Health economic evaluations help inform payers of the best use of scarce health care resources

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ABSTRACT

Objectives. The number of new health technologies has risen over the past decade. These new technologies usually are more effective but they also cost more compared to existing ones. In a publicly funded health care system such as Canada, the aim is to maximize the health of the population within the resources available. As a result, it is unavoidable that choices and trade-offs have to be made because there will always be more treatment options than resources will allow (i.e., scarcity of resources) as well as alternative uses for those resources (i.e., opportunity costs). The objective of this paper is to provide an overview of economic evaluations and how these tools can be used to help inform payers of the best use of scarce health care resources.

Study design. This descriptive paper includes a summary of key concepts and definitions in economic appraisal and draws upon recently published papers as illustrations.

Methods. Background on the necessity and role of economic evaluations is provided, followed by a description of the approaches for, and types of, economic evaluations. Two illustrative examples are used and some implications for rural, remote and circumpolar communities are discussed.

Results. There are 2 main approaches for conducting an economic evaluation (trial- and model-based) and 3 types of evaluations which can be considered to inform payers of the best use of health care resources (cost-effectiveness, cost-utility and cost-benefit analyses).

Conclusions. Techniques of economic evaluation are useful tools and an important input into the decision-making process. Although these techniques have universal application, there are issues specific to rural, remote and circumpolar communities which can affect the results of economic appraisals.

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INTRODUCTION

Health care decision-makers are increasingly facing difficult funding and resource-allocation decisions. This has arisen partly because of rising demand on public expenditures in general, but also because the number of new health technologies (e.g., drugs, procedures, programs and medical devices) has risen dramatically over the past few decades. New health technologies usually are more effective but also cost more compared to existing treatments. Compounding the problem is the fact that the demand for health care is also on the rise at all levels of decision-making (i.e., national, provincial, local health authority, hospital, program), causing an accumulation of expenditure pressures from various sources in the health care system. In a publicly funded health care system such as Canada's, the aim is to maximize the health of the population within the resources available. It is unavoidable that choices and trade-offs have to be made because there will always be more treatment options than resources will allow (i.e., scarcity of resources) as well as alternative uses for those resources (i.e., opportunity costs).

Prior to bringing a new technology to market, it is assessed for efficacy (does it work in a controlled environment?) and safety (does it have side effects and are these acceptable and manageable?). Newer technologies are also evaluated to determine their effectiveness (does it work in the real world?) as well as cost-effectiveness (does it represent good value for money?). Health economists make a distinction between 2 types of efficiency: technical and allocative. Technical efficiency refers to maximizing outputs for a given level of inputs (or minimizing inputs for a given output level). Allocative efficiency refers to the optimal level of resource allocation in society. In other words, technical efficiency is about making efficient use of inputs, while allocative efficiency is about the best mix of inputs and outcomes for society. Since decision-makers are interested in determining whether the increased cost of a new technology justifies the health benefits it generates, they are interested in technical efficiency. However, they are also interested in doing what is best for society as a whole, independent of technical efficiency, and therefore need to also consider resource-allocation decisions (allocative efficiency). The objective of this paper is to provide an overview of economic evaluations and how these tools can be used to help inform payers of the best use of scarce health care resources.

MATERIAL AND METHODS

The alternative approaches for economic evaluation and main types of economic evaluations are described. The importance of the perspective adopted for the analysis and accounting for uncertainty are discussed, as are the specific implications that rural, remote and circumpolar communities might have on economic evaluations. For illustrative purposes, 2 recent examples of economic evaluations that are relevant for rural, remote and circumpolar communities are used. These examples include economic appraisal of respiratory syncytial virus (RSV) and idiopathic thrombocytopenic purpura (ITP). Finally, the ways in which economic appraisal can be used to help inform and make tough resource-allocation decisions are considered.
RESULTS

