risk. In many cases the equipment, if issued after certain dates, must comply with agreed European or national standards.

These new regulations will operate alongside some of the existing legislation, such as the Control of Substances Hazardous to Health Regulations, which already require employers to protect employees from such hazardous substances as glutaraldehyde, anaesthetic gases, infected blood, and other body tissues.¹ Accident and emergency staff who do not wear suitable personal protective equipment may therefore be in breach of new health and safety legislation, specifically the Personal Protective Equipment at Work Regulations and, generally, the Health and Safety at Work, etc, Act 1974 and the proposed "general provisions" regulations. It is rumoured that when the general provisions regulations are finally agreed they will be renamed the Management of Health and Safety at Work Regulations, which would put the onus of compliance for health and safety on management.

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When to stop a clinical trial

EDITOR,—Stuart Pocock's article on when to stop a clinical trial should be essential reading for anyone embarking on a large clinical trial.¹ Pocock asks many of the most important questions regarding the size and need for regular review of a trial and supplies many of the answers.

I am surprised, however, by the cursory manner in which he deals with smaller trials. Even in these days of multicentre "megatrials" only a select few workers have the facilities to organise and run such studies. Many new forms of management are first assessed in a small study, which may be ethically more controversial than the subsequent larger study based on it. In such circumstances the closed paired sequential design of trial described by Armitage,² to which Pocock barely refers, can be most useful.

Briefly, this is a graphical representation of the study as it progresses, the x axis representing the number of experiments and the y axis depicting whether the "new" (positive) or "old" (negative) treatment shows an improvement in outcome. Initially the statistical power required for the study is estimated and the borders plotted according to Armitage's calculations.² The observers performing the study can be blind to both the treatments and the results, depending on the study's design. One person, however, must have immediate access to all results, which are plotted according to the results of each individual experiment. The experimental plot starts at the origin of the graph, and the study ends when the plot crosses one of the predetermined borders. If the medial border is crossed first a significant difference is unlikely to be found between the two treatments, no matter how long the study continues. On the other hand, if the upper (lower) border is crossed first the new (old) treatment is likely to be significantly better.

The advantage of a statistical tool such as this is that it allows for continuous monitoring of the trial, which then ends as soon as a likelihood of a significant result is achieved. This can be helpful when seeking ethical approval as a minimum

number of patients are exposed to the less advantageous form of management. The method would have been ideally suited to the randomised trial comparing extracorporeal membrane oxygenation with conventional medical treatment in newborns with persistent pulmonary hypertension cited by Pocock.

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- 1 Pocock SJ. When to stop a clinical trial. *BMJ* 1992;305:235-40. (25 July.)
- 2 Armitage P. *Sequential analysis*. 2nd ed. Oxford: Blackwell Scientific, 1975.

EDITOR,—Properly designed and executed randomised controlled clinical trials are the most powerful tool we have to establish the effectiveness of a new treatment and to persuade doctors to adopt that treatment. A meta-analysis of several trials is even more persuasive. Lau *et al* estimated that cumulative meta-analyses would have allowed the efficacy of intravenous thrombolytic treatment in myocardial infarction to be accepted by 1973, after only eight trials.¹ The results of the next 25 trials, which enrolled an additional 34 542 patients, had no effect on the odds ratio establishing efficacy but merely narrowed the confidence interval.

Patients must not, however, be recruited into a clinical trial unless both they and their doctors are honestly ignorant of the relative merits of the two or more arms of the trial. Stuart J Pocock acknowledges the ethical dilemmas of communicating interim results of a trial to the doctors who are participating (and, of course, to the general public).² He recommends, however, either the O'Brien-Fleming rule that up to five analyses should be made at yearly intervals, the p values ranging from <0.0000001 for the first to the <0.009 for the last, or the Peto-Haybittle rule that a flexible number of interim analyses should be made, the p value being fixed at <0.001. If the first analysis shows p=0.01 the trial should continue. I doubt, however, whether doctors and patients can maintain their ignorance of the relative merits of the treatment regimens if they are told that there is a 99% chance that regimen A is better than regimen B.

Perhaps the rule should be that the trial co-ordinating committee should keep the results of interim analyses secret.

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- 1 Lau J, Antman EM, Jimenez-Silva J, Kupelnick B, Mosteller F, Chalmers TC. Cumulative meta-analyses of therapeutic trials for myocardial infarction. *N Engl J Med* 1991;327:248-54.
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Exposure to radon

EDITOR,—D P B Miles discusses whether radon causes lung cancer.¹ I am writing to identify some of the key documents on the subject.

