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Unlicensed and off label drug use for paediatric patients

General practitioners prescribe SSRIs to children off label

EDITOR—Turner et al highlight the fact that children admitted to hospital are often prescribed unlicensed drugs and drugs given outside the terms of their product licence (off label).¹ The appropriateness of such prescribing is uncertain, and a high rate of adverse drug reactions has been observed in children prescribed such drugs.² The problem is not limited to hospitals. General practitioners may be asked to prescribe unlicensed or off label drugs by specialists or may consider initiating such treatment themselves. Little information exists on the extent of such prescribing in primary care.

We examined the prescribing of selective serotonin reuptake inhibitors to children in general practice by accessing a computerised database of 100 British general practices (349 doctors) using the AAH Meditel System 5 computer system to enter medical records (Doctors Independent Network).³ We determined the number of children aged 12 and under who had at least one prescription for a selective serotonin reuptake inhibitor between January 1992 and December 1996. For each child we ascertained age at first prescription; sex; name, dose, and formulation of the drug; number of prescriptions issued during the study; and reason for prescription. To be certain that we had identified children, we included only subjects who had an immunisation record in their notes, with dates consistent with their recorded age.

Overall we identified 25 children who met the entry criteria for the study, except that we had to exclude six because of doubt over their age. The table shows the reasons for the prescription of the drugs. The commonest antidepressant prescribed was fluoxetine capsules. The *British National For-*

mulary states that prescribing these drugs for children is not recommended.

These data from a small number of practices (under 1% of all British practices) suggest that nationally there are probably hundreds of children who have been prescribed off label antidepressants in general practice. Research suggests that some children are prescribed these drugs in general practice soon after their launch, when clinical experience is limited.⁴ We agree with Turner et al that all drugs used to treat children should be evaluated for their paediatric efficacy, safety, and quality. Doctors should have enough information to be able to discuss with parents the likely benefits and risks of using these drugs.⁵ Research should also assess the appropriateness of such prescribing in general practice.

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- 4 Mackay FJ, Dunn NR, Wilton LV, Pearce GL, Freemantle SN, Mann RD. A comparison of fluvoxamine, fluoxetine, sertraline and paroxetine examined by observational cohort studies. *Pharmacoepidemiol Drug Safety* 1997;6:235-46.

Prescribing of selective serotonin reuptake inhibitors in children aged 12 and under in 100 general practices in Britain

Drug	No of children given drug*	Mean (range) age (years)	Record linked diagnoses (No of children)
Fluoxetine 20 mg capsules	10	5.9 (1-12)	Depression (3), obsessional neurosis (2), anxiety state (2), febrile convulsion (1), mental disorders (1), unknown (1)
Fluoxetine 20 mg/5 ml	5	10.6 (8-12)	Encopresis (1), bereavement (1), behaviour problem (1), anxiety state (2)
Paroxetine 20 mg	2	7 (4-10)	Depression (1), anxiety (1)
Sertraline 50 mg	1	3	Endogenous depression (1)
Fluvoxamine 50 mg	1	6	Depression (1)
Total	19	7.3 (1-12)	

*Mean number of prescriptions per child during study was 2.2 (range 1-11).

5 Mann RD. Unlicensed medicines and the use of drugs in unlicensed indications. In: Goldberg A, Dodds-Smith I, eds. *Pharmaceutical medicine and the law*. London: Royal College of Physicians of London, 1991.

Optimal dosing schedules with gentamicin are needed for premature neonates

EDITOR—Turner et al report unlicensed and off label drug use in the paediatric setting but do not mention off label drug use in neonatal intensive care.¹

Gentamicin is a renally excreted aminoglycoside antibiotic frequently used in neonatal intensive care units. The serum concentration achieved is critical because of its narrow therapeutic index. Renal excretion is reduced at birth and increases during the first months of life. Premature neonates are affected more than term neonates, and appreciable increases do not occur until 34 weeks of gestational age. The rate of renal maturation in neonates varies widely, and critically ill premature neonates develop more slowly than term neonates.² Consequently the dose regimens required to achieve appropriate serum concentrations in these patients are different from those in older children and adults, whose renal function is more adequate. Examples of such regimens are found in several paediatric formularies.^{3,4} The dose recommended ranges from 2.5 to 5.0 mg/kg/dose given at intervals of 8-36 hours, depending on the criteria used.

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Three manufacturers produce gentamicin injection. Each has a licence for the treatment of neonatal infections and recommends doses for all ages from birth onwards.⁵ These doses vary slightly, from 2 to 3 mg/kg/dose at intervals of 8 to 12 hours. Each recommends that doses be adjusted so that serum trough concentrations of <2 mg/l and peak concentrations of 4-10 mg/l are achieved. Blood samples are normally taken around the third or fourth dose. A premature neonate is therefore likely to receive doses more appropriate for a term neonate for two days if these recommendations are followed. Excessive and potentially toxic serum concentrations are likely to result.

Many dosing schedules for gentamicin have been drawn up in the United Kingdom. All attempt to account for the factors influencing drug handling in premature neonates, such as gestational age, weight, postnatal age, concurrent drug treatment, and maternal drug treatment. Is it not time that the manufacturers of such widely used drugs determined the optimal dosing schedule by trials specifically designed for this population?

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- 5 Association of the British Pharmaceutical Industry. *ABPI compendium of data sheets and summaries of product characteristics* 1998-1999. London: Datapharm, 1998.

Childhood vaccination should have been included in asthma study

EDITOR—Kaur et al's finding that children aged 12-14 years in cities had less asthma (30.3%) than those in rural areas (35%)¹ must lead to questions about the role of air pollution in asthma.

What I found disappointing was the absence in the questionnaire of any questions about childhood vaccination. Odent found that children aged 8 years who had been immunised against whooping cough as babies had nearly six times the incidence of asthma compared with children who were not immunised.² And in Christchurch, New Zealand, the Wellington asthma research group studied 1265 children aged 10 years³ and found that none of the 23 children who had not received diphtheria, pertussis, and tetanus or polio immunisations had recorded consultations for asthma or other allergic illnesses whereas 23% of the immunised children had had episodes of asthma and 30% had had consultations for other allergic illnesses.

These reports point a strong finger of suspicion at childhood immunisation being the cause of the remarkable increase in childhood asthma and allergies over the past few decades. A thorough programme of unbiased research into the short and long term side effects of childhood immunisation is essential. To continue saying that vaccinations are safe in the absence of sound clinical evidence may be no truer than the claim of the emperor that his new clothes were the finest ever made.

