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Health Technology Assessment in Canada.

Opportunities for Optimization and Redesign



Health Technology Assessment in Canada: Opportunities for Optimization and Redesign

Kelly Grimes, Gabriela Prada, Philip Astles, Vicki Foerster, and Jessica Brichta

Preface

This report discusses the landscape of health technology assessment (HTA) in Canada, documents the challenges in HTA, assesses two international approaches and learnings for Canada, identifies opportunities for HTA redesign to ensure value for money, and explores innovative approaches in the HTA world.

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Accessibility Officer, The Conference Board of Canada

Tel.: 613-526-3280 or 1-866-711-2262 E-mail: accessibility@conferenceboard.ca

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CONTENTS

i	EXECUTIVE SUMMARY
	Chapter 1
1	Introduction
2	What Is HTA?
3	How Is HTA Generated and Used?
3	The Intent of This Report
4	Methodology
4	Limitations
	Chapter 2
5	The Fundamentals of HTA
	Chapter 3
8	The Changing Landscape of HTA in Canada
9	A Pan-Canadian Perspective
11	Ontario's Experience
12	Quebec's Experience
13	Alberta's Experience
14	British Columbia's Experience
15	HTA in Other Countries
	Chapter 4
16	Online Survey Results From HTA Producers
17	Areas of Focus
17	Number and Type of Staff
18	Size and Sources of Funding
18	Types of HTA Work Undertaken
19	Important Factors Affecting HTA Project Selection
20	Opinions on Importance and Effectiveness of HTA for Technology Adoption and Displacement
21	Types of HTA's Produced and Methods Used
23	Opinion on Functioning of Phases of the HTA Process
	Chapter 5
24	Challenges for HTA and Innovation in Canada
25	Identifying and Selecting of Technologies
29	Conducting HTAs
32	Disseminating and Implementing HTA Findings
33	Evaluating of the Impact of HTA on Health Policy
	Chapter 6
34	International Models of HTA
36	United Kingdom
40	Germany
	Chapter 7
45	Opportunities for Redesign in HTA
48	Issues and Opportunities for HTA Redesign in Canada

	Appendix A
49	Methodology
49	Literature Review
50	Key Informant Interviews
51	International Case Studies
51	Online Survey
	Appendix B
53	Key Informant Interview Guide
53	Section A: Key Informant Interview Profile (5 minutes with introduction)
53	Section B: Background (10 minutes)
53	Section C: Challenges and Opportunities (20 minutes)
55	Section D: Issues and Trends (15 minutes)
55	Section E: HTA Assessment Measures (10 minutes)
	Appendix C
56	Online Survey
	Appendix D
58	Survey Questions
	Appendix E
62	Types of Economic Analyses
64	Example of a CEA
65	Cost-Utility Analysis
	Appendix F
67	Bibliography

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About the Centre for the Future of Health

The Centre for the Future of Health at The Conference Board of Canada is a recent merger between the Centre for the Advancement of Health Innovations and the Centre for Health System Design and Management. The Centre is a research centre and forum for leaders in the health arena to address complex issues and build capacity for strategic solutions. It aims to improve Canada's health care system and commercialization capacity through innovation. The members of the Centre included the following organizations in 2015–16 and 2016–17.

- Alberta Health Services
- AbbVie Canada
- AstraZeneca Canada Inc.
- GlaxoSmithKline Canada
- Health Canada
- Johnson & Johnson Inc.
- Medavie Blue Cross
- Medtronic Canada Ltd.
- Merck Canada Inc.
- Ontario Ministry of Health and Long-Term Care
- Southlake Regional Health Centre
- Stilco Corporation
- Sykes Assistance Services Corporation
- University of British Columbia

EXECUTIVE SUMMARY

Health Technology Assessment in Canada: Opportunities for Optimization and Redesign

At a Glance

- Health technology assessment helps stakeholders make informed decisions that harness the benefits of technology while getting value for money.
- In Canada, HTA infrastructure is complex, with a mix of centralized and decentralized structures and processes.
- This report discusses the HTA landscape in Canada, assesses two international approaches and learnings for Canada, and identifies opportunities for HTA redesign to ensure value for money.

Health Technology Assessment involves the systematic and unbiased evaluation of the efficacy/effectiveness, cost-effectiveness, and socio-economic consequences of drugs, devices, therapies, diagnostics, and health care systems. Its purpose is to review or produce unbiased evidence related to adopting new technologies, divesting from obsolescent ones, and ensuring appropriateness of use.

HTA is used to determine the relative costs and benefits of health technologies, often employing health economic evaluation to inform decision-making regarding access, prioritization, reimbursement, and pricing. Its purpose is to help stakeholders make informed decisions that harness the benefits of technology while getting value for money.

Notwithstanding growing global interest in the role and power of HTA, it remains a relatively undeveloped and uncoordinated activity in many countries. In Canada, the HTA infrastructure is complex, with a mix of centralized and decentralized structures and processes, especially on the non-drug side.

The Canadian Agency for Drugs and Technologies in Health (CADTH) oversees much of Canada's HTA effort as both an evidence producer and information coordinator, especially for provinces and territories that do not have HTA processes. There is also a pan-Canadian HTA Collaborative that includes membership from CADTH and other Canadian HTA producers. The Pan-Canadian Pharmaceutical Alliance is a more recent development that allows the provinces and territories to work together to achieve greater value for publicly funded drug programs.

In 2015, The Conference Board of Canada surveyed a number of Canadian HTA producer organizations to document the HTA landscape and explore its challenges and opportunities. Respondents noted that HTA in Canada is important in all areas of technology for adoption and disinvestment, although they felt that the actual impact of HTA does not fully reflect this importance. Respondents also noted that the conducting

Does HTA adequately influence decisions and does it support an efficient and effective health care system?

of HTA (producing reports, etc.) is the field's most effective contribution, while evaluation of the impact of HTA on health policy is its least effective.

Key informants were interviewed to better understand the HTA environment. Challenges identified by the interviewees included a fragmented HTA approach to non-drug technologies, a need for greater involvement of decision-makers in HTA's design, a need to better integrate patients and clinicians in the development of HTA processes, harmonization of criteria within regulatory and commercialization processes, consideration of a centralized approach to HTA to reduce duplication, a need to improve HTA methodologies, a need to ensure an appropriate workforce to conduct HTAs, and better knowledge translation and implantation activities.

This report discusses the HTA landscape in Canada, assesses two international approaches and learnings for Canada (the United Kingdom and Germany), and identifies opportunities for HTA redesign to ensure value for money. One of the important challenges to be addressed in HTA is how it is used from a policy and practice perspective—that is, does HTA adequately influence decisions and does it support an efficient and effective health care system?

CHAPTER 1

Introduction

Chapter Summary

- Stakeholders want and need information and evidence to support decisions surrounding health technology development, bringing new health technologies to market, and procuring, using, and paying for these technologies.
- With new approaches and more nuanced assessments of value, important qualitative improvements need not come at the expense of fiscal sustainability.
- Health care systems and the populations they serve can reap the benefits of new technologies or innovations while maintaining value for money by optimizing processes with the help of health technology assessment (HTA).

Health care providers, hospital administrators, public and private payers, government leaders, patients/individuals, manufacturers, and regulators want and need information and evidence to support decisions about developing new health technologies, bringing them to market, procuring them, using them, and paying for them. HTA can help stakeholders make informed decisions that harness the benefits of technology while getting value for money.

Health care spending throughout the developed world is coming under increasing scrutiny as budgetary constraints mount. Although the introduction of new technologies into health care systems has in the past been perceived as a significant cost driver, new approaches in procuring innovation and more nuanced views on value generate hope that important qualitative improvements need not come at the expense of fiscal sustainability. With optimal processes, health care systems and the populations they serve can reap the benefits of new technologies or innovations while maintaining value for money. HTA is an important aid in these processes.

What Is HTA?

According to the World Health Organization, HTA refers to “the systematic evaluation of properties, effects, and/or impacts of health technology. It is a multidisciplinary process to evaluate the social, economic, organizational, and ethical issues of a health intervention or health technology. The main purpose of conducting an assessment is to inform policy decision making.”¹ Typical health technologies evaluated include but are not exclusive to drugs, devices, therapies, diagnostic procedures, and health care services.

HTAs often consider both the direct (intended) and indirect (unintended and/or spin-off) consequences of technologies and interventions. Value

1 World Health Organization, *Health Technology Assessment*.

HTA is integrated into decision-making and procurement processes where it is meant to have effect.

for money is an increasing focus, including (at least in Canada) the desire to re-evaluate the way in which “value” is defined, measured, and interpreted within the context of HTA.^{2,3}

How Is HTA Generated and Used?

HTA’s purpose is to systematically review or produce unbiased evidence related to adopting new technologies, divesting from obsolescent ones, and ensuring appropriateness of use. HTA is used to determine the relative costs and benefits of health technologies, usually employing health economic evaluation to inform decision-making regarding access, prioritization, and reimbursement. Its purpose is to help stakeholders make informed decisions that harness the benefits of technology while getting value for money.

Notwithstanding growing global interest in the role and power of HTA, it remains a relatively undeveloped, fragmented, and uncoordinated activity in many countries. In Canada, the HTA infrastructure is complex, with a mix of centralized and decentralized structures and processes, especially on the non-drug side. HTA functions are carried out by national groups, provincial bodies, and hospital-based units. Most health care funding and purchasing decisions are made by individual provinces and territories, rather than by a single national health care body as in some other countries. In individual Canadian jurisdictions, HTA is variably integrated into decision-making and procurement processes where it is meant to have effect.

The Intent of This Report

This report shines a light on the contemporary HTA landscape in Canada and documents the challenges of HTA functions. A comparison with other countries, including two international approaches to HTA in the United Kingdom and Germany, reveals potential lessons for Canada.

2 Best Medicines Coalition, *Position Paper*.

3 Menon, “Health Technology Assessment: The Journey Continues.”

Methodology

Research for this report was conducted through The Conference Board of Canada's Centre for the Future of Health. The Conference Board's work within the health innovation space is committed to enhancing the sustainability of Canada's health care systems through successful commercialization and diffusion of new medical and related technologies. Multiple methods were used to gather information and insights, including a rapid review of the published literature (peer-reviewed journal articles) and grey literature (white papers and reports and other non-peer-reviewed documents), key informant interviews, and an online survey of HTA producers (organizations that are involved in the process of implementation of HTA). Included in this report are two international case examples that were informed by key informant interviews and literature. Details on the methods can be found in appendices A, B, and C.

Limitations

The report was based on a 2015 review of the literature and consultation process. Since that time, changes to the HTA landscape, both in Canada and internationally, have occurred. These changes are reflected in a report update (with further consultation) conducted in April 2017.

CHAPTER 2

The Fundamentals of HTA

Chapter Summary

- HTA is used to determine the relative costs and benefits of health technologies. This information can be used to inform decision-making regarding access and prioritization.
- Health economic evaluation is contextual by jurisdiction, and results vary depending on the assumptions in the models and approaches used.
- For new technologies, there can be limitations to traditional health economic modelling methods—especially with respect to lack of comparator data.

HTA is often used to determine the relative costs and benefits of different technologies. The evidence may cover clinical effectiveness and cost-effectiveness as well as the social, ethical, legal, and organizational implications of introducing a new technology or innovation.¹ Outcomes typically include changes in mortality and morbidity although (depending on the jurisdiction) the number and types of comparators vary, with the most appropriate comparator generally being the best existing therapy based on the evidence.²

HTAs can be conducted by national groups, provincial bodies, hospital-based units, and others. They are typically supported or advised by multidisciplinary committees that rely on the input and expertise of people like physicians and other health care providers, health economists, and decision-makers, and sometimes have input from patients/consumers and industry experts. These committees generally play an advisory role.

Relative clinical benefit is the primary evaluation in HTA. Cost-effectiveness addresses whether improvements in outcomes due to a technology justify the costs (although thresholds may not be explicitly formulated and this can be a secondary consideration). The economic aspects of a technology's use are not routinely investigated by all agencies or in all cases, but they are increasingly being viewed as important.

Evaluation of cost-effectiveness is not a precise science, and results vary considerably depending on the assumptions in the models and approaches used. There can be a lack of consensus between HTA bodies and governments on which costs or values to include and how

1 For the purpose of this work, the Conference Board defines "innovation" as a "process that extracts economic and social values from knowledge using the generation, development, and implementation of ideas to produce new or improved products, services, or processes." The Conference Board of Canada, *Innovation Defined*.

