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Colorectal Cancer Canada (CCC) is the national Canadian not-for-profit corporation dedicated to colorectal cancer (CRC) awareness and education, support for patients and their caregivers, and advocacy on their behalf. CCC is comprised of dedicated volunteers, members, management and is governed by a National Board of Directors. An Expert Medical Advisory Board, made up of top healthcare professionals in the field of colorectal cancer, provides counsel to CCC to ensure members are kept abreast of the latest medical advances in the diagnosis and treatment of the disease.

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BACKGROUND

Colorectal Cancer in Canada

Colorectal cancer (CRC) is the fourth most commonly diagnosed cancer in Canada. In 2023, an estimated 24,100 (13,500 men, 10,600 women) Canadians were diagnosed with the disease, and 9,300 (5,200 men; 4,100 women) died from it.

Organized screening programs are available in most Canadian provinces and territories, though 1 in 2 people with CRC are diagnosed at a late-stage (stage III or IV). This is significant, as stage at diagnosis is closely linked to survival for colorectal cancers, with the greatest likelihood of survival associated with stage I. Although the incidence of colorectal cancer is declining in older adults thanks to increased screening, incidence rates are increasing among Canadians under 50.

The current landscape in Canadian oncology research involves considerable therapeutic innovation. Unfortunately, the high cost of cancer drugs has resulted in increased pressure on the healthcare system to make difficult decisions regarding the reimbursement or coverage of oncology drugs, as well as other treatment options.

The shift toward value-based medicine has permitted various stakeholders to comment on topics such as pharmacogenomics, therapy management, compliance issues, and a patient's quality of life. However, the perspectives of patients are most central to the definition of value, yet they remain the least understood and the most difficult to measure. Consequently, it has been a challenge to attribute an explicit weight to patient preferences in health technology assessment (HTA) decisions regarding provincial oncology drug reimbursement.

CLINICAL BENEFIT

(Effectiveness, safety, burden of illness, need)

ECONOMIC EVALUATION

ADOPTION FEASIBILITY (Economic, organizational)

PATIENT-BASED VALUES

pcODR's expert committee uses a deliberative framework for drug funding recommendations and considers Patient Values

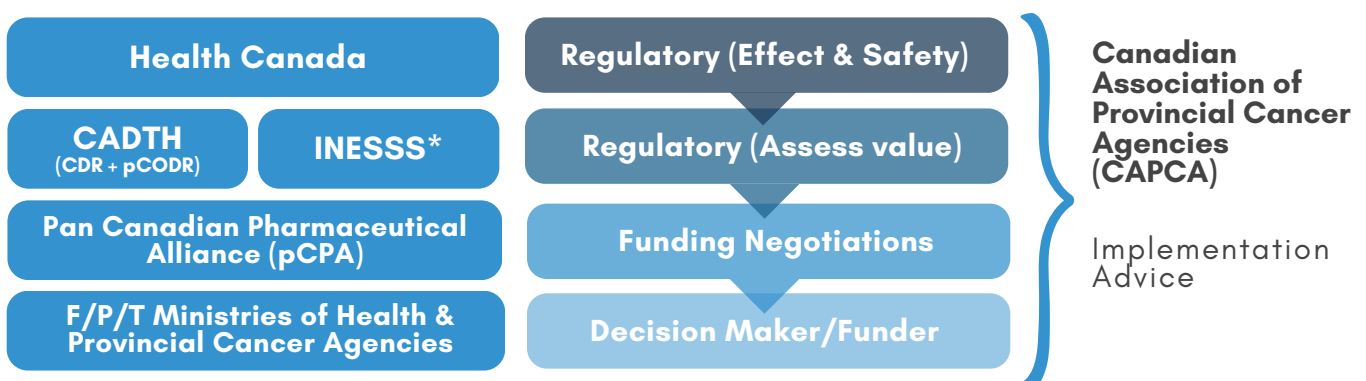
The Patient Voice in Health Technology Assessment

In Canada, the HTA process has evolved to include the pan-Canadian Oncology Drug Review (pCODR) as part of the Canadian Agency for Drugs and Technologies in Health (CADTH). This enables patient groups to provide experiential input as part of the criteria to be evaluated by expert committees responsible for recommending the reimbursement of new cancer drugs to provincial and territorial health ministries.

