Letters

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Using patient identifiable data without consent

Obtaining individual consent may hinder studies

EDITOR—The editorial by Al-Shahi and Warlow is timely and well argued.[1] The implications of a strict requirement for written consent from patients in observational and epidemiological research are extremely serious. Research in histopathology would be particularly severely affected. It is essential that patients' consent is obtained in interventional studies or where information, or, in the case of pathology, tissue, is collected solely for the purpose of research. However, applying this requirement for every study of archived biopsy, surgical or necropsy tissue blocks, or review of patient records, where diagnosis has been made and where patient management will not be affected, is impracticable.

Studies of archival material have been the core of research in histopathology. A glance at the methods section of the papers of any pathology journal reveals that most have used archival tissue with no indication that specific patient consent has been obtained. For recent issues of the *Journal of Pathology*, *Histopathology,* and the *Journal of Clinical Pathology* the proportions of archival, non-consented research were 9/16, 9/9, and 11/13 papers, respectively.

Until now, this form of research has been simple and cheap to undertake, and has provided valuable information on the causes and pathology of many human diseases. It is unlikely that any of the large studies of gastric biopsies, cancers, etc would have been conducted had every patient or their relatives had to be contacted to obtain consent. We would be left with only anecdotal information on which to base prognosis and treatment for many common cancers and we would know much less about many common diseases. Despite considerable problems in obtaining funding for research in histopathology, authors in the United Kingdom continue to produce papers of high quality, but it is doubtful that this will continue if individual consent for each study becomes a legal requirement.

Either a general consent for use of residual tissues for research should be allowed or alternatively the NHS needs to fund the staff necessary to obtain the consent from central or regional research and development budgets, which could be accessed by researchers wishing to undertake archival studies. This would, however, be both cumbersome and costly. If observational research in pathology or other subjects and epidemiological studies are to be outlawed, the public interest will be damaged and patients in the future will be the losers.

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1 Al-Shahi R, Warlow C. Using patient identifiable data for observational research and audit. *BMJ* 2000;321:1031-2. (28 October.)

Argument for consent may invalidate research and stigmatise some patients

EDITOR—We would like to congratulate Al-Shahi and Warlow on their editorial.[1] A blanket requirement for anonymisation of data and informed consent from all participants to use identifiable data about them would jeopardise the methodological integrity of research and audit. This point has been highlighted during our recent work.

Patients with schizophrenia suffer from increased physical ill health and excess mortality.[2 3] As such patients increasingly rely on primary care for their physical health care, it is important to audit that the care they receive is comparable to that of patients who are not mentally ill. Our study, addressing this issue, was a case-matched retrospective review of primary care records. Local research ethics committees originally requested that patients provide consent. But systematic bias could invalidate the findings of observational studies if people were excluded because they did not consent.[1] Obtaining consent heightened this risk in our study for two reasons. Firstly, we are examining care given to patients—those feeling strongly about this (having had very good or poor care) may be more likely to consent. Secondly, study patients have schizophrenia and characteristics of the disease themselves—for example, paranoia—may reduce the likelihood of unwell patients consenting. Therefore, consenting patients could be less ill and better approximated to the control population. The need for consent may minimise the effect observed, potentially invalidating the results.

Production of substandard flawed research is less ethical than the use of anonymised data by professional researchers. Mental health research poses unique problems, and adopting the argument for consent may further stigmatise an already stigmatised group by the production of low quality research. After discussion, the three local research ethics committees we approached agreed with this. We were also confused by the Data Protection Act 1998 while trying to clarify whether our research fell under the umbrella "necessary for medical purposes." Practice recruitment was hindered by our inability to give firm guarantees about the work not breaching the Data Protection Act. We agree that the law needs clarification, to protect both researchers and the public. It may be appropriate for a committee to be appointed to review protocols prospectively in a similar manner to research ethics committees. We aim to research issues of clinical importance and attempt to select the most robust methods. It is inappropriate for researchers to have to choose between adopting a weaker and biased method or risk breaching the act.

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1 Al-Shahi R, Warlow C. Using patient identifiable data for observational research and audit. *BMJ* 2000;321:1031-2. (28 October.)
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Integrity of communicable disease surveillance is important patient care

EDITOR—As Al-Shahi and Warlow point out in their article there are conflicting goals: the drive toward greater patient autonomy and the wish to maintain an evidence base for medical practice by collecting and interpreting observational data.[1] Both are important, but the former should not needlessly jeopardise the latter.

The General Medical Council's guidance acknowledges the legal requirement for local statutory notification of certain infectious diseases without explicit consent (paragraph 43).[2] But non-statutory laboratory and clinical reporting systems have added appreciably to our understanding of communicable diseases. There is great concern that bias will arise in national reporting of incidents of infectious disease, either as a consequence of patients not agreeing to their infections being reported or because clinicians do not have the time or the opportunity to obtain explicit consent. Both will diminish, and potentially destroy, the surveillance of communicable diseases. In the short term, there might be failures to recognise or mount timely responses to adverse reactions to vaccines or to outbreaks of infectious disease, especially those that do not form local clusters but occur as a series of apparently sporadic cases countrywide. Only rigorous national surveillance and national collation of data will identify these events as coming from a common source.[3]

At the surveillance centres we rely on the goodwill of health professionals for prompt reports of communicable diseases. We are aware that all data relating to individual patients must be secure. Some within the healthcare professions, and some patients, however, feel that patients' right to privacy overrides the need to maintain surveillance. In response to such concerns we are continuing to seek ways of reinforcing the security of data entrusted to us.

The consequences if the surveillance of infectious diseases unravels include reduced quality or even loss of trend data; absence of monitoring residual incidence of infections preventable through immunisation programmes and inability to monitor effectiveness and safety of vaccines; delayed response to outbreaks; incomplete national data on HIV and other infectious diseases with serious long term consequences; possible failure to recognise imported and nosocomial infections and zoonoses; and inability to monitor effectiveness of interventions such as infection screening.

Just as detrimental in the long term would be loss of familiarity among health professionals with the epidemiology of infection, resulting in inferior care of patients and their contacts. The integrity of surveillance of communicable diseases is as important to the care of individual patients as to the health of the community as a whole. Strict precautions are already in place to protect confidentiality. Insisting on explicit individual consent as a prerequisite to the reporting of infectious diseases will serve neither patients' interests nor the wider public health.

