

# HEALTH TECHNOLOGY ASSESSMENT

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## INFLUENCING DECISION- AND POLICY-MAKING WITH HEALTH TECHNOLOGY ASSESSMENT (HTA)

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### MODULE 6

Workshop Manual  
April 2006

Surgery Strategic Clinical Network: Evidence Decision Support Program



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## **WELCOME**

Welcome to the **sixth** module of six in a series on Health Technology Assessment (HTA). The primary objective of this sixth module and workshop is to provide you with an overview of how Health Technology Assessment (HTA) information can be utilized to influence decision- and policy-making.

We hope that the fundamentals presented in this module will not only assist you in making health technology decisions and policies at a local level, but also provide you with the tools required to influence the decisions and policies made at broader and larger, national and international levels.

We look forward to sharing this experience with you and your colleagues. Your feedback and comments on both the module and workshop will be greatly appreciated!

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## **CONFLICT OF INTEREST**

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Based on the statement above, no conflict of interest exists with the author(s) and/or external reviewers of the second module.

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## **1.0 OBJECTIVES**

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In the previous modules in this workshop series we examined what Health Technology Assessment (HTA) is and how HTA information can be produced. In this final module, our focus is on the use of HTA evidence in decision-making. Thus, we take the process full circle.

The primary goals of this HTA module are to:

1. Examine the demand and supply of HTA.
2. Present a conceptual framework for the decision-making process, and differentiate between concepts such as decision analysis and economic evaluation.
3. Determine barriers to the transition from HTA to decision-making.
4. Discuss methods to improve the integration of HTA into health-care decision-making.
5. Evaluate the limits and the potential impact of implementing an HTA process in a clinical environment.

By the end of this HTA module, participants will be able to:

1. Discuss the importance of HTA in healthcare decision-making.
2. Describe the process of how decisions are made and discriminate between concepts such as decision analysis and economic evaluation.
3. Identify the barriers to implementing HTA to policy.
4. Explain how HTA bridges the gap between research and policy.
5. Identify ways to strengthen the use of HTA in the uptake and diffusion of technology within surgery.

## **2.0 INTRODUCTION**

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According to Greenberg, Peterburg, Vekstein, and Pliskin (2005), the acquisition of new technologies and the determination of how and when they should be used are among the most important administrative decisions made in the health-care system in general and by hospital executives in particular.

In many cases, often, due to lack of budgets allocated for Health Technology Assessment (HTA) and limited data on clinical efficacy and economic merit, assessments are available for decision-makers only after technologies have been adopted and widely used (Greenberg, Peterburg, Vekstein, & Pliskin, 2005). In spite of this, health-care decision makers are faced with the challenging task of harnessing the opportunities created by health technologies, while simultaneously ensuring that the health-care system remains sustainable and equitable (OECD, 2005).

Since considerable amounts of scarce resources are invested in HTA, it is important to maximize the benefits from HTA activities. Most researchers involved in HTA argue that the ultimate objective of their work is to improve decision-making about the diffusion and use of health technology (Drummond & Weatherly, 2000). However, in practice it is not clear which HTA findings impact upon decision-making, or how they do so (Drummond & Weatherly, 2000). Thus, it is assumed that better knowledge of decision-making processes contributes to a better understanding of the widespread variation in technology diffusion and utilization (OECD, 2005).

In the subsequent sections we will examine why HTA plays a critical role in health-care decision-making, and how it can achieve optimal success in influencing policy.

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### **3.0 HTA AND ITS INFLUENCE ON DECISION-MAKING**

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The existence of multiple definitions of Health Technology Assessment (HTA) and the variation in the way HTA is practiced and integrated into health-care systems, has made it difficult to present one clear and comprehensive definition of HTA. While some countries have national assessment agencies that conduct or coordinate all HTA activities, other countries have more devolved responsibilities for producing HTA (OECD, 2005; Oliver, Mossialos, & Robinson, 2004). In spite of this variation, a review of some of the major agencies and guidelines reveals that the definition of HTA always converges on the importance of HTA informing clinical decision-making and policy.

According to the Canadian Coordinating Office for Health Technology Assessment (CCOHTA), HTA is the process of systematically reviewing existing evidence and providing an evaluation of the effectiveness, cost-effectiveness and impact of health technology and its use, both on patient health and on the health care system ([https://www.ccohta.ca/entry\\_e.html](https://www.ccohta.ca/entry_e.html)). From CCOHTA's perspective, HTA is among the tools and services health care decision makers can rely on for making well-informed health technology choices.

According to the Organization for Economic Co-Operation and Development (OECD, 2005), the HTA process comprises three steps:

- (1) The identification of questions, including the prioritization of the topic and development of a strategy to answer these questions.
- (2) The systematic retrieval of scientific evidence and analysis, critical review and summary of the evidence, including comment on the validity and strength of the evidence.
- (3) The appraisal of evidence, including judgments about the meaning of the evidence obtained by systematic review and the formation of views as to the value of a technology in the health-care system. The evidence and its appraisal then inform the decision-making process.

At a minimum, HTA addresses the efficacy of technologies, including: 1) the health benefits to patients, 2) potential side effects, and 3) comparisons (of health benefit) with alternative technologies (OECD, 2005). Broader HTA frequently includes economic evaluation, typically in the form of cost-effectiveness analysis (CEA). The complexity of HTA is increased given that HTA both influences and is influenced by a wide array of disciplinary (e.g., epidemiologists, economists), sectoral (e.g., academics, policy makers), and stakeholder (e.g., patients, industry) groups (Oliver, Mossialos, &



Robinson, 2004). The scope of HTA is generally wide, since the use of a health-care technology affects not only patients, but also health professionals, the health system, and society (Ohinmaa & Hailey, 2002).

However, HTA is not simply more research. HTA goes far beyond counting scientific publications in peer-reviewed journals. According to Bensing, Caris-Verhallen, Dekker, Delnoij, and Groenewegen (2003), quantity of publications is irrelevant if no one ever takes the time to read or act upon them. Instead, for HTA to be effective, it should serve as a bridge between scientific evidence, the judgment of health professionals, the views of patients and the general public, and the needs of policymakers ([\).](http://www.nhshealthquality.org/nhsqis/qis_display_wide.jsp;jsessionid=F0D7F612355159B7DC5C0E9A06F893EB?pContentID=2568&p_applic=CCC&p_service=Content.show&)

Given the current state of our health care, it is not surprising that making better decisions about the uptake and diffusion of health technologies is an issue of increasing concern to consumers, health care providers, and policy makers. There has been a movement to create a greater evidence base so as to provide decision-makers with the best available evidence on the effectiveness of interventions to prevent, treat, and manage disease (OECD, 2005). Health Technology Assessment (HTA) has contributed to this movement in a substantial and significant way. Proponents view HTA as a valuable source of information, since it considers both the effectiveness and wider implications (e.g., social, legal, economic) of existing and emerging technologies (OECD, 2005). HTA can be used to guide decisions about the use and diffusion of technology and resource allocation, so as to produce optimum levels of health outcomes. Decisions in clinical practice and in health care resources management do not only determine results in terms of patients' health and quality of life, but also determine the economic sustainability of health care systems (Granados, 1999). To this end, HTA has been described as "the bridge between evidence and policy making" (Battista & Hodge, 1999).

Yet, more recently, it is recognized that there is a gap between the production of scientific evidence and its utilization to inform decision-making (Ganon, Sanchez, & Pons, 2006). At the health policy level, previous work has reported that HTA recommendations could influence decision-making, however based on a multi-method study of the implementation of guidance issued by the National Institute for Clinical Excellence (NICE) in England and Wales, the extent to which HTA led to changes in practices was variable (Ganon, Sanchez, & Pons, 2006). Moreover, a review of HTA utilization in four European countries indicated that, in spite of substantial human and financial investments, the actual impact of HTA on policy-making was still limited (Ganon, Sanchez, & Pons, 2006).

Consequently, it has been argued that access to high-quality evidence is a necessary, but not sufficient requirement to manage the uptake and use of health technologies effectively (Granados, 1999; OECD, 2005). The decision-making process itself is increasingly recognized as an important part of successfully using evidence and implementing recommendations reached through evidence-based assessment (OECD, 2005). While health care policy might benefit from health services research in developing evidence-based policy, according to Bensing, Caris-Verhallen, Dekker, Delnoij, and Groenewegen (2003), research will always be only one of the many inputs that determine policy.

### **3.1 DEMAND AND SUPPLY OF HTA**

According to the OECD (2005), there are a number of factors that explain the demand for and supply of HTA activities.

- (1) HTA arrived at a time when policy makers were becoming increasingly concerned about health expenditures, with technology perceived as a major driver of those costs (OECD, 2005).
- (2) There was a growing concern over the possible ineffective (or even harmful) uses of untested technologies (OECD, 2005).
- (3) The advent of randomized control trials and resultant availability of data led to strong methodological developments in HTA-related fields, including health economic evaluation techniques (OECD, 2005).
- (4) The widespread variation in technology use has led to questions about the optimal use of technology – as a consequence the need for evidence that allows decision-makers to strive for optimum diffusion and uptake rates (OECD, 2005).
- (5) The growth in medical research and technology, alongside developments in information technology, has made it impossible for decision makers (such as purchasers and medical practitioners) to keep up with all the new developments reported in the literature. There is a growing demand from decision makers for high quality, comprehensive and manageable information, such as that provided by HTA (OECD, 2005).