**Approaches for economic appraisal**

Health economic evaluation is a systematic, comparative analysis of competing decisions or alternative courses of action in terms of both their costs (use of resources) and their consequences (health benefits) (1). The goal is to identify which service, program or course of action is most efficient. An economic evaluation requires that we identify, measure and value the costs and consequences of alternative health interventions. The costs of an intervention are defined as the costs of receiving and administering the technology (e.g., drug acquisition costs, diagnostic testing costs, health care professional costs). The cost may also include downstream costs associated with ongoing treatment, or the management of adverse events or side effects of the treatment. Consequences are defined as the outcomes of interest caused by a treatment, which are either clinically measured or reported by the patient. The outcomes could be health improvements in terms of reduced mortality (life years saved) or morbidity (increased quality of life), or any number of clinical endpoints such as decreased hospitalizations, patients in total remission or other clinical effects linked to health status (e.g., improved physical functioning).

There are 2 main approaches for conducting an economic evaluation. Trial-based economic appraisals are concurrent clinical and economic evaluations where the primary focus of the study is typically clinical, with economic questions and data collection being added onto the data collection for the clinical trial. In addition to adding on data collection related to various resource utilization items (e.g., hospitalizations, tests and procedures, clinic and doctor visits, drugs, time off work, out-of-pocket costs), since an economic evaluation adopts a broader perspective than just clinical outcomes, broader outcome measures such as quality of life and health-systems impact are typically added on to the clinical outcome measures as well.

The second approach for economic appraisal is a modelling-based approach, which involves the use of decision-analytic modelling techniques. With this approach the decision problem is structured like clinical pathways where the treatment options, outcomes and disease/illness progression are mapped out in a decision-tree format and probabilities from clinical trial data, observation studies and registry data are used to estimate the probability of going down each unique pathway in the decision tree. Costs, outcomes and quality of life associated with each pathway are combined with pathway probabilities to estimate the cost and outcomes of each treatment option being compared.

Although conceptually different, both approaches for economic evaluation are similar in that they estimate costs and outcomes associated with alternative courses of action and both can use different outcome measures for the primary valuation of consequences or outcome benefit.

**Types of economic evaluations**

There are 3 main types of economic evaluations: (1) cost-effectiveness analysis (CEA); (2) cost-utility analysis (CUA); and (3) cost-benefit analysis (CBA). As shown in Table I, the measurement and valuation of costs is the same across these types of economic appraisal, with the key difference being how consequences are measured and valued in each type of evaluation. CEA compares alternatives with outcomes of the same type, achieved to different degrees (e.g., cases detected for different types of mammography screening programs). The result of a CEA
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is a ratio of incremental cost to incremental effect (e.g., $20,000 per adverse event avoided, $50,000 per cancer case detected or $100,000 per death averted). This provides decision-makers with an estimate of the value for money where there is a comparison of the cost-per-unit outcome. The goal is to maximize output (effects) from input (available resources).

CUA is used when the interventions being compared do not necessarily produce the same consequences. For example, an intervention might have an impact on length of life (i.e., survival benefit) and quality of life (e.g., pain reduction). In these cases, it might be desirable to use a more generic outcome measure which can capture the varied outcomes in a single measure of benefit. With this approach, the health consequences are valued using quality-adjusted life-years (QALYs). In calculating QALYs, health states experienced by patients are valued relative to perfect health (usually assigned a value of 1) and death (usually assigned a value of 0), and then each health state is weighted by the length of time the patient spent in that state. For example, if a patient was in perfect health for 2 years followed by immediate death, the patient would be assigned 2 QALYs. This type of analysis is particularly useful for those health interventions that extend or improve life at the expense of side effects. The appeal of the QALY and CUA is that results from various CUA can be compared across a variety of programs that measure the same QALY outcome. This helps decision-makers because without a common metric for comparison, it is difficult to compare the relative costs and outcomes from different interventions all using different measures of outcome and treatment success.

