Letters

Suspension of nurse who gave drug on consultant's instructions

What has happened to clinical freedom?

EDITOR—My first reaction on reading John M Kellett's article was one of anger. The article concerned the suspension of a nurse who, on a consultant's instructions, had added haloperidol to a cup of tea given to a patient who had refused the offer of admission or a tranquilliser.¹ Why should what, in my experience as a psychogeriatrician, was a not uncommon procedure be made the subject of such administrative overreaction?

But as I brooded on the matter my anger gave way to concern. I noted that the unit general manager subsequently instructed the consultant "to stop releasing information of this type [that is, an account of his clinical actions and the reasons for them] to relatives or patients." I also noted that the consultant was "invited" to meet the unit general manager and senior community physician to "discuss" the matter; that this was in fact a disciplinary procedure is clear, the consultant being told to "avoid publicity" pending a regional inquiry.

When I was a student I was taught that the responsibility of doctors to their patients was a personal one and that their actions were subject only to the judgment of their peers (that is, the General Medical Council) or the courts—usually civil but, in extreme instances, criminal. When did it become acceptable for a manager (who presumably has no medical training at all) and a community physician (who, despite his or her own skills, is unlikely to fulfil the college's requirements for a consultant post in the psychiatry of old age) to give instructions to or discipline a consultant? What has happened to clinical freedom?

As for the unfortunate sister, it should have been sufficient defence for her to say that she had done as the consultant instructed—had done it not in slavish obedience but because, in discussion, she agreed that it was the correct approach. This would make it a joint decision but the consultant's responsibility. Then when, very properly, the patient and his family were told what had been done and accepted that it had been done in the patient's best interests, that should have been the end of the matter.

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1 Kellett JM, Griffith D, Bell A, Short J, Adshead G. A nurse is suspended. BMJ 1996;313:1249-51. (16 November.)

Doctor and nurse were subjected to "macho management"

EDITOR—The events described by John M Kellett are disturbing but not unique.¹ Putting haloperidol in the patient's tea was surely preferable either to letting him go home untreated or forcibly restraining him so that he could be given an intramuscular neuroleptic. That this approach, although deceitful, was the most appropriate clinically and ethically—and valid legally—is beyond dispute. The contentious aspect of this case, I believe, is the treatment not of the patient but of the nurse.

It is disappointing that neither of the commentaries refers to the ethics of allowing one person (the senior nurse manager) to have the power of ordering immediate suspension in such circumstances. At best the decision seems to have been uninformed; at worst it could be seen as vindictive. Certainly, the rationale for the suspension was flawed. Yet, although the act inevitably resulted in great distress for the nurse and the loss to the local service of an experienced member of the team, the nurse manager has remained unaccountable. The consultant, although treated less outrageously, was still disciplined and subjected to quasilegal constraints on his clinical autonomy and freedom to communicate with colleagues. Both individuals were subjected to "macho management" that has done nothing to improve patient care and may have adversely affected the effective functioning of the multidisciplinary team.

Discussion on the ethics and legality of clinical acts is, of course, vital. I believe that this forum should also have considered the ethics of the actions of the health service managers in this case.

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1 Kellett JM, Griffith D, Bell A, Short J, Adshead G. A nurse is suspended. *BMJ* 1996;313:1249-51. (16 November.)

Ethics of giving drug treatment covertly needs further discussion

EDITOR—I was pleased to see John M Kellett's article about the disciplinary action taken against a sister at a day hospital who administered a drug covertly on the instructions of a consultant.¹ I hope there will be further professional consideration of the ethics of giving drug treatment covertly, as well as of the disciplinary processes invoked.

The paper and one of the commentaries on it, however, contain several inaccuracies.

When Kellett sought my advice as chairman of the consent to treatment committee of the Mental Health Act Commission I made it clear that the commission did not give advice on the ethics of treatment or on the application of the Mental Health Act to individual cases. I also emphasised that any indication by me that this case might represent an exception to the general rule, on the basis of the information supplied by Kellett, was entirely a personal opinion. In fact, the provisions of the Mental Health Act that concern consent to treatment do not apply in the situation described. The patient was not detained under the act and, contrary to Dave Griffith and Alison Bell's conclusion,1 he was not "liable to be detained." This term applies only to patients who are detainedfor example, patients on leave of absence under section 17. It does not apply to patients being considered for detention.

Griffith and Bell also refer to the terms of section 62(1), relating to urgent treatment. This section applies only to detained patients subject to the provisions of section 58. Neither the act nor the code of practice includes the phrase "if medication has to be administered by force." The issues relating to

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Letters should be typed and signed by each author, and each author's current appointment and address should be stated. We encourage you to declare any conflict of interest. Please enclose a stamped addressed envelope if you would like to know whether your letter has been accepted or rejected.

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Letters will be edited and may be shortened.

the covert administration of drugs were referred to in the commission's sixth biennial report, when the commission suggested that the Royal College of Psychiatrists and the Royal College of Nursing should consider this issue.2 In the most recent edition of the Mental Health Act Manual Jones refers to this suggestion and interprets the commission's comments as "equivocal" and "regrettable" on the grounds that common law tests cannot override the clear statutory language of section 58(3)(a).

Chapter 15 of the current code of practice describes the principles that should be considered in such cases. Kellett does not make it clear whether he concludes that the patient had the capacity to consent, as is implied by his being "cognitively intact," or whether he lacked capacity at the relevant time, in which case different legal considerations apply.

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- Kellett JM, Griffith D, Bell A, Short J, Adshead G. A nurse is suspended. *BMJ* 1996;313:1249-51. (16 November.)
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Engage staff in programmes to raise ethical awareness

EDITOR-John M Kellett gives details of a case in which a nurse was suspended after the surreptitious administration of haloperidol to an elderly patient. This shows well the damage wrought by a traditionalist management style on a multidisciplinary team faced with hard clinical choices, none of which are intuitively right but some of which may be considered less wrong than others. How much better it would be if managers helped valued employees to develop effective strategies for working through difficult decisions, thereby distributing responsibility for actions and eschewing this dysfunctional activity of apportioning blame. We contend that such pragmatism would lead to improvements in the quality of the delivery of services and give morale a much needed boost. This view is further strengthened by the recognition in common law that health providers that fail to install adequate procedural support for the actions of their employees may be vicariously or even primarily liable.2

One approach being explored by our organisation is that of a trustwide ethics initiative engaging employees across all disciplines and at all levels within the hierarchy. At a recent consensus workshop attended by a representative sample of 59 employees 55 (93%) answered a questionnaire. Forty two respondents identified at least one major ethical dilemma at work per week and 40 reported that most dilemmas involved some aspect of patient care. The most commonly encountered difficulties concerned patients' rights (48 respondents), patients' autonomy (37), and the appropriateness of treatment (34).³

In response we propose to develop an "ethical culture" with a view to enhancing employees' understanding and management of ethical problems and permitting better working relationships at all levels of the organisation. We are evaluating our existing level of skill and recognise the need to engage staff in development and audit programmes to raise ethical awareness. By encouraging explicit and transparent decision making we hope to obviate any need for draconian measures. Disciplinary procedures should be reserved for clear cases of misconduct and not misapplied when occasionally, by the nature of our work, things do not turn out as we would wish.