- (6) Trends in health system reforms have resulted in decentralized decision-making, so that health-care choices are made closer to the patient. Consequently, the value of HTA is likely to increase and more decision makers throughout health-care systems will require access to high-quality evidence in order to make informed choices (OECD, 2005).

### **3.2 DECISION-MAKING MODELS**

A lack of a decision-making process is viewed as creating barriers to the efficient uptake of technologies. One reason for this is because it creates doubt over the legitimacy of decisions, thereby possibly making it less likely to be supported by stakeholders. A second reason is that incorporating evidence into ill-defined decision-making processes is more complex as the producers of evidence will be less likely to deliver timely and relevant advice (OECD, 2005; Weatherly, Drummond, & Smith, 2002).

Thus, decision-making frameworks for health technology assessments have become a major concern in the industrialized world (Johnson-Masotti & Eva, 2005). Consequently, the National Institute for Clinical Excellence (NICE) in the United Kingdom published a series of guidelines during 2004, with the aim of increasing the transparency of processes and providing a structure for the assessment of health technologies (Johnson-Masotti & Eva, 2005). The Alberta Heritage Foundation for Medical Research and Alberta Health and Wellness are examples of organizations that have published guidelines to aid decision makers in the complex process of prioritization at the district or Regional Health Authority (RHA) level (Johnson-Masotti & Eva, 2005).

Decision making in any health-care system is a complex set of interactions among a wide array of stakeholders (OECD, 2005). In broad terms, decisions can be categorized into three levels:

- (1) Macro (decisions made at national, provincial, or insurance company level)
- (2) Meso (decisions made at regional health authority or hospital level)
- (3) Micro (decisions made at provider or patient level).

Health-care providers are typically charged with the decision to recommend whether or not a certain technology should be used at the individual patient level (Coburn, 2005). However, decisions made at the macro and meso levels also influence the answer to this question. These questions tend to focus on: Should this technology be paid for or reimbursed? Who should have access to this new technology? Where should the technology be available? Should use of the new technology be encouraged in preference to older technologies (Coburn, 2005)?

The rate of diffusion and the level of uptake of new health-care technologies are the aggregate outcome of a large number of decisions made by politicians, health-care administrators, doctors and patients (OECD, 2005). Specifically, what influences the decision-making process?

(1) Health-care objectives

- Promoting access to provision of effective and appropriate health services.
- Promote equity of access to service provision.
- Efficiency of health service provision.

(2) Environmental factors

- Interests of stakeholders.
- Political agendas and prevalent norms and values.
- Research.
- The idiosyncrasy of governmental organizations.
- Aggregate income levels (the amount of money available).
- Reimbursement mechanisms (financial incentives for purchasers to buy, and providers to adopt, new technologies, including the way in which health care is financed and organized).

(3) Social imperatives

- Stakeholder interests may diverge.
- Sometimes efficiency is sacrificed if the extra costs deliver benefits to more deserving groups in society, such as children, veterans or patients with a high burden of disease (Coburn, 2005).

Implementation programs cannot be designed without consideration of the wider health system influence on clinical behavior. The institutional and financial aspects of the health system can have an important influence on whether decisions will be successfully implemented. Some aspects of the health system will serve to facilitate decision implementation, whereas other factors may impede implementation (OECD, 2005). It appears that when no additional funding is available to implement technologies (and implementation has to be met out of the existing budget), there is an incentive to take up technologies that are cost saving. At the same time, this creates disincentives to take up technologies that can increase costs, regardless of how effective the technologies may be (OECD, 2005).

## MODULE 6: Influencing Decision- and Policy-Making Using HTA

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The historical development and evolution of health-care systems play an important role in setting the institutional characteristics of the decision-making processes (OECD, 2005). The decision-making process may differ across countries in one or more of the following ways:

- HTA may be compulsory in the decision-making process or it may be voluntary.
- Decision may occur at the national, provincial, or regional levels.
- Research, development, and health service evaluation may occur internationally.

Adopting the conceptual model from the OECD project (2005; see Appendix A for the figure), we can see that decision-making is at the center of the health care system.

Important inputs into the decision-making process include:

- (1) HTA and evidence on the impact of new technologies, and
- (2) Appraisal of evidence and other factors such as economic conditions, organizational features, and national and international regulations.

With these inputs, decision-makers can determine whether it is possible, and how one can adopt and implement the new technology. Still, although several theories have been suggested to describe hospital behavior and adoption of new technology, Greenberg, Peterberg, Vekstein, and Pliskin (2005) argued that none have sufficiently explained technology adoption decisions. We now consider each of these models in turn.

### Profit-Maximization, Price Competition, or Fiscal-Managerial System Model

- Uses traditional economic theory to explain hospital behavior
- Assumes hospitals evaluate new technologies from the perspective of hospital profitability, and technologies are acquired when the expected present value of revenues exceeds the expected cost over the useful lifetime of the product, offering a profitable return on investment (Greenberg, Peterburg, Vekstein, & Pliskin, 2005).

### Technology Competition, Technological Preeminence, or Strategic-Institutional Model

- Derives from three different theories of hospital behavior:
  - (1) **Sales Maximization Theory** where hospitals want to be the largest,

- (2) **Conspicuous Consumption Theory** where hospitals want to show that they are the most technologically advanced, and
- (3) **Physician Cooperative Theory**, where hospitals will acquire technology that maximizes physician income (Greenberg, Peterburg, Vekstein, & Pliskin, 2005). According to this theory, hospitals adopt capital-intensive technologies unrelated to their cost to achieve technological superiority, to enhance their image and prestige as leaders in the technological realm, attracting patients, physicians, and researchers (Greenberg, Peterburg, Vekstein, & Pliskin, 2005).

#### Utility-Maximization Model

- Hospital managers invest in technology, subject to budget constraints, to enhance the quality and quantity of services the hospital provides.
- The medical-individualistic perspective focuses on delivery of services according to the definition and demands of physicians and hospital medical administrations.
- Based on fundamental assumptions that the physicians and the hospital adopt new technologies based on the clinical needs of the population they serve, even if fiscal considerations, competition, or calculation of hospital prestige suggest alternative actions (Greenberg, Peterburg, Vekstein, & Pliskin, 2005).

### **3.2.1 DECISION ANALYSIS**

Whether we are aware of it or not, each decision we make is based on an evaluation of the options at hand, followed by a choice based on the perceived outcomes derived from that choice (Kucey, 1999). According to Kucey (1999), decision analysis:

- Is a mathematical tool that attempts to emulate the human decision-making process.
- Seeks to provide a systematic approach to decision-making under conditions of uncertainty by providing an intuitive framework through which complex problems can be studied.
- Is merely an aid for clinical reasoning, not a substitution for sound clinical judgment, and it must always be used and interpreted with this in mind.

According to Soto (2002), the decision analytic model:

- Is a systematic approach to evaluate the impact of medical interventions on costs and other outcomes under conditions of uncertainty.
- Combines data from many sources (RCTs, observational studies, epidemiologic data, expert opinion, etc.) to produce detailed estimates of the clinical and economic consequences of different therapeutic alternatives, thus permitting to represent the complexity of the real world in a more simple and comprehensive form and simplifying and evaluating complex decision problems as an aid in the decision-making process.
- Consists of a series of branches, each representing different options (decisions or events) that arise at different points, referred to as nodes (e.g., decision nodes and chance nodes).
- Shows the consequences and complications of different therapeutic interventions and it should correspond as much as possible to the real-life situation of the disease in each setting.
- Produces results that must be used by decision makers to allocate resources correctly. Therefore, it has to fulfill some requirements, such as whether we want results that are valid, reliable, and relevant for all end users (Soto, 2002).

### **3.2.2 ACCOUNTABILITY FOR REASONABLENESS FRAMEWORK**

The “accountability for reasonableness” framework was developed by Daniels and Sabin (1997, as cited by OECD, 2005, p.77) to evaluate whether priority-setting decisions could be considered “fair”. The framework has four conditions, each of which will be discussed below.

- (1) Relevance. For decisions to be considered relevant, they must rest on reasons that stakeholders who are predisposed to decision-making can agree are germane to meeting context specific needs under resource constraints (OECD, 2005).
- (2) Transparency. Decisions are to be transparent in that information regarding the decision-making process, the evidence used, and the rationale for the decisions is publicly accessible (OECD, 2005).
- (3) Appeals. The decision process must include a mechanism for challenge and dispute resolution regarding priority-setting decisions (OECD, 2005).
- (4) Enforcement. To ensure the first three conditions are met, there must be voluntary or public regulation (OECD, 2005).

The OECD (2005) survey results supported the notion that the degree of “reasonableness” may be influential in bringing more widespread acceptance of the decision. This is likely to be an important contributing factor when it comes to implementing decisions successfully (OECD, 2005). Furthermore, the survey results provided some support for the notion that a more formal decision-making process is more likely to use HTA to support a decision. Over 85% of decisions taken in the more formal process drew on HTA. This figure dropped to 60% for “informal” decision-making (although the sample size for the number of informal decision was small, accounting for only 20% of the sample; OECD, 2005).