2 Ibid.

The economic aspects of a technology's use are increasingly being viewed as important.

they should be measured. Direct costs are medical resources consumed within the health care delivery system for inpatient care, outpatient care, and technology products and services. Indirect costs account for societal expenditures and loss of productivity due to time spent attending appointments, disability, mortality, etc. Good data on such factors are not always available.³ Economic evaluation guidance, such as material recently updated by the Canadian Agency for Drugs and Technologies in Health (CADTH), can be useful.⁴

These matters are further complicated by the scope and duration of an assessment. For instance, a therapy may be deemed cost-effective for treating one symptom of a disease, but less so once other co-symptoms are included in the analysis. Likewise, when the time frame of an assessment changes from the short to the long term, health outcomes may also change. These and other factors can alter the perceptions of true value, especially for medical devices whose benefits may arise only after long application or in the area of systems improvement rather than patient outcomes per se.

Some variables can be controlled or tested via sensitivity analysis to afford greater confidence in HTA results. For new technologies such as companion diagnostics and precision therapeutics, there are limitations to traditional health economic modelling methods, especially around the lack of comparator data and use of a system perspective.⁵ A more detailed discussion on the economics of HTA evaluations can be found in Appendix E.

3 Boccuzzi, "Indirect Health Care Costs."

4 CADTH, *Guidelines for the Economic Evaluation of Health Technologies*.

5 Slater and others, "The Emergence of Precision Therapeutics."

CHAPTER 3

The Changing Landscape of HTA in Canada

Chapter Summary

- CADTH oversees much of Canada's HTA effort as both an evidence producer and an information coordinator, especially for jurisdictions that lack capacity, and particularly for drug-related topics.
- A pan-Canadian HTA Collaborative includes membership from CADTH and other HTA producers, such as Quebec's l'Institut national d'excellence en santé et en services sociaux (INESSS), Alberta's Institute of Health Economics (IHE), and Health Quality Ontario (HQO).
- The Pan-Canadian Pharmaceutical Alliance is a recent development co-led by Nova Scotia and Saskatchewan on HTA focusing on generic drugs, with Nova Scotia and Ontario being co-leads for brand-name drugs. The Alliance allows the provinces and territories to work together to achieve greater value for publicly funded drug programs.

This chapter describes the HTA landscape in Canada, with a review of the pan-Canadian as well as jurisdictional perspectives and experiences for select provinces.

A Pan-Canadian Perspective

National Initiatives

Established in 1989 in Ottawa, and funded by the federal, provincial, and territorial governments, the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) marked a coordinated approach to HTA in Canada. CCOHTA was designed to better inform funding decisions at various health system levels. CCOHTA has since changed names and evolved to become CADTH, an organization that oversees much of Canada's HTA effort as both an evidence producer and an information coordinator, especially for jurisdictions without established HTA capacity.¹ Health Canada is now CADTH's largest funder.

To support decisions related to government drug plan inclusion at the federal, provincial, and territorial level, a centralized review process exists at CADTH through the Common Drug Review (CDR)² and pan-Canadian Oncology Drug Review (pCODR).³ These services are foundational to jurisdictional decision-making for drug coverage decisions. However, for non-drug technologies such as devices and procedures, no centralized process exists, which adds complexity. Local context can become important, especially with respect to factors such as infrastructure/capital equipment needs and system capacity, funding, and physician and staff training.⁴

A pan-Canadian HTA Collaborative currently includes membership from CADTH, INESSS, IHE, and HQO. Secretarial support is provided by CADTH. The Collaborative shares information on planned and ongoing projects to increase efficiency and reduce topic overlap. To

1 Menon, "Health Technology Assessment: The Journey Continues."

2 CADTH, *CADTH Common Drug Review*.

3 CADTH, *About the pan-Canadian Oncology Drug Review*.

4 Menon and others, "Introduction of a New Health Technology Into a Provincial Health System."

A pan-Canadian Pharmaceutical Alliance allows the provinces and territories to work together to achieve greater value for publicly funded drug programs.

date, the Collaboration has initiated and supported the development of a Canadian HTA search interface for an international HTA database based on a partnership with the United Kingdom's National Institute for Health Research Centre for Reviews and Dissemination. The database provides a common repository and search tool for HTA reports and includes materials produced by Ontario, Quebec, Alberta, and CADTH, as well as the 52 members of the International Network for Agencies for HTA (INAHTA)⁵ and 20 other HTA organizations. It has been proposed that the database incorporate structured decision-relevant summaries to ensure decision-makers have access to evidence in a user-friendly format, housed in a central repository.⁶ The Collaboration also acts as a forum for discussing and sharing information on other important HTA initiatives.

A pan-Canadian Pharmaceutical Alliance,⁷ founded in 2010, is co-led by Nova Scotia and Saskatchewan for generic drugs and by Nova Scotia and Ontario for brand-name drugs. This Alliance allows the provinces and territories to work together to achieve greater value for publicly funded drug programs. An office to support the Alliance's work has been created in Ontario. The Alliance is responsible for entering into negotiations with manufacturers and its recommendations are often contingent on cost-effectiveness or other factors that are raised during reviews.

HTA Resources in the Provinces and Territories

Canada's territories and smaller provinces do not have the infrastructure to undertake their own HTAs and therefore rely heavily on CADTH (through staff members known as liaison officers) and other provincial producers. Quebec remains separate with its own assessment organization, INESSS. Other provinces that also have their own HTA organizations in place, particularly for non-drug technologies, include British Columbia (BC Health Technology Review), Alberta (the Alberta Health Technologies Decision Process through Alberta Health, IHE, and

5 INAHTA, *Welcome to INAHTA*.

6 Polisen and others, "Supporting the Use of Health Technology Assessments by Decision-Makers."

7 Council of the Federation Secretariat, *How the pan-Canadian Pharmaceutical Alliance Works*.

HTA units at the universities of Alberta and Calgary), and Ontario (HQO). While mandates vary widely, most were established to enable their own capacity and to ensure a standard local approach to HTA. A level of HTA producers exists through some hospitals and regional health authorities to help with funding and acquisition decisions, as well as implementation.

Ontario's Experience

A key part of HQO's mandate is to make evidence-based recommendations about what patients can expect from the health care system. HQO makes recommendations to the Minister of Health about what health care services should be funded, and about clinical care standards through its Quality Standards program. Its website⁸ makes HTA reports, funding recommendations from the Ontario Health Technology Advisory Committee, and Quality Standards from advisory committees composed of patient and clinician experts available.

One area in which HQO does not make recommendations about public funding is prescription drugs. Typically, the provincial drug benefit plan accepts recommendations from CDR about whether drugs should be publicly funded or not, and for whom. Where additional research is needed, the Ministry of Health and Long-Term Care frequently works with the Ontario Drug Policy Research Network (ODPRN). Established in 2008, ODPRN is a collaboration of researchers that rapidly responds to policy-makers' needs for evidence to inform decision-making. Ontario is also rich in academic HTA groups, such as:

- Programs for the Evaluation of Technologies in Health (PATH) Research Institute at St. Joseph's Healthcare Hamilton, affiliated with McMaster University;⁹
- Toronto Health Economics and Technology Assessment (THETA) Collaborative;¹⁰
- Li Ka Shing Knowledge Institute of St. Michael's Hospital in Toronto.¹¹

8 See Health Quality Ontario, *Health Quality Ontario*.

9 See PATH, *Programs for Assessment of Technology in Health*.

10 See Theta Collaborative, *Toronto Health Economics and Technology Assessment Collaborative*.

11 See St. Michael's, *The HUB Health Research Solutions*.

Quebec has been working on improving access to promising innovative technologies in the health care field.

Quebec's Experience

The mission of INESSS is to promote clinical excellence and the efficient use of resources in the health and social services sector. Its core activity is assessing the clinical advantages and costs of the technologies, drugs, and interventions used in health care and personal social services. INESSS issues recommendations concerning adoption, use, and coverage by the public plan and develops guides to clinical practice to ensure optimal use.

INESSS employs 171 people and has a budget of approximately \$20 million. INESSS reports directly to the Ministère de la Santé et des Services sociaux to evaluate and recommend adoption of health interventions and devices, including drug and lab procedures. INESSS publishes lists of drugs and lab procedures that qualify for reimbursement by the government. The organization also develops practice guidelines and quality standards. Its approach focuses on the relevance of interventions through the integration of multiple knowledge sources (e.g., scientific literature, experience, and context).

Quebec has also been working on improving access to promising innovative technologies in the health care field. To speed up the adoption of those technologies, INESSS, collaborating with others in the field (government, industry, etc.), proposed an Optimized Process of Innovative Technologies Evaluation. At the heart of this approach is the introduction of considered promising innovative technologies (in a restricted context) and the development of proof of value based on data produced in real health care settings.

Several Quebec university health centres are linked with INESSS. A unit within a hospital may be asked by the government to undertake an assessment that will then be shared with other hospitals. An example is the Health Technology Assessment Unit at McGill University Health Centre, which was established in January 2001. Its purpose is “to advise the hospital in difficult resource allocation decisions, using an approach based on sound, scientific technology assessments and a transparent, fair decision-making process.”¹²

12 McGill University Health Centre, *Technology Assessment Unit of the MUHC*.

Quebec has also established the Advisory Committee on HTA and Innovative Technologies¹³ with wide stakeholder group representation, including patients, physicians, pharmacists, industry, researchers, HTA producers, and government. The Committee's task is to agree on a common language on innovation and challenges around technology innovation. In addition, the Conference Board's Institute du Québec has just released *Adopting Health Care innovations in Quebec: Suggested Alternative Models*, a report surveying the existing supply arrangements for Quebec's health care delivery system.¹⁴ The report recommends a shift from the current cost-based system to one that is value-based (i.e., shifting responsibility to bidders for suggesting solutions to problems defined by the purchaser). It states, "Elsewhere in the world, value-based procurement methods have made it possible to integrate innovation efficiently, without explosive cost increases for public systems."¹⁵

Alberta's Experience

In 2003, on the advice of Alberta's Expert Advisory Panel to Review Publicly Funded Health Services, the province adopted the Health Technologies Decision Process. This process involves the use of appropriate evidence and information for decision-making on the public provision of health technologies and services, and acts as a bridge among research, public policy, and service delivery. Four guiding principles (patient-centredness, transparency, efficiency, and quality) are the foundations of the process through the following steps: setting priorities; conducting health technology assessments; developing policy options, consulting stakeholders, and developing recommendations; and monitoring and evaluating the impact of policy decisions.¹⁶

Alberta Health has a Health Evidence and Policy Unit that administers the HTA process. Alberta Health, Alberta Health Services, or health professionals may make a request for a review and in some cases an HTA is required. Gaps between new innovations and the resources to

13 L'Institut national d'excellence en santé et en services sociaux, *HTA and Innovative Technologies Forum Report*.

14 Côté, Thomas, and Prada, *Adopting Health Care Innovations in Quebec*.

15 *Ibid.*, 29.

16 Alberta Health, *Alberta Health Technologies Decision Process*.

Strategic Clinical Networks could be used for disinvestment decisions.

provide them have necessitated a shift in the focus of HTA to informing decision-makers how best to adopt and deliver technologies and services in the most efficient manner from a systems perspective, with the purpose of optimizing health technologies. Exploring disinvestment in interventions that are no longer considered effective is also a priority.

Strategic Clinical Networks (SCNs) are becoming the vehicle to identify health technologies based on strategic clinical needs; they could also be used for disinvestment decisions. Created in 2012, Alberta's SCNs comprise researchers, physicians, patients, and managers who work together in a specified area to find new and innovative ways of delivering care (e.g., in oncology). There are now 14 SCNs based on clinical needs and supported by research and quality improvement. Alberta Innovates: Health Solutions (Alberta's leading health research and innovation organization¹⁷) works with the SCNs to help develop capacity. It is hoped that collaboration will lead to co-development, particularly through hospital-based HTA and perhaps early field evaluation.

The production of evidence for the provincial Health Technologies Decision Process is conducted by three research groups and is funded by Alberta Health, the Health Technology & Policy Unit at the University of Alberta in Edmonton, the IHE in Edmonton, and the HTA Unit at the University of Calgary.

British Columbia's Experience

On the medical technologies side (devices, diagnostics, and procedures), British Columbia has a centralized Health Technology Review process where health authorities can request assessment of a topic at a provincial level. This "bottoms-up" approach is practical for topic identification. Criteria are used to prioritize and select topics for assessment and reassessment, such as existing alternatives and patient, population, and cost impact. For technology that fits the scope of a review, an HTA report is commissioned with the work currently being done by independent organizations under contract. The Health Technology Assessment Committee, composed of representatives of the province's health

17 Alberta Innovates, *Supporting Health Research and Innovation in Alberta*.

authorities and a number of experts, meets regularly to review HTA topics and reports, and to make recommendations about implementation.