Specifically, accredited cancer patient groups may provide evidence regarding the patient experience of living with the illness, the needs and preferences of patients in managing symptoms and side effects of treatment, and the limitations that the illness imposes upon patients and their loved ones.

Unfortunately, patient views are often deemed subjective, and the concern is that this evidence may only be used to add qualitative information if cost effectiveness is established by the evaluating expert committee. To avoid tokenism of the patient voice, a novel evaluation process involving a new criterion to permit patient preferences to be held on equal standing with others is required by pERC's (pCODR Expert Review Committee) Deliberative Framework for drug funding recommendations.

It is essential that the patient voice on values be clear and evidence-based, and obtained through transparent and structured research. However, this is both a lengthy and costly process for cancer patient groups entailing a literature review, the development and execution of surveys, the analysis of patient reported outcomes (PROs), and appropriate reporting. It may also involve contacting patients internationally when clinical trials are not carried out in Canada. It also requires lengthy, detailed and comprehensive phone interviews with patients and caregivers which permit the thoughtful capturing of disease and drug-related information that may be incorporated in the patient group submission to HTA authorities.



*INESSS is not directly linked to pCPA

*The Institut national d'excellence en sante et services sociaux (INESSS) in Quebec will soon streamline their patient engagement process to allow for better patient group input.

THE VALUE OF THE PATIENT VOICE

The explicit incorporation of patient preferences in HTA processes in Canada is still a relatively unexplored area despite the growing emphasis on patient reported outcomes and patient engagement. Individual patient perceptions of value may vary with different treatment options. They may also change with age, presence of other co-morbidities, personal finances, individual goals, religious beliefs, and other life circumstances. The unique knowledge and perspectives that patients have impact treatment compliance and adherence, and can provide a broader view of real-world health technology efficiency. Patients' needs, goals, and preferences must be considered in a dynamic framework, yet little research has been done to define, measure, and attach a weight to these values.

Incorporation of the patient voice in HTA offers many benefits:

Relevance

Patients have knowledge, perspectives, and experiences that are unique and provide essential evidence for HTA

Fairness

Patients have the same rights to contribute to the HTA process as other stakeholders and have access to processes that enable effective engagement

Equity

Patient engagement in HTA contributes to equity by seeking to understand their diverse needs with a particular health issue, balanced against the requirements of a health system that seeks to distribute resources fairly among all users

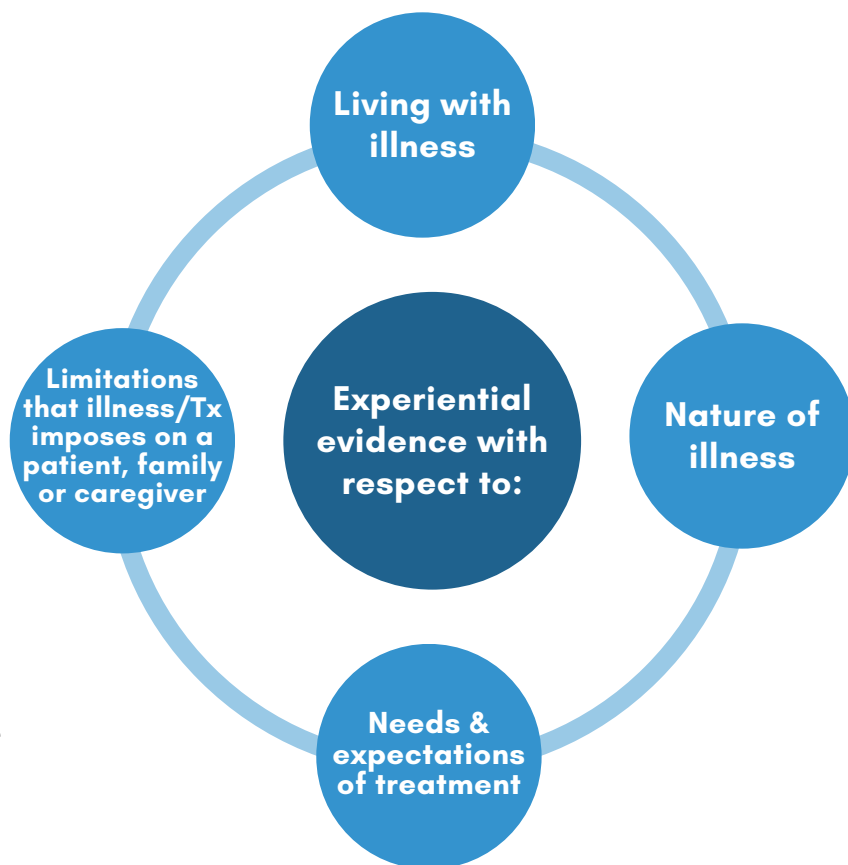
Legitimacy

Patient involvement facilitates those affected by the HTA recommendations to participate in the process, contributing to the transparency, accountability, and credibility of decision-making

