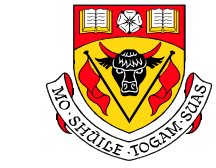
Putting HTA into Practice

MODULE 1v3
BACKGROUND TO HEALTH TECHNOLOGY ASSESSMENT

Revised: August 2012

Surgery Strategic Clinical Network: Evidence Decision Support Program



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Alberta Health Services

WELCOME

Welcome to "Module 1v3: Background to Health Technology Assessment," which is the first part of an educational series entitled "Putting HTA into Practice." This module is an up-dated version of a previously developed education module (1) in 2005, which was one of a six-part series on Health Technology Assessment (HTA).

The original 2005 Health Technology Assessment Modules were prepared for the **Department of Surgery** by **Elizabeth Oddone Paolucci, PhD,** Medical Education & Research Unit, Educational Consultant; **Tyrone Donnon, PhD,** Medical Education & Research Unit, Assistant Professor, Faculty of Medicine; **Paule Poulin, PhD,** Associate Director, Office of Surgical Research, Calgary Health Region. (1), with funding provided by the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) now known as the Canadian Agency for Drugs and Technologies in Health (CADTH).

The purpose of this revision is to provide a background to HTA and the HTA framework in Alberta for those undergoing workshops on "Putting HTA into Practice" — a training program for putting HTA Into Practice available for Clinical Networks and other Operation Leaders within Alberta Health Services.

This module describes HTA terminology, the principles and purpose of HTA, examples of HTA producers and users, the HTA framework in Alberta, and some of the limitations and challenges when integrating HTA into practice.

Your feedback and comments on both the module and training workshops will be greatly appreciated! Please send comments to paule.poulin@albertahealthservices.ca.

August 2012

CONFLICT OF INTEREST

Conflict of interest is considered to be financial interest or non-financial interest, either direct or indirect, that would affect the research contained in a given report, or creation of a situation where a person's judgment could be unduly influenced by a secondary interest such as personal advancement. Indirect interest may involve payment which benefits a department for which a member is responsible, but which is not received by the member personally, e.g. fellowships, grants or contracts from industry, industry sponsorship of a post or a member of staff in the department, industry commissioning of work.

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

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1.0 OBJECTIVES

The primary goals of this Module are:

1. To present an overview of Health Technology Assessment (HTA) including terminology, principles and purposes of HTA, examples of HTA producers and users particularly in Alberta, and
2. To explore how HTA can be applied to inform decisions in our local environment.

By the end of this Module, readers will be able to:

1. Define HTA using related descriptions and terminology,
2. Understand the rationale for HTA,
3. Identify and distinguish between HTA producers and HTA users, and
4. Describe the HTA user framework in Alberta.

2.0 INTRODUCTION & TERMINOLOGY

The proliferation of new and sometimes expensive technologies has created a need for patients, health care workers, and policy makers to be more informed and accountable about the decisions they make surrounding health care technologies. When a new technology is introduced, people typically question:

- whether it has been adequately tested for safety and efficacy,
- how the new technology compares to existing technologies in current practice, and
- how cost-effective (or costly) the new technology is (2).

These questions reflect the practical realities of constrained healthcare spending. Thus, HTA has become an essential tool for understanding the potential costs, benefits, and side-effects that new technologies offer (3). While once only the domain of government agencies and policy makers, HTA is now the business of healthcare professionals at every level (4):

- Purchasers seek accountability and value for the money they spend for health care services,
- Health plans need information to guide their coverage of procedures and services,
- Public policymakers need to know about the effectiveness and efficiency of health care technology to make informed coverage decisions and set sound regulations, and
- Physicians need to know which technology is most effective for their patients, recognizing that they should be prudent with resources but responsive to their patients (5).

In Canada, various government and academic agencies have developed a strong capability for producing HTA reports (6), often at the request of decision makers. However, for an HTA report to have an impact, evidence must be translated into information that is useful for physicians and decision makers (5,7). As well, decision makers must evaluate whether a technology is appropriate for their local environment — whereas HTA helps to improve the quality of health services by evaluating the technology itself, other factors such as local population needs, local effectiveness, and local resources also need to be considered in a systematic manner. Therefore, there has to be a well defined "HTA Receptor Framework" to integrate HTA information provided in reports with local decision making by examining the local environment in which a technology will be used.

In 1997, the Department of Surgery & Surgical Services within the Calgary Health Region recognized the need to have such an "HTA Receptor Framework" — a standardized, fair, and systematic process for evaluating requests for new technologies from its members that considers both HTA reports and the local environment. The Department created an "Introduction of New Technology" form and process that were designed to gather sufficient information to make clinical, needs, impact, technical, and cost assessments on the new technology. From 1997 through to 2005, this "Local HTA Decision Support Program," as it came to be known, was used to review technologies requested by surgeons.

In 2005, a series of HTA educational modules were created and delivered to health practitioners, managers, purchasing specialists, and administrators in the Department of Surgery & Surgical Services (8). Outcomes of this educational program were recognition of the value of the Local HTA Decision Support Program and a desire to see it adopted by other departments. Between 2005 and 2009, the Local HTA Decision Support Program in the Department of Surgery & Surgical Services underwent four cycles of evaluation and revision in cooperation with seven other departments in the Calgary Health Region (9-12). The latest revision of the Local HTA Decision Support Program (January 2009) is now being adapted for use by Strategic and Operational Clinical Network Health Technology Assessment and Innovation (HTAI) Committees within Alberta Health Services (AHS).

The purpose of this Module is to provide a background to HTA and the HTA framework in Alberta for those undergoing workshops on "Putting HTA into Practice" — a training program for Strategic and Operational Clinical Network HTAI Committees within AHS.

To begin, it is important to clearly define measurable health outcomes and the various terms surrounding health and health technology.

2.1 What is Health Technology?

The International Network of Agencies for Health Technology Assessment defines health care technology as prevention and rehabilitation, vaccines, pharmaceuticals and devices, medical and surgical procedures, and the systems within which health is protected and maintained. In the operational context of AHS, health technology spans the entire continuum of health care from health promotion to end-of-life care. Pharmaceuticals are the purview of the Pharmacy and Therapeutics initiative at AHS, although pharmaceuticals maybe considered by HTA Committees if they are considered part of a larger care management program in which the opportunity for tradeoff or complementarity must be considered. Health information systems may be treated likewise - if they are an integral part of the care process, then they may be considered.

Technologies can also be grouped according to their health care purpose:

- ***prevention*** (intended to protect against disease by preventing it from occurring, reducing the risk of its occurrence, or limiting its extent or sequelae; e.g., immunization),
- ***screening*** (intended to detect a disease, abnormality, or associated risk factors in asymptomatic people; e.g., Pap smear),
- ***diagnosis*** (intended to identify the cause and nature or extent of disease in a person with clinical signs or symptoms; e.g., electrocardiogram),
- ***treatment*** (designed to improve or maintain health status, avoid further deterioration, or provide palliation; e.g., drugs for cancer pain), or
- ***rehabilitation*** (intended to restore, maintain or improve a physically or mentally disabled person's function and well-being; e.g., incontinence aid) (13).

2.2 What is Health Technology Assessment?

Multiple definitions of Health Technology Assessment (HTA) exist, thereby making it difficult to present one clear and comprehensive definition. Some define HTA by its methods, some treat it as research, and others focus on whatever it is that those who assess technologies do (14). The International Network of Agencies for Health Technology Assessment defines HTA as the systematic evaluation of properties, effects, and/or impacts of health care technology. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its main purpose is to inform technology-related policy decisions in health care. HTA is conducted by interdisciplinary groups using explicit analytical frameworks drawn from a variety of methods. HTA can be context-sensitive or context-free. Context-free HTA is generic in its approach and may or may not be applicable to all social environments, whereas context-sensitive HTA customizes the findings of HTA to take into account local conditions and factors that would have a significant impact on the performance of the technology.

2.3 What is Health Technology Appraisal?

Health technology appraisal builds on a HTA, and rather than providing a set of findings based on the best evidence available, it makes implementation recommendations based on clinical and economic evidence on the use and cost-effectiveness of new and existing licensed technologies within the local context. Appraisal asks whether AHS should implement the health care technology and whether AHS can afford it. The appraisal process solicits input from a wide range of stakeholders such as health care policy makers, patient care groups, care provider groups, and manufacturers for example.

2.4 What is Health Technology Management?

Health Technology Management is the due diligence conducted to ensure that the development of specifications, process of procurement, and selection of technology is done to the best of international standards of business practice. Health Technology Management processes must be integrated and coordinated with HTA activities.

2.5 What is Quality Assurance?

Quality Assurance ensures that the best available knowledge concerning the use of health care to improve health outcomes is properly used. It involves the implementation of health care standards, including activities to correct, reduce variations in, or otherwise improve health care practices relative to these standards. Quality assurance involves a measurement and monitoring function, quality assessment. Quality assessment is, primarily, a means for determining how well health care is delivered in comparison with applicable standards or acceptable bounds of care.

A comparison of these four terms, HTA, Health Technology Appraisal, Health Technology Management and Quality Assurance is shown in Table 1.

