Evaluation of CADTH 2016–17 to 2020–21

Final Report—December 9, 2021

BBMD Consulting Inc.

Table of Contents

Tables and Figures

Abbreviations

ACT	Adoptive Cell Transfer
AI	Artificial Intelligence
CAR	Chimeric Antigen Receptor
CDIAC	Cancer Drug Implementation Advisory Committee
CDR	Common Drug Review
CIHR	Canadian Institutes of Health Research
CIRS	Centre for Innovation in Regulatory Science
CMII	Canadian Medical Imaging Inventory
DRDs	Drugs for Rare Diseases
F/P/T	Federal, Provincial and Territorial
HB-HTA	Hospital-based Health Technology Assessment
HTA	Health Technology Assessment
HTAi	Health Technology Assessment International
HTM	Health Technology Management
HTR	Health Technology Review
IO	Immuno-oncology
INESSS	Institut national d'excellence en santé et en services sociaux
ISKM	Implementation Support and Knowledge Mobilization
ISPOR	International Society for Pharmacoeconomics and Outcomes Research
NAS	New Active Substance
NICE	National Institute for Health and Care Excellence
NOC	Notice of Compliance
NOC/c	Notice of Compliance with Conditions
OU	Optimal Use
PBAC	Pharmaceutical Benefits Advisory Committee
PCAC	Patient and Community Advisory Committee
PCHO	Pan-Canadian Health Organization
pCODR	Pan-Canadian Oncology Drug Review
pCPA	Pan-Canadian Pharmaceutical Alliance
PMPRB	Patented Medicine Prices Review Board
RBM	Results-based Management
RRS	Rapid Response Service
RR	Rapid Response
RWE	Real-world Evidence
SGBA	Sex and Gender-Based Analysis
TGA	Therapeutic Goods Administration

Summary

CADTH is an independent, pan-Canadian health organization (PCHO) created in 1989 by the federal, provincial and territorial (F/P/T) Ministers of Health to support the optimal use of drugs and non-drug technologies in Canada's healthcare system. CADTH's mandate is to deliver timely, evidence-based information about the clinical- and cost-effectiveness of pharmaceuticals and other health technologies, including devices, procedures and systems, to governments and healthcare decision-makers. This promotes evidence-based policy making that can lead to more effective use and purchasing of health technologies and pharmaceuticals.

CADTH is one of several federally-funded PCHOs. An independent organization, CADTH is held to account by its primary funders, the F/P/T governments. Core funding is provided to CADTH through financial contributions from Canada's F/P/Ts, excluding Quebec, which is served by its own health technology assessment (HTA) agency, Institut national d'excellence en santé et en services sociaux (INESSS). CADTH also obtains revenue through industry application fees and other fee-for-service contracts.

CADTH's Contribution Agreement with Health Canada requires periodic evaluations to assess CADTH's ongoing relevance, results and cost-effectiveness in the delivery of its programs and services. This evaluation focussed on the five-year period 2016–17 to 2020–21, and was conducted by BBMD Consulting Inc. between December 2019 and November 2021. The evaluation involved a review of internal documents, external literature and administrative and performance data, key informant interviews with CADTH and a sample of customers and stakeholders, a survey of Rapid Response Service (RRS) customers, and case studies. The Evaluation Steering Committee, composed of CADTH and Health Canada representatives, provided guidance and support to the evaluation team, including reviewing several drafts of this evaluation report.

Key Findings and Conclusions

Relevance

CADTH was found to be aligned with the statements of priorities of F/P/T Ministers of Health, specifically those in 2016 and 2018 expressing a common vision of creating a more adaptable, innovative and affordable healthcare system for all Canadians. CADTH has also aligned its structures, processes, products and services at all levels to respond to the priorities and the needs of its F/P/T funders and other stakeholders.

The Health Technology Management (HTM) landscape continued to evolve rapidly during the evaluation period. For the most part, CADTH has recognized the major HTM developments that have taken place, made good progress in its shift from an HTA to an HTM organization and adjusted its product and service offerings accordingly. Of note, CADTH improved Optimal Use (OU) reports to provide information about drug implementation issues, introduced the new RRS "living rapid review" and "ultra-rapid review" to provide timely information to customers, introduced the new Policy Service to support F/P/T health policy decision-making, and expanded the Implementation Support and Knowledge Mobilization (ISKM) team to improve implementation support. To ensure optimal alignment of new processes and implementation feasibility, CADTH has been working closely with Health Canada, as they develop a national strategy for drugs for rare diseases.

While Canadians have been afforded more timely access to drugs through the joint efforts of Health Canada and CADTH, the challenges related to increasing access to medical devices in Canada's healthcare system, an objective of CADTH's most recent strategic plan, are complex and the market path for medical devices is less straightforward than for drugs.

CADTH's products and services were found to generally complement those of other Canadian HTA bodies at the provincial and territorial and regional/local levels. A closer working relationship with INESSS was one identified improvement opportunity. There is general agreement, however, that duplication does exist in the review of non-drug health technologies at the local/hospital level. The 2018 review of PCHOs called for increased coordination of HTA work on non-drug technologies across Canada.

Design and Delivery

CADTH has made great strides in improving its engagement with its customers and stakeholders, including policy makers, patient support groups, clinicians and industry through a variety of mechanisms, and is widely viewed as a customer-centric organization. The main improvement opportunities identified include providing more guidance to patient groups and feedback on how their input is being used, increasing transparency of expert committees and enhancing engagement with clinicians.

While CADTH has made some progress in incorporating Sex and Gender-Based Analysis (SGBA) considerations as part of its HTA process, it is at an early stage in determining how to engage Indigenous Peoples and to reflect their concerns, along with those of other marginalized communities, at a very practical level. CADTH's Board of Directors has made clear the importance of Indigenous considerations and an internal working group on Indigenous initiatives has been established, among other efforts made in this regard. The challenge is to bring together different Indigenous voices, values and perspectives that considers evidence in a different manner against the backdrop of accelerating assertion of Indigenous data sovereignty.

CADTH appears to be adequately resourced to accommodate modest growth in demand for its various products and services in some programs, but remains challenged to meet capacity in the Formulary Program for which it cannot control demand or timelines for deliverables. CADTH has demonstrated that it is able to accurately project annual outputs of its Formulary Program and its HTM knowledge products and services, and has been able to leverage its human and financial resources to meet customer needs, though this has led to delays in work in HTM. Overall, actual production was generally consistent with projections over the evaluation period, indicating that CADTH has an accurate understanding of customer needs.

There are opportunities for CADTH to improve transparency and accountability, and efficiency and effectiveness, by enhancing its approach to Results-based Management (RBM). This includes improving the quality of performance indicators (and associated targets) relevant to sex and gender, and those for LGBTQ2+ and BIPOC communities, to better reflect CADTH's aspiration in terms of its products and services and SGBA considerations, improving the approach to assess the impact of its products and services, and developing a complete picture of the full cost of its products and services.

Effectiveness

CADTH's main customer and stakeholder segments generally have a high level of awareness of the CADTH's main products and services. One exception are clinicians involved in health technology adoption (clinical interventions and medical devices) at the local/hospital level. CADTH struggles for recognition among clinicians who are not directly involved in its review programs. Strengthening engagement with clinicians is an important part of closing the gap between evidence, policy and practice.

Demand for CADTH's HTM products and services has continued to grow and there is a high level of customer satisfaction. The wide range of implementation support activities and tools have helped to equip healthcare decision-makers with increased knowledge and skills related to drugs and devices.

CADTH's products and services appear to be contributing to the optimal use of drugs and devices. CADTH has contributed to a well-functioning process for listing of drugs by provinces and territories by providing evidence-based recommendations that are respected. The Formulary Program has facilitated more consistent official policy across jurisdictions. There has continued to be a gap between appropriate use and actual use on the ground, but to address this, CADTH has tried to specifically engage clinician groups, and introduced a wide range of implementation tools intended to change or influence practice or policy in pharmaceutical optimal use and medical device use decisions. CADTH has also helped decision-makers understand and use evidence to make better decisions about the use of medical devices. However, CADTH has experienced challenges engaging clinicians and other decision-makers involved in device adoption at the local/hospital level. It is questionable whether CADTH should provide evidence to inform decisions about optimal use of devices at this level given the sheer volume of new medical devices entering the market each year, the complexity of the market path to entry and adoption, the speed of innovation and patient demands, and the intrinsically more complex lifecycle management compared to drugs. There would be value, however, for Health Canada and jurisdictions to clarify where there may be common value to enhancing the use of HTA in the pan-Canadian or large jurisdictional procurement (or disinvestment) process for devices.

Efficiency

CADTH has ranked favourably in the Centre for Innovation in Regulatory Science's annual performance metrics benchmarking of eight HTA agencies related to New Active Substances. Next to Australia, Canada had the fastest median rollout time from regulatory submission to first HTA recommendation and the shortest median time between regulatory approval and HTA recommendation. However, in terms of median time from first world-wide regulatory submission to jurisdictional HTA recommendation, Canada was close to the bottom along with France and England.

In contrast to its collaborations with organizations across Canada, there are opportunities for CADTH to build on the general respect it enjoys as a leader among HTA agencies to collaborate more internationally. A major long-term opportunity is for CADTH to pursue formal collaborative efforts with other HTA agencies internationally, as Health Canada has done in the regulatory space.

CADTH continues to provide value-for-money on behalf of its F/P/T funders, although this picture is clearer for drugs than for devices. There are opportunities for CADTH to further increase its value proposition, by ensuring it has the required capacity to assess the latest technologies, such as immune-oncology drugs, to provide jurisdictions with implementation support.

The eventual introduction of a Canadian Drug Agency could yield efficiencies for the healthcare system. However, F/P/Ts will face many challenges in dealing with the fiscal impact of the COVID-19 pandemic. This could very well lead to increased demands being placed on CADTH in the coming years.

Considerations

The following factors were considered in developing the recommendations resulting from this evaluation.

The impacts of COVID-19 on the F/P/T fiscal frameworks will likely emerge in the near future. It is inevitable that fiscal restraint will be a fixture across Canada for many years. This could affect F/P/T jurisdictions in many ways, such as putting yet more pressure on healthcare budgets and reducing in-house HTA capacities.

The evaluation confirmed that CADTH continues to meet the majority of needs of the F/P/T funders and other stakeholders. Throughout the COVID-19 pandemic, CADTH has demonstrated that it can be agile and nimble.

This strongly suggests that there will be increasing demands placed on CADTH.

The above suggests that CADTH may face challenges in accommodating this potentially substantial increase in demand. In addition, there are no obvious new revenue streams for CADTH to pursue. Consequently, CADTH may be challenged to meet its timelines and quality standards, which could lead to reputational risk.

The federal government has been taking concrete steps to establish the foundations for national pharmacare leading to the creation of a Canadian Drug Agency, although the timing is uncertain. Establishment of a Canadian Drug Agency may well determine CADTH's future mandate and scope of products and services.

Given the above, it is evident that CADTH is at a critical juncture in its evolution.

Recommendations

The following recommendations are provided to help ensure that CADTH continues to provide value-for-money for Canadians.

Recommendation 1: The current strategic planning process should confirm the needs of F/P/Ts with respect to CADTH's Formulary Program and identify the implications for CADTH's processes and capacity

The HTM landscape continues to evolve rapidly and there are other trends and developments that are affecting, or will affect CADTH. The current strategic planning process should consult with provinces and territories to discuss and confirm these trends and developments. An action plan should be developed to ensure that CADTH is able to continue to offer a Formulary Program that is responsive to external trends and customer needs.

Recommendation 2: Review CADTH's role in the medical device space

Given the sheer volume of new medical devices entering the market each year, many of the issues faced by CADTH in the drug space, such as a high rate of innovation and patient demands, are an order of magnitude greater in the non-drug technologies space. While CADTH has achieved some success with medical devices, it cannot address all of the needs associated with the review of devices.

It is recommended that CADTH develop a strategy to guide its role in the medical device space and allocate resources to those areas with potentially the greatest patient impact. To maximize its impact, CADTH could focus on reviewing only those medical devices and clinical associated with pan-Canadian priorities (e.g., care of the elderly, virtual care, mental health, drugs).

Recommendation 3: Develop a comprehensive stakeholder engagement strategy building on CADTH's successful efforts to date

CADTH has made major strides in recent years in terms of its stakeholder engagement practices, and in this, CADTH is viewed as a leader internationally. However, public and patient engagement is complex.

As part of its transition to an HTM organization, it is recommended that CADTH develop a multi-pronged engagement strategy that considers the needs of the various customer and stakeholder groups, which includes a clear vision at the organizational level (i.e., not simply within discrete engagement processes).

In developing the engagement strategy, the issues to be considered include goals for engaging clinicians, guidance to patient groups, opening up expert committee deliberations to patient groups, and providing feedback about how their input is being used by expert committees.

Ensuring accountability of a senior-level position for stakeholder engagement is also recommended.

Recommendation 4: Improve engagement of Indigenous Peoples and other diverse communities to better reflect, at a very practical level, the different voices, values and perspectives

There are many disparities in Canada's healthcare system. CADTH has made important strides in addressing these by considering sex, gender and geography as part of its HTA process.

There remains an opportunity, however, to improve engagement with Indigenous Peoples and other marginalized communities, such as the LGBTQ2+ and BIPOC communities, while remaining sensitive to the long history of widespread discrimination and abuse these groups have faced through Canada's healthcare system, and the collection and use of data about Indigenous Peoples for purposes not in their best interests or benefit.

The Board of Directors has made clear the importance of Indigenous considerations, and CADTH has introduced some measures to engage Indigenous Peoples, including establishing an internal working group on Indigenous initiatives.

However, CADTH has struggled with how to reflect different Indigenous voices, values and perspectives, and those of other marginalized communities, in its work. The lack of data to support analysis of these subgroups, for example in drug reviews, is an additional challenge, particularly against the backdrop of accelerating assertion of Indigenous data sovereignty

This is not something that CADTH can (or should) attempt to do in isolation. Indigenous Peoples themselves are in the best position to determine if they would like to engage with CADTH and the manner in which to do so.

The main Indigenous representative organizations—Assembly of First Nations, Inuit Tapiriit Kanatami, Métis National Council, and Native Women's Association of Canada—have a long experience and wealth of knowledge in the health sector. It is recommended that these organizations are approached to begin the discussion, with the aim of developing a comprehensive strategy to reflect the different Indigenous voices, values, knowledge and perspectives in all aspects of CADTH's work.

Recommendation 5: Develop a strategy for collaborating internationally on drug reviews

CADTH is well-respected and considered a leader among HTA agencies. CADTH has successfully pursued collaborations with several international HTA agencies, but little has been accomplished in terms of concrete working level collaboration (in contrast to Health Canada's progress in international collaboration in the regulatory space).

CADTH's international collaborations have been mostly with English-speaking countries—there are other countries with similar healthcare systems as Canada, such as Italy and Spain, that should be considered.

In addition to generating potential efficiencies (e.g., reducing the cost of drug reviews worldwide and the time to market), collaborations have proven to be a valuable opportunity for CADTH's program and service innovation.

It is recommended that CADTH develop a strategy for collaborating with international HTA agencies on the conduct of drug reviews, focussing on knowledge exchange, alignment and joint initiatives.

Recommendation 6: Enhance the approach to Results-based Management

While CADTH has many of the components of RBM in place, the following improvement opportunities will strengthen transparency and accountability, and CADTH's ability to assess efficiency and effectiveness.

Firstly, improve the quality of performance indicators to better reflect CADTH's aspiration in terms of its products and services and SGBA considerations.

Secondly, develop a strategy to guide the selection of products and services for impact assessment (including reach), and a methodology to do so.

Thirdly, fully cost products and services through the refinement of its cost allocation model which would bring together indirect and overhead costs with direct program and service costs. This is the first step in developing a greater understanding of the relationship between corporate and support functions, programs and services, and the achievement of CADTH's expected results.

1. Introduction

1.1 Background

This report contains the findings and recommendations stemming from an evaluation of CADTH, covering the five-year period 2016–17 to 2020–21. This evaluation fulfills a requirement of CADTH's Contribution Agreement with Health Canada to periodically conduct an evaluation to assess CADTH's ongoing relevance, results and cost-effectiveness in the delivery of its programs and services.

Appendix A contains CADTH's logic model, a graphic displaying its main activities, outputs and intended outcomes.

The evaluation was conducted by BBMD Consulting Inc. between December 2019 and November 2021. The Evaluation Steering Committee, composed of CADTH and Health Canada representatives, provided guidance and support to the evaluation team, including reviewing several drafts of this evaluation report.

1.2 About CADTH

CADTH is an independent, pan-Canadian health organization (PCHO) created in 1989 by the federal, provincial and territorial (F/P/T) Ministers of Health to support the optimal use of drugs and non-drug technologies in Canada's healthcare system. CADTH's mandate is to deliver timely, evidence-based information about the clinical- and cost-effectiveness of pharmaceuticals and other health technologies, including devices, procedures and systems.

CADTH provides governments and healthcare decision-makers with evidence on the clinical and cost-effectiveness of drugs, medical devices, diagnostics and procedures. This promotes evidence-based policy making that can lead to more effective use and purchasing of health technologies and pharmaceuticals.

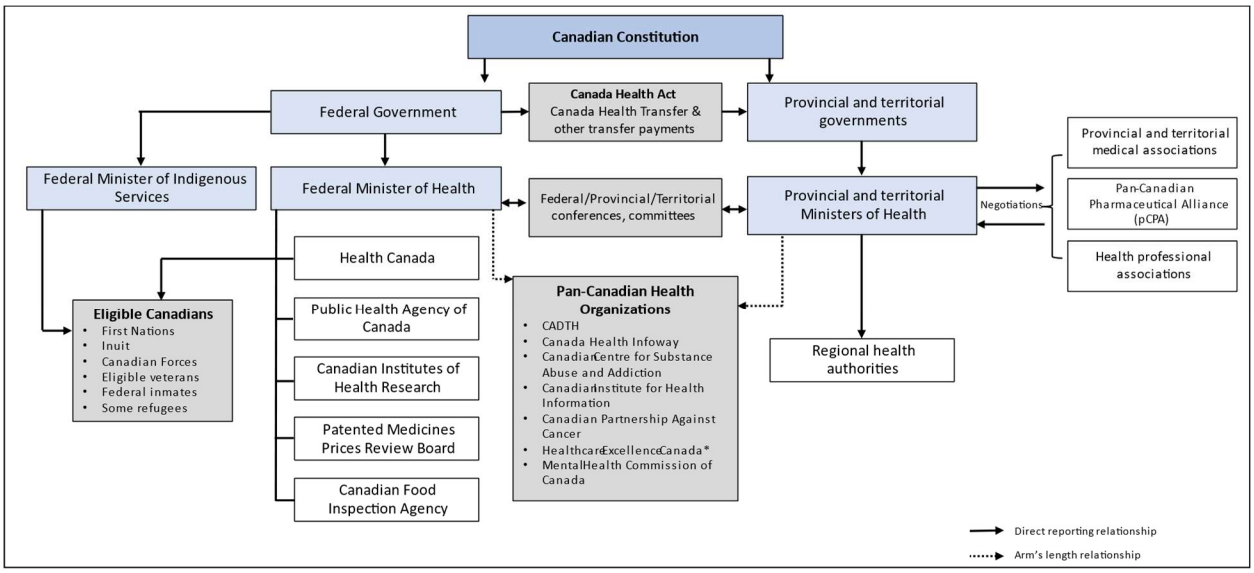
As shown in Figure 1 (p. 2), CADTH is one of several federally-funded PCHOs. An independent organization, CADTH is held to account by its primary funders, the federal government and the provincial/territorial governments. All of the PCHOs are expected to collaborate with F/P/Ts, health system leaders, healthcare providers, researchers, patients, the public and with each other to varying degrees.

Core funding is provided to CADTH through financial contributions from Canada's F/P/Ts, excluding Quebec, which is served by its own health technology assessment (HTA) agency, Institut national d'excellence en santé et en services sociaux (INESSS).

The federal government committed to provide CADTH up to $124.3 million in funds as specified in a Contribution Agreement covering the period April 1, 2018 to March 31, 2023. CADTH also obtains revenue through industry application fees and other fee-for-service contracts.

CADTH's budget for fiscal 2020–21 was $36.9 million, of which $26.1 million was provided by the federal government.

Figure 1: Canada's healthcare system.[1]



* The Canadian Patient Safety Institute and Canadian Foundation for Healthcare Improvement were amalgamated into Healthcare Excellence Canada on March 3, 2021.
Source: Adapted from D. Martin et al., *Canada's universal healthcare system: achieving its potential*, Lancet. 2018;391(10131):1718-1735.

CADTH's suite of products and services includes:

- **Drug reimbursement recommendations**—This service provides rigorous reviews of the clinical, cost-effectiveness, and patient and clinician evidence for drugs, in an effort to provide formulary listing recommendations to the publicly-funded drug plans in Canada (except Quebec, which is served by INESSS). The drug plans use this information to support their coverage decisions. There are two streams: i) the Common Drug Review (CDR), which reviews non-cancer drugs to make funding recommendations; and ii) the pan-Canadian Oncology Drug Review (pCODR), which reviews cancer drugs to make funding recommendations to cancer agencies and health ministries (with the exception of Quebec). In 2020, CDR and pCODR were combined to form a single Formulary Program.
- **Health Technology Management (HTM) Program**—Includes the following product categories:
    - **Rapid Response Service (RRS)**—Provides Rapid Response (RR) reports of health technologies.
    - **HTA Service**—Delivers a comprehensive assessment of the clinical and/or economic evidence on health technologies, as well as patient and caregiver perspectives and experiences, ethics analysis and organizational (implementation) considerations.
    - **Optimal Use (OU) Service**—Delivers a CADTH HTA, with recommendations from an expert panel or committee.

1 Adapted from D. Martin et al., "Canada's universal health-care system: achieving its potential," *The Lancet*, 391 (2018): 1718–1735.

  - **Environmental Scans**—Reviews current healthcare practices, processes or protocols to enable a better understanding of the national or international landscape.
  - **Horizon Scans**—Reviews new and emerging health technologies that are likely to have a significant impact on the delivery of healthcare in Canada.

- **Implementation Support and Knowledge Mobilization** (ISKM)—CADTH has an integrated ISKM approach that is applied throughout the product development and development life cycle and which facilitates two-way interaction between CADTH's staff and its customers and other stakeholders. A number of products, tools and events are developed to support decision-makers and "move the evidence into action":
  - **Evidence Bundles**—Web-based tools housed on the CADTH website that present findings from various CADTH reviews (mainly RR) on a specific topic.
  - **In Briefs**—These supplement CADTH's reports (i.e., RR, HTA, OU), providing a snapshot of the key information, findings and key messages from the report.
  - **Quizzes**—A web-based tool to engage clinicians on various topics related to CADTH products.
  - **Infographics**—Provide visual representations of key messages based on a CADTH review. Written in plain language, infographics are intended for multiple audiences.
  - **Newsletters**—Present findings from a CADTH report or reports on a specific topic, and are intended for multiple audiences (including clinicians, administrators, patients and the general public).
  - **Topic Teasers**—Provide a list of recent CADTH reports (typically those from the last five years) on a specific topic. Topic Teasers are often used at conferences to increase awareness of the range of topics reviewed by CADTH and may also be shared with customers.
  - **Knowledge Events**—Training sessions (e.g., skills building sessions and workshops) and educational events (e.g., webinars, conferences and presentations)
- Other Programs and Services:
  - **Scientific Advice**—Offers advice on a fee-for-service basis to pharmaceutical companies on their early drug development plans from an HTA perspective.
  - **Policy Service**—Provides decision-makers in F/P/T ministries of health with customized, fit-for-purpose policy support that complements CADTH's other HTM service offerings.

