to them to set up strong audit structures in their units (£42.1 million in 1992-3)⁴ they have only themselves to blame for a remarkable lack of initiative. But then effective audit requires not only hard work but also the active participation and commitment of senior doctors. On the other hand, picking up the telephone and complaining to the press is so much simpler and avoids the rather tedious business of systematic and critical analysis. For all that, it is time that we recognised and used the right whistle.

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Feedback from patients and colleagues

EDITOR,—The personal view written in the form of an anonymous letter to her surgeon by a patient who felt unable to challenge the consultant's management of her case at the time raises an important issue.¹ Who can be the patient's advocate in such circumstances? The patient's general practitioner is not mentioned at all in the article but was presumably the referring doctor. Was the patient unable to express her concerns to him or her, or did she do so but find the general practitioner unwilling to intervene on her behalf?

I know that an intraductal carcinoma of the breast presents difficult decisions of management,² but the patient, as she highlights, should have had the options explained to her and been allowed time to assimilate the information. As a general practitioner I acknowledge my consultant colleagues' expert knowledge, but I am sure that if I had heard this patient's story I would have contacted the surgeon with her permission to express my concern.

Who else besides her general practitioner could have acted for this patient? One would have hoped that perhaps a member of the surgical or nursing team would have recognised her distress and offered to listen and to advise her to speak to the consultant. I suspect, however, that if a general practitioner was reluctant to intervene then hospital junior staff would feel similarly handicapped.

What can be done, therefore, to remedy poor performance, particularly when the result is a damaged doctor-patient relationship? Medical students in Leicester become accustomed to receiving feedback not only from their practice and departmental tutors but from real and simulated patients, which they find invaluable in improving their consultation performance.^{3,4} It is hoped that this experience will not only encourage students to continue to ask for feedback from their colleagues and patients as they progress up the career ladder but also empower them to give appropriate feedback to others, no matter how eminent or powerful.

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Trials and tribulations in pursuing an MD

EDITOR,—David Gray's account of his first year as a research registrar makes sorry reading, and his disappointment, frustration, and anger are clear.¹ Understandably, he seeks to apportion blame for what seems to have been an unproductive year, and he chooses to assign most of it to an (unidentified) pharmaceutical company. My reading of his narrative suggests, however, that he would be well advised to assign the blame elsewhere.

He seems to have stumbled into an administrative role on a project that he did not conceive of and in which he may have had little interest. Many of his assertions do not stand up to scrutiny and should not pass unchallenged. Because the company preferred to study thrombosis in patients with myocardial infarction rather than patients having hip surgery he asserts that "Clearly emotion played a greater role in decision making than statistics" without pausing to consider alternative explanations. Indeed, the sensible size of the study population—550 patients—suggests that some careful decisions had been made on the basis of a power calculation. Things got off to a shaky start and unexpected problems arose. This is typical of clinical research, and, though it may have surprised Gray, his professor should have anticipated it.

The beneficial effects of aspirin and streptokinase were not unheralded, and a literature review before the start of the study might have indicated the consequences of the second international study of infarct survival for Gray's investigation. It seems unfair to castigate the pharmaceutical company for stopping a study that was behind schedule, with under a quarter of the patients recruited, and whose continuation some physicians might have considered to be unethical.

An MD (or an MS) is a senior research degree and is intended to recognise original work to which the recipient has made a pivotal contribution. Acting as a pair of hands for somebody else's drug study hardly fulfils these requirements. A programme of research for such a degree should have some clearly defined goals and at least one attainable intermediate objective. The responsibility for the adequacy of an MD programme rests firmly with the trainee's supervisor.

Gray has good reason to be disappointed, but he should not cast all his stones at the pharmaceutical industry; rather, he should re-examine his motives for getting the job in the first place and question whether he has been well served by his supervisor. All of us would benefit if people stopped getting involved in clinical research for career reasons alone.²

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1 Gray D. Trials and tribulations in search of an MD. *BMJ* 1992;**304**:1576. (13 June.)
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British-Polish workshops on substance misuse services

EDITOR,—Karin Chopin has examined health issues in Poland in illuminating detail.^{1,2} Intravenous drug misuse and HIV are major public health challenges, but, numerically, the task of tackling morbidity and mortality related to alcohol is greater. Consumption of alcohol (in terms of absolute alcohol) has doubled or trebled since the 1950s, and about three quarters of the alcohol is consumed as vodka. If anything, legislation on

alcohol has been liberalised with the shift towards a market economy. Britain has little definitive advice to offer the Poles in view of the alcohol crisis here.