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1 Al-Shahi R, Warlow C. Using patient identifiable data for observational research and audit. *BMJ* 2000;321:1031-2. (28 October.)
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Authors' reply

EDITOR—We are delighted by the supportive responses to our editorial. It is surely testament to the far-reaching implications of strict confidentiality and data protection guidance that authors from so many other disciplines have echoed our concerns: pathology, public health laboratory sciences, primary care and general practice, and unpublished electronic responses from oncology and clinical audit.[1] This further reinforces the need for urgent action to protect the wide range of activities carried out by bona fide professionals with a utilitarian desire to improve the public health.

It is absolutely essential that policymakers and the public are fully aware of the detrimental effects of excluding people—who cannot, or do not, consent—from ethically approved and peer reviewed observational studies (authorisation bias). As Cox, Roberts and Wilson, and Evans and Ramsay persuasively argue, studies subject to such bias may generate the wrong conclusions, thereby discriminating against current and future patients. The profound impact of authorisation bias does not seem to be as clear to policymakers as it does to researchers, perhaps due to the sparse literature on the subject.[2] We encourage anyone concerned about this issue to explore their own datasets for authorisation bias and publish their results. Moreover, this concern needs to be explained more to the public both in the national press[3] and by doctors when seeking their patients' consent.

Legislation and professional guidance on confidentiality and data protection have both moved on since our editorial. Clause 59 of the Health and Social Care Bill now enables the health secretary in England to sanction the use of patient-identifiable information for medical purposes in the interests of improving patient care or in the public interest.[4] The General Medical Council has given cancer registries a breathing space until October 2001 in which to put appropriate mechanisms in place for seeking and recording consent according to their guidance on confidentiality. But surely registries of all important diseases, and not just cancer, should be included? Nevertheless, any observational study will struggle to avoid authorisation bias under the GMC's terms.

We would welcome a return to pragmatic guidance on the conduct of observational studies that both protected patients and promoted medical progress.[5] But for now, will the medical community just stand back and allow people, with the best of intentions, to compromise the greater good of research, disease surveillance, audit, and clinical governance?

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1 Electronic responses. Using patient-identifiable data for observational research and audit. bmj.com 2000;321 (on www.bmj.com/cgi/eletters/321/7268/1031; accessed 30 Mar 2001).
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Postherpetic neuralgia

Findings differ from earlier results

EDITOR—The article by Helgason et al provides new data about the prevalence of postherpetic neuralgia in Iceland.[1] Their findings differ markedly in some respects from earlier retrospective findings. Two points in particular are at variance with British and American studies. The first is the proportion of patients with herpes zoster who develop postherpetic neuralgia and its duration. The Icelandic values are lower in both categories than those previously published from other countries.

A datum that is unfortunately missing from all studies is the age at which chickenpox, and therefore immunity, was acquired. It is well known anecdotally that postherpetic neuralgia is both rarer and less severe in people born on the Indian subcontinent; and there is considerable evidence that chickenpox occurs at a later age in this population.[2] Most doctors working in pain clinics have seen patients with severe postherpetic neuralgia of 20 or more years' duration. Most such patients have had their herpes zoster when they were younger than 50 years.

The second point is that the intensity of postherpetic neuralgia pain is rated as considerably more severe by most European and North American sources than it is by Helgason et al. The mean visual analogue pain intensity score of 246 successive patients attending our centre for pain relief was 86.2 at presentation, with 142 patients having a score of over 90 (L Cossins et al, fifth international congress on the pain clinic, Jerusalem, 1992). Although herpes antibody titres are probably a guide to the severity of herpes zoster and postherpetic neuralgia, this cannot be performed on whole populations. It would be interesting to

speculate, especially in view of the evidence from the Indian subcontinent, whether the age at which chickenpox occurs might give some prognostic indication of the incidence and severity of postherpetic neuralgia. Might this differ in the isolated Icelandic community in comparison with western Europe and North America?

The associated editorial by Cunningham and Dworkin advocates the pre-emptive use of low dose tricyclic antidepressants along with one of the newer antiviral drugs in the treatment of herpes zoster and prevention of postherpetic neuralgia.[3 4] Since we have urged primary care doctors in our area to prescribe low dose tricyclic antidepressants from the onset of herpes zoster, referrals to our pain clinic for postherpetic neuralgia have dropped from more than 100 per year to fewer than 30 per year.

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Competing interests: None declared.

1 Helgason S, Petursson G, Gudmundsson S, Sigurdsson J. Prevalence of postherpetic neuralgia after a single episode of herpes zoster: prospective study with long term follow up. *BMJ* 2000;321:794-6. (30 September.)
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Authors' reply

Editor—Bowsher's suggestions regarding the pathogenesis of the severity of pain after zoster are interesting. Our study was not designed to answer these questions, which therefore warrant further studies. The age at which children in Iceland acquire chickenpox is generally thought to be low and similar to northern Europe and the United States. Most children acquire chickenpox during the preschool years (aged from about 18 months to five years). We have no accurate data on this for most of our study subjects. In another study (by us) into young people who developed herpes zoster at a younger age than 20 years, information on age at time of chickenpox was available for 77 children.[1] Their mean age at the time of chickenpox was 3.1 years.

Contracting chickenpox late in life may be protective against postherpetic neuralgia, but that is not likely to have been the case for our study population. We share with Bowsher his recommendation of prescribing a low dose tricyclic antidepressant from the onset of herpes zoster but point out that these recommendations are based on only one study.[2] Further research is thus needed on the protective effects of tricyclic antidepressants on the development of postherpetic neuralgia.

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Competing interests: SH has received honoraria from GlaxoWellcome for lecturing on herpes zoster.

1 Petursson G, Helgason S, Gudmundsson S, Sigurdsson JA. Herpes zoster in children and adolescents. *Pediatr Infect Dis J* 1998;17:905-8.
2 McQuay HJ. Antidepressants and chronic pain. Effective analgesia in neuropathic pain and other syndromes. *BMJ* 1997;314:763-4.