### **3.3 UNCERTAINTY IN DECISION-MAKING**

Evidence is not always available to make informed decisions; sometimes because there are conflicting results from various sources of evidence, sometimes because evidence suggests a range of possible outcomes and it is only possible to make a best guess, and other times because there is no available evidence at all on the technology. Uncertainty creates problems for decision-makers because they are charged with choosing between various scenarios when there is insufficient definitive information on which to base decisions (Coburn, 2005). In health care, the stakes for such decisions are high and may carry both high financial and health risks and rewards. Furthermore, the overarching imperative and responsibility for decision-makers is to make decisions, even if on poor quality evidence. To defer consideration of a matter until the perfect evidence is in, is in effect, to decide (Coburn, 2005). Therefore, uncertainty is a source of risk decision-makers are expected to manage.

Specifically, evaluators of clinical research and decision-makers are at risk of making two kinds of errors:

- (1) They may conclude a treatment is effective when it is not, and risk approving or encouraging access to an ineffective, inefficient, or even harmful technology; or
- (2) They may conclude that a treatment is ineffective when it is actually effective, thereby impeding or denying access to technologies that are beneficial and efficient (Coburn, 2005).

According to Coburn (2005), there are various approaches one can employ to aid decision-making in the face of uncertainty. These approaches include:

- (1) Develop dialogue and understanding between producers and users of HTA in order to increase the usefulness and relevance of HTA and economic



evaluations, and create opportunities for the development of more practical guidance on decision-making (Coburn, 2005; Hivon, Lehoux, Denis, & Tailliez, 2005).

- (2) Encourage training in HTA methods for those whose “core business” is technology decision-making and who are in proximity to appraisal processes (Coburn, 2005).
- (3) Insist on the underlying data as it is critical to understand the limitations of data so as to be able to make judgments about the strength of evidence against policy objectives (Coburn, 2005).
- (4) Avoid summaries provided by measures such as incremental cost-effectiveness ratio (ICER), since they appear to be a neat summary measure of all the information needed for decision-making, but they do not permit judgments to be made in conjunction with broader objectives (Coburn, 2005).
- (5) Beware of the limitations of economic evaluation tools. The inappropriate use of cost-effectiveness analysis (CEA) is at best inconsistent with policy objectives and in Canada has resulted in adverse consequences. The use of CEA within the framework of a fixed budget is only appropriate when used in conjunction with the concept of opportunity costs (Coburn, 2005).
- (6) Don't be limited to “all or nothing” approaches or single benchmarks for evidence. Factors such as availability of alternative treatments, seriousness and prevalence of disease, likelihood of harm, and potential budget impact, may all bear on the resources put into HTA, the strength of evidence required for effectiveness and the acceptable shadow price for a technology (Coburn, 2005).
- (7) “Catch-up” evaluation of diffused technology requires case-by-case decision-making. Tensions arise in evaluating technologies that have already been diffused in the health-care system. The tensions arise in large part out of conflict between provider and patient expectations. The decision-maker has to judge the degree to which these expectations are reasonable (Coburn, 2005).
- (8) Develop strategies to minimize post-decision risk. Uncertainty can arise in the rate of take-up and utilization of technology, and in this case, decision-makers do not know what the likely level of technology diffusion will be once a decision has been made. This can be addressed by establishing risk-sharing agreements

between government and industry through pricing arrangements or to agree to connect the price of a new technology to the expected level of relative effectiveness (Coburn, 2005).

- (9) Balance the evidence against other objectives, as not all Quality-Adjusted Life-Year (QALY)s are equal. There is a lack of clear and detailed guidance on how to incorporate social preferences into decision-making and how to weight evidence and economic analyses around these (Coburn, 2005). It is not clear, however, that taking social preferences and other objectives into account in decision-making is incorrect in either a procedural or policy sense. Efficiency is only one of many health policy objectives and economic evaluation remains the servant of policy objectives, not its master (Coburn, 2005).

### **3.4 ECONOMIC EVALUATION AND DECISION-MAKING**

As we have seen, evidence, including information on whether a new technology presents value for money, plays a key part in aiding decision-makers to make informed choices (Coburn, 2005). Given the increased awareness of the importance of cost-effectiveness, or value for money, in health care, there has been a growth in the number of published economic evaluations in recent years (Soto, 2002; Walker, 2001). This also reflects the increased recognition received by economic evaluation in the policy arena. For example, the Province of Ontario in Canada has made the provision of an economic evaluation a mandatory requirement for reimbursement (public subsidy) of health care products (OECD, 2005; Walker, 2001). According to Krahn (1999), when measuring the effects of health programs on both resource consumption and health, economic evaluation allows us to see how much health care “bang” we are getting for our “buck.”

An important issue according to Nixon, Phipps, Glanville, Mugford, and Drummond (2002) is that those responsible for making decisions may be unfamiliar with the methodology of economic evaluation. There is therefore a need for rapid access to clinical and economic effectiveness information derived from relevant studies. However, even with greater emphasis on economic evaluations in decision-making, considerable uncertainties over the cost and effectiveness parameters of treatments will persist, making decisions about coverage complex (OECD, 2005). Moreover, cost and effectiveness parameters change over the life cycle of a technology so decisions need to be revised regularly if they are to consider the latest and most accurate information (OECD, 2005). Therefore, decision-making processes need to move away from the idea that a technology can be evaluated once and for all, on the basis of research findings collected before its use in everyday practice (OECD, 2005).

Although often a component of HTA and an invaluable tool for understanding the economic and health consequences of clinical policies (Coburn, 2005; Krahn, 1999), economic evaluation faces its own set of challenges. Two of the main challenges or limitations of economic evaluation include:

- (1) The potential lack of transferability of evaluation studies from setting to setting. This is in fact one of the primary reasons that economic evaluations are often not used in local decision making. The variables used in an economic evaluation may differ from those of the decision maker's local circumstances. Empirical research has shown that the way most economic evaluations are reported makes it difficult for local decision- makers to assess whether the study does (or does not) bear relevance to the local setting (Coburn, 2005).
- (2) Economic evaluation is not prescriptive but, rather, a first (albeit important) step in the evaluation of an intervention (Krahn, 1999). The distribution of costs and health benefits (who gains and who loses) and availability (matching resources to locations where they are accessible to those who require them) must also be considered (Krahn, 1999).

### **3.4.1 ASSESSING COSTS AND EFFECTS**

Cost-effectiveness analysis (CEA) compares the costs and effectiveness of alternative treatments (e.g., technology A and technology B). The level of effectiveness can be measured using outcomes such as "life years saved" or "number of cases prevented" (OECD, 2005). Cost-effectiveness analysis provides a systematic and transparent framework by which to assess the relative costs and consequences of different interventions that can assist in priority-setting exercises (Walker, 2001).

The results of CEA are reported in a ratio. The numerator is given by the incremental effectiveness of technology A over technology B (OECD, 2005). The results of a CEA can be presented on the cost-effectiveness plane (refer to Appendix B). A CEA result in quadrant I should be interpreted as technology A having a greater level of effectiveness at a lower cost than technology B. In quadrant II, technology A has greater effectiveness but also greater costs. In quadrant III, technology A has greater costs but lower effectiveness, and in quadrant IV technology A has lower costs and lower effectiveness than technology B (OECD, 2005).

For the decision maker who is using economic evaluation to guide decisions, a CEA result in Quadrant I or III is fairly straightforward. A result in Quadrant I suggests it would be desirable to implement a technology that is both more effective and less costly (OECD, 2005). A result in Quadrant III indicates it would be undesirable to implement a technology that is less effective and more costly. A CEA result in Quadrant IV would require a decision maker to sacrifice effectiveness for lower costs, and many decision makers would see this as undesirable (OECD, 2005). In contrast, a CEA result in Quadrant II requires decision-makers to decide how much more they are willing to spend for an additional level of effectiveness (OECD, 2005).

Thus, it is easy to see why this form of analysis would make decisions more politically complex. Decision-makers are expected to make transparent choices about how much they value additional health benefits, which sometimes involve decisions of life or death (OECD, 2005).

### **3.4.2 MEASURING QUALITY OF LIFE**

CEA can also incorporate a measure of morbidity in the level of effectiveness, using “quality adjusted life years” (QALYs) as an outcome measure (OECD, 2005). Although the clinical status of the patient usually describes the changes in clinical condition fairly accurately, HTA researchers recommend that the patient’s own assessment of his/her health status and its effects on everyday life should also be measured. For these purposes, a variety of health-related quality of life (HR-QOL) measures have been developed (Ohinmaa & Hailey, 2002). The selection of the HR-QOL measure is partly influenced by the requirements of the possible economic analysis of the study (Ohinmaa & Hailey, 2002).

### **3.4.3 SENSITIVITY ANALYSIS**

Sensitivity analysis is the main tool analysts use to evaluate whether the qualitative conclusion reached in economic analyses, particularly those based on decision models, are robust to the uncertainties in the model (Krahn, 1999). Sensitivity analysis involves varying one or several parameters across the range of uncertainty to determine whether the analytic result changes (Krahn, 1999). Sensitivity analysis is vitally important in economic evaluation precisely because so many assumptions are required. More complex and comprehensive approaches to evaluating uncertainty are less common. It is often difficult, therefore, for a consumer of published analyses to know how much uncertainty is attached to a reported result (Krahn, 1999).

