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Health Technology Assessment in Canada: 20 Years Strong?

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Introduction

For over 40 years, Canada has had a publicly funded, national health-care system designed to ensure residents receive "reasonable access" to "medically necessary" health-care services, regardless of their ability to pay [1]. However, unlike many of its European counterparts, Canada's system is a decentralized one, comprised of 13 separate provincial and territorial health insurance plans. Guided by common values (e.g., equity and solidarity) and responsible for meeting basic standards of coverage, these plans determine how best to organize, manage, and deliver health care within their jurisdictions. Decisions regarding which new technologies to include in the basket of publicly funded services, therefore, rest with individual provinces and territories, and the role of the federal government remains primarily limited to premarket approval and, in the case of patented pharmaceuticals, price regulation. It has, however, retained responsibility for providing services to limited populations, such as veterans, the military, first nations, and inmates.

Canada's history in health technology assessment (HTA), a field developed to support purchasing or coverage decisions, reflects the decentralized nature of the country's health-care system. Its roots predominantly exist at the provincial level, with the establishment of the *Conseil d'evaluation des technologies de la sante* (CETS) (now called the *Agence des technologies et des modes intervention en sante* [AETMIS]) in Quebec 20 years ago [2]. At around the same time, a joint committee representing the federal, provincial, and territorial ministries of health identified HTA as one of its key priorities and announced the creation of a national, independent HTA body called the Canadian Coordinating Office of Health Technology Assessment (renamed the Canadian Agency for Drugs and Technologies in Health (CADTH) in 2006). Funded by the provincial, territorial, and federal governments, its mandate is to provide impartial, evidence-based information on the clinical and economic implications of drugs and other health technologies (including devices, procedures, and systems) to the 13 public insurance plans. Since then, HTA has played an increasingly important role in technology coverage policy in Canada. With the demand for assessments exceeding resources available to the national HTA agency and the types of requests broadening to include context specific questions framed from perspectives other than that of society, the past 20 years have seen the emergence of local HTA initiatives in hospitals, regional health authorities, and provinces across the country. Now more than ever, decision-makers at all levels of government are investing in "institutionalized" HTA, creating a landscape shaped by a combination of ongoing national and local efforts.

In this article, the production and use of HTA in health-care decisions in Canada is described in Section I. Current issues in technology assessment are discussed in Section II. Section III represents our personal views on lessons learned from the HTA experience in Canada.

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SECTION I: HTA AND ITS USE IN HEALTH-CARE DECISIONS IN CANADA

Coverage decision-making processes vary not only by province or territory, but also by type of technology (i.e., pharmaceutical vs. nonpharmaceutical technologies), influencing the way in which HTA is conducted and used.

National Efforts to Produce HTA

CADTH, Canada's national HTA agency, remains the largest producer of HTA in the country. Governed by a board representing the federal, provincial, and territorial ministries of health (not including Quebec), CADTH carries out assessments on technologies deemed to be of national interest [3]. Specifically, potential technologies (including devices, systems, and existing drugs) are identified by the various levels of government and forwarded to one of two CADTH committees, depending on their type: the Advisory Committee on Pharmaceuticals or the Devices and Systems Advisory Committee. These committees, whose members also represent the federal, provincial, and territorial ministries of health, review the requests and identify those that should receive highest priority, from a national perspective, for assessment. HTAs of the selected technologies are then carried out in-house or commissioned to external public or private research organizations. Therefore, only a handful of the devices, systems, and existing drugs that comprise Canada's health-care system undergo formal reviews of their clinical and cost effectiveness. This is not the case for new drugs (i.e., those recently approved for sale in Canada but not yet reimbursed or covered through one of the publicly funded drug benefit plans). In September 2003, Canada launched the Common Drug Review (CDR) process, through which all new drugs, except for anticancer agents, must pass before a listing decision is made by the federal, provincial (not including Quebec), or territorial drug plans (CDR is a voluntary initiative for provincial and territorial plans) [4]. Housed at and managed by a dedicated directorate within CADTH, the CDR undertakes HTAs of new drugs for the purposes of providing listing recommendations to all of the drug plans. Accordingly, it represents an effort to reduce duplication and maximize the consistency and quality of assessments being used to aid such decision-making across the country [5]. The CDR process broadly comprises three steps [6]. A submission is prepared by the manufacturer in accordance with explicit

