



THINK TANK

Enhancing the Delivery
of Take-Home Cancer
Therapies in Ontario

PROCEEDINGS REPORT
DECEMBER 2014

Disclaimer

This report is an overview and summary of a think tank held by Cancer Care Ontario (CCO) on May 8, 2014. CCO does not make any representation or warranty as to the completeness, accuracy or currency of the information contained in this report, including, without limitation, any information derived from data sources.

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Executive Summary

On May 8, 2014, Cancer Care Ontario (CCO) hosted a policy planning and consultation session with partners and stakeholders called *Think Tank: Enhancing the Delivery of Take-Home Cancer Therapies in Ontario*. The principal aim was to evaluate the current delivery model for take-home cancer medications. If one message resonated throughout the day and among participants, it was that cancer treatments are changing—and Ontario’s cancer system must change as well.

Take-home cancer medications, such as oral chemotherapy, are emerging as a standard treatment option for many cancers. Highly effective, yet potentially toxic, these treatments are challenging providers and patients to find new ways to maximize benefit while minimizing risk. Current delivery models, designed primarily around hospital-administered injectable therapies (e.g., intravenous (IV) chemotherapy), must adapt to ensure appropriate prescribing, dispensing, handling, and monitoring of these therapies. Open communication, whether between patients and health providers, or between the different health-network databases that monitor use, is essential.

While the increased use of take-home cancer medications may partially mitigate the growing burden on cancer centres, it has also introduced issues of safety, accessibility, equity, and responsiveness, all of which affect the overall quality of patient care and effectiveness of the cancer system. Ontario is facing some formidable challenges, most notably:

- **Quality:** The system lacks oversight and comprehensive data collection to inform quality improvement processes.
- **Patient safety:** Provincial guidelines and safety standards for take-home cancer medications are needed, and practices may be inconsistent across the province.
- **Equitable access:** Public funding for take-home cancer medications is less comprehensive than for hospital-administered treatments, and private insurance is a reality for many.
- **Systems integration:** Linkages between primary care and local providers (e.g., community pharmacies) and hospitals/cancer centres are not present to facilitate responsive and timely care.

Recognizing the challenge and opportunity of take-home cancer medications, the think tank included stakeholders from across the healthcare spectrum. The objective was to explore, in an open and collaborative manner, how to enhance Ontario’s delivery model for take-home cancer medication by examining the following areas (or dimensions) for change:

- quality and safety
- reimbursement and distribution
- information management (IM) and information technology (IT)

Through panel discussions and facilitated small group discussions, participants gained a detailed understanding of the way Ontario delivers these therapies to patients, and the limitations of existing approaches.

The think tank also sought input from other provinces, including those with more integrated systems. Speakers emphasized the need for equivalent standards for hospital-administered and take-home cancer medication. They also noted the need to restrict access to specialized cancer centres or pharmacies with the capacity and experience to provide these treatments in safe, effective ways.

Following the morning sessions, participants collaborated to generate ideas on how to bolster the current Ontario model. For each dimension, participants identified several areas for system enhancements for each dimension (refer to summary Table 1). Upon collectively considering all participant feedback, four primary themes emerged (Figure 1).

Table 1: Potential Areas for Enhancing Ontario’s Delivery Model for Take-Home Cancer Medications

Dimension	Suggested Enhancements
Quality and Safety	<ul style="list-style-type: none"> • Provide comprehensive, multidisciplinary, standardized patient education. • Use an electronic method of prescribing with a standardized template. • Establish guidelines for safely prescribing, dispensing and handling take-home cancer medications. • Develop patient and provider tools to monitor adherence. • Create an infrastructure for patient support and side-effect management. • Utilize an integrated error reporting system. • Provide specialized education, training and support to cancer care providers.
Reimbursement and Distribution	<ul style="list-style-type: none"> • Resolve inequitable cancer drug funding. • Simplify complex reimbursement processes to support ease of access to timely, integrated quality care. • Identify best practices for value-based reimbursement. • Determine the best drug distribution chain for Ontario patients.
Information Management/Technology	<ul style="list-style-type: none"> • IM and IT solutions should support continuity of care. • Simplify the system and reduce its administrative burden. • Create a system for robust data collection at all points of care.

Based on an analysis of participant feedback collected at the afternoon breakout sessions

Figure 1

Primary Themes
1. Patients, providers and administrators want a more integrated system —one that simplifies access to benefits, coordinates care across delivery location, and ensures that all providers have access to relevant patient information.
2. Patients, providers and administrators want a more responsive system , one that delivers services efficiently, minimizing treatment delays.
3. Patients, providers and administrators want a system that is simpler and more comprehensive , delivering take-home therapies in a model with the same quality standards as hospital-administered treatment.
4. Patients, providers and administrators want a person-centred system to oversee access and quality of care, regardless of the site of care delivery. A single administrator should monitor access, safety and quality.

Participants made a compelling case. Ontario's model is difficult for patients and providers to navigate. Despite multiple reimbursement programs, it still lacks integration and universality. The quality and safety of the current model is unclear, owing to limited insight into dispensing practices. The information systems and technology that support these programs also lack integration, limiting the collection of data necessary to evaluate performance and improve care quality and cost effectiveness.

Fortunately, Ontario can look to other provinces to help guide its planning, by leveraging best practices and considering lessons learned. Approaches in other provinces include:

- Ensuring equitable access to all cancer medications through first-dollar and universal coverage public funding programs.
- Restricting dispensing to specialized oncology pharmacies, but also implementing practices to facilitate patient care close to home.
- Integrating provider information systems for comprehensive data collection.
- Standardizing patient education, communication and monitoring protocols.

While participants acknowledged the important work already underway to enhance the safe and effective use of take-home cancer medication, many argued for more transformational change that could address the limitations currently unaddressed in Ontario's model. It was this challenge that participants emphasized to CCO.

The need for a cancer system that delivers take-home cancer medication with the highest quality will continue to grow over the next several years. The think tank offered a forum for stakeholders to make the case for change, and CCO appreciates the feedback of all participants as it works to build the best cancer system in the world.

Introduction

Cancer treatment is changing. New therapies have emerged over the past two decades that are moving treatments from the chemotherapy clinic to the home setting. A growing number of new cancer treatments can now be administered orally, eliminating the need for regular cancer clinic visits for intravenous (IV) chemotherapy. This trend is expected to continue, as recent estimates suggest that approximately half of new cancer drugs in development are oral medications.

Although oral cancer medications have been a part of cancer treatment for several decades, their use has traditionally been limited because of the properties of the drugs themselves.¹ With many of the newer targeted treatments, the old barriers to oral therapy (e.g., side-effects or unpredictable absorption) are less problematic. In addition, the emergence of non-IV injectable therapies has moved even more cancer treatments away from the traditional cancer clinic setting. As a group, these treatments are sometimes referred to as take-home cancer medications to distinguish them from hospital-prepared, hospital-administered injections. Take-home cancer medications are dispensed from a pharmacy directly to a patient and are usually self-administered. Today, some patients can receive all of their treatment in the form of take-home therapy.

Patient preference is another driver of the transition to take-home medications, as patients may perceive them to be more convenient, minimally invasive and less disruptive of daily activities compared to drugs delivered in a hospital setting.^{2,3,4,5} There are also potential economic benefits to this approach, given the reduction in healthcare resource utilization (e.g., nursing and pharmacy time) compared to delivering IV chemotherapy in a hospital.⁶

Moving treatments from the hospital to the home also introduces new challenges to providing safe, accessible and high-quality systemic treatment. These challenges include the need to modify our approaches to patient education, prescribing and handling chemotherapy, monitoring adherence and managing toxicity. Foundational to solving these issues is the need for enhanced communication within the wider circle of care: the traditional hospital-based care team, community providers, family physicians, patients and their family members. Meanwhile, a 2012 survey of Ontario cancer centres found considerable variation in oral chemotherapy practices, with a lack of formal policies and established standards across the province.⁷

The move to take-home medications has introduced another challenge to cancer care: funding. Current provincial benefit programs ensure almost all hospital-administered IV cancer therapies are provided at no cost to Ontario residents. Public benefit programs, however, are not as comprehensive for take-home cancer medications. In this setting, private insurance covers a substantial component of cancer drug costs, while deductibles and copayments mean many patients face out-of-pocket costs. Gaps in coverage, and the steps required to qualify for benefits, have introduced concerns about overall equity, as well as the reality that patients may be responsible for out-of-pocket costs that would not exist if treatment were hospital administered and fully funded. The lack of first dollar and universal coverage for take-home cancer medications in many provinces, including Ontario, has been cited as a significant barrier to optimal care for some cancer patients.⁸

Take-home cancer medications have also introduced system challenges in the form of information management (IM) and information technology (IT). The current information systems were primarily

designed for cancer medications prescribed and administered in hospitals. Linkages between primary care and local providers (e.g., community pharmacies) and hospitals/cancer centres do not exist. Additionally, systems for public and private insurance funding still rely on paper- and facsimile-based application processes that are not integrated with hospital IM and IT systems.

