different scales are used. In such a case the intraclass correlation coefficient computed for each method will indicate which is the more reliable, provided each method of measurement uses the same population, as in a dataset we recently examined.¹ In summary, we agree with Chinn when she says that "the intraclass correlation coefficient should be used only for comparative purposes. The within-subject standard deviation or 95 per cent range for change should be calculated as the absolute measure of repeatability."²

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Toxic dilatation and infective diarrhoea

EDITOR,—In their article on non-specific inflammatory bowel disease in the ABC of colorectal diseases S Pettit and M H Irving state: "Toxic dilatation is a life threatening condition which has to be treated by urgent colectomy . . . regardless of underlying aetiology."¹ Over the past decade the regional infectious diseases unit in Sheffield has seen 20 cases of toxic dilatation of the colon complicating acute diarrhoea (of less than three weeks' duration) of largely infective aetiology (unpublished data). Intensive medical management consisting of intravenous steroids, antibiotics, and supplementary nutrition similar to the Truelove regimen² resulted in resolution in 17 patients. Three patients required subtotal colectomy and ileostomy for actual (two) or incipient (one) perforation of the transverse colon, but none developed a severe peritonitis and all subsequently recovered with eventual reversal of the ileostomy.

Like others,³ we believe that in toxic dilatation with a likely infective aetiology initial aggressive medical treatment offers a good chance of recovery with preservation of the colon. Naturally, the risk of perforation must be minimised and any complication identified early. Our policy is to involve a surgical team in case medical management fails and operative intervention is necessary.

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Medical audit in general practice

EDITOR,—The North of England Study of Standards and Performance in General Practice claims to have shown that medical audit and standard setting can change doctors' behaviour and improve the care of patients.¹ A problem is that the study seems neither to have completed any medical audit nor set standards in the usually accepted sense.

In *Medical Audit Tools* the authors write: "An explicit standard is a declared, usually written,

statement. For medical audit it will describe a desired state of affairs and state a recommended level of performance."² I agree—as do most authors.^{3,6} On the other hand, in a report of this study they write: "A clinical standard is an explicit statement of what a doctor's performance should be. . . . The most common form is the structured essay. . . . We set out only to describe standards, not to make judgement of their quality."⁷ Such clinical standards are usually referred to as guidelines, which are usually much too diffuse and comprehensive to be used as a measure against which performance can be compared.⁸ It is this form of standard that the study used.¹

Again, the authors write that their objective was "to estimate the effect of medical audit, particularly setting standards, on clinical behaviour."¹ But setting standards—or, as I have suggested, developing guidelines—seems to be the only part of the audit cycle undertaken. No targets were set; although data were collected for research purposes, they were not fed back as part of an audit process—indeed, the paper states that after the end of the study data were well received by trainers; and no resolutions for change were made by comparing targets with performance.

So what did happen? Apparently, groups of trainers studied certain conditions and drew up guidelines for management. After that their behaviour changed to accord more closely with the guidelines they had developed themselves, but not in response to guidelines drawn up by others. That seems a believable and likely result of an educational exercise, but it is not standard setting in the usually accepted sense of the word and it is not audit. Such confusing use of terminology can only delay a generally agreed understanding of medical audit and setting standards.

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Agenda for health in Europe

EDITOR,—Surely in setting the agenda for health in Europe it must be relevant to include the public health problems of other parts of the world, particularly the Third World, otherwise the North-South divide will increase.¹ Any action undertaken in the developed world must not have a "dumping" effect on the developing world; this was the main theme of the earth summit in Rio de Janeiro.² It is not just environmental issues that are of global importance but also matters related to health.

Take, for example, the harmful effects of cigarette smoking. If the Western world is successful in reducing tobacco consumption and at the same time does not discourage the manufacturers from continuing to produce cigarettes these companies will inevitably sell their product in countries whose market can be exploited. These tend to be

the poorer nations of the world. The net result will be to shift the problem from a well organised society to an impoverished state. Several other examples of this exist, including the sale of discarded brands of drugs and the encouragement of artificial breast feeding.

