Drugs, money and society

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The rising cost of health care internationally has prompted examination of the effectiveness and costs of medical interventions. Although drug therapy is a relatively small proportion of health service spending, it has come under particular scrutiny, since the absolute amounts spent are large, are rising rapidly, and are easily measured. A recent report by the UK Audit Commission [1] has suggested that there are large savings to be made in prescribing without compromising patient care, and the government may see the drug bill as one of the more manipulable areas of health expenditure, and possibly a target for cost containment. The reasons why the drug bill is rising so rapidly include an ageing population with more morbidity, new therapeutic advances that extend effective therapy to new groups of patients, new drugs displacing other less expensive products and often adding new benefits, and more demand by a better informed public. There is also a change in developed countries in the aims of health care, which in the past were reactive and disease oriented, but in the future will be proactive and promote health.

What does society want from drug therapy? This may be summarised as efficacy, effectiveness and efficiency.

1 Efficacy i.e. does the drug work under the optimal conditions of the clinical trial? I include under this heading safety and tolerability, which are the remit of drug regulatory bodies such as the Medicines Control Agency and their advisory bodies such as the Committee on Safety of Medicines. These are better studied for pharmaceuticals than for most other medical interventions.

2 Effectiveness i.e. does the drug work under conditions of everyday use, where there is less investigation, less patient selection, and less monitoring than in the clinical trial? We know very little about this, especially in primary care where 80% of all prescribing occurs, and not only for drugs but for most medical interventions. This deficiency has led to the development of outcomes research, and the related health technologies' assessment [2], which seek to define which interventions are effective and what benefits they bring, and which do not.

3 Efficiency This might be defined as ensuring that for every pound spent, the greatest possible benefit is gained. In the health service, we work within a cash limited budget, such that increased spending on drugs takes resources away from other areas of health care. We may argue whether this budget is sufficient, but

this is a political rather than a strictly medical decision. In general, drug therapy represents good value for money by reducing expenditure on other areas of health care, but this cannot be assumed in all cases and expenditure on drug therapy needs justification.

Reforms of health care are under way internationally to meet the new challenges and improve efficiency. In the UK, these changes include the division of providers of health care (e.g. hospitals, general practitioners) from purchasers (health authorities and fundholding GPs), so that providers may compete for funding in a new internal NHS market, in the hope that market forces will improve efficiency and responsiveness of the health service; and the development of a new research agenda, which focuses on seeking practical answers to problems facing the NHS, rather than the pursuit of knowledge for its own sake [3].

Clinical pharmacology has a major role to play in delivering these demands of society in relation to drug therapy, but must embrace three other disciplines, besides its traditional involvement in assessing efficacy and drug safety: these are epidemiology, economics and education. These will be new to many of us, and we can achieve them best as part of multidisciplinary teams, including health economists, pharmacists, general practitioners, statisticians and professional educationalists.

1 Epidemiology Pharmacoepidemiology is the study of the use and effect of drugs in large populations [4]. Drug safety is an aspect of this with which clinical pharmacologists are familiar, but pharmacoepidemiology goes beyond this and asks why doctors prescribe; what conditions doctors are prescribing for, and what they prescribe for those conditions; and what are the outcomes of prescribing. This information is essential in assessing the appropriateness and quality of prescribing, and to inform economic evaluation [5, 6].

2 Economics This asks how we can accomplish most with the resources available to us and how we can achieve our aims most efficiently. Much of the current debate about the drug bill hinges on their acquisition cost. While this is important, we must widen the debate to ask what is the value of drug therapy, and does it offer value for money compared with alternate interventions. Taking a wider view may mean, for example, that the least expensive drug in terms of acquisition costs may not be the most cost effective.

Health economics assesses the costs and the benefits in the widest sense of medical intervention, to help in

making decisions about what we should do. This will encourage a move of resources towards effective and efficient interventions, and away from the less effective and efficient. We must bear in mind that economic efficiency in medical intervention may not always be the imperative—we must also consider compassion and political and social factors. Health economics should not make decisions for us, but rather help us to arrive at better informed judgments [7].

Measuring costs and benefits may not be easy. 'Costs' are more than simple acquisition costs and include costs of administration, monitoring, capital costs and all other direct costs, including those of adverse effects. There is some debate over whether it is appropriate to consider indirect costs such as loss of productivity but recent government/ABPI guidelines have come out in favour of this [8]. These are usually measured in pounds and pence. The term 'cost' is also used in a different sense by health economists; that of opportunity cost, i.e. what are we missing elsewhere by using resources in a particular way? This is a fundamental concept in health economics.

Benefits may also be difficult to measure, and may include outcomes such as lives saved, or quality of life. We may wish to measure both the benefits and the costs in pounds to allow easier comparison between, for instance, a hip replacement and thrombolytic therapy for myocardial infarction. Such measures may be very subtle, and the tools to measure them unfamiliar and sometimes not well validated.