CADTH is governed by a 13-member Board of Directors, composed of an independent chair; a regional distribution of 6 jurisdictional F/P/T representatives; 5 non-jurisdictional representatives representing health systems, academia and the general public; and 1 observer (representing INESSS). The Board has overall responsibility for administering the affairs of CADTH and providing strategic direction.

CADTH collaborates with other HTA organizations across Canada, including Ontario Health (formerly Health Quality Ontario), INESSS (Quebec), the Institute of Health Economics (Alberta) and the British Columbia Health Technology Review, as well as with a large number of hospital-based HTA units that assess non-drug technologies.

1.3 Evaluation Approach

The first step in the conduct of the evaluation was to develop the research design. This involved conducting interviews with a sample of CADTH managers and Board members, which contributed to the preparation of an evaluation matrix listing the evaluation issues and questions, measurement indicators and data collection methods (Appendix B provides the evaluation questions and indicators).

The evaluation investigated the following issues which are in accordance with the Treasury Board of Canada's *Policy on Results*, supplemented by additional issues of interest to both CADTH and Health Canada:

- **Issue 1: Relevance**—Evaluation questions included an assessment of whether CADTH's products and services continue to meet the needs of the F/P/T funders; the extent to which CADTH has evolved in response to the major shifts in the HTM landscape; and whether CADTH's products and services duplicate or complement those provided by other healthcare organizations in Canada.
- **Issue 2: Design and Delivery**—Evaluation questions included an assessment of the extent to which CADTH effectively consults and engages with stakeholders (including patients, industry and clinicians); whether CADTH's activities, products and services reflect gender-based considerations and other considerations related to the needs of Indigenous Peoples and other diverse communities; and the extent to which CADTH has sufficient resources to meet the current and future needs of decision-makers.
- **Issue 3: Effectiveness**—Evaluation questions included the extent to which: health decision-makers are aware of and are accessing CADTH's evidence on drugs, clinical interventions and medical devices; CADTH is equipping them with knowledge, skills and supports; and CADTH is contributing to Canada having a modern and sustainable healthcare system.
- **Issue 4: Efficiency and Economy**—Evaluation questions included an assessment of the extent to which CADTH is producing its various products and services efficiently, and whether CADTH is providing overall value-for-money on the part of its funders and for Canadians in general.

The evaluation involved the following data collection methods:

- **Review of internal documents and external literature**—The Evaluation Working Group provided the evaluation team with a considerable volume of internal documents, including the previous 2016 evaluation report; CADTH's strategic plans and annual business plans; and CADTH's annual progress reports to Health Canada as required by the Contribution Agreement. The evaluation team also undertook an extensive literature review which focused on identifying relevant reports and articles related to the various evaluation issues and questions.
- **Review of administrative and performance data**—CADTH maintains a performance measurement framework and gathers and analyzes performance data related to the outputs and outcomes in the logic model. The evaluation also reviewed information from CADTH's

impact database as well as administrative data (e.g., financial data, volumes of outputs of the main products and services).

- **Key informant interviews**—A total of 88 telephone interviews were conducted within CADTH (29) (including members of the Board of Directors, CADTH's expert and advisory committees, all senior managers and a selection of other managers and staff) and with a sample of customers and stakeholders representing the following groups: F/P/T healthcare policy makers and drug plan managers (26); patient support groups (4); clinicians (5); members of the pan-Canadian HTA Collaborative (4); members of the pan-Canadian Pharmaceutical Alliance (pCPA) (4); pharmaceutical and medical devices industries (4); academics (6); and representatives of the international HTA community, including a sample of HTA agencies in other countries (6).
- **Survey of RRS customers**—An online survey was conducted of the population of 534 RRS customers over the four-year period April 2016 to March 2020. A total of 121 responses were received (response rate of 23%).
- **Case studies**—A total of six case studies were carried out which involved a focused examination of the following topics: 1) CADTH's reviews of two CAR T-cell products and provision of implementation support; 2) CADTH's Policy Service; 3) CADTH's Scientific Advice Program; 4) the Canadian Medical Imaging Inventory developed by CADTH; 5) CADTH's Evidence Bundle product offering, pertaining to pain management; and 6) ISKM's regional approach to customer support. Each case study involved a review of relevant documents and literature, and interviews with CADTH representatives and a sample of customers and other stakeholders.

1.4 Limitations and Mitigation Strategies

Most evaluations face constraints that may affect the reliability of findings.

Table 1 (p. 6) summarizes the limitations faced by this evaluation as well as the mitigation strategies put in place to increase the reliability of the evaluation findings.

Table 1. Limitations and mitigation strategies.

Limitation	Mitigation Strategy
The sample of key informants consisted of individuals who were knowledgeable about CADTH's activities. No interviews were conducted with non-users (i.e., clinicians who are not aware of CADTH and do not make use of CADTH's products and services).	The literature review did provide useful information on the healthcare system's perspectives, including those of non-users, towards CADTH.
In BBMD's experience conducting evaluations of federal programs, access to important foundational documents is not typically entirely or partially restricted. CADTH permitted only partial access to the *Health Canada/CADTH Contribution Agreement*. As a Cabinet document, and given the need to preserve Cabinet confidence, Health Canada could not permit access to the *Treasury Board Submission* related to the additional funding for CADTH announced through federal Budget 2017. Additionally, limitations were placed on the use of the 2021 *Key Program Operational Review: Recommendations Report* prepared by Optimus SBR.	CADTH did provide the evaluation team with selected sections of the *Health Canada/CADTH Contribution Agreement*, which are referenced in this evaluation report. The evaluation team did reach similar findings to the *Key Program Operational Review: Recommendations Report*, based on a review of performance data and input from key informant interviews. Regarding the *Treasury Board Submission*, Health Canada provided a summary of sections pertaining to CADTH and officials were available to discuss its contents; however, the extent to which this approach mitigated the limitation cannot be determined given the evaluation team did not have access to the entire contents of this document.
It was not possible to quantitatively assess CADTH's reach of all of its HTM knowledge products and services (i.e., the extent to which target audiences access and make use of them).	Some qualitative evidence was gathered on reach via the document review (e.g., CADTH gathers data on the usage made of some of its HTM reports), and from the key informant interviews, literature review and case studies.
Challenges experienced in assessing CADTH's performance in achieving its ultimate outcome: "CADTH contributes to Canada having a modern and sustainable healthcare system."	The evaluation was able to assess the various intermediate outcomes. Given CADTH's theory of change, it was assumed that achievement of the intermediate outcomes would contribute to achievement of the ultimate outcome.

2. Findings: Relevance

2.1 Do CADTH's products and services align with the needs of F/P/T funders, other customers and decision-makers?

Finding 1: Over the evaluation period, the joint statements issued by successive F/P/T Ministers of Health have reiterated the common vision of creating a more adaptable, innovative and affordable healthcare system for all Canadians. Statements have included shared commitments to support health innovation and improve the affordability, accessibility and appropriate use of prescription drugs, including harmonizing of drug plan formularies, and measures to reduce pharmaceutical prices and support appropriate prescribing, while striving to improve health outcomes. F/P/T Ministers of Health have also committed to working with First Nations, Inuit and Métis to improve access to health services and health outcomes for Indigenous Peoples. Successive federal budgets have reflected F/P/T shared priorities, including funding commitments to federal and PCHOs to support pharmaceutical policy initiatives, health innovation and implementation of national pharmacare.

In a January 2016 statement, the F/P/T Ministers of Health agreed to move ahead on shared health priorities, working collaboratively and guided by the common vision of creating more adaptable, innovative and affordable healthcare system for all Canadians. The statement included a commitment to enhancing the affordability, accessibility and appropriate use of prescription drugs, and considering a range of other measures to reduce pharmaceutical prices and support appropriate prescribing, while striving to improve health outcomes. F/P/T Ministers of Health also committed to improving care in the community, home care and mental health, fostering innovation in healthcare services, improving technology management, and examining how the existing PCHOs, such as CADTH, and provincial counterpart organizations could support system transformation.[2]

The *Common Statement of Principles on Shared Health Priorities*, issued by F/P/T Ministers of Health in 2018, focused on two priority areas: home and community care, and mental health and addictions. The statement noted that in addition to these shared priorities, F/P/T Ministers of Health would continue to work on areas of mutual interest, including supporting health innovation and improving the affordability, accessibility and appropriate use of prescription drug, including taking steps towards harmonizing drug plan formularies.[3] Federal priorities with respect to healthcare are further described on the Health Canada website which states that, "with an aging population, new technologies and increasing rates of chronic disease, it is more important than ever that our healthcare systems adapt to deliver better care and better outcomes at a cost that is affordable."[4] The statement also distinguished disparities in Indigenous health outcomes compared to the

2 CADTH, Better Health. Better Value. Better Patient Experience. Transforming How We Manage Health Technologies in Canada in Support of the Triple Aim (Ottawa, 2016), p. 1.

3 Health Canada, *A Common Statement of Principles on Shared Health Priorities* (Ottawa, 2018), pp. 1, 3. https://www.canada.ca/content/dam/hc-sc/documents/corporate/transparency_229055456/health-agreements/principles-shared-health-priorities.pdf.

4 Health Canada, *Shared Health Priorities and Safe Long-term Care Fund* (Ottawa, 2021). https://www.canada.ca/content/dam/hc-sc/documents/corporate/transparency_229055456/health-agreements/principles-shared-health-priorities.pdf.

Canadian population, noting that the F/P/Ts are committed to working with First Nations, Inuit and Métis to improve access to health services and health outcomes for Indigenous Peoples.[5]

Following the agreement on the *Common Statement of Principles on Shared Health Priorities*, the federal government negotiated and signed bilateral agreements with each province and territory that established details of how each jurisdiction would use federal funding to improve access to home and community care and mental health and addiction services.

Successive federal budgets have reflected F/P/T shared priorities. Federal Budget 2017 committed $11 billion over ten years to provinces and territories for improvements to home care and mental health services, and $544 million over five years to federal and pan-Canadian organizations to support pharmaceutical policy initiatives and health innovation.[6] Federal Budget 2017 also included measures aimed at improving access to prescription medications, lowering drug prices and supporting appropriate prescribing by allocating $140 million to Health Canada, the Patented Medicine Prices Review Board (PMPRB) and CADTH to work together in furthering these priorities.[7] Federal Budget 2019 identified a number of priorities related to healthcare, including support for innovation in health and bio-sciences, modernizing clinical trial regulation and implementation of national pharmacare.

With respect to national pharmacare, the Advisory Council on the Implementation of National Pharmacare released its Final Report on June 12, 2019. The report recommended a stepwise implementation of a universal, single-payer national pharmacare program. It also recommended that F/P/Ts work together to establish a universal, single-payer, public system of prescription drug coverage in Canada that reflects the five principles of the *Canada Health Act*—universality, portability, comprehensiveness, accessibility, and public funding and administration. The Advisory Council recommended that pharmacare be established through legislation separate from the *Canada Health Act* and should outline the cost sharing arrangement, federal responsibilities and how provinces and territories could go about opting in to a national pharmacare program. Consistent with the external review of PCHOs report and the Council's interim report, the Advisory Council recommended F/P/T collaboration on the creation of a Canadian Drug Agency.

5 Health Canada, *A Common Statement of Principles on Shared Health Priorities* (Ottawa, 2018), p. 3. https://www.canada.ca/content/dam/hc-sc/documents/corporate/transparency_229055456/health-agreements/principles-shared-health-priorities.pdf.

6 Forest, P-G., & Martin, D, Fit for Purpose: Findings and Recommendations of the External Review of the Pan-Canadian Health Organizations (Ottawa, 2018).

7 Ibid.

Finding 2: CADTH has aligned its governance structures, planning and reporting, and its products and services to respond to the priorities of its F/P/T funders, other customers and decision-makers. CADTH's Board of Directors includes F/P/T representatives which positions the Board to influence the work of CADTH to ensure it is meeting the ongoing needs of F/P/T funders. CADTH's strategic plans, annual operational plans and business plans describe how CADTH responds to the priorities of its F/P/T funders, other customers and decision-makers, while its annual reports to Health Canada describes progress in this respect.

CADTH's Board of Directors includes seven jurisdictional representatives, including the federal government. According to its charter, the Board is responsible for setting the CADTH Vision, Strategic Goals and Core Values, setting the strategic direction of CADTH to ensure it meets the needs of its members, and approving the strategic plan. Given the responsibilities of the Board, members are in a position to influence the work of CADTH to ensure it is meeting the needs of F/P/T funders as they evolve. Board meeting agendas reviewed for this evaluation reflect the focus of the Board in ensuring that CADTH is in alignment with the priorities of its F/P/T funders, other customers and decision-makers.

Over the evaluation period, CADTH has implemented two strategic plans (2015–18 and 2018–21[8]), both describing how CADTH responds to the priorities of its F/P/T funders, other customers and decision-makers. In recent years, CADTH annual operations and business plans describe how CADTH will work over the course of the fiscal year to make progress on commitments in the corresponding strategic plan.[9] CADTH tracks its progress and reports annually to Health Canada, as required under its Contribution Agreement.

CADTH's products and services are structured to respond to the priorities of its F/P/T funders, other customers and decision-makers. The 2015–18 and 2018–21 strategic plans both include three high level goals and nine objectives which refer to CADTH's commitment to respond to evolving F/P/T priorities. Likewise, CADTH's annual operations plans refer to the ongoing work of ensuring CADTH's programs and services continue to align with F/PT priorities. For example CADTH's 2019–20 progress report to Health Canada identifies "Priority Initiative 1: Align CADTH efforts and investments with Federal, Provincial, and Territorial priorities for health improvement."[10] In the 2018–19 annual operations plan, one of CADTH's priorities was to "develop programs and processes that reflect the current priorities of the health system, such as mental health and addiction services, home and community care, services for seniors, and provision of care for Indigenous populations and Canadians living in rural and remote areas."[11]

8 The 2018–21 Strategic Plan has been extended through 2021–22.

9 CADTH describes its operational plan as the organization's annual "to-do list." The operational plan identifies the major activities CADTH has committed to working on during the year, and links the daily work of CADTH to the five priority initiatives in the corporate Business Plan.

10 CADTH, Annual Operations Plan 2019–2020 (Ottawa, 2019).

11 Ibid., pp. 5–6.

This remainder of this section describes the extent to which CADTH has evolved its products and services in responding to the needs of its primary funders (F/P/Ts), other customers and decision-makers.

Finding 3: During the evaluation period, CADTH continually evolved its products and services to respond to the needs of its F/P/T funders, other customers and decision-makers. Significant improvements were made to its Formulary Program in order to provide Canadians with more timely access to drugs. Provincial and territorial funders are looking to CADTH and Health Canada to develop procedures for the review of drugs for rare diseases, including the use of real-world evidence. CADTH has also been focused on improving its various HTM products and services and introduced new offerings in response to customer needs—a prime example being its efforts to provide the healthcare system with timely information related to COVID-19.

CADTH improved the efficiency of formulary reviews in response to stakeholder needs

As described in Section 1, CADTH has two main business lines—formulary reviews and HTM knowledge products and services. In producing drug reimbursement recommendations, CADTH has worked closely with Health Canada to provide Canadians with more timely access to drugs. Several operational improvements were implemented during the five-year evaluation period. For example, CADTH and Health Canada worked to align their review processes. In March 2018, CADTH announced that its CDR program would begin accepting submissions up to 180 days before the anticipated receipt of Health Canada's approval (Notice of Compliance (NOC)).[12] In February 2018, CADTH launched a streamlined biosimilar review process, with fewer submission requirements and a shortened review period. Following a consultation process, in June 2019 CADTH announced it would no longer review biosimilar drugs. This was made for several reasons, including not delaying Canadians' access to new biosimilar treatments and enabling CADTH to redeploy its limited resources to other drug reviews.[13] Key informants gave CADTH high marks for its work as a convenor in bringing stakeholders together to arrive at this decision.

In July 2019, following public consultation, the mandate of the Cancer Drug Implementation Advisory Committee (CDIAC) was transferred to CADTH's pCODR process. The purpose was to provide recommendations regarding treatment algorithms, that is how a new therapy could be used in comparison to existing funded treatments and the impact on the sequencing of other existing therapies. The decision to transfer the mandate of CDIAC to CADTH sought to increase efficiency and avoid duplication of effort.[14] Patient support groups had also voiced concerns about the lack of transparency of the work previously carried out by CDIAC.[15]

12 CADTH, *Health Canada, CADTH, and INESSS Collaborate to Align Drug Review Processes* (Ottawa, 2018). https://www.cadth.ca/news/health-canada-cadth-and-inesss-collaborate-align-drug-review-processes

13 CADTH, *CADTH Pharmaceutical Reviews Update—Issue 8* (Ottawa 2019). https://www.cadth.ca/cadth-pharmaceutical-reviews-update-issue-8

14 CADTH, Webinar: Consultation on Proposal to Integrate Key Functions of the Cancer Drug Implementation Advisory Committee into CADTH's pan-Canadian Oncology Drug Review Process (Ottawa 2019). https://cadth.ca/events/webinar-consultation-proposal-integrate-key-functions-cancer-drug-implementation-advisory

15 Canadian Cancer Survivor Network. Webinar: CDIAC to CADTH – How the pan-Canadian Oncology Drug Review (pCODR) is changing to accommodate provincial cancer agency needs (March 15, 2019). https://survivornet.ca/news/watch-our-most-recent-webinar-canadian-real-world-evidence-for-value-of-cancer-drugs-canrevalue-2/

In November 2019, CADTH expanded its tailored review process to include additional selected products, such as new formulations of existing drugs.[16]

In late 2020, CADTH merged CDR with pCODR to create an integrated Formulary Program. The goal was to take the best features of both processes to make a more robust program and to more efficiently use staff by streamlining the process.

Finally, CADTH undertook an operational review of the Formulary Program (along with other processes) in 2020–21 with the intention to implement recommendations in 2021–22.

CADTH has been working closely with Health Canada, as they develop a national strategy for drugs for rare diseases

Key informants representing provinces and territories noted they are under increasing pressure from patients to introduce the latest treatments, especially drugs for rare diseases (DRDs), which can hold great promise but are often very costly. From an HTA perspective, assessing the value of these drugs is complex, as there is usually little evidence available on their efficacy at the time the manufacturer makes a drug review submission. DRDs tend to be introduced in other countries before the manufacturer decides to submit them for review in Canada, to Health Canada for regulatory approval and to CADTH (and INESSS in Quebec) for a drug reimbursement recommendation.

Many other jurisdictions are including separate tailored HTA processes (a different appraisal standard) for rare disease technologies in their modernization activities.[17]

Federal Budget 2019 proposed to invest up to $1 billion in a national strategy for high-cost drugs for rare diseases, over two years beginning in 2022–23, with up to $500 million per year ongoing. In the 2020 *Speech from the Throne*, the federal government announced that it would develop a rare disease strategy so as to help families save money on high-cost drugs. Health Canada published a discussion paper,[18] completed a consultation process in March 2021[19] and published the results of the consultation in July 2021.[20] To date, CADTH has made some accommodations for DRDs in its formulary review framework,[21] but it has not yet developed procedures for reviewing them on a priority basis. The Health Canada-led consultation identified several issues related to the review of

16 CADTH, *CADTH Pharmaceutical Reviews Update—Issue 11* (Ottawa 2019). https://cadth.ca/cadth-pharmaceutical-reviews-update-issue-11

17 Nestler-Parr, S., Korchagina, D., PhD, Toumi, M., Pashos, C.L., Blanchette, C., Molsen, E., Morel, T., Simoens, S., Kaló, Z., Gatermann, R., & Redekop, W, "Challenges in research and Health Technology Assessment of Rare Disease Technologies: Report of the IPSOR Rare Disease Special Interest Group," *Value in Health*, 21:5, (2018): 493–500. https://www.sciencedirect.com/science/article/pii/S1098301518302742#f0005.

18 Health Canada, *National Strategy for High-Cost Drugs for Rare Diseases: A Discussion Paper for Engaging Canadians*, (Ottawa, 2021). https://www.canada.ca/content/dam/hc-sc/documents/services/health-related-consultation/National-Strategy-High-Cost-Drugs-eng.pdf

19 Health Canada, *National Strategy for High-Cost Drugs for Rare Diseases Online Engagement* (Ottawa, 2021). https://www.canada.ca/en/health-canada/programs/consultation-national-strategy-high-cost-drugs-rare-diseases-online-engagement.html

20 Health Canada, *Building a National Strategy for Drugs for Rare Diseases: What We Heard from Canadians* (Ottawa, 2021). https://www.canada.ca/content/dam/hc-sc/documents/programs/consultation-national-strategy-high-cost-drugs-rare-diseases-online-engagement/what-we-heard/what-we-heard-national-strategy-high-cost-drugs-eng.pdf

21 See CADTH's environmental scan related to the review of DRDs: CADTH, Drugs for Rare Diseases: A Review of National and International Health Technology Assessment Agencies and Public Payers' Decision-Making Processes (Ottawa, 2021). https://www.cadth.ca/sites/default/files/es/es0355-drugs-for-rare-diseases-pw.pdf

DRDs, including the need for them to be assessed and monitored differently so that patients are not kept waiting for treatment. Canadians expressed an interest in innovative approaches to approval and coverage, such as pay-for-performance, early access and managed access where real-world data is collected to inform decisions about coverage.[22]

CADTH key informants stated that they are working closely with Health Canada to develop a national strategy for DRDs. The federal government stated it will work towards launching the strategy in 2022.[23]

CADTH responded to the need to develop a process for reviewing cell and gene therapy products

A major development in the treatment of cancer in recent years is the emergence of immunotherapy, which consist of therapies that enlist and strengthen the power of a patient's immune system to attack cancer tumours. A rapidly emerging immunotherapy approach, termed "adoptive cell transfer" (ACT) involves collection of the patient's own immune cells to treat their cancer. There are several types of ACT, but the furthest advanced in terms of clinical development is the "CAR T-cell therapy."

CAR T-cell therapy involves drawing blood from patients and separating out the T cells. Next, using a disarmed virus, the T cells are genetically engineered to produce receptors on their surface, called chimeric antigen receptors, or CARs. These special receptors allow the T cells to recognize and attach to a specific protein, or antigen, on tumour cells. Once the collected T cells have been engineered to express the antigen-specific CAR, they are "expanded" in the laboratory into the hundreds of millions. The final step is the infusion of the CAR T cells into the patient, which, if all goes well, further multiply in the patient's body and, with guidance from their engineered receptor, recognize and kill cancer cells that harbour the antigen on their surfaces.

What sets CAR-T cell therapies apart from traditional drug therapies is that they pose many implementation issues in the hospital setting, including: the requirement to develop personalized treatments; the need for clear patient eligibility criteria to ensure appropriate use and equitable access; the likely need for patient and caregiver travel due to the availability of limited treatment sites across the country; the need for clinical expertise to manage adverse effects associated with CAR-Ts; and the requirement for cold-storage of the CAR-T cell products.

The evaluation team conducted a case study of CADTH's reviews of the first two such therapies to enter the marketplace in Canada. One was tisagenlecleucel (sold under the brand name Kymriah), used for the treatment of children with acute lymphoblastic leukemia. The other was axicabtagene ciloleucel (sold under the brand name Yescarta), used for the treatment of adults with advanced lymphomas. Kymriah was the first-ever approved gene therapy to enter the market. Both drugs are intended for patients whose cancer has relapsed or failed to respond to conventional treatment. Since Kymriah and Yescarta are processes rather than drugs, with many implementation issues in the hospital setting and, as yet, limited data on their efficacy, the review of these therapies is complex.