Recognizing the increasing use of take-home cancer medications, current system challenges and the overarching need to ensure the quality of systemic therapy, the Systemic Treatment Program and Provincial Drug Reimbursement Programs of Cancer Care Ontario (CCO) hosted a one-day event called *Think Tank: Enhancing the Delivery of Take-Home Cancer Therapies in Ontario* on May 8, 2014. This event invited representatives from a variety of stakeholder groups, including healthcare providers (e.g., oncologists, nurses, pharmacists), patients, drug access navigators, cancer researchers, government and cancer agency representatives, and the pharmaceutical industry to explore possible program and policy opportunities to enhance the overall quality of patient care and to review opportunities to provide more equitable access to these treatments.

The meeting was divided into two parts. The morning session featured a series of panel discussions and was designed to give participants a detailed understanding of the challenges and opportunities that take-home medications present to Ontario's cancer system. It included presentations from several other Canadian cancer agencies to allow participants to understand how each jurisdiction had adapted to, and is addressing, the growing use of take-home medications. The afternoon session used small group discussions and polled audience feedback to identify opportunities for enhancing Ontario's model. The organizers highlighted three dimensions for specific focus:

- quality and safety
- reimbursement and distribution
- IM and IT

This report summarizes the key ideas and concepts discussed at this event, the opportunities and priorities participants identified, and the overall themes highlighted. Briefing notes provided to participants before the event have been extensively expanded and revised, and accompany this report in the form of backgrounders that are included in the appendices. These backgrounders provide a more detailed description of the current state of Ontario's delivery model and are written to complement and act as reference to the material presented at the think tank.

The challenges and opportunities that take-home therapies pose to the cancer system should not be underestimated. The existing infrastructure for cancer therapy delivery was designed for an era when take-home medications were a minor component of cancer care. It is hoped that this summary will be the first step in acknowledging the issues, identifying the obstacles and outlining opportunities for future discussion and deliberation. All this work is essential to ensure that Ontario has the best cancer system in the world.

Terms

Cancer therapy has its own terminology, some of which is unique to Ontario. While jargon has been minimized to the greatest extent possible in this synopsis, the following terms are used in the report and defined as follows:

Adherence: The extent to which patients take medications as prescribed.

Cancer care providers: healthcare professionals (e.g., oncologists, nurses, pharmacists) that specialize in the diagnosis and management treatment of cancer patients. These providers work in hospitals and cancer centres.

Computerized Prescriber Order Entry (CPOE): Computer-based systems designed specifically for automating the medication ordering process. CPOE allows oncologists, pharmacists and nurses to manage the process of ordering, dispensing and administering chemotherapy drugs electronically.

Copayment: A fixed amount paid by the patient per prescription.

Deductible: The total amount of prescription costs that a patient must pay before any insurance or benefit program will cover any expense.

Drug access navigator: dedicated reimbursement specialists who are responsible for helping patients find and obtain drug coverage.

First dollar coverage: refers to drug coverage where the patient does not incur any out-of-pocket costs (e.g., copayments or deductibles) for a funded drug.

Hospital-administered cancer therapy: Cancer medications that are administered in an outpatient hospital setting (e.g., chemotherapy suite, infusion or day clinic).

Inpatient: A person who receives health services and requires hospitalization (i.e., the person is admitted to hospital and is assigned a bed in an inpatient area).

Intravenous (IV) chemotherapy: Cancer medications given through a needle and injected into a vein.

Oncologist: For the purpose of this report, an oncologist refers to any physician who specializes in treating cancer (e.g., medical oncologist, hematologist, radiation or surgical oncologist).

Oncology Patient Information System (OPIS): An outpatient oncology CPOE system, developed by CCO, which is used by more than half of Ontario's hospitals.

Oral chemotherapy: Any drug taken by mouth for use in the active treatment of cancer. This includes cytotoxic chemotherapy (drugs that kill tumour cells), targeted therapies (drugs that target specific types of cancer cells with less harm to non-cancer cells) and hormonal therapy (drugs that slow or stop the growth of hormone-sensitive tumours).

Outpatient: A person who receives health services from a hospital or clinic and leaves the same day.

Outpatient cancer medication: A cancer medication dispensed by a community pharmacy or administered in a hospital's outpatient area (e.g., chemotherapy suite, infusion or day clinic).

Pharmacy terms:

Community pharmacy: A drugstore located in the community that fills prescriptions for cancer and non-cancer medications. There are thousands of community pharmacies in Ontario.

Cancer centre pharmacy: A pharmacy located in a cancer centre or hospital that fills prescriptions for cancer medications. In Ontario, some cancer centre pharmacies dispense take-home cancer medications, while others only prepare hospital-administered cancer medications.

Regions: From a cancer treatment delivery perspective, Ontario is divided into 14 regions. Regional Cancer Programs are responsible for the localized planning and delivery of cancer care. All hospitals that deliver systemic treatment are formally affiliated with Regional Cancer Programs.

Supportive therapies: These prevent or treat the symptoms or problems associated with cancer treatment. Supportive therapies can include anti-emetics (to prevent and treat nausea and vomiting) and colony-stimulating factors (medications that increase the number of certain blood cells).

Systemic treatment: An umbrella term for cancer treatments. Systemic treatments include drugs for the active treatment of cancer as well as supportive therapies. Systemic treatment can be taken orally or administered into the vein, muscle or skin by injection.

Take-home cancer medication (also called take-home cancer therapy): Typically refers to oral medications, but also include drugs for self-injection (e.g., drugs injected into the skin or muscle). These medications may be used in the active treatment of cancer or as supportive therapies.

Where We Are

1.0 Welcome and Overview

Michael Sherar, PhD, President and CEO, Cancer Care Ontario

CCO is the Government of Ontario's cancer advisor and the agency responsible for continuously improving cancer care. In his introductory remarks to the think tank, CCO's president and CEO, Mr. Michael Sherar, described the need for Ontario's cancer system to deliver the highest quality cancer care, regardless of where treatment is administered. Mr. Sherar noted the expanding role of take-home therapies in Ontario and the growing demand on health systems to fund all cancer drugs.

Mr. Sherar remarked that the lack of first dollar and universal coverage for take-home cancer medications has been cited as a significant barrier for some cancer patients. In addition, Ontario's mixed delivery and administration system has generated discussion on the opportunities to enhance the current funding and delivery model to bring oversight, data collection and quality measures for take-home therapies in line with hospital-administered treatments.

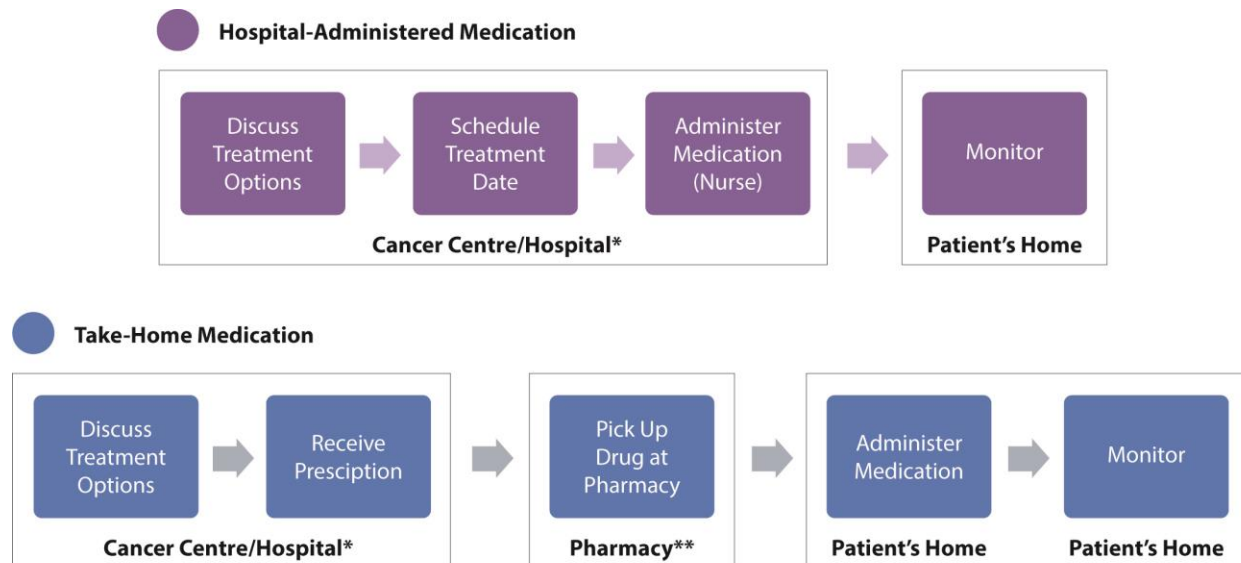
The patient case for take-home therapies seems clear. A take-home cancer medication may be preferred because it may be seen as more convenient and less intrusive than other forms of systemic treatment. However, take-home cancer medications expose patients and caregivers to risks involving handling, exposure and adherence, which is why quality considerations are key concerns. Opportunities to improve data collection and analysis could drive quality improvements and are part of CCO's overall focus on patient safety, which is part of all programs and corporate plans at CCO.