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- 1 Kaur B, Anderson HR, Austin J, Burr M, Harkins LS, Strachan DP, et al. Prevalence of asthma symptoms, diagnosis and treatment in 12-14 year old children across Great Britain (international study of asthma and allergies in childhood, ISAAC UK). *BMJ* 1998;316:118-24. (10 January.)
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- 3 Kemp T, Pearce N, Fitzharris P, Crane J, Fergusson D, St George I, et al. Is infant immunization a risk factor for childhood asthma or allergy? *Epidemiology* 1997;8:678-80.

Interaction between warfarin and oral terbinafine

Manufacturer does not agree that interaction was with terbinafine

EDITOR—Warwick and Corral report on a patient whose international normalised ratio changed while she was receiving multiple drugs, including oral terbinafine and warfarin.¹ The authors suggest that this was because of an interaction between warfarin and terbinafine, but the case is more complex than it seems. The patient was taking four other drugs besides terbinafine (glibenclamide, metformin, frusemide, and spironolactone), which may have been interacting with warfarin after its biotransformation by a number of cytochrome *P*-450 enzymes. In addition, warfarin may interact with many other compounds, including beverages, food supplements, food stuffs, and food additives.²

Both terbinafine and warfarin are metabolised by cytochrome *P*-450 2C9 subclass. Terbinafine, however, has a low potential to induce cytochrome *P*-450, as it does not affect the disposition or the metabolism of antipyrine.³ Also, a pharmacokinetic study of a single dose of warfarin in healthy volunteers treated with terbinafine showed no significant interaction.⁴ Additionally, in a postmarketing surveillance study of the use of terbinafine in over 10 000 patients, a total of 26 patients received concomitant warfarin. No adverse events associated with coagulation were reported.⁵

Since oral terbinafine was launched in 1991 over seven million patients are estimated to have received it. The adverse events reported to Novartis Pharma AG include single cases in which both prolongation of as well as a reduction in the prothrombin time has been described. Single reports describing inconsistent patterns exist with other oral anticoagulant treatments.

On review of the reported case, and in the light of all other available evidence, we believe that one cannot make a generalisation regarding an interaction between terbinafine and warfarin. In those rare cases in which terbinafine and warfarin are combined with other drugs, routine follow up (as is general medical practice in patients taking warfarin) should ensure adequate detection. Since its launch, oral terbinafine has shown an excellent safety profile.

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- 1 Warwick JA, Corral RJ. Serious interaction between warfarin and oral terbinafine. *BMJ* 1998;316:440. (7 February.)
- 2 Stockley IH. *Drug interactions*. 4th ed. London: Pharmaceutical Press, 1996:994-5.
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- 5 O'Sullivan DP, Needham CA, Bangs A, Atkin K, Kendall FD. Postmarketing surveillance or oral terbinafine in the UK. *Br J Clin Pharmacol* 1996;42:559-65.

Authors' reply

EDITOR—Gantmacher et al from Novartis suggest that other drugs taken by our patient may have contributed to the observed interaction between oral terbinafine and warfarin leading to a fall in her international normalised ratio. Not only were all her other drug treatment stable for 24 months before the course of terbinafine, however, but none of these medicines (glibenclamide, metformin, frusemide, and spironolactone) are listed by the *British National Formulary* as having the potential to interact with warfarin. Our patient had no major changes in diet or alcohol consumption during this time. Furthermore, studies of single doses of warfarin in healthy volunteers treated with terbinafine may satisfy the requirements of the regulatory licensing authorities but are inadequate to detect the relatively gradual process of induction of liver enzymes.

We still believe that our observations merited a report. We would also be interested to know whether Novartis has received any other reports of interactions with warfarin from any of the voluntary schemes for reporting adverse drug reactions.

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Systematic review of interaction profile of warfarin is needed

EDITOR—Warwick and Corral's description of a possible interaction between warfarin and terbinafine¹ was an unwelcome addition to the jumble of anecdotal data surrounding warfarin, an old drug known to interact with numerous prescription only medicines, over the counter remedies, and foodstuffs. As Dollery et al have pointed out, warfarin has a

narrow therapeutic index and thus suspicions of interactions are easily occasioned by random fluctuations in the international normalised ratio.²

The number of drugs listed in the September 1997 issue of the *British National Formulary* as having important interactions with warfarin is large (74 drugs from 23 classes are named explicitly), and Stockley lists 275 reported interactions, including at least 12 involving over the counter preparations and over 20 involving beverages, food-stuffs, food supplements, and food additives.³

Reliable published data show that warfarin does not have a kinetic interaction with terbinafine.⁴ Furthermore, a postmarketing surveillance study of terbinafine carried out in Britain and Northern Ireland did not find any cases of warfarin interacting with terbinafine even though 26 patients were taking both drugs.⁵ Clearly there is little cause for concern.

Anecdotal case reports of drug interactions involving warfarin do little to inform prescribers. What is needed is an up to date systematic review of the interaction profile of the drug. The need for this has become more urgent now that warfarin is being used much more frequently in the management of an ever growing range of circulatory disorders.

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- 1 Warwick JA, Corral RJ. Serious interaction between warfarin and oral terbinafine. *BMJ* 1998;316:440. (7 February.)
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Study is needed of visual field defects associated with any long term antiepileptic drug

EDITOR—Since Eke et al's report of severe persistent visual field constriction associated with vigabatrin¹ there has been growing interest in studying visual fields in patients taking this drug. MacKenzie and Klistorner report visual field defects in two patients and suggest that field defects may be more common in asymptomatic patients.² Harding, however, suggests that routine ophthalmological screening of all patients taking vigabatrin cannot be justified until a benefit:risk ratio can be calculated for individual patients.³

As a result of the questions raised by such reports, we examined the visual fields in asymptomatic patients receiving long

term treatment with vigabatrin. Our preliminary findings suggest that field defects may be surprisingly common in such patients: 11 of the first 15 patients showed appreciable visual defects on testing with the Humphrey's field analyser.

If visual field defects are as common as our initial results suggest, then—contrary to Harding's suggestions—routine ophthalmological screening would be justified. Lack of visual symptoms and normal confrontation fields do not guarantee the absence of visual field defects, and, in any case, before any benefit:risk ratio can be calculated the incidence of such defects in patients taking other antiepileptic drugs needs to be fully investigated. Indeed, as Hoechst Marion Roussel has been made aware of the potentially serious side effect³ it is surprising that this has not already been done. As a result of the findings in our small initial series a study to investigate visual field defects in all patients taking long term antiepileptic drugs is under way at this centre.