22 Ibid., p. 11.

23 Ibid., p. 6.

CADTH worked closely with provinces and territories and other stakeholders (including industry and patient support groups) to determine the appropriate approach for reviewing these new therapies. The decision to adopt the medical devices and clinical interventions pathway for the first review was seen as a sound choice, as it enabled CADTH to examine the many implementation issues associated with cell therapies. CADTH played a critical role in educating provinces and territories on the various implementation issues, including the significant cost implications. While the first review was a learning process on the part of all stakeholders, CADTH improved its collaborative approach in working with industry as the review progressed.

Following the first two reviews, CADTH developed a revised process for the review of cell and gene therapies building on the strengths of both programs. The majority of these therapies will be reviewed through the Formulary Program. Those that are highly complex and/or present unique and previously unencountered implementation issues will be reviewed through the medical devices and clinical interventions pathway with recommendations from the Health Technology Expert Review Panel. This new process offers stakeholders the benefits of firm performance targets.

Reviews of drugs and therapies are increasing in complexity and F/P/Ts are looking to CADTH to provide greater support on implementation

Several key informants noted that the complexity of drugs and therapies submitted for review to CADTH (and INESSS) is growing, a prime example being the reviews of CAR T-cell therapies described above. This growing complexity is raising numerous implementation issues in the hospital setting. For example, a CADTH drug reimbursement recommendation may include a restriction related to a particular sub-population based on age (e.g., for people over 18 years), based on the clinical evidence that was submitted by the manufacturer. F/P/T drug plan managers may then ask CADTH about whether the drug can be given to younger patients. A key informant representing a provincial jurisdiction commented that it is very difficult to tell a patient aged one year under the recommended age range that they cannot be given a newly approved medication. In order to respond to these sorts of questions, CADTH has assembled implementation panels, whereby clinicians are asked to provide guidance on whether the clinical trial results may be generalized to other sub-populations. The results of these panels are published by CADTH in order to provide feedback to healthcare practitioners.

The emergence of medications that can be used to treat multiple diseases and indications is another example of the increasing complexity of HTA reviews. Immuno-oncology (IO) drugs are transforming the field of oncology, as they impede a tumour's ability to disrupt recognition by the immune system. These drugs have demonstrated excellent therapeutic responses and are being used to treat metastatic melanoma, renal cell carcinoma and lung cancer. Stakeholders are increasingly asking CADTH for guidance on specific implementation questions, such as whether a new IO drug can replace a chemotherapy medication currently used to treat the disease. In response to this need, CADTH is publishing reports focused on answering these sorts of questions. For example, in 2019 CADTH published an OU report focused on the dosing and timing of IO drugs.[24]

24 CADTH, *Technology Review: Optimal Use 360 Report, Dosing and Timing of Immuno-Oncology Drugs* (Ottawa, 2019). https://www.cadth.ca/sites/default/files/ou-tr/ho0008-dosing-timing-immuno-oncology-drugs.pdf

In summary, key informants representing the F/P/Ts commented that they are looking to CADTH to provide more support on these sorts of implementation and appropriate use issues, a space that CADTH has already been evolving into as noted above.

CADTH introduced a Scientific Advice Program targeted to pharmaceutical firms

CADTH introduced a Scientific Advice Program in January 2015, a fee-for-service program that provides pharmaceutical firms with advice on their early drug development plans from an HTM perspective. The intent of the program is to provide pharmaceutical firms with the opportunity to adjust their development plans based on advice from CADTH. In 2019, CADTH and the United Kingdom-based National Institute for Health and Care Excellence (NICE) launched a new collaboration to offer parallel scientific advice. CADTH completed a total of 24 Scientific Advice projects during the five-year evaluation period.

The case study of this program conducted for this evaluation found that that the advice provided is useful to pharmaceutical firms and that CADTH's program compares favourably to similar programs offered by other HTA organizations internationally. Some feedback was received from industry key informants that the market for this service for DRDs specifically may be limited since clinical trials are very small and a pharmaceutical firm would likely use a scientific advice program offered in the country where the new product would first be marketed.

A variety of improvements were made to CADTH's suite of HTM knowledge products and services

Turning to the HTM knowledge products and services business line, CADTH continued to evolve its portfolio of products and services to reflect customer needs. For example, as noted above, it has introduced OU reports that are focused on customer needs for information concerning drug implementation issues.

On the device side, CADTH has been working towards more custom HTA/OU reports that include information relevant to a decision being made.

CADTH introduced the Policy Service to support F/P/T health policy decision-making. The case study of this new service offering conducted for this evaluation found that the Policy Service is meeting customer needs. Examples of projects completed through the Policy Service include: a jurisdictional/environmental scan to provide input to improve the performance of a prescription monitoring program; a jurisdictional scan as part of an evaluation of a medication review program that helps patients get the most benefit from their medications; and a jurisdictional scan to help inform a decision to enhance a provincial organ donation program.

CADTH has also continued to ensure that its RRS caters to customer needs, particularly during the COVID-19 pandemic. CADTH introduced a "living rapid review" in response to the pandemic. Living reviews are reviews that are updated regularly to ensure the version available to customers is the most up-to-date possible, particularly on subjects where evidence is being continually produced.[25] CADTH also introduced "ultra-rapid" reviews in 2020.

25 An example of a "living review" prepared in response to COVID-19, which has now been issued as a final report, is on convalescent plasma therapy. See https://cadth.ca/convalescent-plasma-therapy-treatment-covid-19-review-clinical-effectiveness.

While fewer key informants were familiar with other HTM knowledge products and services, such as horizon scans and environmental scans, those that had requested these services from CADTH were generally positive.

The case study of an "evidence bundle" conducted for this evaluation focused on pain management (including opioids). The case study concluded that CADTH had excelled in developing an authoritative and comprehensive source of pain management evidence.

CADTH's strategy to improve the management of clinical interventions and medical devices is a work in progress

CADTH has made some progress in its strategy to improve the management of clinical interventions and medical devices in Canada. In 2017, CADTH created a medical devices and clinical interventions group led by a CADTH vice president and established the Device Advisory Committee . This committee provides advice to CADTH about health system issues and decision points where evidence could enable better management of medical devices (defined as medical devices, clinical interventions, diagnostic tests, and medical, dental and surgical procedures).

Health Canada key informants noted that CADTH has put more focus on medical devices over the past few years and indicated that CADTH has developed a closer working relationship with the department's Medical Devices Directorate. CADTH provides information that contributes to the department's regulatory decisions related to devices.

The Medical Devices Directorate at Health Canada also carries out post-market surveillance, compiling incident reports submitted by healthcare professionals, patients and device manufacturers. Once the number of reports pertaining to a device reaches a certain threshold, a risk assessment is triggered, which allows Health Canada to take a regulatory decision. CADTH may be consulted during this process to find out how the device is being used throughout the healthcare system.

Health Canada key informants commented that they would like to continue to develop a closer working relationship with CADTH.

Key informants representing the medical devices industry also welcomed CADTH's increased involvement in this sector, noting that the creation of a vice president position for medical devices and clinical interventions was a strong signal of CADTH's intentions to be more active in this space.

These key informants indicated that CADTH can play an important role in increasing the availability of cost-effective medical devices in the healthcare system. They noted that CADTH's 2018–21 Strategic Plan has an objective of increasing access to medical devices.[26]

Several key informants, both within and external to CADTH, commented on the challenges related to increasing access to medical devices in Canada's healthcare system. Following approval by Health Canada, the path to market entry is less straightforward compared to drugs, as there is no central

26 CADTH, 2018–21 Strategic Plan (Ottawa, 2018), p. 6.

decision-making authority at the provincial and territorial level. Clinical interventions also enter the healthcare system at different levels.

Overall, key informants representing the medical devices industry expressed the view that CADTH has achieved less in the medical devices space than perhaps CADTH had envisaged. There is a perception that CADTH is more focused on the assessment of clinical interventions than on devices. While it was noted that CADTH has issued many RR reports focused on devices, relatively few of the larger reports (e.g., Health Technology Reviews (HTR) and OU reports) have done so. Industry key informants noted that while one-off RR reports can support procurement decisions at the local level, the larger reports are viewed as potentially having broader system-wide impacts on procurement.

2.2 Do CADTH's products and services overlap, duplicate or complement those provided by other Canadian organizations?

Finding 4: There is considerable HTA capacity across Canada, particularly at the regional and local levels. CADTH's products and services generally complement those provided by other Canadian organizations. All F/P/Ts rely on CADTH's drug reimbursement recommendations (except Quebec, where INESSS also produces recommendations). Smaller provinces and territories do not have the same HTA capacity as larger provinces, and so are highly dependent on CADTH's products and services. In terms of devices, while some collaboration is taking place among the various HTA providers as part of the pan-Canadian HTA Collaborative, there is an opportunity for greater collaboration in the conduct of individual HTA assessments. Similarly, while local HTA has been found to complement HTAs conducted at the federal and provincial levels, collaboration and exchange of expertise and knowledge present improvement opportunities.

There has been a substantial expansion of HTA capacity across Canada over the last 25 years.[27] A CADTH environmental scan of collaboration in HTA across Canada identified 44 Canadian organizations involved in HTA.[28]

Significant HTA capacity exists at the provincial level in the larger provinces, including Ontario Health, INESSS (Quebec) and the Institute of Health Economics (Alberta). In British Columbia, the Health Technology Assessment Office commissions the production of HTAs.

The smaller provincial and territorial jurisdictions lack in-house HTA capacity, particularly specialized expertise (clinicians, health economists, etc.) and a lack of resources to conduct patient and clinician engagement. They are highly reliant on CADTH's products and services. If CADTH were to discontinue any of these, the smaller jurisdictions would experience challenges in obtaining them elsewhere (e.g., through health consultancies) due to budget pressures.

27 Martin, J.P., Dendukur, N., Rhainds, M., & Sampietro-Colom, L, "Local health technology assessment in Canada: Current state and next steps," *International Journal of Technology Assessment in Health Care*, 32:3 (2016): 175–180.

28 CADTH, *Collaboration in Health Technology Assessment in Canada: An Environmental Scan* (Ottawa, 2020). https://www.cadth.ca/collaboration-health-technology-assessment-canada-environmental-scan.

At the regional and local levels, there are many HTA units based in hospitals (e.g., Technology Assessment at The Hospital for Sick Children in Toronto) and in regional health authorities (e.g., Calgary Health Region Department of Surgery/Surgical Services). There are also several university-based units (e.g., Health Technology Assessment Unit of McGill University Health Centre). The focus of most of these HTA units tends to be on the non-drug side (i.e., reviews of medical devices, clinical interventions, diagnostics, preventive health and screening interventions and mental healthcare). While individual hospitals are responsible for the majority of drug and technology decisions, relatively few Canadian hospitals have formally implemented hospital-based HTA (HB-HTA), except in Quebec where HB-HTA is mandatory for teaching hospitals, and there are few practical frameworks to guide the formulation of recommendations at HB-HTA units.[29,30]

Because Canada's decentralized healthcare system means that decisions about health technologies are made in different jurisdictions and at various levels of the healthcare system, a certain amount of distributed HTA capacity across Canada is to be expected. Furthermore, given that more than 8,000 new medical devices enter the market each year, it is not feasible for a single organization (such as CADTH) to ever have the ability or resources to review all of them.

While there is considerable HTA capacity across Canada, the literature review found that the HTAs conducted by regional/local bodies complement rather than duplicates the HTAs conducted at the federal and provincial levels. But it was also noted that "there is a need to facilitate collaboration and exchange of expertise and knowledge between these entities regarding the role of local HTA in Canada."[31]

Key informants expressed a desire for increased collaboration among the many HTA organizations. As noted in the CADTH environmental scan, collaboration offers several benefits, including avoiding duplication of effort, the opportunity to share expertise, improved timeliness of HTAs and the ability to produce more HTAs on a wider range of technologies. But at the same time, achieving collaboration presents many challenges. For example, decision-makers in the various jurisdictions may have differing needs and there may be a need for local contextualization.

The 2018 review of PCHOs called for increased coordination of HTA work on non-drug technologies across Canada. It proposed a model whereby CADTH would coordinate an HTA network and HTA bodies would conduct assessments within a common framework and in accordance with a common set of priorities, to avoid duplication and to build overall capacity. Several key informants noted that this review has prompted the members of the pan-Canadian HTA Collaborative to increase joint work and to attempt to avoid duplication wherever possible.

CADTH has recognized the need to increase the level of HTA collaboration and engagement, a goal of its 2018–21 Strategic Plan. The main mechanism for achieving this goal is the pan-Canadian HTA Collaborative, which CADTH formed in 2011. The Collaborative's goals are to share best practices,

29 Sampietro-Colom, L & Martin, J, Hospital-Based Health Technology Assessment: The Next Frontier for Health Technology Assessment (Switzerland: Springer, 2016).

30 Almeida, N.D., Mines L., & Nicolau, I, "A Framework for Aiding the Translation of Scientific Evidence into Policy: The Experience of a Hospital-Based Technology Assessment Unit," *International Journal of Technology Assessment in Health Care*, 35:3 (2019): 204–211.

31 Martin, J.P., Dendukur, N., Rhainds, M., & Sampietro-Colom, L, "Local health technology assessment in Canada: Current state and next steps," *International Journal of Technology Assessment in Health Care*, 32:3 (2016): 175–180.

minimize duplication of effort by sharing information, and identify and contribute to joint initiatives. The pan-Canadian HTA Collaborative brings together representatives from provincial and pan-Canadian HTA producers, specifically Ontario Health (Quality), INESSS (Quebec), the Institute of Health Economics (Alberta), the British Columbia Health Technology Review and CADTH.

Over the evaluation period, CADTH increasingly played a leadership role in the Collaborative and continued to provide secretariat support.

However, key informants provided only a few examples of where the members of the Collaborative have collaborated on individual HTA assessments. For example, CADTH and Ontario Health collaborated on an assessment of minimally invasive glaucoma surgery, although each agency produced its own recommendations.[32] Ontario Health and Alberta's Institute for Health Economics only discovered that each was conducting a review of gene expression profiling tests for breast cancer once the reviews were underway. They then began collaborating by sharing information.[33]

Key informants suggested there are opportunities for members of the Collaborative to work more closely together on individual HTA assessments.

In terms of drug reviews, CADTH and INESSS are the two major players in Canada, with INESSS producing drug reimbursement recommendations on behalf of the Quebec government. Key informants representing the two agencies indicated that they have increased their level of collaboration in recent years. For example, in 2018, as part of Health Canada's regulatory review of drugs and devices initiative, CADTH, Health Canada and INESSS announced that drug manufacturers would have the option of participating in an aligned review process.[34] Key informants representing CADTH and INESSS reported that they share information and have created common expert panels (e.g., when reviewing DRDs where there are few clinical experts to draw upon). However, CADTH and INESSS do not work together on a day-to-day basis. One challenge to doing so, reported by some key informants, was a perceived lack of sufficient official languages capability at the working level. Key informants representing F/P/Ts expressed the view that the two organizations should explore opportunities for a closer working relationship (e.g., by collaborating on individual drug reviews and by issuing joint drug reimbursement reports).

Finally, turning to CADTH's HTM knowledge products, the survey of CADTH's RRS customers found that there is limited capacity outside CADTH to prepare these types of reports. Only one in ten (9%) survey respondents had obtained a similar RRS from elsewhere, indicating that CADTH is the primary RRS supplier in Canada. This finding is similar to that of the previous 2016 evaluation, which found that 13% of CADTH's RRS customers had obtained a similar service from elsewhere.

32 CADTH, *Optimal Use of Minimally Invasive Glaucoma Surgery: A Health Technology Assessment* (Ottawa, 2019), https://www.cadth.ca/optimal-use-minimally-invasive-glaucoma-surgery-health-technology-assessment, and Ontario Health (Quality), *Minimally invasive glaucoma surgery: a budget impact analysis and evaluation of patients' experiences, preferences, and values* (Toronto, 2019), https://www.hqontario.ca/Evidence-to-Improve-Care/HealthTechnology-Assessment/Journal-Ontario-Health-Technology-Assessment-Series.

33 Ontario Health Quality, "Gene Expression Profiling Tests for Early-Stage Invasive Breast Cancer: A Health Technology Assessment," *Ontario Health Technology Assessment Series*, 20:10 (2020). https://www.hqontario.ca/Portals/0/Documents/evidence/reports/hta-gene-expression-profiling-tests.pdf.

34 https://www.cadth.ca/news/health-canada-cadth-and-inesss-collaborate-align-drug-review-processes

The 9% of respondents who had obtained a similar RR service from elsewhere were asked to compare the two sources. Although the sample size was very small, the survey found that CADTH excels in the comprehensiveness and the credibility of the content of its reports, with timeliness of the reports being the main opportunity for improvement (36% indicated that CADTH's timeliness was worse than that of other providers). As discussed in Section 2.1, CADTH has worked to improve the timeliness of its RRS.

2.3 How have the landscape and priorities related to health technology management evolved over the past five years? To what extent did CADTH prepare for shifts in its external environment?

Finding 5: The HTM landscape continued to evolve rapidly during the evaluation period. For the most part, CADTH has successfully responded to the needs and priorities of F/P/T funders and other customers and decision-makers, successfully addressing many challenges and leveraging opportunities, particularly in the drug space.

The document and literature reviews together with the key informant interviews identified several trends and issues facing the HTM landscape in Canada. Key informants were also asked to comment on CADTH's performance in responding to these shifts. Their main observations are summarized below.

CADTH is making the shift from an HTA to HTM organization

CADTH began its shift from an HTA to an HTM organization in 2016, and since then it has continued to be a major priority.

The transition to an HTM organization was a driving force in shaping CADTH's current Contribution Agreement with Health Canada. As outlined in the agreement, the strategy for CADTH to transition to an HTM enterprise encompasses a number of high-level goals which are identified in its 2018–21 Strategic Plan, including "closing the gap between evidence, policy and practice" (e.g., providing implementation support); developing a life-cycle approach to HTA (e.g., providing implementation support and developing programs for drug and device reassessment and disinvestment); and "anticipating health system and technology trends and developing agile management strategies" (e.g., focus on the assessment and management of technologies that have the most potential to meet patient needs).

Some key informants were unclear about what this shift means at a practical level for CADTH and Canada's healthcare system. Others questioned the feasibility of the strategy, concerned that CADTH's resources will be stretched too thin (e.g., the requirement to cope with the growing volume and complexity of drug reviews while increasing its efforts related to implementation support).

Several key informants indicated that a major feature of CADTH's transition to an HTM agency will be its success in assisting the provinces and territories with disinvestment decisions. For example, determining whether to exit a technology, such as delisting a drug from a provincial and territorial

formulary, may require CADTH to assess real-word evidence (RWE), and as noted above, Health Canada and CADTH have yet to develop the necessary procedures for drug reassessments.

A specific issue raised by key informants representing the F/P/T drug plans related to CADTH's efforts in providing implementation support concerning treatment algorithms associated with drug reimbursement recommendations. As noted earlier, the former CDIAC had this mandate until mid-2019, when it was transferred to CADTH. Key informants highlighted the importance of this function and indicated it was too early to assess whether CADTH is effective in carrying out this new responsibility.

CADTH has made progress in other aspects of its shift towards becoming an HTM organization, as outlined below:

- CADTH has worked to improve its major OU reports by including implementation considerations. The prime example mentioned by several key informants is CADTH's work in developing a review procedure for cell and gene therapies, which have complex implementation issues in the hospital setting (see Section 2.1).
- CADTH has been more focused in helping the provinces and territories make formulary listing decisions following the publication of CADTH's drug reimbursement recommendations. For example, CADTH's economics team is providing ongoing support.
- In 2016, CADTH developed a pan-Canadian HTM strategy focused on devices, which became part of CADTH's 2018–21 Strategic Plan, which included such themes as priority setting, assessment and evaluation throughout the entire device lifecycle.
- CADTH is developing a clinician engagement strategy (see Section 3.1)
- CADTH continue to add resources to its ISKM team to provide implementation support (see Section 4.1.1).

Overall, the evidence suggests that CADTH's is making progress in shifting from an HTA to an HTM organization. CADTH may wish to more clearly articulate in practical terms what this shift means for Canada's healthcare system.

Provincial and territorial healthcare budgets are under increasing pressure

A major trend identified by key informants representing provincial and territorial jurisdictions is the growing volume of high-cost drugs entering the marketplace, particularly DRDs. The PMPRB reported that of the 51 new drugs first approved in the Europe, Canada and the United States during 2018, more than two-thirds were high-cost (annual costs exceeding $10,000) and over 60% were treatments for rare diseases.[35]

At the same time, jurisdictions face pressure from patients and caregivers to provide access to the latest treatments. The ever-increasing use of social media has amplified this trend, as patients have immediate knowledge of when the latest treatment is approved in another country.

35 Patented Medicine Prices Review Board, *MEDS Entry Watch 2018* (Ottawa, 2020). https://www.canada.ca/en/patented-medicine-prices-review/services/npduis/analytical-studies/meds-entry-watch-2018/intro.html.

Some F/P/T drug plan managers stated that they would like CADTH's CDR program to review older drugs and therapies that are costly (i.e., drugs that were added to formularies prior to the establishment of the CDR process in 2002). An example is the medication Prolastin-C, which is used to treat lung problems and can cost upwards of $100,000 per patient annually. An F/P/T drug plan manager commented that they had been asked to consider adding this medication to the formulary. They noted that this drug had not been subjected to CADTH's CDR process (as the drug predated the CDR process), and was assessed by a Rapid Response report instead (an added complication in this case is that Prolastin-C is plasma-derived so there is overlap with the Canadian Blood Services' coverage mandate).[36] This key informant commented that a drug reimbursement recommendation is preferred, as it is a requirement in order to add the drug to the provincial formulary. CADTH key informants estimated that there is a relatively small number of such drugs that fall into this category.

CADTH's strategy for considering real-world evidence in drug reimbursement decision-making is yet to be developed

Several key informants representing provincial and territorial drug plans and CADTH's expert committees noted that many new drugs, particularly high-cost DRDs, tend to be conditionally approved by the regulator (Health Canada), receiving a Notice of Compliance with Conditions (NOC/c). This enables promising drugs for serious diseases to reach the market faster than is possible through the standard approval process. The NOC/c stipulates that the manufacturer will undertake further studies to confirm the benefit of the drug. Following their submission to CADTH, these drugs are often conditionally recommended due to the limited data available on their efficacy.[37]

In facing the challenges associated with the increasing volume of DRDs along with rapidly rising costs, several key informants representing provincial and territorial drug plans and CADTH's expert committees viewed the use of RWE as a valuable source of information as it can be used to inform post-market decisions about continuing to fund a drug, to support price renegotiations with the manufacturer, or to support a decision to delist a drug currently on a formulary. RWE is often defined as clinical evidence derived from sources other than traditional randomized controlled trials.

Key informants commented that Canada's approach to incorporating RWE in the drug review process is still being developed. It was noted that the Canadian Institutes of Health Research (CIHR) has funded an ongoing project to develop a framework for the use of RWE for cancer drug funding decisions in Canada, which brings together many stakeholders (including Health Canada, CADTH, INESSS, researchers, provincial and territorial ministries of health and patients).[38]

CADTH has recognized the opportunity presented by RWE. CADTH's 2018–21 Strategic Plan identifies the related strategic goal to "adopt a life-cycle approach to health technology

36 Prolastin-C has not been subject to a review by CADTH's CDR program, as it predated the CDR process, but CADTH has conducted a Health Technology Review of Prolastin-C, see https://www.cadth.ca/sites/default/files/hta-he/he0013-prolastin-C-economic-report.pdf.

37 A 2019 study found that of the 22 oncology drugs receiving a NOC/c from Health Canada, 21 were subsequently submitted to CADTH for review (1 was withdrawn). Of these 21 submissions, 11 received a recommendation of reimbursement with conditions, 1 received an unconditional reimbursement recommendation, and 6 received a do not reimburse recommendation, see: Andersen, S.K. , Penner, N., Chambers, A., Trudeau, M.E., Chan, K.K.W., & Cheung, M.C., "Conditional approval of cancer drugs in Canada," Current Oncology, 26:1 (2019). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6380633/.