Pathogenesis of postherpetic neuralgia should be determined

Editor—The article by Helgason et al suggests that postherpetic neuralgia is infrequent and benign.[1] This has not been our experience. In a community based study conducted over the past two years, general practitioners in East London referred acute cases of shingles for evaluation. Of 247 cases referred, 202 (84%) were confirmed as shingles by immunofluorescence and polymerase chain reaction. A total of 136 patients with a laboratory diagnosis have been followed up for six months and 134 for a year. Most patients (68%) were treated with aciclovir or analogues in therapeutic doses by their general practitioners. Patients were asked to report the presence of pain at six weeks, three months, six months, and 12 months, and the severity was assessed by subjective evaluation including interference with daily activities, visual analogue scores, and McGill questionnaires.

Numbers (percentages) of patients with postherpetic neuralgia who required analgesia after shingles by age

Time after shingles	Age <50 (n=57)	Age ⩾50 (n=79)
6 weeks	2 (3.5)	25 (32)
3 months	1 (1.8)	15 (19)
6 months	2 (3.5)	8 (10)
12 months	2 (3.5)	6 (8)*

*Data missing on two patients.

We found that of those aged 50 years and over, 15% (12/79) still had pain at six months and 12% (9/77) at one year. This is comparable with the Icelandic study, in which 8% of patients over age 50 still had pain at 12 months. The fact that 16% of patients with shingles in our study were wrongly diagnosed suggests that the figure for postherpetic neuralgia reported by Helgason et al is low. In contrast to the findings of the Icelandic study, our data suggest considerable morbidity from postherpetic neuralgia. Ten per cent of older patients (8/79) still required analgesia at six months and 8% at one year (table).

Postherpetic neuralgia was severe enough to interfere with daily activities, including sleep, in 9% (12/136) of our cohort at three months and 7% (9/136) at six months. The incidence of prolonged postherpetic neuralgia in our cohort, most of whom received antiviral treatment, is comparable with that in treated groups reported in other studies and lower than is seen in most untreated groups.[2 3] This would tend to support a role for antivirals in prevention of postherpetic neuralgia, and we therefore caution against abandoning their use in vulnerable groups. We agree with the editorial and commentary that more work is now needed to determine the pathogenesis of postherpetic neuralgia and to improve early identification of those at most risk of prolonged pain.

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1 Helgason S, Petursson G, Gudmundsson S, Sigurdsson J. Prevalence of postherpetic neuralgia after a single episode of herpes zoster: prospective study with long term follow up. *BMJ* 2000;321:794-6. (30 September.)
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Treatment with amitriptyline is cheaper than with aciclovir

Editor—Helgason et al report a low incidence of postherpetic neuralgia and suggest that as the absolute benefits of antiviral drugs are small, they may not be necessary.[1] They do not, however, mention evidence that the antidepressant amitriptyline also prevents postherpetic neuralgia[2]; neither do they estimate the cost of treatment. Our best estimate of the effectiveness of antiviral drugs is that oral aciclovir started within 72 hours of the onset of symptoms, reduces the incidence of pain at six months by 46%.[3] Our best estimate of the effectiveness of amitriptyline 25 mg a day in postherpetic neuralgia is that it reduces the incidence of postherpetic neuralgia at six months by 55% if started at presentation and continued for 90 days.[2] Consideration of the resource implications may clarify the relative merits of the interventions. A course of aciclovir costs £93.12 and 90 days' treatment with amitriptyline £0.77.

Using the estimates of Helgason et al of the incidence of postherpetic neuralgia at one year, we can calculate the numbers needed to treat to prevent a case of postherpetic neuralgia and the prescribing costs per case prevented (table). About 130 patients aged 70 or over will have to be treated with aciclovir to prevent one case of postherpetic neuralgia: a cost per case prevented of £12 146. About 109 patients aged 70 or older will have to be treated with

Cost per case of postherpetic neuralgia prevented

		Aciclovir		Amitriptyline	
Age (years)	Prevalence of pain at 12 months (%)	No needed to treat	Cost per case prevented (£)	No needed to treat	Cost per case prevented (£)
60-69	1.5	146	13 563	122	93
⩾70	1.7	130	12 146	109	83

amitriptyline to prevent one case of postherpetic neuralgia: a cost per case prevented of £83.

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Competing interests: None declared.

1 Helgason S, Petursson G, Gudmundsson S, Sigurdsson J. Prevalence of postherpetic neuralgia after a single episode of herpes zoster: prospective study with long term follow up. *BMJ* 2000;321:794-6. (30 September.)
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Why burden the pain clinic?

Editor—Cunningham and Dworkin's advice is stark and unequivocal: patients who get troublesome postherpetic neuralgia should attend pain clinics.[1] They have mentioned antidepressants in passing, but only as possible prophylactic drugs; they have not mentioned gabapentin at all. Yet these two drugs can be used in a general practice setting. Antidepressants for postherpetic neuralgia were comprehensively dealt with in an editorial in the *BMJ* three years ago.[2] Gabapentin is effective and improves mood, sleep quality, and quality of life.[3] It is licensed and has few side effects. Pain clinics are overstretched, waiting lists ridiculously long, and many consultants who run them read the *BMJ*. Such a journal should not be making out that the pain clinic is a sort of "black box" into which readers can pass specific troubles: it should be disseminating evidence based knowledge to a wide readership.

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1 Cunningham AL, Dworkin RH. The management of postherpetic neuralgia. *BMJ* 2000;321:778-9. (30 September.)
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Could fewer islet cells be transplanted in type 1 diabetes?

Insulin independence should be dominant force in islet transplantation

Editor—Waugh is correct in saying that demand for islet transplantation will exceed supply and the ratio of risk to benefit should be balanced for the individual patient.[1] Balancing the societal benefit of cost and utility hinges more on the definition of success. Accepting glucose stability rather than insulin independence has been discussed among our group but in the first instance we believe that freedom from insulin should be the goal. Unfortunately, the fact that few patients given islet transplants during the past two decades have become insulin independent has affected advances in the discipline. If we lower the goal posts now, when outcomes of islet transplantation have been radically transformed, this could delay advances further.

