viral, or toxic diseases may explain this "pseudo decline."^{1,2} In conclusion, Reye's syndrome should be reassessed.

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Water births given a bad press

EDITOR,—The response of the Royal College of Obstetricians and Gynaecologists to questions on the safety of water birth and the resulting widespread publicity generated last year, raise issues that should concern all health care professionals.

Water birth is a new technique that needs to be properly tested for effectiveness, efficiency, and safety. Although some obstetric interventions in the past were introduced without evaluation, the introduction of water birth has been cautious and well documented, and the technique is currently under study. The John Radcliffe Hospital in Oxford is halfway through a three year study to assess the outcome in women using a water pool. Initial published results give details of the 300 women who used the pool between August 1990 and August 1991.¹ More than 600 women have now used the pool during labour, and over 300 of them have given birth under water. In addition, the Department of Health has sponsored the National Perinatal Epidemiology Unit to collect and evaluate data on the use of water birth throughout the country.

This must be the proper way to proceed. Until these studies and trials are completed no one can judge the effectiveness or safety of the procedure. By drawing attention to water birth in the way in which it did, however, the Royal College of Obstetricians and Gynaecologists may have jeopardised the success of these clinical studies. Some women may well withdraw from the trials. The Royal College of Midwives has supported the cautiousness of the advocates of water birth. We agree that many women find being in water comforting during labour, but we realise that there is much yet to be learnt. The use of studies, trials, and audit seems wholly responsible.

A further point is the naivety of some professionals in their dealings with the media. News values being what they are, it should have been obvious that there would be little attempt to balance views on the safety of water birth. Without the hysteria, the popular press would not have had a story at all. The passing of opinion and conjecture as established medical fact caused many women, midwives, and obstetricians needless anxiety.

The way to deal with controversial new procedures is through multiprofessional debate, research, rigorous audit, and consensus. To cause distress on the basis of so little evidence and to put at risk the current research which is hoped will give that evidence seem to be wholly irresponsible.

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Chemotherapy in advanced small cell lung cancer

EDITOR,—I E Smith argues that there is good evidence for the place of chemotherapy in controlling symptoms and prolonging survival in advanced non-small cell lung cancer.¹ Smith's argument is largely based on comparison of the data available with data on other "standard" treatments. Simply to assert that the evidence supporting the use of chemotherapy in advanced non-small cell lung cancer is as good as that for using palliative radiotherapy in the same disease² or chemotherapy in advanced breast cancer is hardly persuasive. Neither of these could be described as thoroughly studied cancer treatments, and neither is notably successful.

The survival data referred to³ also fall short of being conclusive since they are derived from an overview of published trials. In such overviews and meta-analyses trials with different entry criteria and treatment regimens are amalgamated. It is well known that they may be influenced by a positive publication bias in favour of "good results." Finally, the evidence of an impact on patients' symptoms is taken from a small non-randomised study in a single institution.

In the historical development of new treatments there is often a relatively narrow time window in which to accumulate comprehensive, reliable information on the impact of treatment. Fashion and the understandable desire to offer some treatment where previously there was none can overtake scientific endeavour. Evidence of a treatment effect, such as the response rate, is not sufficient to justify recommendation of a treatment in a journal such as the *BMJ* with a worldwide influence.

We are currently running randomised controlled trials of chemotherapy (mitomycin, ifosfamide, and cisplatin⁴) in inoperable non-small cell lung cancer with survival as well as quality of life end points. Over 600 patients have been randomised, with a target of 800. These two trials (one in localised and one in advanced disease) will provide more definite information that will allow oncologists to make informed judgments concerning the place of this treatment among other priorities in health care systems with limited resources. We urge Smith and others to help us by collaborating in this work.

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GP facilitators and HIV infection

EDITOR,—Peter Saunders¹ and subsequent correspondents² raise many issues relevant to general practitioner facilitators and HIV infection in Lothian. Of 1000 adults known to have HIV infection in Lothian, 60% have acquired HIV through needle sharing, but for the past three years heterosexual transmission has been the commonest mode of spread. At the suggestion of a group of interested general practitioners, Lothian Health Board established a facilitator team in 1989. In

1992 it was expanded to three part time staff: a working general practitioner, a retired general practitioner, and a retired health visitor.³ The nurse facilitator concentrates on non-medical members of the primary care team, focusing on issues of HIV prevention, while the medical facilitators support general practitioners to care for drug users and for people with HIV infection. We work closely with hospitals and non-statutory agencies, and the emphasis has been on supporting primary care teams in their care of people with HIV infection rather than on asking them to do more at a time of increasing demands on general practice.