Mr. Sherar noted that CCO's responsibility for a high-quality system would continue to grow in the coming years as the number of cancer patients increases. About two in five Canadians will develop cancer in their lifetime.⁹ And about two thirds of those who are diagnosed with cancer will receive some form of systemic treatment.¹⁰ Given the growing use of take-home medications, a high-quality systemic treatment system is a key element of safe, high-quality care. Mr. Sherar concluded by thanking the think tank's participants for their hard work and dedication to Ontario's cancer patients and their families.

2.0 Ontario's Decentralized Model

Currently in Ontario, the treatment journey for cancer patients receiving cancer drugs differs significantly depending on whether they are prescribed a take-home cancer medication or receive a hospital-administered medication (e.g., IV chemotherapy) (Figure 2).

Figure 2: Patients' Treatment Journey: Hospital-Administered vs. Take-Home Cancer Medication



* Refers to an outpatient area of the hospital (e.g., chemotherapy suite, infusion clinic).

** Prescriptions may be filled at a cancer centre pharmacy or a community pharmacy.

There are five common elements (Figure 3) of a typical outpatient's treatment journey:

- **treatment decision**, or the process of selecting a cancer therapy
- **prescribing**, or the ordering of the medication by the oncologist
- **dispensing** the medication by the pharmacy
- **administering** the medication, which may be self-administered or given by a nurse
- **monitoring** the therapy to evaluate the patient's response to treatment and possible side-effects

Figure 3: Patients' Treatment Journey



Education regarding a patient's disease, treatment options, potential side-effects and his/her role in safe administration is required at every step of this journey.

Receiving take-home cancer medications in Ontario can be complex for both patients and providers. Other than the treatment decision, all other aspects of the journey change. Patients may still visit their cancer specialists at their local hospital or cancer centre, but instead of receiving treatment on site they are usually given a written prescription and are responsible for having their prescription filled. Selecting a take-home medication means patients are automatically more responsible for safe administration and monitoring.

Panel Discussions

To assess Ontario's current system from multiple perspectives, a panel discussion was held to examine the system according to quality of care, drug funding, and IM and IT infrastructure. Dr. Carol Sawka moderated the panel and gave the panelists a fictitious patient scenario to help frame their discussion.

Patient Scenario — "Grace"	
<ul style="list-style-type: none"> • Age/Gender: 50-year-old female • Diagnosis: Lung cancer (epidermal growth factor receptor [EGFR] positive, locally advanced, non-small cell lung cancer) • Drug Coverage: <ul style="list-style-type: none"> ○ No private plan (self-employed: \$60,000 annual salary) ○ May be eligible for public funding (Ontario resident holding a valid Ontario health card) • Treatment Centre: <ul style="list-style-type: none"> ○ 300 km to nearest cancer centre ○ 10 km to nearest hospital ○ 5 km to community pharmacy • Medications Prescribed: <ul style="list-style-type: none"> ○ First line: Oral chemotherapy (gefitinib) (discontinued upon disease progression) ○ Second line: IV chemotherapy (pemetrexed/cisplatin) 	<p>Patient Experience:</p> <p>Grace lived far from a cancer centre and therefore was happy to start an oral cancer medication (gefitinib). However, she found that the time frame from treatment decision to initiating therapy was prolonged. Grace had to complete and mail an application to the Trillium Drug Program; at the same time, her oncologist had applied to the Exceptional Access Program for funding. In about a week's time, Grace's oncologist notified her of the approval from the Exceptional Access Program and gave her a prescription to fill at the pharmacy. Two weeks later, she was notified by Trillium that she was registered and she went to a community pharmacy close to her home to have her prescription filled. Upon filling her initial prescription, she paid \$100 out of pocket towards her deductible (Grace had no private insurance to offset the costs). After her deductible was paid, Grace incurred a \$2 copayment on each prescription she filled.</p> <p>When Grace initiated IV chemotherapy, she required funding for pemetrexed, a drug costing \$3,000 to \$4,000 per dose. She met the drug-specific funding criteria under the New Drug Funding Program (NDFP), was approved for coverage and did not incur any out-of-pocket drug costs. Grace's oncologist had no direct conversations with her about drug coverage, and he was able to determine her funding eligibility at the time of prescribing because the hospital's prescribing system was integrated with CCO's funding system.</p>

2.1 Quality and Safety

Dr. Leonard Kaizer, Provincial Head, Systemic Treatment Program, Cancer Care Ontario

Dr. Leonard Kaizer noted that quality and safety are priorities at every step of cancer patient's treatment journey, regardless of how a medication is taken. Safety and treatment-quality issues can emerge at the time of treatment selection, prescription, medication dispensing, administration or monitoring. Dr. Kaizer noted that Grace's experience interfacing with the cancer system could have been quite different, depending on how her treatment was administered. He summarized the current quality gaps as follows:

- **Need for comprehensive patient education**
Patients on take-home medication not only need comprehensive education to provide informed consent to initiate treatment, they also need to understand how to take their medication, manage their side-effects and safely store and/or dispose of their medications. Education programs for IV chemotherapy tend to be extensive and multidisciplinary (e.g., oncologist, nurse, pharmacist). In a survey conducted by CCO of 13 Regional Cancer Programs, it was noted that less than 25% of regions currently provide an equivalent coordinated approach to patient teaching for patients starting oral chemotherapy.⁷ Gaps may include guidance on safe handling, disposal, drug interactions and how to deal with missed doses.
- **Minimal use of computer-generated prescriptions**
Computer-generated and pre-printed orders are considered much safer ways of writing a prescription. More than 90% of hospital-delivered IV chemotherapy is ordered using a CPOE system.¹¹ In contrast, handwritten prescriptions are commonly used for take-home cancer medications.
- **Dispensing of take-home cancer therapies by community pharmacies**
IV chemotherapy standards and guidelines have been developed to ensure safe dispensing and administration. These medications are routinely double-checked by multiple healthcare professionals who have specific certification and/or training in the provision of cancer care. No such standards exist for take-home cancer medications dispensed by community pharmacies.

IV therapies are prescribed and dispensed in the same facility, with cancer care providers working closely together. This arrangement facilitates communication about all aspects of a patient's care (e.g., treatment plan, medication history, test results). Communication links between the cancer care providers and community pharmacists are generally not as strong when it comes to take-home cancer medications, and may be limited to verifying prescriptions with the oncologist.
- **Community pharmacists' education**
Whether located in a hospital, cancer centre or in the community, any pharmacy in Ontario may dispense a take-home cancer medication. Canadian community pharmacists have reported a lack of comfort with dispensing take-home cancer medications and counselling patients on taking them. There is no formal certification process to assure patients and other health providers that a community pharmacist has specific training or expertise in the provision of take-home medications.

