

Drug use and prisoners

SIR,—Prevalence data show that in Belgium the proportion of drug users in prisons increased from 5.6% in 1982 to 9.7% in 1985 and to 11.9% in 1986.¹ From a prevalence study in 1982 it seems that 5.5% of prisoners had used drugs before being sentenced (298/5454) and that 0.1% started to use drugs while in prison (6/5454).²

Dr Anthony Maden and colleagues found that two thirds of the women in prison who were dependent on drugs reported having attended treatment services before entering prison.³ Similarly, they found that of 189 men identified as drug dependent, 85 had had treatment before entering prison.⁴

These data do not contradict our findings among a population of drug users who were interviewed while attending help agencies in Antwerp, Belgium.⁵ Among the drug users surveyed over three months in 1989 (n=126) a high proportion had a history of imprisonment (45%). Of those who had consulted help agencies more than once, half seemed to have been in prison. Surprisingly, of those who consulted only once for treatment, only a quarter had been in prison. Among the drug users interviewed during three months in 1990 (n=234) 30% (59/194) admitted to having been in prison, 55% once and 45% more than once. As with the data for 1989, 35% of those who consulted a help agency more than once had been in prison, compared with only 15% of those who consulted only once for treatment. As these differences could not be explained by age or sex we assume that the problems related to drug use and addiction can be considered as the main responsible factor.

The role of the judicial services in dealing with the drug problem is therefore important. Our data confirm that even if a large proportion of the people intend to seek treatment when released this will be no guarantee of their staying out of prison. As Dr Maden and colleagues suggest,⁴ prisons have an important role in preventing and treating drug addiction problems. On the other hand, good cooperation among prison, social services, and treatment agencies is essential to help people after they have been released from prison. Drug treatment agencies should be able to start their programme in prison in order to continue afterwards when people have been released.

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General practitioners' attitudes to drug users

SIR,—I look after a young woman who has symptomatic HIV disease and is a drug user. I treat her HIV disease jointly with the local hospital. Her drug use is stable, and she has not used illicit drugs for almost a year.

Because of her illness she was able to be rehoused in more appropriate accommodation. This meant leaving my list and having to find a new general

practitioner, and I decided that I would try to transfer her care directly. I was shocked by the response I got from the general practitioners I spoke to. In the end I had to speak to 11 general practitioners before one would finally take her on, and even then the doctor agreed to take her on only in terms of her HIV disease and not her drug prescription. The responses of these general practitioners varied from a polite "No thank you" to "People like this ought to be shot." Not one was willing to listen to the advances that she had made; all seemed to be completely blinded by prejudice.

If drug users are going to be the next wave of people affected by HIV what hope do they have of good care in general practice?

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Tribulations for clinical trials

SIR,—Though I agree with Mr I M C Macintyre's views on clinical trials,¹ an often overlooked issue in conducting such trials is the importance of being able to recruit adequate numbers of subjects in a given trial centre. One of the problems in recruiting subjects may be (and in my experience has been) the number of trials with the same target population being conducted in the same centre.

A suggestion for circumventing this problem would be to charge local ethics committees with the responsibility for assessing the number of trials that are feasible at any one time. In my opinion this is an important ethical issue, for if patients are entered into trials that will fail to recruit adequate numbers to yield meaningful results they are being asked to participate in pointless research and the researchers are wasting efforts and resources that might be better used elsewhere.

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- 1 Macintyre IMC. Tribulations for clinical trials. *BMJ* 1991;302:1099-100. (11 May.)

SIR,—Professor Raymond Levy's concerns about the probable influence of the American Food and Drug Administration's new guidelines on the design of trials of potential new pharmacological agents for Alzheimer's disease¹ have already been experienced for some years in the field of epilepsy, for which the Food and Drug Administration also demands parallel group studies.

The new drug vigabatrin (Sabril; Merrell Dow) illustrates the point. The drug was first licensed in this country on 20 November 1989, the evidence for efficacy having been accepted by the Department of Health on the basis of six European double blind crossover trials² and one European trial of Amery-Dony design,^{3,4} which includes a double blind parallel group phase. Since then, several other European countries have licensed the drug on the same evidence. By a remarkable coincidence, the advisory committee of the Food and Drug Administration met on 20 November 1989 to consider the further evaluation of vigabatrin in the United States. I was present at that meeting and it was my clear impression that a somewhat reluctant committee, concerned mostly about toxicity, eventually agreed to advise resumption of clinical trials in the United States under the pressure of the European experience, including the decision to license the drug in the United Kingdom. Parallel group trials of vigabatrin are now under way in the United States and, as in the cases of carbamazepine and valproate, it is likely to be several years behind Europe in marketing the drug.

If the epilepsy experience is replicated in Alzheimer's disease Professor Levy may find that American companies will first undertake crossover trials in Europe and, when evidence of efficacy

without unacceptable toxicity emerges, will then commence the parallel group studies required in the United States.

A possible solution to Professor Levy's dilemma of recruiting patients to a parallel group study, in which half the patients will not receive the drug, is the Amery-Dony design.¹ This design, like all designs, has its own problems and it may be less suitable for Alzheimer's disease than for epilepsy. However, all the patients are exposed to the drug and the responders who have not also experienced unacceptable side effects later enter a double blind, placebo controlled, parallel group phase, which I have been led to believe is acceptable to the Food and Drug Administration.

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SIR,—I share Mr I M C Macintyre's concern that too few patients are being entered into clinical trials and welcome his suggestions for increasing recruitment.¹

It is of interest that, in the Scottish breast conservation trial, only four of 42 eligible patients (10%) were deterred by the random element.² Most non-entrants (8/12; 75%) refused to receive the elective adjuvant chemotherapy that was prescribed for all patients with negative or low oestrogen receptor levels, regardless of randomisation.

This suggests that most patients, if properly counselled, are willing to accept randomisation. Low entry rates may therefore often be caused by the reluctance of clinicians to consider patients for trials. As patients may fare better if treated in trials³ would it not be appropriate to require that all patients eligible for trials are given the opportunity? Surely it is just as unethical to deny a patient the option of entering a trial from which they may benefit as it is to include a patient without informed consent.

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Appraising journals' reviewing procedures

SIR,—Drs F G R Fowkes and P M Fulton highlighted the difficult task of a reviewer in undertaking a critical appraisal of published research.¹ In line with this, we suggest ways in which peer review and editorial standards of papers submitted to medical journals might be improved.

We believe that the time has come for medical journals to operate a double blind review procedure—that is, authors' names and affiliations should be removed from manuscripts sent for review and referees should remain anonymous. Authors ought to receive copies of the referees' full reports with the editor's decision and be given the chance to appeal against an editorial decision.