38 In 2017 CIHR's Partnership for Health Systems Improvement initiative funded the Canadian Real-World Evidence for Value of Cancer Drugs (CanREValue) collaboration, see https://cc-arcc.ca/canrevalue/.

assessment."[39] This strategic goal is reflected in its 2019–20 Business Plan, which states that planned actions are to "further elucidate and implement a framework for collecting and analyzing real-world data" and to "implement a reassessment program."[40] In 2020, CADTH published an environmental scan on the use of RWE in single-drug assessments.[41]

In June 2020, Health Canada and CADTH announced that an action plan would be developed to optimize the process for integrating RWE into both regulatory and reimbursement decision-making.[42] CADTH key informants noted that a lead for RWE was hired in August 2020 and that work on this action plan is continuing into 2021–22.

Several key informants noted that incorporating the use of RWE in drug reimbursement decision-making is a complex subject, a point which is noted in the literature.[43] For example, roles and responsibilities of all stakeholders involved in RWE data collection will need to be developed, as will standards pertaining to the collection and analysis of RWE data. On a practical note, key informants representing the provincial and territorial drug plans stated it could be challenging for a jurisdiction to delist a drug following a CADTH reassessment that considered RWE, as there could be considerable pushback from patients, clinicians and industry.

CADTH determined the appropriate approach for reviewing new cell and gene therapies

As discussed earlier, CADTH worked closely with stakeholders to decide on the appropriate pathway for reviewing CAR-T cell gene therapies. Stakeholders representing provinces and territories and patient groups were complimentary towards CADTH's leadership and stakeholder engagement efforts. One of the patient groups commented that they would have liked CADTH to have developed its review approach earlier, as CADTH was aware these new therapies were in the pipeline.

The emergence of artificial intelligence in healthcare

Artificial Intelligence (AI) is poised to revolutionize the way in which medicine is practiced and thereby transform how healthcare is delivered.[44] Health Canada is seeing an emergence of machine learning mostly in image-based healthcare applications, such as diagnostic imaging/radiology, and several licences have been issued as of 2018.[45] Several key informants, including academics and representatives of the international HTA community, noted that conducting HTAs of AI poses many challenges and methodologies are still to be developed. They stated that this is an important area for CADTH to be working in. In February 2021, CADTH released a horizon scan that identified several

39 CADTH, *CADTH 2018-2021 Strategic Plan* (Ottawa, 2018) p. 4. https://www.cadth.ca/news/cadth-2018-2021-strategic-plan.

40 Ibid., pp. 4–5.

41 CADTH, *Use of Real-World Evidence in Single-Drug Assessments Environmental Scan* (Ottawa, 2020). https://www.cadth.ca/use-real-world-evidence-single-drug-assessments-environmental-scan.

42 CADTH, Progress Report: April 1, 2019 to March 31, 2020 (Ottawa, 2020).

43 Clausen, M., Mighton, C., Kiflen, R., Sebastian, A., Dai, W.F., , Mercer, R.E., Beca, J.M., Isaranuwatchai, W., Chan, K.K.W. & Bombard, Y., "Use of real-world evidence in cancer drug funding decisions in Canada: a qualitative study of stakeholders' perspectives," *Canadian Medical Association Journal* 8:4 (2020): E772–E778. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7721249/.

44 Kassam A. & Kassam N., "Artificial intelligence in healthcare: A Canadian context," *Healthcare Management Forum* 33:1 (2020): 5–9.

45 Dumouchel, T., *Regulatory challenges of AI products—A pre-market perspective* (2020). https://cadth.ca/sites/default/files/symp-2019/presentations/april15-2019/A3-presentation-tdumouchel.pdf.

emerging AI-related health technologies.[46] In June 2021, CADTH published an environmental scan of AI and machine learning in mental health.[47]

Growing momentum behind national pharmacare

A major development in the healthcare landscape over the evaluation period has been the growing momentum behind national pharmacare. In the 2020 *Speech from the Throne*, the federal government stated its commitment to a national, universal pharmacare program and its intention to accelerate steps to achieve it, including the establishment of a national formulary.[48] This commitment was also included in Federal Budget 2021, along with an announcement of ongoing $500 million funding for a program focussing on high-cost DRDs.

The 2019 final report of the Advisory Council on the Implementation of National Pharmacare stated that a Canadian Drug Agency would perform several functions currently carried out by multiple organizations, including CADTH, Health Canada, the pCPA and the PMPRB.[49] These would include: assessing the clinical effectiveness of drugs compared to other treatment options; assessing the cost-effectiveness of drugs compared to other treatment options; deciding which drugs and related products (e.g., devices) should be on the national formulary; negotiating prices with manufacturers; providing advice on how best to use drugs; and monitoring the safety and effectiveness of drugs in real-world use.[50] Although the introduction of the Canadian Drug Agency is likely a few years away, key informants noted it will be important for CADTH to continue to consult with the federal government on its vision for the proposed Canadian Drug Agency, and its strategies for pharmacare and rare diseases.

New PMPRB pricing guidelines

Another major development is the introduction of the new PMPRB pricing guidelines. These guidelines have been postponed to January 1, 2022, due to ongoing challenges related to the COVID-19 pandemic. The proposed guidelines have received considerable opposition from industry and patient groups due to the concern that they will reduce access to new drugs in Canada. If approved, the PMPRB would rely on CADTH's pharmacoeconomic data and models. CADTH's drug reimbursement recommendations would likely be under increased scrutiny.

46 CADTH, CADTH Watch List: Artificial intelligence, connected devices, and COVID-19 home sampling among health technology trends gaining momentum in 2021 (Ottawa, 2021). https://www.cadth.ca/news/cadth-watch-list-artificial-intelligence-connected-devices-and-covid-19-home-sampling-among.

47 CADTH, *Artificial Intelligence and Machine Learning in Mental Health Services: An Environmental Scan* (2020). https://www.cadth.ca/artificial-intelligence-and-machine-learning-mental-health-services-environmental-scan.

48 Government of Canada, *Speech from the Throne to Open the Second Session of the Forty-Third Parliament of Canada*. (Ottawa, 2020). https://www.canada.ca/en/privy-council/campaigns/speech-throne/2020/stronger-resilient-canada.html.

49 Advisory Council on the Implementation of National Pharmacare, A Prescription for Canada: Achieving Pharmacare for All--Final Report of the Advisory Council on the Implementation of National Pharmacare (Ottawa, 2019). https://www.canada.ca/en/health-canada/corporate/about-health-canada/public-engagement/external-advisory-bodies/implementation-national-pharmacare/final-report.html

50 Ibid., pp.69–70.

3. Findings: Design and Delivery

3.1 To what extent has CADTH effectively consulted and engaged with stakeholders?

Finding 6: CADTH has made major strides in improving its engagement with key stakeholders, including the pCPA, patients, and the pharmaceutical and medical devices industries. While CADTH is viewed internationally as a leader in patient engagement, a clear vision for engagement at the organizational level should be established. There is also an opportunity for CADTH's expert committees to increase transparency and provide more feedback to patient groups on their drug review submissions.

CADTH consults and engages with a wide range of customers/funders, especially F/P/Ts, and with many stakeholders, including patient support groups, clinicians and their professional societies, and the pharmaceutical and medical devices industries. The main types of CADTH engagement activities are discussed below.

Policy Makers

Over the evaluation period, there was significant engagement at all levels of CADTH with F/P/Ts, including through the various advisory committees. The CEO of CADTH met regularly with deputy ministers of health and other senior ministry staff to help jurisdictions get the most out of the evidence available from CADTH. This two-way dialogue is vital to CADTH—it ensures that CADTH can quickly respond to changing jurisdictional priorities while at the same time making senior health officials aware of the full range of products and services available from CADTH. In addition, the CEO of CADTH regularly contributed to national policy issues such as the National Pharmacare Policy.[51] CADTH also maintains ongoing contact with provincial and territorial jurisdictions through its various committees and ISKM's regional approach to customer support.

Pan-Canadian Pharmaceutical Alliance

The pCPA relies on CADTH's drug reimbursement recommendations to support its price negotiations with pharmaceutical firms. Key informants representing the members of the pCPA indicated that CADTH has enhanced its working relationship with the pCPA over the past few years. For example, it increased the provision of analytical support to provinces and territories as well as to the pCPA office in Toronto. CADTH also played an important role in assisting the pCPA with its biosimilars consultation.

Public and Patients

A preoccupation in the HTA field has been how to meaningfully engage the public and patients, suggesting a desire to move away from less meaningful practices that have characterized prior efforts, or a need to ensure that the approaches taken will add value to the process and to the parties involved. [52]

51 CADTH, Progress Report: April 1, 2019 to March 31, 2020 (Ottawa, 2020), pp. 17–18.

52 Abelson, J., "Patient engagement in health technology assessment: what constitutes 'meaningful' and how we might get there, " *Journal of Health Services Research & Policy* (2018). https://pubmed.ncbi.nlm.nih.gov/29411660/.

There are a number of complexities related to public and patient engagement, including the way in which patient engagement is defined and assessed, the need to disentangle the role of advocacy groups as organized interests versus representatives of patient values and experiences, and what might be needed to make further progress towards optimized patient engagement. [53] It has been suggested that to do so a clear vision for engagement at the organizational level should be established, not simply within discrete engagement processes but across the entire pathway of HTA and management activities.[54]

CADTH's 2015–18 Strategic Plan had as an objective to deepen CADTH's engagement with patients.[55] CADTH engages patients to address relevance (i.e., the quality of assessments of medical procedures, devices and drugs), fairness (i.e., publicly funded procedures, devices and drugs, and the impact on patients), equity (i.e., the diversity of needs of individuals and healthcare settings across Canada), and legitimacy (i.e., ensure good governance of CADTH's processes).[56] Patient input is sought for the Formulary Program and CAR-T cell therapies. In addition, individuals and/or groups work with CADTH teams on HTA/OU projects (medical devices and procedures), Horizon and Environmental Scans and Scientific Advice. CADTH also periodically scans academic literature for patient perspectives and experiences. CADTH's CEO has actively engaged with organizations such as Myeloma Canada, Health Charities Coalition of Canada and the Best Medicines Coalition. As part of ongoing review activities by Scientific Affairs, Patient Engagement and International Affairs, CADTH is able to address emerging best practices in patient engagement by incorporating them, as needed, into its business planning.[57]

Key informants representing patient support groups indicated that CADTH has made great strides in improving its engagement with them through the drug review process. However, while appreciating the opportunity to provide input, they view CADTH's expert committee deliberations as a "black box" and are not sure how their input is used by the committees in arriving at drug reimbursement recommendations. They would appreciate receiving feedback on how committees used their input, for example, by tracking citations of patient input in reports. Several key informants noted that the Scottish Medicines Consortium permits patient groups and the public to sit in on expert committee meetings, and suggested that CADTH should consider adopting this mechanism.

Patient support groups are also struggling with the work associated with preparing their submissions to CADTH as part of the drug review process. It is challenging for them to identify and then to engage patients who have participated in clinical trials for the drug that is being reviewed. Preparing submission is time consuming and many of these patient support groups operate on limited budgets. Patient groups suggested CADTH consider increasing industry fees, to create a fund which would be used to compensate patient groups for their efforts in preparing drug review submissions. Some key

53 Abelson J., Wagner, F. & DeJean, D, "Public and patient involvement in HTA: framework for action," *International Journal of Assessment in Health Care* 32:4 (2016).

54 Ibid.

55 CADTH, *CADTH 2015-2018 Strategic Plan* (Ottawa, 2015), p. 4. https://www.cadth.ca/sites/default/files/corporate/planning_documents/2015-2018_Strat_Plan_e.pdf.

56 Mujoomdar, M, *Scientific Affairs* (Ottawa, 2019).

57 CADTH, 2015–2018 CADTH Strategic Plan Performance Measures (Ottawa, no date).

informants from patient groups also suggested that CADTH could do more to mentor groups on how to prepare submissions while expressing a desire for a closer working relationship with CADTH.

A concern of many key informants is the perceived conflict of interest of some patient groups, particularly those receiving funding from the pharmaceutical industry.[58] One author observed that caution is required when interpreting the patient voice in the process since the pharmaceutical industry has a substantial ability to influence patient groups, including too much influence of the drug industry in patient reports, with manufacturers often involved in writing patient group submissions.[59] Another author noted that the large majority of patient groups making submissions about funding of particular drug indications had conflicts of interest with the firms making these products, and patient groups' views about these products were almost always positive.[60] In a study of Formulary Program input from patient groups, of the 372 submissions from 93 different patient groups, 87.1% of submissions declared a conflict of interest with the manufacturer of the product. However, irrespective of whether there was a conflict of interest, there was no statistically significant difference between views of patient groups and Formulary Program recommendations.[61]

CADTH formed the Patient and Community Advisory Committee (PCAC) in 2019 in response to feedback during the 2018 listening exercise for future direction.[62] PCAC advises CADTH across all of CADTH's programs. Key informants, both internal and external to CADTH, indicated that PCAC is still finding its way. For example, patient groups assume (incorrectly) that PCAC exists to represent their interests but do not know how to access it. CADTH key informants indicated that the purpose of this committee is to provide advice on all of CADTH's programs. Patient groups also perceive that CADTH's patient engagement team is "buried" in the organization and indicated they do not have sufficient access to CADTH's senior management in order to voice their views and concerns.

Key informants representing the international HTA community view CADTH (along with the United Kingdom-based NICE) as a leader in patient engagement. They commented that CADTH's engagement is underwritten by integrity, transparency and good faith relationships with stakeholders. CADTH's efforts in the cancer space has been viewed as a notable success, balancing the needs and interests of a wide range of stakeholders and political pressure. The former pCODR was viewed as a leader in providing an opportunity for the patient voice in its deliberations by accepting patient group input, which continues to be a priority for the aligned Formulary Program.[63]

58 Wranikabc, W.D., Zielińskacd, D.A., Gamboldef, L. & Sevgure, S., "Threats to the value of Health Technology Assessment: Qualitative evidence from Canada and Poland in Health Policy," 123 (2019). https://www.sciencedirect.com/science/article/pii/S0168851018303373.

59 Ibid.

60 Lexchin J., "Association between commercial funding of Canadian patient groups and their views about funding of medicines: An observational study," *PLoS One* 14:2 (2019). https://pubmed.ncbi.nlm.nih.gov/30768629/.

61 Ibid.

62 Mujoomdar, M, *Scientific Affairs* (Ottawa, 2019).

63 pCODR-CADTH, *pCODR Expert Review Committee Deliberative Framework* (Ottawa, no date). https://www.cadth.ca/sites/default/files/pcodr/The%20pCODR%20Expert%20Review%20Committee%20%28pERC%29/pcodr_perc_deliberative_frame.pdf.

Clinicians

CADTH struggles for recognition among physicians not involved in its programs.[64] Placing increased emphasis on the engagement of clinicians was a key goal of CADTH's 2015–18 Strategic Plan—"expanding CADTH's reach beyond traditional audiences to build receptivity for health evidence."[65] CADTH's 2015–18 Strategic Plan also identified a priority to improve its engagement with clinicians in order to effect evidence-based behaviour change in clinical practice.[66] Clinicians include physicians, pharmacists, nurses and nurse-practitioners, dentists, allied health professionals (e.g., physical therapists, occupational therapists, dieticians, paramedics).[67] Once a technology is approved and publicly funded, clinicians decide how and how often it is used. By working with clinicians and their professional societies, CADTH supports the efforts of clinicians to use technologies appropriately, and to reduce unnecessary tests and treatments. This is intended to increase the likelihood that clinicians will use evidence from CADTH reports as a source of credible, reliable and relevant information to guide clinical decision-making.[68]

CADTH engages with clinicians on a number of fronts including in expert committees, implementation strategies, and collaboration on knowledge mobilization initiatives as well as awareness and capacity building. Key thrusts of CADTH's engagement with clinicians over the evaluation period have been the development of partnerships with professional societies and regulators, and implementation of the Clinician Engagement Strategy in 2017–18.[69]

As of 2019–20, CADTH was maintaining regular connections with over 50 jurisdictional and national clinically-focused organizations (e.g., Canadian Cardiovascular Society, Canadian Association of Radiologists, Canadian Association of Medical Radiation Technologists, Society of Obstetricians and Gynaecologists of Canada). At least 40% of these organizations are clinician-focused and aligned with CADTH's clinician engagement strategy.[70] The evaluation conducted interviews with several professional societies which indicated there is a good working relationship with CADTH. CADTH also created the position of Clinical Liaison Officer in 2020 to provide oversight and coordination of clinician engagement, but as of mid-2021 CADTH has yet to start recruitment for this position. As noted in Section 4.1.2, approximately 40% of CADTH's knowledge events (i.e., information sessions) at conferences were specifically targeted at various clinician groups. Over the evaluation period, CADTH has delivered several large jurisdictional events engaging a broad range of customers and stakeholders including clinicians, on various topics (e.g., Antibiotics Matters, Internet-based Cognitive Behavioral Therapy, non-pharmacological management of pain webinar series, development of new opioid tools to inform and guide patients, clinicians and policymakers).[71]

64 Rich, P., "Low awareness about CADTH among practising doctors in Canada," *Canadian Medical Association Journal* 190:18 (2018). https://doi.org/10.1503/cmaj.

65 CADTH, Clinician Engagement Strategy—Draft (Ottawa, 2016).

66 CADTH, *CADTH 2015–2018 Strategic Plan* (Ottawa, 2015). https://www.cadth.ca/sites/default/files/corporate/planning_documents/2015-2018_Strat_Plan_e.pdf.

67 CADTH, Clinician Engagement Strategy—Draft (Ottawa, 2016).

68 CADTH, Progress Report: April 1, 2018 to March 31, 2019 (Ottawa, no date), pp. 16–17.

69 CADTH, Clinician Engagement Strategy—Draft (Ottawa, 2016).

70 CADTH, Progress Report: April 1, 2019 to March 31, 2020 (Ottawa, 2019), p. .19.

71 CADTH, Progress Report: April 1, 2018 to March 31, 2019 (Ottawa, no date) and CADTH, Progress Report: April 1, 2019 to March 31, 2020 (Ottawa, 2019), p. 19.

CADTH convenes these types of forums for clinicians to also engage with experts to discuss their own practice patterns and experiences, with a view to improve.[72]

Clinicians play an important role in providing input as part of CADTH's formulary review process. CADTH key informants noted it has been challenging for CADTH to engage clinicians, particularly specialist clinicians to provide input to drug reviews. Some patient groups noted that they have taken on the challenge of obtaining clinician input in preparing their drug review submissions.

CADTH also provides a range of implementation tools for drugs and devices to support decision-makers and move evidence into action. While many of these were aimed at clinicians, little data is tracked by CADTH on its reach within this key stakeholder group (e.g., as measured by the extent to which clinicians use CADTH's various HTM knowledge products to inform clinical guidance).

The case study of the Evidence Bundles implementation tool found that the series of 200 pain and opioids reports and implementation tools were packaged in a user-friendly online bundle (and supported by knowledge events), provided an authoritative and comprehensive source of pain management evidence, and successfully met the needs and topics identified by customers and stakeholders broadly, including national clinician and allied health professional associations.

Industry

CADTH engages with senior representatives of the medical devices and pharmaceutical industries. This engagement is intended to facilitate a clear understanding of CADTH procedures and operations, and create opportunities for joint problem-solving on issues that affect industry and CADTH. For example, industry engagement undertaken by CADTH over the evaluation period has included regular updates to the pharmaceutical industry, through the CADTH Pharmaceutical Industry Liaison Forum, and to the medical devices industry, through the CADTH Medical Device Industry Liaison Forum. Regular meetings are held with the presidents of Innovative Medicines Canada, BIOTECanada, and MedTech Canada, and with the presidents and general managers of many pharmaceutical and medical devices firms. CADTH also participates in international meetings and forums that have included representatives from the pharmaceutical and medical devices industry, including the Health Technology Assessment International (HTAi) Global Policy Forum and meetings convened by the Centre for Innovation in Regulatory Science (CIRS).[73] Finally, CADTH information sessions are open to patients, clinicians and industry representatives, such as the annual CADTH Drug Portfolio Information Session and CADTH Medical Device and Clinical Intervention Portfolio Information Session.

Key informants representing the pharmaceutical industry commented that CADTH's relationship with industry has improved greatly in recent years. Key informants indicated that the relationship has been contentious in the past but it is now more collaborative. No concerns were raised by any key informants that this improved relationship has affected CADTH's reputation for independence and objectivity.

72 Rich, P., "Low awareness about CADTH among practising doctors in Canada," *Canadian Medical Association Journal* 190:18 (2018). https://doi.org/10.1503/cmaj.

73 CADTH, Progress Report: April 1, 2019 to March 31, 2020 (Ottawa, 2019), p. 18.

3.2 Do CADTH's activities, products and services reflect considerations related to gender, diversity, Indigenous Peoples, and rural and remote communities?

Finding 7: Recognizing that biological sex has specific application on the analysis of impact on health outcomes, CADTH has made some progress in incorporating Sex and Gender-based Analysis considerations as part of its HTA process. Sex and gender-based considerations are part of CADTH's topic selection process as well as the development of the research protocol and are reflected in CADTH's HTA and OU reports. CADTH recognizes the importance of considering the needs of Indigenous Peoples and other groups, such as the LGBTQ2+ and BIPOC communities. Some efforts have been made in this regard, but the evidence suggests that CADTH is at an early stage in its journey in determining how to engage Indigenous Peoples and to reflect their concerns, along with those of other marginalized communities, at a very practical level.

Sex and Gender-based Analysis (SGBA) is an analytical process used by Health Canada and other federal health agencies to assess how different groups of women, men, girls, boys and gender-diverse people may be impacted by federal initiatives. It considers the intersectionality of many other factors which comprise identity (e.g., race, ethnicity, religion, age, education, sexual orientation, culture, income, language, and mental or physical disability), and how the relationships between these identity factors impact the manner through which government programs and initiatives are experienced. All Health Canada-funded programs, including CADTH, incorporate an SGBA lens. SGBA is also a shared value among PCHOs.

Recognizing that biological sex has specific application on the analysis of impact on health outcomes, CADTH has made some progress in incorporating SGBA as part of its HTA process. CADTH's Contribution Agreement with Health Canada notes that CADTH has designated a SGBA champion on the research team (although some CADTH key informants were unaware of this position, suggesting it is not well known throughout the organization), and holds quarterly teleconferences with the Scientific Director of CIHR's Institute of Gender and Health to inform and enhance the approach of the organization to the analysis of sex and gender issues.[74] Sex- and gender-based considerations are part of CADTH's topic selection process and development of research protocols, and are reflected in CADTH's HTA and OU reports.

CADTH's ability to influence the inclusion of SGBA considerations in drug reviews is limited by CADTH's reliance on synthesizing the primary research of others. CADTH has responded to this barrier by providing early advice to drug sponsors at the development stage through its Scientific Advice Program. This program provides an opportunity for CADTH to apply SGBA considerations to the design and implementation of clinical trials. When data is available, CADTH performs subgroup analysis based on sex, gender and geography (i.e., rural/remote). This information informs the conclusions in CADTH reports and the deliberations of the expert committees responsible for making recommendations.

74 Health Canada, Health Canada/CADTH Contribution Agreement: Appendix A – Overview (Ottawa, no date).

CADTH recognizes the importance of considering the needs of Indigenous Peoples and other groups, such as the LGBTQ2+ and BIPOC communities. Its Board has articulated objectives signalling the importance of Indigenous considerations. During 2017–18, CADTH established an internal working group on Indigenous initiatives to examine all aspects of CADTH and to identify those practice s, products and services that should be reviewed and potentially revised to ensure that CADTH: becomes a safe space for Indigenous people; achieves meaningful engagement and collaboration with Indigenous Peoples; and its program offerings respectfully and appropriately respond to the evidence needs of Indigenous healthcare decision-makers. In 2018, working group members participated in the Assembly of First Nations' *First Nations Health Transformation Summit*, the Chiefs of Ontario's *12th Annual Health Forum* and in Upstream's *Closing the Gap Conference—The Next 150: Reconciliation and Health*.

