Accounts Commission for Scotland

The bitterest pill

Decision making for new drugs

DECEMBER
1 9 9 7

Contents

The Accounts Commission is a statutory, independent body which through the audit process assists local authorities and the health service in Scotland to achieve the highest standards of financial stewardship and the economic, efficient and effective use of their resources.

The Commission has five main responsibilities:

- securing the statutory external audit
- following up issues of concern identified through the audit to ensure a satisfactory resolution
- reviewing the management arrangements which audited bodies have in place to achieve value for money
- carrying out national value for money studies to improve economy, efficiency and effectiveness in the NHS and local authorities
- issuing an annual direction to local authorities setting out the range of performance information which they have to publish.

The Commission assists the NHS in achieving value for money by highlighting good practice, providing comparative information, and supporting auditors in reviewing performance locally. Its Health and Social Work Studies Directorate is responsible for managing a national programme of value for money studies. Part of the 1997 programme included a review of how health boards manage the introduction of new drug treatments.

Acknowledgements

This study was managed by Sara Twaddle under the general direction of Caroline Gardner, Director of Health & Social Work Studies. The Accounts Commission is grateful to all the individuals and organisations who assisted this study. Responsibility for the contents and conclusions rests solely with the Accounts Commission.

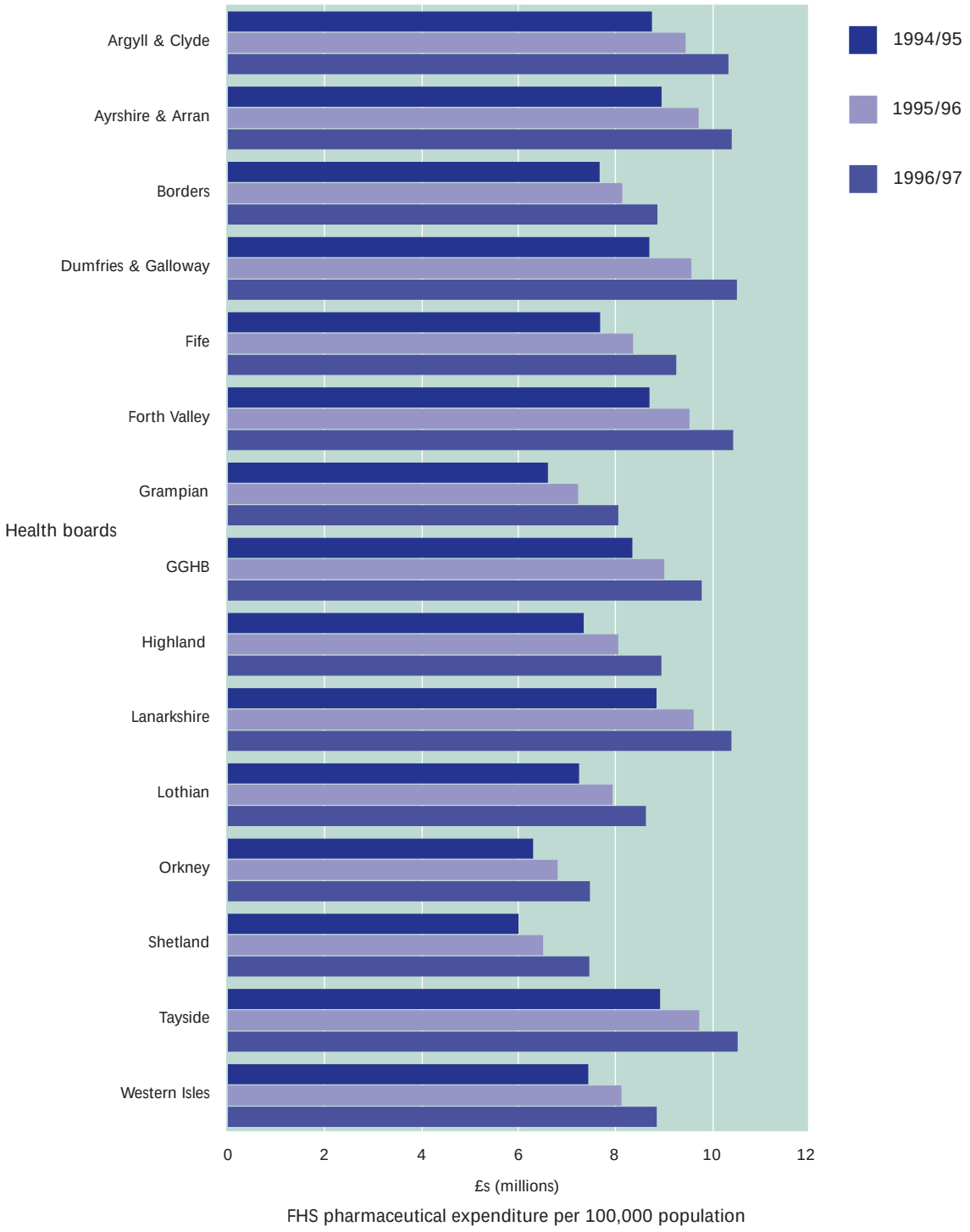
The study was supported by an advisory group consisting of a Board General Manager, a Director of Public Health, an acting Chief Administrative Pharmaceutical Officer and a Professor of Oncology.