Transplantation of islets is beginning to emerge as an alternative treatment to transplantation of the whole pancreas in highly selected patients with type 1 diabetes. The risks associated with chronic long term immunosuppression are much less readily accepted by patients if freedom from insulin is not the predominant goal. Rather than accept second best, intensive research to expand the quantity of transplantable islet mass, coupled with anti-inflammatory strategies designed to promote the engraftment and long term survival of islets after implantation, will in time provide similar success with single donors. The goal posts of islet transplantation should not be lowered in favour of a subtherapeutic implant mass, at least until these avenues have been explored.

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1 Waugh N. Could fewer islet cells be transplanted in type 1 diabetes? *BMJ* 2000;321:1534. (16 December.)

Author's reply

Editor—I welcome the comments from Shapiro et al and wish them well with the research into harvesting outlined in their second paragraph. Better retrieval of islet cells would, however, not remove the question of best possible use. The cells could still be used for individually optimal use for one patient (insulin independence), or perhaps to provide less good results (good control but continuing injections) for two.

There are several research questions.

Firstly, what do people with type 1 diabetes think? Would they prefer one person to have insulin independence, or two to have good control but still need injections?

Secondly, what dose of islet cells is needed for very good control—and hence what options are available with one donor?

Thirdly, we need an economic study taking into account all costs and benefits, including quality of life impacts of insulin injections and immunosuppressant medications, good control of diabetes with reduction of both short and long term complications, and adverse effects of immunosuppression. Some of these questions may be unnecessary if islet cells can be grown in vitro, as envisaged in a review by Serup et al.[1]

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1 Serup P, Madsen OD, Mandrup-Poulsen T. Islet and stem cell transplantation for treating diabetes. *BMJ* 2001;322:29-32. (6 January.)

Non-combatants are often injured while clearing mines

Editor—Having worked for the HALO Trust—a British mine clearance organisation—as doctors (SH, EC) and mine clearers (PJ) in various parts of the world, we were interested in Hanevik and Kvåle's paper on landmine injuries.[1] We were surprised that most injuries were pattern 3 type as this type is uncommon in most populations after conflicts.[2 3] We suspect that the explanation given by the authors, of accidental handling of landmines, is incorrect, and we offer an alternative.

In our experience of countries after war, the returning civilians commonly attempt to clear landmines themselves as there is usually a delay before formal landmine clearance operations start. The population must clear essential buildings and water sources and establish supplies of food; it is a calculated risk. These operations are usually attempted by young males, often with disastrous consequences. The high incidence of pattern 3 injuries reported by the authors may be due to the deliberate handling of munitions by young men trying to make an area safe for their community.

We have found that pattern 3 is a common injury type among professional de-miners. The high incidence of this injury pattern in a young male civilian population suggests that these civilians have been engaged in amateur mine clearance. This underlines the diverse dangers of landmines to non-combatants and reflects the need for the prompt intervention of professional mine clearance agencies once the conflict has been stabilised.

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1 Hanevik K, Kvåle G. Landmine injuries in Eritrea. *BMJ* 2000;321:1189. (11 November.)
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3 Chaloner EJ, Mannion SJ. Antipersonnel mines: the global epidemic. *Ann R Coll Surg Engl* 1996;78:1-4.

Africa deserves better treatment from the West

Editor—HIV infection and AIDS have reached a critical level in Africa. We all know

that the most important tool we have is health education to create awareness about the disease and make people change their attitudes and eventually their practices, but more has still to be done.

As Editor's choice of 6 January pointed out,[1] HIV/AIDS is wiping out the cream of the continent—teachers, doctors, and farmers. The option of prevention has long passed for many. Any amount of education cannot bring back their lives; they can only be taught not to pass the disease on to others.

Doesn't the West think that a single life matters? Now millions in Africa are on death row. What does the West have to say about it? How about the babies born infected through no fault of their own? How much do people in the West talk about mad cow disease in Europe, which does not, as HIV/AIDS does, wipe out a whole generation? Anyone who has the means to save people from dying at the rate that they are in Africa and holds back is perpetrating genocide. Some of the West's wealth was built with the gold and diamonds of Africa and by African slaves breaking their backs in their plantations. Africa's younger generation deserves better treatment from the West.

The West is saying that even if it makes drugs available in Africa we in Africa don't have the means to deliver them to our patients. What nonsense. How about when the West sold the most modern war machinery to Africa? The world recently witnessed one of the most sophisticated wars between Ethiopia and Eritrea. Ethiopia has the infrastructure to fly its jet planes. If the West makes the drugs available I am sure that we can deliver them, though we might need a little help to do so.

You in the West must rally round to save lives in Africa. Forget about patents; put patients first. This time it is not about money, it is about lives.

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1 Editor's choice. Africa: a continent for the millennium. *BMJ* 2001;322(7277). (6 January.)

Osteoporosis is a risk factor, not a disease

Editor—The principal results of the Medical Research Council's trial of mild hypertension were published in 1985.[1] Many at the time were disappointed by the modest benefits of treatment, particularly for the cardiovascular (as opposed to the cerebrovascular) system. This work has resulted in re-evaluating how to prevent stroke and myocardial infarction. Hypertension is not of course a disease but one of several risk factors for stroke and coronary heart disease, and we as doctors can now give accurate assessments of absolute and relative risks to individual patients. This in turn allows us to focus our advice and treatment more appropriately.

As Masud and Francis point out in their editorial on the increasing use of peripheral bone densitometry,[2] osteoporosis describes the bone mineral density when it falls below an arbitrarily defined threshold. It is not a disease in its own right. Like hypertension it is a risk factor, one of several which may lead to the patient having a fracture.

Bone density scanning is popular. It is popular with doctors and patients as it gives a number which they believe they understand, with government as it can be used as a measure of activity in fracture prevention, and with hospitals as it generates income. Bone density scanning is, in short, sexy.

Bone density is, however, at risk of becoming the only treatable end point. Experience with hypertension and diabetes has shown that treating single risk factors yields poor results. For example, falls are crucial in the genesis of many fractures yet prevention of them is rarely discussed. All too often clinical decisions on treatment are based not on risk evaluation but on bone density values. Treatment is almost always with drugs, and doctors cannot be sure that their advice on the timing of treatment is appropriate at least in the case of hormone replacement therapy.