There is conclusive evidence, from epidemiological studies of miners and experimental studies on animals, that products of radioactive decay of radon induce lung cancer,^{2,3} and there is a clear indication that the doses of radiation to the lung in miners and other groups are comparable.⁴ The collective results of epidemiological studies of lung cancer and domestic exposure to radon being conducted in Europe and the United States may eventually lead to refinements in the present coefficients of risk.

Against this background, international authorities have developed recommendations for protection against radon at work and in the home,^{5,6} which are reflected in developments in the United

Kingdom.^{7,8} What informs these moves is the desire to prevent high exposures to radon and keep the risk of lung cancer within reasonable bounds in various circumstances.

Government policy on radon in the home is strongly focused on the most affected areas in the United Kingdom^{9,10}: new houses are required to have preventive measures, measurements are made free for householders, technical advice is given on remedial measures when the radon concentration exceeds the action level of 200 Bq/m³; and grants for necessary work are available in cases of need.

Unlike employers, householders are not obliged to take action. Rather, they must be persuaded that the risk is real but easy to reduce.

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Poliomyelitis in developing countries

EDITOR,—The World Health Organisation's commitment to eradicating poliomyelitis from the world by 2000 is based on the assumption that the disease is a serious problem in developing countries.¹ We have challenged this assumption because the paralysis described as poliomyelitis in the tropics differs fundamentally from the classic disease and the diagnosis is retrospective, based on surveys of lameness rather than on observation of the children in the acute phase of the disease.^{2,3} Furthermore, estimated incidences derived from these surveys of lameness are 30 times greater than recorded incidences in Malawi and South Africa before vaccination was introduced.³

Recently there have been reports from China of an acute paralytic disease that differs from poliomyelitis⁴ and may be similar to a syndrome described in Mexican children.⁵ In the Mexican children postmortem examination showed a neuropathy that was not poliomyelitis despite isolation of the virus; this led to the comment that "the mere presence of poliovirus in the intestinal tract is no proof that the paralytic disease was caused by the virus."⁶ This statement supports our conclusion that isolation of the virus on its own is not diagnostic and that an accurate history must be taken, a clinical examination performed, and the cerebrospinal fluid examined before a definitive diagnosis can be made.³ In a report on a child in Bangladesh who developed an illness similar to that reported in China the authors suggested that "Asian paralytic syndrome" may be a more appropriate name for these diseases, implying that

the syndrome may be widespread within that continent and hence readily confused with poliomyelitis.

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- 1 Hall AJ. Polio eradication as 2000 approaches. *BMJ* 1992;305: 69-70. (11 July.)
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Polio immunisation for children before going swimming

EDITOR,—David Isaacs's response to a question on immunising children before they are taken swimming¹ is in part helpful, but in part is illogical. I wholeheartedly agree with his advice that children should be allowed to go swimming in public baths whatever their polio immunisation status. I also agree that "recommendations on swimming in the sea should reflect local levels of pollution." However, I would base this on the risk of developing a bacterial illness. I know of no cases of polio acquired in this way. Moreover, the protection against type 3 poliovirus varies from 76% to 98% after the second dose, depending on the study.² Logic requires that either there should be no restriction in terms of vaccination status or children should be required to have all three doses of the primary course before swimming in polluted waters.

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- 1 Isaacs D. Any questions. *BMJ* 1992;305:290. (1 August.)
- 2 Melnick JL. Live attenuated poliovaccines. In: Plotkin SA, Mortimer EA, eds. *Vaccines*. Philadelphia: W B Saunders, 1988.

Women's preference for place of birth

EDITOR,—Martin Johnson and colleagues surveyed pregnant women and report that only 8% said that they would prefer to have their labour at home.¹ They acknowledge that their sample was biased and that results cannot be extrapolated to predict the number of women nationally who would choose a home birth.

There are other difficulties in finding out about preferences. The Institute for Social Studies in Medical Care has carried out several surveys based on national samples to find out the views of those using maternity services.² In our experience preferences are difficult to study because they are not usually based on experiences of the possible alternatives: women tend to "prefer" whatever type of care they have had. One of our studies found that 91% of the women who had had their last baby at home said that they would prefer to have their next baby at home, compared with 15% of those who had had their baby in hospital.³ Among the few women who had experienced both a home birth and a hospital birth 76% preferred the home birth.⁴

In our most recent surveys of maternity services, in 1984 and 1989, only 1% of the women sampled had experienced home births. Realistic comparisons of preferences will be possible only when more women give birth at home.