On the drug side, BC PharmaCare makes drug coverage decisions based on the work done by Health Canada and CDR, plus a provincial review. The province has a Drug Benefits Council (DBC) that is an independent expert committee composed of physicians, pharmacists, health economists, and the public who review drugs for consideration of listing. There are three steps in the provincial review: (1) gather information and input; (2) obtain a recommendation from the DBC; and (3) make a final PharmaCare coverage decision. If CDR recommends that provincial plans should not cover the drug, DBC will usually not review it; in these cases, the final PharmaCare decision is based largely on the CDR recommendation and input.¹⁸

HTA in Other Countries

This report examines two international HTA models as examples of other types of systems: the United Kingdom and Germany.

- In the U.K., the National Institute for Health and Care Excellence is an arm's-length organization from government that provides advice through technology appraisals to the health and social care system (primarily to the National Health Service England).
- The German Agency for Health Technology Assessment at the German Institute of Medical Documentation and Information produces reports used for the development of health policy in Germany, which include health, economic, ethical, and social measures.

These international models, and subsequent potential lessons for Canada, are explored in greater detail in chapters 6 and 7. The research conducted for this report identifies redesign opportunities for alignment and optimization. These opportunities, if leveraged, could help improve Canada's use of HTA as a tool to provide knowledge for informing decisions on the adoption and appropriate use of innovative drugs and medical devices.

18 B.C. Ministry of Health, *The Drug Review Process in BC*.

CHAPTER 4

Online Survey Results From HTA Producers

Chapter Summary

- In 2015, the Conference Board surveyed 13 organizations conducting HTAs in Canada (“HTA producers”) to better understand these organizations. A 42 per cent response rate limited estimating of values for the 28 non-responding organizations.
- Respondents thought that HTA in Canada is important for all areas of technology for both adoption and displacement, although they felt that the actual impact of HTA does not fully reflect this importance.
- They also noted that the actual process of conducting HTA is the most effective phase of the HTA assessment process, while the evaluation of HTA impact on health policy is not as effective as it could be.

Areas of Focus

Most respondents (11 of 13) said one of their main mandates is to generate HTA reports to support decision-making. Roughly half (6 of 13) also indicated that research to support public policy and resource allocation was a main focus. Only two organizations indicated that professional training in HTA methods was a main part of their mandate.

Number and Type of Staff

The number of staff reported to be working on HTA within any particular organization ranged from fewer than 20 in most organizations to more than 150 in the two largest. While most organizations said that their staff roster includes two or more types of role, one hospital-based unit reported that only clinicians undertake HTA research (while another hospital-based unit indicated that no clinicians were directly involved). Seven of the 12 respondents who answered this question reported that clinicians were involved in their HTA work. Of the other types of staff listed as being involved in HTA work, seven organizations reported medical librarians/information specialists, epidemiologists, and clinicians; six reported health economists; and five reported statisticians. (See Table 1.) In 10 of 12 organizations, all staff members involved in HTA work have at least a master's degree as their highest qualification. Six of the 12 reported that at least 50 per cent of their staff members have PhDs or MDs.

Table 1
Organizations Reporting Staff Roles Involved in HTA Work (for >5)

Role	Number
Medical librarian/information specialist	7
Clinician	7
Epidemiologist	7
Health economist	6
Statistician	5

Source: The Conference Board of Canada.

Size and Sources of Funding

Eight organizations reported that their budget for HTA activities was less than \$500,000 in 2014.¹ The other organizations reported 2014 HTA budgets of \$1 million or more. Nine of 13 (69 per cent) said this was about the same as previous years, with three saying the 2015 budget was higher than the 2014 budget and two saying 2014 was higher than 2013. For four organizations, the entire funding envelope is provided by the government,² with one respondent receiving no funding from a government source. After government, the other most common funding source was research grants (6 of 13 respondents), which made up the majority of funding for two organizations.

Types of HTA Work Undertaken

When asked which HTA areas they commit time to, all respondents indicated that they address more than one area, and 10 of the 13 listed three or more areas.³ A summary of areas of technology addressed is provided in Table 2. The area most commonly addressed was processes of care, reported by 12 of the 13 organizations.⁴ Medical devices and medical procedures were the next two most common areas of HTA completed (11 and 9 of 13 organizations, respectively), followed by combination technologies (8), pharmaceutical products (5), modes of intervention/organization of services (1), and laboratory testing/screening (1). When asked if their HTA work in these areas is used to provide evidence for technology adoption, displacement, or both, most respondents indicated that it was used for both.

- 1 Two other organizations reported that their HTA budget was \$0, which we interpreted to mean that HTA information is derived from activities whose main goal is not HTA.
- 2 Two other organizations listed their budget as being solely derived from the hospital budget. While not direct flow-through government funding, hospital budgets are largely public money. Other respondents considered the hospital budget to be a government source.
- 3 Of the 13 respondents, 12 directly answered this question. Areas for the single organization that did not complete this question were inferred from another part of the survey. Two organizations also only indicated later in the survey that they assess combination technologies.
- 4 One of the 13 responding organizations said that most of its HTA was in the area of modes of intervention/organization of services.

Table 2

Number of Organizations Reporting HTA Work for Adoption, Displacement, or Both

Technology area	Both	Adoption	Displacement	Don't know	Total
Processes of care	7	2	1	2	12
Medical devices	9	2	0	0	11
Medical procedures	8	0	0	1	9
Combination technologies	6	1	1	0	8
Pharmaceutical products	4	1	0	0	5
Modes of intervention/ organization of services	1	0	0	0	1
Laboratory testing/ screening	1	0	0	0	1

Source: The Conference Board of Canada.

Important Factors Affecting HTA Project Selection

All 13 respondents selected the top three most important factors in decisions regarding which HTA projects to undertake. (See Table 3.) Five factors were cited as being the most important for one or more organization, with burden of target disease and economic impact being the most commonly prioritized as the first or second most important.

Table 3

Importance of Factors Influencing Decisions to Undertake HTA Projects

Factor	Most important	Second most important	Third most important
Burden of target disease: mortality, morbidity, prevalence, incidence, disability adjusted life-years, quality-adjusted life-years	5	1	1
Economic impact	4	1	1
Critical evidence gap	2	1	2
Unmet health care need	1	4	1
Expected benefit of the innovation	1	2	1
Added value to decision-making	0	4	5
Other	0	0	2
Confirm expected benefit	0	0	0

Source: The Conference Board of Canada.

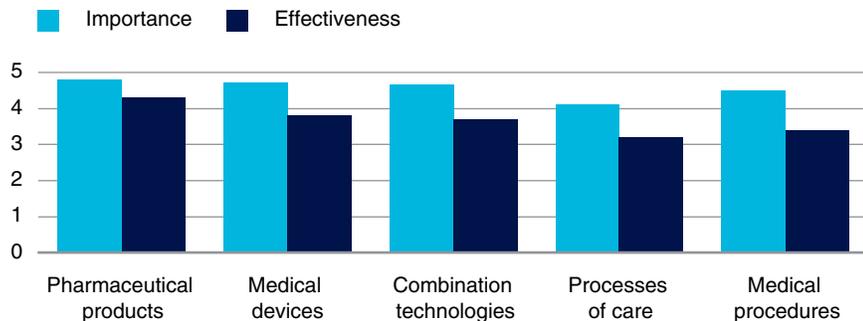
Opinions on Importance and Effectiveness of HTA for Technology Adoption and Displacement

The survey asked about the importance and effectiveness of HTA in providing evidence for the adoption of new technology and the displacement of existing technology. (See charts 1 and 2.) Most (12 of 13) survey respondents provided opinions regardless of their involvement in those technology areas. Although the low number of respondents makes statistical testing unreliable, it is still possible to see some trends in the data. Respondents thought that HTA in Canada is important for both adoption and displacement, although they felt that HTA effectiveness does not fully reflect this importance. Across all technology areas, the difference between importance and effectiveness of HTA was more pronounced in technology displacement than adoption.

Chart 1

Mean Score of HTA Importance and Effectiveness in Technology—Adoption

(1 = not important, 5 = very important)

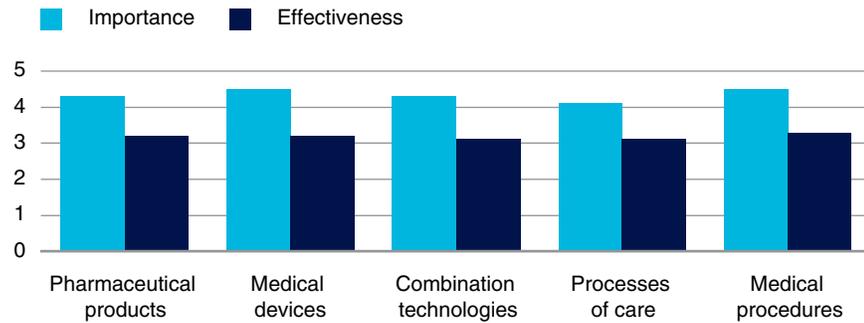


Source: The Conference Board of Canada.

Chart 2

Mean Score of HTA Importance and Effectiveness in Technology—Displacement

(1 = not important, 5 = very important)



Source: The Conference Board of Canada.

Types of HTAs Produced and Methods Used

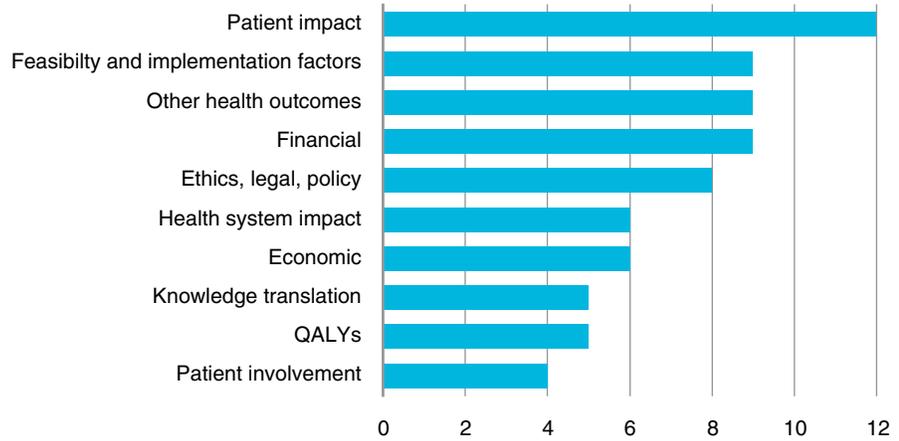
With respect to types of HTAs produced, all 12 responding organizations said they produce at least some full HTA reports. Eleven also produce rapid assessments. Six produce policy briefings to communicate their findings and two sometimes produce a different type of assessment (manufacturer appraisals and a report level between full and rapid assessments). All analysis types provided as choices on the survey were used by survey respondents. (See Chart 3.) All respondents stated that they use at least four types of analysis, and one reported that it uses them all. The analysis type most frequently cited was patient impact.

At least one respondent used all investigative methods itemized in the survey, although relatively few organizations used benchmark-testing, group judgment, clinical trials, and post-marketing surveillance. (See Chart 4.) Systematic review and meta-analysis were the most common.

Chart 3

Organizations Using Selected Analysis Types for HTAs

(number)

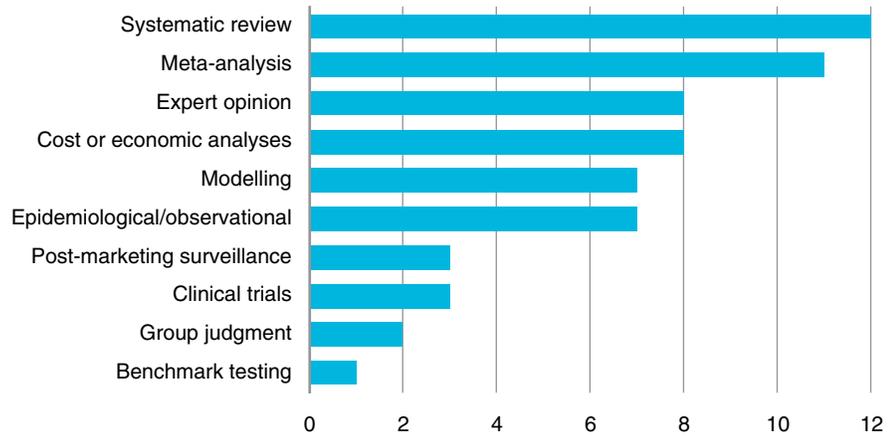


Source: The Conference Board of Canada.

Chart 4

Organizations Using Selected Analysis Types for HTA Assessments

(number)



Source: The Conference Board of Canada.