Masud and Francis point out the difficulties associated with measuring bone density and interpreting its results. As they state, fracture prevention is a multifactorial problem. They offer the prospect of risk evaluation based on multifactorial analysis to give both absolute and relative risks. Widespread screening should not be promoted until such risk evaluation is possible. When it is, doctors will be able to advise people at high risk about the appropriate mode of intervention and its timing and avoid overtreating those at low risk.

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1 Medical Research Council Working Party. MRC trial of treatment of mild hypertension: principal results. *BMJ* 1985;291:97-104.
2 Masud T, Francis RM. The increasing use of peripheral bone densitometry. *BMJ* 2000;321:396-8. (12 August.)

Refugee doctors find it hard to get back into practice

Editor—Cheeroth and Goraya reflect on the issue of asylum seekers and refugee doctors.[1] As a refugee doctor myself, I have some experience of what happens.

I graduated from the University Hospital Centre of Tirana, Albania, and then worked for 18 months as a senior house officer. I have been an asylum seeker in the United Kingdom for the past three years and at the moment am working as a nursing assistant in the oncology day care at the Harley Street Clinic. Since arriving in Britain I have passed the International English Language Testing System test with distinction twice (in June 1997 and, because the first certificate expired after two years, in January 2000). The General Medical Council will grant me limited registration as soon as I am offered a job, possibly a recognised training post.

It is not clear from the article that the council will not grant limited registration to doctors who have passed the Professional and Linguistic Assessment Board test unless they have a job offer. Applying in open competition without registration for a post, and coming from a current employment like mine, means that there is no chance of getting a job. I don't feel that I have been equal with other doctors who have gone for the same job as me.

The article suggests that clinical attachments are helpful. But most trusts charge overseas doctors up to £200 a week for such attachments. Doctors in these posts do not get paid for their work; that is fair enough if they are receiving benefit, but what if they are not, as in my case? How are we supposed to live? Another issue with regard to clinical attachments is that overseas doctors are not legally covered to see patients in these posts. How are they going to learn?

The NHS is short of junior doctors, and there may be 1000 refugee doctors in the United Kingdom. We could help if the various bodies such as the GMC, the BMA, and the Department of Health got together and resolved this issue; it would not cost anything near the £200 000 and five years that it takes to train a student through medical school.

NHS Carriers runs adaptation courses for nurses who want to get back into practice, and nurses are paid while doing them. Perhaps something similar could be organised for asylum seekers and refugee doctors.

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High dose methylprednisolone must be given for 24 or 48 hours after acute spinal cord injury

Editor—Short's letter about the use of steroids for acute spinal cord injury[1] leads me to question the quality of the purported systematic review that she and colleagues carried out. Trials were missed, and the authors relied heavily on uncontrolled or historically controlled case series and seemed to depend on cat experiments to evaluate risk of mortality.

Since the original trial of high dose methylprednisolone was published[2] it has been repeatedly documented that the second national acute spinal cord injury study included a subgroup analysis, which was specified in the protocol. This analysis was to test the rather obvious hypothesis that earlier administration of methylprednisolone might lead to greater efficacy.[3]

Eight hours was the (only) dichotomy analysed because it was the closest whole number to the median time between injury and the start of methylprednisolone. Subsequent trials in the national study, and other trials, used the eight hour window as an eligibility criterion and in so doing also specifically tested the eight hour hypothesis. Contrary to Short's statement, all the tested and reported comparisons were conducted in randomised patients.

Mortality data are available from three trials and show a relative risk of 0.54 (95% confidence interval 0.24 to 1.25) for death by six months after injury when 24 hour high dose methylprednisolone is compared with placebo or nothing.[4] The relative risk of overall mortality at one year in patients treated with 48 hour versus 24 hour high dose methylprednisolone is 1.11 (0.46 to 2.66). Thus there is no evidence in the literature on human spinal cord trials to raise concern about mortality. In all of these trials the absolute mortality among all patient groups is lower than might be expected from previously reported case series.

Evidence from all trials of acute spinal cord injury continues to indicate significant improvement in neurological motor function after high dose methylprednisolone is given for 24 or 48 hours.[4 5] Any new assessment of methylprednisolone and spinal cord injury might consider why the only documented pharmacological treatment to offer some improvement in neurological recovery without significant risk of harm is being denied some patients. People who continue to be uncertain about the role of methylprednisolone should conduct randomised controlled trials that address their concerns.

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Competing interests: Professor Bracken is principal investigator of the three North American national acute spinal cord injury trials, which were funded by the United States National Institutes of Health. He is an occasional paid consultant to Pharmacia-Upjohn, which is one of the manufacturers of methylprednisolone.

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Television programmes could market breast feeding

Editor—Henderson et al's paper looking at how breast feeding and bottle feeding are represented in the British media raises no surprises.[1] Perhaps this is the time for health authorities to consider working with the media to create and implement a social marketing initiative, using positive health messages, in soap operas or other programmes.

South Africa had an excellent social marketing initiative when I was there in 1996. Called "Soul City," it was based around eight key health messages, of which breast feeding was one. It was targeted at low income women aged 18-35 through a television soap opera, *Soul City*, with a tie-in radio programme and a specially written magazine.

In Britain, as happened in South Africa, market research would need to be done to ascertain the sorts of programmes that the target group watches and how these could benefit from input. Henderson et al's paper is a good starting point. It would seem from this that working mothers from "ordinary" backgrounds need to be portrayed positively, breast feeding at home and using a breast pump at work. The difficulty would be in convincing writers and producers to accept input without compromising their creativity. A financial contribution towards script development might have to be included in the budget for any such health promotion initiative.

No matter how well mothers are prepared for breast feeding prenatally, and how much support they receive while in hospital, after discharge they are likely to abandon breast feeding early unless wider community attitudes unsupportive of breast feeding change.

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1 Henderson L, Kitzinger J, Green J. Representing infant feeding: content analysis of British media portrayals of bottle feeding and breast feeding. *BMJ* 2000;321:1196-8. (11 November.)