- Safe labelling**
 Cancer medications must be appropriately labelled so that a patient's name, drug, dose and directions for administration are easily identifiable to the patient and provider. Additionally, warning labels advising that a drug is cytotoxic may need to be affixed. Unlike IV chemotherapy, there are no guidelines or specialized requirements for standardized labelling of take-home cancer medications.
- Lack of adherence tools**
 With take-home medications, patients may miss doses, take the wrong dose, take additional doses or take the right dose at the wrong time. Dose omissions or errors can compromise treatment effectiveness or cause serious side-effects. In Ontario, tools to track adherence and dose changes to take-home cancer medications are limited. Tools include calendars, patient diaries, blister packs and manual pill counts; however, there is no information to suggest that they are used routinely for take-home cancer therapies.
- Protocols for managing toxicity**
 Patients on take-home therapies may have fewer clinic visits, yet they still need adequate instruction on disease and side-effect management. Patients may believe that oral chemotherapy is less toxic; however, they can experience drug toxicities and problems just like those associated with IV therapies. They may not know who to call or the steps to follow, in the event of dosing errors, complications, side-effects or if they have questions about their therapy.
- Underutilization of error reporting systems**
 Medication errors at any point of the treatment journey (e.g., prescribing, dispensing, administration) can have serious and fatal consequences for cancer patients. Error reporting systems improve patient safety and are typically a mandatory requirement for hospitals (although the rate of reporting of critical incidents is not optimal). Error reporting by community pharmacies is not mandatory, and the rate of error reporting for take-home cancer medications is even lower compared to hospital-administered drugs.

2.2 Reimbursement and Drug Distribution

Scott Gavura, Director, Provincial Drug Reimbursement Programs, Cancer Care Ontario

Two Systems, One Patient

Mr. Scott Gavura's presentation highlighted the challenges with the current reimbursement model for outpatient cancer medications. Take-home and hospital-administered drugs follow distinct reimbursement models wherein considerable variations exist in eligibility for benefits, how those benefits are accessed and how the two systems are compensated. Mr. Gavura noted that Grace would have a very different experience accessing her oral medication compared with her IV treatments, and he summarized the current reimbursement and drug distribution gaps as follows:

- One public funder, two funding administrators, multiple reimbursement programs**
 The Ontario Ministry of Health and Long-Term Care provides public funding for outpatient cancer medications through several different reimbursement programs. The Ministry manages public reimbursement for take-home cancer medications through the Ontario Drug Benefit (ODB) Program. Some take-home cancer medications additionally require prior approval

through the Ministry's Exceptional Access Program (EAP). CCO, primarily through the NDFP, manages funding for expensive injectable drugs that are administered in the outpatient hospital setting (e.g., chemotherapy suite, infusion or day clinics). While integrated at a policy level, the different reimbursement programs are not integrated at the point of care.

- **Disparities in patient eligibility for public benefits**

For hospital-administered drugs, patients may access public benefits simply by providing proof of Ontario residency and a valid Ontario health card. Access to benefits for take-home medications is more restricted and is based on individual patient eligibility factors. The ODB is an age- and income-based plan that offers benefits mainly to seniors (i.e., persons over 65 years), and patients who are on social assistance or receiving home care. Any Ontario resident who is not automatically ODB-eligible can apply to the Trillium Drug Program to obtain ODB drug coverage. However, Trillium is associated with income-based copayments and deductibles, and has a separate registration process. Mr. Gavura noted that Grace would need to register for Trillium to be eligible for public benefits, and this registration would need to be completed before she could obtain any public-funding support. He also noted that Trillium's application process is a paper-based system that patients must complete themselves; processing times have been reported as 17 days.¹²

- **Lack of first-dollar coverage**

Unlike hospital-administered drugs, publicly funded take-home cancer medications are usually associated with out-of-pocket costs in the form of copayments and deductibles. Private insurance may play the primary role in funding an Ontario resident's take-home cancer treatments. Mr. Gavura noted that Grace lacked private insurance, but could register for Trillium to help with the costs of her take-home therapy. She would need to pay prescription drug costs up to a calculated deductible (approximately 4% of her household net income) before she would be eligible for any funding assistance.

- **Complex and disjointed application processes**

Application processes for patient access to public funding for take-home and hospital-administered medications differ significantly and are not integrated at the point of care. For take-home medications, physicians may need to fax an application to the EAP that outlines the reason and rationale for use. Turnaround times are slowed if applications do not have complete information for the EAP to make a drug-funding decision. Timely adjudication is contingent on the provision of sufficient documentation to demonstrate that the request satisfies the funding criteria. Upon a review of an application, the EAP faxes a decision letter to the patient's physician. If approved, the patient can then fill the prescription at the community pharmacy of his/her choice.

EAP approvals are uploaded to the Ministry's adjudication system, the Health Network System, which processes ODB claims. Uploading to this system allows pharmacies to submit electronic claims directly to the ODB when a patient fills their prescription. However, the EAP does not assess ODB eligibility; therefore, if a patient is not ODB eligible he/she will be charged at the pharmacy despite having an approval in place. As noted earlier, patients must ensure they are also ODB eligible. The onus for ensuring that both a patient and a drug are eligible for public benefits rests on the patient and his/her prescriber. The complexities of navigating the funding process have led to the emergence of drug access navigators in many cancer centres to help

patients ensure they have all required applications and paperwork in place prior to filling a prescription.

For hospital-administered drugs, the application process is more streamlined. In most hospitals and cancer centres across the province, eClaims, an online application, is used to submit funding requests to the NDFP, often at the same time as the oncologist orders cancer drugs. Rather than stating the reason for funding in writing, criteria are confirmed online and supporting documents (if required) are uploaded. Many funding requests are adjudicated immediately and the oncologist receives an online notification of the decision, often, the same day. There is no billing to patients, as hospitals are reimbursed directly by CCO. When a drug is publicly funded and administered in a hospital, there are no copayments, deductibles or other eligibility checks.

- **Treatment close to home**

Take-home medications may be filled at any of the thousands of community pharmacies in Ontario, making take-home treatments accessible and close to home. However, not all pharmacies may be willing to stock, or feel comfortable dispensing, these products. Grace could potentially get her therapy close to home, but might still experience local challenges.

IV therapies can be delivered by any hospital that is affiliated with one of the province's 14 Regional Cancer Programs. With over 80 sites across the province, Grace may be able to obtain her treatment at her local hospital, avoiding a long-distance commute to a cancer centre.

2.3 Information Management and Information Technology

Dr. Vishal Kukreti, Clinical Lead, eTools and Technology, Cancer Care Ontario

At present, patients receiving take-home cancer medications can receive care from their family physicians, oncologist, community pharmacists and local hospitals for non-cancer-related medical issues.

Information systems and technology that support integrated cancer care and treatment can improve quality of care, patient safety and coordination among different healthcare providers and the overall efficiency of delivering health services. The current IM and IT infrastructure primarily supports cancer medications prescribed, dispensed and administered in a hospital setting. With regard to take-home cancer medications, Dr. Vishal Kukreti summarized the gaps and opportunities as follows:

- **Systems integration**

Take-home cancer medications can be filled at any of the thousands of community pharmacies in Ontario. However, there is a lack of integration between the cancer system and community pharmacies, a situation that limits optimal prescribing, dispensing, patient monitoring and reimbursement.

From a prescribing perspective, Dr. Kukreti highlighted the system's inability electronically to transmit a prescription from a hospital prescriber to a community pharmacy. ePrescribing, a solution being piloted for non-oncology drugs, has not yet been explored in Ontario's cancer care system. ePrescribing offers the potential to improve prescription completeness and legibility, collaboration between community and hospital cancer care providers, efficiency of dispensing and patient care provided by community pharmacists.

In terms of patient monitoring, Ontario patients may be using IT tools, such as mobile applications (apps) with pill calendars and symptom management features. In Ontario, however, these applications are not interactive. Interactive mobile apps would allow patients to send information about their symptoms directly to their providers via a web portal, and their providers respond with management advice.

Dr. Kukreti also discussed the data collection issues associated with the current IM and IT infrastructure, which is not optimal for either clinical or administrative purposes. Cancer care providers, located in hospitals/cancer centres, cannot typically access local community pharmacy databases to obtain complete medication profiles for their patients. On the other hand, community pharmacists cannot access cancer centre clinical, laboratory or reimbursement records in order to verify prescriptions. As well, data collected by community pharmacies are not accessible to CCO for quality assurance purposes.

- **Adapting and adopting CPOE**

In Ontario, hospitals may have two different CPOE systems, one for prescribing inpatient medications and another for prescribing cancer medications for outpatients (i.e., outpatient oncology CPOE).

Outpatient oncology CPOE is not implemented in all cancer treatment facilities in Ontario, nor is it routinely used to generate prescriptions for take-home cancer therapies. Challenges with adapting outpatient CPOE to take-home cancer therapies vary depending on the dispensing model, but every attempt must deal with the following:

1. **Chemotherapy prescription standards**

There are no defined standards for the key elements that should be included on a take-home chemotherapy prescription.

2. **Functionality**

The outpatient oncology CPOE features and functionalities specific to take-home cancer medications need to be defined for the safe and effective delivery of chemotherapy (e.g. dispensing logic, alerts, usability). Also, currently outpatient oncology CPOE systems may not be integrated with the hospitals' electronic health records systems and do not connect with community pharmacy databases.