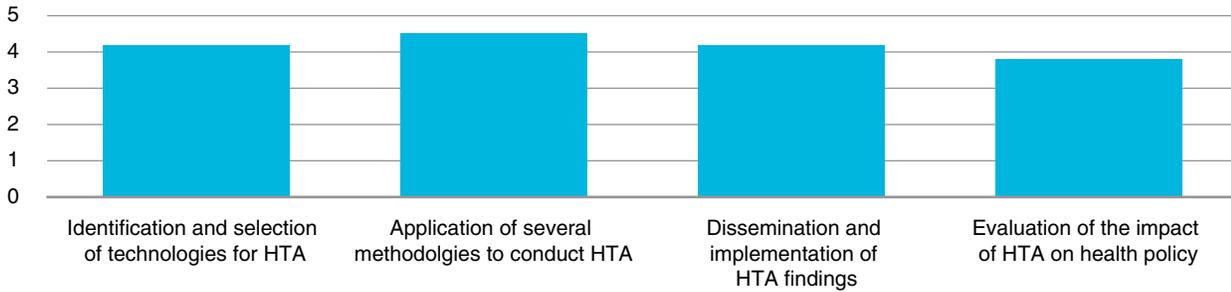
Opinion on Functioning of Phases of the HTA Process

When asked about the four phases of the HTA process in their jurisdiction, respondents identified the conducting of HTA assessments as working better than other phases. (See Chart 5.) They rated the evaluation of HTA impact on health policy as being the phase that worked least well.

Chart 5

Mean Ratings of Functioning of Four Different Phases of the HTA Process

(1 = not important, 5 = very important)



Source: The Conference Board of Canada.

CHAPTER 5

Challenges for HTA and Innovation in Canada

Chapter Summary

- About 40 interviews conducted in 2015 with a diverse group of experts identified challenges in the areas of HTA and health innovation in Canada.
- An overarching challenge is how to use HTA for policy and practice (i.e., how to ensure that HTA influences decision-making and supports an efficient and effective health care system).
- Main challenges included a need for greater involvement of decision-makers in the design of HTA, a need to better integrate patients and clinicians in the HTA process, harmonization of criteria within regulatory and commercialization processes, approaches to HTA non-drug technologies, consideration of a centralized approach to HTA to reduce duplication, improving HTA methodologies and metrics, ensuring an appropriate workforce to conduct HTAs, and better knowledge translation and implementation activities.

This chapter highlights key challenges facing the use of HTA for policy and practice in Canada. A series of expert interviews revealed three key challenge areas: identifying and selecting of technologies, conducting the HTAs themselves, and disseminating and implementing HTA findings. The chapter focuses on the essential elements required in each of these areas to ensure that HTA successfully influences decision-making and supports an efficient and effective health care system.

Identifying and Selecting Technologies

Explicit Priority-Setting and Transparency

The current priority-setting system of “first-in, first-out” can be ineffective. The primary mandate of HTA producers is to provide decision-makers with clinical and economic evidence that has been developed in an unbiased, reproducible, and transparent manner. Canada ventured into HTA more than 25 years ago, yet a disconnect still exists between the evidence provided by HTA and the materials needed for decision-making and implementation. Interviewees cited the need for more horizon- or environmental-scanning where HTA producers go to academic outfits to get advice on which diseases are the most important with respect to mortality and morbidity. Emerging considerations include integrating the patient experience and encouraging innovation. HTA producer mandates are therefore evolving; for example, INESSS produces clinical practice guidelines to accompany new technologies to aid in implementation.

One interviewee noted the reality of “big HTA versus small HTA.” Small HTA is when decision-makers ask researchers to quantify aspects of a technology to facilitate a decision. These topics never reach formal HTA bodies. If decision-makers can be explicit with respect to research questions and priorities, HTA producers can tailor their products

The HTA system is a push model, where CADTH does not actively look for products to assess because so many are queuing up.

accordingly.¹ British Columbia's Centre for Clinical Epidemiology and Evaluation is modelling care pathways and the use of technology along a pathway rather than a narrow question in a point in time.² Other provinces are looking at a range of technologies within a system of care, accompanied by the clinical pathways, tools, and technologies needed to deliver the care. Rare diseases also present a challenge to the HTA process as there can be a shortage of evidence.

Assessing Non-Drug Topics

Is a centralized approach to non-drug technologies needed or desired? Although CADTH and Health Canada communicate on priorities related to drugs, they do not always do so for non-drug topics. Several interviewees noted that the HTA system is a push model, where CADTH does not actively look for products to assess because so many are queuing up. New processes are being put in place, such as a public call for topics where a short list is produced. Interviewees noted that HTA is "something we borrowed from the pharma industry" for medical devices.³

Engaging With Clinicians

Enhanced clinician engagement is beginning, and CADTH's strategic plan has made this a focus, especially with hospital-based HTA. In Alberta, SCNs are composed of patients, providers, researchers, government, and others working together on 14 key areas such as cancer and seniors' health.

Engaging With Patients

At a national level, there is a heightened awareness that there are voices that should be considered and integrated early in the HTA process. Clinician engagement processes have been acted upon but the engagement of patients has occurred to a lesser degree. Many

1 An example came from the U.K. NHS. Researchers discovered that the health system cannot effectively identify stages one and two ovarian cancer in primary care settings. The testing algorithm had low-level sensitivity and was missing many cases. NHS is now going through an evaluation process to actively find available alternative tests.

2 Key informant interview.

3 Key informant interviews.

interviewees believe that more must be done in patient engagement, particularly compared with activities under way in the United Kingdom. CADTH now includes mechanisms for active regular communication involving patients, such as a patient forum and industry liaison positions. Public involvement differs among the provinces, with each having its own selection criteria and process for public submissions on a new technology. Role clarity and training around patient involvement in HTA is much desired.⁴ Choosing Wisely Canada is another initiative that will have an impact on HTA as a national campaign to engage clinicians and patients in conversations on tests, treatments, and procedures in order to make better decisions.

Harmonizing Criteria Within Regulatory and Commercialization Processes

Globally, discussions continue surrounding the harmonization of criteria among regulators, HTA producers, and funders. Opportunities exist for regulation and HTA to inform each other. A common international format for HTA does not yet exist. For drugs, this is required before international alignment of regulation is possible. In Canada, Health Canada regulates for safety and efficacy whereas funders focus more on procurement and use.

In the U.K., the Core Outcome Measures in Effectiveness Trials Initiative (COMET)⁵ brings together people interested in the development and application of agreed-upon standardized sets of outcomes, known as “core outcome sets.” These represent the minimum that should be measured and reported in clinical trials of a specific condition and are also suitable for use in a clinical audit.

Transparency of analysis by manufacturers is a concern to some of those interviewed, especially around assumptions in economic studies. Risk and reward incentives may be needed. Industry can make significant investments in new products, but the demand for data and evidence can be immense. A recent Health Canada decision to increase

4 McMaster Health Forum, *Evidence in Brief: Strengthening Public and Patient Engagement*; Scott and Wale, “Patient Advocate Perspectives on Involvement.”

5 COMET, *COMET Initiative*.

Advances in technology and high patient expectations are challenging traditional methods and limited health care budgets.

transparency in its regulatory process for drugs and medical devices may change attitudes in this regard—apparently the U.S. Food and Drug Administration and European Medicines Agency have recently introduced similar initiatives.⁶

To further build relationships, two interviewees felt that CADTH should look to industry for clarification before releasing a decision. HTA processes could be tied more closely with procurement, especially as evidence is generated through HTA on system impact. There is a desire for scientific advice earlier in the process (pre-market).

The MaRS⁷ Excellence in Clinical Innovation Technology Evaluation (EXCITE) program is looking at a process to assist med-tech companies in addressing regulatory, reimbursement, and HTA evidence requirements for multiple jurisdictions and payers. Its intention is to reduce product time to market. Innovations require resources to test new technology and, although results are often adequate for licensing and regulatory approval processes, they may not be enough to persuade jurisdictions to invest in them. EXCITE's evidence bundle includes field evaluation, systematic review (relative effectiveness), and economic analysis (cost-effectiveness and costs savings to the system).

HTA and Innovation

HTA can be a barrier to innovative technologies. One interviewee reflected on the existing focus on the need for randomized controlled trials and systematic reviews, which slows the process of innovation. However, advances in technology and high patient expectations are challenging traditional methods and limited health care budgets.

Innovation must add value for both the patient and the health system. “Personalized medicine” (care tailored to individual patient needs), precision medicine (biomarkers to identify individual risk of a disease), companion diagnostics (diagnostic tests that link information to a therapeutic product), and precision therapy (combined use of companion diagnostics or other biomarkers to identify eligible patients for targeted

6 Collier, “Health Canada to Increase Transparency.”

7 MaRS is a charitable trust based in Toronto that is focused on technology transfer.

drug therapy) represent a challenge for HTA.⁸ Assessment of test-treatment combinations will challenge both the regulatory processes of Health Canada and funding decisions of governments. Such innovations challenge the HTA process as little evidence may be available.⁹

In April 2015, the Ontario Ministry of Government and Consumer Services created a new program called REACH (Resources for Evaluating, Adopting and Capitalizing on Innovative Healthcare Technology).¹⁰ The purpose of REACH is to support Ontario health care provider organizations in using new methods to procure solutions to their high-priority needs—a process known as “innovation procurement.” REACH is managed by the Ontario Centres of Excellence on behalf of the Government of Ontario.

Conducting HTAs

Decentralization With Multiple Players

The demand for, and understanding of, evidence has come a long way. However, many interviewees commented on the patchwork approach to conducting HTAs in Canada, which often contains duplication and overlap, mostly on the non-drug side. HTA’s structures and processes differ across Canada and this can make sharing difficult. Provinces may negotiate independently with HTA producers. The proliferation of new and/or innovative technologies (especially medical devices and companions) raises concerns. Many interviewees cited the need for increased sharing of completed HTAs (primarily non-drug), although the HTA Database Canadian Search Interface has helped. Better harmonization with multiple players must occur to increase efficiencies. Considering local context is also necessary.

8 Slater and others, “The Emergence of Precision Therapeutics.”

9 Ibid.

10 Ontario Centres of Excellence, *REACH Program*.

Harmonization of methods continues to be a challenge among HTA producers.

HTA Methodology

HTA methodology continues to evolve, especially with respect to the use of wider societal factors and value-based pricing. The clinical and economic data required and available for drug assessments can be very different from those used for medical devices or diagnostics. A detailed discussion on the types of economic analysis to be further explored can be found in Appendix E. When economic analysis is undertaken, which costs to include can be debatable (e.g., a health service versus societal approach).¹¹ Harmonization of methods continues to be a challenge among HTA producers, both nationally and internationally. Using HTA produced in one setting for another is being explored, including via a EUnetHTA (European network for Health Technology Assessment) collaboration that developed an adoption toolkit.¹²

Various frameworks are being used to associate HTA with decision-making. For example, for its HTA work, Alberta Health uses a STEP process (Social characteristics, Technical effectiveness, Economics, Policy development). In Quebec, hospital-based HTA is being conducted in a systematic way through work on complexity, added value, and previous use of current technology (involving families).

In Ontario, there appear to be three main health technology pathways:

- On the drug side, many reviews come from CADTH.
- A number of non-drug interventions that could have a significant impact on the health system go to HQO and are evaluated using a decision determinant framework.¹³
- Some technology bypasses both HQO and the Ministry of Health and Long-Term Care as the technologies may not have significant health system impact and HTA is not a mandated step in decision-making and funding processes.

¹¹ Menon, *Health Technology Assessment: Lessons Learned*.

¹² EUnetHTA, *HTA Adaptation ToolKit*.

¹³ The Ontario Decision Determinants Framework will now include social values of Canadians, such as quality, evidence-informed policy, effectiveness, resource stewardship, resource sufficiency, equity, solidarity, population health, patient-centred care, collaboration, and shared responsibility for health.

HTA Timeliness

Decision-makers often need HTAs quickly—timeliness is a common complaint of HTA producers and recipients. This has led to a product called “rapid reviews” (versus full HTA reviews, which can be labour-intensive). The definition of rapid reviews varies considerably. In early 2015, the U.S. Agency for Healthcare Research and Quality released a white paper showing 36 examples of rapid products produced by 20 organizations, with production time ranging from 5 minutes to 8 months.¹⁴

Metrics

Interviewees queried whether the value of a technology should be measured using metrics such as quality-adjusted life-years (QALYs) and incremental cost-effectiveness ratios (ICERs), both having become part of HTA lingo. Many cited the need to use more non-traditional evidence, although one interviewee noted discomfort with the use of labour productivity. Societal impact, especially around equity, is important to consider and define. This approach may be reflected in an analysis that takes a societal rather than a health system perspective. Another interviewee suggested that interventions should look more at workforce implications when there are changes to scopes of practice and structures such as Ontario Family Health Teams. Ethical, legal, and other qualitative evidence are of increasing importance.

