Inclusion of drugs in provincial drug benefit programs: Should "reasonable decisions" lead to uncontrolled growth in expenditures?

Amiram Gafni, Stephen Birch

Ontario's Drug Quality and Therapeutics Committee (DQTC) reviews submissions by pharmaceutical manufacturers who wish to have their drugs included in the formulary of the Ontario Drug Benefits Program. In making its decisions and developing its recommendations, the committee uses cost-effectiveness information.[1] However, despite the use of such information and the assessment of a previous commentator that the DQTC "makes reasonable decisions in … very difficult circumstances," program expenditures rose by 10% annually between 1996/97 and 1998/99 and by 15% in 2000/01.[1] This growth in expenditures has led both the premier of Ontario and the minister of health and long-term care to question the program's affordability.[1] In this commentary we explain why the cost-effectiveness approach that has been used by the DQTC has led to these continuous and considerable increases in expenditures.

The economics approach

Economics is based on 3 fundamental concepts: scarcity (whatever resources are available, they are insufficient to support all possible activities), choices (because resources are scarce, we must choose between different ways of using them) and opportunity cost (by choosing to use resources in one way, we forgo other opportunities to use the same resources). On the basis of these concepts, resources are used efficiently if and only if the value of what is gained from the use of resources exceeds the value of what is forgone by not using them in all other ways.[2]

Scarcity, choices and opportunity cost reflect the nature of the problem facing decision-makers with regard to the Drug Benefits Program. Thus, it is not surprising to discover, in the case of the DQTC, that because "resources for health care are limited, it seems sensible … that cost-effectiveness is the main criterion used to determine which drugs are reimbursed from the public purse."[1] In other words, the committee recognizes the relevance of economics to inform these decisions as a means to maximize total health improvements with the resources available.[3]

The incremental cost-effectiveness ratio: a prescription for increased expenditures

The economics question of how to maximize health improvements generated by a given level of resources has an obvious attraction for the minister of health and long-term care. But the economics approach differs from the way in which the DQTC uses information on the costs and effects of pharmaceuticals presented for inclusion on the formulary. The DQTC assesses the desirability of a drug by its incremental cost-effectiveness ratio (ICER). The ICER is based on a comparison of the new drug with the current way of treating the patient group for whom the new drug is being proposed (e.g., tissue plasminogen activator [t-PA] rather than streptokinase for the treatment of patients after myocardial infarction). The ICER is calculated by dividing the difference in costs between the new and old treatments by the difference in effects, to yield the additional cost per unit outcome (e.g., $50 000 per quality-adjusted life year [QALY]). This approach is consistent with the guidelines proposed for the evaluation of new technologies in this journal 10 years ago.[4]

However, the question facing decision-makers is not simply a choice between the new drug and the old drug. A positive ICER means that the resources used by the current intervention are not sufficient to cover the costs of the new intervention for the same number of patients. As a result, "most cost-effective drugs are not cost saving and … their use in a substantial portion of the population entails a large cost."[1] Therefore, to address the decision-makers' question (i.e., how to maximize the health improvements generated by a given level of resources) we need to consider the total additional cost of the new drug in its proposed use and compare this with the outcomes produced by the range of other services and interventions that would have to be forgone to fund the new drug. That is, we must incorporate the concept of opportunity costs. But total costs are not part of the ICER calculation. Instead, a value judgement is made, either explicitly or implicitly, about whether an ICER (e.g., $50 000 per QALY) represents a "good buy."

Thus, the ICER ignores the simple reality that, if overall funds are fixed, the additional funds required for a new program must come from other uses, that is, cuts to other programs. Furthermore, funding new technologies that have "acceptable" ICERs requires and hence leads to continuous increases in program expenditures because the new, more costly technologies are added without other programs being cut to generate sufficient resources for the new program.[5] This may explain the observed increases in

drug expenditures in the Ontario Drug Benefits Program. In addition, without considering the source of the additional funds required to support the DQTC recommendations (i.e., the opportunity costs of these additional resources), we do not know if the adoption of a new intervention will lead to an overall increase in health improvements. This is because there is no way to judge if the added health benefits are greater than the health benefits forgone by the elimination of other programs.

