transdermal nicotine patches before marketing them. The patients with heart disease who participated were kept under strict cardiovascular control. Many cases of angina pectoris and arrhythmias were reported, which led to patients being withdrawn from the study, being admitted to hospital, and even undergoing angioplasty. The study concluded that patches are safe only in patients with stable cardiovascular disease.⁴

The pharmacological effects of nicotine (regardless of its source) on the cardiovascular system are well known.

(1) Nicotine increases blood pressure and heart rate directly, because it has sympathomimetic effects on the heart, and indirectly, because it stimulates catecholamine release. These effects increase myocardial oxygen demands, risking the development of angina pectoris due to reversible myocardial ischaemia, especially in patients with coronary stenosis.

(2) It causes vasospasm in coronary vessels because of its sympathomimetic effects and because it stimulates the local release of prostaglandins.

(3) It may cause platelets to hyperaggregate and increase blood fibrinogen concentrations, which increase the risk of coronary thrombosis and myocardial infarction.

In addition, the drug interactions of propranolol and the contraceptive pill with nicotine should be considered as they might increase nicotine blood concentrations unexpectedly.⁵

The pharmacological effects of nicotine on the cardiovascular system need to be carefully investigated in patients with heart disease who use transdermal nicotine patches. Currently, the safety of such patients using them depends on continuous supervision by a physician, especially in those with coronary stenosis or a history of myocardial infarction.

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1 McMurray J, Rankin A. Recent advances in cardiology. I. Treatment of myocardial infarction, unstable angina, and angina pectoris. *BMJ* 1994;309:1343-50. (19 November.)

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Authors' reply

EDITOR,—As discussed by John Rawles and us,^{1,2} analysis of the "early thrombolysis" trials, and not just the Fibrinolytic Therapy Trialists' overview, suggests that giving thrombolysis 60 minutes earlier, a generally feasible time saving, will probably save at least 15 additional lives per 1000 patients treated. This conclusion is much less controversial than how the results of the GUSTO trial (global utilisation of streptokinase and tissue plasminogen activator for occluded arteries) should be interpreted. This controversy was reviewed by us, but two points should be emphasised.

Firstly, Anthony Hall and D M Humphreys fail to point out that the GUSTO trial was not just a comparison of two drugs. It was also a trial of strategies, in which one thrombolytic agent was given rapidly (accelerated alteplase) and the other (streptokinase) at the usual rate.

Secondly, the analysis reported by Hall and Humphreys puts streptokinase at a disadvantage. Accelerated alteplase (currently not licensed in the United Kingdom) is compared with the combined

Numbers of patients who need to be treated to prevent one event

Treatment	Event prevented	No of patients who need to be treated to prevent one event
Of hypertension*	Death, cerebrovascular accident, myocardial infarction	3
Coronary artery bypass grafting for left main stem stenosis	Death	3
Aspirin for transient ischaemic attack	Death, cerebrovascular accident	6
Warfarin for atrial fibrillation	Cerebrovascular accident	7
ACE inhibitor for mild heart failure	Death, admission to hospital	8
After myocardial infarction:		
HMG CoA reductase inhibitor	Death, myocardial infarction, cardiac arrest	11
Aspirin	Death, myocardial infarction, cerebrovascular accident	12

*Diastolic pressure 115-129 mm Hg.
ACE=Angiotensin converting enzyme.

HMG CoA=Hydroxymethyl glutaryl coenzyme A.

streptokinase groups. When given with intravenous heparin (a non-standard treatment), streptokinase caused more strokes and bleeding complications; these complications were less frequent when streptokinase was combined with subcutaneous heparin. It would be more valid to compare the combined death rate and rate of non-fatal disabling stroke (the stroke rate was increased by alteplase) in the accelerated alteplase group with that in the streptokinase and subcutaneous heparin group (6.9% v 7.7%, $P=0.03$).

Even if we accept the analysis of Hall and Humphreys the number of patients that need to be treated to save one life by using alteplase rather than streptokinase is around 100 (though the 95% confidence limits are as high as 240).³ In other words, the cost per extra life saved is of the order of £67 000 but could be as much as £160 000. To this must be added the not inconsiderable cost of an extra disabling stroke. The opportunity cost of routinely switching from streptokinase to alteplase would, consequently, be significant. We cannot agree, therefore, that the cost of the extra benefit from alteplase is small compared with other treatments, even angioplasty (table). We believe that it is entirely appropriate to place these issues in the context of the extra benefit that could be obtained, at no extra cost, by improving current practice to ensure that thrombolysis is given as early as possible.