Capacity Building

Patient involvement processes address barriers to involving patients in HTA and build capacity for patients and HTA organizations to work together

Patient evidence for pCODR review submissions includes the following:



Representing the patient voice in HTA is important for several reasons:

1. Patients have unique knowledge and perspectives that can influence decisions by pointing out what the most important aspects or outcomes are for them in a drug therapy setting
2. Patient preferences directly impact patient compliance or adherence to therapy or treatment and can provide a broader view of real-world health technology efficiency. These outcomes can ultimately influence the cost-effectiveness of treatment
3. Patient preferences may serve as an important and evidence-based source of information and may improve the uptake of current health priorities and policy gaps
4. Including patient engagement in health decision-making processes supports fair and ethical healthcare systems and processes
5. It has been shown that if the drug treatment is consistent with patient preferences, it improves positive outcomes, which can help mitigate the negative effects of illness and can assist clinicians in decision-making

pCODR's expert committee uses a deliberative framework for drug funding recommendations and considers patient values.

CLINICAL BENEFIT

(Effectiveness, safety, burden of illness, need)

ECONOMIC EVALUATION

ADOPTION FEASIBILITY

(Economic, organizational)

PATIENT-BASED VALUES

THE PATIENT VALUES PROJECT

Colorectal Cancer Canada's Patient Values Project (PVP) aims to define, measure, and assign a weight to patient values in cancer drug treatment to ensure Canadian patients are heard in the evaluation of cancer care and the reimbursement of cancer drugs by public agencies.

These weights will be adopted by Canadian and international cancer patient groups to empower them to provide objective input regarding patient values and preferences to inform the HTA deliberative process.

Objectives

- Develop a definition of patient values and determine the appropriate metrics to measure these values
- Determine the relative importance of measured values to form an expert HTA committee decision in drug evaluation
- Provide objective and quantifiable input concerning patient values based on validated research techniques
- Empower patient groups in their effort to provide research-based input to HTA authorities
- Increase timely access to effective treatments
- Allow for a more reasoned and balanced rationale in the assessment of new cancer drugs by the expert committees

Research Phases & Questions

	PHASE I	PHASE II	PHASE III
PHASE AIM	Design and administer a quantitative survey to estimate patient preferences	Development of key metrics/indicators to measure values captured in survey data	Generate/assign a weight to Patient Values to become part of the patient submission to pERC (pCODR Expert Review Committee)
RESEARCH QUESTIONS	<p>How do colorectal cancer patients (early and metastatic) value different aspects of drug treatments when weighing the associated benefits and risks?</p> <p>How do values differ based on patients' demographics, quality of life, stage of cancer and experiences?</p> <p>What are the relative quantitative weights for the benefits and risks of treatment decisions?</p>	<p>What combination of attributes in treatment decisions provide colorectal cancer patients with the greatest personal utility?</p> <p>How can we apply the attributes to inform a framework for drug reimbursement decisions?</p>	<p>How could these patient values be explicitly incorporated into the current HTA cancer patient group submission process for new drug treatment evaluation?</p> <p>What proportion of the expert committee's decision on reimbursement for oncology drugs should be allocated for patient values?</p> <p>How does including patient values as developed in the study impact drug reimbursement decisions?</p>
APPROACH	Survey	Consultation with experts to develop Patient Values Framework	Consultation with experts to develop framework, focus groups and interviews.

