion regarding quality studies, which are already in progress. 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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References

Farthing MJG, Newcombe RG (1997) Reporting of clinical trials in Gut: the CONSORT statement. *Gut* **40**, 563–4.

Newcombe RG (2004) CONSORT guidelines applied to an exemplar paper. *International Endodontic Journal* **37**, 3–6.

Weiger R, Rosendahl R, Löst C (2000) Influence of calcium hydroxide intracanal dressings on the prognosis of teeth with endodontically induced periapical lesions. *International Endodontic Journal* **33**, 219–26.