3. **Limited capability**

Implementation and use of an outpatient oncology CPOE system is not a stand-alone IT solution for take-home cancer medications. CPOE will not facilitate prescription verification, medication adherence, error reporting or communication between providers located in the cancer centre and the community.

Dr. Kukreti concluded his presentation by arguing that an optimized medication management system could facilitate integration among hospital providers and between hospital and community providers. Such a system would give all caregivers complete access to their patients' complete medical records (e.g., treatment plans, medication profiles, results of laboratory and imaging tests) at a single point (i.e., users would need to log in at only one point).

3.0 Take-Home Cancer Models Outside Ontario

To help guide deliberations about Ontario’s challenges, representatives from five other provinces participated in a panel discussion to describe their systems for take-home cancer medications. The objective was to give the audience an awareness of existing take-home cancer medication models across Canada, and recognize feasibility and limitations for adoption in Ontario. To guide comparisons with Ontario, each speaker was asked to comment on the same patient—Grace—and her journey through the cancer system in that province.

Note: This section summarizes the information presented by speakers at the think tank. Refer to Appendix B for a more detailed comparison of provincial cancer programs.

3.1 British Columbia

Susan Walisser, Provincial Pharmacy Professional Practice Leader, British Columbia Cancer Agency

Ms. Susan Walisser opened her presentation with the principles of the British Columbia Cancer Agency (BCCA) that were relevant to take-home cancer medications.

With respect to the take-home therapy prescribed for Grace, Ms. Walisser noted that a British Columbia (B.C.) oncologist would need to obtain prior approval through the BCCA Compassionate Access Program for the drug costs to be covered by the agency.

The BCCA provides full drug coverage only for cancer medications dispensed from designated pharmacies. The amount prescribed at any one time is based on the interval between physician visits, with no refills allowed. To obtain her take-home cancer medication at no cost, Grace would need to travel to the nearest BCCA regional cancer centre pharmacy (six locations) or a Community Oncology Network pharmacy (34 locations) every one to two months.

Ms. Walisser elaborated on the dispensing processes for take-home cancer medications in B.C.. Pharmacies approved by the BCCA have access to a patient’s relevant medical records (e.g., medical history, lab results, medication profile) to allow a pharmacist to verify that a prescription is appropriate for a particular patient (e.g., right drug, right dose, right time). Grace would also attend a group chemotherapy lesson, or receive personal counselling from a pharmacist. The BCCA offers a call-back program for adherence and side-effect monitoring, and Grace might be offered this as part of her treatment. Otherwise, adherence would be assessed at the time of dispensing.

A similar process exists for hospital-administered therapy. Most IV chemotherapies are listed benefits; therefore, prior approval to obtain drug coverage is not required. In the case of Grace, her IV chemotherapy would also be considered a restricted drug and her oncologist would first be required to

BCCA Principles
<ul style="list-style-type: none">• No resident of B.C. should be denied cancer treatment due to financial considerations.• Physicians should not make treatment decisions based on a patient’s ability to pay for therapy.• The route of administration of cancer treatment should not be a consideration for a different funding mechanism.• B.C. residents will have access to evidence-based, publicly funded cancer treatments free of charge through a BCCA managed process.

request prior approval through the Compassionate Access Program. Pre-printed orders and protocols would guide prescribing, and treatments would be provided at the nearest BCCA cancer centre or a community chemotherapy centre capable of administering IV treatments. The dispensing and education process would not differ from the take-home cancer medication, with the exception of a greater role for nursing in the form of assessments and side-effects monitoring. Adherence would be assessed by attendance at treatment visits.

Ms. Walisser briefly summarized B.C.'s data-collection process. All oncology prescription data (including data on all take-home therapies) are housed in a single data warehouse. Prescription data are exported from each system and linked to the BCCA's electronic health record (EHR) system. The result is a single source for all data related to patient demographics, diagnostics and systemic treatments; these data can be requested by cancer care providers and researchers.

The presentation concluded with some of the challenges of delivering take-home cancer medications in B.C.:

- Patients receiving free "compassionate" supplies are not managed through the BCCA system.
- Variations exist in professional practice across different practice sites.
- Patient readiness/ability to self-manage therapy is not systematically assessed.
- There is no structured approach to educating staff and patients.
- Resources vary across regional cancer centres and the regional network.
- Technical supports are lacking to monitor adherence (e.g., calendars, diaries, refill reminders, notification if prescriptions not picked up).
- Variations exist in the safe handling and safe dispensing of hazardous drugs across different practice sites.

3.2 Alberta

Carole Chambers, Pharmacy Director, Cancer Services, Alberta Health Services

Ms. Carole Chambers described how Grace would be managed if she were a patient in Alberta. She prefaced her description by emphasizing that in Alberta there are no significant differences in the delivery of IV and take-home chemotherapy. Specifically, she noted the following:

- Both take-home and intravenous cancer medications would be fully funded in Alberta:
 - No pre-qualification or prior approvals are required.
 - There are no out-of-pocket costs for patients.
- Grace could likely access treatment close to home via a network of cancer centres:
 - Dispensing of take-home cancer medications is restricted to cancer centre pharmacies.
 - Initial prescriptions are filled at major cancer centres, but subsequent prescriptions can be filled at approved community cancer clinics.
 - Cancer centre pharmacies can mail take-home therapies to patients.
- Quality- and safety-monitoring standards do not differ between take-home and IV therapies:
 - In both cases, routine follow-up appointments are required.
 - Patient education and communication protocols are similar.
 - A pharmacy-led oral oncology monitoring program exists to contact patients between treatments.
 - Pharmacists assess medication use with each refill and implement call-back programs when warranted.

Ms. Chambers also explained Alberta's data collection and flow processes. Prescriptions are created through a CPOE system—Aria—that covers almost the entire province. All data from all treatments (IV and take-home) are collected in a single pharmacy-system database—Centricity. Data in this network are shared with the Alberta Pharmacy Information Network to ensure all other health professionals in the province also have access.

3.3 Saskatchewan

Kathy Gesy, Provincial Leader, Oncology Pharmacy Services, Saskatchewan Cancer Agency

Ms. Kathy Gesy noted that the Saskatchewan Cancer Agency's mandate includes the provision of all outpatient cancer medications, including take-home cancer treatments. The agency also funds some supportive care drugs, such as anti-emetics and colony-stimulating factors. The system has a single formulary, which provides complete coverage (no out-of-pocket costs) to eligible beneficiaries.

Ms. Gesy described Grace's treatment pathway in Saskatchewan, observing that she would first attend an appointment at one of the two provincial cancer centres. Grace's treatment pathway for a take-home therapy would include the use of pre-printed prescribing orders, with dispensing being limited to cancer centre pharmacies. In Saskatchewan, refills can be mailed to patients for the sake of convenience; when prescriptions are mailed to patients, providers are available via phone or a telehealth service. Monitoring services provided to patients include a call-back on the initial prescription and in-person follow-up at subsequent clinic visits.

Patients receiving IV cancer therapies largely follow the same treatment pathway. Prescribing and dispensing standards are the same for both groups (e.g., use of pre-printed orders, dispensing restricted to cancer centre pharmacies). Doses are administered by a nurse, and a pharmacist dispenses any supportive care medication, accompanied by counselling. Subsequent treatments can be scheduled at a cancer centre or potentially delivered at a provincial outreach centre, where providers have access to patient information from the main centre.

Ms. Gesy noted that, relative to IV therapy, there is a less formal monitoring process in place for take-home therapies, with somewhat fewer resources dedicated to monitoring safety, efficacy and adherence. She concluded her presentation by discussing the increased utilization of take-home cancer medications (particularly of oral medications), the associated increased costs and the challenges take-home therapies present from a systems perspective. Take-home therapies continue to create new resource demands for the Saskatchewan Cancer Agency, which recognizes that more supports may be needed to ensure take-home therapies deliver the greatest benefits to patients and value to the system.

3.4 Manitoba

Venetia Bourrier, Director, Provincial Oncology Drug Program, Cancer Care Manitoba

Ms. Venetia Bourrier began her presentation by introducing Manitoba's IN SIXTY cancer patient journey initiative, which launched in November 2011. The goal of this initiative is to reduce (no later than 2016) the time of suspicion of cancer to first treatment to 60 days or less.

In Grace's case, she would follow timelines for diagnosis and assessment established for the lung cancer pathway. She would be evaluated as part of weekly thoracic tumour rounds, and her care would be assigned to a member of the thoracic disease site group.