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Postmortem urinary alcohol is unreliable in diabetes

EDITOR—Pounder's editorial states that raised blood alcohol concentrations at post-mortem examination may be misleading and should be corroborated by analysis of other body fluids such as vitreous humour or bladder urine.¹ I would like to issue a word of caution regarding urinary alcohol analysis in people with diabetes (or, I suppose, glycosuria from other causes). We analysed urine in people with newly diagnosed diabetes who had symptoms of genital candidiasis as well as glycosuria and found that urine specimens could spontaneously generate considerable quantities of ethanol.² We concluded that urinary alcohol could not be relied on to reflect ethanol intake in these people.

Diagnosed non-insulin dependent diabetes is common, and there are perhaps as many people again walking around with the condition undiagnosed. Because the disease carries a high mortality, particularly from cardiovascular causes, some people with the condition may be found inexplicably

dead and the subject of a coroner's inquiry. Under these circumstances urinary alcohol concentrations may be as misleading as blood alcohol levels. Whether this would also be the case for vitreous humour, I am unsure.

Distinguishing between the dead sober or the dead drunk can indeed be difficult; it may be even harder in the presence of diabetes.

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- 1 Pounder DJ. Dead sober or dead drunk? *BMJ* 1998;316:87. (10 January.)
- 2 Alexander WD, Wills PD, Eldred N. Urinary ethanol and diabetes mellitus. *Diabetic Med* 1988;5:463-4.

Test meta-analyses for stability

EDITOR—An editorial on meta-analysis that one of us wrote¹ noted in passing two difficulties with a paper by Le Lorier et al that showed apparent discrepancies between results of meta-analyses and of individual trials.² Le Lorier and Gregoire have written to counter those criticisms,³ but we think that they have missed the salient methodological issues.

Le Lorier et al defined a negative trial as "one in which the treatment resulted in an equal or worse outcome at the conventional level of statistical significance." The editorial defined a negative trial as one in which "a clinically significant effect on predetermined end points was ruled out" by "post hoc examination of the confidence intervals around the treatment effect size estimate in the trial." These definitions are quite distinct.

The first definition presupposes that a P value above 0.05 is accepted at face value, despite the ubiquity of β errors arising from inadequate sample sizes, overestimation of event rates, optimistic assumptions about treatment effectiveness, and inappropriate discounting of the importance of small effects on outcomes such as death and disability. The second definition demands evidence that a given trial had statistical power to rule out clinically important differences and means that many trials will yield indeterminate results that are neither definitively negative nor positive. Increasing imprecision in effect sizes with decreasing trial size and the consequent expectation of greater—but symmetrical—scatter of outcomes around the central estimate as trial size decreases is what lies behind the concept of funnel plots as a screening test for bias in meta-analysis.⁴

The editorial also noted that the paper by Le Lorier et al excluded some publications that might have altered its conclusions.² Le Lorier and Gregoire argue that these were prespecified exclusions, not oversights.³ The distinction is helpful, but the criticism stands. Since the point of any meta-analysis is to consider the totality of the evidence, what rationale is there for comparing prior meta-analyses with subsequent trials drawn from four journals and four years? If

the trials and meta-analyses address similar questions the test of the meta-analyses is to determine whether the results are similar or stable after all (not some) of the subsequent trials are compared or combined with the original findings. Conversely, if the newer trials are distinct they should neither be combined with nor compared with any prior meta-analysis.

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Providing primary care in accident and emergency departments

Referral back to primary care is cheaper

EDITOR—The options discussed by Robertson-Steel for providing emergency primary care¹ do not apply to many departments. The figure of around 40% of new attenders at accident and emergency departments having problems that could be treated by primary care is not true for all departments. The figure generally refers to busy inner city departments, although managers and politicians often imply that it applies across the board.

In Exeter, for example, a recent audit involving general practitioners found that only around 4-7% of our new attenders had primary care problems (this proportion was higher at weekends and bank holidays but lower in office hours). Thus for us and similar departments where there is a relatively stable local population and a good general practitioner service, primary care attenders are not a major issue. Providing general practitioner services in accident and emergency would therefore not help such departments and may even create a problem by encouraging primary care attenders to come to the hospital out of hours.

We agree that a national triage category for primary care attenders would be useful, but such a category would also need to be agreed locally if such patients are to be sent straight back to primary care. The introduction of general practice out of hours cooperatives in Exeter has slightly reduced the number of primary care attenders in our audit. Cooperatives could also enable easy referral from accident and emergency back to primary care. This strategy has the advantages that primary care patients are more likely to receive appropriate treatment from

a primary care doctor² and that accident and emergency staff would be able to concentrate on emergencies.

Rather than employing a new system of general practitioners or nurse practitioners it would be cheaper to refer the patient directly on to primary care services in the community after triage provided that those services are adequate.

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- 1 Robertson-Steel IRS. Providing primary care in the accident and emergency department. *BMJ* 1998;316:409-10. (7 February)
- 2 Dale J, Green J, Reid F, Glucksman E, Higgs R. Primary care in the accident and emergency department. II. Comparison of general practitioners and hospital doctors. *BMJ* 1995;311:427-30.

National triage scale exists

EDITOR—Accident and emergency departments and general practitioners have a shared role in providing primary care to many communities.¹ The huge range of problems presented at accident and emergency departments as well as increasing numbers of patients adds to the challenge of planning and providing optimal care.

Resources cannot always match demand and appropriate triage according to clinical need is essential. The British Association for Accident and Emergency Medicine worked with the Accident and Emergency Nursing Association of the Royal College of Nursing to agree a triage scale for allocating priorities in accident and emergency departments. After widespread consultation, this was adopted by these organisations in 1996. The box summarises the five point framework of the UK national triage scale. The colours are not obligatory but do have some intuitive meaning (for example, red for danger) and are useful for labelling and teaching.

An early draft described the non-urgent category as primary care. This was strongly criticised, particularly by colleagues working in primary care. Their patients present with problems of varying urgency. Many do fall into category 5 but some are in 4 or 3. The identification of patients appropriate for primary care is not just a question of priority but also concerns the nature of the problem and the situation of the whole patient. The scale is designed to be a practical framework for grouping patients solely according to clinical priority.

