ing data as they accumulate during a trial. Group sequential methods, based on frequentist analysis, are currently the standard used for recommending early termination of a trial when interim data indicate clear benefit or harm from one of the treatments. However, there is no agreed method of calculating a P value or confidence interval for the treatment effect after the use of a group sequential method.[11] Nor are the methods flexible to the emergence of new external data that might influence early termination.[12] Bayesian methods that express prior scepticism about the existence of benefit from a new treatment seem to carry the same advantages of group sequential methods but also take account of new external data in making the final inference.[12] These methods have been used recently for the design, monitoring, and analysis of several cancer trials sponsored by Britain's Medical Research Council.[13]

Another advantage of Bayesian methods involves the interpretation of multiple hypothesis testing. Clinical trials often address the effect of a treatment in different subgroups of patients. Epidemiological studies are often designed to test hypotheses about a range of putative risk factors for a given disease. Frequentist methods aim to control the probability of finding false subgroup effects or risk factors. This means using more stringent significance levels, such as Bonferroni procedures, where the degree of conservatism in the conclusions increases with the number of subgroup effects or risk factors tested. Bayesian methods of dealing with this multiple testing problem depend not on the number of subgroup effects or risk factors but on the prior information regarding the possibility of these effects. The frequentists' idea that conclusions about risk factor W must become more conservative simply because a study also considers risk factors X, Y, and Z makes the Bayesian approach seem scientifically more sensible.[14] Nevertheless, specification of prior distributions in multiple testing problems is difficult, and more research in this area is needed.

Ten years ago, Bayesian calculations were difficult for all but the simplest problems. But advances in statistical computing techniques using Monte Carlo sampling methods[15] have led to an explosion of interest among statisticians. Nowadays, a large proportion of research papers in theoretical statistics journals deal with Bayesian methods. It is only a matter of time before their use becomes more widespread in medicine. To prepare for this, doctors may like to ask their statistical colleagues to teach them about Bayesian methods or read the recently published book by Berry.[16] They will be pleasantly surprised by the natural simplicity of the concepts.

LAURENCE FREEDMAN
Acting chief

Biometry Branch,
Division of Cancer Prevention and Control,
National Cancer Institute,
Bethesda, MD 20892,
USA

1 Lilford RJ, Braunholtz D. The statistical basis of public policy: a paradigm shift is overdue. *BMJ* 1996;313:603-7.
2 De Dombal FT, Leaper DJ, Staniland JR, McCann AP, Horrocks JC. Computer-aided diagnosis of acute abdominal pain. *BMJ* 1972;266:9-13.
3 Titterington DM, Murray GP, Murray LS, Spiegelhalter DJ, Skene AM, Habberna JDF, *et al.* Comparison of discrimination techniques applied to a complex data set of head injured patients (with discussion). *J R Stat Soc, Ser A* 1981;144:145-75.
4 Trimble IM, West M, Knapp MS, Pownall R, Smith AFM. Detection of renal-allograft rejection by computer. *BMJ* 1982;286:1695-9.
5 Jensen FV. *An introduction to Bayesian networks*. London: Cower Press, 1996.
6 Ripley BD. *Pattern recognition and neural networks*. Cambridge: Cambridge University Press, 1996
7 Detsky AS. Using economic analysis to determine the resource consequences of choices made in planning clinical trials. *J Chron Dis* 1985;38:753-65.
8 Eddy DM, Hasselblad V, Shachter R. A Bayesian method for synthesising evidence: the confidence profile method. *Int J Technol Assess Health Care* 1990;6:31-55.
9 O'Quigley J, Pepe M, Fisher M. Continual reassessment method: a practical design for phase 1 clinical trials in cancer. *Biometrics* 1990;46:33-48.
10 Thall PF, Simon RM, Estey EH. Bayesian sequential monitoring designs for single-arm clinical trials with multiple outcomes. *Stat Med* 1995;14:357-79.
11 Rosner GL, Tsiatis AA. Exact confidence intervals following a group sequential trial: a comparison of methods. *Biometrika* 1988;75:723-9.
12 Spiegelhalter DJ, Freedman LS, Parmar MKB. Bayesian approaches to randomised trials. *J R Stat Soc, Ser A* 1994;157:357-416.
13 Parmar MKB, Spiegelhalter DJ, Freedman LS. The CHART trials design and monitoring. *Stat Med* 1994;13:1297-312.
14 Dixon DO, Simon R. Bayesian subset analysis in a colorectal cancer clinical trial. *Stat Med* 1992;11:13-22.
15 Gilks WR, Clayton DG, Spiegelhalter DJ, Best NG, McNeil AJ, *et al.* Modelling complexity: applications of Gibbs sampling in medicine (with discussion). *J R Stat Soc, Ser B* 1993;55:39-102.
16 Berry DA. *Statistics, a Bayesian perspective*. Belmont, CA: Duxbury Press, 1996.