Medical software's free future

All software developed at public's expense should be licensed as open source

Editor—The open source model for software is so sensible that it is bizarre that closed source models have held sway for so long.[1] Unfortunately, the title of Carnall's editorial gives the impression that open source software costs you nothing. This is not generally true. Open source software is "free as in speech, not as in beer."[2]

Commercial companies can make money out of open source software by charging for services such as distribution, warranties, support, installation, and tailoring. But these fees are likely to have some relation to the work involved. The up-front licence fees charged for closed source software are out of line with the cost structure. In no other industry are the products deliberately kept secret when that secrecy cannot be justified by safety or security concerns.

An obvious route forward for the public sector would be to state that all software developed at the public's expense be licensed as open source, although the General Public License may not be the optimum licence.[3] Licensing the software as open source provides optimum protection for the taxpayer; crown copyright, as it is currently used, does not do this. The gift culture ethos of the open source movement should fit in well with that of the NHS. As Carnall has argued elsewhere, "Open source is the future: all we have to do is build it."

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1 Carnall D. Medical software's free future. *BMJ* 2000;321:976. (21 October.)
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More and better programmers are needed

Editor—Carnall is correct when he says that the NHS is having problems with software procurement, but his view of open source development is too rosy.[1] Any large data handling project is a huge undertaking and needs expert developers, who have to make a living. The NHS simply does not employ these people in quantity, and it seems unlikely that developers working elsewhere will program software for altruism's sake. As with all open source projects, these developers would gain income from support, leaving us just as tied in to their system as to any other and still paying for the system. Free software is free as in "free speech."

The idea that having the source code would allow us to fix problems and take over the system's development is again optimistic. Reading code written by another developer, even if it is well structured, is extremely difficult. Bugs are as likely to be introduced as fixed.

The real problem with lots of the software used in the NHS is that it is badly written. Because we need so much so quickly, large numbers of low ability programmers can make money with low quality software. The ubiquity of Microsoft Windows as a desktop operating system, with its visual development tools, has meant that it is frighteningly easy for someone with little or no knowledge of good system design to turn out, say, a database. Often such systems work well in the author's setting, with the constant support and tweaking that that brings, but they are incapable of configuration for a different site with different requirements.

The real cost of a data system is the cost of collecting and inputting the data, its real value the information that you can get out of it; the cost of licensing software is trivial in comparison. The real software problem is

that we need better programmers—lots of them—and we need to pay for them.

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Summary of rapid responses

EDITOR—We received 34 responses to this editorial in addition to the letters published above.[1] Most (31) were in favour of a wider adoption of free software in the healthcare domain, but several authors raised notes of caution.

Richard Stallman noted that the GNU General Public License does not require software authors to publish any changed version of the software but compels them to respect the freedom of their users if they do. Steve Hajioff argued that free software did not have clearly established lines of accountability in the event of error and that, as its manufacturers' main revenue stream is from support, they have a perverse incentive to increase the number of support calls.

Obstacles that still stand in the way of the adoption of free software, according to Saal Seneviratne, include primitive user interfaces and inferior office software compared with proprietary equivalents made by companies such as Microsoft. Jan Paleta noted that the costs of licensing software tools are small in comparison to overall costs of a project, and Iain Buchan, Jonathan Honeyball, and Barry Tennison point out that most commercial entities choose to share the risk of maintaining critical software by buying software and that if they do not have software development as a prime function they would pay more and gain less than from using free software. These contributions were themselves the subject of debate: read it in full at www.bmj.com/cgi/eletters/321/7267/976.

Douglas Carnall *associate editor, BMJ*

1 Electronic responses. Medical software's free future. bmj.com 2000;321 (www.bmj.com/cgi/eletters/321/7267/976; accessed 19 Mar 2001).

Distinguishing between partial seizures and panic attacks

Psychotic and behavioural symptoms are also common in elderly patients

EDITOR—Thompson et al highlighted the considerable challenge in differentiating partial seizures from panic disorder and the considerable overlap that exists between the two disorders.[1] Patients with these disorders often present to old age psychiatry services and, perhaps not surprisingly, show slightly different psychopathology from that reported by Thompson et al.

In a series of 69 elderly patients identified through the Salford case register presenting to the old age psychiatry service with epilepsy (42 women), both generalised anxiety disorder (18) and depression (18) were common. Thirty three of these patients had partial seizures, nine of whom (seven women) presented with panic attacks. The frequency of these attacks was less than reported by Thompson et al, and five had fewer than one attack every three months. This no doubt contributed to the delay in diagnosis.

As well as symptoms of panic, these nine patients all had overt psychotic symptoms and behavioural disturbance. Three patients had delusions (paranoid, grandiose, and of reference), which were central to the clinical picture. Hallucinations were seen in seven patients (olfactory (three patients), auditory (two), and visual (two)), and several patients had a complex mixture of both delusional and hallucinatory psychopathology. Six patients described an aura, and three were noted to have automatisms. In three patients the original referral was precipitated by verbal and physical aggression, and this group presented particular management difficulties. The initial electroencephalogram showed epileptiform changes in five of the nine cases, with abnormalities being mainly on the right side (four cases). Three patients met ICD-10 criteria for depressive disorder, and three patients had a dementia illness (Alzheimer's, vascular, and alcohol related).

The complex relation between partial seizures and panic not only reflects the direct association between the two but also the independent relations that exist between both conditions and the diagnosis of depression, dementia, and alcohol misuse. Clinicians need to be alerted to this association not only in the clinical settings highlighted by Thompson but also in patients with more overt behavioural and psychological disturbances, as these features are common and seem to make diagnosis of partial seizures more difficult.

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Epileptic panic attacks are not limited to adults

EDITOR—Thompson et al pointed out that similarities in the clinical presentation of panic attacks and certain partial seizures can lead to difficulties in their classification.[1] Although we totally agree with this statement, we feel uncomfortable about the list of features typical of partial seizures that they presented. Age over 45 years at onset does not seem to be a distinctive feature of partial seizures. Since the incidence of epilepsy shows a bimodal distribution, with peak incidences among elderly people and in early childhood, partial seizures have to be considered also in children and young adults.[2]

We have recently seen a 7 year old boy who had recurrent nightly and daytime attacks with intense fear and vegetative symptoms. Among other differential diagnoses such as panic disorder, pavor nocturnus, and nightmares, an adjustment disorder was suspected because of misleading psychosocial circumstances (divorce of the parents). The boy received psychotherapy for more than two years without any effect on the attacks. Focal epilepsy was diagnosed only when two typical attacks with left temporal ictal epileptic activity were recorded by long term video electroencephalography. His condition was successfully treated by anticonvulsive drugs.