UK national triage scale	
1 Immediate resuscitation	Patients in need of immediate treatment for preservation of life
2 Very urgent	Seriously ill or injured patients whose lives are not in immediate danger
3 Urgent	Patients with serious problems, but apparently stable condition
4 Standard	Standard cases without immediate danger or distress
5 Non-urgent	Patients whose conditions are not true accidents or emergencies

Our triage scale is already widely used. It is incorporated in the Health Services Accreditation publication *Standards for Accident and Emergency Services*.² Unfortunately, agreement on the scale does not guarantee uniform application. Robertson-Steel is correct that we do not yet have an agreed triage system. However, an elegant set of decision making pathways has been developed by Mackway-Jones and his colleagues in the Manchester triage group.³ It is based on common presenting symptoms rather than diagnoses and is already working in 138 accident and emergency departments in the United Kingdom and Ireland. Careful audit, with correlation of triage data, admission figures, and diagnoses is needed to ensure consistency. In Australia, triage category has been found to correlate well with use of resources.⁴ If this also proves to be true in the United Kingdom we hope to gain a reliable casemix measure as well as a necessary clinical method.⁵

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- 5 Brayley N, Marrow J. Health care resource groups in accident and emergency medicine. *J Accid Emerg Med* 1996;13:143-4.

Telephone triage could help

EDITOR—Robertson-Steel rightly emphasises the potential for optimising the management of patients who require emergency primary care.¹ However, the leap from concept to practice may prove elusive. The conditions presenting as emergencies cover a wide spectrum of acute illness and injury. Within this continuum there is a group of patients who can be managed equally well by accident and emergency specialists, general practitioners, or emergency nurse practitioners in a suitably equipped environment.

The percentage of patients currently attending accident and emergency departments who would fall into this "primary care" category is variable, as Robertson-Steel acknowledges. Dale et al's widely quoted figure of 40%² should not be taken as the national picture. Nevertheless, there must be increased collaboration between accident and emergency departments and general practitioners providing emergency cover. To this end the British Association for Accident and Emergency Medicine and the Royal College of General Practitioners are meeting to identify and address the key issues.

The fundamental problem is accessibility to emergency health care. Difficulty in obtaining an early consultation with a general practitioner is a commonly quoted reason for patients within the "primary care group" attending accident and emergency departments. In some areas general

practitioner cooperatives have facilitated access to a general practitioner within a timescale regarded by the patients as acceptable. However, the service remains patchy.

Delegating the provision of emergency primary care to accident and emergency departments would contradict the principle that general practitioners should be available on an urgent basis around the clock throughout the week. It is the responsibility of general practitioners to ensure such availability and to organise themselves appropriately. The use of accident and emergency departments as a catch-all should not continue.

A model where patients have a single local telephone number for immediate advice and are then referred to a primary care facility or the accident and emergency department, as appropriate, would provide the accessibility which patients crave and ensure reasonable allocation of workload. This would allow accident and emergency departments to concentrate resources on providing high standards of care to patients with more serious illness and injury.

However, until there is a nationally agreed model for providing emergency primary care, general practitioners' enthusiasm for such a scheme will remain variable. If the government provided adequate incentives for general practitioners to organise themselves in this way we would have an arrangement that would serve the interests of both specialities and the patients.

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Departments should try educating patients first

EDITOR—Robertson-Steel argues that patients will continue to use accident and emergency departments for primary care problems as they have always done.¹ The assumption is that inappropriate behaviour cannot be modified through patient education. He concludes that departments therefore need to organise general practitioners to meet this demand.

I question the assumption that demands for such services must be met by accident and emergency departments in areas where effective out of hours services are now available through cooperatives and primary care centres. One option is to educate patients to use the services that are most appropriate. We need a study where patients are triaged into those who really do need urgent accident and emergency care and those who should be educated about the out of hours service available and how it should be used. This group would be informed that coming to the accident and emergency department is inappropriate and would not receive treatment.

By meeting the demands of patients who attend accident and emergency departments for primary care, without any attempt at educating patients, we are reinforcing inappropriate behaviour and wasting scarce resources. We are also duplicating a service which is readily available but not being used appropriately. We need a trial of intensive patient education versus current provision of primary care services in accident and emergency departments. The objective should be to encourage appropriate and cost effective out of hours behaviour. We should not assume that patient education is useless and that the only solution is to bring general practitioners into accident and emergency departments just because patients always turn up and demand treatment.

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1 Robertson-Steel IRS. Providing primary care in the accident and emergency department. *BMJ* 1998;316:409-10. (7 February.)

Disclosure of child sexual abuse

Maintaining confidentiality is not in best interest of woman or others

EDITOR—In the recent ethical debate on child sexual abuse an allegation of a serious criminal offence was made in a situation of assumed confidentiality.¹ Revealed child abuse (physical or sexual) is rarely an isolated occurrence, and perpetrators tend to escalate their activities with time.² Sexual abuse of children is a personality disorder which does not spontaneously resolve and is refractory to intervention.³ If these allegations are true, other children may have been or may still be being abused.

Medical training inculcates an ability to make decisions. This can create an expectation of making a decision when it may be inappropriate for the decision to be made by an individual doctor. A fundamental tenet of child abuse work is to share information. Indeed, the Children Act makes this a duty.⁴ One person may be unaware of all the information. David is not in a position to make a decision not to proceed. Immediate medical and social work colleagues would be his first points of reference and, thereafter, the trust's medical director (who will have access to legal advice) and his defence society.

If abuse to others occurred after the date of this woman's disclosure and was uncovered and it then became known that David had had this information, it is not certain how a judge or the General Medical Council would regard a choice of maintaining confidentiality. Would a victim be able to sue the professor for placing confidentiality ahead of a future victim's physical and psychological safety?

What of the woman's best interests? It is difficult to take life decisions which are for the best in the long term but which will precipitate extreme short term difficulties. She has bulimia, and the prospects of resolving this without addressing the underlying

psychodynamics are poor. Her main obstacle to disclosure is the real fear of further psychological difficulties. Victims of child abuse need help in coming to full disclosure. Did David inform her of the support and therapeutic options which could help her to cope and recover after disclosure?

He should meet this woman again to see if she has altered her views. If she has not, he should explain why he has to make disclosure. He should tell her how he intends to address her needs and liaise with her general practitioner.