All health board general managers in Scotland were asked to nominate individuals within the board who should be part of the study. Those identified were then interviewed using a semi-structured questionnaire, covering aspects of decision-making about those drugs the respondents felt had potential to place pressure on resources. In 13 boards interviews were face-to-face; in another the interviews were by telephone. The remaining board provided a written summary. The interviews took place in the period April to August 1997.

1. Introduction

Drugs are an important element in increasing health service costs. In the period 1994/95 to 1996/97 the cost of drugs prescribed by general practitioners in the NHS in Scotland rose from £415 million to £492 million, an increase of 19%. The pattern is similar throughout Scotland (exhibit 1). The cost of drugs prescribed in Scottish hospitals is not collected centrally, but the rise is thought to be similar. [1]

Exhibit 1: FHS pharmaceutical expenditure per 100,000 population



Source: Skipper plus 3.1

A range of factors have contributed to the continuing increase, summarised in exhibit 2.

Exhibit 2

- Development of drugs for diseases with no previous treatment (eg Pentamidine for Pneumocystis carnii)
- Development of new drugs with fewer side effects (eg SSRI anti-depressants)
- Development of drugs which change the pattern of care for diseases (eg the effect of acid-suppressant drugs on gastric surgery rates)
- Drugs initiated as a result of screening (eg statins for the prevention of coronary heart disease)
- Development of drugs which are more effective and safer than older drugs (eg Olanzapine for schizophrenia)
- Moves towards multiple therapy (eg triple therapy in HIV/AIDS)
- Changes in demography
- Increased numbers of patients being treated
- Commercial pressure from the pharmaceutical industry.

The problems posed by drugs are, however, not solely related to their increasing cost. Indeed in some cases they may lead to savings in other areas of the NHS. The real issue is whether the drugs are effective, and how decisions about their use are made.

There is an increasing realisation within the NHS of the need to demonstrate the effectiveness of treatments with robust evidence. This is never easy. Choices will always have to be made between competing priorities for funds, so that decision-makers need to ensure that resources are being used to maximum benefit. There are two key areas for decision:

- the withdrawal of ineffective drugs already in use
- the introduction of new drugs where there is robust evidence of their benefits. If there is evidence that new drugs are ineffective, they should not be introduced. If the evidence is not yet available, the drugs should be introduced in a controlled way, linked to randomised controlled trials which will provide the necessary evidence in future.

These options are summarised in exhibit 3.

Exhibit 3

	Definite or possible harm	No effect	Possible benefit	Definite benefit
Existing treatment	Withdraw	Withdraw	?	Continue
New treatment	Withhold	Withhold	?	Introduce

The most difficult problems arise with high cost, low volume drugs which may have some benefits for some patients, but where the evidence is not yet robust enough to be able to quantify how much benefit and for which patients. With drugs like these, the problem is heightened where there is no other effective treatment. For example, there is some evidence that Donepezil may delay the progress of symptoms for a short period for some patients with mild to moderate symptoms of Alzheimer's disease, but without affecting the disease's underlying progression.

The question then is how much society is willing to pay for this possible effect. If Donepezil were prescribed for all patients in Scotland who might benefit on the basis of the current evidence, the estimated cost would be £6.5 million per year.[2] However, there are many alternative uses for this money which would provide proven benefit to these or different groups of patients, and these competing priorities need to be weighed against one another.