Finally, a CBA expresses both the costs and consequences of different interventions in monetary units so that they compare directly and across programs/interventions. With this approach, respondents (patients or members of the general public) are asked what they feel the anticipated outcomes of an intervention are worth to them in dollar terms. For example, someone may be asked how much they are willing to pay for a 10% relative risk reduction of obtaining a stroke or a 1.2-year gain in life expectancy. The willingness-to-pay (WTP) approach can also be used to assess the value of taking something away (e.g., removing an insured benefit). Since costs and outcomes are valued on the same metric (i.e., dollars), as long as the monetary benefits of a program exceed the costs, the intervention is considered worthwhile. This is one of the main advantages of CBA, as it can directly address allocative efficiency, and no judgement is required regarding the value for money of the intervention.

| Table I. Comparison of different types of economic evaluations. |
|---------------------------------------------------------------|
| **Type of economic evaluation** | **Measurement and valuation of costs** | **Measurement and valuation of outcomes** |
| Cost-Effectiveness Analysis (CEA) | Measured and valued in dollars ($) | Measured and valued in natural units (e.g., deaths, life years, strokes, disability days, symptom days, events, clinical outcome measures) |
| Cost-Utility Analysis (CUA) | Measured and valued in dollars ($) | Either measured in natural units and converted to quality-adjusted life-years (QALYs) or measured and valued directly in QALY units |
| Cost-Benefit Analysis (CBA) | Measured and valued in dollars ($) | Outcomes measured in natural units and valued in monetary terms ($) |
Study perspective

With both trial-based and modelling-based appraisals and with all 3 types of economic evaluations, it is important to take into account the perspective of the study. Often called the cost viewpoint of the analysis, as this concept affects cost rather than outcome measures, the study perspective relates to the person, organization or community affected by the viewpoint considered. For example, a study that is considered from a patient’s perspective would only consider costs incurred by the patient. Similarly, studies from a hospital’s perspective would only consider costs incurred by the hospital. A Ministry of Health perspective is broader and would consider hospital costs, professional fees and drug costs, while a society perspective would be even broader, including costs from the patient perspective as well. As an illustration, productivity losses (i.e., time off work that results in a loss of income) borne by a patient would be considered a cost from both a patient and societal perspective as the patient is a member of society, but would not be considered a cost from a hospital or Ministry of Health perspective.

Importance of accounting for uncertainty

Although quantifying costs and outcomes in a systematic and transparent fashion is important for decision-makers, it is important to be reminded that there is inherent uncertainty not only in the clinical outcomes, but also in resource utilization, costs and patient valuations of health states or outcomes in general. In trial-based analyses, this uncertainty is usually assessed using sensitivity analyses where assumptions made in the analysis or uncertainty around patient outcomes (i.e., stochastic uncertainty) are varied in a series of alternative analyses to test their impact and the confidence of the base-case results. For example, the upper and lower confidence intervals of a relative risk reduction for an event might be tested in a sensitivity analysis, or alternative estimates of the cost of a day-long stay in hospital might be used. It is common practice today in trial-based analyses to use bootstrapping techniques (i.e., sampling with replacement) to express the stochastic uncertainty around cost and outcomes for patients in a trial. This allows for a continuous measure of costs and outcomes where variances, standard errors and confidence intervals can be calculated for statistical comparisons.

In modelling-based economic appraisals, uncertainty assessment is equally, if not more, important to assess. This is because models are generally constructed from various data sources, including different trials, and this uncertainty needs to be adequately explored. As with trial-based analyses, uncertainty around methodological assumptions (e.g., cost of a hospitalization, discount rates for future costs and effects) and uncertainty from clinical trials should be assessed using sensitivity analysis. With models, the uncertainty around probabilities of events/outcomes, around costs and around outcomes/utility values can be assessed using simulation techniques. With these techniques, probability distributions are defined for all the variables in the model and then several thousand simulation draws of these distributions are used to derive a series of cost and outcome measures that can then be used to calculate variances and confidence intervals. Unfortunately, some model-based economic analyses focus on point estimates only and do not fully account for uncertainty in the analyses. For example, using a relative-risk-reduction point estimate which was not statistically significant would result in a cost-effectiveness point estimate which did not account adequately for the
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uncertainty around the relative risk reduction. As a result, a number of important developments around the handling of uncertainty in model-based analyses have occurred over the past few decades, including the use of probability distributions in models as opposed to single point estimates.