We did not wish to imply that transdermal nicotine replacement treatment is completely safe in patients with coronary heart disease. Instead we concluded that the role of nicotine replacement in helping patients to stop smoking after a myocardial infarction should be explored further. We still think that this is the case. The study we cited is a double blind placebo controlled five week trial in 156 patients and is, therefore, of considerable value. May R Arnaot, however, cites only individual case reports as evidence against the safety of nicotine replacement treatment. Few such cases have been reported to the United States Food and Drugs Administration.⁴

Arnaot summarises the well known effects of nicotine on the cardiovascular system. Nicotine itself, however, has less pronounced effects than smoking on some of these variables.⁴ Concomitant smoking should ideally be avoided and only patients whose condition is stable should be considered for treatment. We think, however, that the role of nicotine replacement as an aid to smoking cessation in survivors of myocardial infarction should not be dismissed without fuller evaluation.

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1 Rawles J. Treatment of myocardial infarction and angina. *BMJ* 1995;310:465. (18 February.)

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GPs accept patients' vote on fundholding

EDITOR,—My partners and I were interested to read of the ballot of patients in a practice in Oxfordshire over whether their practice should become a fundholding practice.¹ Our patient participation group, in association with Leicestershire Family Health Services Authority, funded and carried out a similar exercise in 1991. I write not to claim a first but to compare the outcome.

The fundholding facilitator of the family health services authority and the patient participation group's committee agreed a foreword to the voting paper, explaining the pros and cons of fundholding. No indication of the general practitioners' views was given. The voting papers were sent to a 10% random sample (chosen by the family health services authority) of our adult patients. All voting papers were anonymous and were returned in prepaid envelopes.

Altogether 850 papers were distributed; 372 were returned. The number of patients in favour of the practice becoming a fundholding practice was 108, with 262 against (two spoilt papers)—that is, 70% of the respondents were against fundholding for the practice. The commonest reason against fundholding was the problem of patients' confidence in their doctors' decisions once money had entered into the equation.

Our practice did not become fundholding, and we have seen no reason since then to change our minds.

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1 Leaver M. GPs accept patients' vote on fundholding. *BMJ* 1995;310:349-50. (11 February.)

Reductions in defence medical services

EDITOR,—While fully understanding the concern expressed by the BMA's armed forces committee over the proposed changes in the medical defence services, I cannot accept that the changes will have an "adverse effect on the quality of care which will be offered to serving personnel in the future."¹ In addition, the statement that doctors are unlikely to be recruited on short career commissions in the future is not correct. There will be a full and rewarding career in the, albeit smaller, armed forces medical service of the future, and short term commissions will, as at present, form the bedrock of our recruiting policy.

The changes in the armed forces medical services merely reflect the changing role of the armed forces themselves and the operational scenarios for which medical support might be required in the future. The fact that the core hospital at Haslar will be for all three services and enlarged in terms of both the number of beds and the range of specialties represented will enable us to provide an even greater range of postgraduate training than at present. The introduction of the military units in large district general hospitals will again allow greater training opportunities than we have previously been able to provide in our small service hospitals. I can therefore confidently state that training opportunities for the doctors who remain will be enhanced and their service career patterns will not be affected. Uniformed patients will be referred, as at present, to uniformed consultants, either at the core hospital at Haslar or, if it is more convenient, to the nearest military-civilian unit, and they will receive the same treatment as they presently enjoy.

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1 Beecham L. Reductions in defence medical services causes BMA concern. *BMJ* 1995;310:196. (21 January.)

Life expectancy in children with cerebral palsy

EDITOR,—In their paper on life expectancy in children with cerebral palsy¹ Jane L Hutton and colleagues remark on our findings in two selected studies,^{2,3} stating that our subjects with developmental disability seemed to have a much shorter life expectancy than they found. We studied people who had devastating learning disabilities as well as people with less severe disabilities. Some groups had a very poor prognosis—that is, those who were immobile, could not roll over, were tube fed, had no use of their arms or hands, etc. In one of these groups who could roll over, however, estimated survival was similar to that in Hutton and colleagues' group who required a wheelchair.

We did not use the wheelchair item in our papers because it did not discriminate between the degrees of immobility. Hutton and colleagues chose to ignore differences in the severity of disabilities, including levels of mobility and types of feeding, when they discussed the differences between our findings and theirs.