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Professor David is Head of the academic department to which I belong. I have not discussed the case, or this letter, with him.

- 1 David TJ; Wynne J; Kessel AS; Brazier M. Ethical debate: Child sexual abuse: when a doctor's duty to report abuse conflicts with a duty of confidentiality to the victim. *BMJ* 1998;316:55-7. (3 January)
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- 4 *Children Act 1989*. London: HMSO, 1994.

Doctor has duty to warn others

EDITOR—David describes a case which should be of interest to all doctors and people in positions of trust.¹ Disclosure of sexual abuse experienced as a child may occur at any time but is more likely in a safe setting with trusted individuals. Given that doctors in general are still seen as among the most trusted in society, disclosure might occur with any doctor, independent of issues such as whether a therapeutic relationship exists.¹

The argument is not whether it is the duty to patient or society that is paramount but how best to fulfill our duties to both. I would proceed by having a further detailed discussion with the woman concerned on the dilemma her disclosure has presented to me. The discussion would include dealing with the issue of a duty to warn others. This duty has been established in the United States for physical threat² and the broader implications for the United Kingdom have recently been described.³ I would also want to share with her that it would probably be necessary to contact other agencies with a view to safeguarding other children. I would thus hope to sway her to agree to further action, which could be anonymous.

I believe that the basic principles of ethics would be satisfied by this approach. Autonomy is achieved by giving the woman the opportunity to discuss fully her situation as well as the effects of disclosure in an open, adult manner. Beneficence and non-maleficence are upheld by ensuring that the woman is at least offered counselling and professionally advised on the decision about possible prevention of future abuse by the abuser. Justice might then be done in that the abused, the abuser, and society are dealt with fairly.

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- David TJ, Wynne J, Kessel AS, Brazier M. Ethical debate: Child sexual abuse: when a doctor's duty to report abuse conflicts with a duty of confidentiality to the victim. *BMJ* 1998;316:55-7. (3 January.)
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Most practices would use open access spirometry in hospitals

EDITOR—Abbasi highlights the importance of spirometry in the assessment of patients with chronic obstructive pulmonary disease.¹ Guidelines published recently by the British Thoracic Society encourage the wider provision of this service by general practitioners.² We have recently performed an audit that identified issues that need to be considered if these proposals are to be implemented.

We surveyed general practices in North Staffordshire that serve a total population of 500 000 in order to define the provision of spirometry before the guidelines were circulated. We also determined the knowledge and training of staff who performed the tests and sought preferences for different locations for spirometry, including a specific reference to an open access service in hospitals.

The telephone survey achieved a response rate of 88% (84 out of a total of 95 practices). Eighteen practices possessed a spirometer, although eight did not use it. Only two users had received formal training in performing spirometric tests and interpreting the results. Three practices used a pneumotachograph spirometer, but none were aware that it needed to be calibrated daily.³

Respondents were given a choice of three options for where spirometry should be performed. Provided that adequate training had been undertaken, the most popular location was the general practitioner's surgery (44 practices). Twenty nine practices favoured an open access hospital service, and 11 thought that spirometry should be organised through referral to a respiratory specialist. Altogether 73 practices said that if an open access hospital service were available they would use it for some of their patients.

In the practices that performed spirometry, the lack of formal training among the staff casts doubt on the validity of the results obtained. The most commonly used spirometers were rotary vane models, which do not produce hard copies of the volume-time curve. Information on the subjects, effort, and technique is therefore available only by observation. One study in general practices that used these devices showed that only half of practice assistants were able to perform spirometry "satisfactorily," despite comprehensive training.⁴

If spirometry in general practice is to become widespread and valid, suitable spirometers and adequate training must be provided. This may be expensive and time consuming. Open access spirometry in hospital is an alternative solution, and most practices stated that they would use such a service. Interpretation could accompany

spirometric results but doctors requesting the results must remember to consider any results in light of the clinical findings.

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- Abbasi K. GPs should have access to spirometry for assessing COPD. *BMJ* 1997;315:1560. (13 December.)
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Breast lumps in young women

Reassurance is appropriate only after clinical, radiological, and pathological assessment

EDITOR—Reed's Personal View about her doctors' failure to investigate her breast cancer is generous.¹ The incidence of breast cancer in her age group may be low but is not negligible, being 25/100 000 in those aged 30-35.² It would not be acceptable in a breast clinic to reassure a 32 year old woman on the assumption that a palpable lump is a fibroadenoma without having done adequate triple assessment by clinical, radiological, and pathological methods. The risk in Reed's case was not just the loss of a breast; it was the loss of a daughter, a sister, a partner, a friend, and, most tragically, a mother of a young child.

The general practitioner is also part of the team; he or she must initiate the patient's referral, for without that the specialist services cannot function. Failure to refer denies the possibility of early diagnosis and treatment to any young woman with breast cancer. The guidelines are now clearly stated.²

Reed's generosity may be admired but cannot be commended. Publication of this Personal View should not be taken as an indication of a satisfactory standard of practice.

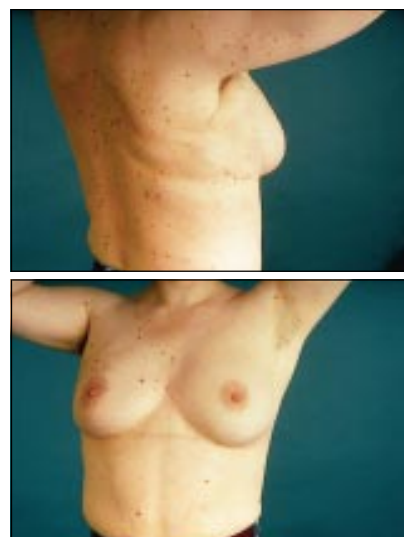
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- Reed J. I lost my breast but is anyone to blame? *BMJ* 1998;316:400-1. (31 January.)
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New technique has excellent cosmetic results

EDITOR—Reed's Personal View shows that although the risk of death is the main concern of women with breast cancer, loss of breast is an important issue.¹ A new technique is now available that allows the removal of large volumes of tissue from the breast, with the resultant defect in the breast being filled with autologous tissue. This can lead to a reduction in the number of patients, particularly younger women, with breast cancer who have to lose their breast.