Issues specific to rural, remote and circumpolar communities

The techniques of economic evaluation are broad and can be applied to any intervention and in any context. However, there are a few issues specific to rural, remote and circumpolar communities which should be highlighted. First, the clinical outcomes observed in a trial or estimated from a modelling-based analysis may not be generalizable to rural, remote and circumpolar communities. For example, the patient population and associated risk factors may be different or the intervention may not work the same way in these communities for a variety of reasons. Since outcomes and events are a critical component of an economic evaluation, it is critical that the generalizability of the outcomes to these communities be assessed and adjusted accordingly if necessary. It may also be the case that patient preferences for outcomes may be different in these communities than those observed and measured in clinical trials, or that patient monetary valuations of outcomes (as in a CBA) may be different due to differences in income levels.

Similarly, on the cost side of an economic evaluation, the costing of outcomes and events will be different if the clinical outcomes need to be adjusted to reflect the likely outcomes observed in these communities. There are other cost factors to consider as well. For example, the cost of administering interventions may be very different in rural, remote and circumpolar communities, as the cost of transportation of medicines or supplies may be much higher or relative wages may be different. Also, costs from a patient or societal perspective may be much higher due to higher transportation costs or increased time away from work or other productive activities. As with the outcome side of the economic evaluation, the resource utilization and costing side of the analysis may need to be adjusted to better reflect rural, remote and circumpolar communities.

Illustrative examples

Before undertaking an economic evaluation one has to determine if there is clear and well-documented clinical evidence for the technology to be compared to the available alternative(s). Two recently published economic evaluations about conditions that are prevalent in children, respiratory syncytial virus (2) and idiopathic thrombocytopenic purpura (3), are used to illustrate some of the features of an economic evaluation.

Respiratory syncytial virus (RSV)

RSV is a major cause of morbidity and mortality after the neonatal period (4) and is the leading cause of lower respiratory tract infections, with high infection rates seen in Canadian Inuit infants (5–8). Palivizumab is a humanized monoclonal antibody which has been shown to reduce RSV-related hospitalizations, but its drug-acquisition cost is high. The largest cost component of total treatment cost is for in-patient hospital care (9), therefore criteria for use of this medication were restricted to preterm infants or to those infants who were born between 33 and 35 weeks gestation in isolated communities where access to hospitals was limited (10). A recent study demonstrated that palivizumab prophylaxis for term Inuit infants in rural communities on Baffin Island resulted in cost savings to the government...
A cost-effectiveness study was subsequently undertaken to determine the value of universal prophylaxis (compared to no prophylaxis) for all infants less than 1 year of age living within the Baffin region was subsequently undertaken (2). The inputs used in this cost-effectiveness model were palivizumab effectiveness data, direct medical costs and indirect costs. The original population tested with palivizumab were infants of ≤35 weeks gestation from Canada, the United States and the United Kingdom (12). Since the effectiveness of palivizumab was not known for term infants on Baffin Island, the authors had to assume that the drug would have similar efficacy in this population. The outcomes they incorporated into their model were the hospitalization rate for RSV and the infant mortality rate associated with RSV hospitalization. Both these rates came from the published results of the first trial (12–14). They then applied these rates to the actual hospitalization rate reported in a study of Inuit children in eastern Canada to determine the final hospitalization rates (11).

Direct costs included the acquisition price of the drug obtained from the manufacturer and the costs for monthly administration of intramuscular injections obtained from the hospitals. Mean length of hospital stay and the costs of medical evacuation and return to the community were obtained from the Government of Nunavut. One outcome that was not incorporated into this model was adverse events because the drug is thought to be well tolerated. Indirect costs included in this model were future loss of productivity due to premature infant death. Statistics Canada supplied data regarding average weekly earnings which were used, along with the employment rate, to calculate an average annual wage. This wage was then used to represent the wage loss for children who die prematurely due to RSV.