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- Kellett JM, Griffith D, Bell A, Short J, Adshead G. A nurse is suspended. $BM\!J$ 1996;313:1249-51. (16 November.) Lybert v Warrington Health Authority (1995) 25 BMLR
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Over a third of psychiatrists had given a drug surreptitiously or lied about a drug

EDITOR-John M Kellett's article and the accompanying commentaries raise an interesting ethical debate on the surreptitious administration of drugs.1 The debate is of particular interest to us because we work in a mental health trust.

David Griffith and Alison Bell briefly mention issues concerning the Mental Health Act 1983.1 Of course, medical treatment can be given without consent in emergency or life threatening situations.2 We believe that, in the case presented, treatment under section 2 of the Mental Health Act 1983 would have been more appropriate; section 2 of the act, however, would still not have allowed the surreptitious use of drugs.

We were curious to find out doctors' experience of surreptitious prescribing and their honesty in giving patients information about drugs. We devised and used a questionnaire to survey a random sample of senior, middle grade, and junior psychiatrists working in Heathlands Mental Health NHS Trust. There was no requirement for doctors to give their name, and all 21 psychiatrists whom we approached replied. Six of the psychiatrists admitted to having ordered a drug to be given in a disguised way. Only one admitted to having given the drug personally. Five doctors said that they had lied about the type of drug prescribed. Three more admitted to having lied about the dose and the effects of the drug. Of the eight psychiatrists who admitted having taken part in any of the above practices, two said that they had always told the patients afterwards, four sometimes, and two never, but all thought that their practice was justified.

In total, therefore, over a third of doctors in our sample (38%) admitted either having participated in surreptitious prescribing or

having been economical with the truth when giving information to patients. This figure, however, may be an underestimate because on direct questioning several respondents said that they felt uncomfortable about admitting to lying. We suggest that any similar such inquiries should be non-judgmental and may be better addressed either by a peer at the same professional level or by anonymous questionnaires.

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- Kellett JM, Griffith D, Bell A, Short J, Adshead G. A nurse is suspended. *BMJ* 1996;313:1249-51. (16 November.)
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Concealed administration of drug treatment may represent thin end of the wedge

EDITOR-The article by John M Kellett and the associated commentaries about the suspension of a nurse raise many ethical issues.1 In response, the higher trainees in psychiatry on the Charing Cross Hospital rotation recently devoted an academic session to discussing these matters.

Firstly, we were surprised to find that there is little specific guidance on the issue of deception, as noted in the commentary by David Griffith and Alison Bell.1 Certainly, the BMA's publication on ethics does not address these matters directly.2 In such circumstances doctors must seek to draw their own conclusions. The unanimous conclusion of our meeting was that the doctor and nurse involved in the case that Kellett reports acted in the patient's best interest. The alternative course of action-restraint and forced drug treatment-might well have caused more physical and psychological harm. Concern was expressed that deception cannot be differentiated ethically from lying,3 although we did not consider this to be a sufficient argument to alter our general conclusions.

Secondly, we thought that caution was necessary. Many of us had witnessed the concealed administration of drug treatment during our training—often in cases in which it was less clearly in the patient's best interest than in the case discussed by Kellett. We believe that some groups of patients are more vulnerable to such practice-for example, they have a reduced ability to detect concealed drug treatment, are more likely than other groups to be injured by physical restraint, and are often not in a position to protest. With this in mind it is well to take account of arguments against deception: that it may potentially destroy trusting relationships with patients and, particularly, may represent the thin end of the wedge and give rise to abuse.

Finally, it has been our frequent experience that nursing management can be extremely punitive. There was no clear

agreement, however, over whether such knowledge should influence our practice. Whereas one could argue that doctors finding themselves in the same position as the doctor in the case discussed by Kellett should give the drug treatment themselves, an equally strong argument can be made that this constitutes medical paternalism and that other professionals should be able to make decisions for themselves.

In view of the obvious problems raised by this case, is it not time for the BMA to address the issue of deception directly, preferably in conjunction with the nursing and other professions?

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- Kellett JM, Griffith D, Bell A, Short J, Adshead G. A nurse is suspended. *BMJ* 1996;313:1249-51. (16 November.)
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**We received 13 other letters commenting on Kellett's article, all of which criticised the management and argued that the nurse should not have been suspended.-Editor

Criticism of study of childhood leukaemia near French nuclear reprocessing plant is unfounded

EDITOR-Two weeks ago Dominique Pobel and I reported our case-control study of leukaemia among young people near La Hague reprocessing plant. Dr Jacqueline Clavel, of Unit 170 of Inserm, which is the French national institute of health and medical research, has been quoted in the French lay press as criticising our results.² She argued that the geographical location of the homes of subjects who participated in the study could explain the significant results (use of local beaches and residence in a house built of granite materials) by acting as a confounder.

We were obviously aware that living in the immediate vicinity of one of the beaches might increase the likelihood of a child visiting a beach to play, but, as we stated in our discussion, controls were matched on the general practitioner's catchment area. In Dr Clavel's opinion, however, this was insufficient. She postulated that the higher proportion of cases reported to have used the local beaches simply reflected the geographical distribution of their homes. Furthermore, she said that houses built of granite materials were not unlikely to be located on the coastline and therefore reflected proximity to the sea. Unfortunately, she did not provide any figures to support these statements, which contradict what is known about local traditional dwellings: that they are mainly located in the country and not on the coast, to avoid the effects of wind.