We circulate regular information sheets to general practitioners, organise courses for doctors and nurses, and visit practices to provide information, training, and support to all members of the practice team.³ We have developed teaching aids and resources (such as a leaflet and a combined pill and condom pack) to support general practitioners and primary care nurses in their prevention work and have been involved in auditing the quality of community care for people with HIV infection.⁴ In 1991 and 1993 a 99% response to a survey of all practices in Lothian provided a detailed picture of the epidemiology of HIV infection and drug use in Lothian general practice.⁵ By 1993, 70% of the 133 practices in Lothian as a whole—including 93% of the 76 practices in the city of Edinburgh—had experience of patients with HIV infection. Only four practices were caring for more than 20 people with HIV infection, and most practices (46%) had between one and five patients with HIV infection.⁵

We share with Singh *et al*⁶ an interest in evaluating the work of facilitators, and from the team's inception we have consistently evaluated individual activities.³ As for the wider impact of facilitation, we have been unable to distinguish this from the effects of the Lothian approach to HIV care in general. We can, however, point to the increasing involvement of Lothian general practitioners in shared care and the continuing goodwill associated with facilitator activities, of which the remarkable response rate to our epidemiological survey is an example.

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Bias in assignment to clinical trials

EDITOR,—Despite the many biases to which clinical trials are subject, trials are still considered the best way to show the efficacy of a new therapeutic or prophylactic measure.¹ Perhaps the most important biases are those of selection and measurement, as they most determine the validity of a study. The respective techniques of random assignment to study treatment groups and of blind experimentation are attempts to remove these biases.

We have detected a type of selection bias that does not affect the assignment of subjects in a single study to different groups but rather the

assignment of patients to different clinical trials. In other words, one patient meets the criteria for inclusion in parallel trials being carried out in the same department or by the same researcher. Assignment to either study is not randomised but depends on conscious or unconscious factors that are not in any way controlled and therefore may affect the final results.

Clinical trials concerning diseases such as cancer and AIDS for which there is no curative treatment and which confound help oriented and experimental practices are most likely to present this type of bias.

This phenomenon would deserve no further mention were it not for the fact that clinical trials of several different drugs are being performed by the same researcher or research group, each trial having similar inclusion and exclusion criteria. We will not analyse how this arises but we would like to point out some of its consequences. The researcher might think that some of the drugs in one study are more effective than those being tested in others, which means that he or she might include patients whose condition is most critical in that study. Or, he or she may find that the drugs in one study are more appropriate for treating patients with certain characteristics and only include patients with them. In both cases the external validity of the study is compromised as the study group is not representative of the population to which the conclusions were intended to apply.

One possible solution to the problem would be random assignment of patients to different studies. This would create considerable practical difficulties, however, as studies are not usually proposed or initiated by researchers all at once. Perhaps the only feasible alternative for researchers is to promote awareness of the importance of this fact and to comply with standards of good clinical practice, which state that researchers are responsible for providing the sponsor with a list of the human and technical resources at their disposal, recruitment possibilities, commitments obtained, etc.² In addition, the possibility of being audited and inspected by health authorities, as the Food and Drug Administration in the United States has been doing,³ is another inducement worth considering.

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The preregistration year

EDITOR,—The befuddled thinking that permeates medical education is evident in P I M Allen and B M Colls's uncritical enthusiasm.¹ They praise New Zealand's trainee intern year, which originated partly because of a shortage of house officers and partly because of deficiencies in medical training. They offer no objective evidence of its benefits other than that expressed by self selected Australian medical students.

The described programme is proof of how the postgraduate years trap the curriculum. The programme does not recognise that over half of the graduates will spend their practising life outside hospitals. The authors proudly proclaim a "seam-

less transition" to junior hospital posts without seeing what a terrible waste of time and effort these years are—a form of indentured slavery. Apprenticeship is claimed to be a good idea. It is. But if you are going to be a general practitioner, a researcher, or an administrator, what use is being apprenticed (for short spells) to a variety of hospital consultants?