In 2018, CADTH leadership and staff underwent professional development training (now mandatory since April 1, 2020 and offered several times per year) to learn how to work effectively with Indigenous Peoples, external contractors have been retained to support knowledge mobilization activities with implications for Indigenous Peoples, and an Indigenous writing style guide has been adopted.[75] CADTH's PCAC has an Indigenous representative (as well as of the LGBTQ2+ community). However, several CADTH key informants stated that CADTH needs to be more diverse at all levels of the organization.

The evidence suggests that CADTH is at an early stage in its journey in determining how to engage Indigenous Peoples and to reflect their concerns, along with those of other marginalized communities, at a very practical (operational) level. As one CADTH key informant noted, CADTH prides itself as an evidence-based organization, but its methods are rooted in a Western perspective. The challenge is to bring together different Indigenous voices, values, knowledge and perspectives that considers evidence in a different manner.

As required by its Contribution Agreement, CADTH has developed, in consultation with Health Canada, a set of performance indicators that will provide information relevant to the considerations of sex and gender in the design and delivery of CADTH programs and services.[76] However, there is no indication that this data is being collected and provided to Health Canada in CADTH's Annual Progress Reports to Health Canada. The view within CADTH is that these performance indicators are not reflective of CADTH's aspiration in terms of its products and services and SGBA considerations (e.g., "percentage of participants at educational events who are female").

75 CADTH, Health Canada Progress Report: Contribution Agreement Number: 6816-15-2013/11450001 (Ottawa, 2018), p. 9.

76 Health Canada, Health Canada/CADTH Contribution Agreement: Appendix A – Overview (Ottawa, no date).

3.3 To what extent does CADTH have sufficient human and financial resources to meet the current and future needs of decision-makers?

Finding 8: CADTH's annual production of drug reimbursement recommendations and HTM knowledge products and services has been generally consistent with projections, indicating the CADTH has a good understanding of customer needs and demands. CADTH appears to be adequately resourced to accommodate modest growth in demand for its various products and services in some programs, but remains challenged to meet capacity in the Formulary Program for which it cannot control demand our timelines for deliverables.

CADTH prepares annual projections for the outputs of its Formulary Program and various HTM knowledge products and services to ensure that sufficient human and financial resources are available to meet customer needs. For the Formulary Program, annual production is driven entirely by demand (i.e., the volume of drug submissions made by manufacturers). For HTM knowledge products and services, planned production represents a balance between customer demand and available human resources.

Table 2 (p. 34) summarizes CADTH's output over the five-year evaluation period, organized by the Formulary Program (CDR and pCODR) and HTM knowledge products and services. CADTH has demonstrated that it is able to accurately project annual outputs of its Formulary Program and its HTM knowledge products and services, and has been able to leverage its human and financial resources to meet customer needs, though this has led to delays in work in HTM. Overall, actual production was generally consistent with projections over the evaluation period, indicating that CADTH has an accurate understanding of customer needs. Some of the main observations are as follows:

- A total of 173 CDR reimbursement recommendation reports were produced over the five years, below the planned production of 200–250 reports. As noted above, the volume of reports is driven entirely by demand.
- A total of 125 pCODR reimbursement recommendation reports were issued over the five years, which was at the top end of the planned volume of 100–125 reports. The last two years witnessed a jump in the number of reports produced, which corresponds with the comments made by F/P/Ts concerning the rise in the volume of oncology drugs entering the global market.
- A total of 1,505 RR reports were issued over the five years, consistent with the planned volume of 1,450 to 1,750 reports. Note that several different types of RR reports are produced, each requiring a different level of effort. The number of reports increased substantially over the first four years, then dropped in the last year. CADTH key informants commented that this was mainly due to the healthcare system being focused on dealing with the COVID-19 pandemic, and the RR team was involved in custom work to meet pandemic-related needs (e.g., preparation of HTR reports).

- The number of OU reports was below plan and declined in the final two years, while the number of HTA reports (without recommendations) increased substantially over the same period. For these types of reports, CADTH listens to the needs of its customers in assessing the level of interest on a particular topic before deciding whether to proceed.

CADTH key informants were asked to comment on whether CADTH has sufficient financial and human resources. The overall view was that some parts of the operation are adequately resourced, such as the ISKM team and the RR team. However, the Formulary Program continues to face resourcing challenges, experiencing a deficit in 2019–20, although Federal Budget 2017 did earmark additional funds for drug reviews. Key informants noted that the volume of drug review submissions is expected to continue to increase, particularly for oncology drugs and DRDs. The complexity of these reviews continues to increase as well, a prime example being the review of cell and gene therapies described in Section 2.1. CADTH key informants noted that the Formulary Program struggles to keep up with its core business of conducting drug reviews, let alone respond to additional potential demands (e.g., therapeutic class reviews). As discussed earlier, CADTH does not control when manufacturers submit their drug review submissions, and there is considerable volatility, as submissions peak in the spring and fall. CADTH key informants indicated that the solution is not to simply add more staff as there have been periods when very few submissions were received. A standing offer of qualified contractors to be quickly brought in as needs arise has been introduced to help alleviate this issue.

In terms of specific human resources requirements, CADTH key informants identified only a few needs. They indicated ethicists need to be added (instead of relying on contractors). As noted in Section 2.3, assuming the new PMPRB pricing guidelines are implemented in January 2022, CADTH may need to bolster its health economics capacity.

It is difficult to find external clinical experts to provide input to the drug review process due to the limited pool of clinical specialists. As noted in Section 3.1, CADTH is currently developing a clinician engagement strategy which presumably will address this issue.

Finally, CADTH key informants noted the challenges in recruiting talent. CADTH competes with universities and the pharmaceutical and consulting industries that offer very attractive compensation packages.

Finding 9: CADTH's revenues and expenses both increased by just under one-third over the evaluation period. Insufficient information is available to CADTH managers on the costs of products/services and on staff productivity.

Table 3 (p. 35) presents CADTH's annual revenues and expenses for the five-year evaluation period. Actual revenues and expenses have been very close to projected, with an average 1% annual over- or under-estimate. Revenues and costs increased by about the same rate over the five years: 29% and 30%, respectively.

CADTH experienced a deficit of $566,000 in FY 2019–20, its first since 2015–16. This deficit was largely due to a deficit of $666,000 in the pCODR Program (along with deficits of $96,000 in the HTA

Service and $34,000 in the CDR Program). These deficits were partially offset by a surplus of $230,000 in the OU Service. CADTH returned to a surplus position of $288,000 in 2020–21.

The growth in both revenues and costs over the five years can be attributed to a number of one-time projects and ongoing revenue infusions. Federal funding increased by $10 million between 2017–18 and 2020–21, which was allocated to the HTM program.

As shown in Table 4 (p. 35), CADTH's administrative cost ratio ranged from 13% to 19% during the evaluation period. The increases during 2019–2020 and 2020–21 were driven by the amortization of design, management and construction costs associated with renovations.

Some of the CADTH senior-level key informants noted that that timely information is not available to managers on the costs of products, services and projects, which makes it difficult to assess costs and staff productivity.[77] This impacts CADTH's ability to determine its efficiency.

77 A corporate cost allocation model is a common way to capture indirect costs (e.g., corporate) in direct costs (e.g., products, services and projects).

Table 2: Volume of outputs of CADTH's products and services, 2016–17 to 2020–21.

Product/Service	2016–17		2017–18		2018–19		2019–20		2020–21	
	Plan	Actual	Plan	Actual	Plan	Actual	Plan	Actual	Plan	Actual
Formulary Reviews and Reimbursement Recommendations										
CDR	40–45	47	40–45	30	40–45	36	40–45	31	40–45	29
pCODR	20–25	19	20–25	23	20–25	22	20–25	32	20–25	29
HTM Products and Services										
Rapid Response	300–350	272	250–300	279	250–300	305	325–375	394	325–425	255
Optimal Use	4–8	4	4–8	3	5–10	7	5–10	2	-	-
HTAs without recommendations	6–10	3	6–10	6	6–12	12	6–12	18	15–30	31
HTAs for Blood Products	1–2	1	1–2	0	1–2	1	1–2	2	-	-
Environmental Scans	6–10	6	7–10	10	10–15	14	10–15	6	10–15	8
Horizon Scans	10–15	10	7–10	22	15–25	8	15–25	15	15–25	23
Scientific Advice	-	-	-	-	-	7	5–10	9	5–9	9
IMPRESS	-	-	-	-	-	19	Pilot	59	20–25	46
Policy Service	-	-	-	-	-	-	1–4	12	5–10	8

Source: Health Canada annual progress reports.

Table 3: CADTH revenues and expenses, 2016–17 to 2020–21.

Type	2016–17 ($)		2017–18 ($)		2018–19 ($)		2019–20 ($)		2020–21 ($)	
	Plan	Actual	Plan	Actual	Plan	Actual	Plan	Actual	Plan	Actual
Revenue	27,604,814	27,968,527	30,396,974	30,553,572	32,503,814	32,998,728	36,099,314	35,815,267	36,870,149	36,067,411
Expenses	27,604,814	27,503,095	30,396,974	30,371,753	32,503,814	32,936,427	36,099,314	36,381,402	36,870,149	35,777,808
Net Revenue	-	465,432	-	181,819	-	62,301	-	(566,135)	-	289,603

Source: CADTH annual financial statements for 2016–17 to 2020–21.

Table 4: Administrative and overhead costs (including amortization of renovation costs), 2016–17 to 2020–21.

Cost Type	2016–17	2017–18	2018–19	2019–20*	2020–21*
Administrative costs total	$3,604,882	$3,566,994	$4,335,377	$6,268,125	$6,806,372
% of total budget	13%	12%	13%	17%	19%
Total overhead	$3,249,003	$3,379,435	$3,951,679	$6,058,555	$6,127,393
% of total budget	17%	11%	12%	17%	17%

Source: CADTH annual financial statements for 2016–17 to 2020–21.

*Includes amortization of renovation costs.

4. Findings: Effectiveness

4.1 Achievement of Expected Outcomes

4.1.1 Immediate Outcome: Healthcare decision-makers access CADTH's evidence on drugs and medical devices

Finding 10: Key informants representing F/P/Ts reported a high level of awareness of CADTH's HTM knowledge products and services, except for those that are not yet widely promoted (IMPRESS and the Policy Service). Clinicians and those decision-makers involved in health technology (i.e., devices) adoption reported a lower level of awareness. CADTH's regional approach to customer support has raised awareness of, improved access to, and driven demand for CADTH's products and services, particularly within the smaller provinces that lack the internal resources to meet the needs of their decision-makers.

F/P/T decision-makers interviewed for this evaluation reported a high level of awareness of CADTH's products and services, except for IMPRESS and the Policy Service which have yet to be widely promoted. One exception are clinicians and other decision-makers involved in health technology adoption (devices) at the local/hospital level.[78] Since the adoption of medical devices occurs at the local/hospital level and is not centrally managed through jurisdictional formularies (as are drugs), engaging the many decision-makers across Canada has been a substantial challenge for CADTH.

CADTH has, however, had some success with respect to medical devices. The evaluation team conducted a case study of CADTH's biennial survey of medical imaging providers in Canada, the Canadian Medical Imaging Inventory (CMII). In Canada, medical imaging is a vital service within the healthcare system, providing the basis for diagnosis, staging, and monitoring in a variety of diseases and conditions. Medical imaging funding decisions are made at the provincial, regional and local levels. Leading up to the most recent CMII survey, CADTH undertook a consultation and planning exercise to consider the future direction of the CMII, with 82% of respondents reporting awareness of the CMII.

CADTH's regional approach to customer support has proven to be a successful model to raise awareness of and improve access to CADTH's products and services. The ISKM team works with jurisdictional customers to understand their needs and helps select the right CADTH products and services. ISKM helps support the formulation of preliminary questions that address customer needs, and facilitate further clarification and refinement in collaboration with others at CADTH, such as the research team's topic refiners, for those questions to move forward for answers.

A key component of the ISKM model are the jurisdictionally-based Liaison Officers, established in 2004 under a centralized model. In 2017, service delivery shifted to a regionally-focused, decentralized model, with the ISKM team located in four regions—West, North, Central and East—

78 Rich, P., "Low awareness about CADTH among practising doctors in Canada," *Canadian Medical Association Journal* 190:18 (2018). https://doi.org/10.1503/cmaj.

reporting to a pan-Canadian team. Saskatchewan's Ministry of Health expressed interest in being a pilot for the new delivery model, and in 2018 an Implementation Support Officer and Program Advisor were added to the Liaison Officer in the province, and later, the Northern Team.[79] As several CADTH key informants stated, Liaison Officers are the "eyes and ears" of CADTH.

Based on the feedback provided by customers in F/P/Ts, the model has proven to be a successful mechanism in maintaining strong customer relations and driving demand for CADTH's products and services, particularly among the smaller provinces (without the expertise and access to specialist networks).

Some CADTH key informants commented that some of the needs identified by the Liaison Officers may be based mainly on individual personal relationships/networks and may not be representative of the highest priority audiences that CADTH seeks to reach. For example, the distribution of RRS users across Canada appears to correspond to the presence of regional teams rather than share of the Canadian population. With 3% of Canada's population, Saskatchewan has 21% of RRS users, Alberta, with 12% of the population, has 20% of RRS users, and Manitoba, with 4% of the population has 12% of RRS users. In contrast, Ontario is under-represented, with 38% of the population and 18% of RRS users. This may be explained by Ontario's recent restoration of full funding to CADTH in 2018, accompanied by a shared Liaison Officer.

In contrast, CADTH key informants had mixed views on the roles and responsibilities and value added by the ISKM function. ISKM has little involvement on the drug review side (preparation of HTAs and OU reports). This was confirmed by the interviews with F/P/T drug plan managers who noted that they have direct access to CADTH's drug review team, are also involved with CADTH's various committees and so have little need to communicate their needs to CADTH through the Liaison Officer intermediaries. ISKM is much more involved in the work associated with device reviews through RRS (75% being device reviews), HTA and OU, and has a close working relationship with the device team.

ISKM's role in providing implementation support was questioned by some CADTH key informants, given the range and vast numbers of local/hospital level stakeholders (e.g., clinicians, professional societies). CADTH struggles for recognition among clinicians not involved in its programs—for example, the provincial medical lead of primary care for the Ontario Renal Network reported awareness of CADTH only through involvement with HTA committees focusing on publicly funded drug formularies.[80] Key informants reiterated this issue. Knowledge translation targeting practising physicians was a particular area for improvement through more effective dissemination strategies to better support appropriate prescribing in clinical practice.[81] As noted in Section 3.1, CADTH's 2015–18 Strategic Plan has identified strengthening engagement with clinicians as an important part of closing the gap between evidence, policy and practice.

79 In 2020, the Western regional model more fully expanded the Saskatchewan Team to reflect a more Western regional focus. An Eastern Team has yet to receive approval to proceed as has the inclusion of a Clinician Liaison Officer as part of ISKM.

80 Rich, P., "Low awareness about CADTH among practising doctors in Canada," *Canadian Medical Association Journal* 190:18 (2018). https://doi.org/10.1503/cmaj.

81 Ibid.

Some CADTH key informants were concerned with the high level of resources devoted to the ISKM function, particularly given the growth in the volume and complexity of work on the drug review side, its high public profile, and the important role it plays in supporting the pCPA in carrying out price negotiations with manufacturers.

Finding 11: CADTH provides a wide range of products and services available to target audiences and other stakeholders. Trends in various measures of access, such as the number of E-Alert subscribers and report downloads show a fairly steady increase during the evaluation period. The more populous Canadian provinces and international audiences tended to be the greatest users of CADTH products and services.

CADTH tracks several measures of access, including metrics related to website traffic, report downloads and the number of individual subscriptions to E-Alerts.

CADTH's website metrics demonstrate positive trends, with a general increase in the number of website visits, particularly in 2019–20 which saw a 52% increase over the previous year (Table 5). The number of website page views followed a similar pattern, with a 39% increase in 2019–20. CADTH does not track the number of unique website visitors.

The number of E-Alert subscribers increased substantially in 2017–18 (by 34% over the previous year) but has remained relatively constant since then.

Table 5: Trend in access by number and type of product/service, 2016–17 to 2020–21.

Product/Service	2016–17	2017–18	2018–19	2019–20	2020–21
Web Visits (sessions)	615,872	551,976	666,660	1,012,515	1,137,468
e-Alert Subscribers	8,167	10,904	10,904	11,446	11,106
Report Downloads	2,830,837	2,714,209	3,521,176	4,682,342	4,733,014
Page views	1,744,563	1,673,974	1,704,661	2,366,312	2,472,362

Source: Health Canada progress reports.

The number of report downloads increased substantially during the evaluation period: an increase of 30% in 2018–19 and 33% in 2019–20 (Table 5). Among the top CADTH products, RR reports were the most commonly downloaded over the evaluation period (36%), followed by OU and Therapeutic Reviews (20 %), Environmental Scans (14%) and HTAs (13%) (Table 6, p. 39).

There is no discernable pattern in the year-to-year increase or decrease in downloads of any particular report type. Downloads of RR reports decreased 81% in 2017–18 and 41% in 2020–21, but increased by 246% in 2019–20. Downloads of OU and Therapeutic Reviews increased by 88% and 86% in 2018–19 and 2019–20 respectively, but decreased by 88% in 2017–18 and 33% in 2020–21. Downloads of HTAs decreased in all years (by 64% in 2017–18, 17% in 2018–19 and 20% in 2020–21), with the exception of 2019–20 which increased by 98%. While downloads of Horizon Scan Bulletins only increased in 2019–20 (26%), during 2020–21 downloads of the Horizon Scan Newsletter and the Horizon Scan Roundup increased by 206% and 3325% respectively.

Table 6: Number of CADTH's top product downloads by type, 2016–17 to 2020–21.

Report Type	2016–17	2017–18	2018–19	2019–20	2020–21
Rapid Response	24,683	4,734	4,323	14,942	8,827
Optimal Use and Therapeutic Review	15,201	1,884	3,551	6,620	4,413
Health Technology Assessment	7,690	2,736	2,275	4,514	3,600
Environmental Scan	9,332	3,433	5,155	2,201	1,805
Horizon Scan Bulletin	-	4,799	3,406	4,286	1,045
Horizon Scan Roundup	6,102	323	37	36	1,233
Horizon Scan Newsletter	-	1,862	2,129	233	714

Source: Health Canada progress reports.

French versions of CADTH reports are prepared on demand. For the three fiscal years with available data, reports in French were far less frequently downloaded than English—2% in 2018–19 and 3% in 2019–20. There were no downloads of reports in French during 2020–21 (Table 7).

Table 7: Number of French report downloads by type, 2018–19 and 2019–20.*

Report	2018–19	2019–20
Optimal Use In Brief: Tisagenlecleucel dans le traitement de la leucémie aigüe lymphoblastique et du lymphome diffus à grandes cellules B	49	88
Optimal Use Summary: Utilisation adèquate des interventions pour les adultes atteints d'insomnie	159	983
Optimal Use In Brief: Utilisation adèquate des interventions pour les adultes atteints d'insomnie	147	-
Health Technology Assessment In Brief: Dépistage du Chlamydia Trachomatis et du Neisseria Gonorrhoeae durant la grossesse: évaluation des technologies de la santé	92	-

Source: Health Canada progress reports.

*French versions of reports were not requested during 2020–21.

For the two fiscal years with available data, international users were responsible for the most downloads of reports (43% in 2018–19 and 70% in 2019–20), followed by Ontario (30% during 2018–19 and 11% in 2019–20) and Quebec (9% in 2018–19 and 13% during 2019–20) (

Table 8, p.40).

The distribution of E-Alert subscribers followed a similar pattern as report downloads, with the highest number of subscribers from the more populous provinces (e.g., Ontario 34%, Alberta 13%) (Table 9, p. 40). Although the absolute numbers are small, the most substantial year-over-year growth in subscribers occurred in Nunavut (300% in 2018–19 and 683% during 2019–20), while Quebec saw the lowest growth in 2019–20 (27% decrease from 2018–19).

Table 8: Proportion of report downloads by jurisdiction, 2018–19 and 2019–20.*

Jurisdiction	2018–19 (%)	2019–20 (%)
Ontario	30.2	11.1
Quebec	9.0	12.5
British Columbia	4.8	2.0
Alberta	4.6	1.5
Manitoba	2.0	0.6
Saskatchewan	1.8	0.5
Nova Scotia	1.8	0.6
New Brunswick	1.6	0.3
Newfoundland and Labrador	0.7	0.3
Prince Edward Island	0.6	0.3
Yukon	0.1	0
International	42.9	70.4

Source: Health Canada annual progress reports.

*Data unavailable for 2016–17, 2017–18 and 2020–21.

Table 9: Number of E-Alert subscribers by jurisdiction, 2016–17 and 2018–19 to 2020–21.*

Jurisdiction	2016–17	2018–19	2019–20	2020–21
British Columbia	342	452	465	485
Alberta	613	741	778	783
Saskatchewan	225	447	535	540
Manitoba	336	362	389	395
Ontario	1,410	2,014	2,133	2,199
Quebec	431	572	415	465
New Brunswick	342	379	396	402
Nova Scotia	232	292	287	287
Prince Edward Island	100	115	156	161
Newfoundland and Labrador	87	187	204	208
Yukon	80	126	184	174
Northwest Territories	117	133	138	138
Nunavut	3	12	94	88
Total number of subscribers with a declared province	4,318	5,832	6,174	6,325
Total number of subscribers with no declared province	3,849	5,072	4,934	4,781
Total E-Alert subscribers	8,167	10,904	11,108	11,106

Source: Health Canada progress reports.

*Data unavailable for 2017–18.

Finding 12: F/P/T decision-makers report a high level of use and reliance on CADTH's products and services. There has been a high degree of concordance of jurisdictional drug plan listing decisions with CADTH's reimbursement recommendations.

Key informants representing F/P/Ts reported a high level of use and reliance on CADTH's products and services. As noted above, there has been a general growth in access to CADTH products and services, a reasonable proxy for "use" by decision-makers.

While there is no legal requirement for the different drug plans to accept a CDR recommendation, a positive CDR recommendation was found to be a strong predictor of subsequent provincial and territorial listings,[82] suggesting that the Formulary Program has facilitated a more consistent approach across jurisdictions. Between 2015–16 and 2020–21, the average level of jurisdictional concordance was 94% for CDR and 96% for pCODR reimbursement recommendations (Table 10, p. 42).

Similar findings have been noted in recent studies. A 2020 review of the CDR process for non-cancer drugs reported that between 60% and 96% of recommendations are adopted by provinces and territories.[83] A 2018 review noted that of 174 medicine-indication pairs in CDR reports (2009 to 2015), there was 78.9%, 81.1% and 78.8% agreement between CDR recommendations and listing decisions in Alberta, British Columbia and Ontario for all drugs respectively. However, in the same review, data for 22 orphan drugs indicated only 59.1% and 63.6% agreement with CDR recommendations in Alberta and Ontario respectively, but 86.4% agreement in British Columbia; only 36.4% of the drugs had the same recommended listing in all three provinces. Conversely, a negative CDR recommendation does not necessarily preclude provincial listing; in Ontario 50.0% of all drugs with a negative CDR recommendation were subsequently available in the province.[84] Of the 22 orphan drugs, 45.5% had a negative CDR recommendation, but despite this 60.0% were listed in Ontario. This heterogeneity in provincial listing decisions for orphan drugs in Canada has also been noted in other studies.[85] Patient population profile and other contextual factors also influence provincial and territorial decisions to list a drug.