To address this issue I have estimated three distances as the crow flies: the distance between the home of each case and control and the closest coast (in whatever direction), and the distance between the home and the two most popular beaches in this area (Vauville and Urville-Nacqueville). Vauville beach is located near the pipeline used by the nuclear reprocessing plant to release liquid nuclear effluents, and Urville-Nacqueville beach is situated not far from the mouths of the rivers coming from the reprocessing plant and the low level radioactive waste depository. There was no significant difference between the groups of cases and controls in each of the three distances (P > 0.36, Mann-Whitney test; table 1).

The potential geographical bias suggested by Dr Clavel can therefore be dismissed and does not affect our study's results. I hope that this additional information will clarify the debate surrounding the conclusions of our study.

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epidemiology Department of Public Health, Faculty of Medicine, 25030 Besancon, France

- Pobel D, Viel JF. Case-control study of leukaemia among young people near La Hague reprocessing plant: the environmental hypothesis revisited. *BMJ* 1997;314:101-6.
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Study design and nature of diabetes may explain findings of Finnish study

EDITOR-Seppo V P Koskinen and colleagues show that the expected social class gradient in mortality is abolished in Finnish people with diabetes. They suggest that the most likely explanations are a lack of social class differences in health behaviours and an equitable health service. But it is difficult to see why Finnish people with diabetes adopt healthy lifestyles regardless of social class whereas non-diabetic Finnish people do not. Several studies indicate that the social class gradient in health behaviours persists in people with diabetes² and that glycaemic control-in part a reflection of equity in access to health care—is poorer in lower social classes, even in Finnish adolescents.5

Table 1 Mean (SD) distance of cases' and controls' homes to sea in La Hague area

Distance (km)	Cases (n=27)	Controls (n=192)	P value
Closest coast	5.41 (5.38)	5.57 (5.61)	0.99
Vauville beach	18.79 (8.17)	20.55 (8.36)	0.36
Urville-Nacqueville beach	15.96 (8.95)	16.97 (10.13)	0.75

Other explanations need to be sought. Non-insulin dependent diabetes is more prevalent in people of low socioeconomic status, while there is little evidence for a social class gradient in insulin dependent diabetes.4 Thus the proportion of all diabetes that is insulin dependent will be highest in the most affluent people, and insulin dependent diabetes in this nonelderly cohort is associated with a greater risk of death than non-insulin dependent diabetes. Furthermore, patients who were treated with diet alone could not be identified as having diabetes and were therefore not included in the study population. The proportion of diabetes that is treated by diet alone is highest in the uppermost social classes. These people have a more favourable mortality experience than diabetic patients treated with drugs or insulin, and their exclusion may thus have attenuated the social class gradient in mortality.

Finally, it is clear that the development of diabetes depends on a complex interaction between genetic and environmental factors. While it is reasonable to assume that the genetic burden of diabetes is similar across social classes, the environmental trigger (usually obesity) is more common in more deprived groups. There is evidence that lean people with diabetes have a strong genetic burden of disease and are at an increased risk of complications.5 Again, these people will constitute a greater proportion of the diabetic population in the higher social classes, and this would also attenuate the social class gradient in mortality.

We suggest that there are more plausible explanations for the Finnish findings, which have more to do with study design and the nature of diabetes than with changes in health behaviours or healthcare services.

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Data on eligibility for thrombolytic treatment can indeed be generalised

EDITOR-Eligibility for thrombolytic treatment in patients presenting with acute ischaemic chest pain depends on the electrocardiogram at the time of admission, the delay from the onset of symptoms to presentation, and the presence or absence of contraindications. Adam D Timmis¹ does not seem to have considered the appreciable number of patients with a discharge diagnosis of definite myocardial infarction who presented with ST depression, T wave inversion, or a normal electrocardiogram—32% in our prospective series, 36% in Trent, and 31% in the second international study of infarct survival. The remainder (64-69%) represent the ceiling for eligibility for thrombolytic treatment before the delay from the onset of symptoms is taken into account. In the second international study of infarct survival only 69% were eligible for thrombolytic treatment on the basis of electrocardiographic criteria alone, and 15% of the total group presented more than 12 hours after the onset of symptoms.

Timmis uses a discharge diagnosis of definite infarction as his denominator. We consider this approach to be unhelpful for audit because it is retrospective, includes a varying percentage of patients who do not fulfil the criteria for treatment, and excludes patients in whom infarction may have been aborted by reperfusion treatment. Indeed, 7% of our patients with ST elevation or bundle branch block did not have an increase in myocardial enzymes to twice the normal value. What is critical is the proportion of eligible patients (that is, those presenting within 12 hours with ST elevation or bundle branch block of new onset and without contraindications) who are treated. The number of patients with these criteria will vary from hospital to hospital, but the goal should be to treat them all.

Our data from Auckland were derived from four coronary care units covering the entire metropolitan area and rural areas (composing a tenth of the region's population) roughly 60 km to the north and south. Altogether 77% of our patients presented within 12 hours of the onset of symptoms. We consider that our results can be generalised and that appropriate rates of use of thrombolytic treatment should be audited on admission, with full consideration being given to the criteria relating to indications and contraindications. If this is done, about half of patients presenting with suspected acute myocardial infarction are eligible to receive thrombolysis, and in our series 88% of these were treated.

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 Timmis AD. Data on eligibility for thrombolytic treatment cannot be generalised. BMJ 1996;313:941. (12 October.)

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- 2 French JK, Williams BF, Hart HH, Wyatt S, Poole JE, Ingram C, et al. Prospective evaluation of eligibility for thrombolytic therapy in acute myocardial infarction. BMJ 1996;312:1637-41. (29 June.)
- 3 Ketley D, Woods KL. Selection factors for the use of thrombolytic treatment in acute myocardial infarction: a population based study of current practice in the United Kingdom. The European Secondary Prevention Study Group. Br Heart J 1995;74:224-8.
- 4 ISIS-2 (Second International Study of Infarct Survival) Collaborative Group. Randomised trial of intravenous streptokinase, oral aspirin, both, or neither among 17 187 cases of suspected acute myocardial infarction: ISIS-2. Lancet 1988;ii:349-60.

Promoting health in prisons

NHS would provide an inferior service

EDITOR-As a practitioner in prison health for the past 14 years, I am becoming increasingly irritated by those who criticise the prison healthcare service from the outside. I also believe that the claim that the NHS provides the gold standard of patient care can no longer be rationally justified. How many NHS patients can be seen with comparative ease by a doctor whom they know at, say, 2 o'clock in the morning, as prisoner patients can expect? How many NHS patients at a similar time of day will be attended by a doctor who has full and ready access to his or her medical history? How many NHS patients can be seen without an appointment on the day that they decide that they wish to see their general practitioner? How many NHS patients can be seen by a consultant in a far shorter time than is available to those in the community? How many NHS patients will receive their medication and all treatment free?