This dilemma is illustrated by the experience of one Scottish health board, which found that more than 40% of the funds available to it to fund service developments were spent on new drugs rather than on introducing or extending other services. Even at this level of expenditure, many bids for new drug treatments were not funded.

The organisation of the NHS in Scotland adds another dimension to the problem. The fifteen Scottish health boards are responsible for assessing the health needs of their populations, setting priorities for treatments within the resources available to them, and arranging for those treatments to be provided. However, health boards have different approaches to deciding which drugs they will fund for which patients, and therefore reach different conclusions. This means, for example, that two patients with the same disease may receive very different treatment, solely because they live in different health board areas.

The role of the health board in making decisions about these drugs is to influence doctors' prescribing behaviour - there are few controls. These decisions therefore need to have local credibility with the doctors involved. The need for such decisions to be transparent is reinforced by public awareness of individual drugs, particularly those for conditions with no previous treatment, and the increasing role of patient groups for particular conditions. At a conference entitled *Rationing in the NHS: Time to Get Real*, George Levvy, the chief executive of the Motor Neurone Disease Association, said that his members 'would not expect that every patient could get every new drug, but they wanted to know the criteria that were being used and see that they were applied fairly'.[3]

Where different policies for the use of drugs exist, these have attracted wide media attention and, more recently, a number of legal challenges. In the light of one of these cases, where a successful challenge was made to the decision of North Derbyshire Health Authority not to fund beta interferon for multiple sclerosis, health authorities have now been advised to review their policies on providing funding for expensive new therapies.

All of the above factors have contributed to calls for a Scotland-wide approach to the introduction of new drugs. A recent article by the Chief Medical Officer addressed the issue and concluded: 'Three things are certain: the pressure on the drugs bill will always be upwards, new expensive and potentially valuable treatments will continue to emerge, and a robust mechanism must be developed to cope with these pressures, ensure that expectations are appropriate and reassure the public about their equity of access. Such matters should not be left to the courts'.[4]

This report looks at how health boards reach decisions about new drug treatments. The challenge is three-fold - to ensure that:

- ineffective or harmful drugs are not introduced;
- drugs which offer positive benefits are introduced; and
- drugs of uncertain benefit are introduced in a controlled way and evaluated.

The report does not examine how boards ensure that their decisions are implemented in practice by doctors in hospitals and in general practice; this will be the subject of a future report. Neither does it examine how GPs deal with new drugs. Their decisions are, however, another potential source of inequity between people with similar needs.

Chapter 2 discusses the issues which face boards in making decisions about high cost, low volume drugs, and Chapter 3 describes how boards currently make decisions about them. Chapter 4 suggests a way forward, based on a range of good practice.

2. The nature of the problem

In principle, new drugs pose similar problems to other heath care innovations. In practice, however, several factors mean that drug decisions are more difficult. These include the way in which drugs are prescribed; the different funding of drug budgets in hospitals and in primary care; and British drug licensing arrangements.

The prescribing decision

The issues which confront health boards in managing the introduction of new drugs are similar in principle to those relating to other new health care interventions, such as operative procedures or diagnostic techniques. In practice, however, they are more difficult to manage because of the nature of prescribing decisions. For doctors to prescribe a new drug no initial investment is required, in contrast to the equipment often required for new diagnostic techniques, and the need for skills and training is less apparent than for operative procedures. Any doctor can prescribe a drug which has been licensed. These factors mean that a new drug is often introduced as the result of a series of individual decisions rather than through any explicit policy about its use.

This is highlighted by the experience of health boards with Riluzole, a drug which is claimed to have some benefit for patients with motor neurone disease, but for which the evidence is disputed. [5] A Drug Briefing Note produced by the Scottish Health Purchasing Information Centre (SHPIC) recommended that, on the present evidence, the drug should not be used outwith well-designed research studies. Exhibit 4 summarises the position in Scottish health boards.