### **3.4.4 COST BENEFIT ANALYSIS**

During the past two decades, cost-benefit analysis has become the dominant method used by policy makers to evaluate government intervention in the areas of

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health, safety, and the environment (Ashford, 2002). The measurement of costs refers to the use of resources in the production of a certain service (Ohinmaa & Hailey, 2002). The estimation of costs involves three stages:

- (1) The identification of cost factors,
- (2) Measurement of the physical units of the cost factors, and
- (3) Monetary valuation of the cost factors (Ohinmaa & Hailey, 2002).

In theory, cost-benefit analysis of a policy option:

- Enumerates all possible consequences, both positive and negative;
- Estimates the probability of each;
- Estimates the benefit or loss to society should each occur, expressed in monetary terms;
- Computes the expected social benefit or loss from each consequence by multiplying the amount of the associated benefit or loss by its probability of occurrence; and
- Computes the net expected social benefit or loss associated with the government policy by summing over the various possible consequences (Ashford, 2002).

The reference point for these calculations is the state of the economy in the absence of the government policy, termed the “baseline” (Ashford, 2002).

As a decision-making tool, cost-benefit analysis offers several compelling advantages:

- It clarifies choices among alternatives by evaluating consequences systematically (Ashford, 2002).
- It professes to foster an open and fair policy-making process by making explicit the estimates of costs and benefits and the assumptions upon which those estimates are based (Ashford, 2002; Evers, Goossens, de Vet, van Tulder, & Ament, 2005).
- By expressing all gains and losses in monetary terms, it permits the total impact of a policy to be summarized in a single dollar/euro figure (Ashford, 2002).

Cost-benefit analysis also possesses the following main limitations:

- It is difficult, even arbitrary, to place a monetary value on human life, health, and safety, and a healthy environment (Ashford, 2002; Krahn, 1999).
- A prerequisite for the rational allocation of resources within a fixed regime is information on the net effectiveness and costs of medical interventions, and this detailed information is often not available (Magnell, Brown, Moskowitz, & Gelijns, 2005).

- By translating all these consequences into equivalent monetary units, discounting each to present value and aggregating them into a single dollar/euro value, the effects on the economy from investing now in future health, safety, and environmental benefits are weighted far more heavily than those benefits that occur in the future, including those to future generations (Ashford, 2002).

### **3.5 PATIENT PREFERENCES AS POWERFUL PRESSURES IN HTA**

The HTA program has adopted the definition of a consumer as:

“patients, carers, long-term users of services, organizations representing consumers’ interests, members of the public who are the potential recipients of health promotion programs, and groups asking for research because they believe they have been exposed to potentially harmful circumstances, products or services” (Royle & Oliver, 2004).

The public has a direct role to play in terms of its contribution to the decision-making process. As consumers of healthcare interventions, the general public, and patients in particular, are an important focus of HTA (Drummond & Weatherly, 2000; Oliver, Mossialos, & Robinson, 2004). As we have seen, making better decisions about the uptake and diffusion of health technologies is an issue of increasing concern to policy makers. Better educated health consumers, providers of health services, a large scale international health industry, media reporting and advertising may create expectations that health technologies will become available in a timely (or even instantaneous) way (OECD, 2005). This often includes an expectation of public funding. Consequently, a range of expectations put pressure on policy makers and health system decision makers in a way that is sometimes characterized as the “technological imperative” (OECD, 2005).

The challenge for many policy makers is to create policies that can harness the benefits of technology and innovation, but at the same time achieve multiple health system objectives within the constraints of fiscal policy (OECD, 2005). At times, adding to this challenge are the conflicting pressures and demands from patients (and tax payers), health professionals, the producers of new technologies, and a range of other pressure groups (Hivon, Lehoux, Denis, & Tailliez, 2005; OECD, 2005). In fact, it is expected that patient preferences are likely to become more important in determining the value of new technologies.

According to Devereaux and Yusuf (2003), evidence should not be used to tell patients what to do; rather evidence should be used to allow patients to make informed decisions. All treatment decisions involve a weighing of the potential benefits, risks,

inconveniences and costs. Patients' preferences may weigh these potential outcomes differently allowing individuals to rationally make different decisions despite being presented with the same evidence (Devereaux & Yusuf, 2003). For example, patients may prefer one technique over another, even when the expected health outcome is the same. While measures of patient preferences could be used alongside measure of health outcome and quality of life, methodologies, including measures of patient preferences need to be better understood and defined by users and producers of HTA.

A subsequent challenge will be to incorporate such information in the decision effectively (Coburn, 2005; Devereaux & Yusuf, 2003; Hivon, Lehoux, Denis, & Tailliez, 2005). Clinical expertise will be required to establish, balance, and integrate the patient's clinical state and circumstances, preferences, and actions, and the best research evidence. Therefore, according to Devereaux and Yusuf (2003), clinical expertise requires both clinical and content area knowledge, skills at critical appraisal and clinical diagnosis – all tempered with good judgment based on incorporating the patient's preferences and circumstances.

### **3.6 BARRIERS TO IMPLEMENTING HTA FINDINGS**

It is well-known that better knowledge about the risks, benefits, and costs of technologies have reduced the uncertainty involved in the decision-making process, and have resulted in more informed decision-making. As already indicated, it is also recognized that a gap exists between the production of scientific evidence and its utilization to inform decision-making. While HTA is purported to be the "bridge" reducing the gap, recently it has been acknowledged that the actual impact of HTA on policy and decision-making is still limited (Ganon, Sanchez, & Pons, 2006). However, when one considers the number of stakeholders involved from the time empirical evidence is established through to the time decisions are made, it is not surprising to learn that various obstacles in the way of implementing HTA findings exist.

Drummond and Weatherly (2000) identify 10 potential barriers to the implementation of HTA at the policy level. Each of these barriers will be presented below and discussed briefly.

- (1) Differing perspectives between decision-makers and HTA researchers. At the health policy level, factors that relate to the decision-making environment are significant barriers to behavior change. Perhaps the most fundamental issue obstructing the implementation of HTAs is the divergence between the public policy and the HTA framework (Drummond & Weatherly, 2000). In the public policy field, the environment tends to be action-orientated and concerned with what is practicable, given constraints such as time and finance. Decisions must be made often, over a relatively short period of time, and of course, unequivocal answers to policy questions are best (Drummond & Weatherly,

2000). In contrast, much research is conducted over a long time horizon and involves uncertain outcomes (Drummond & Weatherly, 2000). The question is: *to what extent do HTA findings meet the objectives of the decision makers?* Different tools are required to disseminate and communicate HTA findings, depending on the audience targeted (Drummond & Weatherly, 2000).

- (2) Timeliness and accessibility of HTA findings. Although a costly experience, HTA needs to be conducted early in the life cycle of medical technologies and repeated as new data become available (Drummond & Weatherly, 2000). In order for HTA findings to influence policy, HTA must be available, readily identifiable, and accessible (Drummond & Weatherly, 2000; Hailey, 1993). Policy makers' receptivity to behavior change is, in part, a reaction to the accessibility of the HTA (Drummond & Weatherly, 2000). Hailey (1993) discusses how it is often surprising for assessors who have not had direct experience in policy areas to learn that their results and reports may have limited impact. No matter how eloquent the presentation and rigorous the analysis it will not be helpful to policy makers if the assessment arrives too late, cannot be understood and does not take account of realities within the health care system (Hailey, 1993; Magnell, Brown, Moskowitz, & Gelijns, 2005).
- (3) Reliability of study findings depends on the quality of the research. HTA results are system-dependent in the sense that they can only be as good as the data on which they are based and from the perspective and context on which they were assessed (Drummond & Weatherly, 2000). Although the gold standard for evaluating the efficacy of healthcare interventions is the randomized controlled trial (RCT), in regular practice effectiveness is paramount (Drummond & Weatherly, 2000; Magnell, Brown, Moskowitz, & Gelijns, 2005). RCTs have high internal validity, but are conducted under artificial, idealized conditions. As a result, estimations have to be made about the effectiveness of the interventions as used in regular clinical practice. The generalizability of results at key decision points may be debatable. Therefore, to make progress, often an element of judgment is required in the absence of adequate data (Drummond & Weatherly, 2000).
- (4) Incentives and uncertainties. The incentives that motivate actions differ within the environments of researchers, HTA agencies, consultancies, and public policy makers (Drummond & Weatherly, 2000). Researchers' careers largely depend upon publishing their findings in good quality journals. Yet, this is not considered the optimal medium if one wants research results widely known among policy makers, who are the principal target group for much health services research (Bensing, Caris-Verhallen, Dekker, Delnoij, & Groenewegen, 2003). Instead, public policy makers advance in their careers by providing solutions to policy questions. The incentives of these two groups are not



complementary, nor are they constructed to promote cooperation between the two groups. Added to this, the professional training of either group shares little in common with the other (Drummond & Weatherly, 2000).

