DRUG UTILIZATION AND THERAPEUTIC AUDIT

'Operational research on the use of drugs, measurement of the incidence of adverse reactions and assessment of the value of drug therapy will constitute a new discipline of therapeutic auditing. The development of this new, exacting and difficult discipline will be a major challenge to clinical pharmacology in the next decade.' (Wade, 1970).

The decade is nearly over and the European Office of the World Health Organization has published a valuable report of the present status of drug utilization studies (WHO, 1979). Owen Wade concludes the opening chapter as follows: 'The aim of drug utilization studies is to be able to carry out a complete therapeutic audit; to see clearly what is prescribed, with what intention and with what benefit or what ill effects and at what cost to the community. A beginning has been made but a full picture has yet to emerge.'

We have always been vaguely aware that drugs are used differently in other countries, in other hospitals or even by other doctors in the same practice. It is also obvious to anyone that there is now far more scope than formerly for sub-optimal prescribing, with alarming implications in terms of missed benefits, more adverse effects and unnecessary cost. Yet considering the resources devoted to developing, testing and controlling new drugs, there has been, at least until recently, little effort to discover how they are ultimately used in the community. This is all the more surprising since the first studies on antibiotics, hypnotics and antidiabetic agents yielded some remarkable results. For example, it was found that in December 1962 a mere 4% of general practitioners in Northern Ireland accounted for more than 25% of all the chloramphenicol prescribed and 2 years later there had been little change. A survey in 1966-7 conducted in six European countries showed that in most of them chloramphenicol accounted for only about 1% of antibiotic sales, but in Germany the figure was 25%. There was also wide variation in the prescribing of other antibiotics (see Wade, 1970).

In 1969, as a result of these findings, the Regional Office for Europe of WHO held a meeting on drug consumption. This led to the formation of a Drug Utilization Research Group in which scientists from fourteen countries are now participating, with the continued support of WHO. Two important methodological advances have been the development of a drug classification system sufficiently detailed to identify individual products and a standard unit of measurement. This is the Defined Daily Dose, which is no more than an agreed arbitrary unit for every drug

(e.g. insulin 40 international units, tolbutamide 1.5 g). Together, these permit valid comparisons to be made over time, or, when related to population, between countries.

It may be no accident that almost all the countries involved, certainly at first, were small ones in northern Europe where drug control and regulation were already well advanced. The addition of Czechoslovakia to the group was of particular interest, because it represented a different system of health care and drug provision. Indeed all the countries have their own characteristics and there are national differences even within Scandinavia. In Denmark, for example, the reimbursement system influences the pattern of prescribing. Surprisingly, the consumption of psychotropic drugs fell marginally between 1971 and 1976 in the four that were studied.

Information on drug utilization may be derived from a variety of sources—national statistics, records of manufactures and distributors, from pharmacists, hospitals, doctors or consumers. Another important source is the market research which is continually carried out to provide, at a considerable price, information for manufacturers on the prescriptions of family doctors. These surveys are usually done by the use of an anonymous carbon copy on which additional data are recorded.

Of special interest to British readers of the book is an unusually detailed description of the monitoring that is done by the Prescription Pricing Authority. The underlying purpose is to promote more cost-effective prescribing and experience has shown that the better informed the doctor, the more efficient his prescribing is likely to be. During 1976 it processed nearly 293 million prescriptions in England, 62% of which were exempt from charges. The average cost was £1.54, equivalent to £9.88 per person per year. For eleven months of each year samples are obtained so that the prescribing costs of every general practitioner in England (20,500 in 1976) can be calculated during the course of the year. The information is sent to the respective Family Practice Committee, which passes on an extract to the doctor concerned. If the average cost per patient is 1.25 or more times the area average, a detailed statement is also sent and the practice is often visited by the Regional Medical Officer. A reduction in costs usually results. The prescribing of drugs of special interest can also be followed. More detailed analyses are made from a 0.5% sample of prescriptions and regular tabulations are prepared and published. From these concern arose about the continued large-scale use of barbiturates. The campaign to reduce it was funded by the DHSS.

Drug utilization can therefore be studied at different levels, by using gross sales figures or prescription and related data, or by more detailed monitoring for specific purposes. The techniques now available can focus down on particular classes of drugs or groups of prescribers, or even individuals within them. The information can be used for economic and planning purposes; to improve the quality of prescribing and the use of limited resources; to assess the incidence of adverse drug reactions and interactions; to identify problems needing further investigation; to indicate where influence might usefully be exerted and to study the effects of any legislative or educational change.

The Drug Utilization Research Group can be congratulated on their achievements so far, though several members say that the methods still need to be improved. Hitherto the emphasis has been on drug consumption. They have demonstrated considerable differences between regions and with time, but it is often difficult to interpret the results when the appropriate level of consumption is unknown and is affected by other varying factors. Easier access, better diagnosis and alternative treatments may make preconceived ideas completely out-dated.

At present the U.K. Prescription Pricing Authority uses the well established technique of 'management by exception' and concentrates on departures from the norm. Some hospitals do the same. This is useful especially in revealing what is obviously wrong, but it does not follow that the norm is right. At present it is difficult to know what is right, because the huge differences between various countries in the numbers of drugs available and in their usage have no evident effect on national mortality and morbidity statistics. This is presumably because such records are too

crude to show *en masse* what we can see daily with our own eyes. In the next decade we must try to develop better methods of assessing whether the economic and clinical benefits offset the cost or justify the risk. Our present intuitive beliefs are not very convincing. Only when the therapeutic auditor can see both sides of the balance sheet will he be able to say that the accounts represent a 'true and fair view' of the whole situation. If we could do this, the full picture, which Wade says 'has yet to emerge', might look quite different from the poor impression we have now. Even if some of the conspicuous imperfections remained, we might see them in clearer perspective.

The difficulties are formidable, some probably insuperable. How can we isolate from everything else the benefits attributable to medicines? How can we assess their contribution to the quality of life of millions of patients, or take into account, as part of the cost, the occurrence of sometimes serious adverse effects? In the meantime we should encourage this line of thought and feasible studies that might serve as indicators. As a small example, a week in hospital costs more than one hundred prescriptions. If even one of those prescriptions keeps a patient out of hospital for a week, does it mean that the rest are virtually free? An economist would probably say that although a corresponding amount of money has been saved, it is not so simple as that because the hospital bed is there anyway and someone else would fill it. Someone off the waiting list perhaps?

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