Ms. Bourrier also explained the role of the Home Cancer Drug (HCD) Program. The HCD Program was launched in 2012 to give outpatients access to specific oral cancer and supportive drugs at no cost. It covers Manitoba residents, but not residents with coverage under any other federal or provincial programs (e.g., First Nations and Inuit Health Branch).

To access benefits, a patient first registers with the Manitoba Pharmacare Program and then registers with the HCD Program (Cancer Care Manitoba completes applications on patients' behalf and registration takes approximately 24 to 48 hours). Once a patient has been registered with the HCD Program, benefits are covered at 100%. There are no copayments or deductibles.

With respect to Grace's treatment pathway, Ms. Bourrier's presentation illustrated the following:

- Universal coverage applies to both take-home and hospital-administered cancer medications.
 - Grace would incur no out-of-pocket expenses for drugs covered under the HCD Program formulary.
- Prescriptions for both oral and IV chemotherapy are computer generated (i.e., using the Aria CPOE system).
- Care can be accessed close to home.
 - IV chemotherapy could be delivered at one of 16 community cancer programs. Cancer Care Manitoba trains family physicians to oversee this process, while patients remain under the care of their primary oncologists.
 - Once registered in the HCD Program, patients can fill their prescriptions at any community pharmacy in Manitoba.
 - Monitoring by healthcare teams in urban and community cancer programs is possible.
- Quality and safety monitoring is not optimal for take-home medications.

3.5 Nova Scotia

Larry Broadfield, Manager, Systemic Therapy Program, Cancer Care Nova Scotia

Mr. Larry Broadfield described Nova Scotia's approach to take-home therapy, which is the closest in design to Ontario's model. Take-home cancer medications are dispensed by community pharmacies, and the province has a mix of public and private coverage. Consistent with other presenters, Mr. Broadfield highlighted the rapid growth in the number of patients and prescriptions for oral chemotherapy. Mr. Broadfield described Nova Scotia's efforts to enhance the safety of the current model. He identified the following safety issues associated with oral cancer medications:

- Oral prescriptions are not verified with the same level of scrutiny as in-hospital treatment orders.
- There is a lack of standardized training and guidance for community pharmacists to help them verify prescriptions for oral cancer medications.
- There is also a lack of standardized training and guidance in how to administer cancer drugs for community nurses who lack cancer expertise.
- Hospitals do not meet clinical or handling standards when patients are admitted for reasons other than cancer.

In view of the current challenges, Mr. Broadfield explained a variety of ongoing initiatives to improve the current state. Cancer Care Nova Scotia has developed online toolkits to help pharmacists and nurses provide oral treatments safely and appropriately. Nova Scotia is also considering the creation oncology

pharmacy case managers that would work in cancer centres to verify prescriptions, confirm coverage and coordinate care with community pharmacies.

3.6 Summary of Inter-Provincial Variations

While variations in take-home cancer delivery models exist among the provinces represented at the think tank, panelists described similar stories of barriers and opportunities for quality care. Key points emerging from the panel discussion are highlighted in Figure 4.

As each provincial representative relayed their best practices and challenges with take-home cancer medications, it became apparent that there were some similarities—but also sharp differences—among the six provinces. Most notably, in the three western provinces (i.e., British Columbia, Alberta and Saskatchewan):

- Prescribing is restricted to cancer specialists.
- Cancer care providers can access all health records.
- Universal and first dollar coverage are provided for all medications used in the active treatment of cancer.
- Dispensing is restricted to specialized cancer pharmacies.

Figure 4

Key Points from Panel Discussion
<ul style="list-style-type: none">• There is a need for equivalent prescribing and safety standards for take-home and IV cancer therapies.• While recognizing the challenges associated with the safe provision of take-home therapies, it is important to treat them—from a funding perspective—like other cancer therapies.• Eligibility requirements for cancer medications should be consistent across Canada.• There is a trend to restrict the prescribing and reimbursement of cancer drugs by prescriber and to cancer agency-affiliated pharmacies.• For cancer care systems that rely on community pharmacies, it is important to ensure quality-assurance measures are in place for dispensing cancer medications.• Provider support and resources to manage take-home cancer medications may be lacking and needs to be addressed.• In the western provinces, government recognition of the specialized clinical and administrative support requirements essential to safe, high-quality care has led to an explicit acknowledgement that “cancer is different.” From this acknowledgment has flowed the decision to provide and fund take-home cancer medications in a manner consistent with hospital-administered IV treatments.

4.0 The Patient's Perspective: Opportunities and Options

Joanne MacPhail and Lillian Clarke, Cancer Survivors

Patients may prefer take-home cancer medications because of convenience and ease of administration. There may be fewer trips to the hospital when they are unwell, and patients can avoid the need for IV lines and the risks of associated complications (e.g., infections, blood clots). However, patients must assume significant responsibility for their own care, as cancer medications are often associated with complex dosing and side-effect management protocols.

To assess Ontario's current system from the patient perspective, two cancer survivors described their experiences. Ms. Esther Green moderated the discussion and comments from the audience. Ms. Joanne McPhail shared her experience as a two-time breast cancer survivor who received treatment with both oral and IV chemotherapy in two different decades. Ms. Lillian Clarke, a thyroid cancer survivor, had required treatment with an injectable medication that was purchased from a community pharmacy for in-hospital administration. She also had radioactive-iodine treatment administered in hospital and was sent home immediately after. Both cancer survivors, while having distinct cancers and treatment plans, echoed similar experiences across their patient journeys. Their key perceptions regarding the delivery of outpatient cancer medications are summarized in Figure 5.

Figure 5: Perceptions of Two Cancer Survivors

Need for Patient Education
<i>"It is so important that patients and their families or caregivers are given information about all medication we have to take; in particular, the drugs we have to take in our home. It will help to reduce our anxiety; to take them as they should be [taken]; to know what to do if we experience side-effects; how to store them properly; what not to eat or drink while taking the drug; ... [and how to] protect our family."</i> <i>"I may have felt more comfortable going home had I, or my family, been provided with clear instructions on how to care for me during my recovery."</i>
Fear of Putting Others at Risk
<i>"I was worried about exposing my family to radiation, so I checked myself into a hotel, even though I had been instructed not to, and was careful not to interact with anyone while there. I felt abandoned by the hospital."</i> <i>"My children were quite young and very inquisitive about things. I worried constantly that they would get a hold of those pills. I kept changing my storage place to an area I thought they wouldn't be able to get to."</i>
Lack of Coordination and Continuity of Care
<i>"I was told my treatment would include Thyrogen injections at the hospital and that I would have to purchase them from my own pharmacy at my own expense. When I showed up for my first appointment, not only did they not have my appointment in their schedule, they told me I had to wait for the Thyrogen to be delivered from the hospital pharmacy. Meanwhile, I had already purchased it as instructed and brought it with me. It was clear to me at this point, early on, that there was significant miscommunication between the hospital and my healthcare providers."</i> <i>"Since I had been sent away from the hospital, I was told to return on my own for blood work just two days later, while I was still radioactive. I discovered in advance that three of the lab technicians were pregnant and that they had not been given any prior knowledge that I would be turning up."</i> <i>"It would have also helped to have a line of communication open so that there was someone I could call if I had any questions or concerns."</i>