This case underlines the importance of considering partial seizures at any age, especially when panic attacks fail to respond to treatment. In addition to prolonged electroencephalography, as proposed by Thompson et al, ictal video electroencephalography may be needed to establish the correct diagnosis.

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1 Thompson SA, Duncan JS, Smith SJ. Partial seizures presenting as panic attacks. *BMJ* 2000;321:1002-3. (21 October.)
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Delivering bad news

Receiving bad news will always be unpleasant

EDITOR—Bad news is called bad news because it is … bad news. Most doctors are excellent communicators, but they have to give complicated, difficult, or unpleasant news to people who are anxious or frightened, or guilty or upset. The experience for patients or parents should be awful.

The anonymous Personal View by a patient diagnosed as having a sarcoma of the hand shows several of the tensions inherent in the doctor-patient relationship, which are exacerbated under the circumstances described.[1]

Firstly, there is the arousal gap. Every phrase, silence, and gesture is given a meaning by the patient far beyond its intention. The author complains about being ushered in first. Had that not happened, presumably the complaint would have been about being kept waiting. The patient found the direct eye contact and silences unnerving. The alternative might also have been criticised ("he avoided eye contact" or "he talked so I couldn't think or get a word in").

Secondly, the author thinks that he or she is a mind reader and the doctor should be one too. The author complains about the promised one month appointment taking place after three months (was it promised or just said?) and that the other people in the room were not introduced. But why didn't the author ask why the appointment was

longer and who the others were? The doctor should have explained why the appointment was delayed (but there turned out to be more important issues to talk about) and should have introduced the other people in the room. But the complaint might then have been, "he talked about the waiting time and the other people in the room when all I wanted to know about was the biopsy result."

Thirdly, the patient tells us that he or she is a psychotherapist. I am unimpressed when parents play the professional card. I tell them that when I take my children to the doctor I go as a parent, not a paediatrician. I need someone to think with the head, not the heart.

In the same issue of the *BMJ* a doctor who became a patient wrote, "Let the experts manage your treatment. . .. Embrace the sick role. For the time being you are not in control."[2] Despite training, the author of the Personal View clearly does not recognise the anger, guilt, and fear that are motivating much of what is described, including the petulant remarks about omniscience, which belie the claims for professional recognition. The *BMJ* could helpfully have asked the orthopaedic surgeon to give his side of the story.

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2 Hosking E-J. How to cope with time off sick [career focus]. *BMJ* 2000;321(classified section 11 Nov):2-3. www.bmj.com/cgi/content/full/321/7270/S2-7270

Not all surgeons can counsel, and fewer psychotherapists can operate

EDITOR—I sympathise with the experience of the author of the Personal View in the inability of his or her orthopaedic surgeon to break bad news,[1] but what did the author expect?

In all my undergraduate and postgraduate training I have never been taught how to approach this subject. Some people have a natural ability to be more sympathetic than others, and some—such as the surgeon in the article—do not. But does this really matter? In the ideal world all surgeons would, as well as being technically brilliant, be sensitive, gentle, caring, and understanding people who were adept at counselling. To some of us this may come naturally; to others it may have to be taught. However, I would rather have surgeons who had spent more time improving their operative skills than learning how to be a psychotherapist.

Assuming that all qualities are not often found in one person, would the author of the article rather have a rude, insensitive, but competent surgeon or a gentle and sympathetic one who couldn't tie his or her shoelaces let alone operate. I would speculate that most of the readers of the *BMJ* would have no difficulty in deciding which one to choose.

The author of the article is a psychotherapist and was looking for qualities in the surgeon that psychotherapists deliver in their own professional activities. The author forgets, however, that sensitivity is the very essence of a psychotherapist's work while surgery is the very essence of ours. Not all surgeons can counsel, and even fewer psychotherapists can operate.

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1 Delivering bad news. *BMJ* 2000;321:1233. (11 November.)

Communication skills must be part of medical education in all specialties

EDITOR—I read the anonymous Personal View with sadness.[1] At one level the doctor whom the author is talking about has succeeded in diagnosing and treating a malignant sarcoma. He exhibited great skill and technique, and the end result was good. The surgeon won a victory and cured the cancer. Surely we should be celebrating?

Instead we see the results of failing to communicate with the patient. The surgeon seems not to realise that language is a sharper and more dangerous instrument than any scalpel. By his use of language he has caused a wound to appear that need never have been made. This is an iatrogenic injury and should be regarded as badly as any other unnecessary side effect of medicine.

To receive my certificate of approval to work as a general practitioner I had to demonstrate basic competence in communication skills by means of a series of videotaped consultations. So far as I know, none of the hospital based specialties has this requirement in their training programmes, even though all doctors are communicating constantly with their patients and each other.

In the light of cases such as the one described in this article, it is surely time for teaching and formal assessment of communication skills to be a key part of undergraduate and postgraduate medical education in all specialties.

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1 Delivering bad news. *BMJ* 2000;321:1233. (11 November.)

Empathy is important for enablement

EDITOR—Reilly's editorial on enhancing human healing mentions the pilot work that we have done on the impact of homoeopathic consultations on patient enablement.[1] "Enablement" describes the effect of a clinical encounter on a patient's ability to cope with and understand his or her illnesses.[2]

We collected 200 valid questionnaires from 230 consecutive outpatients attending the Glasgow Homoeopathic Hospital, an NHS facility that integrates complementary and orthodox approaches. Measures included the patient enablement instrument,[2] perception of the doctor's empathy,[3] and knowing the doctor well.[2]

The mean consultation length was 56 min for new patients (n = 26) and 20 min for follow up patients (n = 174). Enablement was not directly related to length of consultation but correlated with the patient's perception of the doctor's empathy (Spearman's correlation 0.371, $P < 0.001$). The overall average enablement score (mean 4.7) was some 50% higher than the average in primary care.[2] Overall, 118 of the 200 patients rated the consultations at Glasgow Homoeopathic Hospital as better (n = 66) or much better (n = 52) than their usual consultations with their general practitioners; 99 of the 118 rated the consultations as better (n = 38) or much better (n = 61) than consultations with other hospital specialists.