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submission guidelines and sent to the CDR Directorate. A Review Team (consisting of in-house and contracted reviewers and external experts) is assembled to draft a report based on clinical and economic evidence provided by the manufacturer and identified through independent literature searches. The report is then reviewed by the Canadian Expert Drug Advisory Committee (CEDAC) (a national, appointed body of physicians, pharmacists, other health-care professionals, and a member of the public), which evaluates the comparative therapeutic benefits and cost-effectiveness of the drug relative to accepted therapy and makes one of three funding recommendations to participating plans: list without conditions ("yes"), list with conditions, or do not list ("no"). Lastly, the recommendation is considered separately by each plan, which independently makes its own final decision. The CDR reviews drug submissions on a first-come-first-served basis, and manufacturers, as well as physicians seeking coverage for a new drug through one of the participating drug plans can initiate the process. However, exceptions may be made for drugs that meet criteria for priority review (new drug for an immediately life-threatening condition or serious disease for which there is no comparable available drug or new drug that could significantly (i.e., ≥$2.5 million Cdn/year) reduce drug expenditures. Since its inception, the CDR has reviewed approximately 120 new drugs.

Local Efforts to Produce HTA

The ministries of health in three of Canada's 13 provinces and territories have created and invested considerably in HTA initiatives designed to meet their specific needs. AETMIS, the HTA unit at the Institute of Health Economics (previously housed within the Alberta Heritage Foundation for Medical Research [AHFMR]) and the Medical Advisory Secretariat within Ontario's Department of Health and Long-Term Care comprise government-funded HTA bodies whose sole role is to produce assessments for policymakers in Quebec, Alberta, and Ontario, respectively. In both Alberta and Ontario, their work is supplemented by that of university-based programs, which hold grants from the ministries of health to not only conduct HTAs but also build HTA capacity in the two provinces [7,8]. On an even more local level, some hospitals in Quebec and regional health authorities in Alberta have established their own HTA units to generate information needed for specific technology acquisition and management decisions [9].

Although the scope, structure, format, and components of the reports vary with the requesting body (e.g., government, RHA, hospital, etc), approaches to ensuring their quality do not. Canada's HTA community has long been engaged in developing and implementing mechanisms for preparing rigorous, scientifically credible HTAs, producing one of the first sets of critical appraisal criteria and economic evaluation guidelines [10–12]. Adherence to these or similar guidelines is, if not mandatory, expected by those requesting and undertaking HTA across the country, regardless of the type of technology. In addition, each HTA organization has an established review process, overseen by a governing or advisory board, that incorporates input from clinical and methodology experts who are appointed on a per project basis. Lastly, reports are typically submitted for publication, in one form or another, to relevant peer-reviewed journals, with acceptance serving as a measure of their international credibility.

National use of HTA. Approximately 5 years ago, a comprehensive, pan-Canadian strategy for HTA, "which assesses the impact of new technology and provides advice on how to maximize its effective utilization in the future," was commissioned and approved by the Conference of Federal/Provincial/Territorial Deputy Ministers of Health [13]. Shortly thereafter, financial contributions to CADTH by the federal government increased exponentially. Although it may be argued that such a funding commitment is, in itself, an indication of the value of HTA to policymakers across the country, there have been relatively few formal attempts to examine, on a national level, exactly how it is used in decision-making [14].

Local use of HTA. Evidence of the use of HTA by local decision-makers is similar in quality and quantity to that reported nationally. Government investment in the three provincial HTA programs, informed by evaluations of their effectiveness from the funder's perspective, continues to increase at a time when there is heightened public accountability and scrutiny over expenditures on all health-care services and programs. Although such evaluations appropriately address questions of whether or not HTA is used, they generally provide little insight into the way in which it is used [15,16]. Recognizing this, Alberta's HTA unit, then located at AHFMR, developed a conceptual framework for assessing the impact of HTA. Although not yet implemented, this framework takes into account the various roles that HTA can play in decision-making, and encourages those involved to give careful consideration to the role that HTA has played in such processes [17].