It is traditional to regard drug misuse, mental illness, and suicide among prisoners as indicating failure by prison doctors. Drug misuse in prisons is caused not by prison doctors but by failure to stop drugs coming into the establishments. The incidence of mental illness in prisoners is caused by lack of community resources and by magistrates having no alternative but to remand people into custody as a place of safety. The incidence of suicide in inmates does not reflect directly on doctors who practise in prisons; more often than not it reflects on an unwillingness of psychiatric colleagues to take these subjects, who would be more appropriately assessed in NHS facilities. It is remarkable that I can have a prisoner patient seen and admitted for secondary care for a physical illness virtually by lifting the telephone, whereas if the patient is suicidal-in my opinion, a more fatal condition-he or she often has to wait days to be assessed and even then will probably not secure an NHS bed.

The idea that the NHS can provide better health care for patients is a glib popular assumption. From what I can see, particularly in my own establishment, the NHS would provide an inferior service.

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 $1\,$ Squires N. Promoting health in prisons. BMJ 1996; $313{:}1161. (9~{\rm November.})$

Prison service for England and Wales has been designated a WHO collaborating centre

EDITOR—In response to the proposal by the chief inspector of prisons that prison health care should be handed over to the NHS, Neil Squires writes that "to focus only on the physical and mental illness of prisoners... would be to ignore the role of non-health professionals and agencies inside and outside prison in promoting prisoners' health and wellbeing."¹

This comment accords with important recent developments of which Squires does not seem to be aware. Last year the prison service for England and Wales was designated the World Health Organisation's collaborating centre for the European health in prisons project. This project aims to set up a network of countries promoting health in prisons in Europe, with the object of exchanging information on good practice and ultimately improving health. Also last year, the prison service launched a health promotion awards scheme in prisons in Britain. Important factors in determining eligibility for an award include a multidisciplinary approach to health promotion and the development of projects promoting the health of staff and visitors as well as prisoners. A crucial element of the approach is that prisons should be regarded as communities.

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 Squires N. Promoting health in prisons. BMJ 1996; 313:1161. (9 November.)

Do fetuses feel pain?

Can fetal suffering be excluded beyond reasonable doubt?

EDITOR—The *BMJs* initiation of a debate on fetal pain is commendable, because the subject is often dismissed as being off limits because of its associations with abortion: women seek assurances that fetal pain will not occur.¹ As the author of a paper on behalf of the pro-life parliamentarians mentioned,² I wish to respond.

One comment in the articles in the debate encapsulates the dilemma—namely, Vivette Glover and Nicholas Fisk's that "currently we have no direct way of assessing pain in fetuses." Omit "currently" and there's the rub. Pain cannot be directly assessed in non-communicating subjects; ignore this and we drive into an epistemological layby.

The dismissal of fetal withdrawal from noxious stimuli as "only reflex" is a secondary inference that is naive unless one can confidently exclude suffering. Independent verification of that exclusion requires comprehensive understanding of the structure of pain pathways in the developing nervous system. Accepted correlations between structure and function in this context, however, are unreliable. How can aborted fetuses respond to touch before the "required" end organs develop?3 How can the essentiality of an intact cortex for the experience of pain be consistent with the reality of anencephalic infants?⁴ Two questions—whether the cortex is normally involved in the appreciation of pain and whether it is necessary for this—are regularly conflated. To assert that a cortex is essential for pain and hence that pain does not occur in its absence begs the question. The existence of alternative pain pathways is illustrated by failures of cordotomy.

A decade of reappraisal of neonatal anaesthetic practice has established a trend suspect distress when it was not previously considered. Convention now requires that, before embarking on interventions with potential to inflict suffering, one accepts the burden of proof when relevant data are incomplete. Can fetal suffering be excluded beyond reasonable doubt?

Semantics confuses the issue further. Neurophysiologists' working definition of pain differs from the beliefs of the community at large. Why should experiential and emotional components be required before suffering in response to tissue damage becomes real? Aborted fetuses respond to trigeminal stimulation by seven weeks' gestation,⁵ and the relevant thalamic nucleus approaches maturity by 12 weeks' gestation. How sound are claims that motor responses in the first trimester are totally reflex? Old canards, such as the supposed need for myelination for pain, have been discredited; are new ones replacing them?

Perhaps parliamentary "excitement" about fetal pain reflects its non-accidental causes. If parliamentary claims of fetal suffering are tactics to undermine abortion how should we interpret opposing claims?

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- Derbyshire SWG, Furedi A, Glover V, Fisk N, Szawarski Z Lloyd-Thomas AR, et al. Do fetuses feel pain? BMJ 1996;313:795-9. (28 September.)
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We should give them the benefit of the

EDITOR-The "range" of experts who give their view of whether or not fetuses feel pain largely represent one side of the argument and leave too much room for doubt. The absence of reflex movement does not mean that pain has not been felt, any more than the presence of reflex movement proves conscious perception of a noxious stimulus. The relation between reported levels of pain and hormonal stress response, at least in adults, is highly variable.2 We do not even know whether consciousness of pain is a purely cortical sensation. Observations in anencephalic infants, patients with hydrocephalus, and some patients in a persistent vegetative state suggest that the thalamus may also play an important part. Who would dare make the parallel claim that patients with Alzheimer's disease cannot feel pain, simply because they are incapable of remembering it later?

Pain is subjective, and conclusions based on reflex activity, hormone concentrations, the complexity of neuronal connections, or reportable memory can take us only so far. In the light of this uncertainty and our growing appreciation of the fetus as a patient in its own right, should we not be giving these most vulnerable members of our species the benefit of the doubt? The recently published report of the Commission of Inquiry into Fetal Sentience suggests that a fetus may feel pain as early as six weeks.3

The perception of pain by fetuses is a fascinating issue but far less intriguing than the perception of guilt by doctors. We who once pledged to "maintain the utmost respect for human life from the time of conception"4 have simply rewritten our ethics and shelved our scientific integrity in the process. "Hath not a [fetus] eyes? hath not a [fetus] hands, organs, dimensions If you prick us, do we not bleed? ... if you poison us, do we not die?"5

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Computerised automatic warnings about drug interactions are now available

EDITOR-Duncan Raistrick and colleagues' report about the interaction between methadone and rifampicin is yet another reminder that adverse interactions are not always easy to identify and prevent.1 This particular interaction was first identified over 20 years ago² yet seems to have been overlooked by whoever first prescribed rifampicin to the patient reported on by the authors.

