Data from transnational study of oral contraceptives have been misused

EDITOR,—The unpublished data from the transnational study of oral contraceptives have been misused and misinterpreted in Britain because of inexplicable haste and urgency not thought necessary by other major regulatory agencies. My colleagues and I do not agree that our findings justify the drastic actions taken in Britain, whereby a "Dear Doctor" letter was sent to doctors, warning that oral contraceptives containing desogestrel and gestodene are associated with an increased risk of thromboembolism (pp 1112, 1117, and 1172).¹ Doctors should be vigilant but not stampeded. Patients need not panic. In particular, the risk estimates in Britain are systematically lower than those in the four other European countries that participated in the study.

On 8 October my colleagues and I completed the analysis of venous thromboembolism in this study (the two other components examine myocardial infarction and stroke). Voluntarily, we briefed medical officers at the Medicines Control Agency and a subcommittee of the Committee on Safety of Medicines within two days. As we did with the German drug safety authorities, we shared the data in confidence, believing that this was in the public interest. To our dismay, without consulting the scientists who had provided the data after five years' fieldwork, the Medicines Control Agency and Committee on Safety of Medicines invoked our findings four working days later to justify sending out the "Dear Doctor" letter.

Unchallenged, that letter will effectively eliminate half of the oral contraceptives now on the British market. This effectively bans the drug while letting the committee off the hook about a banning decision. Despite Professor Michael Rawlins's attempt to mitigate the negative impact, its message seems to have caused a "pill scare," given the newspaper headlines the morning after. As a pharmacoepidemiologist and principal investigator of the study I believe that the associations shown do not justify haste in decision making. After one week's reflection my colleagues and I are uncertain whether the modest increases in the odds ratio for venous thromboembolism can be best explained by bias or as causally significant. Our statistical advisory group believes that five unavoidable biases might be driving the risks up spuriously. Moreover, conventional epidemiological wisdom holds that when drug safety is being considered, relative risks (such as odds ratios) should give way to absolute risks or attributable risks when they are available or can be derived. We presented attributable risks to the Medicines Control Agency and Committee on Safety of Medicines. They were very low, and yet the "Dear Doctor" letter states "twice the risk," an expression of relative risk that is both misleading and alarming.

Our results for venous thromboembolism are equivocal, being neither fully reassuring nor alarming. But I thought that the absence of danger or imminent danger afforded the opportunity to evaluate the results carefully and deliberately, to present them to scientific critique and feedback, and to submit them to a peer reviewed journal. The Medicines Control Agency and Committee on Safety of Medicines chose to short circuit the formal peer review process to make decisions about

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third generation oral contraceptives in the absence of a community health emergency. This is an unacceptable precedent, and I vigorously object to having our unpublished data used thus without the benefit of the investigators' interpretation of the findings or the assessment of disinterested peers.

Conversely, preliminary estimates of attributable risk in the myocardial infarction component of our study suggest that the newer progestogens may convey protection. Nevertheless, because of the adverse publicity we may not be able to complete the fieldwork to determine this. We intend to present our definitive findings on venous thromboembolism to scientific peers at the next annual meeting of the British Pharmacological Society.

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1 Committee on Safety of Medicines. *Combined oral contraceptives and thromboembolism*. London: CSM, 1995.

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Medical aspects of fitness to drive

Unfit patients are a common and difficult problem

EDITOR,—I share Jo Alexander's concern about elderly people who continue to drive.¹ I agree that "if... elderly or sick drivers... steadfastly maintain that they are fit to continue it seems there is no way for a concerned third party to have the case reviewed before an accident occurs." Three cases in my own general practice have left me concerned about just this matter.

In the most recent case I received, in the same day's post as the issue of the *BMJ* containing Alexander's article, a letter from the Driver and Vehicle Licensing Agency (DVLA) informing me that "following satisfactory answers by your patient to a structured medical questionnaire he has been informed by the licensing authority that he or she may drive and that the licence is not subject currently to regular medical reviews, in order to remove unnecessary bureaucratic involvement with the case." This letter concerned a patient who had been wheelchair bound and house bound for many months with a deteriorating condition and whose spouse has recently developed

mental health problems because of his lack of insight into his problems generally. I took little comfort as a road user from the letter's continuing words: "Your patient was told that should the medical condition change so that the ability to control a motor vehicle becomes impaired, driving should cease and the DVLA be notified. It is primarily your patient's responsibility to report such changes to the DVLA."

