Cost-effective prescribing: trying to hit the target in Ontario and Australia

Bernie J. O'Brien, Department of Clinical Epidemiology and Biostatistics, McMaster University and Centre for Evaluation of Medicines, St Joseph's Hospital, Ontario, Canada

SYNOPSIS

The Canadian province of Ontario does not subsidise prescription drugs for all of its citizens. Despite serving fewer beneficiaries, the Ontario system is facing the same financial pressures as the Australian Pharmaceutical Benefits Scheme. Both systems are using similar strategies to encourage the cost-effective use of drugs. Some drugs can only be prescribed for specific indications and others require the approval of the government before they can be prescribed. Ontario recently tried to limit its expenditure on new drugs to the costs forecast by the manufacturers. The outcome of this controversial policy is not yet known, but it emphasises the need for accurate information about prescribing patterns.

Index words: cost of drugs, Pharmaceutical Benefits Scheme.

(Aust Prescr 2002;25:128–30)

Introduction

In Canada and Australia expenditure on prescription drugs is growing. The government of Ontario in Canada annually spends close to Can$2 billion of taxpayers' money on prescription drugs. This is the equivalent of A$2.25 billion (A$1 = Can$0.88). As in Australia, an evaluation system has been established to ensure that medicines are used where they are most cost-effective. The Ontario experience has some lessons for and from Australia. Both countries are wrestling with the same problem: of designing a system that effectively guides prescribers to treat patients cost-effectively, yet maintains an appropriate degree of clinical freedom.

Drug subsidy in Ontario

Canada has a comprehensive national system of universal public health insurance for medical services similar to Australia. Unlike Australia, out-of-hospital prescription medicines are not covered by the national system and are considered a fiscal responsibility for each province. Consequently, in provinces such as Ontario there are multiple payers for drugs. For example, employed people commonly have prescription drug coverage as an employment benefit although they would share some of the costs. The public payer for drugs in Ontario is the Ontario Drug Benefits Program. This covers about 18% of the population of the province. The primary beneficiaries are those aged over 65 years and people with a specific catastrophic illness or low income.

Drug cost in Ontario

In 2000–01 the Ontario Drug Benefits Program had 49 million prescription claims from its 2.08 million beneficiaries for a total government cost of Can$1.9 billion. The majority of expenditure (67%) is for elderly people. A small percentage of claimants (5%) have annual claims over Can$3000 and account for 27% of all drug costs. The three largest categories of drug expenditures are cardiovascular (Can$422 million), antilipidaemic (Can$226 million) and gastrointestinal (Can$200 million). The 'top ten' drugs in terms of expenditures (Table 1) are similar to the top 10 drugs prescribed in Australia.[1] For example, in 2000–01 the lipid lowering drug atorvastatin was number one in Ontario (Can$87 million) and number two in Australia (A$280 million).

A major concern in Ontario is the increasing rate of growth of expenditure. In 2000–01 annual expenditure grew by 15% (Can$248 million) compared with only 2% in 1992–93. The introduction of 10 new products in 2000–01 accounted for 70% of expenditure growth. A significant impact (Can$45 million) resulted from the introduction of celecoxib and rofecoxib for treatment of arthritis.

Table 1

Top 10 drugs by cost in the Ontario Drug Benefits Program[2] and the Australian Pharmaceutical Benefits Scheme[1] 2000–01*

Rank	*In Ontario*	*In Australia*
1	atorvastatin	simvastatin
2	omeprazole	atorvastatin
3	amlodipine	celecoxib
4	enalapril	omeprazole
5	simvastatin	olanzapine
6	olanzapine	pravastatin
7	blood glucose test strips	sertraline
8	diltiazem	ranitidine hydrochloride
9	fluticasone propionate	insulin (human)
10	ranitidine	bupropion

* The Ontario Drug Benefits Program only covers 2 million people (approximately 18% of the population) whereas all Australians are covered by the Pharmaceutical Benefits Scheme.