What is needed, therefore, is a strategy that improves the health status of people in Europe without prejudicing the lives of people in other parts of the world. The global need for health must influence the European strategy.

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Black dog of depression

EDITOR,—The author of a recent personal view gives an eloquent and moving account of his 40 year struggle with depression; it is admirably free of the "tendency towards self pity and wallowing in gloom" that he fears may antagonise those who surround him.¹ How sad it is, therefore, to read that he is too embarrassed to reveal his identity and does not want the people he mixes with to know of his illness. Presumably if he had been reporting a lifetime as a doctor coping with blindness or some disabling neurological disorder he would have thought this a worthwhile struggle and one of which he need not feel ashamed.

Mental illness still, it seems, carries enormous stigma, and I am not suggesting that sufferers should be unwillingly "outed" in medical journals. Perhaps we should ask ourselves why a senior doctor, writing in a column that will principally be read by his professional colleagues, is unwilling to be identified as someone who has achieved success in both the personal and professional spheres of his life despite having a chronic incurable disability. I hope that psychiatrists are not alone in entreating patients and their families and colleagues to regard psychiatric illnesses as what they are: just illnesses. Mental illness is as deserving of attention and treatment as any other, and those who have overcome it equally deserve our admiration.

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1 Black dog of depression. *BMJ* 1992;304:1702. (27 June.)

Poland: collaboration or advice?

EDITOR,—Karin Chopin's article on aid to Poland¹ was published the day we left with five other clinical biochemists from Glasgow and Dublin to serve as lecturers on a postgraduate course on strategies in clinical biochemistry held in Professor S Angielski's department of clinical biochemistry in Gdansk, Poland. This was one of the activities of the joint European project "clinical biochemistry education in Poland" supported by the European Community's TEMPUS programme. It is a collaborative project between the departments of clinical biochemistry at the Western Infirmary and university in Glasgow, St James's Hospital and Trinity College in Dublin, and the Medical Academy in Gdansk.

The project's overall aim is to update undergraduate and postgraduate teaching in clinical biochemistry in Gdansk and to strengthen education on preventing cardiovascular disease. The

programme combines consultative activities with intensive training of Polish staff in Scotland and Ireland and provides the infrastructure to support these activities (for example, advanced desktop publishing facilities). On completing their training Polish staff immediately participate in the day to day management of the programme. A lipid clinic has been established by the Gdansk-Glasgow team and is now run by Polish staff trained in Glasgow. The postgraduate course in which we participated was designed by the three nation team, led by Dr Z Jakubowski from Gdansk.

We should emphasise that the course was not advisory: it entailed critical comparison of the three systems. The 30 senior Polish clinical biochemists who participated were selected from over 60 applicants. They had extensive theoretical and research knowledge of their subject but face the consequences of the past centralised planning of purchase of equipment combined with little, if any, management training. This was probably the most serious problem that emerged from discussion.

We submit that this programme illustrates a different approach to what is generally termed aid or "foreign advisers . . . spending a great deal of time and money arriving at conclusions which [Polish professionals] reached long ago." In our view, the best approach is carefully planned, integrated programmes that combine training and interchange of staff and consultation, with funds to support the infrastructure required for development. Such collaboration should be followed by the establishment of longer term contacts between participating institutions. Advice is best taken from people you know; this takes time.

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1 Chopin K. Too many advisers, not enough aid. *BMJ* 1992;**304**: 1429-32. (30 May.)

Withdrawal of a monopoly treatment

EDITOR,—Over the past 20 years the renal unit in Dundee has investigated and advocated the use of intravenous iron dextran to treat anaemia in patients receiving dialysis.^{1,3} The advent of recombinant human erythropoietin has brought intravenous iron treatment to the fore again⁴ as the drawbacks of oral iron (gastrointestinal side effects, lack of compliance, and variable absorption from the gut) are more relevant when the need for iron is increased.

We are therefore seriously affected by Fisons Pharmaceutical Division's recent action in stopping the production of its iron dextran product (Imferon). The situation has been made worse by the lack of prior notice and the lack of an intravenous alternative. To date information has been circulated only to hospital pharmacists, not to physicians. Our understanding is that production of Imferon has ceased, with no indication of when or if it will resume, so that the production system can be updated to meet new regulations of the US Food and Drug Administration on dextrans for intravenous use.