Exhibit 4:

Board	Prescribing policy
1	The drug has not been considered by the Drugs & Therapeutics Committee, but 'in principle prescribing should not be a problem'
2	A shared care protocol has been developed
3	GPs prescribe on the advice of a neurologist
4	Decision pending; the drug has not yet been assessed by the Drugs & Therapeutics Committee, but some GPs are prescribing it
5	The drug is not recommended on the grounds of insufficient evidence on efficacy, but some GPs are prescribing it
6	GPs prescribe on the advice of a neurologist
7	Decision still pending; some GPs are prescribing the drug
8	No requests have been made for the drug, and the conditions under which it will be prescribed have not been considered
9	Currently prescribed by neurologists. Shared care protocol is being developed; not yet fully operational
10	GPs prescribe on the advice of a neurologist
11	Decision still pending; not yet assessed by the Drugs & Therapeutics Committee, but some GPs are prescribing
12	GPs prescribe on the advice of a neurologist
13	Neurologists prescribe and monitor; a limit of 25 patients has been set

Source: MND Association survey 1997 [6]

In three boards, no decision has yet been made about the use of the drug, but some GPs are already prescribing it. In a fourth, the board has made a decision not to recommend the drug because there is insufficient evidence of its efficacy, but some GPs are prescribing it in spite of this decision.

This problem is exacerbated for health boards by the unpredictability of future drug developments. The drug industry spends millions of pounds each year on researching and developing new drugs, and the pace of change is increasing. This makes it hard for each individual board to have a clear picture of what new drugs might emerge in future, and to plan its response in advance.

The difficulty of influencing doctors' prescribing behaviour is heightened by the growth of patient advocacy. Groups representing patients and their carers are becoming increasingly knowledgeable about particular conditions and developments in drug treatments. This is accompanied by increasing assertiveness in demanding new drugs which may offer some hope of treatment, particularly where no alternatives are available. This demand is understandable, since the diseases concerned often cause extreme suffering or death, and some doctors share the feeling that it must be better to do something than nothing. However, the unregulated use of drugs for which there is no evidence of benefit may do no good for the individual patient, may do harm, and uses resources which could provide care of proven benefit for others.

Drugs budgets

Budgets for drugs prescribed by hospital doctors and by general practitioners are handled differently. Drugs prescribed in hospital are funded from the hospital's budget, which is limited to the amount agreed between the trust and the health board. By contrast, drugs prescribed by GPs are paid for from the General Medical Services budget, which is not cash limited (except for those prescribed by fundholders).

This means that there is an incentive for hospital doctors to pass responsibility for prescribing high cost drugs to their GP colleagues, since their budgets are seen as elastic. There have been many attempts in the past to increase control over the cost of drugs prescribed by GPs, such as indicative prescribing budgets and GP fundholding, but overall prescribing costs have continued to rise as shown in exhibit 1. In any case, passing responsibility between doctors in this way to avoid budget restrictions does nothing to address the underlying issue of effectiveness, and may damage the quality of care received by patients.

Drug licensing arrangements

The difficulties faced by health boards in managing the introduction of new drugs are exacerbated by the British drug licensing process. In order to obtain a license for a new drug, manufacturers need to demonstrate efficacy, safety and stability, but not cost-effectiveness. Once a drug has been licensed, it is immediately available for prescription, probably before those responsible for health policy have had the opportunity to assess the quality of the evidence for the drug's effectiveness relative to other treatments, and its cost-effectiveness. The Australian system, whereby an economic evaluation has to be included in each submission to add a new drug to the national pharmaceutical subsidy programme, is a good example of how this issue can be addressed. Under this system, drugs are compared with their main comparator, resulting in information about the relative cost effectiveness of drugs before they are commonly used.

3. The decision-making process

Scottish health boards make decisions about new drugs in a variety of ways, but most do not have access to all the specialist skills they require. The way in which decisions are presented also varies between boards, and some do no more than set out a view on the usefulness of the drug, without giving guidance on when and how it should be used. There are significant gaps in the information available to boards to support their decisions, with potential for overlap and misjudgements as boards attempt to generate their own information. Most importantly, the criteria which are used for decision-making are unclear, so that decisions cannot readily be understood by those affected by them, particularly doctors and patients. This is far from the 'robust mechanism' to 'reassure the public about their equity of access' demanded by the Chief Medical Officer.

Area Drug and Therapeutics Committee

The main mechanism which health boards use to make decisions about new drugs is the Area Drug and Therapeutics Committee (ADTC). Each board has its own ADTC, except Orkney and Shetland Health Boards, which participate in Grampian Health Board's Committee. There is no national guidance on the role of ADTCs, and in practice their role varies significantly between boards (exhibit 5). In all cases the role of the ADTC is advisory.