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- 1 Johnson M, Smith J, Haddad S, Walker J, Wong A. Women prefer hospital births. *BMJ* 1992;305:255. (25 July.)
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EDITOR,—I was surprised that, although Martin Johnson and colleagues found that 8% of pregnant women using two hospital antenatal clinics in Leeds would prefer to have a home birth, they concluded that this was not evidence of "considerable unmet demand for home birth."¹ As currently fewer than 1% of women have a planned home birth, this shows that in Leeds only one in eight women who would like to have a home birth actually manages to arrange one. By anyone's standards that is surely a considerable shortfall. The needs and wishes of these women are simply not being met.

The actual number of women, however, who might choose a home birth if the opportunity was offered is, not surprisingly, relatively small. The current generation of childbearing women has grown up in a climate in which childbirth has become anonymous with hospital and medical management.

Finally, to correct misinformation in Johnson and colleagues' letter, the select committee on maternity services did not advocate more women having their babies at home.² It in fact said: "the policy of encouraging all women to give birth in hospitals cannot be justified on the grounds of safety. . . . Given the absence of conclusive evidence, it is no longer acceptable that the pattern of maternity care provision should be driven by presumptions about the applicability of a medical model of care based on unproven assertions" (paragraph 33). The committee concluded that "women need to be given a choice on the basis of existing information" (paragraph 96). This is all the National Childbirth Trust is asking.

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- 1 Johnson M, Haddad S, Smith J, Walker J, Wong A. Women prefer hospital births. *BMJ* 1992;305:255. (25 July.)
- 2 House of Commons Select Committee on Maternity Services. *Maternity services, second report*. London: HMSO, 1992.

EDITOR,—In 1991 we asked 926 consecutive women attending a family planning clinic in Edinburgh whether they would prefer to have a baby in hospital or at home; we pointed out that if complications arose women choosing home delivery could be transferred to hospital or attended to by the flying squad. One hundred and seventy five of the women had had at least one baby. Altogether 150 (86%) of those who had had a baby said that they would prefer hospital delivery compared with 616 (82%) women who had never had a baby. Whatever the views of the House of Commons Select Committee on Maternity Services,² among our population there was an overwhelming desire for hospital delivery. We thought it likely that had we asked the same questions of women who were pregnant and facing

imminent childbirth an even greater percentage would have preferred hospital delivery. The fact that 92% of women in Martin Johnson and colleagues' study wanted delivery in hospital supports this hypothesis.¹

We also asked the women how long after delivery they would like to stay in hospital. Increasingly the tendency is towards early discharge as a result of pressure both from consumer groups and from managers, who see short stays as economical. Of the women in our survey who had had experience of childbirth, most (117; 67%) wanted to stay in hospital for "a few days"; only five (3%) wanted to go home immediately. In contrast, only 330 (44%) women who had never had a baby envisaged wanting to stay in for a few days, a greater proportion (338; 45%) saying that they would prefer to go home 24 hours after delivery. Perhaps women who have experienced childbirth have a more realistic view of the value of a few days of professional help with a first baby or a rest from the demands of other children.

Our survey adds weight to the recommendation of the maternity services committee that, within reason, mothers should be free to choose how long they stay in hospital after childbirth. The opinions expressed in our survey and Johnson and colleagues' survey may be more representative of what the average British woman wants than those expressed by many of the special interest groups who gave evidence to the select committee. Before any radical reorganisation of maternity services is made it might be wise to take account of these women's views.

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Epidural analgesia and backache

EDITOR,—C MacArthur and colleagues' paper,¹ which forms part of their larger study into health after childbirth,² draws attention to the association between epidural analgesia in labour and complaints of backache and headache in the three months after delivery. Obstetricians and anaesthetists are still left with no idea of how this finding should affect clinical practice.

The difficulty lies largely in the constraints imposed by the study itself. Firstly, it was retrospective, requiring recall as far back as nine years. There is a huge gap between recall and actuality. Secondly, only symptoms were asked about, and many of these would have been identified by most people as having occurred in the past year. If health is the same as absence of symptoms then few people are healthy. Thirdly, the severity of the symptoms was not recorded, nor their effect on the quality of life—a deficiency acknowledged by the authors as inimical to the proper assessment of their findings.² Backache is extremely common and is experienced by virtually everyone at some time. Did the mothers think that their epidural analgesia had been worth it or not?

The study had several positive conclusions, including that epidural blockade increased the incidence of backache by a factor of 1.8 but neither the epidural needle nor the injection of local anaesthetic caused this increase; also, that being in labour, especially with a long second stage, was a prime factor in the backache, both with and without epidural analgesia. The authors' explanation is that postural changes as the fetus passes through the pelvis and the inability of the paralysed musculature to protect against damage to the joints