Although health economics considers all medical interventions, and not just drug therapy, drugs are targeted because of their cost and visibility, and because they are so well studied, unlike many medical interventions: this provides data which can be used for economic assessment. Economic evaluations of drug therapy are also encouraged by the pharmaceutical industry, who may see it as a means of justifying rises in costs and supporting marketing efforts. But economic evaluations of drug therapy have wider importance. The industry may use them to assess whether a particular line of development should be continued or abandoned for commercial reasons, to set the price of a new drug or to support reimbursement decisions. The health service should also have a major interest in such evaluations: governments, purchasers and prescribers are all interested in achieving the most efficient use of resources, and can be guided by such studies. Furthermore, the purchaser/provider split may provide the mechanism for the application of the results of such studies.

These are powerful arguments in favour of economic assessment of drugs, but there are also arguments against: that economic evaluation is only a cost containment tool; that decision makers, purchasers and prescribers, have no training in or understanding of economic evaluations, and are in any case only concerned with their own budget. Doctors and managers may therefore be suspicious of the motive of the sponsors of such studies, whether government or pharmaceutical industry, and there is no clear source of independent studies or of validation of such studies for the NHS. Furthermore, current tight budgetary constraints mean that decision makers

must take a short term view, and may not be able to justify increased expenditure now for a putative health gain in the future. There is also a lack of flexibility between budgets, such that when costs occur in one budget and benefits in another, there is currently no way to transfer money.

For instance, inhaled corticosteroids used in asthma increase the primary care drug bill, but may save hospital costs; because of the nature of health services funding in the UK, there is no easy way to move the money from the hospital budget to the primary care budget.

Worse still, doctors may feel that health economics implies rationing on grounds of cost, and feel that it is unethical for them to participate in the process; there is a fundamental clash between the role of the doctor, fulfilling the Hippocratic model as advocate for the patient, and the utilitarian ethic, as the purse holder for society. The conflict of ethics may be more apparent than real: health economics aims to make best use of resources and what could be more unethical than waste of limited resources? Doctors increasingly accept this, although the tension will persist—as perhaps they should. Economic evaluation makes the tensions explicit. This may be uncomfortable for doctors, patients and government. A statement such as 'patients will always receive all the drugs they require' fudges the real issue: will a government fund an effective but expensive drug and pass over more efficient non drug therapies? Health economics neither creates the problem, nor does it provide the answer: it will allow a better informed decision [7].

Health economics is a young science whose methodologies are not yet fully developed. Some are agreed, such as the need for incremental analysis, that direct costs should be considered, that costs should be discounted, that a sensitivity analysis be performed and that there should be transparency of the reporting. The perspective of a study is also important as we may get very different answers if we consider costs and benefits from the points of view of a government, a health service or society. The wider societal perspective is thought most appropriate; but in reporting, costs and benefits should be separated so that other perspectives can be considered.

Some are not agreed: for instance how best to measure quality of life, how to undertake a particular study, and whether economic assessments of drugs should be regulated. Although superficially attractive, there are many objections to regulation. Government objections might include the risk that economic evaluation could constrain policy; i.e. if economic evaluation is mandatory, will not also its implementation be? This might drive resources into interventions simply because they have been evaluated and away from those less well studied, such as health education. Academic objections might be first that economic evaluation is not yet up to the task, as seems to be the case in the Oregon experiment in the United States [10], and secondly that premature regulation would stifle the development of the science. The pharmaceutical industry might protest that economic evaluation might become a fourth hurdle to drug licensing, increasing research costs and commercial

risk and discouraging broad based research. In practice, regulation by law is probably unnecessary (although agreed guidelines are useful [8]), since market forces will effectively be a more rigorous form of regulation and will create the fourth hurdle, and other sciences are adequately 'regulated' by pressures of peer review.

For the future, economic evaluation of drug therapy must be kept within the context of total health care. Budgetary constraints are likely to get worse, but health economics will help us to take a longer term and broader view of value and value for money. There is a need for independent validated economic assessments, which could then feed into the purchaser-provider split [9].

3 Education. Even if we know what to do, informed by clinical pharmacology, epidemiology and economics, how do we actually apply it and alter practice? Medical audit has shown clearly the inconsistencies of medical practice. This is in part due to poor education, and in relation to drug therapy, academic clinical pharmacologists must accept some responsibility. Clinical practice might be changed by the dictat of the purchaser, and this is already happening in hospitals. But education is likely to be more effective and acceptable, and to produce longer lasting change. Postgraduate education is currently a low priority for most

clinical pharmacologists [11]. Many are involved in writing clinical guidelines for formularies, but these are best seen as educational, and not management, tools. The changes currently in progress in the undergraduate curriculum may seem a threat to clinical pharmacologists, but may be an opportunity to reassert the relevance of clinical pharmacology to the practising doctor. We must build bridges into postgraduate education and make clinical pharmacology a more practical and less academic discipline within the NHS, as it is already in the pharmaceutical industry. We must promote an understanding of the principles of safe, effective drug therapy, and by promoting rational therapy, limit the need for rationing of therapy. A similar role for clinical pharmacologists has been mooted in the United States recently [12].

Society expects efficacy, effectiveness and efficiency from drug therapy. Clinical pharmacology, by building on its traditional strengths in efficacy and education, and taking on the scientific study of epidemiology and economics in relation to drug therapy, has a bright future in delivering these.

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