The Drug Quality and Therapeutics Committee

Like the Pharmaceutical Benefits Advisory Committee in Australia, Ontario has a committee which advises the Minister of Health. This Drug Quality and Therapeutics Committee (DQTC) consists of 10 physicians and two pharmacists. It meets monthly to consider submissions made by pharmaceutical manufacturers for the listing of their products on the Ontario formulary. In addition to data on a drug's effectiveness and safety, the manufacturer is required to provide evidence of cost-effectiveness or 'value for money'. Guidelines were published in 1994 on the required form, content and conduct of such economic analyses.[3] Members of an economic subcommittee of DQTC carry out expert technical reviews of the economic analyses in the submissions.

Formulary listing options

The DQTC has several options open to it when recommending a drug for reimbursement. A drug can be listed on the formulary as a 'general benefit' which means it can be prescribed without restriction by any licensed medical practitioner. At the other extreme, a so-called 'Section 8' reimbursement means that the physician must make a written application to the Ministry of Health to justify the need to use the restricted drug. For example, the osteoporosis drug alendronate is a Section 8 benefit; the cost will only be reimbursed if the doctor documents that their patient has 'failed' therapy (e.g. poor efficacy or tolerability) with etidronate. In 2000–01 there were 2466 requests for reimbursement for alendronate under Section 8 of which 75% were approved at a cost of Can$788 000.

Between a general benefit and Section 8 is a category of reimbursement which is expanding rapidly. This 'limited use' category is a form of restricted reimbursement that requests the physician to prescribe the drug for patients meeting defined clinical criteria. The key difference between limited use and Section 8 is that it is simply an 'honour system' which trusts the physicians to follow prescribing guidance. There are many examples of limited use drugs, but the most recent debates have been about celecoxib and rofecoxib. Physicians are asked to only prescribe these drugs for patients with arthritis who have an increased risk of gastrointestinal bleeding because it is in these patients that the drugs are most beneficial and cost-effective.

The risk of 'leakage' and the need for drug utilisation review

Placing celecoxib and rofecoxib on the Ontario formulary under the limited use category exposes the government to financial risk if prescribers do not abide by the honour system and ignore the limited use criteria. For the government, the 'nightmare scenario' is that the aches and sprains adequately managed with cheap anti-inflammatory drugs get switched to more costly new drugs. In the Australian context I have heard this phenomenon referred to as 'leakage'; once a drug is subsidised for a specified indication and patient group, usage can 'leak' into other patient groups where the drug is less cost-effective. The risk of leakage raises questions of measurement and management. How can a government payer create systems for monitoring appropriate drug use and how should the risk of leakage enter into negotiations with manufacturers?

There are two ways in which drug utilisation review can be used to support limited use criteria. The first is using aggregate or patient-level administrative claims data to monitor trends in drug usage, substitution and other health care usage following formulary listing. For example, the extent to which celecoxib and rofecoxib will lead to reduced prescribing of gastro-protective drugs such as misoprostol is a component of cost-effectiveness models and will be watched keenly. The second method is the use of 'real-time' prescription advice and/or adjudication for reimbursement using office-based electronic medical records. The electronic medical record holds great promise for precisely determining a patient's eligibility for a limited use medicine, but it clearly poses some threats, both to the clinical freedom of prescribers and to the privacy of patients.

Risk management, envelopes and strategic bargaining

As part of the submission for listing provided to DQTC a manufacturer must make a forecast of how much of the drug will be prescribed over the next three years and how much this will cost. This forecast is known as a 'budget impact analysis' and the chief executive officer of each company, prior to listing, must provide a signed letter to the Ministry of Health declaring this forecast.

The forecast of drug expenditure has become a crucial part of the submission because the Ministry of Health has changed its approach to expenditure risk management. In an initial stance – which totally 'blindsided' the industry – the Ministry announced that it would only pay for a new medicine up to the expenditure forecasted in the submission. Faced with a storm of protest on this risk-shifting policy, the Ministry softened its position somewhat and established the Drug Utilization Advisory Committee as an advisory board on circumstances where a manufacturer 'overshoots' their forecast expenditure. It is too early to know how the Drug Utilization Advisory Committee will work and so the 'penalty' for overshooting the forecast remains unclear.

These recent policy developments on agreed expenditure envelopes have some important strategic implications for manufacturers making submissions. Essentially a manufacturer is now entering into a price-volume agreement with the government where it can control the price but has less than 100% control over utilisation once the drug is in the hands of prescribers. The risky business decision for the company is where to set its forecast expenditure for the drug, given two important unknowns: the precise extent of utilisation and the potential penalty for an overshoot in expenditure. It is also a game of strategy for the government which must decide to accept or reject the listing of a drug based on both the cost-effectiveness data and the uncertain forecast expenditure.