The authors claim that the "student's educational requirement" is paramount. How this is ascertained is not described, and the listed weeks of the trainee internship do not seem elastic enough to fit such a concept. The authors' description of who teaches the trainee interns is a whitewash. Those who undertake this task—the junior house officers, the registrars, and most of the consultants—have no training in teaching; often have no interest in it; are unsupervised; and, because of the short attachments, have no incentive to perform well.

My random and non-representative sampling over the years does not support the authors' claims. Most trainee interns have enjoyed having a job, being paid, and having increased contact with patients; but many of them feel used, lack direction, and have put the "books" aside, immersing themselves in the minutiae of surviving in the hospital environment.

Allen and Colls missed the down side of the year they described. They also missed the need to rethink the whole of medical education. The postregistration years are the key to change. A shorter undergraduate course, more self learning, early vocational choice, and wider choices of apprenticeships after registration are the main requirements for a better system. The way that hospitals are staffed must be changed—for their sake and for the sake of young entrants to medicine.

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1 Allen PIM, Colls BM. Improving the preregistration experience: the New Zealand approach. *BMJ* 1994;308:398-41. (5 February.)

Maladministration at Welsh Office

EDITOR,—On 18 February the secretary of state for Wales signed an order prohibiting general practitioners from "supplying" childhood vaccines from 1 March (amending paragraph 44/5 of the statement of fees and allowances for general practitioners). After 10 days' delay this was faxed late on 28 February to family health services authorities, and it was received by general practitioners on 4 March. Many general practitioners were purchasing vaccines and recouping the cost by forwarding prescriptions to the Welsh Pricing Bureau. Supplying is cheaper and more reliable than having the cumbersome and inefficient district health authority provide vaccines to general practitioners' surgeries.

The only warning of this action was in articles in *Pulse* and *General Practitioner*. Powys Family Health Services Authority contacted the Welsh Office last December and was informed that there were no plans to instigate this ban in Wales even though it had been mooted for England. Thus when this edict was published four days late the family health services authority was embarrassed; the Welsh Pricing Bureau had not been informed; the district health authority had no contingency plans to provide extra vaccines; our local pharmaceutical representative was still selling vaccines; and many general practitioners were left with several months' worth of unusable vaccine stock. Natural justice surely warrants three months' warning.

This is not the first time that the Welsh Office has been guilty of maladministration in this respect. Three years ago, on Christmas Eve, it "black-listed" certain drugs from 1 January, but the order was not circulated to dispensing doctors until mid-January.

The first, and constantly changing, blacklist of 1986 was sprung on us at relatively short notice. Dispensing doctors, because of their attempts to provide a service and to overcome problems with supplies, were left with several months' stock of potentially unusable blacklisted drugs. We read rumours of a new blacklist, together with unofficial claims that certain drugs have been reprieved. All attempts at clarification are fruitless. It is impossible to plan ahead because of fears that the next blacklist will be announced retrospectively.

What is particularly irritating is that the "secretary of state orders" are prefixed with the statement "after due consultation with representatives of the profession." What are our representatives doing to eliminate this maladministration?

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World Medical Association

EDITOR,—In her article on the World Medical Association, Tessa Richards has not broken down the figures in the table, where Spain, for instance, is shown to have declared 5600 members. As far as I have been able to ascertain, there is no equivalent of the British Medical Association in Spain. So whom do these members represent, and who pays their dues? Could it be that some subscriptions are subsidised by the government?

The World Medical Association's credibility is jeopardised if it is not shown from the beginning that the members are independent of governments and genuinely represent the main body of medical opinion in their countries. I hope that this does not sound idealistic. But the constitution of the WMA demands this or it cannot have a *raison d'être*.

The BMA already exerts an authoritative and respected influence world wide. Its council should consider carefully before rejoining the WMA and should make clear its reasons if it rejoins.

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1 Richards T. The World Medical Association: can hope triumph over experience? *BMJ* 1994;308:262-6. (22 January.)

Choosing photographs

EDITOR,—It is a pity that the photograph shown to illustrate John Roberts's article on milk in the United States¹ was of a cowboy herding Hereford steers, the archetypal beef cattle. No one in their senses would try to get milk from a Hereford—or beef from a milk cow such as a Friesian/Holstein. The journal needs an agricultural consultant.

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1 Roberts J. US milk cannot be labelled hormone free, says FDA. *BMJ* 1994;308:495. (19 February.)

** The *BMJ* regrets offering readers a load of bull. The statement in the caption that what the cows produced "cannot be labelled 'natural'" turned out to be truer than we thought.—ED, *BMJ*