It is beyond anybody's capacity to remember all the important interactions, and inevitably oversights like this one happen. In this case the patient came to no harm, but some drug combinations are hazardous, and a few are killers. It is not enough to have the information in a book on the shelf (such as the British National Formulary, MIMS (Monthly Index of Medical Specialties), or a reference book like mine on adverse drug interactions³). What is needed is a system that automatically gives an alert when an attempt is made to prescribe or dispense pairs of drugs that interact adversely.

Most pharmacists already have automatic warning messages on their computers, but many doctors either do not have this facility or are given unhelpful messages. That is why I have produced a suite of purpose written warning messages about drug interactions for the World Standard Drug Database (Safescript). This Read coded database "bolts on" to virtually any of the surgery or clinic computer systems available, and the following is the warning message that comes up if an attempt is made to prescribe methadone and rifampicin together:

"METHADONE serum levels reduced by RIFAMPICIN. Withdrawal symptoms may occur. If either newly prescribed, be alert for the need to use an increased METHADONE dosage (possibly 2-3 fold) or to increase the dosing frequency."

This short message is designed to take about 5 seconds to read and has three elements. It says (a) what will happen and (b) what to do. It also carries a conditional clause ((c)—"If either newly prescribed") to distinguish between the responses appropriate to the first and any later attempts to prescribe these drugs together.

I have assembled many hundreds of similar messages covering the range of clinically relevant interactions, and these are constantly being updated. There is little reason these days for not having this kind of warning facility about drug interactions available in every surgery and clinic. Drug databases such as the World Standard Drug Database are inexpensive, and when linked to good, compatible computer technology they can considerably improve the safety of prescribing. All that is needed is minimal computer literacy and the will to take advantage of what is now available.

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Differences in mortality between African Caribbean and European people with non-insulin dependent diabetes

Authors' method of assigning ethnic group was wrong

Editor—The of methodology Nish Chaturvedi and colleagues' 20 year follow up of patients with non-insulin dependent diabetes mellitus is worrying.1 The authors compared mortality and morbidity in African Caribbeans and Europeans. Their first mistake was in taking it upon themselves to assign people to ethnic groups: ethnicity is a self designation that, in many cases, changes over time. They made the further error of assigning the subjects to an ethnic group "on the basis of appearance and country of birth." They give no indication of the physical characteristics that led to a person being assigned to the African Caribbean or the European group, and they assume that two or more people looking at the same person will agree completely about that person's appearance.

The African Caribbean group are said to be those "people of black African descent who either were born in the Caribbean or were descendants of those born in the Caribbean"—that is to say, two different populations. This assertion contradicts the authors' statement that "all [their] participants were first generation migrants." And who, in any case, are Europeans?

It is unfortunate that anyone wishing to replicate this study cannot do so because of the poor selection of the sample population, a situation that reflects the problems I addressed in the *BMJ* a few weeks ago.²

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- 2 Azuonye IO. Who is "black" in medical research? BMJ 1996;313:760. (21 September.)

Lack of ethnic differences in renal complications of diabetes is puzzling

EDITOR—Nish Chaturvedi and colleagues' study shows that low rates of coronary heart disease in African Caribbeans persist in those with diabetes.¹ Two other findings are puzzling.

The first is the low risk of death from all causes in African Caribbean diabetic patients compared with their European counterparts (it is about half). An analysis based on the 1991 census for England and Wales shows a 3.5-fold higher mortality from diabetes in African Caribbean born men compared with national rates, and a sixfold higher mortality in African Caribbean born women (VSR et al, unpublished findings). While much of this excess may be explained by the higher prevalence of diabetes in African Caribbeans, the possibility of an excess related to diabetes cannot be ruled out. Although an analysis based on country of birth looks at only first generation migrants, most African Caribbeans who die of diabetes are older and were born overseas (as in Chaturvedi and colleagues' study). There is no obvious reason for an ethnic bias in recording of the cause of death.

The second puzzling finding is the lack of ethnic differences in renal complications of diabetes. Data for 1991-2 from the national renal review for England show that African Caribbeans have a fourfold higher acceptance rate for renal replacement treatment than white people; the rate for African Caribbean women aged ≥65 is eightfold higher.2 3 Diabetes dominates as the underlying cause: the risk of end stage renal failure secondary to diabetes is six times greater in African Caribbean than white patients and rises with age.3 These patterns are consistent with American data for African Americans, and studies adjusting for the restricted access to health care of this population still show increased diabetic renal failure.4 In England more equitable access to services, inner city residence, and proximity to renal units could indicate a higher rate of referral for renal replacement treatment in African

Caribbeans rather than greater need. However, multilevel modelling analysis adjusting for access and deprivation confirms increased rates in African Caribbeans (PR, unpublished findings). This suggests that African Caribbean patients with diabetes may be more likely than white patients to develop end stage renal failure (mortality from renal disease in African Caribbeans is about four times greater than national rates (VSR *et al*, unpublished findings)).

Chaturvedi and colleagues' study raises issues that are also relevant for Asians, who have a high prevalence of diabetes, coronary heart disease, and end stage renal failure. The interpretation of these patterns remains tentative, and further studies are needed to monitor outcomes in ethnic minority patients with diabetes.

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- 1 Chaturvedi N, Jarrett J, Morrish N, Keen H, Fuller JH. Differences in mortality and morbidity in African Caribbean and European people with non-insulin dependent diabetes mellitus: results of 20 year follow up of a London cohort of a multinational study. BMJ 1996;313:848-52. (5 October.)
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Absolute risk of coronary heart disease is not low in African Caribbeans

EDITOR—Nish Chaturvedi and colleagues present valuable data on the relative frequency of macrovascular complications of non-insulin dependent diabetes mellitus among ethnic groups. They conclude that "African Caribbeans with non-insulin dependent diabetes maintain a low risk of heart disease. Management priorities for diabetes developed in one ethnic group may not necessarily be applicable to other groups." This statement, which might seem to imply that conventional risk factors for heart disease in diabetes are not a priority in African Caribbeans, needs qualification.