Table 1. Comparison of Terms

Health Technology Assessment *Are we doing the right thing?*	**Health Technology Appraisal** *Should we be doing this?*	**Health Technology Management** *How do we do the right thing?*	**Quality Assurance** *Are we implementing correctly?*
• Clinical effectiveness • Cost effectiveness • Safety	• Appropriateness • Affordability • Post-implementation evaluation	• Specification • RFP • Procurement • Selection • Commissioning	• Implementation program • Monitoring

2.6 What is Innovation?

Whereas HTA has traditionally been associated with being a gatekeeper in the health system – ensuring the use of high quality evidence to inform decisions about adoption of new technologies and keeping technologies that are not effective (clinically or cost) from diffusing inappropriately – it is not to be overshadowed by the opportunities that are offered by supporting and introducing innovations that will improve the sustainability of the health care system for Albertans. Innovation is the ability to change the conditions in a care setting to improve the achievement of intended results (effectiveness) or the ability to deliver them (efficiency). Innovation can involve a new technology used to improve access, quality, and sustainability or it could use a well-established technology in a new way. Innovation is often equated with an invention plus an enabling social condition. To be effective, innovation should be managed to achieve the goals of an organization.

The concept of Innovation can also be considered as a pathway with at least three key stages:

1. *Invention* (identification) – where new ideas are generated. Increasingly it is recognized that this invention stage works best when responding to the identification of unmet needs.
2. *Testing and Piloting* – seeing how ideas work in practice and learning from this. This phase is inherently different for different types of innovations, e.g. drugs require large multi-phase trials, devices require smaller iterative trials, and service improvements may be best introduced with rapid Plan-Do-Study-Act cycles if small scale or in pilots if larger scale.
3. *Adoption and Diffusion* – process whereby new ideas that have been proven elsewhere are ideally pulled into new areas with appropriate adaptation.

2.7 What is Access with Evidence Development?

Healthcare payers are entering into "innovative reimbursement agreements" to manage interim or conditional funding for new but expensive treatments and to obtain value (measured in terms of clinical effectiveness, improved quality of care, health-related quality of life etc.) for money. These reimbursement mechanisms have been given many

names, including "field evaluations", "risk sharing", "coverage with evidence development" and "health impact guarantees". In Alberta, the umbrella term "Access with Evidence Development (AED)" is used (15). AED has also been defined as "the general approach of linking some form of access to the healthcare market with the generation of additional evidence relating to the value of the healthcare intervention under evaluation, with an explicit aim of aiding future decision making" (16).

2.8 What is Clinical Safety?

Clinical safety is a judgment of the probability of an adverse outcome and its severity (i.e., risk), associated with using a technology in a particular situation (13).

2.9 What are Efficacy and Effectiveness?

Efficacy and effectiveness are terms used to refer to how well a technology works to improve patient health as measured by relevant health outcomes. However, from a HTA perspective, a subtle but important distinction exists between these terms.

- ***Efficacy*** refers to the benefit of using a technology for a particular problem ***under ideal conditions***, such as within the protocol of a carefully managed ***randomized controlled trial***, involving patients meeting narrowly defined criteria, and/or conducted at a "center of excellence"; In contrast,
- ***Effectiveness*** refers to the benefit of using a technology for a particular problem ***under general or routine conditions***, such as by a physician in a community hospital for various types of patients (13).

2.10 What is Outcomes Research?

In practice, outcomes research has been used interchangeably with the term effectiveness research. It refers to the investigation of the health benefits associated with using a technology for a particular problem, under general or routine conditions. For example, outcomes research includes the use of:

- epidemiological studies and administrative data sets,
- varying practice patterns and their relationship to patient outcomes, and
- examining patient roles in clinical decision-making.

The increasing attention given to outcomes research reflects the greater demand for data on patient and provider experiences with technologies beyond what can be learned from the limited number of carefully circumscribed trials (13).

2.11 What is Horizon Scanning?

Horizon scanning is a new area of research that identifies new and emerging techniques and technologies before their widespread publication. In health care, the early detection of new technologies can be of considerable value:

- in the development of clinical guidance,
- consideration of cost, and

- evaluation of safety and efficacy.

The information is used to provide regular updates to surgeons, government, and healthcare providers or funders on where the next advances are likely to occur in surgical care (7).

3.0 PRINCIPLES AND PURPOSES OF HTA

This section introduces the principles of health technology assessment (HTA) and its place in healthcare decision making. It describes a journey from the regulation of technologies, through the mechanisms underpinning the evidence based approach for their funding and adoption by healthcare systems to the influence of HTA on the continued development of new technologies, i.e., innovation.

3.1 Principles of HTA

To be most effective, HTA should empower the health care system, including physicians and patients in making objective, unbiased informed decisions. In addition, the application of HTA requirements must not stymie the innovation of breakthrough technologies (17). Assessments should be made at the right time. Premature assessment of a new technology can lead to unnecessary and extensive delays in access to important new treatment options. HTA organizations should establish open procedures that allow all stakeholders to participate in the assessment process. This transparency and accountability will ensure that all relevant information from patients, physicians, and manufacturers is being considered (17). It is important that the advice that emanates from HTA be accurate, relevant, timely, clear, and accessible. Accuracy must always be dependent on available knowledge and, therefore subject to constant re-assessment (18).

3.2 Purposes of HTA

HTA can be used in many ways to advise or inform technology-related policymaking. Among these are to advise or inform (19):

- Regulatory agencies such as Health Canada or the US Food and Drug Administration (FDA) about whether to permit the commercial use (e.g., marketing) of a drug, device or other technology
- Health care payers, providers, and employers about whether technologies should be included in health benefits plans or disease management programs, addressing coverage (whether or not to pay) and reimbursement (how much to pay)
- Clinicians and patients about the appropriate use of health care interventions for a particular patient's clinical needs and circumstances
- Health professional associations about the role of a technology in clinical protocols or practice guidelines
- Hospitals, health care networks, group purchasing organizations, and other health care organizations about decisions regarding technology acquisition and management
- Standards-setting organizations for health technology and health care delivery regarding the manufacture, use, quality of care, and other aspects of health care technologies

- Government health department officials about undertaking public health programs (e.g., vaccination, screening, and environmental protection programs)
- Lawmakers and other political leaders about policies concerning technological innovation, research and development, regulation, payment and delivery of health care
- Health care product companies about product development and marketing decisions Investors and companies concerning venture capital funding, acquisitions and divestitures, and other transactions concerning health care product and service companies

3.3 Timing of HTA

Technologies may be assessed at different stages of diffusion and maturity, and while there may be no single correct time, there are tradeoffs inherent in decisions to conduct a HTA. On one hand, the earlier a technology is assessed, the more likely its diffusion can be curtailed if it is unsafe of ineffective. On the other hand, to regard the findings of an early assessment as definitive or final may be misleading (13). An investigational technology may not yet be perfected; its users may not yet be proficient; its costs may not yet have stabilized; it may not have been applied in enough circumstances to recognize its potential benefits; and its long-term outcomes may not yet be known. Further, the "moving target problem" can complicate HTA. By the time a HTA is conducted, reviewed and disseminated, its findings may be outdated by changes in a technology, in how it is used, or in its technological alternatives for a given problem (13). More and more HTA is considered to be an iterative process rather than a one-time analysis (13). Assessment should be an ongoing, even continuous, effort to ensure that the appropriate and most efficacious technology is used to provide care (5).

4.0 HTA PRODUCERS

Since the onset of the formal process of HTA in the mid 1970s, numerous HTA agencies (HTA producers) have been established in various countries (14). A more detailed discussion of the history of HTA is given in Appendix 8.1. Organizational structures for HTA vary from country to country, and in some countries, from region to region. Some countries have developed national-level agencies, while others have regional or provincial organizations. In general, HTA organizations are established in rough correspondence to administrative structures of health systems (14). Still, although the purposes, scope, and methods of health technology assessments that are conducted or sponsored by these organizations may vary widely, they do share a common impetus of improving the quality of healthcare.

HTA producers engage in a wide range of activities in addition to primary evaluations of defined techniques. Typically there are insufficient resources for the assessment of all unevaluated and novel technologies, so the first step often involves prioritizing the technologies to be assessed. After the assessment itself, HTA producers may or may not make specific recommendations about the adoption of the technology; however, actual approval of the technology for implementation usually resides at the local level within the specific health care provider infrastructure, hospital or health region (HTA users).

Appendix 8.2 presents a list of Canadian, surgery-specific, and international HTA producers that have been established over the last 30 years. Since websites are provided for each of these organizations, it is possible to further investigate the purpose, focus, and types of HTA processes they employ.

We will now examine at least one of each type of HTA producer at the national, provincial, and regional levels in Canada. However, before we focus on individual Canadian agencies, it is necessary to discuss the "glue" that keeps these organizations together in order that information, experiences, and expertise may be shared – the international societies.

4.1 International HTA Societies

In general, effective HTA organizations are likely to be those that are best able to ensure methodological rigour and use multidisciplinary inputs to produce and disseminate high quality policy-relevant research to decision-makers within the health system (14). The challenge of measuring the effectiveness of medical technology and improving its use through evidence honors no boundaries. Therefore, the sharing of valuable information, such as new approaches to assessment, with colleagues around the globe has the potential to reduce redundancy of effort and make better use of resources (5). The international HTA societies attempt to fill this role.

4.1.1 HTA International

In 1985, the International Society of Technology Assessment in Health Care was formed and served as an international forum for researchers and clinicians working for scientifically-based assessment of technologies in health care. It sponsored annual meetings and a peer-reviewed scientific journal, the *International Journal of Technology Assessment in Health Care* until 2002. In 2003, it was dissolved and replaced by HTA International (http://www.htai.org/).