The articles suggest that the West's support of the evolution, planning, and provision of services in Poland has been misguided. I went to Poland last year as a member of a training team running a four day workshop entitled "Substance misuse services: treatment and rehabilitation." Twenty two participants from many disciplines and from statutory and voluntary agencies came from all over Poland. Group work, lectures, and debates went well despite, or possibly because of, Polish passions being roused. Indeed, this was no exercise in arrogant, Western paternalism: native presenters ensured lively discussion with cross fertilisation of philosophies and practices between nations and, I suspect, also between the Poles themselves.

Recently, six Polish delegates came to London for a five day intensive workshop on the strategic planning of substance misuse services: further reciprocity is planned. These workshops were organised as part of a structured academic link between the Institute of Psychiatry and Neurology in Warsaw (and other Polish institutions) and the division of addictive behaviour at St George's Hospital Medical School, London, supported by the British Council. While the World Health Organisation is an important umbrella, direct links of this sort are an adjuvant to the process of developing collaborative approaches to the health issues described. Perhaps the European Community will promote similar programmes (if it is not already doing so), given the economic and political shifts of East toward West and the link between economics and health.

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Smoke hoods in aeroplanes

EDITOR,—Ian R Hill's editorial is a reminder of the need to minimise mortality and morbidity in air crashes,¹ but smoke hoods have disadvantages in this context. We studied the use of smoke hoods, having gained approval for the study from Grampian's regional joint ethics committee.

Six fit healthy firemen (used to wearing respiratory protection, although not trained in using the device tested) put on a commercially available smoke hood. They rested and exercised for five minutes (to 100 W) in air and in an atmosphere containing roughly 5% carbon dioxide and 15% oxygen, as might be expected near an enclosed fire. The table summarises the effects on ventilation.

Mean (SD) ventilation (l/min) at rest and during exercise in six firemen wearing and not wearing smoke hoods in air and in test atmosphere

Test condition	At rest	During exercise
Air, no hood	10.1 (4.1)	38.2 (8.7)
Air, wearing hood	18.1 (2.8)	49.4 (7.8)
Test atmosphere, no hood	29.9 (5.6)	84.8 (13.5)
Test atmosphere, wearing hood	34.2 (7.3)	102 (13.1)

Donning the hood caused a considerable increase in ventilation; this was due to rebreathing within the hood, which rendered respirable gas oxygen depleted and carbon dioxide enriched and so limited exercise ability. In fire smoke oxygen depletion is accompanied by a rise in atmospheric carbon dioxide concentrations, so potentiating the effects of rebreathing in a smoke hood with a filter.

During the trial two subjects failed to don the equipment correctly and one suffered extreme rebreathing, which limited his exercise tolerance in the test atmosphere to less than two minutes. Two volunteers refused to undergo the session in the test atmosphere wearing the hood as they perceived it as too stressful.

We have also studied two other commercially available smoke hoods with filters in two volunteers exercising in air at only 75 W. One resulted in a ventilation of 109 l/min in one subject, while the other subject was unable to exercise beyond two minutes when his oxygen saturation fell to 87% and his ventilation reached 91.9 l/min. The other device resulted in ventilations of 103.1 l/min and 107.7 l/min in the same volunteers.

Our subjects represent the healthiest of those who travel by air, whose range of states of health and disease is wide. Tolerance to wearing a smoke hood is probably reduced in less healthy people, elderly people, and children. The hazards of rebreathing while wearing a smokehood and attempting to escape from fire need to be investigated further before widespread use of smoke hoods can be recommended. Our study further emphasises the widely held view that people who wear respiratory protection should be specifically trained in its use. Without training, such equipment carries a risk that might limit escape from fire even if the atmosphere is minimally toxic.

We believe that existing smoke hoods carry an intrinsic risk to the wearer that in some instances outweighs their potential benefits.

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1 Hill IR. Smoke hoods in aeroplanes. *BMJ* 1992;304:1326. (23 May.)

Postmarketing surveillance studies

EDITOR,—P C Waller and colleagues' review of postmarketing surveillance studies found deficiencies in the numbers of patients studied and weak study design and concluded that there was a strong case for attempting to improve such work.¹ In addition to the possible solutions that the authors present there is another that might have potential in overcoming these difficulties.

Collaboration between an academic department and Rhone-Poulenc Rorer has meant that some of the substantial resources invested in postmarketing surveillance of a new drug (celiprolol) are being used for an additional study of a large number of hypertensive patients drawn from all over the United Kingdom: the cardiovascular outcome and risk evaluation study. This "piggybacking" of epidemiological and health services research initiated by an academic department on to routine postmarketing surveillance, such as the prospective postmarketing study on the safety of celiprolol, has tangible benefits for both the pharmaceutical industry and the academic department.