In another recent case a patient who already had major limb problems had a stroke, which left him with contralateral hemiplegia and sensory impairment. He also had lack of insight into these neurological deficits and maintained that he was fit to drive his car.

The third patient had rapidly accelerating severe dementia; his inappropriate behaviours included telephoning various emergency services up to 20 times in a single night and physically assaulting members of his family. I witnessed him once leave his car parked across a street, blocking both directions of traffic, with the engine still running.

In the second and third cases I did my best to be proactive: I liaised with the close relatives, who arranged urgent sale or disposal of the car in question, but only at considerable emotional stress to themselves.

I agree with Alexander that there should be "a quick and reliable method for concerned people to have the fitness of drivers independently assessed before the worst happens."

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1 Alexander J. Drive on. *BMJ* 1995;311:269. (22 July.)

Enabling patients to drive is also important

EDITOR,—Jo Alexander expresses concern about the lack of interest by health care professionals in an elderly woman's medical fitness to drive.¹ This may not be an uncommon phenomenon. A more general interest in medical fitness to drive is recent, and many doctors are unaware of the regulations for medical fitness to drive and have never had any training in the matter.²

The simple linking of advanced age to dangerous driving is, however, unhelpful. If Alexander's concern is for the loss of innocent life on the road then alcohol, youth, speeding, and possibly testosterone should be targets, rather than old age. There is clear evidence that older people represent a low risk group³ but that those affected by diseases related to age represent a higher risk. Geriatricians on both sides of the Atlantic have written about methods of assessing medical fitness to drive, and referral for multidisciplinary assessment is appropriate in cases of doubt.⁴

A worrying trend for older people is that most of the literature is expressed in terms of who should not drive rather than in terms of enabling or rehabilitating people with illnesses related to age to drive more safely and easily. Less than 5% of the papers in my database of over 600 papers on the subject have an emphasis on enabling. If this trend is not reversed we risk our patients viewing us as police rather than as advocates. Patients with remediable conditions may not seek medical help if they fear that they may not be allowed to drive as a result of the consultation.

While screening for medical fitness to drive may seem an attractive idea, it is unrealistic. Not only is there a lack of effective screening tests but recent data suggest that this sort of strategy may be not only ineffective but also harmful. Some European countries have attempted to screen for illness relevant to driving by demanding a doctor's certificate at regular intervals after the age of 70. A comparison of accident rates between Sweden (where there is no medical control) and Finland (where regular medical recertification is required after age 70) showed no reduction in fatalities in motor crashes and an increase in pedestrian and cycle fatalities in Finland. This may be a result of stopping older people driving unnecessarily and forcing them into the much higher risk group of pedestrians and cyclists.¹

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- 1 Alexander J. Drive on. *BMJ* 1995;311:269. (22 July.)
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Assessments should be independent

EDITOR,—We agree with Jo Alexander that some elderly drivers are a hazard to themselves and other road users.¹ The author is provocative, however, in suggesting that general practitioners may have a vested interest in keeping their patients on the road. Although the ability to drive to the surgery may reduce the need for home visits and prevent social isolation, we are sure that general practitioners would not knowingly put people's lives at risk.

We believe that general practitioners are not the appropriate people to assess whether their patients are fit to drive, for several reasons: good general health does not imply good control behind the wheel; the relationship between a doctor and patient, which has been built up over many years, may be ruined if the general practitioner has to stop the patient driving; and there is no standard assessment system, and general practitioners' decisions would be subjective. We believe that an independent assessment, which should include a medical examination and a practical driving test, should be arranged by the Driving and Vehicle Licensing Agency.

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Rigid rules for hypomanic patients are unfair

EDITOR,—Jo Alexander is concerned about elderly people who continue to drive.¹ I wish to highlight the stigmatisation and unnecessary hardship suffered by some hypomanic patients because of the inflexible application of the Driving and Vehicle Licensing Agency's regulations, with limited rights of appeal. Current regulations require a person admitted to hospital with hypomania to inform the agency.² After a time, while

medical reports are sought, the person loses his or her licence for six to 12 months. Appeal (within 21 days) is through the courts (and hence is public). Most appeals are lost, with the applicants having to bear their own costs and those of the agency. The case may be reconsidered after six months, and if the medical reports are supportive the licence may be restored.

Admission to hospital is a poor indicator of the severity of illness, depending more on social factors and perceived level of support.³ Apart from in a few dramatic cases of speeding, mania and hypomania are not associated with increased accident rates.⁴ No one whose road safety is impaired by illness or drug treatment should drive. Hypomania, however, is usually brief and recovery from it complete. Once well, people are keen to return to their usual lifestyle, and driving is essential for most. Losing the right to drive for six to 12 months can mean losing employment and access to social activities and can cause great hardship, especially in rural areas with limited public transport.