These findings suggest that empathy is important in enabling patients; no patient reported a high enablement score with a low empathy score. Clearly the generalisability of this association needs to be established in other settings. In general practice, enablement is enhanced by longer consultations and continuity of care,[2] and we are currently investigating the role of empathy in this.

Empathy is often cited as a core value in the health profession, yet its lack in modern medicine seems to be widespread.[4] The call to integrate complementary treatments into the NHS is one issue, but the organisational, structural, and personal limitations that general practitioners and hospital specialists in conventional medicine face in trying to provide holistic care is a wider one. Needing to prove that compassion is not a luxury but a fundamental requirement of a healthcare system is a damning indictment of our current ways of thinking. Yet without the scientific method and focused research, it seems certain to slide from neglect[5] to decay.

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1 Reilly D. Enhancing human healing. *BMJ* 2001;322:120-1. (20 January.)
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Radiation dose from depleted uranium can now be measured

EDITOR—In her editorial about depleted uranium McDiarmid agrees that there is no

justification for any claims of radiation induced lung cancer and leukaemia in veterans of the Gulf war.[1] She makes no mention, however, of how individual radiation doses can be measured in any screening of Gulf war and Balkan veterans.

This is important not only for veterans' peace of mind but also for medicolegal purposes. For due process of law in the courts of the United States and the United Kingdom, where some veterans are currently taking legal action for possible radiation induced illnesses, depleted uranium must first be ruled in before being ruled out if the doses are found to be too low. Global dose estimates or results of mathematical modelling are too inaccurate to be used as dose values for an individual veteran. To date no practical method has been proposed for measuring the expected small doses received by veterans.

I suggest that electron paramagnetic resonance dosimetry using tooth enamel would be an appropriate method. It has already been used after the 1986 accident at Chernobyl for some of the clean-up workers and evacuees from the 30 km exclusion zone.[2] Electron paramagnetic resonance dosimetry using tooth enamel has also been used for some of those exposed in the Techa river area and Mayak facility in the eastern Urals, where Soviet nuclear warheads were produced for many years, resulting in widespread contamination. This was reported by a group at the Institute of Metals in Ekaterinburg.[3] The research at Ekaterinburg has continued at the National Institute of Standards and Technology of the United States Department of Commerce in Gaithersburg, Maryland, to which some of the Ekaterinburg scientists have relocated.[4]

The national institute's group can now measure electron paramagnetic resonance dose estimates down to a level of 20 mSv.[2] The institute is organised such that, if requested, it can undertake electron paramagnetic resonance tooth enamel dosimetry for any source, including European veterans. This was confirmed to me by the chief of the ionising radiation division at the institute (B Course, personal communication, 1999). Hence at least one centre can be incorporated into any screening programme for veterans; as the technology becomes more widely available more facilities can be expected to be suitable for this form of low level radiation dosimetry.

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Competing interests: None declared. RFM is not employed as a consultant to the National Institute of Standards and Technology; he only corresponds and exchanges academic papers with the institute. He is a consultant in radiation oncology.

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Trial experience and recollection of consent

Editor—Elbourne et al in their article discuss a common, and entirely avoidable, problem.[1] People asked to sign consent forms, for both research and treatment, often do not recollect the exact details later. This is perfectly understandable. The courteous and common sense thing to do is surely to give all trial participants, parents of children in trials, and ordinary patients not in trials, a copy of the consent form they have just signed. The form should be accompanied by an information sheet giving all relevant details (including randomisation if any).

This should not replace verbal explanation but supplement it. This strategy would avoid much confusion, unhappiness, and even perhaps litigation. It is amazing to us that such a simple procedure, which is routine in business transactions, is still not observed routinely in clinical practice in the United Kingdom.

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1 Elbourne E, Snowdon C, Garcia J, Field D. Trial experience and problems of parental recollection of consent. *BMJ* 2001;322:49-50. (6 January.)

Most psychiatrists oppose plans for new mental health act

Editor—In his editorial Szmukler expressed concerns about government plans to introduce legislation that would enable the preventative detention of people classified as having a dangerous severe personality disorder.[1] We believe that most psychiatrists in Britain share these concerns.

This view is supported by the results of a survey that we conducted last year, which entailed sending a brief questionnaire to every consultant psychiatrist in England and Wales. The questionnaire provided background information on what at that point was known about the proposals.[2]

We mailed the questionnaire to 2655 consultant psychiatrists and received 1171 (44%) replies. Overall, 735 (62%) responded that they were against the plans, 230 (20%) supported them, and 214 (18%) said that they were unsure about them. In addition to this, a substantial minority (363 (31%)) said that they would be prepared to refuse to implement this legislation, and 625 (53%) wrote additional comments in a space provided on the form. The most frequent comment was that more information was needed before a clear view about the proposals could be reached. Many expressed concerns about the reliability and validity of this diagnosis. Others felt the proposals were oppressive and antitherapeutic and would result in psychiatrists becoming increasingly involved in the process of social control. Few comments in favour of reviewable detention were made.

At a time when psychiatrists and other healthcare professionals are rightly being encouraged to practice evidence based medicine, evidence concerning the management of people who are diagnosed as having personality disorders remains largely absent. What we do know is that discrete personality disorders do not exist and that levels of agreement between clinicians about who should be classified in this way are often no better than chance.[3 4] Antisocial personality traits tend to persist, and no interventions have been shown to change their course.[5] Although society has a right to be protected from those who commit violent offences, the moral basis for allowing the detention of those who have not been convicted of a crime is as questionable as the evidence to suggest that the medical profession can be involved in their "treatment."

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4 Moran P. *Should psychiatrists treat personality disorders?* London: King's College, University of London, 2000. (Maudsley discussion paper No 7.)
5 Black DW, Baumgard CH, Bell SE. A 1- to 45-year follow-up of 71 men with antisocial personality disorder. *Comprehensive Psychiatry* 1995:36;130-40.