In eight boards, the ADTC or a sub-committee considers all new drugs, while in four boards the ADTC only considers a drug if there are funding implications, or if the drug has implications for primary care. In one board new drugs are not considered by the ADTC, which sees its role as concerned with developing the formulary and guidelines. Three boards have parallel structures, in which new drugs are considered by both the ADTC and a Clinical Effectiveness Committee.

The way in which decisions are made and presented also varies between boards. In seven boards decisions are graded, generally in terms of the way in which the drug may be used. There may be a recommendation that the drug can be prescribed only for named patients, only in hospital, within a shared protocol of care, or for general use. The decision may be refined further to develop a protocol for the use of the drug, setting out, for example, criteria for which patients are most likely to benefit, who should be involved in the prescribing decision, and rules for involvement in clinical trials. In the six boards which do not grade decisions, the committee simply offers a view about the usefulness of the drug, in terms of efficacy rather than value for money.

Professional involvement

A number of different professions have a legitimate interest in decisions made by ADTCs, and each has important skills and knowledge to bring to bear on the decision (exhibit 6).

Exhibit 5: Current approaches to decision making about high cost, low volume drugs in health boards

Board	Prescribing policy
1	Area Drug & Therapeutics Committee (ADTC) considers new drugs New drugs may be funded by trusts or presented to the Board as a development proposal
2	New drugs are evaluated by Trust DTCs If funding is required a new drugs sub-committee of ADTC advises the board on the cost and value implications
3	New drugs are considered by Trust DTCs They are reviewed by ADTC if drug has primary care implications or requires additional funding. The ADTC may advise the Board directly or refer to Board Clinical Effectiveness Group if funding is an issue
4	Trust DTCs consider new drugs The ADTC is concerned with formulary development, guidelines, and links between hospital doctors and GPs. The board is developing a multi-disciplinary group to review new drugs
5	A sub-group of the ADTC is concerned with drug evaluation. It advises the Board on funding issues
6	The ADTC reviews new drugs and advises the Board
7	A sub-group of the ADTC is concerned with the evaluation of new drugs The Board Purchasing Committee will consider the issue if there are financial or political implications
8	The ADTC reviews new drugs and advises the Board
9	Two approaches: i) A Primary Care ADTC advises the Board on drug developments in primary care ii) A Clinical Effectiveness Steering Committee advises the Board on drug developments in secondary care.
10	An area wide advisory committee advises the Board on expensive therapies
11	Two approaches: i) Traditional approach involving Trust DTC and ADTC where impact is likely to be wider than the Trust ii) A Clinical Effectiveness Group deals with issues which are likely to be contained within the Trust. Reviews wider implications of new drugs, and aims to identify the best overall solution
12	Main mechanism is Trust DTCs; issues are referred to ADTC if funding is an issue. New drugs are also raised as service development proposals.
13	A sub-group of ADTC reviews all new drugs. The funding of expensive therapies (> £3000 per annum) is considered by an Executive Committee of the Board

Exhibit 6: Professions with an interest in decisions on new drugs

Profession	Role
Hospital doctors	Knowledge of patients' needs, usefulness of drugs in practice.
Pharmacists	Knowledge of the efficacy of drug, other drugs available for the same condition, new developments on the horizon.
Medical prescribing advisors	Encouragement of rational prescribing in primary care.
Pharmaceutical prescribing advisors	Provision of technical advice on drugs used in primary care.
Chief administrative pharmaceutical officers	Provision of advice to health boards about pharmaceutical issues.
General practitioners	Experience of use of drugs in primary care. Knowledge of patients' needs and expectations.
Public health doctors	Provision of population perspective on place of new products.
Clinical pharmacologists	Specialists in evaluation of new products. Usually based in University Departments of Medicine and Therapeutics.
Nurses	Direct involvement with patients and drug administration.
Clinical/medical directors	Finanicial responsibility for use of new products.
Health economists	Assessment of overall economic implications of new products compared with other uses of the same resources.
Finance managers	Assessment of financial implications of new products.
Contracts staff	Assessment of implications for contracts between health boards and trusts.
Patients and those who care for them	Direct experience of the condition.

ADTCs and their sub-groups invariably include the first six of these professions, but the representation of the others varies widely (exhibit 7).