4.1.2 EUnetHTA

An endeavor aimed at bringing together HTA organizations in Europe was achieved with the establishment of the European Network for Health Technology Assessment (EUnetHTA, http://www.eunethta.eu/Public/Home/). More recently, a joint action program has been proposed to develop a general strategy and a business model for sustainable European collaboration on HTA.

4.1.3 International Network of Agencies for Health Technology Assessment

The International Network of Agencies for Health Technology Assessment (INAHTA, http://www.inahta.org/) was established in 1993 with the mission to promote information sharing, to accelerate exchange and collaboration among HTA agencies, and to prevent unnecessary duplication of activities (13,14). The 41-member agencies from 21 countries of INAHTA are non-profit governmental organizations that assess technology in health care. The Network stretches from the USA, Canada and Latin America to Europe, Australia, and New Zealand. The Secretariat is located at SBU in Sweden. The network involves the member agencies in collaborative efforts of mutual interest and produces a range of publications.

(1) The Briefs serve as a forum for member agencies to present overviews of recently published reports. They are published regularly, placed on the INAHTA website, and are linked to the HTA Database and HTA Checklist when details are available.
(2) The Newsletter, which is produced in three languages, provides quarterly updates on recent reports, current initiatives and activities among member agencies, new projects within the Network, recent developments and trends in policy research, publications in the field, and upcoming events.
(3) Joint Projects involve member agencies in collaborative efforts to evaluate medical technologies of mutual interest.
(4) Synthesis Report (first and only one so far, published in 2000) is a meta-HTA report that summarizes and presents information published by a few INAHTA agencies on a particular research topic.
(5) Along with the UK member, Centre for Reviews and Dissemination, INAHTA also manages an HTA database that contains information on healthcare technology assessments.

4.2 A National Example: CADTH

The Canadian Agencies for Drugs and Technologies in Health (CADTH) is the only national HTA organization in Canada. It was formed in 1989 to assess medical devices, but

has evolved into a comprehensive source for evidence-based information on drugs, devices, health care systems, and best practices (http://www.cadth.ca/).

CADTH is funded by Canadian federal, provincial, and territorial governments. In addition to conducting drug reviews, it also provides HTAs, which evaluate the effectiveness, cost-effectiveness and impact of health technologies and their use, both on patient health and on the health care system.

CADTH has three main technology assessment programs.

(1) Health Technology Assessment. During the assessment, data from research studies and other scientific sources are systematically gathered, analyzed and interpreted. A written report then translates the scientific data and research results into information that is relevant to health policy decision makers. CADTH's HTA reports are extensively peer reviewed by leading experts from the scientific and medical communities, including clinicians, methodologists and economists. The final step in the HTA process is dissemination of the results to support and encourage informed, evidence-based decisions about health policy and purchasing, service management and clinical practice.

(2) Health Technology Inquiry Services (HTIS). HTIS responds to inquiries on the assessment of health care technologies including drugs, devices, diagnostic tests, and medical and surgical procedures. Information provided by the HTIS is tailored to meet the needs of decision makers, and takes into account the urgency and potential impact of the request. The HTIS can prepare a variety of products ranging from a reference list to a detailed assessment of the best evidence-based information on a topic The HTIS is available to Canadian health care decision makers in the federal government, provincial health ministries, Local Health Integration Networks, regional health authorities, hospitals, and national and federal health care programs in CADTH-area jurisdictions

(3) The Environmental Scanning Service alerts decision makers to new and emerging health technologies that are likely to have a significant impact on the delivery of health care in Canada. Environmental scanning also involves taking a more comprehensive look at the health care environment and maintaining a pulse on how evidence is being used to inform practice and policy decisions.
Through our active, ongoing literature scanning, we identify health technologies that are in the early development and adoption stages and those that may affect health care finances, facilities, operations, and patient care. Environmental scanning also involves establishing and maintaining networks with key health care stakeholders and scanning the environment to better understand not only what new technologies are on the horizon, but also how old technologies are being used. Environmental scanning also provides insight into research scanning here in Canada and elsewhere.
Our environmental scanning reports and information products help inform decision makers about emerging medical technologies, upcoming policies and practices, and research on the horizon. These products include:

- *Health Technology Update*– a newsletter published twice a year covering new and emerging health care technologies.
- *Issues in Emerging Health Technologies* – four- to eight-page bulletins indexed in PubMed (MEDLINE) and peer-reviewed and web-posted.
- *Environmental Scans* - short reports on current or emerging issues in health care technology.

4.3 A Provincial Example: Institute of Health Economics

The Institute of Health Economics (IHE) was established in 1980 under the Health Research Collaboration Agreement with Alberta Health and Wellness of the Government of Alberta and underwent a series of re-organization since then. It is a non-profit organization committed to producing, gathering, and disseminating health research findings from health economics, health policy, health technology assessment and comparative effectiveness to improve the delivery and sustainability of health care in Alberta. In 2006, the IHE took over the provincial health technology assessment function with the consolidation of the Institute's unit and the HTA unit from the Alberta Heritage Foundation for Medical Research.

The IHE's health technology assessment program (http://www.ihe.ca/research/health-technology-assessment/) produces the following:

(1) HTA Reports are subject to external review and consist of comprehensive appraisals of health technologies, providing a synthesis of data from the literature or reporting on empirical studies.
(2) Information Papers are publications providing information on health technology topics, and they do not involve assessments.
(3) STE Reports
(4) Rapid Assessments (Technotes and Qwiknotes) are not subject to external review and are brief responses to requests for rapid advice, with limited analysis.
(5) Books and Book Chapters

4.4 A Regional Hospital Example: McGill Technology Assessment Unit

Established in 2001, the McGill University Health Centre (MUHC) is a complex of five University Teaching Hospitals, functioning within the Quebec universal coverage healthcare system (20). The hospital group developed an in-house Technology Assessment Unit (TAU; http://www.mcgill.ca/tau/) to assist the hospital administration in difficult technology acquisition issues. In addition to presenting the scientific evidence relating to technology, the TAU develops policy recommendations based on the evidence that are sensitive to local circumstances and reflect community values (20,21). Consistent with its role within a University Health Centre, it publishes its research when appropriate and contributes to the training of personnel in the field of health technology assessment.

The primary objective of the Unit is to provide timely policy advice to the Administration on technology acquisition issues that confront them. The MUHC TAU consists of two separate entities: (1) a professional staff and (2) a Policy Committee representing the

hospital community. The professional staff develops the scientific evidence by accessing all relevant, world wide published information, critically evaluate and then synthesize it, and conduct original research when necessary. The role of the Policy Committee is to develop policy recommendations consistent with community values and local economic realities (20). In developing policy recommendations (note, the institution is still in charge of making policy decisions, not the TAU), the Committee is assisted by subject consultants, and when necessary, ethicists and health economists both from within the institution and externally. The TAU reports are released on their website (http://www.mcgill.ca/tau/publications/).

4.5 HTA Producers versus HTA Users

In general, large international or national HTA agencies, such as those discussed above, produce context-free HTA reports that are generic in approach. However, actual approval of the technology for implementation usually resides at the local level within the specific hospital or health region - these are HTA users. Besides considering information in HTA reports, local decision makers must also acknowledge complexity and consider context (22) by integrating different forms of information – experience, context, and research – to determine whether the technology is appropriate for their local setting. For example, is adoption of the technology justified on the basis of local patient needs? Is there room in the budget? Is there adequate infrastructure? Will the technology require specialized training? Will the technology be compatible with existing equipment? Will the technology provide a significant advantage over the existing standard of care and current practices in the local setting? In other words, whereas HTA reports can inform a decision on the basis of efficacy and sometimes cost-effectiveness, other factors such as local population needs, local effectiveness, and local resources also need to be considered in a systematic manner.

This leads to another level of assessment - integrating information from HTA producers with local information relevant to the HTA user in the form of a health technology appraisal or, as they are sometimes (and somewhat confusingly) called “local HTAs.” Table 2 illustrates the difference in focus between HTA producers and HTA users.

In Alberta, HTA users reside at the macro, meso, and micro level and each have different responsibilities. These will be discussed in the next section.

Table 2: Comparison of HTA Producers with HTA Users

	HTA PRODUCERS	HTA USERS
WHO?	Large government agencies, universities, non-for-profit companies, some health service delivery organizations	Health service delivery organizations, hospital units
	Full-time staff and consultants – not users	Local health care providers or project teams – includes users
	Independent of requester	Requester may be part of the process
MAJOR OUTCOME	Production of an assessment report and recommendations	Adoption of a technology
	Context-insensitive	Context-sensitive
WHAT?		
Forecasting / receive requests	Proactive determination of national health needs	Needs at the local level
Set priorities for reports	Priority for big-ticket items with wide potential impact	Primarily driven by local needs
Clinical evidence	Comprehensive synthesis of high quality primary literature, systematic reviews, clinical trials	Information from HTA reports and scientific literature PLUS experience elsewhere and expert recommendations
Economic evidence	Theoretical cost analysis	Cost analysis reports PLUS local budget, staff, compatibility, and organizational issues
Societal evidence	Ethical, regulatory	Ethics and regulatory issues PLUS local access issues, local values and priorities
Recommendation	An evaluation of the technology	A decision to purchase and implement the technology

5.0 HTA USERS IN ALBERTA

Within Alberta, HTA users who commission or use HTA reports and make funding (coverage and reimbursement), adoption and implementation decisions, occur at various levels:

- macro (provincial government),
- meso (AHS), and
- micro (Strategic and Operational Clinical Networks and other clinical operation leaders).