Better reporting of randomised controlled trials: the CONSORT statement

Authors must provide enough information for readers to know how the trial was performed

Randomised controlled trials are the best way to compare the effectiveness of different interventions. Only randomised trials allow valid inferences of cause and effect. Only randomised trials have the potential directly to affect patient care—occasionally as single trials but more often as the body of evidence from several trials, whether or not combined formally by meta-analysis. It is thus entirely reasonable to require higher standards for papers reporting randomised trials than those describing other types of study.

Like all studies, randomised trials are open to bias if done badly.[1] It is thus essential that randomised trials are done well and reported adequately. Readers should not have to infer what was probably done, they should be told explicitly. Proper methodology should be used and be seen to have been used. Yet reviews of published trials have consistently found major deficiencies in reporting,[2-4] making the task for those carrying out systematic reviews much harder. Almost 50 years after the first publication of a randomised trial,[5] the guarantee of adequate reporting of these important studies is surely long overdue.

In 1994 two groups independently published proposals for requirements for the reporting of randomised trials.[6 7] In an editorial in *JAMA* Drummond Rennie suggested that the two groups should combine to produce a unified statement,[8] and

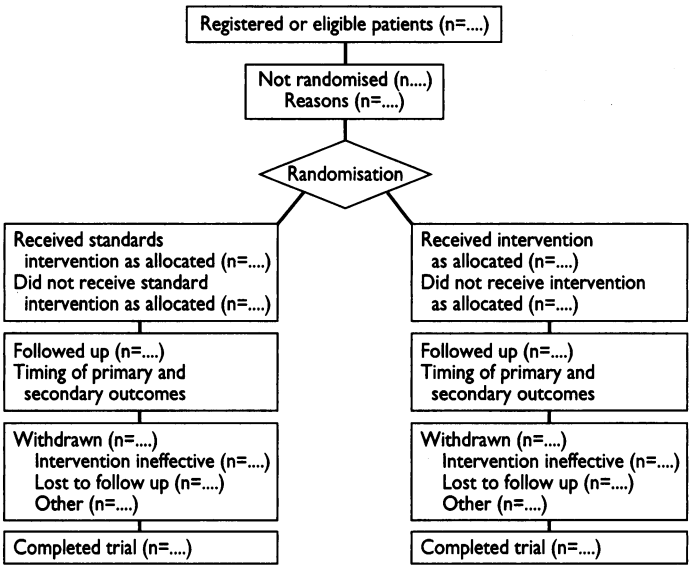

Fig 1—*Flow chart describing progress of patients through randomised trial (reproduced from* JAMA*)*[9]

Table 1—*Items that should be included in reports of randomised trials (reproduced from JAMA)*[9]

Heading	Subheading	Descriptor
Title		Identify the study as a randomised trial
Abstract		Use a structured format
Introduction		State prospectively defined hypothesis, clinical objectives, and planned subgroup or covariate analyses
Methods	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 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 (fig 1) summarising participant flow, numbers and timing of randomisation assignment, interventions, and measurements for 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 interferential 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
Discussion		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 light of the totality of the available evidence

the outcome of this process was published last week.[9] The new CONSORT statement lists 21 items that should be included in a report (see table 1) as well as a flow chart describing patient progress through the trial (fig 1). In addition, a few specific subheadings are suggested within the methods and results sections of the paper. In the spirit of the times, the recommendations are evidence based where possible, with common sense dictating the remainder.

