fetal distress.[4] This observation is in keeping with the findings of others.[5 9] Dunphy et al, reporting an audit of 104 caesarean sections for fetal distress in 9387 deliveries, found no correlation between decision-delivery interval and several outcome measures, including umbilical arterial acid-base state and 5 minute Apgar scores.[5] Tufnell et al did not show any significant relation between decision to delivery interval and admission to a neonatal unit.[7] Moreover, Chauhan et al, reporting an audit of 117 caesarean sections for fetal distress in 9137 deliveries, found that those cases with a decision to incision (not delivery) interval of less than 30 minutes had significantly lower mean umbilical artery pH values and a higher incidence of cases with pH <7.00.[9]

Another interesting observation in the paper by MacKenzie et al is that all cases (not just those for fetal distress) delivered by caesarean section within 30 minutes were associated with significantly lower umbilical artery pH values.[4] The same group had previously reported a similar relation for "fast" assisted vaginal deliveries.[10] They speculate that these findings may be the result of maternal anxiety generating increased catecholamine release and reduced uterine perfusion. However, it also likely that the cases of fetal distress delivered within 30 minutes would include those with more acute hypoxia, such as placental abruption and profound fetal bradycardia, which would bring greater urgency and speed to the delivery. In any case the observation reinforces the importance of not jeopardising maternal health when performing an emergency caesarean section.

Thus a decision to delivery interval of 30 minutes is a useful audit standard, though it is difficult to achieve in practice. There is no evidence, however, that 30 minutes is a critical threshold in intrapartum hypoxia. For most cases delivery after 30 minutes is not associated with adverse fetal outcome, yet for a few cases delivery has to be achieved much faster to avoid disability or death. In practice emergency caesarean section for fetal distress should be undertaken as quickly as possible and ideally within 30 minutes[11]—but we shouldn't consider it poor care if it takes a few minutes longer.

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Better standards for better reporting of RCTs

A revised CONSORT statement should further improve standards of reporting

In the first months of their scientific training students are taught the importance of transparent descriptions of methods and results in scientific communication. Scientists exchange not only beliefs and opinions but also, and primarily, observations and the methods used to obtain them—exposing them to critical scrutiny and the possibility of replication.

These days, not just scientists turn to the medical literature. Clinical practitioners and other decision makers search Medline in the hope of finding evidence in valid studies that apply to their problems. Most decision makers do not even think about or have the means for replicating studies. Yet in this era of evidence based medicine all are aware of the necessity of critical appraisal: to examine the results, not just the opinions; to judge the potential for bias in the design, conduct, analysis, and interpretation of studies; and to evaluate the generalisability (or otherwise) of the findings.

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Randomised clinical trials are rightfully regarded as the best tools for gathering evidence on the effectiveness of health care interventions. Unfortunately, the maturity of randomised trials, now over 50 years old, is not always reflected in the rigour with which they are conducted or the transparency with which they are reported.

In an attempt to remedy the deficiencies in trial reporting, several scientists and editors of biomedical journals developed the CONSORT statement (the consolidated standards of reporting trials). CONSORT comprises a short checklist of essential items and a flow diagram to be used in reporting trials.[1]

The 1996 version of the statement was immediately used by several journals but also met with complaints and mild criticism. In a further attempt to improve the understanding, dissemination, and use of CONSORT, the group developed revised versions of the checklist

and flow diagram, as well as an additional paper explaining it. Last month the new CONSORT statement, with its revised recommendations, appeared simultaneously in the *Annals of Internal Medicine*,[2] *JAMA*,[3] and *Lancet*.[4] The explanatory document was published in the *Annals of Internal Medicine*.[5]

Some of the changes in CONSORT are minor, designed to improve ease of use. More substantial improvements are the more precise requirements for the diagram depicting the flow of patients in the trial, one of the most important elements in CONSORT. Authors are now asked to specify the number of patients in each of the four phases of a trial: enrolment, intervention allocation, follow up, and analysis.

The explanation and elaboration document is undoubtedly the lengthiest (14 000 words) and most impressive addition to CONSORT.[5] In understandable terms, it explains the items in the checklist and provides the rationale and helpful examples on how to use them. For example, the revised checklist has separated out "recruitment" from participant flow and asks for dates defining periods of recruitment and follow up. The explanatory paper argues that dates are helpful to place the study in a historical context. It also emphasises the need to include length of follow up and cites a study of oncology trials in which nearly 80% reported the start and end dates of accrual of patients but only 24% stated when follow up ended.[5]

The journals publishing the revised statement have waived copyright protection, making CONSORT easily available to all readers and trialists. The checklist, the explanatory document, and more can also be found on the internet (www.consort-statement.org).

JAMA has also published two related studies on the use of CONSORT. One is a study on the use of the 1996 flow diagram, of which the results seem to have been incorporated in the revised CONSORT flow diagram.[6] The second is a before and after evaluation of CONSORT: it examined 211 studies in three journals that adopted CONSORT, with the *New England Journal of Medicine* as a comparator journal, and showed improved reporting after the adoption of CONSORT.[7]

The amount of exposure for this new version of CONSORT is both unique and entirely fitting for the importance of this initiative. CONSORT is a logical next step in a continuing process towards efficiency and transparency in scientific communication, following on from the IMRAD structure (introduction, methods, results, and discussion) of a scientific article and the structured abstract. What makes CONSORT so special is that this is the product of a joint effort of editors, methodologists, and trialists, with a specific focus on the important aspects of internal and external validity of trials. This endeavour has been and will be followed by others, directed at other types of studies, such as QUOROM for meta-analyses of randomised trials[8] and STARD (standards for reporting on diagnostic accuracy), which is still being developed. All try to facilitate the critical appraisal and interpretation of studies through better reporting, relying on current methodological knowledge and evidence about the potential for bias and lack of applicability.

A 22 item checklist and a flow diagram are, however, no panacea for sound science. Depending on the application, we would like to see still more detail in the report of a randomised controlled trial in order to judge its validity and appraise the results. CONSORT deserves widespread dissemination and support from everyone who believes—or knows—that better decision making follows from better evidence, to be found in transparent reports of good quality trials.

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Do probiotics prevent childhood illnesses?

They show promise, but bigger studies are needed

Concerns about antibiotic resistance have lead to an increased interest in alternative approaches for controlling common childhood infections. Since prevention would obviate the need for treatment, the prophylactic use of probiotic bacteria to prevent these illnesses has been proposed, and a study in this week's issue examines the effect of a probiotic milk on diarrhoeal and respiratory infections in children attending day care centres in Finland (p 1327).[1]

Papers p 1327

Probiotics are viable bacteria that colonise the intestine and modify the intestinal microflora and their metabolic activities, with a presumed beneficial effect for the host,[2 3] Many of these probiotics are lactic acid bacteria, such as lactobacillus or bifidobacterium, but

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