Exhibit 7: Involvement of other professions in ADTCs

Profession	Number of committees
Public health doctors	4
Clinical pharmacologists/university department of medicine & therapeutics	4
Finance managers	3
Health economists	2
Contracts staff	2
Nursing	2
Community trust doctors	1

Where high cost drugs are considered by committees other than ADTCs (as described in exhibit 5), the group tends to be more multi-disciplinary. Several boards feel that their decision-making process is hindered by the lack of involvement of clinical pharmacologists and health economists, whose skills are essential if robust decisions are to be reached.

There is widespread agreement that involving clinicians in the decision-making process is an important way of developing ownership of decisions among doctors. However, some boards report that it can be difficult to generate and sustain this involvement, because the role of the ADTC is purely advisory.

Information for decision-making

Information on the efficacy, effectiveness and cost-effectiveness of new drugs is crucial to good decision-making, and the amount of information available is increasing steadily. Key sources include:

- Pharmtrak reports from the Pharmacy Practice Division of the Common Services Agency. These reports are universally considered to be of a high standard by boards, providing valuable information prior to the launch of a new drug. Some concerns were raised, however, that the reports do not consider the economic implications of the drug. The reports also have limited circulation, to CAPOs, MPAs and PPAs, hospital pharmacy managers, drug informtion centres and some members of ADTCs. One respondent questioned 'Why is it such a big secret that it has to be kept from doctors?'
- Drug briefing notes from the Scottish Health Purchasing Information Centre (SHPIC) are seen as a useful source of information about the cost-effectiveness of drugs. Notes have so far been produced on Riluzole for motor neurone disease, Finasteride for enlarged prostates, Dexfenfluramine for obesity and Atorvastatin for the prevention of coronary heart disease. The main concern is timeliness, since the notes are sometimes published well after the initial review of a drug's effectiveness. This can have two problems: the information may already be out of date, because of new variants or changes in the relative costs of drugs; and prescribing practice may already have become established, making it more difficult to implement the recommendations of the Note.

In addition to these central initiatives designed to evaluate new drugs in different ways, all boards carry out their own reviews. This is a complex and time-consuming process, requiring specialist skills to locate, appraise and combine the findings of relevant research studies. There are two dangers with widespread local reviews: first, that resources will be wasted by the duplication of similar searches across several different boards; and second, that insufficient skills and resources are available to do the review properly, with the potential for a misleading result and inconsistent decisions. Only three boards mentioned collaboration with colleagues in other health boards.

These problems accompany searches for evidence about most health interventions, but drugs pose particular problems because of the role played by pharmaceutical companies. These are commercial organisations, developing new drugs with the aim of getting them adopted as widely as possible to maximise profits. They sponsor much of the research about new drugs, fund posts in university departments and also act as an important source of research evidence to doctors responsible for prescribing decisions. However, there are many examples of drug companies presenting only favourable evidence about a particular drug, or funding research which is designed to show their drug in the best possible light. A common problem is that new drugs are often tested only against placebo, rather than against the nearest alternative drug, so

that direct comparisons of the drug's effectiveness and cost effectiveness cannot be made.

There are many sources of information available to boards about new drugs, but there are significant gaps. In particular, information about the overall economic implications of a drug is scarce, taking account not just the cost of the drug itself, but also the monitoring costs that may be required and any savings. The information which is produced nationally is not disseminated widely to all those affected by decisions on the use of drugs, and boards currently have no systematic way of knowing what drugs have been evaluated locally by other boards.

Managing expectations

In spite of the difficulties, there is widespread consensus about the need for involvement of professionals in decision-making. There is less consensus about the involvement of lay people, patients and their carers. Most health boards believe that these people should be involved in decisions, and even that it may be possible to make better decisions with their involvement. However, they are very unsure how best to manage this involvement, and express significant concern about the difficulties.

These concerns are magnified by the role play by the media. Boards believe that the media's role is negative at present, since most journalists do not understand the complexity of the issue, and simplistic stories about patients being 'denied treatment' are newsworthy. However boards believe that the media could instead make a positive contribution to the debate, providing accurate information about the effectiveness of new drugs, and explaining the areas of uncertainty which have not yet been resolved.

Boards believe that the main requirement is a more open debate about how decisions on health care provision are made. They believe that the debate on what drugs are funded and why needs national co-ordination. There is a need to involve the public in discussions about why particular drugs may not be funded for general use, and the different circumstances in which they may be valuable. Local health councils may have a role in developing this debate.