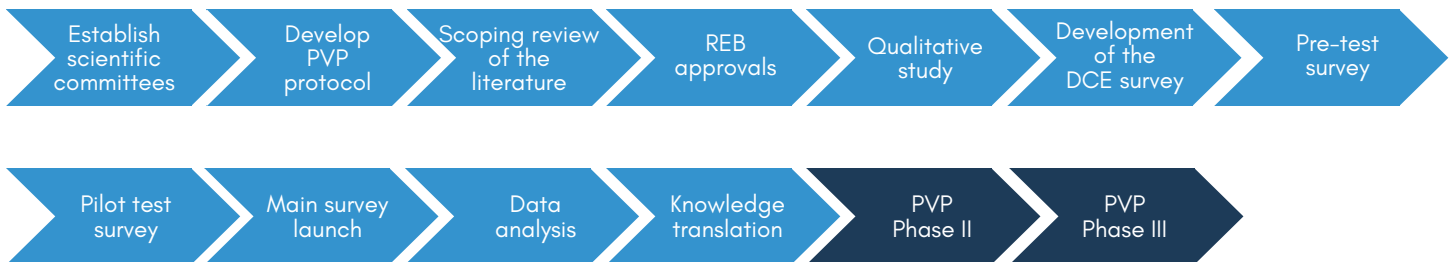
Sections included in Patient Group forms:

- Information about the advocacy group
- Patients' experience with a particular type of cancer
- Patients' experience with current therapy
- Impact on caregivers
- Expectations for the new drug
- Patient experiences with the new drug
- Conflict of interest declaration

Phase 1

Overview

Phase 1 involves the development and administration of a quantitative survey to estimate patient preferences.



The aim of the phase 1 survey is to measure patient preferences and estimate the value of the attributes of colorectal cancer treatments for patients, their families/care givers, and adults without colorectal cancer from across Canada.

To establish the value of different aspects of colorectal cancer treatment more formally we will employ the rigorous economic approach known as discrete choice experiments (DCEs). A DCE is a quantitative method used to elicit patient preferences and utility for various health states and/or other nonmarket goods and services, such as health care. Such approaches to measure preferences are required to estimate the full value of treatment because some important health and non-health outcomes of treatment are not captured by traditional measures. Prior to drafting the DCE survey, a qualitative study was conducted.

The qualitative study was led by Drs. Jennifer Bell and Mary Jane Esplen from Princess Margaret Cancer Centre in Toronto. Colorectal cancer patients (n=12) and caregivers (n=6) were interviewed. The objectives of the qualitative work were to: 1) understand how colorectal cancer patients' values and experiences inform perspectives about new and emerging oncology drug treatments; 2) examine the key personal, social and system factors influencing patients' oncology drug treatment decision making; 3) identify the preferences of colorectal cancer patients regarding difficult risk-benefit trade-offs and scarce resource allocation in regard to drug treatments; and 4) inform the development of the DCE survey.

Following good research practice, the DCE survey was then developed based results of the qualitative work and literature review. The survey was reviewed by colorectal cancer patients using one-on-one think out loud pre-testing interviews. The survey was then pilot tested online with a sample of with colorectal cancer patients. The final main survey contains two DCEs and a best/worst scaling experiment. DCE 1 involves quality of life and survival trade-offs. DCE 2 involves attributes of treatment (i.e., side effects, mode of administration, risks and benefits). The best/worst scaling component involves ranking side effects of treatment. In addition to the 2 DCEs and best/worst scaling experiment, the final survey includes the following components: screening questions, background information, disease experience questions, quality of life measures (general and cancer specific), and participant demographics.

The survey is being administered to the following 4 population groups: patients with non-metastatic colorectal cancer (n=300); patients with metastatic colorectal cancer (n=300); adults who have experience as care givers for colorectal cancer patients (n=300); and adults from the general population (n=3500). Patient and caregiver participants will be recruited online from across Canada and in participating cancer centre clinics across Canada. The survey has been completed in the general population sample and is currently underway in the patient and caregiver samples. This study has been approved by the University of Calgary/HREBA (HREBA.CC-16-1021).

Phase 2 and 3

Overview

Phase 2 and 3 of the PVP involve the development of key metrics/indicators to measure values captured in survey data (Phase 2) and generating/assigning a weight to Patient Values to become part of the patient submission to pERC (pCODR Expert Review Committee) (Phase 3).

A long-term goal of the PVP is that groups collaborating internationally with Colorectal Cancer Canada will be able to:

- Adopt and adapt the Patient Values Survey to their CRC population
- Adopt and adapt the survey to other cancer sites
- Combine information from various surveys to compare patient values between countries

PVP CO-CHAIRS



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