Reliable and accessible reviews of the evidence for the effect of health care: the role of the Cochrane Collaboration and the CONSORT statement

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Recent developments aim to improve the translation of research into clinical practice

The aim of clinical research is to improve patient care. If it is to do so, the main providers of health care along with purchasers and patients need to be informed about the results of research. The medical literature is huge and most people rely on reviews of the literature. In the past, reviews were seen as secondary to clinical research and less important than the primary research on which they were based. This meant that little attention was paid to the quality of the reviews and scientific principles were often ignored in their preparation. At the end of the 1970s, Archie Cochrane, a British epidemiologist, wrote that 'It is surely a great criticism of our profession that we have not organised a critical summary, by speciality or subspeciality, adapted periodically, of all relevant randomised controlled trials'.¹ (Archie Cochrane worked with Fred Hollows in the Rhondda valley in the 1960s. In his autobiography he gives a fascinating account of their elegant work which showed that screening for glaucoma by measuring intraocular pressure was not worthwhile.² After this experience he became very interested in ophthalmic epidemiology. He quickly realised that a major impediment to the field (apart from a lack of ophthalmologists interested in epidemiology) was the difficulty of measuring lens opacity – a problem which still occupies us to this day.)

Currently, for almost all treatments aimed at treating eye disease and/or preventing visual impairment, there are no continuously updated reviews of the relevant research. In other areas of medicine it has been shown that, if continuously updated reviews had been maintained, some treatments would have been shown to be effective many years before such recognition was obtained from traditional reviews.³ Systematic reviews can also identify treatments that are ineffective or dangerous and need to be abandoned.⁴ In many cases, reviews will highlight gaps in the evidence. An important example in eye health is the case of

glaucoma, the second most important cause of blindness worldwide, for which considerable variation in treatment exists. Review of trials of the treatment of glaucoma has shown that appropriate research to guide clinical practice has not been done.⁵

The Cochrane Collaboration has evolved to meet the challenge set out by Archie Cochrane. It is an international network of individuals 'committed to prepare and maintain systematic reviews of randomised controlled trials of the effects of health care, and of other evidence when appropriate, and to make this information readily available to decision-makers at all levels of health care systems.' The Collaboration is relatively young, its first formal meeting being in 1993, but has developed rapidly. Currently there are nearly 40 registered collaborative review groups and 276 reviews and a similar number of protocols. *The Cochrane Library*, a set of databases on CD-ROM, is the main product of the Collaboration.⁶ A Cochrane Eyes and Vision Group has formed and has interested collaborators from Europe, North America, Australasia and the Indian sub-continent.

Much of the raw data for systematic reviews are extracted from reports of randomised controlled trials published in the literature. In order to judge the quality of a trial, a reviewer needs an accurate and complete report of its execution and results. It has been recognised for many years that there are problems in reporting of trials in the literature, even in high-impact general journals, but especially in speciality journals. Poorly reported trials tend to exaggerate the effect of treatment,⁷ probably reflecting the fact that they have been poorly executed. Concern over this problem has led to the development of the Consolidated Standards of Reporting Trials (CONSORT) statement, which sets out the information that needs to be included in the report of a trial in order for its internal and external validity to be assessed by a

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reader.⁸ *JAMA*, *BMJ*, *The Lancet* and other journals have already adopted these recommendations.

Table 1 summarises the CONSORT statement.⁸ Some of these recommendations will come as a surprise to many ophthalmologists. For example, trials where allocation to treatment is predictable and unconcealed (for example alternate allocation) are still common in ophthalmology. The reason the randomised controlled trial is such a powerful study design is that when patients are randomly allocated to treatment group, if the study is large enough and properly conducted, differences in outcome between the two groups can be attributed to the treatment. (In observational studies it is almost impossible to be sure that two groups of patients are genuinely comparable.) For randomisation to be effective, an unpredictable sequence of treatment

allocation must be generated and this sequence must be concealed until the patient has enrolled in the trial. Investigators who do not pay attention to this are in danger of introducing bias into their study which may mean their results are wrong. If the CONSORT statement is widely adopted by journal editors, in the short term the reporting of trials will improve and in the long term their conduct.

In summary, the new developments of the CONSORT statement and the Cochrane Collaboration are leading to constructive changes in the way clinical research is reported and summarised. In the long term this will make fundamental improvements to the quality of research conducted and decisions taken about patient care.

Table 1. Items that should be included in reports of randomised trials

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/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 (e.g. 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 (e.g. capsules, tablets); similarity of treatment characteristics (e.g. appearance, taste); allocation schedule control (location of code during trial and when broken); and evidence for successful blinding among participants, person doing intervention, outcome assessors, and data analysts
	Participant flow and follow-up	Provide a trial profile (Figure) 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 (e.g. 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
Comment		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

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