Capacity

Several interviewees noted that Canada needs to build its HTA workforce capacity, especially with respect to skill in health economics. Interviewees cited “academic haughtiness,” where researchers are evaluated based on the number of peer-reviewed publications instead of types of products (especially those written in language that can be understood by non-scientific readers). Conflict of interest can also be an issue. One challenge is that HTAs may be interpreted (in government and elsewhere) by people without health care/HTA skills but who nevertheless make decisions. The capacity to do systematic reviews

14 Hartling and others. “A Taxonomy of Rapid Reviews.”

is also diminishing since the announcement that Cochrane Canada's funding from the Canadian Institutes of Health Research ended in 2015.¹⁵

Disseminating and Implementing HTA Findings

Disinvestment

The use of HTA for disinvestment decisions is low in Canada. An example of disinvestment concerned coverage of DPP-4 inhibitors, or gliptins (a class of oral hypoglycemic drugs), in British Columbia. In this particular case, the government used a therapeutic review from CADTH and released a tender for manufacturers. One drug was delisted, although this move was controversial.

Several interviewees suggested that disinvestment will naturally happen for drugs; however, medical device decisions are more complex. As only a few technologies follow an HTA path, disinvestment is not a focus. One interviewee noted that being able to alter lab test menus and medical imaging practices after new evidence becomes available would be welcomed. Several suggested that HTA has focused on adoption rather than technology management and should incorporate “the life-cycle assessment of technologies in use, to assess their real-world performance.”¹⁶ There is more excitement about bringing something new to market than getting rid of an older therapy.

Disinvestment continues to be an issue on the international front as well. Health Technology Assessment International (HTAi) has an interest group in place to deal with obsolete or low-added-value technologies.¹⁷ The group aims to be a key international centre for sharing knowledge and expertise, both in methods for prioritizing and assessing obsolete or low-added-value technologies and in the practical application of disinvestment for health systems.

15 Cochrane Canada, *The Future of Funding for Cochrane Canada*.

16 Bryan, Mitton, and Donaldson, “Breaking the Addiction to Technology Adoption,” 379.

17 Health Technology Assessment international, *HTAi Interest Group on Disinvestment and Early Awareness*.

CADTH serves as both a broker of HTA and a producer.

Knowledge Mobilization

Knowledge mobilization and liaison teams work with various jurisdictions to get reviews into the right people's hands, including the use of plain-language summaries, social media, and conferences. CADTH serves as both a broker of HTA and a producer, and the CADTH liaison officers embedded in the provinces work to support health regions. Knowledge-related activities are seen as increasingly important among HTA agencies.

Evaluating the Impact of HTA on Health Policy

Post-Release Implementation Review

HTA must have a role and function. How evidence informs decision-making, especially around funding, procurement, and regulatory decisions, is important but unclear. CADTH looks at drug evaluation and tangible measures of impact; however, the devices side is challenging. In Alberta, IHE created a post-policy implementation review framework for the province.¹⁸ The IHE report noted that delays are usually not attributable to the agencies conducting the assessments but rather often upfront due to decision-makers delaying the development of the research questions. Data acquisition delays can also occur.

To better evaluate the impact of HTA on health policy, different types of evidence are needed. Many interviewees cited the need to invest in disease registries, improve information systems, and broaden access to data. Gaining access to medical information often remains difficult due to confidentiality concerns and rules. The Canadian Institute of Health Information has undertaken a registry for diabetic patients, although one interviewee noted problems accessing data.

18 Institute of Health Economics, *Frameworks for Post-Policy Implementation Review*.

CHAPTER 6

International Models of HTA

Chapter Summary

- Two international models of HTA, those of the U.K. and Germany, are examined in this chapter, including learnings for Canada.
- In the U.K., the National Institute for Health and Care Excellence, an organization that is arm's-length from government, provides advice through evidence to the health and social care system (primarily to the National Health Service England).
- The German Agency for Health Technology Assessment within the German Institute of Medical Documentation and Information produces reports that include health, economic, ethical, and social measures that are used to develop health policy in Germany.

Experts agree that “health systems are strengthened when HTA is integrated into the human and material resources, data, transparent decision- and policy-making, and linked to the overall vision of equity and accountability.”¹

In 2014, the World Health Organization released a resolution for member states to have a national system of health intervention and technology assessment in support of universal health care (through evidence-based policy development and decision-making).² Advanced countries have early warning systems or horizon-scanning processes to identify health technologies for assessment.³ There has also been some talk about aligning HTA internationally, especially for drug assessments; however, no common international format for HTA exists, nor is there alignment of regulation.

Organizations that exist to facilitate HTA collaboration on the international front include:

- EUnetHTA was established to create an effective and sustainable network for HTA across Europe and to include knowledge-sharing and good practices. Some joint assessments have been undertaken.⁴
- HTAi encompasses membership from 65 countries that share information and expertise through the production of papers and a policy forum.⁵
- The International Network of Agencies of Health Technology Assessment (INAHTA) is a network of 54 HTA agencies that share information about producing and disseminating HTA reports for evidence-based decision-making.⁶
- The Guidelines International Network (G-I-N) supports collaboration in guideline development, adaptation, and implementation in 47 countries.⁷

1 World Health Organization, *Health Technology Assessment of Medical Devices*.

2 World Health Organization, *Health Intervention and Technology Assessment*.

3 Oortwijn, Broos, and Vondeling, “Mapping of Health Technology Assessment in Selected Countries.”

4 See EUnetHTA, *Activities*.

5 See HTAi, *Health Technology Assessment international*.

6 See INAHTA, *Welcome to INAHTA*.

7 See G-I-N, *What We Do*.

Over the past four decades, in the European Union, the number of HTA institutions has multiplied.

- The International Information Network on New, Emerging and Obsolete Health Technologies (EuroScan) is a collaborative to exchange information on emerging new drugs, devices, and more. EuroScan currently has 19 member organizations, with a number from outside Europe, including Australia, Brazil, Israel, New Zealand, and South Korea, as well as CADTH and INESSS from Canada.⁸ Membership criteria include (among others) has developed or is developing a program for the early identification and assessment of emerging, new, or changing health technologies; ongoing, officially recognized role in relation to regional or national government; not-for-profit organization; at least 50 per cent funded by public sources; and has no link, other than scientific, with commercial companies or research and development centres.⁹

With respect to the European Union, in the past four decades, many countries have established HTA systems to inform coverage and pricing decisions.¹⁰ Since then, the number of HTA institutions has multiplied, with some European member states having established formal HTA programs and others still evaluating feasibility. In some cases (e.g., in Sweden, France, Netherlands, Spain, and Poland), HTA bodies perform a regulatory function as the conduct of HTA is mandatory, representing a formal step in the decision-making process. Regulation follows an HTA recommendation that is not binding for final coverage and decision-making, but regulatory bodies usually follow the HTA recommendations.

Two countries were selected as case studies for this report: the U.K. and Germany. Each case study includes a review of the country context, HTA processes, and opportunities to optimize HTA in Canada based on observations of the other agency.

United Kingdom

Context

The U.K. health care system comprises four separate health care systems: National Health Service (NHS England); Health, Social Services and Public Safety in Northern Ireland; NHS Scotland; and NHS

8 EuroScan International Network, *Current Organizational Members*.

9 EuroScan International Network, *Becoming a Member*.

10 Integlia and Mazzoni, *Health Technology Assessment in the European Union*.

Wales. The National Institute for Health and Care Excellence (NICE) is the main HTA body in the U.K. with a mandate to provide advice through evidence to the health and social care system. In 2013, NICE became an arm's-length body designed to be independent of political influence, as an Executive Non-Departmental Public Body. Governed by executive directors (a mixture of academics, clinicians, industry, and people interested in social care) and non-executive directors, NICE has an independent chair. All directors must apply and be appointed.

In 2014–15, a £64.5-million annual budget (about C\$100 million) from the Department of Health¹¹ covered 650 staff members, who worked closely with thousands of unpaid professional advisors who sit on independent advisory committees.

NICE technology appraisal decisions are the only legally binding, mandatory recommendations that NICE produces—these apply to drugs available through the NHS, about 100 of which are assessed each year.¹² The rest of the guidance NICE publishes is not mandatory but rather aims to support decisions made by staff working in the health and social care sector. Some standards work is mandated through national policy (e.g., developing indicators for primary care).

HTA Processes at NICE

Identifying Technologies for HTA

NICE has a sophisticated selection process that differs by type of technology. For example, interventional procedures examine safety and efficacy with input from clinicians or manufacturers, and horizon-scanning identifies new drugs for assessment. NICE is joining with innovators to bring new technologies to market, including elements to be evaluated for early-stage adoption. However, a systematic approach to disinvestment has eluded NICE, and NHS England has asked NICE to examine this further.

11 National Institute for Health and Care Excellence, *Strategic and Business Plan*.

12 National Institute for Health and Care Excellence, *Frequently Asked Questions*.

Compared with many countries, NICE has a wider variety of outputs.

Conducting HTAs

Compared with many countries, NICE has a wider variety of outputs, including HTA reports; quality standards; clinical, public health, and social care guidelines; and implementation tools. The National Institute for Health Research Horizon Scanning Centre examines pre-market technologies and thereby allows NHS to gain access to new drugs six months early. The Centre has commissioned at least 100 Medtech Innovation Briefings to assess medical technologies that may impact NHS.¹³

Innovation is allowing the players to start to think differently with industry about new innovative products. A May 2015 initiative was the establishment of an Office for Market Access to help life sciences companies prepare for NICE cost-effectiveness appraisals and improve their chances of gaining a “yes.”¹⁴ The purpose is to engage drug, device, and diagnostics companies in dialogue earlier to avoid problems that can crop up once a technology appraisal is already under way. A few months earlier, the U.K. launched the Early Access to Medicines Scheme to accelerate market entry for the most promising new drugs.

An admitted weakness of NICE is the time taken to produce guidance. For example, assessment for new drugs, devices, and tests takes about nine months to complete and more complex intervention appraisals can take longer.¹⁵ NICE continually refreshes its assessment methods, to help challenges on the devices side where evidence may be scantier.

A major tension exists between policy for the NHS and a more conservative approach. One side wants to introduce innovation and not have barriers, but the other requires a measured evidence-based HTA approach to ensure innovations are properly evaluated to determine risks and benefits. A scientific committee focuses on planning adoption of innovative technologies. A major review of the life sciences industry is under way, which may have significant changes for requests of NICE.

13 National Institute for Health and Care Excellence, *Medtech Innovation Briefings*.

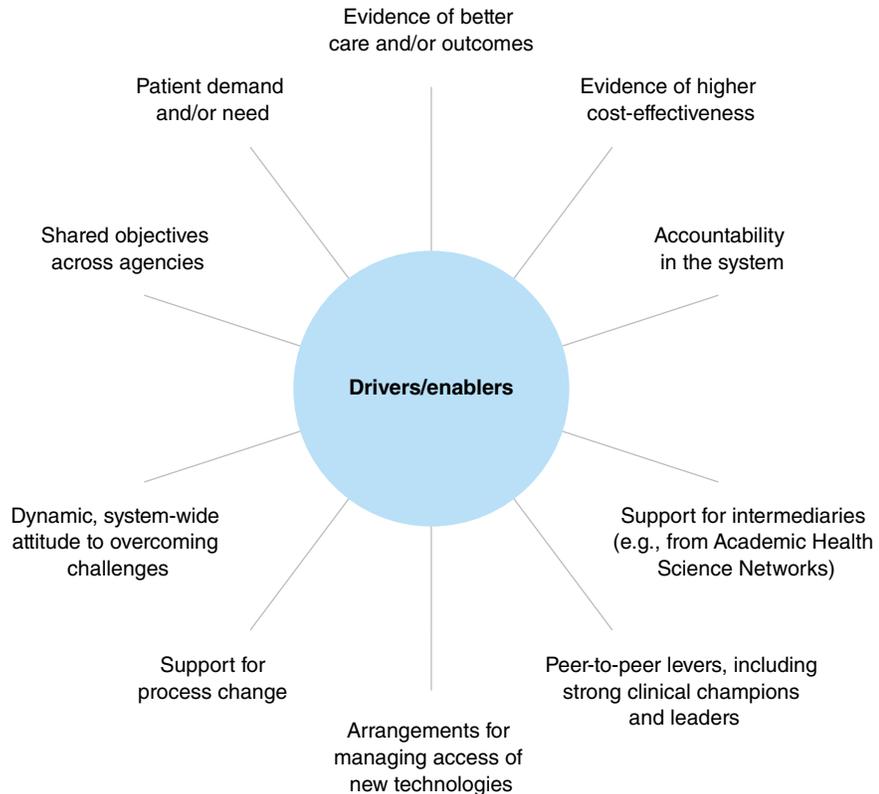
14 PharmPhorum, *NICE to Launch “Office for Market Access.”*

15 Key informant interview.

A report released in October 2015 identifies factors for rapid uptake of innovative products that will be used to build on as a new accelerated access landscape is developed.¹⁶ (See Exhibit 1.)