The scarcity of information describing the use of HTA in Canada, both on a local and national level, may simply be a reflection of the environment in which it is employed. Over the years, several published studies and commissioned reports have highlighted the lack of clarity around how evidence, in general, informs funding decisions, calling for greater transparency in such processes [14,18,19].

SECTION II: CURRENT ISSUES IN TECHNOLOGY ASSESSMENT

Not surprisingly, current issues in Canadian HTA fall into one of two categories, those related to the production of HTA (i.e., assessment of technologies) and those related to its use.

Issues Related to the Production of HTA

Prioritizing technologies for assessment. Determining which technologies to assess and in what order continues to be a challenge for most HTA organizations in Canada. Although this challenge has been minimized for new pharmaceuticals with the creation of the CDR, there is still a need to set priorities when "priority reviews" emerge and disrupt the "first-come-first-served" system. As indicated earlier, the CDR has published criteria for defining priority pharmaceuticals and balancing their review along side those already underway. However, public information on the application of these criteria in practice is scarce. The same can be said for technologies that are not part of the CDR (i.e., existing and nonpharmaceuticals). Despite the availability of criteria developed by CADTH for selecting existing drugs, devices, and systems for assessment (the content of which is similar to those of other HTA organizations around the world), little is known about how these criteria are actually used to guide decisions (e.g., is one criterion weighed more heavily than another?) [20]. In the recent years, it has become increasingly clearer that priority-setting for HTA is value-laden, igniting calls for input from stakeholders beyond that of the funder [21]. Initial efforts to achieve this have focused on the public, with the

conduct of a citizen's jury aimed at identifying criteria the public feels should be used to set priorities for HTA [22]. Last year, the Ontario legislature passed a bill mandating the creation of a Citizens' Council to advise government on the social aspects of pharmaceutical policies and priorities, and commissioned the Institute for Clinical Evaluative Studies to prepare a report presenting recommendations for implementing it [23]. Since then, the report has been released, but a decision by government on how best to proceed has yet to be announced.

The remaining issues pertain to the types of evidence/data often available for assessment. Canada's HTA community has traditionally played an active role in both the development of methodologies for producing comprehensive, scientifically credible HTAs and the establishment of evidence expectations for arriving at decisive recommendations [10]. However, the extent to which these methodologies can be applied and expectations met depend, in part, upon the availability and nature of existing data. In HTA, such data largely consist of international clinical studies and economic analyses. Thus, it is reasonable to expect that the issues described in the further discussion are shared by most HTA producers around the world.

Relative therapeutic value versus relative efficacy. For pharmaceuticals, data are frequently limited to that required for market approval by Health Canada (i.e., evidence of safety and efficacy). As a result, they typically comprise placebo-controlled randomized trials of efficacy, rather than effectiveness, with relatively short follow-up periods. In the absence of the effectiveness data, HTA producers resort to using modeling techniques and sensitivity analyses to examine parameters such as longer time frames and possible variations in efficacy. However, even the most rigorous models often fall short of capturing not only important aspects of a drug when introduced into the "real world" (e.g., therapeutic benefit in the presence of comorbidities, adverse effects caused by polypharmacy, etc.), but also outcomes of value to patients, payers, and the broader public, as trials conducted for regulatory purposes typically focus on narrower, clinical measures (e.g., change in blood pressure or length of survival). In Canada, there is a growing body of literature suggesting that quality of life is one of citizens' top priorities [18,21,22]. Therefore, recognizing uncertainties in the relevance and validity of models, HTA review committees charged with developing recommendations are reluctant to place much weight on their results (Manns B. Chair, CEDAC. Personal communication, 2007) [24]. Given the absence of similar regulatory requirements for nonpharmaceutical technologies, available data are much less predictable, usually comprising studies of weaker design and quality [25]. Consequently, decisions around which of them to include in an HTA become judgment calls, which can lead to different findings across assessments of the same technology [26,27].