Under certain theoretical assumptions the ICER *can* be used to identify interventions associated with an efficient use of resources.[6] However, the required assumptions bear little relevance to the real world of allocating scarce health care resources for which such economic evaluation is intended.[7,8] Even if we assume that new funds will be made available to the program over time as the economy grows, the information provided by ICERs is insufficient to identify efficient uses of these new resources[7,8] (see Appendix 1 for a numeric example). The DQTC experience provides evidence of the failure of the ICER approach in the absence of these theoretical assumptions.

How economics can help

Economics provides valid methods for maximizing the health improvements that can be attained with a given allocation of resources by taking into account the opportunity costs of these resources.[7] These methods can help decision-makers to allocate health care resources efficiently under circumstances of fixed, shrinking or increasing budgets. Although the data requirements for these methods may be substantial, they reflect the complexity of the question being addressed. A modified, less "data-hungry" approach is available for use in practical decision-making.[5,7] However, it involves adjusting the objective from the maximization of health improvements from available resources to the production of an unambiguous increase in health improvements from available resources. This approach requires that the anticipated additional health improvements of the proposed program be compared with the health improvements produced by the combination of programs that must be forgone to generate sufficient funds for the proposed program. Only if the additional health improvements of the proposed program exceed the health improvements of the combination of forgone programs does the new program represent an improvement in efficiency. This approach has been extended to deal with the uncertain nature of costs and outcomes associated with health care interventions.[9]

The following hypothetical example illustrates the informational requirements of using this approach to determine whether a new drug or other intervention will lead to an increase in health improvements from available resources. Assume that a new drug (drug A) is suggested as a treatment for a given condition (e.g., t-PA in place of streptokinase for patients who have had myocardial infarction). The new drug is more effective but also more costly. The first step is to calculate the additional resources required (the additional cost) to provide the new drug, above and beyond the cost of the current treatment (we will suppose that this additional cost amounts to $50 million) and to determine the additional health gains as a result of introducing the new drug (which we will suppose amounts to a gain of 1500 life years).

As explained earlier, for a fixed budget, a necessary condition for implementing a new intervention, one that improves outcomes but costs more, is to identify an existing intervention (or combination of existing interventions) that, if cancelled, will generate the additional resources necessary for the new intervention and reduce the community's health-related well-being by less than the incremental gain produced by the new intervention. In the context of t-PA it might be practical to start by examining interventions for treating patients with myocardial infarction to determine if one other intervention (or a set of interventions) can be found that, if eliminated, satisfy both of these conditions. If we cannot find such interventions within cardiology, we can go to other specialty areas.[10]

Therefore, the second step is to identify an intervention or interventions for cancellation. Assume that we find such an intervention (drug B), where the savings (or resources released) by cancelling the intervention and giving patients the next best alternative are equal to $50 million. Assume also that the incremental effectiveness forgone by cancelling this intervention is equal to a loss of 960 life years. We can thus conclude that adopting drug A and cancelling drug B represents a more efficient use of existing resources, because the community's health-related well-being increases by 1500 minus 960 or 540 life years without any increase in required resources.

Conclusions

It has been argued that decision-makers "should maintain a healthy scepticism about the results of cost-effectiveness analysis and the usefulness of those results in purchasing and planning decisions."[11] Given the outcomes of the DQTC's recommendations, it would be understandable if Ontario's premier and the minister of health and long-term care took this view. One response would be to abandon the Drug Benefits Program as unaffordable. But, as we have shown,[5] the problem arises because the DQTC recommendations are based on noneconomic ways of interpreting economic information, an outcome that was anticipated,[5] given the approach followed by the committee. The economics discipline gives us useful tools that are consistent with the goal of maximizing health improvements produced from a given level of resources. Use of these tools can ensure that new interventions are adopted only if they represent an improvement in efficiency. The level of complexity of such analyses reflects the nature of the problem being addressed. In contrast, simple tools

such as the ICER represent a departure from the economics discipline and hence they fail to address the decision-makers' problems.

This article has been peer reviewed.

From the Department of Clinical Epidemiology and Biostatistics and the Centre for Health Economics and Policy Analysis, McMaster University, Hamilton, Ont.

Competing interests: None declared.

Contributors: Both authors contributed equally to the conception of the paper, the identification of the problem and its resolution through the application of economic concepts. Both authors contributed to the intellectual content of the paper, to drafting the paper and to revisions through successive drafts. Both authors gave final approval of the version presented for publication.