The procedure as we have developed it is performed in two stages. The initial opera-



View showing no obvious resultant defect from removal of latissimus dorsi muscle (top) and excellent cosmetic result from excision of 5 cm carcinoma (bottom)

tion is a wide excision (with the aim of excising the tumour and a roughly 2 cm rim of surrounding tissue) and is performed as a day case procedure. An intraoperative radiograph is used to confirm complete excision. Full pathological assessment is available within three to four days. Provided that the margins of the wide local excision are clear, a second procedure is performed five to seven days later. Through a single axillary incision an axillary nodal dissection is performed and the latissimus dorsi muscle and overlying fat is mobilised from its insertion into the humerus and origins from the spinous processes and thoracolumbar fascia. Lighted retractors are used to visualise the muscle as it passes into the back. The muscle and overlying fat are left attached by only the thoracodorsal vessels and are tunneled deep to the breast into the site of the wide local excision, and the muscle and overlying fat are sutured into the breast defect to achieve breast symmetry (figure). A two stage procedure has the advantage over that described by others^{2,3} because it ensures that the tumour has been completely excised. In cases in which the margins of the initial wide excision are involved our practice is to proceed to a mastectomy with immediate reconstruction. The cosmetic results of this procedure are excellent (figure (bottom)). All patients receive postoperative radiotherapy given to the whole breast to a dose of 50 Gy without a local boost. We believe that this procedure is oncologically sound and can reduce the number of patients who need a mastectomy. We are currently evaluating its psychological benefits.

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- Reed J. I lost my breast but is anyone to blame? *BMJ* 1998;316:400-1. (31 January.)

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Doctors and patients must decide together whether anticoagulation is appropriate

EDITOR—Thomson et al suggest that variations in recommendations for anticoagulant treatment of atrial fibrillation could be overcome by having a single body responsible for producing evidence based guidelines.¹ Might giving this responsibility to one body lead to a form of medical tyranny in which only one view of who should be offered anticoagulant treatment is held to be valid? Evidence based medicine does not preclude the role of the patient in choosing or declining a particular treatment.²

The evidence base for anticoagulant treatment of non-rheumatic atrial fibrillation is strongly influenced by just six trials, five of which have been conveniently pooled. All suggest that anticoagulation with warfarin is beneficial. Further analyses of the data have attempted to stratify differing degrees of risk and potential benefits.³ Evidence based guidelines that could convey this information to clinicians would be welcome, but to suggest that this evidence can then determine the level of risk at which anticoagulant treatment should be recommended is misleading.

The decision to start anticoagulant treatment for atrial fibrillation is difficult for both doctors and patients. On the one hand, in addition to assessing the risk of a particular patient having a stroke doctors must also consider the extent to which the patient wishes to avoid one, which will vary with the patient's own health beliefs. Then they must balance this with the knowledge that the treatment may also cause the event it is meant to prevent. To this has to be added the practical difficulties of anticoagulant treatment for the patient. What evidence there is for this suggests that the patient's own preference can show as much variation as clinical stratification according to relative risk, on which guidelines would presumably be based.⁴ The role of guidelines in this situation should not therefore extend beyond making available the best evidence on which the doctor and patient together can decide if anticoagulant treatment is appropriate.

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- 1 Thomson R, McElroy H, Sudlow M. Guidelines on anticoagulant treatment in atrial fibrillation in Great Britain: variation in content and implications for treatment. *BMJ* 1998;316:509-13. (14 February.)
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Mechanisms of fetal origins of health problems in adults need to be investigated

EDITOR—Stanner et al found that maternal starvation during pregnancy during the siege of Leningrad was not associated with alterations in birth variables or cardiovascular or metabolic pathophysiology in infants.¹ In their commentary on the paper Rich-Edwards and Gillman call for animal studies to determine the underlying mechanisms for the hypothesis of fetal origins that was proposed by Barker et al.

Rich-Edwards and Gillman seem unaware of the advances that have been made in this field in recent years. Considerable data support the hypothesis that not only maternal dietary deprivation (specifically of protein) but also fetal exposure to glucocorticoids act as potential causative mechanisms. Exposure of fetal rats to excess glucocorticoids—either by treating pregnant females with dexamethasone or by inhibiting 11 β -hydroxysteroid dehydrogenase type 2, which forms a physiological barrier to maternal glucocorticoids in placental and fetal tissues—reduces birth weight in offspring and produces permanent higher blood pressures and hyperglycaemia in adult offspring.^{2,3}

Moreover, placental 11 β -hydroxysteroid dehydrogenase type 2 is also attenuated by maternal protein restriction, which suggests that a common mechanism may link the models. While the molecular mechanisms are under investigation, permanent alterations in the expressions of glucocorticoid receptors in specific tissues of the offspring and hyperactivity of the hypothalamic-pituitary adrenal axis have been documented⁴; the latter may of course contribute to the observed rise in blood pressure and glucose. Recent data have correlated plasma cortisol concentrations in middle age inversely with birth weight in one of Barker's "fetal origins" populations, which suggests that the data obtained from the animal study may be applicable to processes in human beings.⁵

Further detailed understanding of the underlying mechanisms is crucial to support the provocative, but highly important, epidemiological associations and to indicate potential therapeutic approaches. Closer awareness and cooperation between the epidemiological investigators and the mechanistic biological ones can only advance this critical process.

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- 1 Stanner SA, Bulmer K, Andres C, Lantseva OE, Borodina V, Poteen VV, et al. Does malnutrition in utero determine diabetes and coronary heart disease in adulthood? Results from the Leningrad siege study: a cross sectional study. *BMJ* 1997;315:1342-9. [With commentary by J W Rich-Edwards and M W Gilman.]
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Use of capitation formulas for primary care groups could result in chaos

EDITOR—Bevan is right in asserting that it will not be possible to have both clinical and financial equity for the new primary care groups.¹ In Warwickshire the locality budgeting working party (a group of general practitioners and health authority staff) has attempted to determine unified budgets for five localities; these budgets would incorporate hospital and community services, prescribing, and cash limited general medical services.

Budgets based on historical activity were calculated with 1996-7 outturn applied to 1997-8 contract values; they were then compared with a fair share of available resources based on the York formula for both hospital and general medical services elements² and with ASTRO-PUs (age, sex, and temporary resident originated prescribing units) for prescribing. Although use of the York formula specifically for general medical services does not have proved academic validity, it can be justified on the basis that this element comprises only 4% of the overall budget.