What We Heard

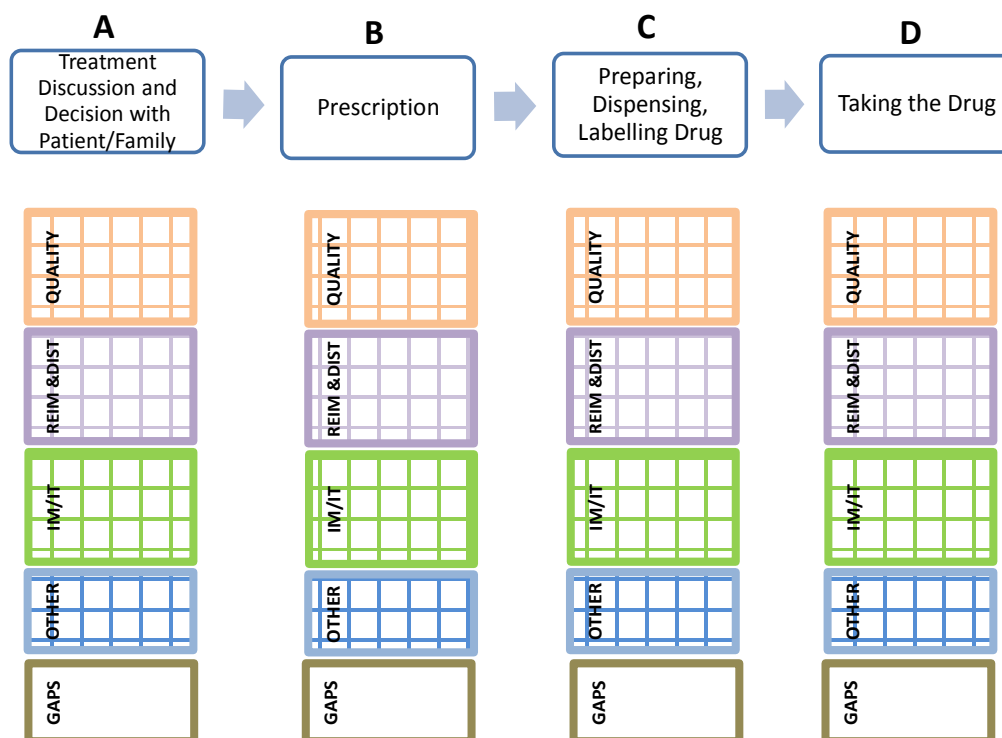
Following the panel presentations, audience members were invited to submit comments as well as questions in real time via text message, and responses were projected onto a screen for the panelists to reflect and comment on. Several key needs were emphasized:

- consistent, appropriate information for patients supported by simple communication tools
- computer-generated prescriptions supported by integrated, connected information systems accessible to all providers
- 24/7 patient support for managing adherence and toxicity
- safe handling and dispensing practices

In the afternoon breakout sessions, participants collaborated to develop ideas for improving Ontario's current delivery model for take-home cancer medications. In exercise one, pre-assigned groups of participants were asked to evaluate the delivery model focusing on three dimensions (i.e., quality and safety, reimbursement and distribution, IM and IT), and to examine the current approach from end to end, focusing on specific checkpoints in the patient's treatment journey. Gaps, opportunities and potential recommendations were transcribed for each dimension and checkpoint (see Figure 6). In exercise two, participants were asked to prioritize potential recommendations. Groups were re-arranged in order to ensure each participant could interact with, and hear the perspective of, as many other participants as possible.

In exercise one, facilitators transcribed and collated 445 participant responses. These responses ranged from brief statements to detailed, specific recommendations. To summarize the extensive feedback received, all transcribed responses were reviewed, categorized, and summarized (see section 6.0). A subsequent analysis looked for common elements across all feedback recorded, as well as the areas that were identified as the highest priority for change. From this analysis, themes were identified and are summarized below (section 5.0).

Figure 6: “Checkpoints” in the Take-Home Cancer Therapy System



IM/IT= Information Management/Information Technology
 REIM & DIST = Reimbursement and Distribution

5.0 Themes Identified

In analyzing participant feedback, overlapping themes were identified, which speaks to the interconnectedness and system-level nature of some of the challenges. Overall, four primary themes were identified:

1. Patients, providers and administrators want a more integrated system.

Cancer services, including the delivery of outpatient cancer medications, need to be coordinated and integrated across provider locations—whether in the community or hospital—to support seamless, person-centred care. Patients should not have to apply to multiple reimbursement programs to obtain drug coverage and providers should have access to all patient information.

2. Patients, providers and administrators want a more responsive system.

Suggestions were repeatedly made to simplify existing policies and procedures to support the efficient delivery of take-home cancer medications. Patients want timely access to services, such as receiving convenient care close to home and easily obtaining drug coverage.

3. Patients, providers and administrators want a system that is simpler and more comprehensive.

The delivery of take-home cancer medications should be equivalent in quality to the existing model for hospital-administered drugs.

4. Patients, providers and administrators want a single, person-centred system to oversee access and quality of care, regardless of the site of care delivery.

System oversight for take-home cancer medications should be consistent with the one in place for hospital-administered drugs. A single administrator should be tasked with monitoring the accessibility, safety and overall quality of outpatient cancer medication delivery and the cancer system's performance (including evaluation of public spending and the value of take-home cancer medications).

6.0 Suggested Areas of Enhancements

Below summarizes participants' key ideas on suggested improvements to the Ontario delivery model for each dimension analyzed.

6.1 Quality and Safety

1. Provide comprehensive, multidisciplinary and standardized patient education and navigation.

Patients require consistent, standardized and comprehensive education and navigation through all stages of the treatment journey. Repetition of information at every opportunity was felt to be imperative. Participants also highlighted the importance of patients being adequately informed and involved with their oncologist or nurse teams at the time of treatment decision, possibly through the use of patient decision aids and reinforced by personalized care plans.

Educational materials should consider patients' literacy level, culture and language preference. Suggested tools included videos that patients could access from home and patient decision aids.

2. Use an electronic method of prescribing that includes a standardized template.

Participants generally agreed that prescriptions for take-home cancer medications should be generated using a CPOE system. Standardized prescription templates, like those used for IV chemotherapy, should be employed, and pre-printed orders should be utilized when CPOE is not available. Handwritten and verbal prescriptions should be eliminated. CPOE should ideally be combined with decision-support tools to facilitate safe prescribing (e.g. software to check for drug–drug interactions). ePrescribing was promoted as a tool that would facilitate electronic transmission of prescriptions directly from prescribers to pharmacies.

3. Establish guidelines for the safe prescribing, dispensing and handling of take-home medications.

Participants discussed the lack of guidelines specific to take-home cancer medications and suggested ideas to improve current practices:

- Limit prescribing to qualified, accredited cancer providers and provide guidance on the appropriate quantity to prescribe per visit.
- Safe dispensing practices should include enhanced prescription verification processes to ensure adequate double-checking for correct dose and drug interactions occurs in all community pharmacies.
- Safe handling practices should include limiting the mailing of take-home cancer medications to drugs that have a low exposure risk.
- Labelling guidelines specific to take-home cancer medications are needed. Prescription labels should be standardized and include clear instructions on how to take, safely handle, store, transport and dispose of a drug.

4. Develop patient and provider tools for monitoring adherence.

There was general agreement that adherence is an important issue that needs to be addressed for all patients using take-home cancer medications. Participants suggested enhanced patient and family education should be supported by a variety of monitoring tools, including standardized call-back programs, blister packaging, pill calendars and mobile applications for treatment reminders.

It was also recognized that it is important to have a method for identifying patients who are at high risk of being non-adherent. These patients would be candidates for additional strategies, such as specific compliance packaging or additional follow-up calls within a call-back program.

5. Create an infrastructure for patient support and side-effect management.

Participants universally endorsed around-the-clock support for patients, families and caregivers. Patients require support systems for 24/7 care and side-effect management, and they need comprehensive instruction on side-effect management. Providers, meanwhile, need systems and platforms to facilitate real-time patient engagement. The creation of innovative e-tools to provide such support was promoted, as was the leveraging of current technologies, such as telehealth or Skype.

6. Use an integrated error reporting system.

Participants advocated for a medication error reporting system that is integrated at the point of care and accessible to all providers in a patient's circle of care.

7. Provide specialized education, training and support to cancer care providers.

Participants identified several opportunities to enhance provider support and considered innovative models of care for patients on take-home cancer medications. Suggestions included the following:

- Increase training, education and support for primary care providers and community pharmacists.
- Expand roles for advanced nurse practitioners and drug access navigators.

**Participant Responses :
Quality & Safety**

- *Patients and families should have 24/7 support.*
- *Patient education should be respectful, consistent and comprehensive, and take into account language, culture and literacy.*
- *Generate prescriptions via electronic ordering using standard pre-printed orders, templates and regimens.*
- *Implement a standardized tool to assess adherence and barriers to self-management.*
- *Use innovative technologies for patient monitoring.*
- *Use CCO's approach to IV treatment as the ultimate goal for oral chemotherapy*

6.2 Reimbursement and Distribution

1. Resolve inequitable cancer drug funding.

Participants strongly supported equal access to cancer medications regardless of age, income, private insurance benefits or place of administration. Public drug coverage for take-home cancer medications should align with the funding model for hospital-administered drugs (where the primary determinants are a drug's clinical and cost effectiveness, not patient socio-economic factors).

2. Simplify complex reimbursement processes for ease of access, as well as timely and integrated quality care.

With a mix of public and private payers as well as different reimbursement processes and administrators, navigating Ontario's drug coverage systems can be a tedious challenge for patients and providers. These difficulties were not lost on participants, who strongly emphasized the need for a simpler and more efficient reimbursement process.