5.1 Macro Level – Alberta government

At the macro level, the ministry of Alberta Health and Wellness has responsibility for decision-making on the public funding (coverage and reimbursement) of health technologies and services, with emphasis on technologies requiring review provincially or nationally. It has developed the Alberta Health Technologies Decision Process,(23) http://www.health.alberta.ca/initiatives/AHTDP.html which comprises 4 main steps:

(1) Setting priorities (selection of health technologies and services for provincial review),
(2) Conducting reviews (health technology assessments) of selected health technologies and services,
(3) Consulting on findings, followed by formulating advice and implementing (communication) the decision, and
(4) Evaluating the impact of policy decisions on the Alberta healthcare system.

5.2 Meso Level – Alberta Health Services (Don looking forward to your comments)

Under its Director, Don Juzwishin, Health Technology Assessment and Innovation (HTAI) supports the managed introduction and evaluation of innovative health technologies through an evidence-informed decision model. The HTAI hub coordinates between the macro and micro levels of HTAI functioning at AHS.

The HTAI decision model helps:

- identify, prioritize, and assess health technologies (devices and processes, excluding drugs) expected to significantly impact patient safety, clinical or cost effectiveness, health outcomes, clinical practice, human resources, and/or policy;
- investigate innovative alternatives for current health technology to improve safety, quality, and/or outcomes;
- promote the effective and appropriate uptake of technologies; and
- validate the effectiveness of promising health technologies with access through evidence development initiatives.

HTAI has two major streams of activity:

- health technology assessment and reassessment—supporting the SCNs and leaders in AHS in a) evaluating new technologies for adoption or b) reassessing existing technologies for possible disinvestment or change in use. These evaluations occur at the front-line clinical level, and at the provincial level through the Ministry's Alberta Advisory Committee on Health Technologies.
- health technology innovation—introducing standard processes, mechanisms, and tools to stimulate innovation at AHS.

Over the past fiscal year and its second year of operation, the HTAI team has operationalized its strategic plan (http://www.albertahealthservices.ca/Researchers/if-res-htai-strategic-plan.pdf) and further developed linkages and coordination with the Strategic Clinical Networks and the Alberta Health Technology Decision Process (http://www.health.alberta.ca/initiatives/AHTDP.html) of Alberta Health and Wellness.

Over the past year, major highlights were:

- Development of a Provincial Strategy on Health Technology Assessment and Reassessment within AHS to embed and support the requirements of the Strategic Clinical Networks, zones and clinical departments.
- Establishment of a screening sub-committee of the Alberta Health Technology Advisory Committee that will identify, prioritize and triage projects at the provincial level.
- Development of a proposed province-wide single point of entry for industry and innovation to improve access and efficiency.
- Development and implementation of a health technology submission form for innovation that is publicized on the external HTAI website and AHS corporate forms website.
- Development of a health innovation program proposal, business plan and resource allocation requirements.
- Development of AHS intellectual property procedures to facilitate health innovation for Alberta with stakeholders in the province.
- Launch of the HTAI website on April 1 at http://www.albertahealthservices.ca/4122.asp .

The group also acts as a "hub" for supporting HTA expertise and capacity in AHS (24). The Hub provided information gathering support for HTAI Nodes distributed amongst the Strategic and Operational Clinical Networks and other clinical operation leaders within AHS. More information about HTAI can be obtained by visiting their web-site www.albertahealthservices.ca/4122.asp.

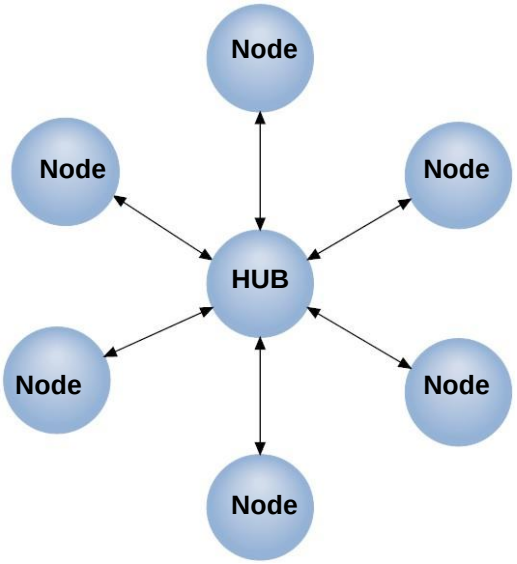

Fig. 1. Hub and Node Model for coordination of HTA activity within Alberta Health Services. Nodes represent Strategic and Operational Clinical Networks and other clinical operation leader within AHS. The Hub represent the HTAI group within the AHS Research Portfolio which provides personnel and expertise to support the Nodes.

5.3 Micro Level – Strategic and Operational Clinical Networks

At the micro level are the Strategic and Operational Clinical Networks and other clinical operation leaders within AHS. The mandate of clinical networks and operation leads is to develop and implement strategies (e.g., clinical pathways and care innovations) to achieve improvements in patient outcomes and satisfaction, improved access to and quality of health care, and sustainability of Alberta's health care system. As part of this mandate, clinical networks may develop their own HTAI Committees, which will appraise technologies for purchase and adoption within the area of expertise of that network. These Strategic and Operational Clinical Network HTAI Committees can be considered as "nodes" which communicate with a central "hub" – the HTAI group of the Research Portfolio (Fig. 1).

Each clinical network will be empowered to make implementation decisions about new technologies within their scope of operations based on the recommendations of their HTAI Committee. However, technologies that may have wider impact may be referred to the meso or macro level for collaborative evaluations.

5.4 The Local HTA Decision Support Program

As previously mentioned, the Local HTA Decision Support Program developed by the Department of Surgery in Calgary is being adapted for use by some HTAI Committees of the Strategic and Operational Clinical Networks. The Program provides a systematic, consistent and transparent process by which HTA users at the micro level can integrate research evidence about a technology with local operational management information in order to make a recommendation about whether and under what conditions the technology will be used.

The operation of the Local HTA Decision Support Program requires the appointment of an advisory committee, which would be the Strategic and Operational Network HTAI Committees in the present framework. This committee manages the evaluation process, reviews the application for suitability and completeness, determines whether the technology can be rapidly approved, and for those technologies requiring further assessment, makes recommendations to the Executive Committee for subsequent decision.

The Local HTA Decision Support Program itself consists of a *Policy*, *Forms*, and *Appendices* (http://www.calgaryhealthregion.ca/surgicalservices/hta.html). The *Policy* sets the guidelines for introduction of new technologies, the *Forms* collect relevant evidence about the technology and the environment in which it is intended to be used, and the *Appendices* provide tools for evaluations, decision-making, and submitting reports in a systematic and consistent manner. The current version of the Local HTA Decision Support Program (January 2009) was the product of several cycles of review and testing by several departments within what was the Calgary Health Region.

A retrospective study examined the outcomes of this Program as used by the Department of Surgery & Surgical Services in the Calgary Health Region over a five-year period from December 2005 to December 2010 (25). Of 68 technologies requested, 15 were incomplete and dropped, 12 were approved, 3 were approved for a single case on an urgent/emergent basis, 21 were approved for "clinical audit" for a restricted number of cases with outcomes review, 14 were approved for research use only, and 3 were referred to additional review bodies. Subsequent outcomes reporting resulted in at least 5 technologies being dropped for failure to perform.

Decisions based on Local HTA Decision Support Program recommendations were rarely "yes" or "no". Rather, many technologies were given restricted approval with full approval contingent on satisfying certain conditions such as positive clinical outcomes, training protocol development, funding etc. Thus, innovation could be supported while ensuring safety and effectiveness in the local setting.

6.0 CHALLENGES OF HTA

HTA is here to stay. The need to contain costs and to reduce unjustified variations in clinical practice and health service provision will mean that decision-makers need more, not less, high-quality information on treatments' impacts (26). Thus, it will continue to remain important that we attend to what works and what does not work, so as to reach a consensus on what should be provided and what cannot be afforded (18). However, there are challenges associated with HTA that should be understood.

6.1 Timing of the Assessment and Coverage Issues

Often, HTA is performed by insurance companies after a technology has been approved. When properly performed, it provides important benefits by empowering patients and physicians with information for making the best treatment decisions (17). Recent trends suggest the result is restricted patient access to innovative medical technology. For example, as a result of technology assessment delays it took Medicare in the United States, seven years to cover a new bone mineral density scanner for osteoporosis. However, whether HTA is beneficial – supporting timely access to needed technologies – or detrimental – delaying or denying access – depends on three critical issues: when the assessment is performed; how it is performed; and how the findings are used.

A health technology can be assessed during any phase of its life cycle (i.e., experimental phase, implementation phase, generalization phase, and decaying phase). Groups responsible for HTA usually become involved during the implementation phase, but remain actively interested through to the decaying phase (27). During the implementation phase, the effectiveness, clinical usefulness, and foreseeable economic and organizational impact of the technology is established. Throughout the generalization phase, information is collected on how long the technology will be used and how it is being used in each individual case. Finally, in the decaying phase, an evaluation of whether it would be beneficial to replace the technology in question with a new technology is conducted (27).