Lessons for and from Australia

Canada can learn from the centralised national system of drug review in Australia. The process of review and evaluation appears to be well organised and resourced by Federal government. In Canada there is duplication of effort as each province conducts its own review of clinical evidence and cost-effectiveness. Discussions are ongoing in Canada about the establishment of a single Federal agency for drug review. One advantage of having a single buyer of medicines, similar to Australia, is that it affords what economists call monopsony power – the government having more power to negotiate the terms of price and reimbursement.

The main lessons for Australia relate to Ontario's experience with the limited use designation which attempts to direct drug usage to patients for whom a medicine is most cost-effective. A member of the DQTC has recently criticised the limited use mechanism saying that there is no evidence that the policy is effective.[4] Producing 'evidence-based' prescribing guidance is the easy part – the difficulty is getting prescribers to comply. The related challenge is having the utilisation data systems in place to monitor how well the policy targets are being achieved. Ontario has made some progress in this respect and Australia needs to keep pushing for this necessary research infrastructure. Finally, whether you welcome or fear the 'brave new world' of the electronic medical record, it clearly holds great hope in the future as a means of real-time, office-based prescribing guidance and reimbursement adjudication. Concerns over prescriber freedom and patient confidentiality will no doubt be voiced as this technological innovation becomes a reality in the doctor's office.

E-mail: obrienb@mcmaster.ca

ACKNOWLEDGEMENT

This paper was written while I was on sabbatical leave at the University of Sydney and I am grateful to my hosts at the Centre for Health Economics Research and Evaluation and the NHMRC Clinical Trials Centre.

REFERENCES

1. Top 10 drugs. Aust Prescr 2001;24:136.
2. The 2000/1 Report Card for ODBP including detailed statistics http://www.gov.on.ca/MOH/english/pub/ministry/odb_report01/drug_rep.html
3. Ontario guidelines for economic analysis of pharmaceutical products. Toronto: Ontario Ministry of Health and Long-term Care; 1994.
4. Laupacis A. Inclusion of drugs in provincial drug benefit programs: who is making these decisions, and are they the right ones? CMAJ 2002; 166:44-7.

FURTHER READING

The Ontario Drug Benefits Program homepage
http://www.gov.on.ca/health/english/program/drugs/drugs_mn.html

The ODBP formulary
http://www.gov.on.ca/health/english/program/drugs/odbf/odbf_mn.html

Ontario guidelines on economic analysis for drug submissions
http://www.gov.on.ca/health/english/pub/drugs/drugpro/dsguide_mn.html

Dr O'Brien is a member of the economic subcommittee of the Ontario Drug Quality and Therapeutics Committee.

Transparency and the Pharmaceutical Benefits Advisory Committee

Alan H. Evans, Chief Executive, Medicines Australia, Canberra

Comment on Professor M.J. Eadie's editorial 'The secrecy of drug regulatory information' (Aust Prescr 2002;25:78–9)

Medicines Australia, which represents the prescription medicines industry in Australia, welcomes discussion on transparency of the evaluation process for new medicines.

Medicines Australia wrote to the Therapeutic Goods Administration (TGA) earlier this year suggesting the establishment of an industry/TGA project team to look at the evaluation process, including the issue of transparency. While the terms of reference for that project team are yet to be established, it is anticipated that consumers will have representation on that team. The project team is expected to consider the level of information that could potentially be made publicly available, the depth and detail of that information and the timing of the release of that information.

Caution should however be taken in making direct comparisons with the types and level of information available to consumers in the USA. The evaluation systems that give rise to the release of the minutes of expert committee reports in the USA vary from those in Australia on some key issues. For example, the evaluation of a new product in the USA includes a public hearing which both the public and the applicant are invited to attend. In Australia, the Australian Drug Evaluation Committee (ADEC) considers applications in closed sessions. Natural justice suggests that companies should have the opportunity to respond to the issues raised by the ADEC before the minutes are disclosed.

With respect to the release of pharmacological and clinical data, it should be noted that Article 39.3 of the World Trade Organization Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), to which Australia is a signatory, states that:

> Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.