An assessment of the impact of the pCODR on provincial and territorial decisions concluded that after the implementation of the pCODR, there was greater concordance in cancer drug funding decisions between provinces and territories.[86] However, cancer drug-funding decisions between

82 McCormick, John I., Berescue, L.D., & Tadros, N., "Common drug review recommendations for orphan drugs in Canada: basis of recommendations and comparison with similar reviews in Quebec, Australia, Scotland and New Zealand" *Orphanet Journal of Rare Diseases* 13:1 (2018).

83 Andersen, S.K., Penner, N., Chambers, A., Trudeau, M.E., Chanm K.K.W. & Cheung, M,C., "Conditional approval of cancer drugs in Canada: accountability and impact on public funding," *Current Oncollogy*, 26:1 (2019). https://pubmed.ncbi.nlm.nih.gov/30853815/.

84 McCormick, John I., Berescue, L.D., & Tadros, N., "Common drug review recommendations for orphan drugs in Canada: basis of recommendations and comparison with similar reviews in Quebec, Australia, Scotland and New Zealand" *Orphanet Journal of Rare Diseases* 13:1 (2018).

85 Ibid.

86 Srikanthan. A., Mai, H, Penner, N., Laupacis, A., ,Sabharwal, M. & Chan,K.K.W., "Impact of the pan-Canadian Oncology Drug Review on provincial concordance with respect to cancer drug funding decisions and time to funding," *Current Oncology* 24:5 (2017). https://pubmed.ncbi.nlm.nih.gov/29089796/.

provinces and territories nevertheless displayed discordance, leading the authors to conclude that political pressure and budgetary constraints affected equity of access to cancer drugs for patients.[87]

Key informants for the case study of CADTH's CMII indicated that they use the CMII regularly and have been doing so for a number of years, and that it provides objective, evidence-based information to facilitate decision-making. CADTH's consultation and planning exercise leading up to the most recent CMII reported that respondents viewed the CMII as a critical resource in supporting planning processes, and that the CMII is used frequently and extensively in decisions about the acquisition and placement of new equipment.

The impacts of CADTH's products and services are described later in this report.

Table 10: Proportion of jurisdictional drug plan listing decisions aligned with CADTH's reimbursement recommendations, by drug review type, 2016–17 to 2020–21.

Drug Review Type	2016–17 (%)	2017–18 (%)	2018–19 (%)	2019–20 (%)	2020–21 (%)
CDR	96	94	93	93	94
pCODR	89	98	100	98	96

Source: Health Canada progress reports.

Finding 13: F/P/T decision-makers reported a high level of satisfaction with CADTH's HTM knowledge products and services.

Key informants representing F/P/Ts reported a high level of satisfaction with CADTH's products and services, corresponding to the results of CADTH's own customer satisfaction surveys (Table 11). Virtually all customers of CADTH's RR reports and participants in symposiums reported high levels of satisfaction.

Table 11: Customer satisfaction levels by type of product/service, 2016–17 to 2019–20.*

Product/Service	2016–17 (%)	2017–18 (%)	2018–19 (%)	2019–20 (%)
RRS	98	99	-	-
Symposium attendees	97	99	-	-
Timelines met CDR	98	100	100	100
Timelines met pCODR	100	100	100	100

Source: Health Canada progress reports.

*Data partially or completely unavailable for 2018–19, 2019–20 and 2020–21.

87 Srikanthan, A., Penner, N., Chan, K.K.W., Sabharwal, M. & Grill, A, "Understanding the reasons for provincial discordance in cancer drug funding-a survey of policymakers," *Current Oncology* 25:4 (2018). https://pubmed.ncbi.nlm.nih.gov/30111966/.

The survey of RRS users conducted as part of this evaluation also found very high levels of client satisfaction, as 87% of respondents indicated that the most recent RR report met their needs, and 93% were satisfied with the CADTH experience.

A 2019 study assessed a diverse sample of journal-published (and non-journal-published RR reports (including those from CADTH) against modified BRIDGE criteria.[88] These criteria were originally developed to promote clear communication in support of support healthcare policy-making. Conformity of the RR reports with modified BRIDGE criteria was determined to be modest. As knowledge translation products, many RR reports were found to have some useful features valued by end-users. The authors concluded that the packaging of information in RR reports was found to be relevant and should best meet the information needs of policy-makers and key stakeholders to optimise the uptake of evidence from RR reports in healthcare decision-making.[89]

The importance of information packaging was raised by those decision-makers interviewed for the case study of CADTH's CMII. While respondents indicated that the CMII provided objective, evidence-based information to facilitate decision-making, there was a prevailing view that the report was too lengthy, difficult to digest, and the information could be better synthesized and made more usable through, for example, infographics.

4.1.2 Intermediate Outcome: CADTH contributes to equipping healthcare decision-makers with increased knowledge, skills and supports on drugs and devices

Finding 14: CADTH delivered many implementation support activities to help bridge the gap between the provision of high-quality, timely and comprehensive HTA information and sound and defensible decision-making. These include the regional approach to customer support, custom services, rapid qualitative reviews, and a range of products, tools and knowledge events.

A number of CADTH documents refer to the importance of implementation support. For example, the 2018–21 Strategic Plan notes that over this time period, CADTH would pursue an approach to implementation support that addresses the needs of decision-makers. In doing this, CADTH committed to embedding resources within the healthcare system to support local contextualization, engagement, integration and policy implementation. These supports were expected to be tailored to health system contexts, needs and preferences.

Over the evaluation period, CADTH has delivered many implementation support activities to help bridge the gap between the provision of high-quality, timely, and comprehensive HTA, and sound and defensible decision-making. CADTH has helped decision-makers (e.g., policy-makers, clinicians, patients) understand and use evidence provided by CADTH to make better decisions about the use of medical, dental and surgical devices, procedures and programs; pharmaceuticals; and diagnostic tests. As noted in Section 4.1.1, CADTH has embedded Liaison Officers within jurisdictional healthcare systems to support local contextualization, engagement, integration and

88 Garritty, C., Hersi, C.H.M., Butler, C., Monfaredi, Z., Stevens, A., Nussbaumer-Streit, B., Cheng, W. & Moher, D., "Assessing how information is packaged in rapid reviews for policymakers and other stakeholders: a cross-sectional study," *Health Research Policy and Systems* 18:112 (2020).

89 Ibid.

policy implementation tailored to local health system contexts, needs and preferences. Consistent with the commitment to providing implementation support and in response to customer needs, CADTH developed several new custom services in 2019–20, including the Policy Service, IMPRESS and rapid qualitative reviews, and provides a wide range of products, tools and knowledge events to support decision-makers and move the evidence into action.[90] Additionally, knowledge mobilization at CADTH includes multiple activities, including brokering, that contribute to the uptake and impact of HTA and HTM evidence.

Finding 15: CADTH has steadily increased the number of implementation support tools since 2018–19, primarily Topic Teasers, Evidence Bundles, Infographics and Newsletters. Infographics and Evidence Bundles saw the most year-to-year growth.

CADTH provides a range of implementation tools for drugs and devices to support decision-makers and move the evidence into action. CADTH delivered 99 implementation support tools in 2018–19, 108 in 2019–20 and 121 in 2020–21 (Table 12). The most common were Topic Teasers (26%), followed by Evidence Bundles (19%), Infographics (17%) and Newsletters (16%). From 2019–20 to 2020–21, Infographics and Evidence Bundles saw the most year-to-year growth at 38% and 30% respectively.

Table 12: Trend in the number of implementation tools by type, 2018–19 to 2020–21.*

Implementation Tool Type	2018–19	2019–20	2020–21
Evidence Bundles (mostly device)	15	16	31
In Briefs (mix of drug and device)	15	20	4
Internet Quizzes (mostly drug)	14	12	6
Infographics (mix of drug and device)	5	13	39
Newsletters (mix of drug and device)	22	12	18
Topic Teasers (mix of drug and device)	28	35	23
Total Implementation Tools	99	108	121

Source: Health Canada progress reports.

*Data unavailable for 2016–17 and 2017–18.

90 CADTH, CADTH 2019-2020: Annual Business Plan (Ottawa, 2019), p. 3.

Finding 16: Over the evaluation period, CADTH has delivered 2,186 knowledge products for technologies, and 472 knowledge events to 16,126 participants. There has been a steadily increase in the number of knowledge products, events and participants. Nearly three-quarters of knowledge events were educational and the remainder training. Knowledge events were most commonly delivered in federal venues, and in Saskatchewan and Alberta. Participants in these were mostly from the federal government, Ontario and Saskatchewan. Approximately 40% of knowledge events at conferences were specifically targeted at clinicians, a group actively engaged by ISKM.

CADTH produces knowledge products through its Formulary Program, and through various other programs and products that include the RRS, HTA and OU, Horizon Scanning, and Environmental Scans. Some of these products include recommendations or advice provided by an expert committee, such as CDR recommendations provided by the CADTH Canadian Drug Expert Committee, pCODR recommendations provided by the CADTH pCODR Expert Review Committee (PERC), and OU recommendations provided by the CADTH Health Technology Expert Review Panel. Over the evaluation period, CADTH developed 2,186 knowledge products for technology types, the most occurring in 2019–20 (27%) (Table 13).

Table 13: Trend in the number of knowledge products completed for different technology types,* 2016–17 to 2020–21.

2016–17	2017–18	2018–19	2019–20	2020–21
438	380	348	585	435

Source: Health Canada progress reports.

*Reports for technologies such as drugs, medical devices, non-surgical interventions, surgical procedures and diagnostics.

During the same period, CADTH delivered 472 knowledge events, consisting of training sessions (e.g., skill building sessions and workshops) and educational events (e.g., webinars, conferences and presentations) (
Table 14, p. 46). The number of knowledge events decreased in 2017–18 (by 32% compared to 2016–17) but increased at a fairly steady rate during 2018–19, 2019–20 and 2020–21 (47%, 42% and 37% respectively). Between 2018–19 and 2020–21 (the only years for which disaggregated data are available), these events consisted of training sessions (26%) and educational events (74%). Between 2018–19 and 2020–21 (the only years for which disaggregated data are available), knowledge events were most commonly delivered in federal venues (38%), followed by Alberta (21%) and New Brunswick (19%).

CADTH delivered knowledge events to 18,626 participants over the evaluation period (Table 15, p. 46). The number of participants increased substantially in each year, the lowest increase was 50% in 2017–18 and the highest increase was 102% in 2020–21. Between 2018–19 and 2020–21 (the only years for which disaggregated data are available), over one-quarter of participants were from the federal government (26%), followed by Ontario (22%) and Saskatchewan (18%). Approximately 40% of knowledge events at conferences (jurisdictional and national) were specifically targeted at various clinician groups. Clinicians were engaged by ISKM team members at least 423 times (nursing 73, allied health 25, physicians 95, pharmacy 21, mixed 203).

Table 14: Trend in the number of knowledge events by type and jurisdiction, 2018–19 to 2020–21.*

Jurisdiction	Training Session			Educational Event		
	2018–19	2019–20	2020–21	2018–19	2019–20	2020–21
British Columbia	4	0	2	2	3	2
Alberta	3	1	0	10	10	15
Saskatchewan	3	10	6	8	13	12
Manitoba	2	1	1	8	10	8
Ontario	2	0	0	2	11	6
New Brunswick	0	1	4	8	10	13
Nova Scotia	5	1	3	2	4	5
Prince Edward Island	1	1	1	6	9	5
Newfoundland and Labrador	0	3	0	1	4	5
Yukon	0	0	1	0	0	1
Northwest Territories	3	2	4	0	5	3
Nunavut	0	0	2	0	0	1
Federal	2	1	17	6	11	35
Total knowledge events	25	21	41	53	90	111

Source: Health Canada progress reports.

*Data for 2016–17 and 2017–18 unavailable disaggregated by knowledge events type and jurisdiction. There were 78 knowledge events in 2016–17 and 53 in 2017–18.

Table 15: Number of participants in knowledge events by jurisdiction, 2018–19 to 2020–21.*

Jurisdiction	2018–19	2019–20	2020–21
British Columbia	60	50	564
Alberta	270	150	748
Saskatchewan	520	1795	589
Manitoba	380	110	302
Ontario	190	590	2730
New Brunswick	80	130	198
Nova Scotia	195	110	236
Prince Edward Island	240	700	52
Newfoundland and Labrador	10	90	144
Northwest Territories	30	115	131
Federal	635	630	2884
Total participants	2610	4470	9046

Source: Health Canada progress reports.

*Data for 2016–17 and 2017–18 unavailable disaggregated by jurisdiction. There were 1000 participants in 2016–17 and 1500 in 2017–18.

Finding 17: Decision-makers agree that their knowledge and information needs are being met by CADTH, and nearly two-thirds reported they would recommend CADTH products and services to colleagues.

CADTH captures limited data on the use made of its OU reports, which impacts its ability to assess effectiveness. For one such report (*Internet-Delivered Cognitive Behavioural Therapy for Major Depressive Disorder and Anxiety Disorders*), 100% of survey respondents indicated that the report somewhat or to a great extent met their organization's information needs. In the same survey, 62% of decision-makers reported they would definitely recommend CADTH products and services to a colleague.

In 2019–20 and 2020–21, CADTH administered a total of 14 and 26 pre- and post-knowledge event surveys respectively. Of the 355 responses to a question regarding acquisition of knowledge in 2019–20, 79% reported a gain in knowledge, while of the 502 responses to the same question in 2020–21, 42% reported a gain in knowledge after attending the event.

4.1.3 Intermediate Outcome: Healthcare decision-makers optimally using drugs and medical devices as a result of CADTH

During 2018–19 and 2019–20, CADTH conducted customer surveys to assess how evidence-based supports were being used by decision-makers and how these contributed to decision-making. The 2018–19 survey found that 73% of respondents indicated that the supports were useful in the context of decision-making, for example, to provide information on specific topics, inform briefing notes, assist with equipment purchases and supporting discussions among colleagues. The 2019–20 survey found that 42% of respondents reported using at least one of the three evidence-based supports related to the OU report *Internet-Delivered Cognitive Behavioral Therapy for Major Depression and Anxiety Disorders*. CADTH has indicated that, in the future, additional customer impact surveys on other products and services will be conducted.

In addition to product-specific surveys, over time, CADTH has refined and strengthened its approach to the impact assessment of its products and services more broadly. Over the evaluation period, CADTH tracked the extent customers used CADTH evidence (i.e., reports) to inform decisions across the following scale of five impact levels:

1. Disseminated and shared, increased awareness or understanding.
2. Informed planning or strategy development, presented or discussed as a meeting agenda item.
3. Resulted in further requests or uptake of CADTH evidence, contributed to patient or staff education or resource development.
4. Resulted in a clinical practice decision, policy decision (regional health authority or ministry) or optimization of resources.
5. Resulted in decommissioning or disinvestment, a purchasing decision or a direct benefit to patients in the healthcare system.

Finding 18: CADTH's products and services are being used by decision-makers and are having an impact on decision-making. Compared to large-scale reports, the small-scale customer-driven reports had a high impact on clinical practice, policy and resource decisions.

CADTH's products and services are being used by decision-makers and are having an impact on decision-making. Between 2016–17 and 2020–21, CADTH captured 175 instances of impact generated by small- and large-scale reports (Tables 16 and 17, p. 49).[91] From 2016–17 to 2018–19, CADTH identified 78 specific instances in which evidence provided impacted decision-making related to effecting clinical practice change (40%), informing policy change (33%) and optimizing healthcare resources (27%)—broadly consistent with Level 4 (Table 16, p. 49)—that is, narrowing the gap between evidence, policy and practice.

Between 2019–20 and 2020–21, small-scale reports were more commonly produced than large-scale reports (86% and 83% of all reports respectively). In both years, small-scale reports had a higher impact than large-scale reports. For example, in 2019–20 and 2020–21, only small-scale reports reached impact levels 4 and 5, while the impact of large-scale reports was confined to levels 1 to 3 (primarily levels 1 and 2). Small-scale reports are typically customer-driven, addressing issues of priority, while the large-scale reports tend to be broad in nature and intended to be applicable across Canada as a whole.

Finding 19: Positive or conditional reimbursement recommendations made under the Formulary Program are expected to be considered for negotiation by the pCPA, and it is very rare that this is not the case.

The pCPA conducts joint F/P/T negotiations for brand name and generic drugs in Canada to achieve greater value for publicly-funded drug programs and patients. Since 2018–19, CADTH has included the pCPA (as an observer) in the formulary processes, providing an opportunity for the pCPA to receive relevant information on drugs reviewed through these processes. It is expected that positive or conditional reimbursement recommendations made under the Formulary Program will be considered for negotiation by the pCPA.

Excluding drug reimbursement recommendations for which the pCPA negotiation status is still under consideration, CADTH issued 203 positive or conditional reimbursement recommendations under the Formulary Program between 2018-19 and 2020–21. Of these, 99% were taken up for negotiation by the pCPA (Table 18, p.49).

91 An example of a small scale-report is the *COVID-19 Remdesivir* report prepared for Alberta, while an example of a large-scale report is *Ongoing Trials for Drugs in the Prevention and Treatment of COVID-19* prepared for New Brunswick.

Table 16: Number of impacts of reports, by impact level, 2016–17 to 2018–19.*

Impact Type	2016–17	2017–18	2018–19
Informing policy change	8	12	6
Optimizing healthcare resources	6	8	7
Effecting clinical practice change	11	10	10
Total impacts	25	30	23

Source: Health Canada progress reports.

*The method to assess impact changed as of the 2019–20 fiscal year. See **Error! Not a valid bookmark self-reference.** for fiscal years 2019–20 to 2020–21. All the impact types in Table 16 are consistent with Level 4.

Table 17: Impacts of small- and large-scale reports by level of impact, 2019–20 to 2020–21.*

Impact Level	2019–20		2020–21	
	Small Reports	Large Reports	Small Reports	Large Reports
Level 1: Disseminated and shared, increased awareness or understanding.	7	4	8	3
Level 2: Informed planning or strategy development, presented or discussed as a meeting agenda item.	9	3	8	3
Level 3: Resulted in further requests or uptake of CADTH evidence, contributed to patient or staff education or resource development.	10	1	6	1
Level 4: Resulted in a clinical practice decision, policy decision (regional health authority or ministry), or optimization of resources.	13		7	
Level 5: Resulted in decommissioning or disinvestment, a purchasing decision, or a direct benefit to patients in the healthcare system.	9		5	
Total impacts	48	8	34	7

Source: Health Canada progress reports.

*The method to assess impact changed as of the 2019–20 fiscal year. See Table 16 for fiscal years 2016–17 to 2018–19.

Table 18: Number of positive and conditional reimbursement recommendations taken up by pCPA, 2018–19 to 2020–21.*

Status	2018–19	2019–20	2020–21
Negotiations pursued[+]	33	99	69
Negotiations under consideration	9	-	-
Negotiations not pursued	1	1	0

Source: Health Canada progress reports.

*Data unavailable for 2016–17 and 2017–18.

4.1.4 Ultimate Outcome: CADTH contributes to Canada having a modern and sustainable healthcare system

Finding 20: CADTH has contributed to a well-functioning process for listing of drugs by the provinces and territories by providing evidence-based recommendations that are respected. There has been a high level of concordance of jurisdictional drug plan listing decisions with CADTH's reimbursement recommendations, and congruence among jurisdictional formularies, while small-scale reports have frequently impacted the Canadian healthcare system. Although CADTH tracks topics of common interest across jurisdictions, other than in 2018–19, no data was available about the impact of CADTH products in multiple jurisdictions.

CADTH's performance in contributing to the achievement of its ultimate outcome can be assessed by an examination of several performance indicators in CADTH'S performance measurement framework, as follows.

As noted in Section 4.1.1, over the evaluation period the average level of alignment of provincial and territorial drug listings with CADTH's drug reimbursement recommendations was very high: 94% for CDR and 96% for pCODR reimbursement recommendations. Key informants have a high level of respect for CADTH's work in this area. Also as noted in Section 4.1.1, a 2018 study considering uptake of CDR recommendations across Canadian jurisdictions concluded that a positive CDR recommendation for drugs was a strong predictor of subsequent provincial and territorial listing, although this was not the case for orphan drugs.[92] However, a negative CDR recommendation was found to not necessarily preclude provincial and territorial listing.[93] An assessment of the impact of the pCODR on provincial and territorial decisions found discordance between provincial and territorial cancer drug-funding decisions, leading the authors to conclude that political pressure and budgetary constraints affected equity of access to cancer drugs for patients.[94]

Also as noted in Section 4.1.3, CADTH's products and services are being used by decision-makers and are having an impact on decision-making. From 2016–17 to 2018–19, CADTH identified 78 specific instances in which evidence provided impacted decision-making related to effecting clinical practice change (40%), informing policy change (33%), and optimizing healthcare resources (27%). Between 2019–20 and 2020–21, only small-scale reports impacted levels 4 and 5—these are impacts associated with modernizing and sustaining the healthcare system as a whole.[95]

CADTH has also helped decision-makers understand and use evidence to make better decisions about the use of medical devices, through the efforts of the Device Advisory Committee, ISKM and the associated HTM products and services. As noted in Section 4.1.1, while CADTH has experienced challenges engaging clinicians and other decision-makers involved in device adoption at the local/hospital level, there is a general high degree of satisfaction with the HTM products and

92 McCormick, John I., Berescue, L.D., & Tadros, N., "Common drug review recommendations for orphan drugs in Canada: basis of recommendations and comparison with similar reviews in Quebec, Australia, Scotland and New Zealand" *Orphanet Journal of Rare Diseases* 13:1 (2018).

93 Ibid.

94 Srikanthan, A., Penner, N., Chan, K.K.W., Sabharwal, M. & Grill, A, "Understanding the reasons for provincial discordance in cancer drug funding-a survey of policymakers," *Current Oncology* 25:4 (2018). https://pubmed.ncbi.nlm.nih.gov/30111966/.

95 Data related to device specific impacts was not available.

services intended to support decision-making in this respect. For example, customer satisfaction levels for RRS (75% being device reviews) were 98% and 99% in 2016–17 and 2017–18 respectively. The case study of the CMII found a high level of awareness (82%) among those decision-makers at the provincial, regional and local levels, who regarded the CMII as a critical resource in supporting planning processes, and used it frequently and extensively in decisions about the acquisition and placement of new equipment.

While CADTH tracks topics of common interest across jurisdictions, including telehealth, healthy aging, opioids, pain management, mental health and dialysis, only in 2018–19 did CADTH report on the use of its products in multiple jurisdictions across Canada. In that year, CADTH identified that 30% of its large-scale reports demonstrated impact in more than one jurisdiction. Since 2018–19, CADTH had planned to implement a new database that will allow more efficient tracing of the multi-jurisdictional impact of its products—this new impact database was launched on April 1, 2021.

5. Findings: Efficiency and Economy

5.1 Is CADTH producing its products and services efficiently? Are there alternatives that would be more efficient?

Finding 21: Over the evaluation period, CADTH actively explored alternative and more efficient approaches to delivering its products and services, particularly the substantial progress CADTH has made in recent years in improving the operational efficiency of the drug review process. CADTH reviewed comparable HTA agencies to understand process differences, resource implications and stakeholder impact. Key informants expressed mixed views about the utility of benchmarking; the substantial jurisdictional contextual differences were viewed as the main barrier. Nonetheless, CADTH has ranked favourably in the CIRS annual performance metrics benchmarking of eight HTA agencies related to new active substances.

