Editorial

Reporting of clinical trials in Gut: the CONSORT statement

By now many journal readers will be aware of the recent development of comprehensive guidelines for the reporting of clinical trials. The CONSORT (Consolidated Standards of Reporting Trials) statement^{1 2} was developed by a team including journal editors, clinical epidemiologists and statisticians. It sets out standards that should be adhered to by those reporting trials. The great majority of the recommendations are supported by published evidence taken from the literature on quality of medical research. Immediately following publication in *JAMA*, the *BMJ* published a leading article³ which included these guidelines and indicated that as from a specified date, submitted papers describing clinical trials would be required to conform to them. It is anticipated that leading journals will adopt these recommendations. The editorial board of *Gut* met in November 1996 and agreed to implement these recommendations in 1997.

The recommendations are encapsulated in a checklist of 21 items that should be included in a report (Table) and a flow chart describing progress of patients through the trial (Figure). Furthermore, a few specific subheadings applicable to the methods and results sections of the paper

are listed, and it is suggested that authors should use these subheadings also and structure their text accordingly. They should submit with their manuscripts a copy of the completed checklist indicating on which page each item is addressed. The checklist will be perused by the Associate Editor assigned to the paper and supplied to referees; it will not be published.

The above mentioned references present a great deal of information regarding the rationale for and development of the guidelines. Authors are strongly encouraged to read these articles; as they are published in widely available journals it would be inappropriate to reproduce much of the detail in each journal adopting the guidelines.

The guidelines refer explicitly to the *reporting* of clinical trials, but the hidden agenda of the *conduct* of such studies is at least as important. A key element to the CONSORT guidelines is *clarity* of reporting the design, execution and findings of the study, a principle that applies equally to other kinds of research. The CONSORT group singled out the randomised controlled trial for detailed attention, because of its central role in research: in evaluating the efficacy of any intervention, the randomised controlled

Items that should be included in reports of randomised trials (reproduced from JAMA)¹

Heading	Subheading	Descriptor
Title Abstract Introduction Methods		Identify the study as a randomised trial
		Use a structured format
		State prospectively defined hypothesis, clinical objectives, and planned subgroup or covariate analyses
	Protocol	Describe Planned study population, together with inclusion or exclusion criteria Planned interventions and their timing Primary and secondary outcome measure(s) and the minimum important difference(s), and indicate how the target sample size was projected Rationale and methods for statistical analyses, detailing main comparative analyses and whether they were completed on an intention to treat basis Prospectively defined stopping rules (if warranted)
	Assignment	Describe Unit of randomisation (for example, individual, cluster, geographic) Method used to generate the allocation schedule Method of allocation concealment and timing of assignment Method to separate the generator from the executor of the assignment
	Masking (blinding)	Describe Mechanism (for example, capsules, tablets) Similarity of treatment characteristics (for example, appearance, taste) Allocation schedule control (location of code during trial and when broken) Evidence for successful blinding among participants, person doing intervention, outcome assessors, and data analysts
Results	Participant flow and follow up	Provide a trial profile (Figure) summarising participant flow, numbers and timing of randomisation assignment, interventions, and measurements of each randomised group
	Analysis	State estimated effect of intervention on primary and secondary outcome measures, including a point estimate and measure of precision (confidence interval) State results in absolute numbers when feasible (for example, 10/20, not 50%) Present summary data and appropriate descriptive and inferential statistics in sufficient detail to permit alternative analyses and replication Describe prognostic variables by treatment group and any attempt to adjust for them Describe protocol deviations from the study as planned, together with the reasons State specific interpretation of study findings, including sources of bias and imprecision (internal validity) and discussion of external validity, including appropriate quantitative measures when possible State general interpretation of the data in the light of the totality of the available evidence
Discussion

Flow chart describing progress of patients through a randomised controlled trial (reproduced from JAMA).¹

trial is logically indispensable. It is important to be clear as to why the randomised controlled trial has this special place in our evidence base. Suppose, for simplicity, that we are considering a trial comparing a new treatment with a standard one. Primarily, the randomised controlled trial is a *trial* – an experiment – in which the clinician admits patients who could equally justifiably receive either treatment, and delegates the choice of treatment to a predetermined, concealed allocation sequence. Then, it is *controlled*, two groups receiving different regimens are compared because otherwise we have no direct evidence of what would happen to such patients when the new treatment is not used. Finally, it is *randomised*, generally the allocation sequence is generated by a computer algorithm that is designed to obviate predictable sources of bias. The randomisation does not achieve *exact* balance between the two groups in respect of characteristics at entry. What it does achieve is balance, *within the limits of chance variation*, with respect to *all* patient characteristics, those that can be measured and those that cannot. The random element invoked in the eventual statistical analyses, confidence intervals and hypothesis tests, corresponds to this randomness at allocation – the need to either check or adjust for baseline imbalance is very limited.

Accordingly, then, it is not our intention in any way to deter investigators from *performing* or *reporting* randomised controlled trials. The first item of the CONSORT checklist

is “Identify the study as a randomised trial”. The first questions that an editorial team member or referee, or indeed a reader should examine when reading an article are, “Is this a randomised controlled trial? Should it be? If not, why not?”.

There is certainly a very important role for other types of study – randomised controlled trials tell you *whether* treatments work, but not *how* they work. The clinical trial is the end stage of the research process, and is preceded by much preliminary investigation, rightly. Occasionally, we have to admit that an uncontrolled study should be published. A paper recently refereed for a gynaecological journal presented a 20 year follow up of bone mineral density in hysterectomised women undergoing oestradiol implantation: clearly, cautious presentation of the results is necessary, to indicate it was not a randomised controlled trial, yet it would be absurd to totally dismiss evidence we would otherwise have to wait many years for.

The guidelines should be regarded as applying also (with obvious minor modifications as necessary) to other study designs that could rightly be described as randomised intervention studies. These include parallel group randomised controlled trials with more than two treatments, perhaps with a factorial design, and crossover studies. The latter, in particular, could be volunteer studies at an early phase of drug development. Intervention studies in health care research are of increasing importance, and should be reported with CONSORT principles in mind; here, the unit of randomisation is often the centre rather than the patient, and the resulting variance inflation needs to be taken into account both in planning the study size and in performing the analysis.⁴

We give authors notice that with effect from October 1997 submitted papers reporting clinical trials are to conform to 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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Editor

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- 1 Begg C, Cho M, Eastwood S, Horton R, Moher D, Olkin I, *et al*. Improving the quality of reporting of randomized controlled trials: the CONSORT statement. *JAMA* 1996; 276: 637–9.
- 2 Rennie D. How to report randomized controlled trials. The CONSORT statement. *JAMA* 1996; 276: 649.
- 3 Altman DG. Better reporting of randomised controlled trials: the CONSORT statement. *BMJ* 1996; 313: 570–1.
- 4 Donner A, Birkett N, Buck C. Randomization by cluster. Sample size requirements and analysis. *Am J Epidemiol* 1981; 114: 906–14.