Equally important is the need for more openness about how decisions on new drugs are made, and the criteria which are used. This report has shown that there are significant differences between boards in the structure and role of their main advisory mechanism on drugs, the Area Drug and Therapeutics Committee, with no clear explanation of why this should be so. The basis on which decisions are made is even less clear, and this can only contribute to misunderstanding and concern among doctors and patients about decisions to withhold certain drugs, or to make them available only in certain circumstances.

Health boards have a responsibility to explain both the process by which decisions are made, and the reasons for individual decisions. This will never be easy, but the alternative is likely to be growing concern about perceived inequity and 'rationing'. Experience suggests that the public understands that choices have to be made between competing priorities, and that some drugs (and other treatments) may have benefits which are too small or too uncertain to justify their cost.

The growth of the patient advocacy movement may actually make this process easier, by developing a group of well-informed patients, carers and others with whom this debate can take place on particular drugs. We found no examples of boards doing this on a systematic basis, but it is likely to offer a useful way of tackling a difficult issue.

4. The way forward

This report has highlighted two important ways in which decisions about high cost, low volume drugs could be improved. First, there are several areas which offer the potential for collaboration between health boards. This would improve the quality of decisions made, and increase value for money. Second, the process of decision-making should be made more transparent, so that decisions are understood and have credibility with those who are affected by them.

Collaboration between health boards

The evaluation of new drugs is a complex and time-consuming process, involving a number of stages from literature review to economic evaluation. There is potential for collaboration between health boards to improve this process; the current duplication of effort wastes resources, leads to different conclusions, and creates a climate which fosters confusion and misinformation.

One option would be to establish a single decision-making body for Scotland, by means of either national guidance from the Management Executive, or a single ADTC for Scotland. This approach is superficially attractive, but it runs the risk of losing the local perspective and damaging local ownership of decisions. Local ADTCs should have a distinct role to play in developing local guidelines and protocols, and overseeing their implementation.

The scope for collaboration is much stronger in the area of collecting and evaluating information on the cost-effectiveness of new drugs, and making recommendations on their use. This would also offer advantages in introducing drugs in a controlled way, for example through clinical trials. In many cases, these require more patients than will be found in any single health board area; collaboration between boards is likely to generate the necessary research evidence much more quickly.

There is already some collaboration between boards. Grampian ADTC includes Orkney and Shetland Health boards; Fife and Borders Health Boards representatives sit on the Lothian drug evaluation panel; and the West of Scotland Health Boards are forming an information sharing group with representatives from each ADTC. This reduces duplication of effort by local ADTCs, while allowing them to retain a local perspective. It does not, however, ensure that all the necessary skills and information are available, unless these are already present in the host ADTC.

Since there is only a small number of high cost, low volume drugs licensed each year, it would be possible for health boards to establish a national policy group to provide advice. The group would provide a view on the efficacy, effectiveness and cost-effectiveness of a drug, but decisions would be made locally about its use and funding. Such a group would offer a number of advantages:

- duplication of effort would be eliminated, with drugs reviewed once only across Scotland
- all the necessary skills and knowledge for robust decisions could be brought together
- transparency of decision-making would be promoted, improving credibility and understanding
- the speed of response would be increased
- it would offer a forum for consultation with specialists in specific areas, and with patient advocacy groups.

The group would need to include individuals with a high level of credibility and competence if its decisions were to be respected. It would also need clear criteria on how to select drugs for review, and on how recommendations will be reached. It could commission evaluations from existing organisations in Scotland with particular expertise, and might also develop sufficient influence to work with pharmaceutical companies to obtain information at an early stage.

Boards would still need to decide locally how to act on the recommendations of the group, determining the level of funding to be provided, assessing the impact on other local services, and placing the drug into an overall package of care. A key part of this process would be to discuss the recommendations of the policy group with local clinicians, in order to develop local understanding and ownership. Local ADTCs would have a continuing role in developing local guidelines and protocols, and overseeing their implementation.

A policy group could, however, deal only with a small number of new drugs each year. For the remainder of new drugs health boards would still rely on local advice. This situation could be enhanced by the use of electronic communication technology, such as bulletin boards, which would further reduce duplication of effort and enable greater sharing of information and expertise throughout Scotland.

