BRITISH MEDICAL JOURNAL

SATURDAY 24 NOVEMBER 1984

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NEWS AND NOTES

SUPPLEMENT

NO 6456 BRITISH MEDICAL JOURNAL 1984 VOLUME 289 1397-1472
BRITISH MEDICAL ASSOCIATION TAVISTOCK SQUARE LONDON WC1H 9JR.

WEEKLY. ISSN 0007-1447
ASTM CODEN: BMJOAE 289 (6456) 1397-1472 (1984)

CORRESPONDENCE

We may shorten letters to the editor unless the authors specifically state that we may not. This is so that we can offer our readers as wide a selection of letters as possible. We receive so many letters each week that we have to omit some of them. Letters must be typed with double spacing between lines and must be signed personally by all their authors, who should include their degrees. Letters critical of a paper may be sent to the authors of the paper so that their reply may appear in the same issue.

Correspondents should present their references in the Vancouver style (see examples in these columns). In particular, the names and initials of all authors must be given unless there are more than six, when only the first three should be given, followed by et al; and the first and last page numbers of articles and chapters should be included.

Pharmacoepidemiology

SIR,—The editorial by Professor D H Lawson (13 October, p 941) reports on the conclusions of two seminars on postmarketing surveillance, held at Minster Lovell in June and October 1984. Surprisingly, it omits any reference to the most important development in "pharmacoepidemiology" in the past two decades. This is the establishment of prescription-event monitoring as the second nationwide scheme for identifying and measuring hazards which may escape the net of premarketing studies or the Committee on Safety of Medicines' yellow card scheme.[1] Prescription-event monitoring is actively supported by more than three quarters of all general practitioners in England, and more than 120 000 case reports have been assembled during the past two years—a figure that closely resembles the total accumulation of yellow cards over 20 years.

Neither Professor Lawson nor I could attend the second of these meetings at Minster Lovell, at which various proposals for record linkage were discussed. Had either of us been there, I feel sure that the success of prescription-event monitoring would not have passed unrecognised, for it was often referred to by those who did attend. Prescription-event monitoring has been developed to the point where, at the present rate of introduction into general practice, all medicines containing new chemical entities are being surveyed in the first 10 000 to 20 000 patients for whom they are prescribed. Admissions to hospital are recorded on our computer, and consultants are contacted when necessary. Deaths are followed up routinely to establish their cause and timing in relation to treatment.

Precisely who first coined the term pharmacoepidemiology is for the historians to decide. I have used it for nearly 20 years to describe my own work and that of Hershel Jick and Sydney Shapiro in the United States. It is not a new specialty, but it is very small, comprising a few individuals who have devoted most of their professional life to postmarketing surveillance of drugs. Pharmacoepidemiology cannot be a part time sideline for clinicians or teachers doing other work. It requires an unusual kind of total dedication. Those who enter the specialty must expect to study many drugs, year after year, with largely negative results, since, as Jick noted 10 years ago and we have confirmed with several drugs studied by prescription-event monitoring, they are remarkably non-toxic.[2,3] If job satisfaction depends on the chance of detecting a thalidomide or a practolol, practitioners must expect a very long wait or should stay away from the specialty.

In the 10 years after the practolol incident there has been much discussion of the need for improved postmarketing surveillance. With the exception of prescription-event monitoring and a small number of commercially sponsored studies, there has been very little action. What really disturbs me, however, is that nobody can tell us what risks are acceptable. Recent drug withdrawals have been made largely on the basis of yellow cards, where the reported incidence of fatal adverse reactions appears to be several orders of magnitude smaller than the incidence of fatal complications of the diseases being treated. Certainly, the risk levels leading to withdrawal are below those which can be measured by postmarketing surveillance. Before allocating resources to developing yet more methods of postmarketing surveillance, we must define in simple numerical terms precisely what levels of risk are acceptable in the treatment of each disease, and what levels of risk should lead to drug withdrawals.[4] Only when these levels have been defined can we develop methods for measuring them reliably. Perhaps the Medicines Commission could establish a group of experts who, independently of the Committee on Safety of Medicines or the licensing authority, could prepare guidelines on the acceptability of risk in relation to the benefits of drug treatment.

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1 Inman WHW. Postmarketing surveillance of adverse drug reactions in general practice. II. Prescription-event monitoring at the University of Southampton. *Br Med J* 1981;**282**:1216-7.
2 Jicks H. Drugs—remarkably non-toxic. *N Engl J Med* 1974;**291**:824-8.
3 Drug Surveillance Research Unit. *PEM News* 1984; No 2, August.
4 Inman WHW. Risks in medical intervention; balancing therapeutic risks and benefits. In: Cooper MG, ed. *Risk: man-made hazards to man.* Oxford: Oxford University Press (in press).

SIR,—It would be regrettable if the term pharmacoepidemiology came to be restricted