- (5) Knowledge and beliefs. There is a long-standing cultural divide between researchers, practitioners, and administrators (Drummond & Weatherly, 2000). Each group of healthcare professionals within the decision-making chain have developed their own technical language, and this may prevent effective communication (Drummond & Weatherly, 2000; Magnell, Brown, Moskowitz, & Gelijns, 2005).
- (6) Lack of consensus. As discussed in previous sections of this module, considerable evidence suggests that marked and systematic variations in medical practice continue to exist within and between countries. Therefore, a major undertaking of HTA is to stimulate the reduction of inappropriate and inefficient care, as well as the inequitable variation in the quality of care (Drummond & Weatherly, 2000). If there is a lack of agreement about what constitutes best practice, then it is likely that the confusion will transmit to the healthcare professional level (Drummond & Weatherly, 2000). Moreover, it seems likely that, if the standards of practice and guidelines recommended by HTA findings do not match current practice, clinicians may be reluctant to adopt them (Drummond & Weatherly, 2000).
- (7) Autonomy and uncertainty. Clinicians are a key audience for economic evaluations, but since clinicians do not appear to think of health care in terms of economic outcomes, different models for implementation are required (Drummond & Weatherly, 2000). It has been suggested that if clinicians are not included within the process of HTAs, the results will have less credibility among the group, and without adequate training in HTA, clinicians will be reluctant to act upon findings, even if these are valid (Drummond & Weatherly, 2000). Furthermore, clinicians are uncomfortable with uncertainty, and this promotes cautious behaviour. Health technology assessors are dependent upon the dynamism of health-care professionals if HTA findings are to translate into practice (Drummond & Weatherly, 2000).
- (8) Financial barriers. There are two different implications related to financial barriers. The first corresponds to the reality that conducting clinical trials is a costly exercise and priorities must be set as to which of the many new and expanded technologies in existence today requires evaluation (Magnell, Brown, Moskowitz, & Gelijns, 2005). Thus, the resources available for conducting clinical evaluative research are finite. The second issue is related to the monetary demand on the health-care system. In a private healthcare system, actual demand will be less than socially optimal if medically beneficial

treatments are prohibitively expensive for the consumers of health care (Drummond & Weatherly, 2000). On the other hand, within public healthcare systems, rationing of the limited supply of available health care at the public policy level may equally prevent the use of appropriate medical care by the general public, in spite of sound economic information advocating the use of the treatment (Drummond & Weatherly, 2000).

- (9) Information asymmetry. Due to the information asymmetry between patients and their doctors, an agency relationship exists (Drummond & Weatherly, 2000). In terms of maximizing health outcome, it is not clear whether people always know what their own best interests are, or that their stated preferences match their actual preferences. Often individuals rely on the doctor's knowledge for their healthcare requirements, but as we have already indicated, sometimes people's own personal perceptions, expectations, and desires to alter their lifestyle may greatly influence the extent to which HTA is implemented. Furthermore, the perspectives of HTA studies vary and are not always compatible with the individual patient preferences, and since few individuals are trained in HTA, many study findings are not immediately accessible (Drummond & Weatherly, 2000).

### **3.7 INCREASING HTA'S INFLUENCE IN DECISION-MAKING**

Better management and integration of health technologies require accurate and timely information about their effectiveness and costs. In the absence of such information, the uptake and diffusion of technologies are more likely to be influenced by a range of social, financial, professional and institutional factors and may not deliver the best possible health care. Therefore, a vital condition for making informed choices is to have access to evidence and to have strategies in place for those situations where detailed evidence is lacking (Coburn, 2005).

In Canada, there is a widespread experience in producing and accepting HTA. However, a federal system such as Canada's, with shared responsibilities for the delivery of health-care and HTA, faces considerable challenges in the effective and efficient delivery of HTA. As such, recent efforts have focused on generating wider use of HTA in decision-making in all parts of the health-care system, as well as more systematic coordination and collaboration in HTA (Duran-Arenas & Coburn, 2005). The effective and appropriate use of HTA requires strong support from policy makers. Just as the producers of HTA have a responsibility to deliver high quality and relevant evidence to decision makers, policy makers have a responsibility to develop the capacity of decision makers and health-care institutions to be receptive to HTA (Duran-Arenas & Coburn, 2005).

HTA is already an important component of both public and private sector decision-making, but it is expected to play an even greater role in the future. The dynamics of medical innovation, as well as recent scientific advances, are likely to increase the pace of technological development (Coburn, 2005). Being required to keep-up with the opportunities and challenges created by new technologies, decision-makers will need access to more high-quality synthesized evidence. Since the value of HTA is likely to increase, some significant challenges need to be overcome if HTA is to fulfill its role in driving greater use of evidence in decision-making (Coburn, 2005).

- (1) It is essential to ensure more comprehensive assessments of a wider set of technologies, reduce potential duplication, and guarantee that assessments are in line with decision-maker's priorities, cooperation and communication among HTA producers, users and other stakeholders. Such models of cooperation also need to reflect the local HTA production capabilities and institutions (Coburn, 2005; Drummond, Manca, & Sculpher, 2005; Hivon, Lehoux, Denis, & Tailliez, 2005). Moreover, greater international collaborations in the synthesis of HTA evidence may generate savings and reduce duplication, as well as raise important methodological issues around transferability (OECD, 2005).
  
- (2) To create a better awareness of HTA results, significant proportions of HTA activity need to be devoted to the dissemination of results. According to Coburn (2005), more research is needed to develop best practice in dissemination techniques; however, there are some indications that a wide range of dissemination strategies may be more effective than a single one. HTA reports are disseminated through a variety of means including the internet, e-mail alerts, conferences, newsletters, education campaigns, media and personal contacts. Such a portfolio approach to dissemination may be the most effective means of reaching numerous health-care decision-makers (OECD, 2005).
  
- (3) To generate greater acceptance and appropriate use of HTA, greater efforts are needed in the area of building decision makers' skills in interpreting and analyzing evidence, and establishing information infrastructure to make evidence more readily available (Coburn, 2005). Despite its growing importance, clinical evaluative research and HTA account for very small proportions of total health-care spending. HTA has been a "value for money" activity. Developing a culture of evidence-based medicine and policy requires secure and long-term investment to ensure the appropriate training of the workforce, the development of expertise, and the development of methodologies that build on the quality and relevance of HTA to decision

- makers. Such investment should recognize the need for better guidance on how assessment, including repeat assessment, can be undertaken for technologies that are at different stages of development. This may involve examining appropriate ways that HTA can be conducted and reported, depending on the maturity and characteristics of the technology (OECD, 2005).
- (4) In order for HTA to influence decision makers, it has to produce the evidence that they require. This means ensuring the timely availability of information, in line with decision priorities, and recognizing the various dynamics of different technology markets (Coburn, 2005). There is a need for better communication between the producers and users of HTA to ensure sound methodology and relevance (OECD, 2005). The involvement of decision-makers early on in the assessment process may help deliver more valued and relevant information. A dialogue that occurs early on in the assessment process is likely to achieve better alignment of HTA content, decision makers' needs and policy issues (Coburn, 2005; Greenberg, Peterburg, Vekstein, & Pliskin, 2005; OECD, 2005; Weatherly, Drummond, & Smith, 2002).
- (5) HTA is applicable to all technologies. HTA has a role in assessing older technologies; firstly, so that the relative impact of new technologies can be measured, and also to overcome the lack of evidence on the effectiveness and efficiency of some current aspects of medical practice (OECD, 2005). Assessments dealing with more mature technologies may have less impact because of reluctance to move away from earlier decisions and established practice (Hailey, 1993). To some extent once technology is in place, even if the cost is high and there are concerns about value for money, the status quo will often prevail for a long time with policy areas perhaps coming to regard it as an inevitable burden (Hailey, 1993).
- (6) It is increasingly recognized that the way in which a decision is made is an important factor in generating greater acceptance of that decision by stakeholders. Decision-making processes that are transparent, based on evidence and incorporate a review mechanism can enhance broader stakeholder support for decisions. In turn, broader stakeholder support is vital to the successful implementation of decisions (Coburn, 2005; Drummond, Manca, & Sculpher, 2005).
- (7) There is a need for a greater understanding of the impact of incentives on efficient purchasing, and identifying methods that align incentives with

evidence and health priorities (Coburn, 2005). The use of high-quality and trusted evidence is an important factor in the successful implementation of decisions, as is greater flexibility of resources and assistance in financing. However, implementation tools also need to be better aligned with the best available evidence. This includes developing or setting policy levers that either create incentives or neutralize incentives, for decision makers to incorporate evidence into their choices (Coburn, 2005). Moreover, to reiterate, decision-makers must be able to re-evaluate their decision, not just in theory but also in practice (Coburn, 2005).

- (8) There is a need to develop more cohesive frameworks for analyzing the extent to which HTA has helped decision makers formulate rational choices. An international framework of analysis with agreed performance indicators, would create greater opportunities to develop best practices in encouraging the use of HTA in decision-making (OECD, 2005).

### **3.8 INFLUENCING DECISION-MAKING AND POLICY AT THE LOCAL LEVEL: DEPARTMENT OF SURGERY**

An essential requirement in seeking to influence policy through assessment is to know the health care system in which the technology is to operate (Hailey, 1993). Thus, to improve the integration of technology into the health-care system and influence procedures at the Calgary Health Region (CHR), the focus should be on the decision-making process and the policy tools used to implement decisions, as well as the transition from HTA to decision making. In the previous modules we examined how HTA could be produced. In this final module we have explored the use of HTA evidence in the uptake and diffusion of technology within health-care decision-making.

