INTRODUCTION

The purpose of an economic evaluation is to “identify, measure, value and compare the costs and consequences of alternatives being considered” to inform “value for money” judgments about an intervention or program. A high-quality economic evaluation should provide decision-makers with useful, relevant, and timely information. Evaluations should be based on rigorous analytical methods, be impartial and credible in the use of data, and be transparent for and accessible by the reader.

National guidance on the conduct of resource costing and economic evaluations has been available through the Canadian Agency for Drugs and Technologies in Health (CADTH) since 1994. CADTH’s guidelines are a resource for analysts who are undertaking health technology assessments of therapeutic products. The objective of CADTH’s guidelines is “to assist the “doers” of economic evaluations (i.e., analysts) to produce credible and standardized economic information that is relevant and useful to decision-makers in Canada’s publicly funded health care system.”

CADTH’s guidelines have been updated periodically. The third edition, which is the most recent version, was published in 2006. CADTH’s Guidelines for the Economic Evaluation of Health Technologies sets the standards for the conduct and reporting of high-quality economic evaluations that can be used by decision-makers for public policy decisions. For those performing economic analyses, CADTH’s Guidelines for the Economic Evaluation of Health Technologies provide clear and practical guidance of a high standard on the preferred methods for the conduct of credible economic analyses. CADTH’s guidelines also provide advice on how to resolve methodological issues while allowing sufficient flexibility in the application of methods given the variable quality of the clinical evidence.

The need for evidence about the value for money of new health technologies is not new or specific to any disease. In 1985, Ontario was among the first jurisdictions to require information on the cost-effectiveness of oral drugs in submissions to its Drug Benefit Program.

More recently, this requirement for cost-effectiveness analysis has been extended to intravenous anticancer drugs, as a result of the integration of the Ontario Drug Benefit Program and Cancer Care Ontario (CCO) drug review and approval processes. The Ontario approach combines a rigorous evaluation of the clinical evidence as synthesized by CCO's Program in Evidence-based Care, with the requirement for economic evaluation of the cost-effectiveness of the new anticancer agent. Building on this approach, the interim Joint Oncology Drug Review (JODR) process, an initiative to provide a common platform for oncology drug recommendations for all Canadian provinces except Québec, also requires an economic evaluation in addition to the evidence of clinical benefit.

Cancer as “Special” Case

There has been a great deal of discussion within the health technology assessment community about whether cancer should be treated as a special case, which implies that the agents used to treat cancer need to be evaluated differently from other health care technologies.
Cancer is responsible for a large burden of illness in Canada and its incidence and prevalence continue to increase each year. In 2008, it was estimated that there were 166,400 Canadians newly diagnosed with cancer and approximately 73,800 related deaths. The incidence of cancer in Canada has been increasing by approximately 2.5% per year, while prevalence has been rising at a faster rate, which is estimated to be 6% per year. The growing burden of cancer has stimulated research into the underlying causes of cancer and the biological changes associated with the malignant process. The increasing knowledge about the biology of cancer at the molecular level has led to the discovery of new therapeutic interventions and new drugs for the treatment of cancer. Most of these new drugs and therapies are very expensive and confer modest clinical benefits.

The burden of cancer, the cost of new anticancer therapies, or the magnitude of benefit that these new therapies confer do not justify a “special case” status for cancer. Similar arguments could be made for other common diseases that affect Canadians; for example, diabetes, cardiovascular disease, arthritis, and HIV infection.

Specific challenges are often encountered during a cancer-related health technology assessment. These challenges include the choice of what outcome to use (e.g., overall survival [OS] versus other measures of disease control, such as progression-free survival); the best method to estimate survival gain (e.g., mean survival, median survival, area under the curve); the time horizon to use, especially because most clinical trials report early results; what toxicities to include in the resource utilization data (e.g., mild versus severe); and what perspective to take (e.g., the perspective of the payer in a publicly funded federal/provincial/territorial health care system versus a societal perspective).

Furthermore, in oncology, the clinical evidence varies in type and in quality (e.g., randomized clinical trial, cross-over studies, non-comparative studies) depending on the type of cancer, stage, and prior therapies. This can introduce heterogeneity and uncertainty into subsequent health technology assessments.

Current general pharmacoeconomic guidelines do not provide sufficient direction to ensure a consistent approach to the conduct of economic analyses in oncology technology assessment. The decision to develop a guidance document was based on the observed heterogeneity and quality of the analyses in oncology submissions to decision-making bodies where some of these economic analyses have been conducted in an inappropriate or misleading fashion.

**Addendum Goal**

This oncology-specific guideline should be considered a companion document to CADTH’s *Guidelines for the Economic Evaluation of Health Technologies* (third edition). Its goal is to provide more specific guidance to analysts on the methods for the conduct of high-quality economic evaluations in oncology using CADTH’s *Guidelines for the Economic Evaluation of Health Technologies* (third edition) as a frame of reference. CADTH’s *Guidelines for the Economic Evaluation of Health Technologies* already defines the parameters that are required for good health technology assessments (e.g., time horizon, population, perspective, modelling).
Not only does this oncology-specific document focus on guidance for the conduct of technology assessment specific to cancer, it also provides guidance on what may be considered acceptable when gold standard methods cannot be used for justifiable reasons.

The oncology-specific guidance in this document is intended to promote the consistent conduct of health technology evaluations of new oncology products. This, in turn, is intended to assist decision-makers in their work. Performing analyses in a standard, clear manner that is useful to those who make recommendations on whether to approve public funding for new cancer therapies is also intended to assure Canadians that there is a fair, high-quality evidentiary basis for decision-making.

It is not the goal of this guideline document to update the methods and content of the current (third edition) of the CADTH guideline document. Any updates to that document will be addressed during the next revision of the CADTH document.

This guideline document also does not provide advice to decision-makers on such issues as threshold values or the decision-making framework (e.g., ethics, social values) that is needed to make drug approval decisions.

**Addendum Audience**

The primary audience for this oncology-specific document consists of economists and health service researchers in the public and private sectors who conduct economic evaluations.

A secondary audience consists of the consumers of economic evaluations. This audience includes Canadian decision- and policy-makers who make funding decisions about health technologies. This group includes health policy advisors in the federal/provincial/territorial Ministries of Health, members of the Common Drug Review and the interim JODR expert panels, and those working in jurisdictional drug plans, regional health authorities, hospitals, and other health care facilities. In addition, academics, medical specialist groups, health care providers, patients, patient advocacy groups, manufacturers, media, and the general public will also have an interest in these oncology-specific guidelines.\(^2\)