For small boards high cost, low volume drugs may continue to cause problems, clinical or financial. Clinically, there may be no-one available with the specialist clinical knowledge necessary to take a role in implementing the recommendations. Financially, the high cost of the drugs, together with the unpredictable nature of demand for them, may mean that they cannot be managed effectively for small populations. There may be potential for further collaboration between small boards, by developing joint guidelines and protocols for the use of these drugs, and identifying pooled budgets to share the risk in funding them.

Finally, there seems to be scope for collaboration between the existing national advisory bodies, the Pharmacy Practice Division and the Scottish Health Purchasing Information Centre. These bodies have different roles but, at present, their work programmes are not co-ordinated. This has two potential effects: there may be duplication of effort as both review the same drugs, since the evidence base used by each is likely to overlap; and the reports produced by each independently may be seen as incomplete.

Co-ordinating the programmes of the two bodies would mean that duplication could be avoided, with each drawing on work already done by the other. The organisations could also carry out joint evaluations of new drugs, bringing together their distinct specialist skills and providing comprehensive information for boards to base their decisions on.

Transparency of decision-making

Increasing the amount of collaboration between boards, in the ways suggested above, offers one means of improving the quality and cost of decision-making about new drugs across Scotland. It is also important, however, that the reasons for decisions, and the process by which they are reached, are transparent. This will increase the likelihood that decisions are understood by the public, by patients and by doctors, and reduce concern that decisions to withhold new drugs are due to a lack of funding. Equally importantly, it will help doctors to respect the decisions which are reached, and to prescribe in accordance with them.

Health boards should make explicit the processes which they use and the factors which they take into account when considering the introduction of a new drug treatment. The process includes the composition of the ADTC or other group, its role in decision-making, and how drugs for consideration are identified. The factors which are considered are likely to include:

- the evidence about the effectiveness of the drug, and the quality of that evidence
- evidence about the cost effectiveness of the drug, taking account of the cost of the drug itself together with any other costs and savings which may be involved
- the costs and benefits of the drug compared with the nearest available treatments
- the total cost involved in making the drug available
- competing priorities for funds.

This information is all needed to reach a robust decision, and to develop local guidelines and protocols. When the board has made a decision, the information should also be made available in summary form to those affected, particularly doctors and patient advocacy groups. Opening up the process in this way will help to reduce concern about the decisions themselves, and develop a common understanding with those affected by decisions about the introduction of new drugs.

Recommendations

A policy group should be established by Scottish health boards to evaluate the small number of high cost drugs. The group should make recommendations about the efficacy, effectiveness and cost-effectiveness of drugs, but individual health boards should continue to make final decisions about funding, and oversee the development and implementation of guidelines and protocols for their use.

Health boards should work together to establish clear criteria on which drugs will be evaluated by the policy group, and how recommendations will be reached. These should be made public, as part of the process of improving the transparency and accountability of decision-making. Boards should also consider how patient groups and the public can be involved in the work of the policy group.

The two Scottish organisations which currently provide evaluations of new drugs (PPD and SHPIC) should collaborate to eliminate duplication of effort, and carry out joint evaluations of new drugs where appropriate.

Health boards should consider how best to use electronic communication technology to enable more effective sharing of information and expertise on drug evaluations in Scotland.

Individual boards should review the structure of their ADTC (or equivalent body) to ensure that it includes the necessary professions and skills to reach robust decisions about new drugs, and to carry credibility with the groups affected by such decisions. They should also review the role of the ADTC to ensure that it covers the key areas of guideline and protocol development, implementation and monitoring.

Individual boards should develop clear and public criteria against which decisions on new drugs are taken. The Local Health Council, patient advocacy groups and other members of the public should be consulted on this process.

References

1 Carter D. From the Chief Medical Officer. Health Bulletin 1997; 55: 279-281

2 Ibid

3 Kennedy I, Levvy G et al. Dear Mr Dobson. British Medical Journal 1997; 315: 147

4 Carter D. From the Chief Medical Officer. Health Bulletin 1997; 55: 279-281

5 SHPIC Drug Briefing Note. Riluzole for Motor Neurone Disease. SHPIC 1997

6 Motor Neurone Disease Association Survey 1997

18 George Street
Edinburgh EH2 2QU
Telephone 0131 477 1234
http://www.scot-ac.gov.uk
ISBN 0906206 47 1