We have seen that while there is substantial international agreement over a number of aspects of HTA methodologies, decision-making processes and the use of HTA tend to reflect the local circumstances, including health needs, health financing and service provision arrangements, policy objectives and the level of influence and control of decision makers themselves (Duran-Arenas & Coburn, 2005). In Alberta, Hailey et al (2000 as cited in OECD, 2005, p.39) reported on the impact of a series of rapid HTA reports ("Technotes") prepared in response to specific requests from the provincial health ministry or health authorities. The policy issues which the reports addressed were related to the possible referral of patients for treatment outside the province, the case for introducing new technology, the purchase of particular items of equipment and the appropriateness of existing clinical practice. Based on written feedback and discussions with those making the requests, the authors concluded that 14 out of 20 reports had exerted some influence on decision-making (OECD, 2005). While there is a

frequent lament that HTA appears to have had relatively little impact on decision-making, studies such as Hailey's (2000) have found that formal HTA exercises can encourage changes in practice for particular technologies. This issue is gaining increasing recognition by decision makers and producers of health technology assessments (OECD, 2005).

Like other Regional Health Authorities (RHAs), CHR is faced with continuous streams of new health technology proposals put forth by stakeholders to consider under budget constraints (Johnson-Masotti & Eva, 2005). External pressure from patients, public and media, drive the requirement for more transparency. Johnson-Masotti and Eva (2005) proposed and tested a method for prioritizing health technologies based on a standard set of 11 criteria. They developed consensus on these criteria through key informant interviews and a focus group. Participants from 35 RHAs provided criteria surveys, from which relative weights could be calculated based on relative importance of each criterion. The results indicated that prioritization processes at RHAs vary from having no formal procedures in place at all to having strict guidelines on detailed aspects. While a number of RHAs merely base their prioritization decisions on health technology proposals alone and/or wish lists from physicians, others utilize elaborate processes with binding rules and guidelines both with respect to the committee's mandate and regarding health technology proposals (Johnson-Masotti & Eva, 2005).

The health technology prioritization tool presented in the Johnson-Masotti and Eva (2005) study cannot replace any existing processes of prioritization, but can supplement existing procedures with the aim to help local, provincial, and federal decision-makers make informed decisions. According to Johnson-Masotti and Eva (2005), by using the tool stakeholders can organize thought processes with regards to using explicit criteria to evaluate health technologies and can consider all important factors in a systematic and comprehensive fashion. Moreover, the scores of individual health technologies can provide concise summaries of the value of health technologies, which in turn can be used to guide the decision-making process (Johnson-Masotti & Eva, 2005).

Surgical practice, by nature, is full of important decision-making scenarios (Kucey, 1999). According to Kucey (1999), surgeons have begun to utilize the decision sciences as a methodology of approaching clinically relevant surgical problems. Uncertainty arises from many sources and in most circumstances surgeons formulate answers to clinical problems by utilizing the store of knowledge and clinical experience they have accumulated over time (Kucey, 1999). For instance, if uncertainty regarding the decision problem remains, a surgeon may seek the experience of senior colleagues or the published experience of peers at other centers. In recent years, surgeons have begun to turn to statistical methodologies to assist in this decision-making process (Kucey, 1999). Although decision analysis does not provide definitive answers for all

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clinical scenarios, it is an important tool and one about which all surgeons should have some basic knowledge (Kucey, 1999).

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## **4.0 CONCLUDING SUMMARY**

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In an era of budget constraints, decision-makers are often forced to make timely decisions regarding the adoption and utilization of new technologies, sometimes even before there is definitive evidence regarding their clinical efficacy and economic merit. Thus, hospitals have to develop their individual set of decision criteria for strategic technology planning with respect to their particular environment (Greenberg, Peterburg, Vekstein, & Pliskin, 2005). Evidence, such as that provided by HTA, provides decision-makers with information on the likely impact that new technologies may have on our ability to prevent, treat, and manage disease.

Throughout the module it has been emphasized that although access to high-quality evidence is necessary, it is not a sufficient condition to integrate technologies into the health-care system effectively. Instead, the successful use of evidence depends, in large part, on the decision-making process (Coburn, 2005; OECD, 2005). Moreover, the health-care system itself can support (or impede) evidence-based decision-making. Many significant challenges remain in establishing a policy environment that sets the conditions to deliver the most effective and efficient technology to the right patients at the right time. Challenges remain around the need for greater convergence between health priorities and innovation (Coburn, 2005). The institutional, organizational, political and cultural dynamics of the health-care system all contribute to the policy maker's ability to integrate health-care technologies successfully (OECD, 2005).

The analysis from the OECD (2005) report demonstrated that many OECD countries are employing HTA to deliver information to policy and decision-makers to enable them to make more informed choices. However, with the additional investment comes a growing recognition that the practical use of HTA in policy and practice is paramount in determining whether HTA has been successful or not. More countries are placing greater emphasis on ensuring that the evidence from HTA (or other sources) is considered in the decision-making process. In addition, a number of countries have established national or regional institutes to coordinate and prioritize activities as well as improve dissemination of assessments (OECD, 2005). There is an impetus to come to a better understanding of the decision-making processes; for instance, how such processes can incorporate evidence, as well as deal with issues of social justice and ethics. More evidence on the partnership between decision-making and HTA, as well as the effect that health-care policy tools have in facilitating (or impeding) the use of HTA, would be useful (OECD, 2005).



**4.1 REVIEW OF MODULE OBJECTIVES**

At the end of this sixth workshop HTA and decision-making module, participants should be able to:

- (1) Discuss the importance of HTA in healthcare decision-making.
- (2) Describe the process of how decisions are made and discriminate between concepts such as decision analysis and economic evaluation.
- (3) Identify the barriers to implementing HTA to policy.
- (4) Explain how HTA bridges the gap between research and policy.

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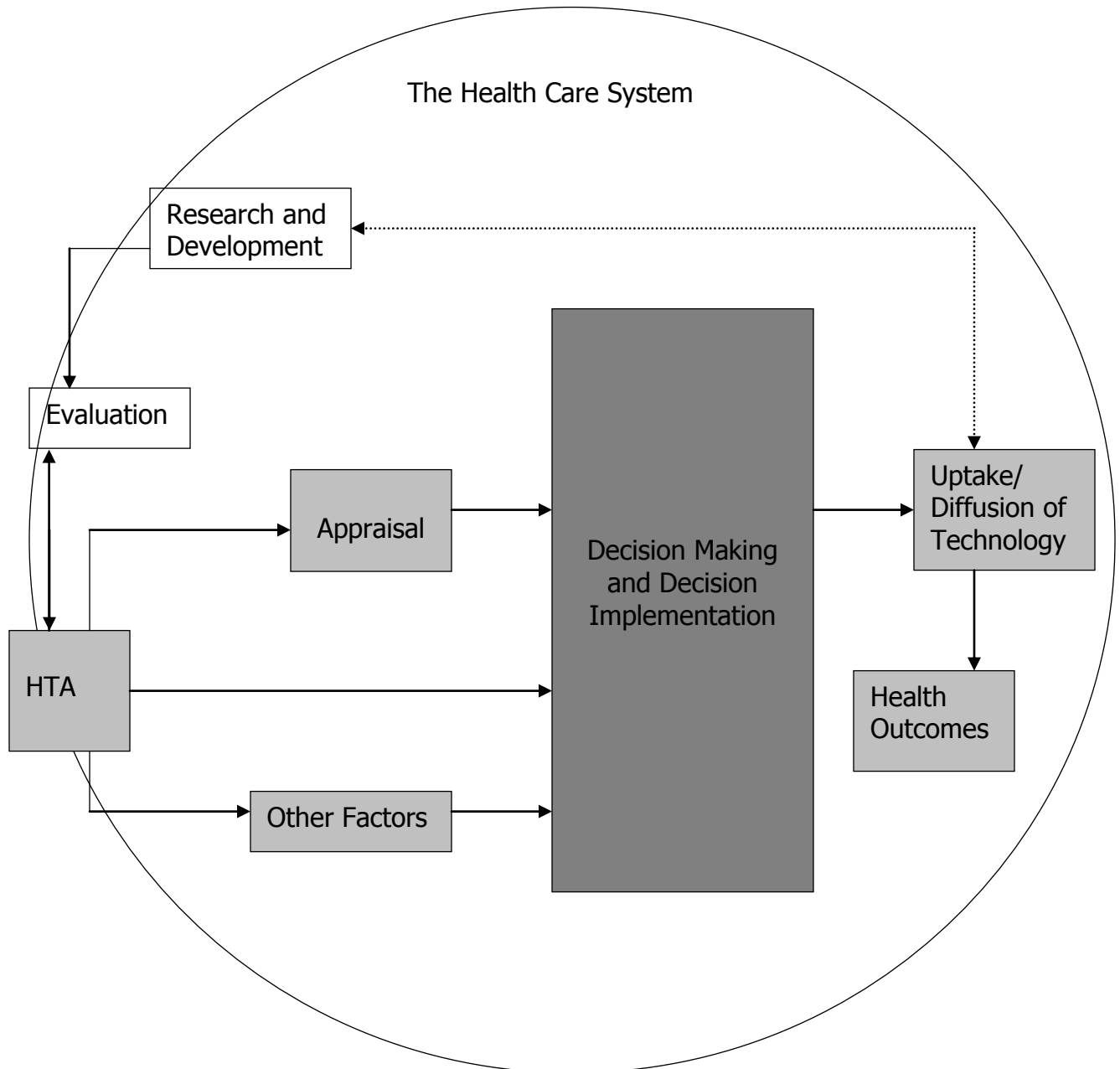
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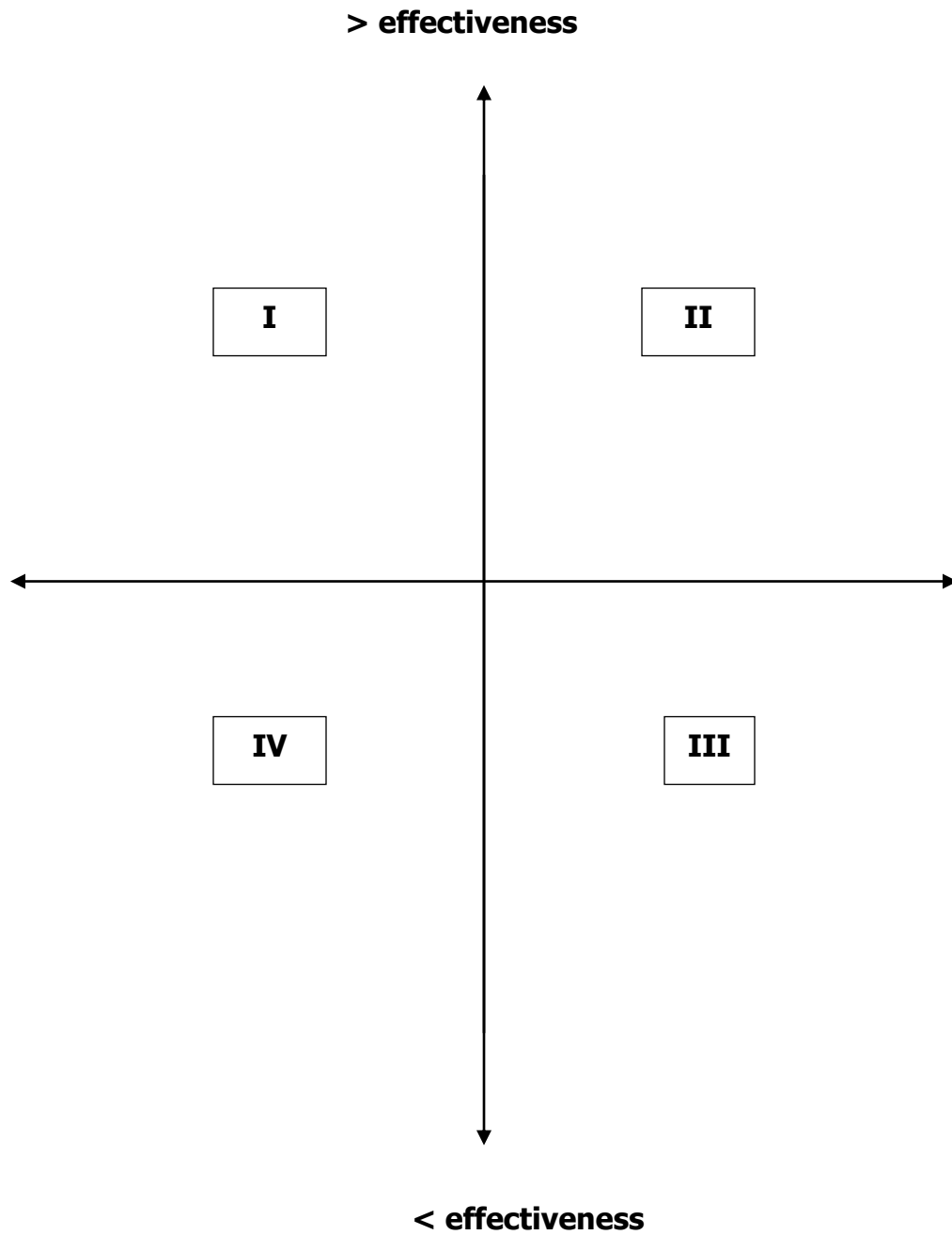
## 6.0 APPENDICES