One problem is that conducting a formal health technology assessment can greatly lengthen the delays in the amount of time it takes insurance companies to set a coverage, coding and payment policy for a new technology. The hurdle posed by HTA can be particularly daunting to the small, innovative companies that characterize the medical technology field. This can discourage companies from pursuing breakthrough technologies (17).

Another problem discovered by The Lewin Group (17) is that HTA is being performed earlier in the life-cycle of new technologies, increasing the risk of coverage policies that are premature and biased against new interventions. HTA agencies, particularly private HTA vendors, have been developing "early warning" and "horizon scanning" systems to identify emerging technologies for assessment. Terms used by HTAs such as "early warning" and "health technology alert" to describe these systems are noteworthy because they may reflect a bias against new technology (17). Premature technology assessment can involve a more fundamental bias because early data tends to be biased against a new intervention.

The costs of a technology often are higher during the early stages of dissemination, and physicians are still gaining experience in its use, making it more difficult to accurately gauge effectiveness and costs (17,28).

Problems can arise at each stage in the assessment of surgical procedures. At the very start of the process, it is difficult to know when to give a new procedure priority for evaluation. If an assessment is done too early, before surgeons have mastered the technique, there is a risk of rejection of an effective procedure. If too late, the technique may have diffused and become established, by which time surgeons will consider it unethical to withhold the procedure. The uptake of minimally invasive surgical techniques provides an example of some of the problems that can arise. Laparoscopic cholecystectomy was adopted in preference to minicholecystectomy by many surgeons without evidence of its effectiveness and is believed by many to have resulted in a higher rate of bileduct injuries while surgeons were learning the technique. Formal evaluations were hampered by widespread optimism about the effectiveness of the minimally invasive approach, which was subsequently found to be exaggerated (29). Today Laparoscopic cholecystectomy is effectively applied.

6.2 Disagreement on Effectiveness Measures

It is clearly important to assess all forms of new healthcare developments to determine whether they are effective and their use is justified. However, there are major differences of opinion on how effectiveness should be determined. As more and more governments seek to control spiraling healthcare costs, it is likely that the determination of cost effectiveness will have a larger role in informing future decisions about which technologies should be used. On the basis of the UK experience, this may lead to delays in the widespread use of effective cancer drugs. To avoid this problem the oncology community needs to work closely with HTA agencies to review the appraisal methodology, particularly in relation to cost effectiveness. Moreover, more effort is required to establish and reach agreement on acceptable measures of effectiveness in cancer care (30).

6.3 Levels of Evidence as a Barrier to Innovation

Another problem cited is that HTA organizations are demanding increasingly high levels of evidence, creating a barrier to innovative medical technologies. The standards of evidence often used by HTA organizations such as randomized controlled trials can be extremely burdensome and sometimes impossible to meet. For example, placebo controls and blinding of patients and physicians to the treatment being used often is impractical or impossible in medical device studies (17). Evidence requirements for HTA cannot be uniform across all technologies. They must be commensurate with the type of technology being evaluated and the conditions under which it is used. Many evidence types of technology being evaluated and the conditions under which it is used. Many evidence types beyond randomized controlled trials should be used to support positive health technology assessments (17).

Agencies that carry out health technology assessment may regard methodological rigour as a key characteristic, but clinicians and managers who use the results do not necessarily

share that view. Randomized trials are methodologically powerful but often impractical to conduct, slow to complete, and limited in the scope of information they provide. Therefore other characteristics of the research inevitably help determine its usability. These include the credibility of the researchers; the type of outcomes associated with the intervention (clinicians will wait for methodologically strong research if there is a risk of a serious side effect but will act on small studies if the risks and side effects are judged to be trivial; and the extent to which the findings fit with previous beliefs and attitudes. Clinicians' own experience is often a greater influence on their practice than research published in journals (28).

For health care interventions, the randomized clinical trial (RCT) is accepted as the most sound methodological design to test the relative efficacy of alternative treatments (e.g., current practice versus new surgical procedure). By random assignment of participants to study conditions, the RCT affords the opportunity to follow patients prospectively in a standardized manner, causally infer the effects of the interventions, and more confidently rule out alternative explanations for the finding. Despite the strength of the design, RCTs do present challenges. To conduct an RCT is notoriously time-consuming, expensive, and for some clinical conditions neither feasible nor ethical. Furthermore, debate exists regarding the extent to which findings from RCTs are generalizable and where the burden of proof for generalizing study results lies. These general barriers are common to all RCTs. The execution of surgical RCTs presents the investigator with a unique set of challenges. For example, it is exceptionally difficult to standardize surgical procedures, as several factors contribute to variation, including a surgeon's experience and skill and unanticipated but necessary modifications to the procedures to accommodate the unique needs of the clinical situation. Because it is impossible to ensure that both the patient and the clinician are blind to the surgical procedure, there are various threats to the validity of the outcome including the placebo effect (i.e., effects observed in a trial that are not due to the treatment or intervention but, rather, to participants' expectations of the effects of treatment) and the Hawthorne effect (i.e., where the participants' knowledge that they are part of a study influences results differentially). Finally, participant accrual to surgical RCTs may be more challenging than RCTs in other domains. Surgical procedures are typically permanent, and therefore, participants in these trials forgo the opportunity to access alternative, and potentially more effective, procedures after the study is completed. Given this limitation, patients may be less inclined to commit to participating in these sorts of trials (31).

Devising ways of encouraging surgeons to recognize uncertainty about the effects of surgical procedures and to be less susceptible to the lure of new and expensive technology that has not been fully evaluated probably represents the greatest challenge to health-technology assessment in surgery. A greater awareness of the need to assess surgical technologies should lead to more and higher-quality evaluations of effectiveness, the opportunity to synthesize evidence from individual studies in systematic reviews, and the incorporation of high-quality evidence into guidelines. There also needs to be wider acknowledgment of the difficulty of carrying out randomized trials in some circumstances and a greater appreciation of the potential value of assessments with non-randomized designs when randomized trials prove to be impracticable (29).

6.4 Using Cost to Limit Access to Technologies

Another problem is that health technology assessments increasingly use cost to limit access to medical technologies and procedures. Using cost as a factor in coverage policies is impractical and biased against new technologies. Early versions of new devices tend to have higher costs than later versions as the technology matures. Health technology assessors face major challenges in accurately comparing the cost-effectiveness of various medical technologies and procedures. Often, the amount of cost-effectiveness information available on each treatment varies as widely as the technologies themselves. In addition, the broad conclusions of cost-effectiveness analysis often conflict with the values and preferences of individuals or subgroups in the population (17). Further, cost-effectiveness analysis by HTAs typically does not account for important societal benefits of new technologies. Many technologies, for example, enable people to return to family, work and volunteer activities by providing quicker, more complete recoveries (17).

6.5 Various Extraneous Influences on Assessment

Technology cannot be assessed in isolation and cognizance should also be taken of the numerous other related and semi-related factors that may or may not play a role in the final analysis. Such factors would range from socio-economic factors through patient expectations to medico-legal considerations. Substantial attention should therefore be paid to the wider impact of health technology, including general economic impacts. Patients *per se* should therefore have the opportunity to provide input into the process and the ultimate appraisal of the technology in question and the recommendations made. By the same token, the actual providers of health care should, as has been stated before, have the opportunity to participate in the process (32).

Another impediment is the inertia of medical practice, for instance, in the form of gravitation toward long-standing practice routines, conservative payment policies and quickly outdated education. This is complemented by lack of opportunities for, or encouragement of, scientific inquiry and skepticism in clinical education. Ever more effective marketing and promotions, including short courses sponsored by medical product companies to train physicians in procedures using these products, can divert attention from key concerns of HTA (13).

The possibility that some surgeons may have better outcomes with one procedure and other surgeons with an alternative procedure – i.e., there is an interaction between surgeon and technique – creates a particular difficulty. The theoretically ideal solution is to randomize eligible patients of each participating surgeon to one or other procedure. There are practical drawbacks with this approach since surgeons who prefer one procedure may be unwilling to participate. More importantly, if there is an interaction between surgeon and procedure, pooling the results across surgeons will give a misleading answer, and quantifying the interaction requires a very large sample size. Randomizing patients to surgeons who use different procedures, or studying the patients of different surgeons observationally, may represent a pragmatic alternative but addresses a different question – namely, what are the effects of the alternative procedures when carried out by surgeons who prefer them (29)? There can be difficulties in weighing up the benefits and costs of new surgical procedures.

Adopting a new surgical technique may not be straightforward, since it is likely to require a surgeon to acquire new practical skills and to develop competence over a number of cases. The costs of mastering a new procedure are likely to be substantial for patients, surgeons, and health services, since surgeons who are learning a new technique typically take longer to carry out a procedure and have a higher rate of complications than do experienced ones. Since the gradient of the learning curve may vary considerably between surgeons, the inclusion of general recommendations in high-quality evidence that is being disseminated can be difficult (29).

6.6 Vendor Information

Many health care providers and agencies get most of their information on health care technologies from the manufacturers of these technologies. Patients also receive information directly from drug and device suppliers. What can be missing from vendor information? What are the risks in relying on vendor information? Answers to these questions direct us to the importance of learning how to critique and supplement vendor information.