Assessing financial equity depends on the availability of good information and consistent approaches to costing. We found that over 70% of hospital and community expenditure could be attributed to localities reasonably reliably, although we encountered considerable difficulties with some areas, especially some of the community and specialist services. Services for people with learning disability posed particular problems not only because of the above issues but also because of different patterns of provision across the county, the use of grants to social services, and the high proportion of purchasing for individual placements. Clinical equity here bears little relation to financial equity, and these services were omitted from consideration.

Overall, we found that four of the five localities were within 3% of their capitation target; the fifth, however, was 9% above target. Analysis of hospital activity showed this to be a result of strategic change in service provision rather than inequitably high levels of clinical care. There is evidence of an urban-rural split, with the urban centres receiving more than their fair share of available resources.

We are now beginning to discuss within the county how this work might inform the degree to which future primary care groups move to their target, the pace of change, and the importance of taking account of strategic issues around services. Although this work is at an early stage, it is clear that the mechanistic application of capitation formulas for primary care groups would result not in clinical equity but in chaos.

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1 Bevan G. Taking equity seriously: a dilemma for government from allocating resources to primary care groups. *BMJ* 1998;316:39-42. (6 January)

2 Carr-Hill R, Hardman G, Martin S, Peacock S, Sheldon TA, Smith P. A formula for distributing NHS revenues based on small area use of hospital beds. York: University of York, 1994.

Doctors' perceptions of patients' wishes influence decision to prescribe drugs

EDITOR—The *BMJ* published several studies last year on the influence of the expectations that patients have of prescriptions.¹⁻³ One of the most striking results of these studies is the fact that not only do patients' expectations influence a doctor's decision to prescribe but so also do the doctor's perceptions of these expectations, whether these perceptions are accurate or not.

This corresponds to the findings of a study we conducted on patients' attitudes towards drug prescriptions in general practices in Germany.⁴ We found that nearly all patients who, in their doctor's opinion, expected a drug left the surgery with a prescription. However, doctors accurately perceived the patient's wish for a drug prescription in only 41% of cases. We did not detect any differences in patient satisfaction whether or not patients' expectations with regard to a prescription were fulfilled.

These results do not really support the stereotype of the demanding and manipulative patient.³ Rather, the doctor who is characterising his or her patient may be the problem. Moreover, in most cases the justified rejection of a patient's wish seems to have no negative effects on the patient's assessment of the consultation.

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1 Cockburn J, Pitt S. Prescribing behaviour in clinical practice: patients' expectations and doctors' perceptions of patients' expectations. *BMJ* 1997;315:520-3.

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Experiments in continuing medical education merit wider reporting

EDITOR—Both Richards's editorial on continuing medical education¹ and Towle's article on changes in health care and continuing medical education for the 21st century² emphasised the importance of self directed learning.^{1,2} This can occur only when learners feel confident, supported, and self motivated. Our experience in south London has shown that personal development plans motivate and change clinical practice. Practice development plans share the same strengths by responding to perceived need and allowing evaluation of outcomes. Joining with groups of practitioners (some have been meeting regularly for up to 20 years) avoids isolation and provides personal support and help with personal development.

The proposed changes in continuing medical education and professional development cannot be introduced, maintained, or developed without corresponding changes to fiscal and administrative structures. The challenge for medical politicians is to negotiate a structure for primary care education at all levels that is controlled by primary care and is adequately funded. It also needs to be flexible enough to allow a variety of individual and local initiatives.

As with hospital senior house officer posts, there is a risk that service will swamp continuing education in primary care whatever form it takes. The new structure needs to be robust enough to resist education being sacrificed in the face of inadequately funded service pressures. For example, an initiative in Greenwich by the London initiative zone educational initiative developed a structure that changed continuing medical education activities from being done out of hours or in participants' leisure time to being an integral part of the working week.

Another political challenge is to address the lack of educational resources to implement the suggestions made by Richards and Towle. Funded staff with the appropriate skills are needed to help doctors and practices with their professional development plans and to help with the development of measures to define and measure quality care as described in the latest white paper.³

Medical journals such as the *BMJ* could support innovation by giving more coverage to reports describing the successes and failures of experiments in continuing medical education.

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1 Richards T. Continuing medical education. *BMJ* 1998;316:246. (24 January)

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Doctors should have ready access to sites about rare diseases on world wide web

EDITOR—In his commentary on the white paper Wyatt criticises the proposed NHS clinical information services for failing to provide for electronic access by all doctors to the knowledge they need to do their work, including up to date evidence based textbooks, directories, and full text journal articles.¹ This is a missed opportunity for helping doctors assessing and meeting the health needs of the myriad groups of patients with rare or uncommon diseases, for whom problems in rapidly accessing up to date knowledge are particularly great.

Previously, limitations in technology and resources have restricted developments aimed at enabling doctors to access knowledge (of, for example, up to date treatment options or treatment centres) when faced with patients with rare diseases. While these are, by definition, small groups of patients, many such groups exist, and together they form a sizeable subpopulation of people with rare diseases. Developments in network technology and the recent encouragement for NHS doctors to use computers² provide an opportunity for the health needs of this subpopulation to be better assessed and met.

We are currently undertaking a survey of doctors to explore whether ready access for doctors to the world wide web might offer solutions to some of the problems that will remain as a result of the deficiencies in the proposed new clinical information services. One area of focus will be the potential use of the individual web sites that are being established by many organisations or associations for patients with rare or uncommon diseases in the United Kingdom. These might, for example, be used to provide immediately accessible sources of up to date knowledge (for example, evidence based texts, clinical guidelines, contacts and treatment centres, caveats for emergency care, literature searches, etc), which their medical expert advisory panels might voluntarily provide. The information on these web sites, while being independently provided, would probably in general be of high quality, given that such organisations seek to appoint doctors with experience and a special interest in the disease as their medical advisors. The cost to the NHS of access to this knowledge might be minimal, given the essentially voluntary basis of such an alternative approach.

The use of such web sites might have an important role in addressing the deficiencies and missed opportunities of the proposed NHS clinical information services.