To prove our point we adopted their cruder definitions of mobility—that is, wheelchair required and help needed for propulsion—and a separate category for manual dexterity, defined as inability to feed and dress without help, as well as their years of birth and degree of learning disability (all had cerebral palsy). We used all ages of admission to the California system. We estimated survival over 11 years for 3792 people meeting the wheelchair criteria. The five and 10 year cumulative proportions surviving were almost identical with those in Hutton and colleagues' study. When we used the criterion "does not feed or dress self without help" our cumulative proportions surviving after five and after 10 more years were also similar to those of Hutton and colleagues. We also used period life tables for Hutton and colleagues' definitions of mobility and manual dexterity. We selected subjects who received services during 1987-90 and estimated their average remaining lifetime. The results again were similar to the median survival estimated by Hutton and colleagues. These findings merely confirm that the definitions used by Hutton and colleagues did not have the precision necessary to replicate our findings on who would and would not have a reasonable survival outcome.

Diagnoses such as cerebral palsy and learning

disabilities are not determinative predictors in as much as most subjects with these diagnoses are not substantially disabled. The category "patients confined to wheelchairs" is too broad to be a definitive predictor.⁴

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Drivers with sleep apnoea

EDITOR,—Ashley Woodcock and Patricia Stone pose the major moral dilemma of how to manage patients with sleep apnoea who hold licences to drive public service or heavy goods vehicles and are reluctant to declare their illness to the Driver and Vehicle Licensing Agency.¹ They mention the temptation to blackmail such patients into treatment with threats of driving bans. The issue here is not the treatment but the ban. The Driver and Vehicle Licensing Agency recommends that people who hold licences to drive public service or heavy goods vehicles should stop driving if they have sleep apnoea. The patient therefore has an obligation to inform the agency about the condition, which is well known to cause accidents, as Woodcock and Stone point out.

Surely there is no moral dilemma here. Doctors' primary responsibility is to the public at large, not to a person who might cause death or disability to other people. The situation is exactly the same in epilepsy. The recommended practice is to inform patients of their statutory responsibility to tell the Driver and Vehicle Licensing Agency about their condition, to write this in the notes, and if necessary to confirm it with a letter to the patients sent by registered post. The patients' response can be checked by asking them, but also by an inquiry to the agency, at which stage the doctor does not need to provide any clinical information. If patients do not report their condition, however, the doctor should send them a letter telling them that he or she is obliged to inform the licensing authority about their condition and recommending that they should consult a solicitor about the issue.

This sounds legalistic, but the communications can be made in a friendly manner, emphasising encouragement rather than threat and expressing regret at the need to take the ultimate action.

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- 1 Woodcock A, Stone P. Should obesity be treated? *BMJ* 1994; 309:1442. (26 November.)

Driving, glaucoma, and the law

EDITOR,—Contrary to the impression given by T Potamitis and colleagues,¹ glaucoma in a single eye need not be notified to the Driver and Vehicle Licensing Agency. The condition can be regarded as a prospective disability and therefore notifiable as soon as field loss in both eyes occurs. It is the patient's responsibility to notify the agency, but the doctor needs to remind the patient of his or her obligations.

The minimum visual field for safe driving is a field of vision of at least 120° on the horizontal measured by a Goldmann perimeter with the III4e settings (or equivalent perimetry). In addition, there should be no appreciable field defect in the binocular field that encroaches within 20° of fixation either above or below the horizontal meridian. By this means homonymous or bitemporal defects that come close to fixation, whether hemianopic or quadrantanopic, are not accepted as safe for driving. Isolated scotomas represented in the binocular field near to the central fixation area may also be inconsistent with safe driving.² Only if the minimum visual field for safe driving cannot be achieved will the driving licence be revoked.

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- 1 Potamitis T, Aggarwal RK, Tisoulamas M, Rene C, McLaughlin J, O'Neill E. Driving, glaucoma, and the law. *BMJ* 1994;309: 1057-8. (22 October.)
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Making routine data adequate to support clinical audit

"Routine" is inadequately defined

EDITOR,—In their editorial on the need for adequate routine data to support clinical audit Martin McKee and colleagues fall into their own trap.¹ They claim that unambiguous definitions are needed, yet use ambiguous words in their title. Our interpretation of "routine data" is data collected as byproducts of clinical care by the clinician and as an integral part of the process of care. Their definition is that the data are managerial data collected through processes outwith the clinician's control. On the basis of their definition it is not surprising that the data are incomplete and invalid. We have shown that data collected as byproducts of clinical care are valid and able to inform education and service planning, with resultant improvement in the service provided.^{2,3}

It is not surprising that routine data as McKee and colleagues understand the term are inadequate to support audit and contracting. The way ahead for the health service must be to establish a culture in which accurate, structured data collection is an integral part of the process of care, as much second nature to clinicians as it has been to write unstructured notes in the clinical record in the past. When that culture is achieved clinicians will own their own data and trust the information that emerges. Then it will be of use not only for clinical audit but also for activity analysis, service planning, management of resources, and research.

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