Incorporating values-based data. In Canada, national efforts to more meaningfully describe the value of a technology through HTA have focused on the ways of capturing the perspectives of patients and payers [3]. For patients, HTA relies on values-based data from studies measuring health-related quality of life (HRQOL). This information is then input into cost-utility analyses, which offer a means of establishing the value of a technology as seen by the payer. However, for some technologies, HRQOL data are not available, precluding the assessment of their value from the patient's perspective. Within the past couple of years, HTA has faced pressures to also examine the value of technologies to the public, and some preliminary work has been done [28]. A conceptual framework for accomplishing this has been developed but not yet implemented [21].

Transferability of economic information. Findings from a scan of HTA reports recently released by CADTH indicated that, where economic evaluations were performed, Canadian costing information—primarily from administrative databases—was used. However, all of the technologies assessed had already been introduced into the health-care system. In the case of new technologies for which no Canadian data are available, costs are generally extracted from sources that most closely reflect the Canadian context (i.e., public health-care system in a westernized country) and then converted into Canadian dollars. In compliance with CADTH's economic evaluation guidelines, sensitivity analyses are carried out around estimates to account for any uncertainties in them [12]. To the extent possible, costs for standard or common items associated with the use of a technology (e.g., operating room time, overnight hospital stay, nursing time, diagnostic tests, physician visits, etc.) are taken from local fee or reimbursement schedules, limiting the number of estimates required to a few technology-specific items [8].

Generating and using real-world data. Traditionally, HTA in Canada has comprised a form of secondary research, relying on existing data from various kinds of scientific studies. However, heightened awareness of the lack of sufficient evidence regarding the effectiveness of many new nondrug-related technologies has resulted in a commitment by the federal government to establish a coordinated Field Evaluation system [13]. As described in Canada's national strategy for HTA, field evaluations are mechanisms for obtaining evidence to support decision-making through primary research on the effectiveness of promising new technologies for which no "real-world" data exist, while meeting the care needs of patients who may benefit. On a local level, the Ontario Ministry of Health and Long-Term Care has already launched it own field evaluation program, partnering with clinical and academic research institutions around the province [29]. Although 10 such projects have been completed, and 24 are currently underway, no public information on the methodologies being applied appears to be readily available.

Field evaluations may also offer a means of dealing with issues of information scarcity surrounding certain high-cost drugs, such as those for orphan diseases. Enzyme replacement therapies used to treat Fabry disease and mucopolysaccharidosis, two extremely rare, inherited metabolic disorders, received negative recommendations from CEDAC on the grounds of insufficient evidence [30,31] This raised questions as to whether or not it would ever be feasible to collect enough information to satisfy a CDR-type organization when the condition affects only 1/100,000 individuals. Such questions remain unanswered.

Importantly, the field evaluation concept is akin to that of Coverage with Evidence Development, which was recently introduced into the United States Medicare and Medicaid Services reimbursement system [32].

Timeliness. HTA producers in Canada and abroad continue to face criticism over the turnaround times for assessments, which have often been well over a year. Nationally, CADTH has responded by creating a Health Technology Information Service, designed to provide information to decision-makers based on the "best available evidence" within 1 to 30 business days, depending on the urgency of the request. Responses range from "a list of the best evidence-based information to a formal report that includes an appraisal of the findings" [33]. Locally, both Ontario and Alberta have created systems through which full HTA

reports are to be completed within 2 and 3 month timeframes, respectively (from topic assignment to submission of the report) [7,8]. However, the extent to which this has actually been achieved remains unclear.

Lastly, to further address some of the issues discussed earlier, Canada's national HTA strategy called for the creation of a network of HTA producers across the country who would share knowledge, information, and experiences related to the collection of evidence and policy advice [15]. Such a network was established by CADTH approximately 2 years ago and is called the Health Technology Analysis Exchange (Exchange) [34]. Explicit details regarding its upcoming activities or priority topics have not yet been released.