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1 Shapiro J, Black N, Wyatt JC, Kleijnen J, Bonsel G, Griffiths S. Encouraging responsibility: different paths to accountability. *BMJ* 1998;316:296-301. (24 January)

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Parents do not see GPs as source of help for emotionally disturbed schoolchildren

EDITOR—The general practice in which I work currently has a project ("Innocence and experience") to increase our awareness and understanding of emotional disorders in children, which Robinson's editorial recognises to be common.¹ To establish their incidence in our practice we sent the Rutter revised questionnaire² to the parents of all the 880 children at primary school; 737 (84%) were returned completed. Altogether 125 had coding levels suggestive of emotional disorder (≥ 13).³

To find out what the practice knew about these children we compared the medical records for the previous 10 years of the 120 higher scoring children and their families who remained on our medical list with those of a randomly selected sample of 120 of the lower scorers and their families; we were blinded for the Rutter scores. The physical and mental health of both sets of children and their families was comparable. Fifty four of the mothers of higher scorers and 43 of the mothers of lower scorers had consulted with an explicit emotional disorder (a measure of morbidity in mothers, and of our awareness of emotional illness in adults). Adverse social factors tended to be more common in the higher scoring families, and the higher scoring children consulted more often than the lower scorers. By contrast, the mothers of both groups had similar consulting rates.

We held two focus groups with parents chosen at random from those who had been sent the questionnaire. The main finding was that, in general, parents did not consider general practitioners or health visitors to be an obvious source of help for an emotionally disturbed schoolchild. They spoke warmly of the care they received from the practice for preschool children and would appreciate some similar, if low key, service for schoolchildren.

Our main conclusion was that emotional disorders seem to be common among primary schoolchildren in our community; we see these children frequently in the surgery—only a tenth of the higher scoring children had not consulted in the previous year. Yet emotional issues are not addressed in the consultation as they are with adults.

What should the role of primary care for emotionally distressed children be? Our practice is committed to improving our knowledge, skills, and service, but this important public health issue needs a more coordinated approach by all those involved in the care of children.

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1 Robinson R. Effective screening in child health. *BMJ* 1998;316:1-2. (3 January.)

2 Rutter M, Tizard J, Whitmore K, eds. *Education, health and behaviour*. London: Longman, 1970.

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Reducing road traffic

Trusts can do much to encourage doctors to lead the way

EDITOR—The media devote much attention to proposed changes in transport policy, and Roberts has written an editorial on reducing road traffic.¹ A poll of medical staff in our hospital showed that virtually all of them drive unaccompanied to work. The usual reasons for this were cited, and they were well aware of individual and communal health benefits from possible alternatives. There was a strong desire, especially among juniors, to combine exercise with commuting, but lack of workplace resources, including poor showering facilities and safe bicycle parks, led to staff continuing to drive.

Doctors are often asked to—and do—lead by example in health issues, so encouraging medical staff to give up their cars is an important early step. Trust boards should provide certain basic requirements as standard. All we want is a safe home for a bicycle and sweaty clothes.

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1 Roberts I. Reducing road traffic. *BMJ* 1998;316:242-3. (24 January.)

First fatal car crash in Britain occurred in 1898

EDITOR—According to Roberts's editorial on reducing road traffic, in 1896 Bridget Driscoll "stepped off the kerb [in London] and into history as the first person to be killed by a car in Britain."¹ Bridget Driscoll was indeed the first person to be killed by a car, but the drama occurred in the grounds of the Crystal Palace. She was run over by a demonstration car, a Roger-Benz, whose speed belt had been mischievously removed by the youthful driver, with the result that the car travelled at more than twice the accepted speed of 4 mph (6.4 km/h) but with less control. She died minutes later of a head injury. This was on 17 August 1896.

The claim that "the coroner said he hoped that such a thing would never happen again" sounds appealing, but I found no evidence from transcripts of the inquest that he ever said it. Nevertheless, William Percy Morrison was the first to apply the term "accident" to violence caused by speed. Coroners have followed his example ever since.

Britain's first fatal car crash occurred 100 years ago. On 12 February 1898, Brighton businessman Henry Lindfield crashed his speeding car into a tree near Purley, Surrey, and died a few hours later in Croydon Hospital. Again, a verdict of accidental death was returned.

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1 Roberts I. Reducing road traffic. *BMJ* 1998;316:242-3. (24 January.)

Parrish's chemical food never contained arsenic

EDITOR—I have only recently seen the short item on the Minerva page submitted by Barrett.¹ It is illustrated by a colour photograph of a finely preserved bottle of Parrish's chemical food, sold by A J Jull of The Pharmacy, Charlbury, Oxfordshire.

The caption to the photograph perpetuates a popular medical misapprehension—that the iron tonic Parrish's food contained arsenic and was withdrawn from sale some 30 years ago. Having checked through the wealth of sources available in the library of the Royal Pharmaceutical Society of Great Britain, I can confirm that this was not the case. This may seem a minor historical point, but during the past few months I have received two inquiries from hospital doctors working in the field of skin cancers who were seeking to make a connection between arsenic supposedly ingested in Parrish's food and the later development of basal cell carcinomas.

Parrish's food is named after its inventor, Professor Edward Parrish, a pharmacist in Philadelphia who died in 1872. The first published description of the compound seems to have been in Parrish's own *Introduction to Practical Pharmacy*, published in 1856,² which ran into several further editions, later appearing as *A Treatise on Pharmacy*. The formula for the food was given in the 1859 edition as protosulphate of iron, phosphate of soda, phosphate of lime, phosphoric acid, carbonate of soda, carbonate of potassa, muriatic acid, water of ammonia, powdered cochineal, water, sugar, and orange-flower water. There is no mention of arsenic, and I can find no evidence of its having been an ingredient of any later variants of the product used in the United Kingdom.

Syrupus Ferri Phosphatis Compositus, with quoted synonyms Chemical Food and Parrish's Syrup, appears in the first edition of Martindale's *The Extra Pharmacopoeia of Unofficial Drugs and Chemicals and Pharmaceutical Chemicals*, published in 1883.³ This publication, now in its 31st edition, is still produced by the Pharmaceutical Press. Parrish's Syrup and the synonymous Parrish's Food were listed until the 1982 edition. The compound appears, again with no arsenic, in all editions of the *British Pharmaceutical Codex* published by the Pharmaceutical Society and Pharmaceutical Press between 1907 and 1968. Researchers are welcome to consult these sources and other supporting material in the library of the Royal Pharmaceutical Society of Great Britain, by appointment with me.

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1 Barrett TG. Minerva. *BMJ* 1997;315:1320.

2 Parrish E. *Introduction to practical pharmacy*. Philadelphia: Blanchard and Lea, 1856.

3 Martindale W. *The extra pharmacopoeia of unofficial drugs and chemicals and pharmaceutical chemicals*. London: H K Lewis, 1883.