**Idiopathic thrombocytopenic purpura (ITP)**

ITP is one of the world’s most common hematological disorders (15) and the incidence of ITP has been estimated to be 4.8 per 100,000 in children (16). Children who were previously healthy usually present with a short history of mucocutaneous bleeding (for example, bruising and petechiae) over a few days to weeks after an infectious viral illness, as well as with a low platelet count (less than 20,000/µL). The main goal of treatment for acute childhood ITP is the prevention of serious and potentially fatal bleeding. Hospitalization and emergency treatment are appropriate for those children with platelet counts of less than 20,000/µL and life-threatening bleeding; those with mucous membrane bleeding; or those who are inaccessible (rural or remote communities) (17,18). There is debate about the optimal management approaches for the condition, which may include close observation without treatment, corticosteroid therapy and splenectomy. An emerging treatment for ITP utilizes intravenous immunoglobulin (IVIg), but this treatment is very expensive and can be in short supply. Recently, the following question was addressed in an economic evaluation: “What is the cost-effectiveness of the use of IVIg for pediatric patients with ITP in Canada” (3)? The alternative treatments that IVIg was compared to were: observation (no treatment), anti-D immunoglobulin (for Rhesus [Rh]-positive children), oral prednisone and IV methylprednisolone.

The effectiveness measure used in this model was the number of days spent with a platelet count less than 20,000/µL, and this was achieved by pooling previously published data from pediatric trials. This model also had to incorporate rates for intracranial hemorrhage (ICH), mortality, immediate death from an ICH and side effects associated with corticosteroid treatment. The costing
data incorporated into the model were the costs of all the medications, including nursing time to administer the intravenous treatments; blood typing tests (since only Rh-positive children would get anti-D therapy); ITP hospitalization; ICH hospitalization; and post-stroke costs. No indirect costs were incorporated into this model.

The authors of both reports concluded that the technology under review is cost-effective. The incremental cost-effectiveness ratio (ICER) for prophylaxis therapy with palivizumab in term infants on Baffin Island was $37,070/QALY, while the ICER for IVIg therapy for pediatric patients with ITP was $56,000/QALY. These ICERs were for the base case analysis incorporating all the assumptions made by the health economists. The study’s authors also conducted sensitivity analyses, varying their assumptions to determine the impact of uncertainty and variability on the ICER. Only the payer (i.e., government, health plan manager) can decide whether these values (or any of the ICERs produced from a sensitivity analysis) are acceptable within the confines of their budget.

There is an abundance of other information that is required to complete the 2 evaluations briefly described above. Utility values for each of the health states described in the models as well as the disutility values associated with the adverse events from the treatments or the disease sequel have not been described. At times these values are not published and assumptions have to be made about what values to use. Appropriate outcome measures and the appropriateness of the comparators also have to be established before undertaking the evaluation. Prior to making the assumptions, discussions with experts familiar with the disease/condition/technology under investigation, with community health care leaders and potentially with patient advocates will have to take place to ensure the assumptions are appropriate. For full details about the economic evaluations described here, the original publications should be consulted to understand all the data incorporated into the models (3,11).

Conclusions

Increasing demands on scarce health care resources require a careful consideration of both clinical outcomes of interventions as well as cost-effectiveness to determine value for money. Whether it be a trial-based or modelling-based analysis, or a CEA, CUA or CBA, an economic evaluation can be a useful tool to assist decision-makers in making tough decisions and making better use of resources in a rational, evidence-based context, allowing them to accrue maximum benefits from scarce resources. In addition to directly addressing technical efficiency, economic evaluations can also help provide information in a systematic, rational and evidence-based format to facilitate tough resource-allocation (allocative efficiency) decisions. For example, the use of a QALY outcome measure in CUA allows a common metric on which decision-makers can base future resource-allocation decisions.

Although the techniques of economic evaluation are broad and can be applied to any intervention and in any context, there are issues specific to rural, remote and circumpolar communities which need to be accounted for in the analysis. Issues such as generalizability of clinical trial findings, differences in patient preferences, differences in patient ability to pay, the costs of offering or operating a program or technology and patient travel and productivity costs are all important considerations when conducting or adopting an economic evaluation for these communities.
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