I believe that the rigid application of the Driving and Vehicle Licensing Agency's guidelines is often cruel and unnecessary, with no basis in accident data. The agency's medical advisers tell me that the regulations are likely to become more rigid when European Union directives are implemented. I suggest instead that each case should be examined individually, with reference to the medical reports already being requested. People with severe illness, frequent relapses, or poor compliance and those who are prone to reckless driving could then be dealt with independently of the majority, who are no more likely to be hazardous on the road than anybody else.

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- 1 Alexander J. Drive on. *BMJ* 1995;311:269. (22 July.)
- 2 Driving and Vehicle Licensing Agency. *At a glance guide to the current medical standards to drive*. Swansea: DVLA, 1994.
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DVLA senior medical adviser's reply

EDITOR,—The problem that Jo Alexander describes—of an aunt who continued to drive into her 90th year—is one of general concern.¹ We will always make medical inquiries if a health condition is declared, but some elderly people refuse to accept that they may be unfit and omit to declare a medical condition even when specifically asked to do so on renewal of their driving licence. Advice about to be published by the General Medical Council on when it is appropriate to release information to the Driver and Vehicle Licensing Agency should make doctors' role clearer.

In response to Eleanor Halloran's letter, I acknowledge that the loss of driving privileges inevitably causes hardship. Although we endeavour not to be unreasonable, our prime concern must be for road safety. The secretary of state must satisfy himself that any person who has a medical condition is fit to drive,² and the driving public expects this duty to be exercised properly.

The decision to revoke a driving licence held by a patient with hypomania is made not just on a history of admission to hospital but on the details of the admission and the previous history. A medical condition must be stable and seen to be controlled before driving is allowed: six months for a patient with severe hypomania does not seem unreasonable. This period may be reduced if it seems safe to do so, or increased for up to one year if not. The driving licence cannot be revoked until the medical evidence has been examined, and

when it has been the patient is given a full letter of explanation and advice. The time allowed for an appeal to be made is defined in law: 21 days in Scotland and six months in England and Wales. In our letter to the patient, however, we suggest that a formal appeal, which can be costly, may not be necessary and that an informal approach by the patient's general practitioner or consultant to one of the medical advisers may be more useful.

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- 1 Alexander J. Drive on. *BMJ* 1995;311:269. (22 July.)
- 2 Section 93. *Road traffic act 1988*. London: HMSO, 1988.

Sexual behaviour of men

Review mis-stated prevalence of anal intercourse

EDITOR,—Project SIGMA (Essex) provided the data on gay men's sexual behaviour that were cited in the *Public Eye* programme "Sex in the Dark," which Richard Momeyer reviews.¹ The data are drawn from sexual diaries (calibrated with data from interviews with the men) and were reported at a conference on behavioural interventions and HIV at the Royal Society of Medicine. The data cited by Momeyer, however, are incorrect. It is not true that 70% of gay men who engage in anal intercourse do not use condoms, as Momeyer reports. It is true, however, that 70% of acts of anal intercourse are unprotected and that 40% of acts of anal intercourse by HIV positive men are unprotected (the unit being the sexual act).

The statistics are undoubtedly high in either event, but our analysis suggests that acts of anal intercourse are fairly concentrated (half of all acts of anal intercourse are performed by a tenth of individuals). It is heartening that "risk rich" individuals are far more likely than occasional practitioners to carry condoms and use them.

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- 1 Momeyer R. Sex crime. *BMJ* 1995;311:394-7. (5 August.)

Survey shows unprotected sex is a common behaviour in bisexual men

EDITOR,—The proportion of men who have sex with both men and women and the pattern of their sexual behaviour have long been recognised as being potentially important in the future pattern of spread of HIV infection and other sexually transmitted diseases.¹ Until now, most information has been based on studies of gay men² or small studies of (mainly) self identified bisexuals.³ The British national study of sexual attitudes and lifestyles estimated that 0.8% of the male population had sex with both males and females in the five years before interview; it acknowledged that several factors made this a lower bound estimate.⁴ The members of this group who do not identify themselves as gay or bisexual have never been included in any numbers by a major European study of sexual behaviour.

In a recent national study commissioned by the Health Education Authority in Britain we interviewed 745 men who reported having had sexual contact with both men and women in the previous five years. Participants had responded to an invitation to take part in anonymous telephone