6.7 Dissemination and Implementation Difficulties

Limited funding has become a permanent condition for health care systems, and governments and private payers continue to press all those involved in the management and provision of care to become more cost-effective.

6.8 Attitudes Toward Economic Evaluation

Many clinicians and patients still believe that considering costs is unethical and that economic evaluation (which is an important component of HTA), is therefore unethical. However, in health care, not considering costs means using up real resources (to benefit one or more particular patients) without regard for the resulting missed opportunities to benefit other (unspecified) patients. Choices between alternatives exist and decisions must be made about how to allocate resources. Economic evaluation is a systematic method of assessing the costs and the outcomes of different alternatives, making all assumptions explicit, and hence helping make policy-makers accountable for their decisions. Understanding economic evaluation studies in HTA and knowing when and how to use them, is an important skill for anyone concerned with setting priorities in health care.

6.9 Lack of Experience with Health Outcome Reporting

Agencies are being asked to set up committees to regulate and assess new technologies and promote evidence-based medical practice with guidelines. However, few agencies or practitioners have much experience with formal assessment of evidence or with health outcome reporting. With most having no nearby source of expertise, there remains both misunderstanding and misuse of evidence-based medicine and evidence-based decision-making. In turn, this misunderstanding and misuse can often lead to suspicion by

physicians that these methods are just another means of cutting costs and taking control of clinical issues out of physicians' hands. Outcome research is often seen as just another unnecessary administrative burden. In fact, all of these methods, used correctly, can lead to more cost-effective health care and a better working and caregiving environment for patients, providers, and managers.

The impression persists in some quarters that the goal of HTA is to limit the innovation and diffusion of health care technology (13). Many areas of uncertainty exist in surgical practice ranging from the indications for surgery to the preferred surgical management and the perceived outcomes following treatment (33). Some are alarmed by the concept of basing practice on external and internal evidence. They are concerned that health policymakers will begin dictating clinical practice by exploiting the lack of good evidence to support some current medical practice patterns. There is fear that innovation will be stifled, and that the art of medicine will be lost. Instead of being frightened by the use of evidence (or lack of it) against us, we as surgeons should seize on the opportunity to steer policymakers and payors in the right direction. If the evidence is lacking, we should take up the challenge to generate it. Policymakers must be prepared to finance these efforts if cost-effective care is to be realized without compromising patient function. If a new technique has been conceived, it should be tested first under controlled study conditions to generate some evidence for its efficacy before being widely disseminated. This is no reason to limit innovation or experimentation; rather, this practice represents a responsible means of ensuring that patients are not unduly harmed by a new technology. Clinicians and clinician scientists should be in the forefront of endeavors to study, test, and adopt the most effective management strategies possible based on valid scientific evidence. Surely the art of surgery can only be enhanced by the thoughtful generation and application of the best possible scientific evidence (33).

6.10 The Moving Target

What makes a surgical technique new is not always easy to define because surgical procedures generally evolve in small steps which makes it difficult to decide when a procedure has changed sufficiently to justify formal evaluation (Reeves, 1999). As a technology matures, changes occur in the technology itself that can reduce the value of a HTA report (19).

Even when new technologies are given priority for evaluation, the required studies are often difficult to establish. The difficulty of assessing a moving target is illustrated by the changing way in which minimally invasive coronary artery surgery is being used. Evaluation of this procedure was given priority by the UK National Health Service in 1997, after early case-series had indicated the success of a minithoracotomy approach for bypass grafting without the need for extracorporeal circulation for patients with single-Vessel disease, who are usually treated by angioplasty. The most important question about this generic technology can be said to have now changed, since some surgeons prefer to use a median sternotomy incision, even for patients with single-vessel disease, and are grafting multiple vessels without the use of extracorporeal cardiopulmonary circulation for patients who would otherwise have undergone standard coronary bypass surgery (29).

7.0 REVIEW & CONCLUSIONS

7.1 Review of Module Objectives

The primary goals of this Module are:

1. To present an overview of Health Technology Assessment (HTA) including terminology, principles and purposes of HTA, examples of HTA producers and users particularly in Alberta, and
2. To explore how HTA can be applied to inform decisions in our local environment.

By the end of this Module, readers will be able to:

3. Define HTA using related descriptions and terminology,
4. Understand the rationale for HTA,
5. Identify and distinguish between HTA producers and HTA users, and
6. Describe the HTA user framework in Alberta

7.2 Conclusions

The HTA process is aimed at facilitating the introduction of new technology and enhancing patient safety and health outcomes. HTA may be viewed as a process of decision-making which encourages clinicians to make decisions about the use of technology, and helping them move beyond working in isolation with patients toward working collaboratively with the entire community.

The present module has presented information on HTA producers and HTA users, with particular emphasis on the framework in Alberta. It is clear that the main purpose of HTA is to consolidate the best available evidence on technologies so as to promote change by providing the necessary and relevant information to appropriately orient decision-makers (e.g., clinicians, patients, financiers, insurers, planner, health service administrators, policy-makers, etc.). When well-conceived and implemented, HTA can make an important contribution to the proper distribution of resources, to the selection of cost-effective interventions, to greater efficiency and more effective services, to quality assurance in care, and to participation by professionals and patients in decision-making (27).

8.0 APPENDICES

8.1 Historical Background and Timeline of Health Technology Assessment

In order to more fully appreciate what HTA involves in its current state, it is useful to consider how HTA originated.

The term Technology Assessment originated in 1965 in the U.S. House of Representatives during deliberations of the Committee on Science and Astronautics. Congress commissioned independent studies by the National Academy of Science, the National Academy of Engineering, and the Legislative Reference Service of the Library of Congress. It was these studies that significantly influenced the development and application of TA. In 1973 the Congressional Office of Technology Assessment was founded, it became operational in 1974, and its health program was established in 1975 (4,13,14,34). Despite its successful period of activity, the office was closed again in 1996 for political reasons (35).

Initially, an HTA committee was set up in Catalonia in Spain in 1984. This committee formed the basis for the foundation of the Catalan Agency for Health Technology Assessment (CAHTA). At the same time equivalent organizations were founded at national level and in the Basque region and in Valencia. At the international level, 1985 saw the foundation of a specialist association, the International Society for Health Technology Assessment (ISTAHC). From 1985 through 2003, ISTAHC held an annual meeting and sponsored a peer-reviewed scientific journal, the International Journal of Technology Assessment in Health Care. HTA International was created in 2003 as the HTA field continued to grow (14).

To approach the problems of double and multiple investigations of the same topic, the International Network for Agencies in Health Technology Assessment (INAHTA) was founded in 1993 (35). In 1987 the Swedish Council for Technology Assessment in Health Care was founded. In 1990, France founded L'Agence Nationale pour le Développement d'Évaluation Médicale, which was renamed L'Agence Nationale pour l'Accrédition et l'Évaluation dans la Santé in 1997. It focuses on the development of standards in the field of hospital accreditation. In 1991 the National Health Service Research and Development Programme for the field of HTA was established in the United Kingdom. In Germany, state activity in the field of HTA began in 1995. The Federal Ministry of Health began its appraisal of this topic with a report on the international situation (35). A National Coordinating Centre for Health Technology Assessment was then set up in 1996 in the United Kingdom. In 1997, the German Scientific Working Group Technology Assessment for Health Care was established. In 1999, the National Institute for Clinical Excellence for England and Wales was founded as part of the National Health Service. Since 1994, other countries have also seen the setting up of national agencies, sometimes differing greatly with regard to their special areas. An information base was set-up in 2000 with the German Law on Health Reform commissioned by the Deutsches Institut für Medizinische Dokumentation und Information (DIMDI). To guarantee optimum collaboration with national and international bodies, the responsibilities of the DIMDI in the field of HTA

have now been collapsed into those of the Deutsche Agentur für Health Technology Assessment (35).

During its 30 years of existence, HTA has expanded in terms of both people involved and importance, and has widened its scope. Many additional agencies were established, most of which are united today under the International Network of Agencies for Health Technology Assessment (34). From the outset, HTA has been fueled in part by the emergence and diffusion of technologies that have evoked social, ethical, legal, and political concerns (e.g., contraceptives, artificial organs, genetic therapy) (13).

HTA originated as a centralized function conducted by federal government, national or regional-level organizations. Consequently, many feared that HTA would be a means by which government would impede the development and use of technology (13). Today, HTA is increasingly a decentralized activity conducted by a great variety of organizations in the public and private sectors that make technology-related policy decisions. Yet, the decentralization of HTA activity has not been a result of a reduction in the level of centralized activity. Instead, it stems from an expansion in activities, primarily in the private sector (13).

A historical timeline of HTA development is given below.