Issues Related to the Use of HTA

HTA and innovation. Historically, HTA has been viewed by many as a "gatekeeper" for the health-care system. Technologies are often selected for assessment because of concerns over their potential financial impact [20]. As a result, HTA is seen as a way to say "no" to such technologies. However, in recent years, HTA has also become recognized as an enabler for the introduction of promising new technologies. Canada's Health Technology Strategy includes both innovation and HTA in its description of the life cycle of technologies and proposes a role for HTA in the development of new products [15]. Such plans to create a system through which HTA feeds into innovation and encourages it have not yet been implemented.

Transparency in decision-making. As discussed earlier, little is available in peer-reviewed literature about how HTA is actually used in decision-making across Canada. In fact, little is known about decision-making processes, both at the national and local levels. The lack of transparency has become particularly frustrating for patients and manufacturers searching for answers to why certain technologies received negative recommendations or decisions [14]. The CDR is taking steps to "open up" its process through the appointment of members of the public to CEDAC.

Independence. In Canada, technology coverage decisions are primarily made at the provincial or territorial level. This has created inequities in access to certain technologies across the country [35–37]. However, whether variations in the use of HTA by different decision-making bodies have contributed to such inequities is difficult to assess, given the lack of transparency around their processes.

One recently implemented initiative that may help to provide insight into such issues is the Health Technology Policy Sharing Forum (Forum) established by CADTH [38]. First proposed in Canada's HTA strategy, it is intended to serve as a mechanism for bringing together decision-makers across the country to discuss common areas of interest related to health technology policy [15].

Health policy and politics. Studies examining resource allocation and priority setting processes in different jurisdictions across the country have revealed that evidence is only one of the many factors that influence decisions [19]. Although phrases such as "an efficient health-care system" and "equitable access to services" are often associated with Canadian health policy statements, there are neither real mechanisms in place nor common, agreed-to definitions to help ensure that either endeavor is achieved. Findings from surveys of decision-makers have indicated that, on occasion, evidence has been "trumped" by political imperatives [39].

Silo budgeting. Health economists have long demanded that economic evaluations of health-care services be conducted from the societal perspective. In fact, most "best practice" guidelines for the production of such evaluations have made this an explicit requirement [12]. The difficulty is that no single "societal" budget exists. Decisions are typically made by budget holders who have responsibility for and authority over a small slice of the health-care pie (e.g., a provincial government drug coverage program, physicians' services, home care, diagnostic services, etc.). Therefore, what might be cost saving for one of these budgets might be cost-increasing for another. As a result, technologies shown to be cost-effective through evaluations conducted from the societal perspective are deemed inefficient because of budget structures. Currently, economic analyses included in HTAs produced on a local level are, more often than not, taking on the funder's or payer's perspective [7,8].

Parallel trade. Because of price differences for pharmaceuticals between Canada and the United States, parallel trade for these products exists. Although the magnitude (in terms of number of prescriptions and expenditures) represents only a small fraction of total pharmaceutical expenditures in the United States, it is significant enough to have drawn considerable media attention in recent years. There are a number of reasons for this, including price regulation at the Canadian federal level and the role of individual provincial formularies in setting price (which essentially becomes the standard price for a product for all buyers) [40]. HTA is an influence insofar as its role in formulary listing decisions are concerned. Although the CDR, based on HTA, offers listing recommendations that a provincial pharmaceutical program might decide to adopt, the process, in itself, is not a factor in price determination.

Patient and provider choice. For pharmaceuticals, there are three groups of payers in Canada: 1) the federal, provincial, and territorial governments (through social assistance, seniors, and other specialized programs, and universal coverage plans in Quebec and Saskatchewan), 2) insurance companies (providing coverage to some individuals and employees of organizations and businesses), and 3) individuals who do not fall into at least one of the first two categories. In the first two groups, patient choice is limited to pharmaceuticals included in formularies or benefit lists, the contents of which are determined by government or the insurance company. Because HTA—through the CDR—is part of all government-based decision-making processes, it has the potential to influence patient access. Insurance companies typically base their coverage decisions on those already made by government. However, physicians may prescribe any product that has received market approval from the federal government. Several years ago, the province of British Columbia implemented reference-based pricing for certain classes of pharmaceuticals. Therefore, if either a provider or patient chooses any product other than the reference product, the patient is responsible for paying the difference out-of-pocket [41]. For nonpharmaceutical technologies, the government is the primary payer. As with pharmaceuticals, governments, through their decision-making processes, determine which new technologies to provide. In provinces where HTA is also a part of such processes, it has been used as a way of ensuring that information on patient preference is considered [8].

