pregnancy. Suspicious findings on ultrasound might direct management towards surgery. Once the bleeding has been evaluated its management may remain with general practitioners[2] or midwives.[13]

As yet the optimal management for women with spontaneous miscarriages is unclear. A Cochrane systematic review of the management of miscarriage is in progress. Also a study in the south west of England, the miscarriage treatment (MIST) study,[14] aims to recruit 1500 women to a randomised controlled trial of surgical, medical (misoprostol and mifepristone), and expectant management. It promises to cast some light on this complex subject.

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Caesarean section for fetal distress

The 30 minute yardstick is in danger of becoming a rod for our backs

Intrapartum hypoxia complicates about 1% of labours and results in death in about 0.5 in 1000 pregnancies and cerebral palsy in 1 in 1000 pregnancies.[1] When it is diagnosed clinically as "fetal distress" swift delivery is the aim, and the standard has become delivery within 30 minutes of diagnosing fetal distress. As two papers in this week's *BMJ* illustrate, however, this standard is hard to achieve. Is it actually necessary?

The pathogenesis of intrapartum hypoxia is often multifactorial but poorly understood. Processes such as uteroplacental vascular disease, reduced uterine perfusion, fetal sepsis, reduced fetal reserves, and cord compression can be involved alone or in combination, and gestational and antepartum factors can modify the fetal response.[2] Methods of screening and diagnosing the condition have limitations.[3] Thus when the condition is thought to be present, diagnosed clinically as "fetal distress," clinicians aim for a swift delivery because they lack a clear understanding of the severity of the hypoxia.

Audit of the speed with which such caesarean sections are performed is important for clinical governance and risk management, and 30 minutes has been adopted as an audit standard. In the United Kingdom, however, most caesarean sections for fetal distress take longer than 30 minutes.[4 5] Delays occur both in getting the patient to theatre and in achieving effective anaesthesia,[6 7] though delivery within 30 minutes is more likely if the patient gets to theatre within 10 minutes.[6 7] In a paper in this week's issue Tufnell et al (p 1330) showed that it is possible to improve the proportion of "urgent cases" achieving a 30 minute decision to delivery interval from 41% to 66% (with 88% delivered within 40 minutes) over a 32 month audit cycle.[7]

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For reasons which are not clear, logical, or evidence based, this audit standard of 30 minutes has become the criterion by which good and bad practice is being defined both professionally and medicolegally. The implication is that caesarean section for fetal distress that takes longer than 30 minutes represents suboptimal or even negligent care. Yet the evidence that 30 minutes represents a clinically important threshold is lacking both in theory and in clinical experience.

In theory, the speed with which hypoxia develops and the ability of the fetus to withstand this insult vary and are difficult to quantify. For example, sudden and profound hypoxia such as occurs with placental abruption or vasa praevia probably requires delivery within 10 minutes if death or serious disability is to be avoided. In contrast, if the hypoxic insult is more slowly progressive (as it usually is) delivery within 30 to 60 minutes is unlikely to result in serious harm. In such cases the usual threshold for intervention is a fetal scalp pH of <7.20, yet serious neurodevelopmental disability probably occurs only when the pH is <7.00.[8]

Practical experience supports this theoretical view and questions the value of an absolute threshold of 30 minutes. The audit of 126 caesarean sections for fetal distress in 5846 deliveries reported this week by MacKenzie et al (p 1334) showed a non-significant trend to lower umbilical artery pH values in babies delivered after 30 minutes by caesarean section for

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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