### 6.1 APPENDIX A: OUTLINE OF HTA, DECISION-MAKING AND IMPLEMENTATION

(Taken from OECD, 2005).



6.2 APPENDIX B: THE COST-EFFECTIVENESS PLANE



Taken from OECD (2005), p.41



## 6.3 APPENDIX C: HTA SURGICAL EXAMPLE – SRS SERVICES

*AHFMR (Alberta Heritage Foundation for Medical Research)*

### Information Paper

**Review of the published evidence or focus on methodological or policy or administration issues/concerns: 3 to 6 months, external review optional**

#### Purpose:

- Provide economic information to decision makers in Alberta Health and Wellness about the treatment alternatives for neurosurgical patients requiring stereotactic radiosurgery (SRS)
- Question – *What is the most cost-effective way to offer SRS services to those neurosurgical patients in Alberta who are appropriate for this procedure?*
- Provide cost estimates for 3 main SRS technologies:
  - 1) GammaKnife (GK)
  - 2) CyberKnife (CK)
  - 3) LINAC (Novalis®)
- The Tom Baker Cancer Centre in Calgary
  - has 1 modified linear accelerator (LINAC) unit that is used to treat some malignant neurosurgical patients
  - does not have any extra capacity to be modified for the treatment of selected patients with non-malignant tumours/conditions
  - interested in establishing a dedicated SRS unit operated with a highly qualified team
- Another treatment option for patients requiring SRS to treat non-malignant tumours would be to send these patients to SRS units available out of province (traditionally, US, Europe, LINAC units in eastern Canada)
- Focus of this report is:
  - the utilization of SRS in the treatment of patients with tumours or conditions in the head or neck area
  - cost minimization analysis (CMA) for the comparison of the costs of alternatives; assumes the effectiveness of the assessed technologies is the same

**Description of the Technology:**

- SRS
  - has been in clinical use for about 3 decades
  - is non-invasive and uses a radiation technique to remove lesions within the brain
  - mainly used for small brain lesions
  - the tumour is specifically targeted for radiation while sparing surrounding healthy tissue
  - patients are treated during a single session in an outpatient clinic
  
- 3 kinds of technology available for SRS treatments:
  - 1) Leksell Gamma Knife
    - One of the two most commonly used SRS technologies
    - Uses a total of 201 cobalt-60 sources arranged in a hemispherical pattern and embedded within the shielded, dome-shaped radiation unit
    - The basic system includes the radiation unit with the patient couch and collimator helmet, the control panel, and auxiliary systems
  
  - 2) Modified linear accelerator
    - Novalis<sup>®</sup> is an example of a commercially available system of this type of equipment
    - The conventional LINAC produces photons from a single point by rotated arcs or sets of arcs
    - The radiation beam is directed at the target lesion for the entire treatment time but passes through other parts of the brain momentarily
    - Prior to treatment, the head of the patient is immobilized by a frame
    - By increasing the dose rate, reducing the machine weight, and targeting the beam, LINACs for SRS treatment are more accurate than conventional LINACs
  
  - 3) CyberKnife
    - A small LINAC that is moved around the target lesion by robotic technology
    - During the CK procedure, the patient's head is kept immobile
    - CK unit includes a video location system that can be used to locate the target point based on the patient's facial features

**Accuracy and Effectiveness of SRS:**

- Accuracy of these 3 SRS technologies is difficult to compare
  - GK has the highest accuracy since there's no movement of the radiation source and LINAC moves during treatment
  - Spatial accuracy of the radiation device is only one aspect of accuracy
    - Imaging, target choice, dose calculation, and setup may be more important
  - In this report there are no good studies comparing the clinical accuracy and its significance among these 3 SRS technologies
  
- Canadian reviews have conclude that there is no evidence that the effectiveness of the GK and LINAC technologies would differ significantly from each other and from conventional microsurgery
  - But these conclusions are not based on RCTs
  - There's still no evidence that any one form of SRS is superior over another
  - SRS using robotic technology (the CK) is now available and enables treatment in any part of the body
  - There's a need to go beyond a cost analysis to the economic evaluation of SRS technologies, taking appropriate account of local circumstances
  - It's essential to have quality assurance and ensure the SRS unit is located in a specialized centre
  - There are no randomized controlled trials on the cost-effectiveness of SRS technologies

**Methodology:**

- The costs are presented as an average cost per patient
- Costs for SRS technologies are divided into direct medical costs and patient
- Direct medical costs include costs for the equipment and construction of the facility, monthly salary of the staff, supplies, and equipment maintenance
- All medical costs are assumed to be fixed
- The SRS related variable costs are assumed to be insignificant since most patients do not require hospitalization after SRS
- Diagnostic tests (MRI and CT images), post-SRS treatments (whole brain radiation, medication), and follow-up procedures are assumed to be similar for all SRS technologies, and the conventional microsurgery alternative
- So costs for any of these services are not included in the model
- Patient-borne costs included are ... i.e., hotel costs during the visit at the SRS centre, lost working time due to the procedure, and the costs of the caregiver required to accompany the patient during SRS visit

### **Patient Group:**

- It is assumed that these technologies are mainly used for patients requiring neurosurgery
- Patients with tumours in the head or neck areas
- The estimated numbers of the potential patients for SRS treatment came from preliminary projections by two groups of Albertan physicians (Calgary and Edmonton)
- Calgary physicians estimated that 185 new cases per year from Alberta and 63 new cases per year from British Columbia (based on 25% estimate of BC population) would benefit from dedicated SRS services
- Edmonton physicians estimated that 130 to 150 patients per year would qualify for SRS according to clinical presentation
- Since it is assumed that an SRS unit would be dedicated to SRS alone with its own full time staff complement, the cost model does not make any provision for patient loads less than 100 per year since at lower volumes the service of this team of experts would not be appropriately utilized