Exhibit 1

Common Drivers of Rapid Access to Health Technologies



Source: Accelerated Access.

Disseminating and Using HTA Findings

As a result of mandatory frameworks, NHS must make funding available within three months of NICE's formal guidance. However, although the guidance may conclude that a technology is cost-effective, NHS may not have the funds to implement it. Cost thresholds are in place (an ICER

16 Accelerated Access, *Accelerated Access Review*.

threshold of £20,000 to £30,000 per QALY), although social judgments may impact decisions. For example, a technology with a favourable ICER threshold may apply to a broad population, making affordability an issue.

The challenge of tracking uptake of new guidance is recognized by key NICE players. The NICE Implementation Collaborative (NIC) was formed in 2012 by 16 organizations drawn from public services, professional and patient bodies, and associations. NIC explores barriers and identifies solutions to overcome persistent problems that prevent change and implementation of NICE guidance. Its goal is to “harness the skills, experience, and dedication of organizations from across the health care system to support faster and more consistent access to NICE recommended medicines, treatments and technologies.”¹⁷

Observations Arising From Exploring NICE and HTA in the U.K.

- There is separation of the HTA production and policy-maker functions.
- As stakeholder engagement is a founding principle of NICE, all products go for public consultation.
- Enhanced transparency is required, especially of the appraisal process (stakeholders should know where topics are in the HTA queue and what the work priorities are).
- World-leading processes and methods for evidence preparation and credible guidance are continually developed and used, especially health economic evaluation.
- Organized guidance (quality standards, technology appraisal, tools, and guidelines) occurs along care pathways.
- Innovation is used as a catalyst for change (this has facilitated a positive change between HTA producers, government, and industry).

Germany

Context

Health care is funded through universal insurance schemes that have been compulsory since 2009. Most people are covered by about

17 Association of the British Pharmaceutical Industry, *NICE Implementation Collaborative*.

The Federal Joint Committee puts into practice the legal framework for health care set out by parliament.

130 “sickness” insurance funds that are primarily financed by the contributions of fund members.¹⁸ Most people use one of the statutory health insurance (SHI) schemes, although about 10 per cent opt into a private health insurance scheme.¹⁹ Both insurance types cover preventative care; hospital and primary care; mental, dental, and eye care; prescription drugs; rehabilitation; hospice and palliative care; and sick leave compensation. Long-term care is financed through a separate mandatory insurance scheme. States own most university hospitals. Municipalities play a role in public health activities and own about half of hospital beds. Otherwise, government has virtually no role in the direct financing or delivery of health care.

The ultimate decision-making body in the German health system is the Federal Joint Committee (FJC), an independent agency under legal supervision from the German government that puts into practice the legal framework for health care set out by parliament.²⁰ The committee consists of 13 voting members: 5 from the association representing the SHIs, 2 from the association representing SHI physicians, 2 from the hospital federation, 1 from the SHI association of dentists, and 3 unaffiliated members. Patient representatives advise voting members but do not vote.²¹

HTA Processes

Conducting HTA

In 2000, the use of HTA in Germany was formalized with the creation of the German Agency for Health Technology Assessment (DAHTA) within the German Institute of Medical Documentation and Information (DIMDI). The reports produced by DAHTA are used for development of health policy by FJC.²²

The powers of the FJC give it regulatory authority to determine which services the SHI schemes must cover and to set policy. FJC formulates

18 Rice and Smith, *Approaches to Capitation and Risk Adjustment in Health Care*.

19 The Commonwealth Fund, *International Profiles*.

20 Fricke and Dauben, “Health Technology Assessment.”

21 The Commonwealth Fund, *International Profiles*.

22 Kuhlmann, Braun, and Graf von der Schulenburg, “The Role of Decision-Analytic Modelling.”

directives that determine which drugs, procedures, and devices are available and reimbursed through the SHI schemes. The bulk of evidence used by FJC for approval and funding purposes is provided by either FJC's own HTAs or from assessments it commissions through the Institute for Quality and Efficiency in Healthcare (IQWiG), an independent scientific agency whose mandate is to report on the health benefit and cost-benefit of drugs, medical procedures (including devices), tests (and companion devices), and practice guidelines.²³

IQWiG and FJC require the use of effectiveness measures in their HTA reports (benefits found under routine or generally occurring practice conditions), whereas DIMDI will accept the use of efficacy data (benefits found under ideal conditions, such as in a lab²⁴).

Identifying Technologies for HTA Assessment

HTA assessments (termed "Benefit Assessments") carried out on new technologies by IQWiG can be commissioned by the FJC, Ministry of Health, or IQWiG itself.²⁵ The commissioning process is usually initiated by an application from physician organizations, sickness funds,²⁶ or a pharmaceutical company.²⁷

Disseminating and Using HTA Findings

FJC decisions are released as directives and further disseminated through the listing of technologies for reimbursement in SHI schemes. Once FJC makes a decision on a new technology, one of three things can happen—the technology can be deemed eligible or ineligible for SHI reimbursement, or assessment can be suspended pending availability of more evidence. This paradigm affects outpatient care, inpatient care, and drug coverage differently. In outpatient care, all new treatments need explicit FJC approval for reimbursement, while new in-patient treatments

23 Institute for Quality and Efficiency in Health Care, *Responsibilities and Objectives of IQWiG*.

24 Eichler and others, "Relative Efficacy of Drugs."

25 Chalkidou and others, "Comparative Effectiveness Research."

26 Fricke and Dauben, "Health Technology Assessment."

27 Ivandic, "Requirements for Benefit Assessment in Germany and England."

All drugs in Germany have been subject to reference prices since 2004.

can be reimbursed as long as FJC has not specifically excluded their use in SHI schemes.²⁸

For new technologies, access to the market is immediate without a price being set while awaiting HTA evaluation, FJC consideration, and the chance for Germany-wide eligibility.²⁹ For this, a temporary (one-year) reimbursement code to cover the use of new innovative products can be sought. The process, known as an NUB application, is performed by individual hospitals.³⁰ If successful, the hospital and the local SHI negotiate the reimbursement level for the year. If the product is not added to the universal reimbursement scheme by the end of the year, another temporary application may be sought. In 2010, NUB applications for 546 new methods were sought, of which 87 were granted temporary reimbursement.³¹

In addition to SHI listing, drug-pricing level is determined in different ways before and after FJC decisions. All drugs in Germany have been subject to reference prices since 2004 unless they show medical benefit over and above existing treatments. IQWiG evaluates cost-effectiveness and either adds the drug to a pricing reference group if there is no additional medical benefit (thus it has the same price as other drugs in the group), or initiates price negotiations between the manufacturer and the Federal Association of Sickness Funds. Starting in 2011, all drugs that have an accompanying scientific dossier demonstrating additional medical benefit are evaluated by IQWiG and FJC within three months.³²

In addition to the dissemination of HTA through FJC directives, DAHTA has a responsibility to maintain a searchable database of all HTA reports produced in Germany (full text is in German although English summaries are available), as well as those of some agencies outside of the country.³³

28 Fricke and Dauben, "Health Technology Assessment."

29 Integlia and Mazzoni, *Health Technology Assessment in the European Union*.

30 International Society for Pharmacoeconomics Outcomes and Research, *ISPOR Global Health Systems Road Map*, Germany.

31 MediClever, *A Shortcut to Medical Device Reimbursement in Germany*.

32 The Commonwealth Fund, *International Profiles*.

33 German Institute of Medical Documentation and Information, *Published HTA Reports*.

Aside from dissemination within the health care community, HTA work is disseminated to the general public when required. IQWiG has a mandate to produce plain-language information for patients and the public, either as accompaniments to the formal benefit assessments performed for FJC or as stand-alone reports on topics in the public interest.³⁴

Observations Arising From Exploring HTA in Germany

- The use of decision analytical modelling, as well as a focus on patient and caregiver perspectives, allows HTAs to be more flexible.
- HTAs can be initiated by a party other than a manufacturer. This counters potential delays in the evaluation process because of fear about withdrawal of reimbursement. This incentive is created by the practice of reimbursing most drugs and other technologies before FJC assessment.
- A clear mechanism to identify appropriate comparator treatments enables drug companies to fulfill the requirement that they provide evidence of added benefit over these existing treatments.
- FJC decisions to list a new item as reimbursable could be linked to disinvestment in existing technologies that have been superseded (similar to prescription exclusion lists that help control drug costs).
- Review of an HTA decision is not automatic but can be requested by FJC or a manufacturer. An automatic review after an FJC decision would stimulate evaluation and validation of initial evidence.
- NUB applications could be considered year-round, rather than once a year. This would bring promising products with successful applications into use more quickly.
- A successful NUB application by one hospital could be applied to a group of hospitals, rather than just to the hospital making the application.

34 Nasser and Sawicki, *Institute for Quality and Efficiency in Health Care*.

CHAPTER 7

Opportunities for Redesign in HTA

Chapter Summary

- Canadian governments are investing in HTA activities to provide a base for evidence-informed decision-making.
- Redesign could help improve Canada's use of HTA as a tool to inform decisions on the adoption and appropriate use of new and innovative technologies.
- Our findings show that there is opportunity for HTA redesign on the non-drug side (devices, procedures, and systems) where a patchwork system exists, in part due to Canada's structure as a confederation of provinces and territories that operate health systems locally.

The literature review, key informant interviews, online survey, and case studies revealed key redesign opportunities to improve Canada’s use of HTA as a tool to provide knowledge for informing decisions on the adoption and appropriate use of innovative technologies. (See Table 4.) Some of these insights were discussed at a Conference Board conference on innovation procurement in May 2015. (See “Conference on Value-Based Procurement.”)

Table 4
Issues and Opportunities for HTA Redesign in Canada

Issue	Opportunity for redesign
Alignment	
1. Priority-setting and transparency	<ul style="list-style-type: none"> • Create explicit, values-based criteria and processes for priority setting based on shared systems goals, distributed widely for transparency. • Separate functions of HTA producers and policy- and decision-makers to enable objectivity. • Explore a more centralized and networked approach for the assessment of medical devices/ procedures/systems. • Gather intelligence earlier on high value innovations.
2. Engagement with patients and clinicians	<ul style="list-style-type: none"> • Establish a public/patient involvement strategy founded on patient preferences and the values of technology. • Ensure early clinician engagement in priority-setting within care models to determine which new technologies are needed and when.
3. Harmonization of criteria among regulatory and commercialization processes	<ul style="list-style-type: none"> • Better align regulation and procurement evidence and processes by building on work already begun, such as temporary reimbursement codes (managed entry of access with evidence development) for new innovative technology and evidence bundles. • Incorporate representatives from industry earlier in HTA processes, especially in system priorities, transparency of analysis done by industry, and procurement decisions.
4. Decentralized system with multiple players	<ul style="list-style-type: none"> • Improve timeliness of assessments through an increase in the sharing of assessments among HTA producers and a centralized repository system.
Foresight	
5. Methodologies	<ul style="list-style-type: none"> • Integrate care pathways and modelling for specific diseases and health issues. • Where possible, standardize methods, frameworks, and formats nationally (and internationally), based on best practices and by types of technology.
6. Metrics	<ul style="list-style-type: none"> • Generate real-world data sets by disease. • Facilitate more research on cost data and their use in health economics.
7. Capacity	<ul style="list-style-type: none"> • Examine skill sets and education of those conducting HTAs. • Create an inventory of institutions producing HTA human resources. • Enhance sharing of methods and approaches among HTA producers.

(continued ...)

Table 4 (cont'd)

Issues and Opportunities for HTA Redesign in Canada

Issue	Opportunity for redesign
Optimization	
8. Disinvestment	<ul style="list-style-type: none"> • Focus on technology management to remove ineffective technologies and practices.
9. Knowledge mobilization	<ul style="list-style-type: none"> • Enhance automation and web-based approaches, such as mobile devices and health apps, especially for medical devices. • Engage decision-makers early and spend time working on the implications of implementation hurdles and barriers.
10. Post-policy implementation review	<ul style="list-style-type: none"> • Monitor and track uptake of technologies to determine impact on policies and outcomes.

Source: The Conference Board of Canada.