Firstly, when considering prevention one is less concerned with relative risk than with population attributable risk, which is a function of the prevalence of exposure to risk factors and attributable risk. In African Caribbean communities in Britain the prevalence of diabetes in adults aged 40-64 is about 13% in men and 18% in women. These figures are two to four times higher than the prevalence found in the European community.² A lower attributable risk from non-insulin dependent diabetes mellitus may be negated by a higher prevalence of the condition. Mortality statistics show that the absolute risk of coronary heart disease is

not low. Coronary heart disease is, in fact, one of the most important causes of death in African Caribbeans in Britain.³ The word "relative" might usefully have preceded "risk" in the concluding words of the abstract.

Secondly, some conventional risk factors for coronary heart disease, such as physical inactivity, excessive intake of energy and fat, and obesity, contribute to the development and progression of non-insulin dependent diabetes. African Caribbeans are not protected from the microvascular complications of diabetes. Studies from the Caribbean consistently show high morbidity and mortality from diabetes. ⁴ Control of lifestyle risk factors for chronic non-communicable diseases in the African Caribbean community is a potentially important approach to the control of non-insulin dependent diabetes and its complications. ⁵

Thirdly, the contribution of environmental factors to differences in cardiovascular risk among ethnic groups is not well defined at present. As cultural differences diminish, risk factor profiles in the African Caribbean community may change and evolve towards those found in Europeans. Such changes might be accompanied by an increase in coronary heart disease.

Much evidence suggests that the African Caribbean community presently has a lower risk of coronary heart disease than the European community, and this contrast may persist in people with diabetes. There are several reasons, however, why conventional risk factors for coronary heart disease should remain an important priority in African Caribbeans.

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- 1 Chaturvedi N, Jarrett J, Morrish N, Keen H, Fuller JH. Differences in mortality and morbidity in African Caribbean and European people with non-insulin dependent diabetes mellitus: results of 20 year follow up of a London cohort of a multinational study. *BMJ* 1996;313:848-52. (5 October.)
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Authors' reply

EDITOR—Some of Ikechukwu Obialo Azuonye's methodological concerns are answered in our paper. The clinics involved were in areas of London that currently have a high proportion of first and second generation migrants from the Caribbean to Britain. As recruitment to the study was over 20 years ago and only adults aged 35-55 were recruited, however, our participants were probably all first generation migrants. The different techniques used to

assign ethnic group, and the use of ethnic group itself in epidemiological work, have often been criticised. Nevertheless, the resulting relatively crude groupings define people with quite different patterns of disease, and investigation of these differences can provide valuable clues to the aetiology of diseases.

Veena Soni Raleigh and Paul Roderick confuse ethnic differences in mortality related to diabetes with risks of death in people with diabetes. Of course, mortality related to diabetes in the whole population is higher in African Caribbeans than Europeans, which may be accounted for by the high prevalence of diabetes in African Caribbeans. But we examined ethnic differences in mortality in only those with diabetes. We do not have access to recent data based on the census, but data for 1981 suggest that all cause mortality is not substantially higher in African Caribbeans than Europeans, probably owing to the relatively low rates of heart disease. This relative protection from heart disease, resulting in a relatively low risk of death from all causes, persisted in our study of people with diabetes.

Our measure of renal disease was relatively crude by current standards, and interpretation is made difficult by the small numbers of people with renal disease in our study. We agree that more robust data from the United States and Britain generally show an increased need for renal replacement treatment in African Americans and African Caribbeans respectively.

We were concerned with relative ethnic differences in disease in our study and agree with Martin C Gulliford that, in absolute terms, heart disease is by far the most important cause of death for most populations. But our argument about management priorities refers to the targeting of particular risk factors to reduce the risk of cardiovascular disease rather than the outcome of the disease. Rates of smoking are relatively low in African Caribbeans, and lipid profiles are relatively favourable.1 Thus a focus on stopping smoking and reducing high cholesterol and triglyceride concentrations might exclude many African Caribbeans with diabetes. Ensuring high quality control of blood pressure may currently be more relevant.

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IgA content of immunoglobulin preparation was overstated

Editor—Siraj Misbah presents comparative data on the IgA content of immunoglobulin preparations available in Britain.¹ The value given in table 1 for Alphaglobin, however, is incorrect. This value was taken from a paper by Buckley and Schiff, which clearly refers to a product called Venoglobulin, which is no longer available in Britain.2 The manufacturer and manufacturing process for Venoglobulin are different from those for Alphaglobin. The 11 most recent lots of Alphaglobin sold in Britain had a mean IgA content of 4.3 mg/l (range 3.0-6.3 mg/l), almost a sixth of that stated by Misbah.

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High voltage power lines and risk of cancer

Conclusions are unjustified

EDITOR-Pia K Verkasalo's study of the magnetic fields of high voltage power lines and the risk of cancer in Finnish adults goes some way to assuring adults who live about 100 m from high voltage power lines that they may not thereby be at an increased risk of cancer in general.1 In their analysis, however, the authors did not isolate the more highly exposed residents, such as those living within 25 m of high voltage power lines. Possible effects on them are lost by dilution in the much wider pool of the authors' highest category of exposure.

The authors measured cumulative exposure over 20 years in μT years. There were five categories of exposure, ranging from $\leq 0.2 \,\mu\text{T}$ years in the lowest category to >2 µT years in the highest category. The mean value in the highest category was 5.04 μT years.

Typical ambient household exposures in Britain, independent of power lines, are in the range 0.01-0.2 T,2 with 0.05 T being a representative value.³ Twenty year exposure to typical ambient fields would give 1.0 µT years, which would fall in the authors' second highest category. The highest category had on average only five times ambient exposure. On the other hand, exposure close to power lines is much higher. Table 1 shows magnetic flux densities (typically at 1 m above ground) according to the horizontal distance from the centre of the power line. The figures from the Central Electricity Generating Board in Britain are taken from an internal report. In general, the fall off varies from roughly the inverse square to the inverse cube of the distance, depending on the phasing of the current.

The 20 year exposure of residents living 100 m from high voltage power lines may typically be around the mean in Verkasalo and colleagues' highest category, at 5 µT years. It would be more interesting to examine the category with a mean exposure of 50 μT years, which would better represent the higher exposure of residents within 20 m of power lines. As it is, the claim in the key message that "the results of the present study suggest strongly that typical residential magnetic fields generated by high voltage power lines are not related to cancer in adults" is unjustified.