The most obvious benefit has been that participating general practitioners view the study as having added value as its goals and activities are wider than the evaluation of short term side effects of treatment, and we suspect that this leads to better recruitment rates and therefore lower overall costs. In our case recruitment has been on target with over 500 patients recruited per month, which is more than double the rates achieved in the studies reviewed. Moreover, as such partnerships between academic departments and pharmaceutical companies will have a defined contract for

a defined period between the department and the company, premature cessation of studies should be less likely. Academics' participation at an early stage of postmarketing surveillance may also lead to wider discussion of study designs and the avoidance of selection bias and lack of comparator groups, which Waller and colleagues highlight.

We think that large postmarketing studies, given their size and cost, should have a wider purpose and be exploited to the maximum advantage of the wider community. Our partnership has reduced the cost of the postmarketing study, enabled a major scientific study, and resulted in cross fertilisation of skills and resources between the pharmaceutical industry and academic medicine.

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EDITOR,—The Medicines Control Agency and Committee on Safety of Medicines clearly express their concern regarding the monitoring of drugs recently introduced to the market.¹ It is now generally accepted that for most newly marketed drugs the assessment of their safety should be extended into the postmarketing phase if unexpected adverse effects are to be detected without undue delay. There are three main methods by which data on safety may be collected: spontaneous reporting, observational cohort studies, and linked record systems. Good arguments support the claim that observational cohort studies, by virtue of their ability to provide a broad range of data of research quality, are the most effective method in the first two or three years after marketing.

I therefore welcome P C Waller and colleagues' paper, which focuses attention on the importance of cohort studies in the continuing assessment of drug safety.¹ IMS International strongly supports any measures that will improve the standards of postmarketing evaluation of safety, particularly in distinguishing between good quality clinical research and worthless studies that are no more than promotional exercises. The paper clearly implies that the quality of observational cohort studies differs widely, but it would have been helpful if the authors had distinguished more clearly the outcomes of studies that met their standards and those that did not.

The views expressed in the conclusion to the abstract, based on all 31 studies taken together, are manifestly unfair to the better studies. As an example, if the criterion of achievement of target numbers was accepted as an indicator of a good study then the worst study cited in the table would be the one done on a drug with *British National Formulary* code 2.7, which achieved only 8%. In fact, this was almost certainly the best of the studies in that it identified a problem in under three months from its start. Subsequent regulatory action, which restricted the drug to hospital prescription, led to the curtailment of the general practice study even though all registered patients (about 780) were monitored for a full 52 weeks.

Although I do not believe that the Medicines Control Agency or the Committee on Safety of Medicines wish to discourage good safety studies, their paper, failing as it does to highlight the benefits of good work, will be a disincentive to doctors to participate in worthwhile investigations. This is a pity as it is in the interests of patients, the good practice of medicine, the regulators, and the pharmaceutical industry that drug safety should be

evaluated to the highest possible standards. I hope that the new, improved guidelines to be issued by the Committee on Safety of Medicines, Medicines Control Agency, BMA, Royal College of General Practitioners, and Association of the British Pharmaceutical Industry will foster this process. Further guidance from the Medicines Control Agency on the required content and format of reports would also be helpful.

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1 Waller PC, Wood SM, Langman MJS, Breckenridge AM, Rawlins MD. Review of company postmarketing surveillance studies. *BMJ* 1992;304:1470-2. (6 June.)

Local and central research ethics committees

EDITOR,—In his letter Michael Drury draws attention to the existence of the central ethics committee of the Royal College of General Practitioners.¹ I applaud the college for setting up this committee, but until local research ethics committees are prepared to accept the rulings of central committees the college's intention will be largely frustrated.

TIL Occam submitted details of a multicentre study to the Royal College of General Practitioners' ethics committee in February, and after some entirely reasonable discussion and minor adjustment it was approved. All the local research ethics committees concerned were informed, as the college's committee requested. Of the 24 local committees, 10 have insisted on full formal review; so far one has rejected the proposal on the grounds that a compound of the same class as the drug to be studied but not closely related chemically, has recently been withdrawn from the market for reasons of toxicity.

The Association of Independent Clinical Research Contractors is holding a meeting for chairpeople of local research ethics committees in Cambridge in September, and the Royal College of Physicians recently held a similar meeting. This interest is welcome, and I hope that some degree of consensus can be achieved on what the proper role of a local research ethics committee is and how that role and the accompanying responsibilities are affected by the prior ruling of a central committee such as that of the Royal College of General Practitioners. Until that consensus is arrived at the value of central committees is limited.

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1 Drury M. Ethics and multicentre research projects. *BMJ* 1992;304:1696. (27 June.)

Measuring height in children

EDITOR,—Jennifer McCann highlights the factors that can frustrate attempts to measure a child's height accurately.¹ Within three days during a stay in the local hospital my son's height increased, according to his records, by a remarkable 10 cm. After a little detective work I established that the difference resulted from the positioning of one of the two paper measuring charts in use such that it began not from the floor but from the top of the skirting board.

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1 McCann JM. Measuring height in children. *BMJ* 1992;304:1572. (13 June.)