- **1965**
  - Term "Technology Assessment" originated in the U.S. House of Representatives
- **1973**
  - Congressional Office of Technology Assessment (OTA) was founded
- **1974**
  - Office of Technology Assessment (OTA) became operational
- **1975**
  - Office of Technology Assessment (OTA) Health Program was established
- **1977**
  - The Social Sciences and Humanities Research Council of Canada (SSHRC) was created by an act of Parliament; a federal agency that promotes and supports university-based research and training in the social sciences and humanities. SSHRC is governed by a 22-member Council that reports to Parliament through the Minister of Industry.
  - "Health for All Strategy"
  - Pan American Health Organization (PAHO) devoted attention to HTA
- **1978**
  - Declaration of Alma-Ata defined primary health care as "essential health care based on practical, scientifically sound and socially acceptable methods and technology … at a cost that the community and country can afford …"
- **1980**

- Alberta Heritage Foundation for Medical Research (AHFMR) was established by the Government of Alberta
- Network of centers called "Cochrane Collaboration" grew and published an electronically accessible "Cochrane Library" that compiles sources on various medical areas

- **1983**
  - Health Technologies Development Unit for PAHO was established
  - The Government of Canada adopted its first National Biotechnology Strategy

- **1984**
  - HTA Committee established in Catalonia in Spain, forming the Catalan Agency for Health Technology Assessment (CAHTA)
  - Equivalent organizations founded at the national level and in the Basque Region and in Valencia
  - The World Health Organization (WHO) European Regional Office stated that prior to 1990 all the Member States should have established a formal mechanism to systematically assess the appropriate use of health technologies and verify that they respond to the national health programs and the countries economies means

- **1985**
  - International Society for Health Technology Assessment (ISTAHC) was founded
  - One of Canada's first Technology Transfer Programs of AHFMR is established to help researchers and private industry take innovations from the lab to the marketplace
  - PAHO coorganized an "Ibero-American Seminar on Medical Technology" in Madrid (Spain)

- **1986**
  - International Society for Health Technology Assessment (ISTAHC) Annual Meeting & Sponsored a peer-reviewed scientific journal (the *International Journal of Technology Assessment in Health Care*)

- **1987**
  - International Society for Health Technology Assessment (ISTAHC) Annual Meeting & Sponsored a peer-reviewed scientific journal (the *International Journal of Technology Assessment in Health Care*)
  - Swedish Council for Technology Assessment in Health Care (SBU) was founded
  - First International Board of Review applauds AHFMR's outstanding success
  - AHFMR research buildings open at the University of Alberta and the University of Calgary

- **1988**
  - International Society for Health Technology Assessment (ISTAHC) Annual Meeting & Sponsored a peer-reviewed scientific journal (the *International Journal of Technology Assessment in Health Care*)
  - Council for Health Technology Assessment of Quebec was created
  - Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) established

- **1989**

- International Society for Health Technology Assessment (ISTAHC) Annual Meeting & Sponsored a peer-reviewed scientific journal (the *International Journal of Technology Assessment in Health Care*)
- The Agency for Health Care Policy and Research (AHCPR) was created; a Public Health Service agency in the Department of Health and Human Services (HHS)
- Canadian Coordination Office for HTA (CCOHTA) was created
- PAHO published a case-study on "HTA: Methodologies for Developing Countries"

- **1990**
  - International Society for Health Technology Assessment (ISTAHC) Annual Meeting & Sponsored a peer-reviewed scientific journal (the *International Journal of Technology Assessment in Health Care*)
  - France founded L'Agence Nationale pour le Développement d'Évaluation Mèdicale
  - Seminar and International advisory group on "Regulation of Medical Devices" was organized in Ottawa and PAHO's Technology Unit was restructured into the Regional Program on Drugs and Health Technology, under the Division of Health Systems and Services
  - "Strategic Orientations and Program Priorities for Quadrennium 1991-1994" (SOPPs) was approved

- **1991**
  - International Society for Health Technology Assessment (ISTAHC) Annual Meeting & Sponsored a peer-reviewed scientific journal (the *International Journal of Technology Assessment in Health Care*)
  - National Health Service Research and Development Programme was established in the United Kingdom
  - WHO held meetings of experts on HTA in Geneva

- **1992**
  - International Society for Health Technology Assessment (ISTAHC) Annual Meeting & Sponsored a peer-reviewed scientific journal (the *International Journal of Technology Assessment in Health Care*)
  - Institute for Clinical Evaluative Sciences (ICES)

- **1993**
  - International Society for Health Technology Assessment (ISTAHC) Annual Meeting & Sponsored a peer-reviewed scientific journal (the *International Journal of Technology Assessment in Health Care*)
  - International Network for Agencies in Health Technology Assessment (INAHTA) was founded
  - WHO held meetings of experts on HTA in Alexandria
  - Alberta Health and Wellness established a HTA Unit
  - National Biotechnology Strategy refocused its policies, with a revised Federal Regulatory Framework for Biotechnology
  - Second International Board of Review affirms AHFMR's leadership in supporting medical research in Canada with effective and innovative granting programs

- **1994**
  - International Society for Health Technology Assessment (ISTAHC) Annual Meeting & Sponsored a peer-reviewed scientific journal (the *International Journal of Technology Assessment in Health Care*)

- In Ottawa, CCOHTA held the first international meeting for information specialists from agencies involved in evidence-based health care and HTA
- Canadian Institute for Health Information (CIHI) was established
- Judith Maxwell, the last Chair of the Economic Council of Canada, founded the Canadian Policy Research Networks
- Centre for Reviews and Dissemination (CRD) was established
- The European Union created the EUR-ASSESS program, aimed at standardizing concepts and defining strategies for the Member States in 4 areas: (1) setting of priorities; (2) assessment methods; (3) dissemination of results, and (4) health coverage and its relation to HTA
- Specific proposals were formulated as a result of WHO holding meetings of a working group to promote HTA in the developing countries

1995

- International Society for Health Technology Assessment (ISTAHC) Annual Meeting & Sponsored a peer-reviewed scientific journal (the *International Journal of Technology Assessment in Health Care*)
- OTA in the United States was abolished
- HTA activity began in Germany
- HTA Unit moved from Alberta Health and Wellness to AHFMR

1996

- Congressional Office of Technology Assessment (OTA) was closed for political reasons
- International Society for Health Technology Assessment (ISTAHC) Annual Meeting (held in San Francisco) & Sponsored a peer-reviewed scientific journal (the *International Journal of Technology Assessment in Health Care*)
- National Coordinating Centre for Health Technology Assessment was established in the United Kingdom
- Interest group was formed within the society for the development of HTA in the developing countries and responding to a PAHO initiative
- INAHTA published its first monthly newsletter in both English and Spanish
- Interest group was formed within ISTAHC for the development of HTA in the developing countries
- Biennial program budget (1996-1997) of WHO includes a chapter on "Quality and Health Technologies"
- Restructuring of PAHO's Division of Health Systems and Services Development

1997

- International Society for Health Technology Assessment (ISTAHC) Annual Meeting (held in Barcelona) & Sponsored a peer-reviewed scientific journal (the *International Journal of Technology Assessment in Health Care*)
- L'Agence Nationale pour le Développement d'Évaluation Mèdicale renamed to L'Agence Nationale pour l'Accrédition et l'Évaluation dans la Santé (ANAES)
- German Scientific Working Group Technology Assessment for Health Care (GSWG-TAHC) was established
- Canadian Health Services Research Foundation (CHSRF) was formed
- INAHTA disseminated its first collaborative assessment project
- Agency for Health Care Policy and Research (AHCPR) announced a strategy change consisting of creating a center for practice and Technology assessment in collaboration with the American Medical Association and the American Association of Health Plans

- EUR-ASSESS underwent a program name change
- $15 million is allocated to the new AHFMR Opportunity Fund that matches funds for strategic research infrastructure initiatives in the province

- **1998**
  - International Society for Health Technology Assessment (ISTAHC) Annual Meeting (held in Ottawa) & Sponsored a peer-reviewed scientific journal (the *International Journal of Technology Assessment in Health Care*)
  - National Biotechnology Strategy refocused its policies in order to address a broader range of emerging issues; the Government developed the Canadian Biotechnology Strategy (CBS)
  - Third International Board of Review declares that AHFMR's "solid commitment to excellence" has nurtured a superlative scientific community

- **1999**
  - International Society for Health Technology Assessment (ISTAHC) Annual Meeting (held in Edinburgh) & Sponsored a peer-reviewed scientific journal (the *International Journal of Technology Assessment in Health Care*)
  - National Institute for Clinical Excellence (NICE) for England and Wales was founded as part of the National Health Service
  - The Agency for Health Care Policy and Research (AHCPR) was reauthorized as the Agency for Healthcare Research and Quality (AHRQ)
  - Canadian Biotechnology Advisory Committee (CBAC) established by the Government of Canada to provide comprehensive advice on current policy issues associated with ethical, social, regulatory, economic, scientific and environmental aspects of biotechnology

- **2000**
  - International Society for Health Technology Assessment (ISTAHC) Annual Meeting (in The Hague) & Sponsored a peer-reviewed scientific journal (the *International Journal of Technology Assessment in Health Care*)
  - Information base was established with German Law on Health Reform commissioned by the Deutsches Institut für Medizinische Dokumentation und Information (DIMDI) --- later collapsed into the Deutsche Agentur für Health Technology Assessment (DAHTA)
  - European Collaboration for Assessment of Health Interventions (ECHTA/ECAHI) was established
  - Premier Ralph Klein (Alberta) announced the intention to form the Premier's Advisory Council on Health comprised of leading health policy experts representing physicians, the nursing profession, and other key policy sectors
  - CCOHTA expanded HTA
  - AHFMR's success inspires the Government of Alberta to create the Alberta Heritage Foundation for Science and Engineering Research, modeled on AHFMR
  - AHFMR announces a new initiative called the Research Prize intended to maintain and improve AHFMR Personnel awards