### **Cost Model:**

- The basic construction of this model is adopted from the model developed by Koningsmaier et al (1998) but has been modified to correspond to the Alberta health care system

### **Fixed Costs:**

- These costs don't vary with the number of patients treated per time period
- Of course, a substantial increase in the volume of patients may increase some of these costs (e.g., need for overtime)
  - *Construction costs*
    - Estimated changeover to an SRS unit is estimated to cost:
      - \$150,000 for renovation and millwork for Novalis<sup>®</sup>
      - \$550,000 for CK
      - \$1 million for GK
  - *Equipment investment costs*
    - It's difficult to obtain exact values for investment costs for SRS equipment since each centre negotiates different terms with the various manufacturers
      - Investment cost estimates for Novalis<sup>®</sup> and CK are a bit uncertain since the equipment has been available on the market for only a short time
      - Novalis<sup>®</sup> is \$4.32 million
      - CK is estimated to be \$4.5 million

- GK is estimated at \$5.5 million
- Duration of life for both CK and Novalis<sup>®</sup> is estimated to be 10 years and for GK 15 years (sometimes to 20 years)
  - GK also requires a replacement of the cobalt-60 radiation unit every 5 to 10 years
  - It's assumed that a replacement of the radiation unit is made twice (every 5 years) and the estimated replacement cost is \$956,000 plus \$200,000 for the cost of removing and disposing of the old sources
- *Maintenance costs*
  - All 3 types of SRS require maintenance
  - GK does not have moving components so the maintenance is mainly covered in a service contract (estimated at \$138,700)
  - The same service contract estimate has been used in CK and Novalis<sup>®</sup> technologies
  - In addition to the service contract, CK and Novalis<sup>®</sup> require technical maintenance
    - CK maintenance cost = \$176,974
    - Novalis<sup>®</sup> = \$73,400 per year
- *Supply costs*
  - The basic supplies used by each technology are about the same
    - Cost for dosimetry, nursing support, hardware cost, and intra-venous contrast is estimated to be \$109,570
    - Cost for cleaning is \$13,500 for each alternative
    - Cost of electricity and water is \$2,500 for both GK and CK and \$10,300 for Novalis<sup>®</sup>
    - GK requires a radiation test that is conducted 4 times per year = \$17,800
    - Novalis<sup>®</sup> and CK require only 1 radiation test per year at a cost of \$4,450
- *Staff costs*
  - These estimates are fixed during a given time since they are dedicated to the SRS unit on a full time basis
  - GK can be run with less staff than the CK and Novalis<sup>®</sup> units because GK cannot be used for purposes other than neurosurgical services
  - The influence of staffing requirements on the costs has been varied in the sensitivity analysis
  - For low patient volumes (100 – 150 patients) the neurosurgeons do not need to use all of their working time for SRS patients
  - Need 1 receptionist at \$33,000 per year for all 3 technologies

## MODULE 6: Influencing Decision- and Policy-Making Using HTA

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- Need 1 clerk III clerical support person per year (\$36,000) for CK and Novalis<sup>®</sup>, while only 1/2 for GK
- Need 1 nurse clinician for each at \$76,358 per year
- Need 2 Radiology technicians for CK and Novalis<sup>®</sup>, versus only 1 for GK at \$69,000 per year
- Need 1/2 time of Radiation oncologist for all 3 at \$150,000 per year
- Need 1/2 to 1 full time neurosurgeon position for each at \$300,000 per year
- Need 1 Medical physicist for CK vs. 1/2 time for Novalis<sup>®</sup> and GK at \$85,000 per year

### **Variable Costs:**

- SRS procedures will mainly be done on an outpatient basis and the staff is on salary, so there are no significant variable cost factors in these calculations
- Cost of complications (e.g., hemorrhage) related to SRS is hard to estimate and it's likely variation in these costs may not be significant among the technologies
  - *Patient costs/Indirect costs*
    - Include: lost working time due to treatment, travel costs, and hotel costs
    - SRS procedure is planned to take place during a 1 day outpatient visit
    - Patients have a small risk for complications after the procedure and are usually required to stay in a hotel overnight after that procedure
    - For safety reasons, patients need a companion caregiver
    - Significant proportion of patients who require SRS and their caregivers do not work and so they don't incur lost production costs due to sickness
    - Hotel costs for out of region patients and caregivers are assumed to be \$150 per day (double room) and are assumed to arrive a day prior to the procedure
  - *Cost of microsurgery*
    - This is complicated by the fact that SRS is used to treat several different types of diseases and no single cost estimate for conventional surgery can be calculated

**Results:**

- Basic cost models for all 3 SRS modalities are shown in the following tables

**Table 2: Novalis<sup>®</sup> average costs per patient**

Number of patients/year	Investment costs (\$)	Maintenance costs (\$)	Staff costs (\$)	Average cost*/patient/year (\$)
100	5,701	3,500	7,009 (5,509)	16,210 (14,710)
115	4,957	3,044	6,094 (4,790)	14,095 (12,791)
130	4,385	2,692	5,391 (4,237)	12,469 (11,315)
150	3,801	2,333	4,672 (3,672)	10,807 (9,807)
175	3,258	2,000	4,005 (3,148)	9,263 (8,406)
200	2,851	1,750	3,504 (2,754)	8,105 (7,355)
225	2,534	1,556	3,115	7,204
250	2,280	1,400	2,803	6,484
275	2,073	1,273	2,549	5,894

\* Staff cost including 0.5 FTE neurosurgeon on the patient volumes between 100 and 200 per year in parenthesis

**Table 3: Gamma knife average costs per patient**

Number of patients/year	Investment costs (\$)	Maintenance costs (\$)	Staff costs (\$)	Average cost*/patient/year (\$)
100	6,008	4,709	6,139 (4,639)	16,856 (15,356)
115	5,225	4,095	5,338 (4,034)	14,657 (13,353)
130	4,622	3,622	4,722 (3,568)	12,966 (11,812)
150	4,006	3,139	4,092 (3,092)	11,237 (10,237)
175	3,433	2,691	3,508 (2,651)	9,632 (8,775)
200	3,004	2,354	3,069 (2,319)	8,428 (7,678)
225	2,670	2,093	2,728	7,491
250	2,403	1,884	2,455	6,742
275	2,185	1,712	2,232	6,129

\* Staff cost including 0.5 FTE neurosurgeon on the patient volumes between 100 and 200 per year in parenthesis

**Table 4: CyberKnife average costs per patient**

Number of patients/year	Investment costs (\$)	Maintenance costs (\$)	Staff costs (\$)	Average cost*/ patient/year (\$)
100	6,218	4,536	7,434 (5,934)	18,187 (16,687)
115	5,407	3,944	6,464 (5,160)	15,815 (14,511)
130	4,783	3,489	5,718 (4,564)	13,990 (12,836)
150	4,145	3,024	4,956 (3,956)	12,125 (11,125)
175	3,553	2,592	4,248 (3,391)	10,393 (9,536)
200	3,109	2,268	3,717 (2,967)	9,094 (8,344)
225	2,764	2,016	3,304	8,803
250	2,487	1,814	2,973	7,275
275	2,261	1,649	2,703	6,614

\* Staff cost including 0.5 FTE neurosurgeon on the patient volumes between 100 and 200 per year in parenthesis

**Table 5: Distribution (%) of costs for each SRS modality**

Equipment	Investment (%)	Maintenance (%)	Staff (%)
Novalis®	35.2	21.6	43.2
GK	35.7	27.9	36.4
CK	34.2	24.9	40.9

- When comparing total health costs per year, at the lowest assumed volume of procedures (100 patients per year), from least to most costly:
  - Novalis® (\$16,210 per patient)
  - GK (\$16,856 per patient)
  - CK (\$18,187 per patient)
- At a workload of 200 patients per year, the costs per patient were:
  - Novalis® (\$8,105 per patient)
  - GK (\$8,428 per patient)
  - CK (\$9,094 per patient)
- Cost differences, especially those between Novalis® and GK technologies are relatively small
- CK is always the most expensive alternative



**Discussion:**

- The main objective was to study the cost implications of different SRS technologies in Alberta
- The results depend on the projected number of patients receiving SRS services per year
- The cost estimations assume that there is no significant difference in the number of short and long-term complications to patients after treatment among the SRS technologies themselves and between SRS and microsurgery
- In the cost analysis, it was not possible to estimate the influence of differences in the severity and/or location of the treated lesions between the SRS and microsurgery alternatives
- Since there are no randomized controlled trials on this topic, it is not possible to adjust the cost (and cost-effectiveness) analysis results to include these clinical differences in the treated patient groups

**Conclusions:**

- This study shows that there is no significant difference between the costs of dedicated GK and Novalis<sup>®</sup> units in Alberta
- A CK unit seems to be significantly more expensive than the other two alternatives
- From a patient's perspective, the SRS technology, where appropriate, is about 1/6 of the cost of microsurgery
- From a societal perspective, the Novalis<sup>®</sup> and GK would be cost saving even at a level of 100 patients per year
  - But at that operational level, health care resources would not be efficiently used due to excess capacity of the SRS team and of equipment
- If the case load and case mix are not seen to be sufficient to make the SRS business case economically sustainable, the province should consider other sustainable alternatives for these patients

Ohinmaa, A. (2003). *Cost estimation of stereotactic radiosurgery: Application to Alberta*. Information Paper: IP14.