Conference on Value-Based Procurement

The Conference Board of Canada held a conference in Toronto in May 2015 called *Strategic Procurement and Innovation: Opportunities for Improving Canada's Health Care Systems*. The conference provided the opportunity to learn about Canadian and international examples of a significant shift toward strategic and value-based procurement in the global health care sector.¹ Participants and attendees discussed what it means to successfully “procure for solutions.” Shared insights were assembled into four key lessons.²

1. A strategic, value-based approach to procurement means taking a longer-term view of success and basing the value of products and services on a broad range of quantitative and qualitative objectives, from containing or reducing costs to creating long-term organizational efficiencies and improving the patient experience. Innovations in technology and the management and provision of health care services can provide substantial benefits over the long term and realize cost savings for both the implementing organization and the system as a whole.
2. Fostering collaboration among public and private stakeholders in health care and innovation is important to reach a clear understanding of the factors that buyers could take into account in addition to price when determining value. A case from the Imperial College Healthcare NHS Trust used private–public collaboration to develop and implement innovations to provide and manage

¹ Prada, *Value-Based Procurement: The New Imperative for Canada's Health Care*.

² Ibid.

cardiac catheterization laboratory services. Quality of care remained consistent or even improved, despite flat budgets.

3. Engaging clinicians and other key opinion leaders in the procurement process is critical to enabling and accelerating adoption. An example from Spain's Hospital Universitario de Salamanca described a complex set of operational constraints and budgetary pressures that showed how clinicians can play an important role in success.
4. Strategic value-based procurement is most successful when it is aligned among funders and buyers, broadly adopted, and informed by relevant data. An example described coordination, alignment, and information-sharing efforts undertaken by Novation Inc. with the help of its member councils, and the Réseau des acheteurs hospitaliers d'Ile de France in Paris that facilitated the adoption of value-based procurement across a diverse group of hospitals in France and elsewhere in Europe.

Source: The Conference Board of Canada.

Issues and Opportunities for HTA Redesign in Canada

Internationally, Canada is a world leader in HTA production. Governments continue to invest in HTA and see it as a foundation for evidence-informed decision-making. Some provinces have moved to separate HTA production, while also using the work of CADTH in relevant areas, particularly in drug reviews. Findings show that an opportunity for redesign lies on the non-drug side (i.e., medical devices, procedures, and systems).

HTA is perceived by some to stifle innovation. Transparency and harmonization could be improved with respect to processes, decision-making, and implementation, through assessment, regulation, and reimbursement and procurement steps. Dialogue among players is particularly important.

In the life cycle of technology, the Canadian system has assisted technology adoption but has had less success in disinvestment from obsolete or ineffective technologies. Canada could improve the managing of innovation and technology over time.

APPENDIX A

Methodology

Literature Review

This report was a synthesis and analysis of relevant literature, not a systematic review. For the initial report, multiple databases and primary search engines were used to identify publications from 2009 to March 2015, inclusive (PubMed, the HTA Database [DARE/NHS], Google, Google Scholar, and The Cochrane Library). Reference lists of pertinent documents were hand-searched to identify additional sources, as were journals specific to HTA such as the *International Journal of Technology Assessment in Health Care*. Additional references were suggested by key informant interviews.

Key words for the search, with synonyms and variations in spelling considered, were a combination of health technology, assessment, impact, review, process, system agencies, drug, pharmaceutical, medical devices. Inclusion and exclusion criteria are listed in Table 1. Both peer-reviewed and grey literature were sought.

Table 1
Literature Review Inclusion and Exclusion Criteria

Inclusion	Exclusion
<ul style="list-style-type: none">• Reputable journal and/or source• Extensive list of references• Regional, national, and international policy reviews analyzing the role and use of HTA within health and innovation systems	<ul style="list-style-type: none">• HTA reviews on specific technologies (unless they were relevant to policy)

Source: The Conference Board of Canada.

The literature review was complemented by a thorough search of websites of the most important HTA agencies in Canada, including CADTH, Quebec's INESSS, IHE, the Ontario HTA Committee, the ARCHE program at the University of Alberta, and the Memorial University Newfoundland and Labrador Centre for Applied Health Research. The websites of key ministries across provinces and the federal government (e.g., health, research and innovation, economic development, industry, finance) were sought in order to understand policy priorities, expectations, and plans around role, development, adoption, and use of new and old technologies in health care.

The report was reviewed and updated in April 2017, although an additional literature search was not done.

Key Informant Interviews

For the initial report, 34 one-hour key informant interviews were conducted over a three-month period from June to August 2015. The interviewees were selected using the criteria listed in Table 2, in addition to advice from experts. These telephone interviews were conducted using a standardized and validated interview guide. The questions focused on gathering expert insight into the opportunities and challenges to optimize HTA processes and function in Canada as well as future trends and current drivers in Canada and internationally.

Table 2

Key Informant Interviewees—Selection Criteria

- Extensive knowledge of HTA and trends (Canadian and international)
 - Producer of HTA: macro (national), meso (provincial), micro (hospitals and universities)
 - Representative of a stakeholder group: policy-maker, industry representative (pharmaceutical, medical devices, medical information), provider, or patient
-

Source: The Conference Board of Canada.

International Case Studies

Two countries were selected for study in order to understand the advantages and disadvantages of alternative HTA policy models. Experts suggested NICE in the U.K. and Germany. The selection criteria in Table 3 were also applied.

Table 3

Case Study Selection Criteria

- HTA used to rationalize health services
 - Mix of regional versus central/federal/national approaches to HTA
 - Have embraced health technology adoption policies that require disinvestment in old technologies to introduce new ones
 - Have linked the HTA model with economic development
-

Source: The Conference Board of Canada.

Online Survey

In 2015, an online survey of HTA organizations in Canada was undertaken in order to assess the size and diversity of Canadian HTA producers. As the number of HTA organizations was estimated to be relatively small, the Conference Board attempted to contact all of the HTA organizations identified. The initial contact list was developed by combining HTA organization lists found online. This list was refined based on consultation with experts.

The initial list of 38 organizations shrank to 31 as 7 were considered to be beyond the scope of this report, either because they are part of, or contribute to, a larger HTA-producing organization or because they did not consider themselves to be HTA producers (the response was incomplete so some non-responders may also not consider themselves HTA producers). The size of the survey universe and response rate is therefore highly dependent on whether those who self-excluded, or did not respond, should be considered in scope. To provide conservative estimates of the extent of our response, the following analysis is based on an assumption that all 31 of the organizations that remained on the

list were in scope. Response rates from different types of producers and provinces are shown below.¹

The most relevant person at each of the 31 organizations was initially contacted by e-mail or telephone. If no particular person could be reached, contact was made via online contact forms or a generic contact telephone number. Those successfully contacted were either sent the survey link via e-mail or noted to be out of scope. No organizations confirmed that they were in scope but unwilling to participate. After at least two weeks following delivery of the survey, a reminder e-mail was sent to all non-responders. After at least two more weeks, this was followed up by another reminder by phone or e-mail.

- Number of organizations identified: 31
- Response rate: 13 (~42 per cent)
- Responses: Quebec = 6/11, Ontario = 4/12, Alberta = 3/6, British Columbia = 0/2
- By producer type: Within a hospital = 6/13, within a university = 3/12, within a government department = 2/4, stand-alone independent = 2/2

The interview guide and survey questions are presented in appendices B and D.

¹ Due to the small population size, the number of responses, and high variability within response categories, an attempt to estimate values for non-responding organizations was not possible.

APPENDIX B

Key Informant Interview Guide

Section A: Key Informant Interview Profile (5 minutes with introduction)

Name of interviewer(s):

Name of interviewee(s), title(s), organization name, province, and date of interview:

Section B: Background (10 minutes)

1. Briefly explain your role and experience with HTA both in Canada and/or internationally. (Probe with selection criteria of extensive knowledge of HTA and trends, producer of HTA, and/or representative of a stakeholder group, pharmaceuticals versus medical devices.)
2. Generally, what do you believe is working in Canada in the assessment of health technologies as a tool to provide knowledge for informing decisions on the adoption and appropriate use of innovations that benefit patients and/or the wider health system? (Probe differences between medical devices and pharmaceuticals, divestment, and displacement.)

Section C: Challenges and Opportunities (20 minutes)

3. What are some of the challenges in Canada in the assessment of health technologies as a tool to provide knowledge for informing decisions on the adoption and appropriate use of innovations that benefit patients and/or the wider health system, as well as disinvestment and displacement

of pharmaceutical products and medical devices currently used? Please consider around the four steps of the HTA process:

- 3.1 identification and selection of technologies for HTA. (Probe how priorities are set, drug products versus medical devices, innovation, and needs of the health system.)
- 3.2 conducting the assessment. (Probe decentralized with multiple players, rapid reviews versus full HTAs, broader stakeholder involvement, harmonization of criteria with regulatory and commercialization processes.)
- 3.3 dissemination of findings from HTA. (Probe sharing of HTAs, transparency, use in disinvestment and displacement, and the role in reimbursement and decision-making, especially local levels.)
- 3.4 evaluation of the impact of HTA on health policy (i.e., how evidence informs decision-making, especially around funding, procurement, and regulatory decisions).

4. What are some of the opportunities to optimize HTA as a tool to provide knowledge for informing decisions on the adoption and appropriate use of innovations that benefit patients and/or the wider health system, as well as disinvestment and displacement of pharmaceutical products and medical devices currently used? Please consider the four steps of the HTA process:

- 4.1 identification and selection of technologies for HTA. (Probe how priorities are set, drug products versus medical devices, innovation, and needs of the health system.)
- 4.2 conducting the assessment. (Probe decentralized with multiple players, rapid reviews versus full HTAs, broader stakeholder involvement, and harmonization of criteria with regulatory and commercialization processes.)
- 4.3 dissemination of findings from HTA. (Probe sharing of HTAs, transparency, use in disinvestment and displacement, and the role in reimbursement and decision-making, especially local levels.)
- 4.4 evaluation of the impact of HTA on health policy (i.e., how evidence informs decision-making, especially around funding, procurement, and regulatory decisions).

Section D: Issues and Trends (15 minutes)

5. What are some of the major issues and trends affecting HTA in Canada over the last 30 years?
6. What are some of the major trends in the future that you believe will have a significant impact on HTA in Canada?
7. Are there lessons or opportunities for redesign to be learned from international jurisdictions in optimizing the HTA role and function in Canada's health care system?

Section E: HTA Assessment Measures (10 minutes)

8. Specifically, in the assessments of health technologies are there other measures (e.g., cost utility or cost-effectiveness, patient preferences, equity, prevention, value of innovation, low-value care, societal and unmet need) that would be helpful in procurement and funding practices?
9. Is there any other advice you could provide to better optimize the HTA role and function in Canada's health care system to ensure greater innovation and value from these investments?
10. Are there any articles, reports, publications, or organizations you would suggest we review for this endeavour?

APPENDIX C

Online Survey

Thank you for agreeing to this survey. This survey will inform a project being undertaken by The Conference Board of Canada on Health Technology Assessment (HTA). It is being done with the help of a Pan-Canadian advisory committee of experts in HTA in Canada from CADTH, INESSS, Medtronic, Health Technology Exchange, MaRS, Janssen, and Alberta Health Services. The study aims to assess the experience in Canada and internationally of HTA as a tool to inform decisions on the adoption and displacement of innovative pharmaceutical products and medical devices. We realize that there are very different HTA processes in place between pharmaceutical products and medical devices, so we have made efforts to separate these in the survey.

Along with our advisory committee, we are aiming to survey all organizations in Canada that perform HTA. In addition to this survey, several other methods will be used to gather evidence for this project, including a literature review, international case studies, and key informant interviews. Your individual responses are confidential and only aggregate results will be included in the project report.

The survey will take approximately 15 minutes to complete. If you do not feel you are the appropriate person to complete the survey, please feel free to pass it on to someone else within your organization. If you have any questions when completing the survey, please contact Philip Astles at astles@conferenceboard.ca. In recognition of your time and efforts for completing this survey, we will send you a summary report that will show the highlights of aggregate results.

A workshop will then be held in Ottawa at the end of the summer to discuss the key findings and dialogue on ways to better align health and innovation policies in Canada and assess the need and options for

optimizing the HTA role and function in Canada's health care system.
We hope to share with you the final report over the summer months. The
final report will be publicly available.

Warm regards,

Dr. Gabriela Prada

Director, Health Innovation, Policy and Evaluation
The Conference Board of Canada

APPENDIX D

Survey Questions

Table 1 contains all of the questions asked during the 15-minute survey.

Table 1
Survey Questions

Please provide the full name of your organization:

In which province is it located?

What is the main mandate of your organization (tick all that apply)?