We question the ethics of this. Should a pharmaceutical company with a monopoly in the treat-

ment of an illness be able to stop producing a drug at will and without either consultation or due warning? Should it be allowed to do this merely to change manufacturing processes, when there is no legal requirement to withdraw the drug from the market on clinical grounds? Fisons has emphasised that Imferon has not been withdrawn because of unacceptable side effects. We do not understand why Fisons cannot continue to supply iron dextran to its customers in the United Kingdom while improving its production to meet the requirements in another country.

Intravenous iron treatment for patients receiving dialysis may represent only a small corner of the market, but there is no substitute. Our plea is for more consultation between drug companies and physicians before the supply of monopoly drugs is arbitrarily stopped.

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**We sent this letter to Fisons Pharmaceuticals, who replied as follows.

EDITOR,—Though I sympathise with Laura W Fleming and colleagues, I must point out that Fisons' decision to stop producing Imferon was not a commercial one. Revised quality control procedures have brought to light questions about the product's acceptability. These were first highlighted after the much publicised discussions with the US Food and Drug Administration.

Fisons is anxious to resume production of Imferon as early as possible and is currently ascertaining whether it is feasible to produce iron dextran in a way that would satisfy all the regulatory authorities of relevant countries.

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Gene therapy

EDITOR,—In the light of David Weatherall's review of my book¹ I urge readers of the *BMJ* to study the Clothier report for themselves.² Though Weatherall states correctly that the Clothier committee decided that germ line gene therapy should not be pursued, he wrongly implies that we therefore need not concern ourselves with its wider ethical implications.

Firstly, the Clothier report, in line with much of the medical scientific literature, recommends banning germ line therapy at present but makes allowance for it happening in future. "Gene modification of the germ line should not yet be attempted," states the report (section 5.2). The reason is, "we are clear that there is at present insufficient knowledge to evaluate the risks to future generations" (7.2).

Secondly, the distinction between somatic cell and germ cell therapy is not clear cut. Well respected commentators ask us to consider that if somatic therapy works then people treated successfully will grow up and reproduce. Would it not be better, they ask, to alter the egg and sperm cells of these people? Another reason for considering germ line therapy in future is that some diseases may not be treatable by the somatic cell approach—for instance, brain cells may be inaccessible to somatic therapy owing to the brain-blood barrier.

Thirdly, as the Clothier report admits, a possible danger is that germ cells may be affected inadvertently. "If the means of inserting the gene were faulty, it is conceivable, although in the present state of knowledge improbable, that the gene, or parts of it, might emerge from the cells and be 'infective,' moving to other somatic cells or germ line cells, or even to other individuals. This might cause harm to the treated patient and to others" (2.27c). Not only may germ lines be affected but people other than the patient may be physically affected.

These matters require intense public scrutiny and discussion. Yet the Clothier report paid relatively little analytical attention to these and other apparently non-scientific issues while much of it was devoted to explaining state of the art methods. The result has been a foreshortening of the discussion and inadequate scrutiny of the ethics of gene therapy.

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Torpid MPs

EDITOR,—John Warden describes parliament as already in a "state of torpor before it goes into three months' hibernation."¹ I know that parliament has some ancient customs, but I think that at this time of the year it aestivates (*Concise Oxford Dictionary*: "spend the Summer espec. (Zool) in state of torpor") rather than hibernates.

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- 1 Warden J. Doctors, dentists, and chemists. *BMJ* 1992;**305**:14. (4 July.)

Balloon inflation and chronic bronchitis

EDITOR,—As a bagpiper, I was interested in Anoop J Chauhan and colleagues' report that inflating rubber balloons may help patients with chronic bronchitis.¹ I have observed over many years that members of my pipe band, many of whom smoke and drink heavily, have a surprising degree of stamina. I suggest that this is due to regular lung exercise and the positive social and psychological factors associated with belonging to a band of musicians.

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