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Authors' reply

EDITOR-We agree with M J O'Carroll that, from the scientific point of view, it would be more interesting to examine residents living, for example, within 20 m of power lines or otherwise exposed to higher magnetic fields. This, however, was not possible, as can be deduced from previously published distributions of buildings and people by proximity to power lines and by calculated annual average magnetic fields¹ and also from the tables in our paper. For instance, in 1989 the total number of Finnish people living within 20 m of high voltage power lines was 2100. Of them, 350 were exposed to a calculated annual average magnetic field of 0.3-0.49 µT,

Table 1 Magnetic flux densities (μ T) according to distance from power lines as found in studies by various bodies

	National Radiological Protection Board ²	Central Electricity Generating Board	US Department of Energy ⁴	National Radiological Protection Board ²	
Rating (kV)	400	400	500	275	
Distance (m):					
0	40	6.1	8.6	22	
20	_	2.1	2.9	_	
25	8	_	_	4	
91	_	_	0.14	_	
100	_	0.17	_	_	
160	_	0.07	_	_	

¹ Chaturvedi N, McKeigue PM, Marmot MG. Resting and ambulatory blood pressure differences in Afri Caribbeans and Europeans. *Hypertension* 1993;22:90-6.

550 to a field of 0.5-0.99 μ T, and 350 to a field of $\geq 1.00~\mu$ T. The highest cut off point for cumulative exposure was set at 2.0 μ T years because one would otherwise expect to have very few cases.

These distributions also give some indication of what can and what cannot be regarded as a "typical residential magnetic field generated by high voltage power lines" (magnetic fields of the order of $\geq 5~\mu T$ are not typical). It is, however, clear that the results of our study "cannot exclude the possibility of an increase in risk at higher magnetic field levels" (as we said in one of our key messages).

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Valjus J, Hongisto M, Verkasalo P, Jarvinen P, Heikkilä K, Koskenvuo M. Residential exposure to magnetic fields generated by 110-400 kV power lines in Finland. *Bioelectromagnetics* 1995;16:365-76.

Doctors, nurses, and terminal care

Nurses need to accept more responsibility, and doctors need better training

EDITOR—I cannot condone the attitude of the medical registrar referred to in the personal view by Staff nurse Jones about the care of a terminally ill patient.¹ The nurse was right to believe that the patient should receive adequate analgesia. I would like, however, to try to explain why the registrar acted in this way.

Firstly, many doctors' training in pain relief is inadequate. I suspect that it was not a lack of compassion that was the problem, though it is difficult to be compassionate when you are rushed off your feet. No, I suspect that the problem was purely a lack of knowledge of how to deal with the patient. Adequate terminal care is rarely taught in medical schools or practised on the wards.

Secondly, it is difficult for doctors to take advice from nurses, for a variety of reasons; one of these reasons is that the advice is not always correct, and it is the doctor who must decide this.

Finally, it is a question of responsibility. It is the doctor who has to take responsibility if something goes wrong in such cases. If something went wrong and there were repercussions then nursing colleagues would be the first to deny all responsibility (and so would many medical colleagues if the situation was reversed). Sadly, many nurses refuse to take responsibility for many aspects of patients' care if there is even the

slightest perceived risk. I gather that the rules of the United Kingdom Central Council for Nursing, Midwifery and Health Visitors state that nurses do not have to do anything they do not feel competent to do. And why won't nurses take responsibility? Because they do not get, or at least do not perceive that they will get, any support from their own profession.

So what is the answer to this problem? There are no easy remedies; it is not just a case of listening to your nursing colleagues "with respect" (and, incidentally, respect is something that should be earned). Doctors need to listen more to nurses, but nurses need to accept more responsibility and should be able to expect, and receive, adequate support from their profession and seniors if there are problems. Doctors must receive better and more relevant training, both before they arrive on the wards and while they are there, and this should include training in terminal care and about relationships with nursing colleagues.

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1 Dear doctor. BMJ 1996;313:888. (5 October.)

Medical students in Cambridge do two nursing shifts

Editor-We were saddened to read the editorial by Staff nurse Jones¹ but think that the advice that "Doctors should spend at least a month in a hospice as part of their training" is both impractical and inappropriate. The main problem seems to have been lack of communication and respect between doctor and nurse, and this can be addressed only by a change of attitude, initiated as early as possible in medical training rather than by doctors spending time in a hospice or clinical students attending modules in the medical curriculum relating to compassion and empathy. We think it essential that student doctors and nurses are brought together early in their training (before the classic stereotypes of doctor and nurse are allowed to develop) so that they understand the importance of each other's role in the multidisciplinary team, which ensures the primacy of the patient. This should prevent the distressing situation described.

To this end Cambridge University School of Clinical Medicine and Addenbrooke's Hospital have combined to provide an opportunity for medical students at the earliest stage of their clinical course to work with their nursing colleagues for two full nursing shifts. The clinical students are then able to appreciate and respect the role of nurses and the importance of working together as a team.

The objective of the two day placement is to enable medical students to work along-side nurses in delivering effective patient centred care based on standard models that encourage the highest standard of practice, including the preservation of the dignity and privacy of the patient—attributes that seemed to be missing in the situation

described in the personal view. The desired outcome from the attachment is that there will be an increase in doctors' understanding of the role of nurses, the relation between medicine and nursing, and the quality of care that is the right of all of our patients.

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1 Dear doctor. BMJ 1996;313:888. (5 October.)

Treating shackled patients

Patient's best interest in receiving most appropriate treatment without delay must prevail

EDITOR—By publishing Richard Smith's editorial entitled "Don't treat shackled patients" the *BMJ* failed in its duty to publish factually correct information.¹ Specific "rules" for treating prisoners in NHS hospitals do not exist. Smith's analogy with the Nuremberg trials is irresponsible and inappropriate.

The rules governing British doctors, in the General Medical Council's guidance *Good Medical Practice*, state: "You should always seek to give priority to the investigation and treatment of patients solely on the basis of clinical need." These rules are breached by a refusal to treat shackled patients.

The BMA's medical ethics committee has set out guidelines (not rules) on treating prisoners (box),³ but these are not referenced in the editorial. The statement by the secretary of state for the Home Office that "when a prisoner is escorted to hospital, physical restraints will continue to be used in most cases unless there is a medical objection" is at variance with these.