Effects on budgets, reimbursement and coverage. As discussed earlier, HTA comprises only one of many factors considered by those involved in making funding decision across Canada, and its weight relative to these other factors remains unclear, even in general terms.

Quality-adjusted life year (QALY) thresholds. A cost/QALY threshold was first suggested in 1992 in Canada [42]. The proposed figure was $20,000 per QALY (1992 dollars) for the threshold below which a new technology ought to be adopted, and $100,000 per QALY for the threshold above which a new technology should not be adopted. A threshold figure that is cited now is US $50,000 per QALY. However, there is no formal evidence that any of these boundaries has ever been accepted or implemented by any Canadian decision-making body [36]. In fact, Laupacis has since stated that the traditional $50K/QALY "would be considered relatively unattractive" [43]. There has also been debate about the relevance of a threshold, and of the ICER itself, in resource allocation decision-making [44]. Thus, although QALY thresholds might exist in an implicit sense, there is no explicit evidence that they have been used during decision-making.

SECTION III: LESSONS FOR OTHER JURISDICTIONS

Health-care systems of the countries included in this Special Issue are, in many ways, very different from Canada's publicly funded, decentralized one. Nevertheless, some of the key challenges that Canada has faced are system-independent.

It is difficult, if not impossible, for a single HTA body to meet the information needs of decision-makers unless it is operating within a single payer system, such as the United Kingdom. In Canada, HTA has evolved to include a combination of national and local initiatives, reflecting the decentralized nature of its health-care system. Local initiatives, comprising HTA programs in several provinces, regional health authorities, and hospitals, provide "tailor-made" assessments framed in a local context. Because they maintain close linkages with the policymaking environment, they are well positioned to be able to respond to HTA requests in accordance with time frames established by decision-makers.

This distributed HTA activity has two consequences. As the decision-making focus moves from the national to a local level, the specific information needs become somewhat different. Although a "one-size-fits-all" approach to HTA may be appropriate for certain technologies, information and data specific to local environments (e.g., patient preference, resource implications, ethical considerations, implementation issues, etc.) is playing an increasingly important role in decision-making. As well, the methodological challenges become different, as, for example, the kinds of data available at a local level might be quite different from a national or state level. Methodological guidelines do exist for HTA, but they generally employ a societal perspective. Typically, health-care authorities take a payer's perspective.

Timeliness continues to be an issue with HTA in Canada. For example, out of necessity, CADTH has had to establish increasingly bureaucratic processes for HTA, and, as a result, these processes become lengthier. At the provincial level, attempts are being made in Alberta and Ontario to speed up the production of HTA reports; but it is not clear, at least at this point, what effect they have had on decision-making.

Transparency of HTA, as well as decision-making informed by HTA, continues to be criticized. For example, the exact role that cost-effectiveness analyses play in decisions of the CDR is not explicit. This is not unique to Canada, as HTA bodies in other countries have faced similar criticisms. Ultimately, though, this might be more of a criticism of decision-making in a complex area such as health care, rather than of the field of HTA itself.

HTA has had a long history in Canada, and governments continue to invest in HTA programs. This would seem to suggest that HTA is of use to these governments. But what has HTA actually accomplished in Canada? There have been external reviews of many of the HTA programs in the country, most of which have been positive, and in some cases, have resulted in additional funding. But important questions like what HTA has done to improve the introduction and management of new technologies in health, what patient and population outcomes it has helped achieve, how it has enhanced the introduction of promising new technologies, and what it has contributed to disinvestment of obsolete or ineffective technologies remain, to a large extent, unanswered.

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