In essence the requirement is that authors should provide enough information for readers to know how the trial was performed so that they can judge whether the findings are likely to be reliable. The CONSORT statement means that authors will no longer be able to hide inadequacies in their study by omitting important information. For example, at present authors can, and often do, hide their procedures behind the single word "randomised." Authors will now be required to give details of the randomisation procedure. If authors have used an inferior approach, such as alternate allocation, they will have to say so. The *BMJ* has in fact refused to publish trials that were not truly randomised since 1991,[10] a position justified by subsequent empirical findings.[1]

As the authors of the CONSORT statement note,[9] the checklist applies to the most common design of randomised trial—trials with two parallel groups. Some modification is needed for special types of trial such as crossover trials and those with more than two treatment groups. Also, the list should be taken in conjunction with existing general requirements—for example, the requirement to specify all statistical methods used in the analysis. This and other items appear on the checklist for controlled trials that has been used by the *BMJ*'s statistical referees for over 10 years.[11]

Some of the items on the checklist would benefit from greater explanation than is possible in the CONSORT statement. In time a fuller accompanying explanatory paper could be valuable. For example, while the advantages of randomisation have been apparent for several decades, understanding the rationale for it remains poor and so its importance is not fully appreciated by researchers.[12]

The *BMJ* supports the CONSORT statement and is adopting its recommendations. So too are *JAMA*, *Lancet*, and some other journals. Trialists are encouraged to follow the statement right away, but from 1 January 1997 they will be required to do so. Authors should submit with their papers a copy of the completed checklist indicating on which page of the manuscript each item is addressed. The checklist will be used by the editors and supplied to referees. In the published papers the *BMJ* will use the additional subheadings suggested by CONSORT.

It seems reasonable to hope that, in addition to improved reporting, the wide adoption of this new publication standard will improve the conduct of future research by increasing awareness of the requirements for a good trial. Such success might lead to similar initiatives for other types of research.

DOUGLAS G ALTMAN
Head

ICRF Medical Statistics Group,
Centre for Statistics in Medicine,
Institute of Health Sciences,
Oxford OX3 7LF

1 Schulz KF, Chalmers I, Hayes R, Altman DG. Empirical evidence of bias. Dimensions of methodological quality associated with estimates of treatment effects in controlled trials. *JAMA* 1995;**273**:408-12.
2 Mosteller F, Gilbert JP, McPeek B. Reporting standards and research strategies for controlled trials. Agenda for the editor. *Controlled Clin Trials* 1980;**1**:37-58.
3 Pocock SJ, Hughes MD, Lee RJ. Statistical problems in the reporting of clinical trials. *N Engl J Med* 1987;**317**:426-32.
4 Schulz KF, Chalmers I, Grimes DA, Altman DG. Assessing the quality of randomization from reports of controlled trials published in obstetrics and gynecology journals. *JAMA* 1994;**272**:125-8.
5 Medical Research Council. Streptomycin treatment of pulmonary tuberculosis. *BMJ* 1948;ii:769-82.
6 Standards of Reporting Trials Group. A proposal for structured reporting of randomized controlled trials. *JAMA* 1994;**272**:1926-31.
7 Working Group on Recommendations for Reporting of Clinical Trials in the Biomedical Literature. Call for comments on a proposal to improve reporting of clinical trials in the biomedical literature: a position paper. *Ann Intern Med* 1994;**121**:894-5.
8 Rennie D. Reporting randomised controlled trials: an experiment and a call for responses from readers. *JAMA* 1995;**273**:1054-5.
9 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.
10 Altman DG. Randomisation. *BMJ* 1991;**302**:1481-2.
11 Gardner MJ, Machin D, Campbell MJ. The use of checklists in assessing the statistical content of medical studies *BMJ* 1986;**292**:810-2.
12 Schulz KF. Subverting randomization in controlled trials. *JAMA* 1996;**274**:1456-8.