There are mixed views regarding the utility of benchmarking, due to the substantial jurisdictional contextual differences across nations (e.g., structure of healthcare systems, access to drug markets, stakeholder composition). One study found that CADTH, NICE, and the United States-based Institute for Clinical and Economic Review each employ drastically different definitions of cost-effectiveness and make equally divergent use of their determinations, an impediment to benchmarking.[96] Some key informants noted that even if absolute differences in benchmarks were not meaningful because of these contextual differences, going through the process of compiling and analyzing information to compare benchmarks is in itself a valuable exercise. Others argued that the influence of jurisdictional differences on benchmarks can be factored into the analysis. Key informants made several suggestions for potential benchmarks, including the cost of product and service categories, duration between regulatory submissions to initial recommendations, quality of recommendations and a measure of expertise deployed on advisory committees.

A 2018 study examined the delays existing between regulatory approval and HTA recommendations.[97] Comparing the HTA agencies in five countries, the research concluded that CADTH had the lowest percentage of HTA recommendations occurring the same year as jurisdictional regulatory approval. Of the products with CADTH recommendations in 2014, 7% were approved by Health Canada in the same year. By comparison, all of the products recommended in 2015 were approved in the same year in Australia through a process by which, after the regulatory application is accepted for review by Australia's Therapeutic Goods Administration (TGA, the Health Canada equivalent), a reimbursement submission may be sent to the Pharmaceutical Benefits Advisory Committee (PBAC, Australia's CADTH equivalent) for parallel review. This parallel process enables a TGA delegate to provide an overview of regulatory status to PBAC during the HTA decision-making process, allowing the PBAC to potentially make a reimbursement recommendation even before a formal TGA approval is granted. For 2014 and 2015, comparing the percentage of HTA recommendations with the jurisdictional regulatory agency approval the same year showed 7%

96 Watson, T. & Mirabella, M. "Cross-country ICER evolution: What does it now mean to be cost-effective?," *Value in Health* (2019).

97 McAuslane, N., Wang, T., & Liberti, L., "Synchronization Of Regulatory Approval And Health Technology Assessment Recommendation Timing," *International Journal of Technology Assessment in Health Care*, 33:S1 (2017).

(2014) versus 29% (2015) for CADTH: 35% versus 37% for Scotland: 35% versus 44% for France; 56% versus 57% for Germany; and 91% versus 100 % for Australia. The study showed that the parallel submission mechanism to enable synchronizing the regulatory decision and first HTA recommendation is effective in Australia, while a synchronization disconnect remains in other countries.

A subsequent 2020 study by CIRS illustrated that the above situation has improved, particularly for Canada. As part of its ongoing study to monitor and benchmark regulatory and HTA performance, CIRS collected data on new active substances (NASs) appraised between 2015 and 2019 by eight HTA agencies (including CADTH), analyzing synchronisation between the regulatory decision and first HTA recommendation in timing and outcome.[98] The main findings of this benchmarking exercise are as follows:

- Between 2015 and 2019, of all NASs approved by regulatory agencies that received a positive or positive with restrictions first recommendation by HTA agencies across all of the studied jurisdictions, Canada ranked fifth. Canada had the fewest positive first recommendations for NASs, and the most with positive with restrictions first recommendation.
- Australia had the fastest median rollout time from regulatory submission to first HTA recommendation in 2019, followed by Canada. There was less variation in rollout time in these two countries in 2019 compared with 2018.
- Between 2015 and 2019, Australia had the shortest median time between regulatory approval and HTA recommendation, followed by Canada.
- Of 37 NASs commonly appraised by seven HTA agencies, Canada showed the lowest proportion of positive first recommendations. England and Scotland had the highest congruence of first HTA recommendations. Canada and England, Canada and Sweden, and Canada and Scotland had the second, third and fourth highest congruence of first HTA recommendations.

CIRS notes that the Health Canada/CADTH parallel review process, which allows for a submission to CADTH within 90 days before the date of anticipated NOC from Health Canada, had been available since 2012, but in 2018, CADTH's submission criteria were changed to within 180 days before the anticipated NOC from Health Canada. Despite a substantial increase in reviews of NASs in 2018–19, this change had a substantial positive impact in reducing the length of time between Health Canada's market authorization and CADTH's drug reimbursement recommendations. The number of days between Health Canada's market authorizations and CADTH's final listing recommendations decreased in 2019–20 by 45% for pCODR and by 82% for CDR (Table 19, p. 54). In 2018–19, the median time taken from regulatory approval to HTA recommendation for the parallel process was 282 days faster that the former sequential process.

98 Recommendations were collected from the Australian PBAC, CADTH (both CDR and pCODR), the United Kingdom NICE, French Haute Autorité de Santé, German Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, Polish Agencja Oceny Technologii Medycznych i Taryfikacji, Scottish Medicines Consortium and Swedish Tandvårds- & läkemedelsförmånsverket, for NASs approved 2012–2019 by the respective jurisdictional regulatory agencies, the Australian TGA, Health Canada and European Medicines Association.

Table 19: Average number of days between Health Canada's market authorization and CADTH's listing recommendation, by drug review type, 2018–19 to 2020–21.*

Drug Review Type		2018–19	2019–20	2020–21
Initial Recommendation	pCODR	146	85	98
	CDR	156	45	51
Final Recommendation	pCODR	256	140	148
	CDR	417	75	125

Source: Health Canada progress reports.

*Data unavailable for 2016–17 and 2017–18.

Finding 22: There may be an opportunity for CADTH to share confidential pricing data to the pCPA under a non-disclosure agreement.

When CADTH conducts its pharmacoeconomic analysis as part of the drug review process it is not aware of the actual price paid by jurisdictions for many drugs (including comparator drugs, drugs used in combination or the submitted drug if it has been previously marketed). Discrepancies may arise due to pCPA negotiated prices, historic jurisdictional product listing agreement, or confidential prices on generics (especially in healthcare environments with direct procurement).

When the pCPA conducts its work, it may conduct customized pharmacoeconomic analysis using the actual drug prices paid by jurisdictions, reconcile divergent HTA assumptions, or adapt to changing market conditions (including newly marketed comparator treatments, generic launches, or recommended changes in clinical criteria or subpopulation). pCPA members suggested that an alternate approach may be for the pCPA to communicate actual pricing information to CADTH under a non-disclosure agreement.

Finding 23: There is a long-term opportunity for CADTH to pursue formal collaboration with other HTAs internationally, which could reduce the cost of drug reviews worldwide and the time to market entry in Canada. The pathway to domestic and international collaboration on devices is much less clear.

Key informants, particularly those from international HTA agencies, stressed that CADTH is well-respected and considered a leader among HTA agencies, as demonstrated through CADTH's active membership of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and HTAi. In addition to ISPOR and HTAi, notable collaborations raised by key informants include that with other Commonwealth countries (Australia, Scotland and England) on COVID-19 and other reviews, and with International Network of Agencies for Health Technology Assessment.

CADTH's 2019 collaboration with the United Kingdom-based NICE is particularly noteworthy, offering parallel scientific advice to the life sciences industry.[99] This work was intended to help drug developers gather cost-effectiveness data during the process of a clinical trial. The resulting scientific advice was provided to help pharmaceutical firms develop evidence that can demonstrate the value of a new treatment. Using expert opinions from a range of contributors (including clinicians, health economists and patient representatives), CADTH and NICE provide detailed feedback on pharmaceutical firms' plans to generate clinical and economic evidence. The paid-for advice was also viewed as assisting these firms prepare for future HTAs by answering their questions and providing key insights on their clinical and health economic development plans.[100] A joint summary of those areas where there is alignment in the advice from CADTH and NICE and separate detailed advice reports from each agency are provided under this program. The first project through this CADTH-NICE collaboration was completed in January 2019.[101] CADTH's Scientific Advice Program is modelled after a similar program at NICE, a direct result of this collaboration.

However, in comparison to the success Health Canada has had collaborating internationally in the regulatory space, key informants observed that CADTH has had limited impact at an operational level resulting from its collaborative efforts with other international HTA agencies. CADTH's collaborations have been biased towards English-speaking countries—opportunities in other countries with similar healthcare systems, such as Italy and Spain, have not been explored. As with benchmarking, respondents stated that different jurisdictional context is the primary barrier to international collaboration. For example, challenges arise when trying to translate economic aspects of HTA across national borders and local standards of care. As noted above, however, there is a high degree of congruence between Canada's first HTA recommendations with England (57%), Sweden (54%) and Scotland (51%). In a recent environmental scan, CADTH has also favourably compared its HTA processes with similar HTA agencies, while noting that the type of processes applied by an HTA organization has implications on the organization's resources and an impact on its stakeholders (e.g., CADTH relies on conducting in-house systematic reviews, which could be a more resource-intensive process relative to the "appraisal" type reviews conducted at other HTA organizations where the applicant submits the systematic review). Nevertheless, there is potential for collaboration in the long-term for harmonization of HTA approaches, and in this respect, CADTH has played an important role, for example, leading the development of a single international definition of "HTA." Key informants also identified devices and DRDs (which are often approved in other countries) and information collection and sharing (e.g., clinical evaluations) as potential areas for international collaboration.

Regarding domestic collaboration, CADTH has cultivated collaborations with a range of organizations. Over the time period of the evaluation, CADTH signed a number of collaborative MOUs with a range of organizations. Activities with organizations involving an MOU include, but are not limited to: information sharing and topic identification, project-specific collaborations, clinician expert identification and annual conference attendance/support. Organizations with which CADTH has signed a collaborative MOU include the Canadian Association of Radiologists, Canadian

99 PMLive, *NICE and Canadian counterpart to offer joint advice service* (United Kingdom, 2019). https://www.europeanpharmaceuticalreview.com/news/83781/scientific-advice/.

100 Ibid.

101 Sood, A., Collaboration and Alignment Across Health Canada, CADTH, and INESSS (Ottawa, 2019). https://cadth.ca/sites/default/files/symp-2019/presentations/april15-2019/C3-presentation-asood.pdf

Association of Medical Radiation Technologists, Canadian Center on Substance Use and Addiction, Canadian Foundation for Healthcare Improvement, Canadian Standards Association, Ontario Health (Quality) and the Institute of Health Economics (Alberta).

CADTH also collaborates with a number of organizations to foster implementation of recommendations, including with the Canadian Standards Association's Healthcare Standards Committee, Canadian Centre on Substance Abuse and the Mental Health Commission of Canada.

CADTH has actively collaborated with other HTA organizations in Canada. For example, the pan-Canadian HTA Collaborative is overseen by a steering committee composed of senior executives from Ontario Health (Quality), INESSS (Quebec), the Institute of Health Economics (Alberta), the British Columbia Health Technology Review and CADTH. The intent of the Collaborative is to share best practices, minimize duplication of effort through the sharing of information, and identify and contribute to joint initiatives in the assessment of health technologies (medical devices, procedures, and diagnostics). Fostering collaboration among regional HTA producers is promoted as a core value and guiding principle of the Collaborative. The Collaborative engages collectively to enhance the development and use of HTA in Canada to improve patient outcomes and health system sustainability. However, the pathway to domestic and international collaboration on devices remains much less clear given the sheer volume of new medical devices entering the market each year, the complexity of the market path to entry and adoption, the speed of innovation and patient demands, and the intrinsically more complex lifecycle management compared to drugs.

Respondents most frequently cited the Collaborative as the primary example of CADTH's collaboration efforts. Key informants did suggest expanding membership of the Collaborative.

5.2 Is CADTH seen as generating value-for-money on the part of its funders and Canadians?

Finding 24: Without CADTH, each jurisdiction would have to create a formulary review capacity, which would result in increased cost for Canadians compared to the current model. There are opportunities for CADTH to increase its value proposition by continuing to implement its strategy to become a HTM agency. CADTH's value-for-money related to its device-related work is more difficult to assess, and some view CADTH as less successful in this space, although there is a high degree of satisfaction with RR reports, the majority of which focus on devices questions.

Decision-makers representing CADTH's key customers and stakeholders agreed that CADTH is providing value-for-money for Canada, particularly through its Formulary Program. All jurisdictions rely on CADTH's drug reimbursement recommendations, and CADTH provides excellent support to the pCPA in conducting price negotiations with manufacturers. The smaller provinces and the territories lack an internal HTA capacity. Without CADTH, each jurisdiction would have to create such a capacity, which would result in increased cost for Canadians compared to the current model.

As noted earlier, there are opportunities for CADTH to increase its value proposition. In continuing to develop and implement its strategy to become an HTM organization, CADTH's funders and other

stakeholders are looking to CADTH to provide more support in helping them cope with the increasing pressure being placed on their healthcare budgets.

There is a long-term opportunity for CADTH to pursue formal collaboration with other HTA agencies internationally for the conduct of drug reviews. Not only could this reduce the cost of drug reviews for each participating jurisdiction, it could also reduce the time to market entry in Canada.

CADTH's value-for-money related to its device-related work is more difficult to assess. As discussed earlier, the path to market entry and uptake is more complex for devices compared to drugs, as there are no F/P/T formularies and purchasing decisions are typically made at the local level. The medical device industry would like CADTH to be more active in the medical device space. It does recognize that CADTH conducts a large number of RR reviews focused on devices, which are valued by individual decision-makers. The medical device industry perceives that CADTH conducts relatively few HTA/OU reports focused on devices, which have broader system-wide impacts. A review of the HTR reports available on the CADTH website revealed that a total of 87 such reports had been published over the evaluation period, of which 42 were focused on drugs, 27 on clinical interventions and 18 on medical devices.

Looking ahead, the eventual introduction of a Canadian Drug Agency could lead to considerable cost savings for the healthcare system, as functions currently being conducted by multiple organizations may be combined within a single agency. As noted in Section 2.3, CADTH will need to be engaged and, as options or models are developed, ensure that it continues to examine its role to minimize duplication and maximize efficiency.

6. Conclusions

This section presents the conclusions of the evaluation, organized by evaluation issue.

6.1 Relevance

CADTH's products and services align with the needs of F/P/T funders and other customers and decision-makers

Joint statements by F/P/T Ministers of Health in 2016 and 2018 have expressed a common vision of creating a more adaptable, innovative and affordable healthcare system for all Canadians. This vision features shared commitments to support health innovation and to improve the affordability, accessibility and appropriate use of prescription drugs, including harmonization of drug plan formularies, and measures to reduce pharmaceutical prices and support appropriate prescribing, while striving to improve health outcomes.

Working with First Nations, Inuit and Métis to improve access to health services and health outcomes for Indigenous Peoples has also remained a priority for F/P/T Ministers of Health.

Successive federal budgets have reflected these F/P/T shared priorities and have committed funding to federal departments and agencies and to PCHOs, including CADTH, to support pharmaceutical policy initiatives, health innovation and implementation of national pharmacare.

For its part, CADTH has aligned its structures and processes at all levels to respond to these priorities and the needs of its F/P/T funders and other stakeholders. The Board of Directors, with several members drawn from jurisdictions, ensures that CADTH responds to the above priorities and to the evolving needs of its F/P/T funders. The two strategic plans that cover the evaluation period clearly describe how CADTH intends to meet the priorities of its customers and other stakeholders. The annual business plans describe how these commitments will be achieved, while the annual progress reports to Health Canada summarize the results that have been achieved.

The evaluation evidence indicates that CADTH's products and services generally align with the needs of its F/P/T funders and with other stakeholders. Canadians have been afforded more timely access to drugs through the joint efforts of Health Canada and CADTH, most notably to improve the time between regulatory approval and HTA recommendations. CADTH also stopped reviewing biosimilar drugs so as to not delay Canadians' access to treatment and created an integrated Formulary Program.

CADTH has successfully responded to the rapidly changing HTM landscape and priorities

The HTM landscape continued to evolve rapidly during the evaluation period. For the most part CADTH has recognized the major developments that have taken place and adjusted its product and service offerings accordingly.

The main issue raised by key informants representing provinces and territories is the budget pressure due to the growing volume of expensive drugs and therapies, particularly DRDs. Patients

and their caregivers are demanding access to the most recent treatments. At the same time there is a political reluctance to reassess existing technologies and to disinvest due to the negative media attention that could ensue. CADTH has been working closely with Health Canada, as they develop a national strategy for DRDs.

CADTH responded to the needs of F/P/Ts to develop an appropriate path for the review of CAR T-cell products. While funders and stakeholders commended CADTH for its collaborative and consultative approach, they believe that CADTH should have moved more quickly to anticipate this requirement.

CADTH has also taken steps to evolve its HTM knowledge products and services business line to reflect customer needs. OU reports have been improved to provide information about drug implementation issues, the new RRS "living rapid review" and "ultra-rapid review" provides timely information to customers, and the new Policy Service to support F/P/T health policy decision-making. These improvements were widely supported by external key informants; in particular, they commended CADTH for its timely response to fulfilling information needs related to the COVID-19 pandemic.

The challenges related to increasing access to medical devices in Canada's healthcare system, an objective of CADTH's most recent strategic plan, are complex and the market path for medical devices is less straightforward than for drugs. CADTH has increased its working relationship with Health Canada's Medical Devices Directorate. While stakeholders appreciated CADTH's increased involvement in the medical device space, industry had expected CADTH would have greater impact in supporting the entry of new medical devices into Canada's healthcare system.

CADTH has made tangible progress in shifting from an HTA to an HTM organization

While CADTH has made good progress in its shift from an HTA to an HTM organization, in some quarters there is a lack of understanding regarding the practical implications of this move. Since early in the evaluation period, CADTH has prioritized the transition to an HTM organization, shaping its Contribution Agreement with Health Canada and the 2018–21 Strategic Plan. Tangible progress is evident, including improved OU reports, increased support to provinces and territories with formulary listing decisions, and expanding the ISKM team to improve implementation support. CADTH could more clearly articulate in practical terms to stakeholders what this HTM shift means for Canada's healthcare system.

CADTH's products and services complement those of other Canadian HTA bodies at the provincial and territorial and regional/local levels

There are many HTA bodies across Canada at the provincial and regional/local levels. Given Canada's decentralized healthcare system, a certain amount of distributed HTA capacity across the country is to be expected. Most of the provincial and territorial and regional/local bodies focus on the review of non-drug technologies (i.e., medical devices, clinical interventions, diagnostics, preventive health and screening interventions and mental healthcare). Smaller provinces and territories do not have the same HTA capacity as the larger provinces, and so are highly dependent on CADTH's products and services.

On the formulary review side, the other major domestic player is INESSS in Quebec, which produces drug reimbursement recommendations on behalf of the Quebec government. While

acknowledging Quebec's jurisdictional autonomy, key informants expressed the view that the two organizations should explore opportunities for a closer working relationship.

While federal, provincial and regional/local HTA has been found to be generally complementary rather than duplicative, there is general agreement that duplication does exist in the review of non-drug health technologies at the local/hospital level. The 2018 review of PCHOs called for increased coordination of HTA work on non-drug technologies across Canada. It proposed a model whereby CADTH would coordinate an HTA network and HTA bodies would conduct assessments within a common framework and in accordance with a common set of priorities, to avoid duplication and to build overall capacity. The pan-Canadian HTA Collaborative, which was formed by CADTH in 2011, is a vehicle for implementing this model. The Collaborative currently has five members; expanding its membership would appear to be a logical next step.

6.2 Design and Delivery

CADTH has made great strides in improving its engagement with its customers and stakeholders, and is widely viewed as a customer-centric organization

CADTH consults and engages with a wide range of customers and stakeholders including policy makers, patient support groups, clinicians and industry through a variety of mechanisms.

Internationally, CADTH is viewed as a leader in patient engagement.

The main improvement opportunities are to provide greater support to patient groups in the preparation of submissions to CADTH as part of the drug review process and to provide feedback on how their input is being considered; increase the transparency of the decision-making process of the expert committees (the approach used by the Scottish Medicines Consortium was frequently mentioned as a model to emulate); and improve engagement with clinicians.

While CADTH has made some progress in incorporating SGBA considerations as part of its HTA process, it is at an early stage in determining how to engage Indigenous Peoples and to reflect their concerns, along with those of other marginalized communities, at a very practical level

Recognizing that biological sex has specific application to the analysis of impact on health outcomes, CADTH has made some progress in incorporating SGBA as part of its HTA process. CADTH has designated a SGBA champion on the research team, holds regular teleconferences with the Scientific Director of CIHR's Institute of Gender and Health, and uses sex- and gender-based considerations as part of the topic selection process.

CADTH's ability to influence the inclusion of SGBA considerations in drug reviews is limited by the fact that CADTH relies on synthesizing primary research of others, a challenge CADTH's Scientific Advice Program is intended to address through the design and implementation of clinical trials. When data is available, CADTH performs subgroup analysis based on sex, gender and geography (i.e., rural/remote), and CADTH has made significant progress in incorporating these considerations in drug reviews.

CADTH recognizes the importance of considering the needs of Indigenous Peoples and other groups, such as the LGBTQ2+ and BIPOC communities. The Board of Directors has made clear the importance of Indigenous considerations and the internal working group on Indigenous initiatives has been established, among other efforts made in this regard. However, at a very practical level, CADTH is at an early stage in determining how to engage Indigenous Peoples and to reflect their concerns, along with those of other marginalized communities. The challenge is to bring together different Indigenous voices, values and perspectives, that considers evidence in a different manner against the backdrop of accelerating moves to assert Indigenous data sovereignty.

CADTH has developed, in consultation with Health Canada, a set of performance indicators to provide information relevant to the considerations of sex and gender in the design and delivery of CADTH programs and services, although these performance indicators are not reflective of CADTH's aspiration in terms of its products and services and SGBA considerations.

CADTH appears to be adequately resourced to accommodate modest growth in demand for its various products and services in some programs, but remains challenged to meet capacity in the Formulary Program

CADTH has demonstrated that it is able to accurately project annual outputs of its Formulary Program and its HTM knowledge products and services, and has been able to leverage its human and financial resources to meet customer needs, though this has led to delays in work in HTM. Overall, actual production was generally consistent with projections over the evaluation period, indicating that CADTH has an accurate understanding of customer needs.

CADTH key informants generally view CADTH to be adequately resourced for current workloads, however, the Formulary Program has experienced a sizeable deficit, and continues to face resourcing challenges due to the ever-increasing growth in the volume of complexity of reviews of drugs and therapies. In terms of specific human resources requirements, CADTH key informants identified a few specific needs, notably health economists to support the introduction of the PMPRB's new pricing guidelines (assuming the guidelines are implemented).

There are opportunities for CADTH to improve transparency and accountability, and efficiency and effectiveness, by enhancing its approach to Results-based Management

Results-based Management (RBM) orients all actions and use of resources towards achieving well-defined and demonstrable outcomes. It helps organizations focus on results and value-for-money by understanding the relationship between inputs (resources), outputs and planned and actual results. This provides the basis for transparency and accountability, and for assessing efficiency and effectiveness.

CADTH has many of the components of RBM in place, both in terms of *performance measurement*, such as an outcomes framework (logic model) and a suite of performance indicators, and *performance management*, such as planning, monitoring, evaluation and review, and providing information to management and the Board for ongoing monitoring of performance.

There are, however, opportunities for CADTH to improve its approach to RBM, as follows.

As noted above, performance indicators (and associated targets) relevant to sex and gender in the design and delivery of CADTH programs and services require attention, as do performance indicators related to LGBTQ2+ and BIPOC communities, to better reflect CADTH's aspiration in terms of its products and services and SGBA considerations.

During the evaluation period, CADTH did refine and strengthen the method to assess the impact of its products and services. CADTH also launched an impact database to allow for more efficient tracing of impact. However, there does not appear to be a strategy to guide the selection of products and services for impact assessment (e.g., based on a random sample or cost threshold). Furthermore, neither data related to device specific impacts nor data related to the reach of products and services appears to be available. Given that the intent of CADTH's products and services is to impact decision-making, these shortfalls may result in important missed opportunities to build on successes and to identify areas for improvement.