- **2001**
  - International Society for Health Technology Assessment (ISTAHC) Annual Meeting & Sponsored a peer-reviewed scientific journal (the *International Journal of Technology Assessment in Health Care*)
  - McGill University Health Centre (MUHC) established an HTA Unit

- Action Plan for Saskatchewan Health Care was released by the province, wherein the Health Services Utilization and Research Commission (HSURC) was dissolved and two new organizations created. The Saskatchewan Health Research Foundation (SHRF) would continue providing research grants and strategy, and Health Quality Council (HQC) would focus on quality improvement
- AHFMR establishes the ForeFront Program which is a new initiative to assist in accelerating the commercialization of medical research innovations and help keep the economic benefits of these innovations in the province

- **2002**
  - International Society for Health Technology Assessment (ISTAHC) Annual Meeting & Sponsored a peer-reviewed scientific journal (the *International Journal of Technology Assessment in Health Care*)
  - Expert Advisory Panel to Review Publicly Funded Health Services for the Premier of Alberta was established
  - Premier's Advisory Council on Health released its report on how to put Alberta's health care system on a sustainable foundation
  - CCOHTA added the Common Drug Review

- **2003**
  - International Society for Health Technology Assessment (ISTAHC) was dissolved
  - HTA International (HTAi) created at an International Meeting in Canmore, Alberta
  - Ontario Health Technology Advisory Committee (OHTAC) was created with secretariat and methodological support from the Medical Advisory Secretariat (MAS) of the Ministry of Health and Long Term Care (MOHLTC); OHTAC is the single portal for providing advice to the health care system regarding the uptake, diffusion and distribution for new health technologies and the removal of obsolete health technologies
  - Expert Advisory Panel from the Premier's Council on Health submits document entitled "Burden of Proof" which outlines the Panel's recommendations for a new appraisal process for health technologies and services in Alberta
  - Alberta Government accepts the proposed three screen process (i.e., Technical, Socio-Economic, and Fiscal), but rejects the creation of an agency
  - CCOHTA increased federal funding

- **2004**
  - Capital Health established an Office for Health Innovation (OHI) to provide a streamlined process for evaluating and introducing new and emerging health technologies to the region
  - Multi-stakeholder advisory committee in Alberta is established
  - Process formalized in Calgary for the Introduction to New Technology In The Department of Surgery
  - CCOHTA added the Canadian Optimal Medication Prescribing and Utilization Service (COMPUS)
  - CCOHTA was confirmed as Canada's Health Technology Agency by Federal, Provincial, and Territorial Health Ministers
  - Canadian Biotechnology Advisory Committee (CBAC) underwent a change of focus to the broader impacts of biotechnology on complex systems such as health care
  - Fourth International Board of Review applauded the Alberta government for its vision in creating AHFMR nearly 25 years ago
  - Marks the publication of the complete electronic textbook (Etext) on HTA information

- **2005**
  - National Institute for Health and Clinical Excellence (NICE) was formed when the National Institute for Clinical Excellence took on the functions of the Health Development
  - Eighteen months after OHTAC was created, MAS commissioned a review of OHTAC and the MAS processes as part of its ongoing quality improvement initiative
  - Premier of Alberta recommits to the implementation of the Expert Advisory Panel to Review Publicly Funded Health Services' advice and more technologies identified for review
  - HTA Process In The Department of Surgery in Calgary explicated
  - AHFMR marks its silver anniversary, having provided 25 years of continuous support to Alberta researchers
  - Alberta Government announced a $500 million addition to AHFMR's endowment which allowed the Foundation to continue to enhance its programs of funding people and activities engaged in health research
  - First HTA Workshop for Latin America, held in Mexico City

8.2 Canadian, Surgery-Specific, and International HTA Agencies

Country	Agency	Organization Website or Email Address
 Argentina	IECS	Institute for Clinical Effectiveness and Health Policy Ciudad de Buenos Aires, ARGENTINA http://www.iecs.org.ar/index-ing.php
 Australia	ASERNIP-S	Australian Safety and Efficacy Register of New Procedures - Surgical Stepney, SA, AUSTRALIA http://www.surgeons.org/racs/research-and-audit/asernip-s
	MSAC	Medical Services Advisory Committee Canberra, ACT, AUSTRALIA http://www.msac.gov.au/internet/msac/publishing.nsf/Content/home-1
 Austria	ITA	Institute of Technology Assessment Vienna, AUSTRIA http://www.oeaw.ac.at/ita/welcome.htm
 Belgium	KCE	Belgian Health Care Knowledge Centre Brussels, BELGIUM http://www.kce.fgov.be/index_en.aspx?SGREF=5211
 Canada	CADTH	Canadian Agency for Drugs and Technology in Health Ottawa, Ontario, CANADA http://www.cadth.ca/
	AETMIS	Agence d'Évaluation des Technologies et des Modes d'Intervention en Santé Montréal, Québec, CANADA http://www.aetmis.gouv.qc.ca
	IHE	Institute of Health Economics Edmonton, Alberta, CANADA http://www.ihe.ca/
 Chile	ETESA	Unidad De Tecnologias De Salud Ministerio De Salud De Chile Santiago de Chile, CHILE http://www.minsal.cl
 Cuba	INHEM	Instituto Nacional de Higiene Epidemiologia y Microbiologia C. Habana, CUBA http://www.inhem.sld.cu/
 Denmark	DACEHTA	Danish Centre for Evaluation and HTA (DACEHTA) Copenhagen, S DENMARK http://www.sst.dk/English/DACEHTA.aspx
	DSI	Danish Institute for Health Services Research Copenhagen, DENMARK http://dsi.dk/english/
 Finland	FINOHTA	Finnish Office for Health Care Technology Assessment Helsinki, FINLAND http://finohta.stakes.fi/EN/index.htm
 France	CEDIT	Comité d'Evaluation et de Diffusion des Innovations Technologiques Paris R.P,. FRANCE http://cedit.aphp.fr/english/index_present.html
	HAS	Haute Autorité de santé/French National Authority for Health Saint-Denis La Plaine, CEDEX FRANCE http://www.has-sante.fr/portail/jcms/c_5443/english
 Germany	DAHTA@ DIMDI	German Agency for Health Technology Assessment at the German Institute for Medical Documentation and Information Cologne, GERMANY http://www.dimdi.de/static/en/hta/
 Hungary	HunHTA	Health Economics and Health Technology Assessment Research Centre Budapest, HUNGARY http://hecon.uni-corvinus.hu/corvinus.php?lng=en

 **Israel**	ICTAHC	Israeli Center for Technology Assessment in Health Care Tel-Hashomer, ISRAEL http://www.gertnerinst.org.il/e/health_policy_e/technology/
 **Latvia**	HSMTSA	Health Statistics and Medical Technologies State Agency Riga, LATVIA http://vsmtva.vec.gov.lv/web/en/index.aspx
 **Mexico**	IMSS	Mexican Institute of Social Security Del. Cuahutémoc, MEXICO http://www.imss.gob.mx/English
 **Netherlands**	CVZ	College voor zorgverzekeringen Diemen, THE NETHERLANDS http://www.cvz.nl/
	RGO	Health Council of the Netherlands – Gezondheidsraad Den Haag THE NETHERLANDS http://www.gezondheidsraad.nl/en
 **New Zealand**	NZHTA	New Zealand Health Technology Assessment Christchurch, NEW ZEALAND http://nzhta.chmeds.ac.nz/
 **Norway**	NOKC	Norwegian Knowledge Centre for the Health Services Oslo, NORWAY http://www.kunnskapssenteret.no/Home
 **Spain**	AETS	Agencia de Evaluación de Tecnologias Sanitarias Madrid, SPAIN http://www.isciii.es/htdocs/en/
	AVALIA-T	Galician Agency for Health Technology Assessment Santiago de Compostela, SPAIN
	CAHIAQ	http://www.sergas.es/MostrarContidos_Portais.aspx?IdPaxina=60538 Catalan Agency for Health Information, Assessment and Quality Barcelona, SPAIN http://www.gencat.cat/salut/depsan/units/aatrm/html/en/dir394/index.html
 **Sweden**	CMT	Center for Medical Technology Assessment Linköping, SWEDEN http://www.imh.liu.se/halso-och-sjukvardsanalys/cmt/?l=en
	SBU	Swedish Council on Technology Assessment in Health Care Stockholm, SWEDEN http://www.sbu.se/en/Home/
 **Switzerland**	SNHTA	Swiss Network for Health Technology Assessment Bern, SWITZERLAND http://www.snhta.ch/
 **United Kingdom**	CRD	Centre for Reviews and Dissemination York, UNITED KINGDOM http://www.york.ac.uk/inst/crd/
	NIHR-HTA	NIHR Health Technology Assessment Programme Southampton, UNITED KINDGOM http://www.hta.ac.uk/
	NHSC	National Horizon Scanning Center Birmingham, UNITED KINGDOM http://www.haps.bham.ac.uk/publichealth/horizon/
	NHS-Scotland	NHS Quality Improvement Scotland Glasgow, Scotland, UNITED KINGDOM http://www.nhshealthquality.org/nhsqis/43.140.140.html
 **United States**	AHRQ	Agency for Healthcare Research and Quality Rockville, MD, USA http://www.ahrq.gov/
	CMS	Centers for Medicare and Medicaid Services Baltimore, MD, USA http://www.cms.gov/

VA TAP	VA Technology Assessment Program Boston, MA, USA http://www4.va.gov/vatap/

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