References

1. Laupacis A. Inclusion of drugs in provincial drug benefit programs: Who is making these decisions, and are they the right ones? *CMAJ* 2002;166(1):44-7.
2. Williams A. The economic role of "health indicators." In: Teeling Smith G, editor. *Measuring the social benefits of medicine*. London (UK): Office of Health Economics; 1983. p. 63-7.
3. Weinstein MC, Stason WB. Foundation of cost-effectiveness analysis for health and medical practices. *N Engl J Med* 1977;296:716-21.
4. Laupacis A, Feeny D, Detsky AS, Tugwell PX. How attractive does a new technology have to be to warrant adoption and utilization? Tentative guidelines for using clinical and economic evaluation. *CMAJ* 1992;146(4):473-81.
5. Gafni A, Birch S. Guidelines for the adoption of new technologies: a prescription for uncontrolled growth in expenditures and how to avoid the problem. *CMAJ* 1993;148(6):913-7.
6. Weinstein M, Zeckhauser R. Critical ratios and efficient allocation. *J Public Econ* 1973;2:147-57.
7. Birch S, Gafni A. Cost-effectiveness/utility analysis: Do current decision rules lead us to where we want to be? *J Health Econ* 1992;11:279-96.
8. Birch S, Gafni A. Changing the problems to fit the solution: Johannesson and Weinstein's (mis)application of economics to real world problems. *J Health Econ* 1993;12:469-76.
9. Sendi P, Gafni A, Birch S. Opportunity costs and uncertainty in the economic evaluation of health care interventions. *Health Econ* 2002;11:23-31.
10. Elit LA, Gafni A, Levine MN. Economic and policy implications of adopting paclitaxel as first-line therapy for advanced ovarian cancer: an Ontario perspective. *J Clin Oncol* 1997;15:632-9.
11. Naylor CD. Cost-effectiveness analysis: Are the outputs worth the inputs? *ACP J Club* 1996;124:A12-4.

Correspondence to: *Dr. Amiram Gafni, Department of Clinical Epidemiology and Biostatistics (HSC – 3H29), McMaster University, 1200 Main St. W, Hamilton ON L8N 3Z5; fax 905 546-5211; gafni@fhs.mcmaster.ca*

Appendix 1: Allocating new resources — an example

Table A1 describes 4 hypothetical new drugs aimed at treating 4 different conditions. Each drug is described in terms of its additional effects and additional costs (for all patients with the disease who are eligible for drug coverage under the Ontario Drug Benefits Program) relative to the current way of treating these patients, as well as its incremental cost-effectiveness ratio.

Suppose that the government has allocated a budget of $20 million for new drugs and has asked the Drug Quality and Therapeutics Committee to recommend which drugs it should pay for. Suppose also that the committee decides that $50 000 per quality-adjusted life year (QALY) is an acceptable "price" to pay for health improvements. Under this approach, the committee approves only drug A, and the total health improvements increase by 360 QALYs. However, drug A does not use up the entire budget available. The residual budget is sufficient to fund only drug D, but this drug fails to meet the acceptable price of $50 000 per QALY set by the committee.

Note that although drugs B and C also fail to meet the acceptable price, using the new budget of $20 million to support those 2 drugs, instead of drug A, would generate 388 additional QALYs, that is, a greater health improvement than would be produced by investing the resources only in drug A.

Even if the residual resources of $2 million that would be left over after buying drug A were to be used on drug D (given that there are insufficient residual resources to purchase drug B or C), the total health improvement generated by adopting both drugs A and D would be 380 QALYs, less that the 388 QALYs that would be produced by drugs B and C. Irrespective of how the residual resources are used, purchasing drug A does not lead to an efficient use of resources. In other words, the use of the incremental cost-effectiveness ratio fails to maximize the health improvements from a given (additional) budget.

Table A1: Incremental costs and effects of 4 new drugs

Drug	Health gain, QALY	Cost, $	ICER, $/QALY
A	360	18 million	50 000
B	312	16 million	51 300
C	76	4 million	52 600
D	20	2 million	100 000

Note: QALY = quality-adjusted life year, ICER = incremental cost-effectiveness ratio.