CADTH senior-level key informants stated that timely information is not available to managers on the costs of products, services and projects, making it difficult to assess costs and staff productivity. Similarly, the evaluation team was unable to comment on the delivery efficiency of products and services since unit cost data was not available. Stepping back, it appears that CADTH does not have a complete picture of the full cost of its products and services—that is, the contribution of indirect and overhead costs to its products and services and the achievement of CADTH's expected results. Improving this will provide CADTH with the precise information required to credibly assess its efficiency and effectiveness.

6.3 Effectiveness

CADTH's main customer and stakeholder segments generally have a high level of awareness of CADTH's main products and services. Demand for CADTH's HTM products and services continue to grow and there is a high level of customer satisfaction

Key informants from the various customer and stakeholder segments consulted by the evaluation reported a high level of awareness of most of CADTH's products and services. One exception are clinicians involved in health technology adoption (clinical interventions and medical devices) at the local/hospital level. CADTH struggles for recognition among clinicians who are not directly involved in its review programs. Engaging these decision-makers has been a challenge for CADTH, due in part because the adoption of medical devices occurs at the local/hospital level and is not centrally managed through jurisdictional formularies (as are drugs). Strengthening engagement with clinicians is an important part of closing the gap between evidence, policy and practice. One area for improvement is knowledge translation targeting physicians through more effective dissemination strategies to better support appropriate prescribing in clinical practice.

CADTH's website traffic metrics demonstrate positive trends in demand over the evaluation period. CADTH's regional approach to customer support has proven to be a successful model to raise awareness of and improve access to CADTH's products and services, and in maintaining strong customer relations, particularly among the smaller provinces and territories.

Customer satisfaction levels are high, as indicated through CADTH's customer satisfaction surveys and verified by key informant interviews and survey of RRS customers undertaken for this evaluation.

CADTH's wide range of implementation support activities and tools have helped to equip healthcare decision-makers with increased knowledge and skills related to drugs and devices

CADTH has delivered an increasingly broad range of implementation support activities and tools to help bridge the gap between the provision of high-quality, timely, and comprehensive HTA, and sound and defensible decision-making. CADTH has helped decision-makers (e.g., policy-makers, clinicians, patients) understand and use evidence provided by CADTH to make better decisions about the use of medical, dental and surgical devices, procedures and diagnostic tests. CADTH has successfully embedded Liaison Officers within jurisdictional healthcare systems to support implementation and help increase the capacity of provincial and territorial healthcare decision-makers. CADTH also developed several new custom services, and provides a wide range of products, tools and knowledge events in response to customer needs.

The limited evidence on the impacts of evidence-supports associated with HTM products indicates that these are useful to decision-makers. However, as noted above, CADTH does not systematically measure the reach and impact of its products and services among its target audiences—an area for improvement.

CADTH's products and services appear to be contributing to the optimal use of drugs and devices

CADTH's knowledge products, including its large-scale HTAs and HTR/OU reports, as well as the smaller scale RR reports, are being used by healthcare decision-makers for a variety of purposes, including effecting clinical change, informing policy decisions and optimizing healthcare resources.

CADTH has contributed to a well-functioning process for listing of drugs by provinces and territories by providing evidence-based recommendations that are respected. Positive or conditional reimbursement recommendations made by the Formulary Program are considered for negotiation by the pCPA, and it is very rare that this is not the case. A positive CDR recommendation for drugs was found to be a strong predictor of subsequent provincial and territorial listing (as well as congruence among jurisdictional formularies), although a negative CDR recommendation did not necessarily preclude provincial and territorial listing. There was some discordance between pCODR recommendations and provincial and territorial cancer drug-funding decisions, likely the result of political pressure and budgetary constraints.

While the Formulary Program has facilitated more consistent official policy across jurisdictions, there has continued to be a gap between appropriate use and actual use on the ground. To address this, CADTH tried to specifically engage clinician groups (although as noted above, this has been a challenge), and introduced a wide range of implementation tools intended to change or influence practice or policy in pharmaceutical optimal use and medical device use decisions. Other products and services, such as knowledge products and events, the Policy Service and the regional approach to customer support have also contributed to narrowing the gap between evidence, policy and practice.

CADTH has also helped decision-makers understand and use evidence to make better decisions about the use of medical devices. CADTH has brough an increased focus on devices through the 2016 pan-Canadian HTM strategy (which became part of CADTH's 2018–21 Strategic Plan), the Device Advisory Committee, ISKM and the associated products and services such as RRS, HTA and OU. However, CADTH has experienced challenges engaging clinicians and other decision-makers involved in device adoption at the local/hospital level. It is questionable whether CADTH should provide evidence to inform decisions about optimal use of devices at this level given the sheer volume of new medical devices entering the market each year, the complexity of the market path to entry and adoption, the speed of innovation and patient demands, and the intrinsically more complex lifecycle management compared to drugs. There would be value, however, for Health Canada and jurisdictions to clarify where there may be common value to enhancing the use of HTA in the pan-Canadian or large jurisdictional procurement (or disinvestment) process for devices.

6.4 Efficiency

CADTH ranks favourably among a group of eight HTA agencies internationally in terms of key performance metrics related to NASs and operational efficiency

CADTH has ranked favourably in the CIRS annual performance metrics benchmarking of eight HTA agencies related to NASs. Next to Australia, Canada had the fastest median rollout time from regulatory submission to first HTA recommendation, and the shortest median time between regulatory approval and HTA recommendation. However, in terms of median time from first world-wide regulatory submission to jurisdictional HTA recommendation, Canada was close to the bottom along with France and England.

It was not possible to comment on the delivery efficiency of products and services as unit cost data was not available.

In contrast to its collaborations with organizations across Canada, CADTH has had limited impact at an operational level from its collaborative efforts with international HTA agencies

Key informants from international HTA agencies emphasized that CADTH is well-respected and considered a leader among HTA agencies. CADTH has successfully pursued collaborations with ISPOR and HTAi, other Commonwealth countries (Australia, Scotland and England) and with the International Network of Agencies for Health Technology Assessment. However, key informants observed that CADTH has had limited impact at an operational level resulting from these collaborative efforts, tending to favour collaborations with English-speaking countries while opportunities in other countries with similar healthcare systems, such as Italy and Spain, have been overlooked.

A major long-term opportunity is for CADTH to pursue formal collaborative efforts with other HTA agencies internationally, as Health Canada has done in the regulatory space.

CADTH continues to provide value-for-money on behalf of its F/P/T funders and there are opportunities for CADTH to increase its value proposition

The evidence indicates that CADTH continued to provide value-for-money on behalf of its F/P/T funders and Canadians in general, particularly on the drug side. There are opportunities for CADTH to further increase its value proposition, by ensuring it has the required capacity to assess the latest technologies, such as immune-oncology drugs, to provide jurisdictions with implementation support (e.g., ensuring CADTH is successfully executing the mandate of the former CDIAC committee related to treatment algorithms), and to reassess DRDs once RWE is available. CADTH's current strategic planning process is an opportunity to discuss and confirm the specific needs of the F/P/T funders.

The value-for-money of CADTH's device-related work is more difficult to assess, as the market path to entry and adoption is much more complex for devices compared to drugs. One measure is the impact of CADTH's RR reports, the majority of which are focused on devices and clinical interventions. The survey of RRS customers found that 87% of customers believed that their RR report met their needs and 93% were satisfied with the RRS service. These RR reports serve a wide variety of needs: the main one being to inform a clinical practice change (identified by one in four customers).

The eventual introduction of a Canadian Drug Agency could yield efficiencies for the healthcare system. However, F/P/Ts will face many challenges in dealing with the fiscal impact of the COVID-19 pandemic. This could very well lead to increased demands being placed on CADTH in the coming years.

7. Recommendations

A number of factors were considered in developing the recommendations resulting from this evaluation.

Firstly, the impacts of COVID-19 on the F/P/T fiscal frameworks will likely emerge in the near future. It is inevitable that fiscal restraint will be a fixture across Canada for many years. This could affect the F/P/T jurisdictions in many ways, such as putting yet more pressure on healthcare budgets and reducing in-house HTA capacities.

Secondly, the evaluation confirmed that CADTH continues to meet the majority of needs of the F/P/T funders and other stakeholders. Throughout the COVID-19 pandemic, CADTH has demonstrated that it can be agile and nimble.

The implication of these two factors strongly suggest that F/P/Ts will place increasing demands on CADTH.

The above suggests that CADTH may face challenges in accommodating this potentially substantial increase in demand. In addition, there are no obvious new revenue streams for CADTH to pursue. Consequently, CADTH may be challenged to meet its timelines and quality standards, which could lead to reputational risk.

The federal government has been taking concrete steps to establish the foundations for national pharmacare leading to the creation of a Canadian Drug Agency, although the timing is uncertain. Federal Budget 2019 provided Health Canada with $35 million over four years, starting in 2019–20, to establish a Canadian Drug Agency Transition Office to work with provinces and territories and other partners to develop a vision and mandate for the new Agency. Establishment of a Canadian Drug Agency may well determine CADTH's future mandate and scope of products and services.

Given the above, it is evident that CADTH is at a critical juncture in its evolution.

The following recommendations are provided to help ensure that CADTH continues to provide value-for-money for Canadians.

Recommendation 1: The current strategic planning process should confirm the needs of F/P/Ts with respect to CADTH's Formulary Program and identify the implications for CADTH's processes and capacity.

As discussed throughout this evaluation report, the HTM landscape continues to evolve rapidly. The factors described above are likely to have significant implications for CADTH's Formulary Program in particular. Several other trends and developments are, or will affect CADTH, including: the continued growth in the volume and complexity of drugs and therapies entering the global marketplace; an expected Health Canada strategy for DRDs; a desire on the part of provinces and territories for CADTH to provide increased implementation support; and new PMPRB pricing guidelines, which, if implemented in early 2022, may have implications for CADTH in terms of its health economics capacity and quality assurance practices.

The strategic plan should consult with provinces and territories to discuss and confirm these trends and developments. An action plan should be developed to ensure that CADTH is able to continue to offer a Formulary Program that is responsive to external trends and customer needs.

Recommendation 2: Review CADTH's role in the medical device space.

Given the sheer volume of new medical devices entering the market each year, many of the issues faced by CADTH in the drug space, such as a high rate of innovation and patient demands, are an order of magnitude greater in the non-drug technologies space. The speed of innovation is much faster, the volume of devices is much greater, and the devices themselves, and their lifecycle management, are intrinsically more complex compared to drugs. The market path to entry and adoption is also complex, involving various levels (F/P/T, regional, local) and entry points. The cost to provide a comprehensive suite of products and services, similar to those on the drug side, could be much higher, and CADTH is not currently resourced to do so. Engaging clinicians and other decision-makers at the regional/local levels has proven to be a challenge for CADTH.

The evaluation found that CADTH has made some progress in the medical device space, such as increasing its collaboration with Health Canada's Medical Devices Directorate. Building on this success and recognizing that CADTH cannot address all of the needs associated with the review of medical devices, it is recommended that CADTH develop a strategy to guide its role in this space and allocate resources to those areas with potentially the greatest patient impact. To maximize its impact, CADTH could focus on reviewing only those medical devices and clinical associated with pan-Canadian priorities (e.g., care of the elderly, virtual care, mental health, drugs). Given ISKM is substantially involved in devices, any change in CADTH's positioning in this space should trigger a corresponding review of ISKM's mandate, roles, responsibilities and budget in this respect.

In developing this strategy, an important factor to consider is the role of the planned Canadian Drug Agency and its implications for CADTH.

Recommendation 3: Develop a comprehensive stakeholder engagement strategy building on CADTH's successful efforts to date.

CADTH consults and engages with a wide range of customers/funders, especially F/P/Ts, and with many other stakeholders, including patient support groups, clinicians and their professional societies, and the pharmaceutical and medical devices industries. CADTH has made major strides in recent years in terms of its stakeholder engagement practices, and CADTH is viewed as a leader internationally. However, public and patient engagement is complex (e.g., disentangling the role of advocacy groups as organized interests versus representatives of patient values and experiences).

As part of its transition to an HTM organization, it is recommended that CADTH develop a multi-pronged engagement strategy that considers the needs of the various customer and stakeholder groups, which includes a clear vision at the organizational level (i.e., not simply within discrete engagement processes). Ensuring accountability of a senior-level position for stakeholder engagement is also recommended.

In developing the engagement strategy, the following issues identified by the evaluation should be considered:

- Confirm the goals for engaging clinicians (i.e., obtaining their input as part of the drug and device review process, and ensuring CADTH's products and services are having the desired effect on clinical practice).
- Provide more guidance to patient groups in how to prepare their drug review submissions. Benchmarking the approaches taken by other HTA agencies internationally should be part of this process.
- Continue to increase the transparency of the drug review decision-making process by opening up expert committee deliberations to patient groups.
- Provide feedback about how the input of patient groups are being used by the expert committees in arriving at drug reimbursement recommendations.

Recommendation 4: Improve engagement of Indigenous Peoples and other diverse communities to better reflect, at a very practical level, the different voices, values and perspectives.

There are many disparities in Canada's healthcare system. Through its governance structures, the Scientific Advice Program and the partnership with CIHR's Institute of Gender and Health, CADTH has made important strides in considering sex, gender and geography as part of its HTA process (including selection of topics). When data is available, CADTH performs subgroup analysis, and has made significant progress in incorporating these considerations in drug reviews.

There remains an opportunity, however, to improve engagement with Indigenous Peoples and other marginalized communities (such as the LGBTQ2+ and BIPOC communities), while remaining sensitive to the long history of widespread discrimination and abuse these groups have faced through Canada's healthcare system, and the collection and use of data about Indigenous Peoples for purposes not in their best interests or benefit.

The Board of Directors has made clear the importance of Indigenous considerations, and CADTH has introduced some measures to engage Indigenous Peoples, including establishing an internal working group on Indigenous initiatives. However, CADTH has struggled with how to reflect different Indigenous voices, values and perspectives (and those of other marginalized communities) in its work. The lack of data to support analysis of these subgroups, for example in drug reviews, is an additional challenge, particularly against the backdrop of accelerating moves to assert Indigenous data sovereignty (e.g., ownership, control, access and possession) by First Nations, Inuit and Métis.

This is not something that CADTH can (or should) attempt to do in isolation. Indigenous Peoples themselves are in the best position to determine if they would like to engage with CADTH and the manner in which to do so. The main Indigenous representative organizations—Assembly of First Nations, Inuit Tapiriit Kanatami, Métis National Council, and Native Women's Association of Canada—have a long experience and wealth of knowledge in the health sector. It is recommended that these organizations are approached to begin the discussion, with the aim of developing a comprehensive strategy to reflect the different Indigenous voices, values, knowledge and perspectives in all aspects of CADTH's work.

Recommendation 5: Develop a strategy for collaborating internationally on drug reviews.

CADTH is well-respected and considered a leader among HTA agencies. CADTH has successfully pursued collaborations with several international HTA agencies, but little has been accomplished in terms of concrete working level collaboration (in contrast to Health Canada's progress in international collaboration in the regulatory space). Furthermore, CADTH's international collaborations have been mostly with English-speaking countries—there are other countries with similar healthcare systems as Canada, such as Italy and Spain, that should be considered.

In addition to generating potential efficiencies (e.g., reducing the cost of drug reviews worldwide and the time to market), collaborations have proven to be a valuable opportunity for programming and service innovation. For example, CADTH's 2019 collaboration with the United Kingdom-based NICE provided parallel scientific advice to the life sciences industry, but also led to CADTH's Scientific Advice Program modelled after a similar program at NICE.

It is recommended that CADTH develop a strategy for collaborating with international HTA agencies on the conduct of drug reviews, where feasible, focussing on knowledge exchange, alignment and joint initiatives.

Recommendation 6: Enhance the approach to RBM.

While CADTH has many of the components of RBM in place, there are important opportunities for improvement which will strengthen transparency and accountability, and CADTH's ability to assess efficiency and effectiveness.

As noted above, it is recommended that performance indicators (and associated targets) relevant to sex and gender, to LGBTQ2+ and BIPOC communities, be improved to better reflect CADTH's aspiration in terms of its products and services and SGBA considerations.

The intent of CADTH's products and services is to impact decision-making, and CADTH has made important improvements in the assessment and tracking of impact. It is recommended CADTH develop a strategy to guide the selection of products and services for impact assessment (for drugs *and* devices), including a methodology to do so. Understanding the reach of its products and services among target audiences is an important aspect of impact to be included.

CADTH requires precise information to credibly assess its efficiency and effectiveness. RBM is the imperative for full costing of programs and services. It is recommended that CADTH fully cost its products and services through the refinement of its cost allocation model that brings together indirect and overhead costs with direct program and service costs. This is the first step in developing a greater understanding of the relationship between corporate and support functions, programs and services, and the achievement of CADTH's expected results.

Appendix A: CADTH Logic Model

Ultimate Outcome (contributing influence—change in the state of the population)	Canada has a modern and sustainable health care system
Intermediate Outcome (indirect influence—behaviour change)	Health care decision-makers optimally use drugs and medical devices
Immediate Outcomes (direct influence—awareness, skills acquisition)	Health care decision-makers access evidence on drugs and medical devices Health care decision-makers are equipped with knowledge, skills and supports on drugs and medical devices
Outputs	Knowledge products (e.g., assessments, reviews, reports, recommendations, guidelines, implementation tools, publications) Outreach Services (e.g., implementation support, events, workshops, conferences, secretariat function, convenor role, joint initiatives)
Activities	Conduct drug reviews, health technology assessments, etc. Knowledge mobilization
Decision-makers	F/P/T Ministries/Departments of Health, publicly funded organizations responsible for health service delivery, and clinicians
Stakeholders	Clinicians, patients, industry, and Canadian and international partner organizations

Appendix B: Evaluation Matrix

Evaluation Questions	Indicators
1. Do CADTH's products and services align with the needs of federal and provincial/territorial funders and other customers/decision-makers?	1.1 Key priorities of federal, provincial and territorial funders and other customers/decision-makers with respect to health technology management over the past five years.
	1.2 Extent to which CADTH products and services have evolved in response to the priorities of federal and provincial/territorial funders and other customers/decision-makers.
	1.3 Alignment of CADTH's Strategic Plans (2015-2018 and 2018-2021) with the priorities of federal, provincial and territorial funders.
	1.4 Gaps and potential areas for improving alignment between CADTH products and services and the priorities of federal, provincial and territorial funders and other customers/decision-makers.
2. Do CADTH's products and services overlap, duplicate or complement those provided by other Canadian organizations?	2.1 Existence/absence of overlap or duplication.
	2.2 Extent to which CADTH products and services are unique in Canada.
	2.3 Complementarity between CADTH products and services and products and/or services of other organizations.
3. How have the landscape and priorities related to health technology management evolved over the past five years?	3.1 Major changes in the health technology management environment over the past five years.
	3.2 Extent to which CADTH has responded to these changes.
	3.3 Challenges and opportunities for CADTH in the context of these changes.
	3.4 Needs and priorities of federal, provincial and territorial funders and other customers/decision-makers (including Indigenous, rural, remote) with respect to health technologies over the past five years.
	3.5 Extent to which CADTH has been able to anticipate health system and health technology trends.
4. To what extent do healthcare decision-makers access CADTH's evidence on drugs and medical devices?	4.1 Targeted users compared to actual users of CADTH products and services (if data is available).
	4.2 Level of awareness of CADTH products and services among target audiences
	4.3 Extent to which specific CADTH products and services are being used by decision-makers.
	4.4 Level of satisfaction of users with CADTH products and services.

Evaluation Questions	Indicators
	4.5 Extent to which CADTH products and services respond to the needs of decision-makers.
	4.6 Average number of days between HC's market authorization and CADTH's listing recommendations.
	4.7 Trends in number of report downloads by jurisdiction, product type and official language.
	4.8 Trends in number of CADTH e-alert subscribers by jurisdiction.
	4.9 # of knowledge products completed
5. To what extent has CADTH contributed to equipping healthcare decision-makers with increased knowledge, skills and supports on drugs and devices?	5.1 Extent to which CADTH builds capacity in the understanding and use of evidence in health technology management
	5.2 Perceived adequacy of implementation tools and support to decision-makers.
	5.3 Number of implementation tools by drug/device.
	5.4 Number of knowledge events by type, jurisdiction.
	5.5 Percent increase in participants in CADTH knowledge events (e.g., workshops, conferences, courses) by jurisdiction.
	5.6 Percent of decision-makers reporting that CADTH's evidence-based supports (e.g., implementation tools such as plain language summaries, decision aids) were useful in the context of decision-making.
6.To what extent are healthcare decision-makers optimally using drugs and medical devices as a result of CADTH?	6.1 Impacts of specific products and services (qualitative, unlikely to have quantitative data).
	6.2 Percent of positive or conditional reimbursement recommendations taken up by PCPA.
	6.3 Percent of healthcare decision-makers reporting use of CADTH's evidence-based information on drugs and medical devices by jurisdiction, type of decision-maker, type of use.
	6.4 Extent to which healthcare decision-makers use CADTH's smaller scale reports.
	6.5 Number of impacts (e.g., policy, practice or procurement decisions) of smaller-scale CADTH reports by type of impact, jurisdiction, and drug/device.
7. To what extent has CADTH contributed to Canada having a	7.1 Extent to which CADTH has assisted decision-makers in effectively and efficiently allocating healthcare resources (value-for-money).

Evaluation Questions	Indicators
modern and sustainable healthcare system as a result of the evidence and advice on clinical and cost effectiveness of therapeutic products provided by CADTH?	7.2 Extent to which CADTH has contributed to narrowing the gap between evidence, policy and practice.
8. To what extent has CADTH effectively consulted and engaged with stakeholders (including patient, industry, clinicians, the Canadian public, etc.)?	8.1 Types of CADTH consultation and engagement activities (including feedback mechanisms) undertaken by CADTH.
	8.2 Perceived effectiveness of CADTH consultation and engagement activities and feedback mechanisms.
	8.3 Extent to which stakeholders and other groups are satisfied with the consultation and engagement strategies and feedback mechanisms of CADTH.
	8.4 Extent to which stakeholders believe CADTH is transparent.
	8.5 Possible improvements to engagement activities and feedback mechanisms.
9. Do CADTH's activities, products and services reflect gender-based considerations? Other considerations related to Indigenous, rural, remote groups?	9.1 Steps CADTH has taken to incorporate Sex and Gender Based Analysis (SGBA), Indigenous, rural/remote considerations into its activities, products and services in the past five years.
	9.2 Key achievements made in incorporating SGBA, Indigenous, rural/remote considerations.
	9.3 Challenges encountered in implementing SGBA, Indigenous, rural/remote considerations.
10. Is CADTH producing its products and services efficiently? Are there alternatives that would be more efficient?	10.1 Benchmarking of key efficiency indicators against comparable agencies internationally (if data is publicly available)
	10.2 Extent to which CADTH has pursued collaborative opportunities that prevent duplication, leverage collective expertise and promote increased spread of recommendations, advice and tools.
	10.3 Key collaborations in the past five years (Canada and internationally).
	10.4 Level of satisfaction on the part of partners with respect to CADTH collaborations.
	10.5 Potential areas for increased collaboration.
	10.6 Impacts/benefits of collaborations (examples).
	10.7 Alternative approaches to delivering CADTH products and services that would be more efficient.

Evaluation Questions	Indicators
	10.8 Percent administrative costs
	10.9 Percent overhead
11. Is CADTH seen as generating value for money on the part of its funders and Canadians?	11.1 Extent to which funders believe they are receiving value for money from CADTH.
12. To what extent does CADTH have sufficient human and financial resources to meet current and future needs of decision-makers?	12.1 Forecast workload
	12.2 Current human and financial capacity.
	12.3 Anticipated needs (human and financial).
	12.4 Challenges with respect to human and financial resources.
	12.5 Extent to which CADTH is leveraging its financial resources.
	12.6 Demonstrated evidence of CADTH's ability to respond to evolving healthcare environment.