- Generate HTA reports to support decision-making
- Train qualified professionals in HTA methods (in any of those methods listed in the fourth last question)
 - If so, how many students graduate each year:
 - What is the demand for these individuals? Please indicate the approximate proportion:
 - With a job offer in a related field before graduation
 - Employed in a related field within six months of graduation
 - Employed in a related field within one year of graduation
 - Conduct research to support public policy
 - Conduct research to support resource allocation
 - Other:

How would you classify your organization?

- Stand-alone, independent HTA agency
- HTA producer within a hospital
- HTA producer within an university
- HTA producer within a government department
- Other

What is the size of your staff? (Full-time equivalents)

What type of staff undertake HTA research in your organization? Please indicate the approximate proportion of:

- Epidemiologists
- Health economists
- System analysts
- Statisticians
- Decision analysts
- Clinicians
- Medical librarians/information specialists
- Other:

What is the approximate proportion of your staff whose highest level of qualification is:

- Master's
- PhD
- Post-doc
- MD
- Other:

(continued ...)

Table 1 (cont'd)

Survey Questions

Please indicate the approximate proportion of your funding over the last five years that has come from the following sources:

- Customer fees
- Research grant(s)
- Government funding
- Private source
- Other:

What was the approximate budget for performing your HTA activities in 2014? Please select the range that encompasses that of your organization:

- Under \$500,000
- \$500,000–\$1,000,000
- \$1 million–\$5 million
- \$5 million–\$10 million
- Over \$10 million
- Don't know

Compared to 2013, in 2014, was your budget:

- Lower
- About the same
- Higher
- Don't know

Compared with 2014, in 2015, is your budget:

- Lower
- About the same
- Higher
- Don't know

Please indicate the approximate proportion of time your organization dedicates to HTA in each of the following HTA areas:

- Pharmaceutical products
- Medical devices
- Combination technologies (drugs and devices)
- Processes of care
- Medical procedures
- Other

From the list below, please rank the top three factors that most influence your decisions on which HTA projects to undertake:

- Critical evidence gap
- Expected benefit of the innovation
- Economic impact
- Burden of target disease (mortality, morbidity, prevalence, incidence, DALYs, QALYs)
- Unmet health care need
- Confirm expected benefit
- Added value to decision-making

How many HTA projects did you complete in 2014?

- Under 5
- 5–19
- 20–49
- Over 50

Is the HTA work you perform used to provide evidence that leads to the adoption or displacement of:

- Pharmaceutical products (adoption/displacement/both/don't know/n.a.)
- Medical devices (adoption/displacement/both/don't know/n.a.)
- Combination technologies (drugs and devices) (adoption/displacement/both/don't know /n.a.)
- Processes of care (adoption/displacement/both/don't know/n.a.)
- Medical procedures (adoption/displacement/both/don't know/n.a.)
- Other (adoption/displacement/both/don't know/n.a.)

(continued ...)

Table 1 (cont'd)

Survey Questions

On a scale of 1 to 5, where 1 is not important at all and 5 is very important, how important do you think current HTA is in providing evidence that leads to the:

- Adoption of innovative pharmaceutical products?
 - Adoption of innovative medical devices?
 - Adoption of combination technologies (drugs and devices)
 - Adoption of innovative processes of care?
 - Adoption of medical procedures?
 - Displacement of existing pharmaceutical products?
 - Displacement of existing medical devices?
 - Displacement of existing processes of care?
 - Displacement of existing medical procedures?
 - Other:
-

On a scale of 1 to 5, where 1 is not important at all and 5 is very important, how effective do you think current HTA is in providing evidence that leads to the:

- Adoption of innovative pharmaceutical products?
 - Adoption of innovative medical devices?
 - Adoption of combination technologies (drugs and devices)
 - Adoption of innovative processes of care?
 - Displacement of existing pharmaceutical products?
 - Displacement of existing medical devices?
 - Displacement of existing processes of care?
 - Displacement of existing medical procedures?
 - Other:
-

What proportion of the assessments your organization produces fit within each category below:

- Full HTA report
 - Rapid assessments
 - Policy briefings to communicate HTA findings
 - Other
-

What type of analysis do you use in your HTA activities? (Mark all that apply.)

- Economic (e.g., ROI)
 - Financial (e.g., business impact analysis/cost-effectiveness analysis/other)
 - QALYs
 - Consumer or patient involvement
 - Other health outcomes
 - Patient impact (quality of life, patient preferences)
 - Ethics, legal, policy
 - Health system impact (e.g., productivity, human resources)
 - Knowledge translation
 - Feasibility and implementation issues and strategies
 - Other. Please specify:
-

What type of methods do you use while assessing technologies during any of your HTA activities? (Mark all that apply.)

- Clinical trials
 - Epidemiological and other observational analyses
 - Cost or economic analyses
 - Comparative analyses
 - Post-marketing surveillance
 - Modelling
 - Expert opinion
 - Group judgment
 - Benchmark-testing
 - Systematic review/meta-analysis
 - Other:
-

(continued ...)

Table 1 (cont'd)

Survey Questions

Regarding health technology assessment in your jurisdiction, **how well would you say that the following processes are working** in supporting the creation of knowledge for informing decisions on the adoption and appropriate use of innovations as well as disinvestment and displacement of old technologies? (scale of 1 to 5, where 1 is not very well at all and 5 is very well)

- a) Identification and selection of technologies for HTA
 - b) Application of several methodologies to conduct HTA
 - c) Dissemination and implementation of HTA findings
 - d) Evaluation of the impact of HTA on health policy
-

What, if any, are the opportunities to redesign HTA to **optimize** its role and function in your jurisdiction and Canada's health care system?

Would you say that HTA infrastructure is well organized, equipped, and aligned within your jurisdiction to appropriately and effectively support decision-making and public policy-making? (yes/no/don't know). Please explain your answer:

Source: The Conference Board of Canada.

APPENDIX E

Types of Economic Analyses

Cost-effectiveness analysis (CEA) is only one type of economic evaluation in health care, although it is important in the field of HTA. Cost-utility analysis is a special kind of CEA that calculates results in terms of a single, common unit of measurement, allowing technologies from different fields to be easily compared. Two other types of economic evaluations are cost-minimization analysis and cost-benefit analysis. (See Table 1).

Table 1
Main Types of Economic Evaluations in Health Care

Types	Number of health outcomes	Unit of health outcome
Cost-minimization analysis	None	None
Cost-benefit analysis	Many	Dollars
Cost-effectiveness analysis	One	Clinical
Cost-utility analysis	One	QALYs

Source: Cape, Beca, and Hoch.

Cost-minimization analysis is restricted to situations in which treatments are known to be identical in effect (health outcome) yet not identical in price. For example, costs will be minimized by prescribing the generic version of a brand-name drug. This technique is limited by difficulties in proving clinical equivalence.¹ In contrast, cost-benefit analysis measures costs and benefits in dollars, and an intervention is favoured when overall benefits exceed overall costs. For example, prenatal care for teenage mothers is associated with lower costs than

¹ Haycox and Martin, *What Is Health Economics?*

no prenatal care as it reduces the rate of pre-term or low-birth-weight babies who require more intensive care and have worse outcomes. Assigning monetary figures to some health outcomes is not always straightforward or accepted, making some people uncomfortable with cost-benefit analysis.²

In a CEA, only one health outcome from an intervention is investigated and compared against one or more alternative interventions to determine the best value for money. The health outcome is not expressed in potentially contentious monetary units, but in clinical or “natural” units, like number of ulcers healed, number of heart attacks avoided, or number of life-years gained.

There are two slightly different methods of comparison in CEA. (See Table 2.)

If interventions are independent of one another, they may be ranked according to their cost-effectiveness ratios (CERs). The lowest CER is the most cost-effective treatment. Independence means that one treatment’s implementation does not affect the costs and outcomes of any others.

If interventions are mutually exclusive, they are assessed by incremental cost-effectiveness ratios (ICERs). An ICER helps to identify whether a new therapy offers additional benefits over another therapy and at what expense. Exclusion exists in the likely scenario that implementation of one treatment restricts use of others due to competing costs or different outcomes.³

Table 2
Equations for Cost-Effectiveness Ratios and Incremental Cost-Effectiveness Ratios

$$\text{CER} = \frac{\text{Cost (C)}}{\text{Effect (E)}}$$

$$\text{ICER} = \frac{\text{Cost (A)} - \text{Cost (B)} = \Delta\text{C}}{\text{Effect (E)} - \text{Effect (B)} \Delta\text{E}}$$

Source: The Conference Board of Canada.

2 Hueston, Quattlebaum, and Benich, "How Much Money?"

3 Anderson and Phillips, *What Is a QALY?*

An ICER can give rise to four possible results: an intervention is more expensive and more effective, more expensive and less effective, less expensive and less effective, and less expensive and more effective. These results can be plotted on a “plane.” (See Table 3.) The second and last cases are clear-cut; they are respectively known as “dominated” and “dominant” (i.e., treatment is more expensive and less effective). CEA is most helpful in the other two cases. If a treatment is more expensive yet more effective, how much would one pay for each unit of improved outcome? If a treatment is less expensive and less effective, what degree of savings justifies each unit of suboptimal care?

Table 3
Cost-Effectiveness Plane

More costly less effective	More costly more effective
dominated, excluded	cost-effective
Less costly less effective	Less costly more effective
questionable	dominant, included

Source: The Conference Board of Canada.

Example of a CEA

In 2008, a group of American researchers sought to determine the cost-effectiveness of diagnosing allergic rhinitis.⁴ The condition is caused by inflammation of the nasal mucous membranes in response to allergens. Many patients experience reduced productivity and decreased quality of life, leading to a significant economic burden.⁵ Correct diagnosis helps to ensure the correct treatment and management of allergic rhinitis. Three common diagnostic methods are modified quantitative testing (MQT), intradermal testing (IDT), and in vitro testing (IVT).

For this study, the researchers calculated the fixed costs of testing supplies. Physician remuneration to administer a test was a variable cost. The measurement of effectiveness was the number of correct diagnoses for every 100 interventions. Assuming a prevalence in the adult population of 20 per cent, the researchers found that IDT had the

4 Lewis, Franzese, and Stringer, “Diagnostic Evaluation of Inhalant Allergies.”

5 Keith and others, “The Burden of Allergic Rhinitis (AR) in Canada.”

lowest number of correct diagnoses, followed by MQT, and then IVT. (See Table 4.)

Table 4
Cost-Effectiveness Analysis for AR Diagnostic Tests

Test	Cost (total charges per 100 tests) (\$)	Effect (correct # diagnoses per 100 tests)	ΔC (\$)	ΔE	ICER
IDT	11,200	77	11,200	77	145.45
MQT	6,630	85	-4,570	8	-571.25
IVT	13,000	87	6,370	2	3,185

Source: Lewis, Franzese, and Stringer.

CEA revealed that IVT is the most effective test. Nonetheless, the researchers recommended MQT as the best intervention in a baseline scenario because of the high incremental cost of IVT to achieve two more correct diagnoses. Sensitivity analysis indicated that the results might not apply in all contexts (e.g., some laboratories might have different expenses associated with each test, and a higher prevalence of allergic rhinitis would decrease the number of patients correctly diagnosed by each kind of test).

Cost-Utility Analysis

Cost-utility analysis is a type of CEA in which outcomes are converted into a common metric known as Quality-Adjusted Life-Years (QALY). The valuations are derived by multiplying the number of years that a patient is expected to live after an intervention by the perceived worth, or “utility” of each year. Utility is a score that is typically produced from standardized surveys where a combination of responses will produce a set number between 0 (death) and 1 (perfect health). Negative scores are sometimes used for conditions deemed to be worse than death. Thus, an intervention that affords a patient four years of life in a health state that is half as good as the ideal (0.5 utility) has an outcome of two QALYs.

The ICERs produced by cost-utility analysis are known as cost-utility ratios that measure cost per QALY. The benefit of cost-utility ratios is that they allow for quick and easy comparison of different treatments and therapies. Because QALYs act as a “common currency,” thresholds

can be established beyond which interventions in any domain will not be considered for funding or will be flagged for scrutiny. In general, QALYs are a useful guide for decision-makers when they are trying to determine resource allocation within health care systems.

Limitations exist. QALYs suffer from a lack of sensitivity when dealing with treatment of less severe health problems or when trying to compare two competing yet similar technologies. QALYs can be a challenge in chronic disease where survival is not a major issue and for preventive measures where the impact on health outcomes may be in the distant future. The concept of “utility” has also been criticized for paying inadequate attention to emotional and mental health problems or impacts on third parties like caregivers and family members. Finally, disagreement persists over how much society should be prepared to pay for a QALY, or whether thresholds should ever be enforced beyond acting as a reference point.⁶

6 Anderson and Phillips, *What Is a QALY?*

APPENDIX F

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