Prisoners have a fundamental right to "the same standards of health care as are available to the rest of society ... and ... the best possible care in the particular circumstances." The prison service has "a responsibility to balance the need to hold prisoners securely with the duty to treat them with humanity and to maintain their dignity and privacy"; the governor has duties of safe custody and care.

Security measures to prevent escapes require individual rigorous assessment of risk for each prisoner attending hospital; this should consider the risks of violence and absconding and the current medical condition.⁵ Doctors, including prison medical officers, can cooperate with the assessment of risk without breaching confidentiality.

A mere refusal to treat the patient leaves the patient as a pawn in the conflicts between the prison authorities, who are enforcing state judiciary decisions, and the duties and responsibilities of an individual clinician. The duty of care of the prison governor requires regular liaison with the medical director of the hospital or place of care to review an individual's custody arrangements, with appeal to the director of prisons.

Guidance for doctors providing medical care and treatment to those detained in prison, set out by BMA's medical ethics committee3

- Detained prisoners must have access to the same standards of care as the rest of society. This includes respect for the patient's dignity and privacy
- · Wherever possible, without compromising the quality of care, treatment should be provided within the prison. Conditions of privacy must be available
- There should be a presumption that prisoners will be examined and treated without restraints, and without prison officers present, unless there is a high risk of escape or the prisoner represents a threat to himself or herself, the health team, or others
- Discussions should take place between the health team and the prison officers to assess the level of risk in each particular case. If, after discussion, the level of risk is low, the doctor in charge should request removal of restraints
- If agreement cannot be reached, the chief executive of the hospital or NHS trust should discuss the case with the governor of the prison
- In an emergency situation, treatment must be provided

The BMA's guidelines were followed in the case that prompted the debate, but the complex issues, which are sub judice, were unresolved; restraints and custody were not fully withdrawn. The shackling of the patient and the continued presence of the officers was degrading and unacceptable.

The message "Don't treat shackled patients" is too simplistic. Ultimately the patient's best interest in receiving the most appropriate care without delay must prevail.

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- R. Don't treat shackled patients. BMJ 1997;314:164. (18 January.) General Medical Council. *Good medical practice*. London:
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*I apologise to Professor Finlay and her colleagues for personal distress caused to them by my editorial. I stand by my assertion that doctors should not treat shackled patients and should insist on them being unshackled.—Editor

Superficiality of editorial gives rise to more anger than do shackles

Editor—Has Richard Smith worked through the implications of his editorial instructing doctors not to treat shackled prisoners?¹ In the district where I work there are two large prisons, one of which is a high security prison holding category A and B prisoners, a constant trickle of whom come through our wards. Last year I had to treat with chemotherapy a young man with lung cancer whose shackles were not allowed to be removed for an instant during his treatment, which rendered private conversation impossible.² I studied the document produced by the BMA's medical ethics committee³ and had discussions with the prison governor. Several points are relevant.

Firstly, many hospital staff are anxious that prisoners may escape or become violent, or that they may themselves be harmed or held to ransom if prisoners are inadequately guarded. All of these, including an armed rescue of a prisoner with cancer attending hospital for radiotherapy, have happened in this area. Many staff want to see

Secondly, attending hospital is the most common circumstance associated with attempted escapes.

Thirdly, prison governors and officers are allowed no flexibility by the Home Office. All prisoners, except those posing a low security risk, have to be shackled to a warder at all times while attending hospital. Even use of a secure room in the hospital would not circumvent this requirement.

Thirdly, the BMA's document recommends individual assessment of the risk posed by a prisoner attending hospital, but the prison service considers that the risk is unpredictable. If this is true, such assessments would not be reliable even if allowed.

Fifthly, when I raised the issue of confidentiality I was advised that prison warders have a code of confidentiality comparable with that of hospital staff.

Finally, the medical ethics committee's recommendation that doctors should attend the prison can be the best solution. Unfortunately, it not always practical; it is also time consuming, especially since new security regulations now add to the delays.

The BMA's medical ethics committee seems not to have taken adequate advice from the prison service or the Home Office. Inquiry led only to the information that there had been lay representation on the committee.

I believe that, ideally, doctors should not treat shackled prisoners, but other hospital staff do not agree and current regulations do not allow otherwise in many cases. It may not even be sensible. Would you refuse to treat a dangerous shackled prisoner who had a myocardial infarction? The problem needs more thorough consideration at the highest level. I find myself angered more by the superficiality of the BMA's document and Smith's editorial than by the shackles.

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- BMA Medical Ethics Committee. Guidance for doctors providing medical care and treatment to those detained in prison. London: BMA 1996

Assumption that shackles will not be used should be ignored only in exceptional cases

EDITOR-Richard Smith rightly draws attention to the shocking case of a dving prisoner being chained until two hours before his death from stomach cancer.1 It is important to emphasise that, however emotive or tragic, such cases should not determine overarching policy.

The media have focused on the wholly unjustifiable use of restraints on severely ill prisoners and on women in childbirth. In these cases the physical condition of the prisoner makes the possibility of flight or escape extremely unlikely. But some prisoners needing medical attention present a real danger of flight or of violence to the public generally or the health workers treating them.

The BMA has issued guidance to help doctors in these difficult circumstances.2 The guidance emphasises that prisoners have the same essential rights as all other patients: to respect for their dignity and the confidentiality of the patient-doctor consultation. It also recognises that, rather than blanket rules mandating shackling in every case or abolishing it entirely, appropriate security measures should be agreed on the basis of a proper assessment of the risk that each prisoner poses in the particular circumstances.

The BMA objects to the use of excessive methods of restraint-including shacklingwhen this is clearly superfluous to the risk being posed and believes that there should be an assumption that shackles will not be used, which should be ignored only in the most exceptional cases. Some hospitals treat prisoners relatively frequently or on a routine basis. Such units should establish areas that are secure, where prisoners can be guarded at a distance that respects their privacy while ensuring the needed level of security.

A balanced assessment of risk should be performed in each case; detailed guidance is available from the BMA's medical ethics department on request.

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- Smith R. Don't treat shackled patients. BMJ 1997;314:164. (18 January.)
- BMA Medical Ethics Committee. Guidance for doctors providing medical care and treatment to those detained in prison. London: BMA, 1996.

Correction

Metabolic efects of antihypertensive treatment should not be overstated

The title chosen for this letter by Peter H Winocour (18 January, p 223) incorrectly encapsulates the content of the letter; a more appropriate title would have been "Case for lack of metabolic effects has not been made."