Participants suggested several ideas for reducing complexity and improving timelines:

- **Create a unified, centralized reimbursement model.**

There was general consensus that the current Ontario reimbursement model should be simplified. Ideally, funding should be centralized through one administrative body for all outpatient cancer medications. The system for take-home cancer medications should mimic that of hospital-administered cancer medications, and there should be alignment with the practices of other provincial cancer agencies that have a single administrator.

- **Simplify policy criteria.**

Policy criteria for reimbursement programs may be difficult for providers to understand, resulting in unnecessary delays in starting treatment. Participants noted that EAP criteria are difficult to interpret.

- **Simplify the application process.**

Multi-step paper-based application processes (e.g., faxing, mailing) should be replaced with electronic systems. Participants suggested simplifying the current EAP application process, but also recognized the need to address the complexities associated with CCO's current online system (eClaims).

- **Implement standardized timelines for reimbursement decisions.**

Participants suggested establishing standardized turnaround times for reimbursement decisions across the province. A 24 to 48 hour time frame was put forward as an ideal target.

**Participant Responses :
Reimbursement and Distribution**

- *Ensure equitable access.*
- *Private insurance, income, age and other variables should not impact public coverage, which should be based on clinical evidence.*
- *Simplify and integrate the prescribing and reimbursement process (i.e., no paper work for patients).*
- *Implement a single drug funding model for IV and oral chemotherapy.*
- *"Reimbursement fairness, make it happen."*

3. **Identify best practices for value-based reimbursement.**

For take-home cancer medications, the funding model is based in large part on the cost of the drug alone. Community pharmacies are reimbursed for a dispensing fee plus an 8 % mark-up. In contrast, hospitals are paid for providing a specific chemotherapy regimen, and are compensated for the actual cost of doses administered.

4. **Determine the drug distribution chain that is best for Ontario patients.**

Participants did not reach consensus on the best model to deliver take-home cancer therapies medications to patients. The following issues were noted:

- **Accessibility:** Patients prefer to have care close to home. However, participants also emphasized a preference for cancer care from a professional that has specialized expertise in cancer medications.
- **Drug availability:** Pharmacies may not always pre-stock infrequently dispensed drugs. Patients may need to order drugs three to four days in advance from their community pharmacy. The risks of treatment interruptions were noted.

- **Dispensing standards:** There was widespread agreement that any pharmacy dispensing take-home medication should be subject to appropriate oncology-specific certification. A variety of potential distribution models were discussed. Suggested recommendations included creating a centralized model where dispensing is limited to cancer centre pharmacies to maximize patient safety and simplify data collection. Alternatively, pharmacies could dispense take-home medications if they were to provide services consistent with hospital standards for IV therapies. Another option was to have the first prescription dispensed by a cancer centre pharmacy and subsequent prescriptions dispensed by a community pharmacy. It was recognized that changes to the distribution model could be complicated and might require regulatory changes and/or legislation and new IM and IT solutions.

6.3 Information Management and Information Technology

The main point emerging from the discussion groups was the need for a centralized, integrated system for both clinical and administrative purposes. Participants identified several key concepts:

1. IM and IT solutions should support continuity of care.

To ensure safe prescribing and dispensing, and to facilitate monitoring, all cancer care providers should have access to their patients' complete medical records, including information on diagnoses, treatment plans, current medications and laboratory and imaging tests. Suggestions included:

- Use an electronic health record system.
- Allow oncology-certified community pharmacies to access hospitals' CPOE systems.
- Use a single integrated system wherein all databases are linked to each other.

2. Simplify the prescribing and funding system and reduce the related administrative burden.

To reduce the administrative workload associated with prescribing and funding, participants suggested integrating funding and prescribing systems: ideally, there should be a single, dual-function system at the point of care. ePrescribing could be used to transmit prescriptions directly from a cancer centre prescriber to a community pharmacy. Existing outpatient oncology CPOE systems could be enhanced with features needed specifically for the safe prescribing of oral chemotherapy.

Participant Responses: Information Management and Technology

- *Standardized information should be housed in one place.*
- *Ontario should move to a centralized, integrated model.*
- *Integrate a robust data system (including reimbursement) across the patient journey.*

3. Create a system for robust data collection at all points of care.

Data collection for take-home cancer medications is extremely limited when compared to hospital-administered drugs. Participants suggested a centralized and integrated system to collect treatment data at all points of care. In terms of using existing tools, suggested ideas included:

- Enhance hospitals' CPOE systems for data collection.
- Use eClaims to track utilization of take-home cancer medications.

What We Are Doing

The challenges and opportunities that take-home medications present to cancer systems have been acknowledged for a number of years. At the time of writing this report, CCO, in partnership with Regional Cancer Programs across Ontario, has already undertaken several quality improvement strategies for take-home medications. These initiatives include:

- **Enhancing patient education:** Many regions are currently working to close the gaps in patient education. Their approaches are being shared with quality improvement teams across the province through the Systemic Treatment Program's Regional Quality and Safety Network, a collaborative of more than 200 cancer care providers supported by monthly meetings, ongoing email discussions and an annual province-wide safety symposium.
- **Promoting safer prescribing and dispensing practices:** In the 2014/15 fiscal year, CCO is funding a provincial quality-improvement effort to promote safe prescribing of oral chemotherapy in every region of the province, with the goal of "no hand-written prescriptions by July 1, 2015." The project also identifies the core clinical requirements for safe prescriptions (i.e., ones that will more effectively convey relevant information to dispensing pharmacists).
- **Addressing safe labelling of oral chemotherapy:** Although not specific to take-home cancer medications, CCO has published guidelines for the safe labelling of chemotherapy. There has been an evaluation of concordance with these guidelines at all facilities delivering chemotherapy in Ontario to identify gaps and inform local quality-improvement efforts.
- **Providing comprehensive oncology-specific pharmacy education:** CCO is currently partnering with the De Souza Institute and the University of Toronto to develop an oncology curriculum for community pharmacists aimed at improving their comfort in counselling patients on oral chemotherapy and highlighting the processes that underlie the safe handling and dispensing of take-home cancer medications.
- **Identifying best practices for patient monitoring:** CCO's Systemic Treatment Program has begun work to assess, validate and endorse tools to support monitoring of oral chemotherapy (e.g., patient calendars, call-back programs, electronic tools and tools to assess risk factors and risk levels).
- **Standardizing side-effect management:** The Systemic Treatment Program has implemented a pilot project in several regions that takes a systematic and proactive approach to assessing and managing chemotherapy-related toxicities using a patient-reporting outcome tool. The project also includes an evaluation of the feasibility, acceptability and impact of the tool on patients, providers and the healthcare system. The plan is to scale up the findings to a province-wide randomized study of the approach in 2015.
- **Increasing error reporting rates:** CCO has been working with the Canadian Institute of Health Information to enable and improve the reporting of chemotherapy-related medication incidents in the National System for Incident Reporting.

Conclusion

The growing importance of take-home medications for cancer treatment has introduced new opportunities and challenges to cancer systems worldwide to ensure safe, high-quality cancer care. The May 8, 2014, think tank was CCO's first consultation to examine Ontario's current delivery model and consider opportunities for both incremental and transformative change.

The case for change became clear over the course of the day. Ontario's model for providing take-home therapies is difficult for patients and providers to navigate, and its multiple reimbursement programs lack integration and universality. The IM and IT systems that support these programs also lack integration, limiting the collection of data to evaluate performance and improve the quality and cost-effectiveness of care.

Ontario does not have to look far for possible templates for change. Each of Canada's provinces and territories has its own cancer care model, and think tank participants had the opportunity to hear how several other provinces are addressing the problem of take-home therapies. Their successes and challenges will guide Ontario's ongoing discussion about what happens next.

While participants raised diverse perspectives, there was also clear consensus around a small set of priorities: Ontario's cancer system should be more integrated. It should be more responsive for patients and providers. By making it more comprehensive, the system can be simpler. And all cancer therapies, whether they are hospital-administered or take-home medications, should be delivered within a single, person-centred system.

Efforts are underway to maximize the quality and safety of take-home cancer medications in Ontario. While this work is essential, it became clear during the day that much more can be done. Think tank participants made a compelling case that the benefits to patients and to providers from system transformation deserve careful consideration.

Acknowledgements

CCO's Systemic Treatment Program and Provincial Drug Reimbursement Programs thank all panelists and participants for their enthusiasm and efforts in initiating this conversation for change in Ontario's delivery of take-home cancer medications. The think tank would not have been a success without participants' focused attention and insightful discussion. The Systemic Treatment Program and the Provincial Drug Reimbursement Programs also acknowledge the members of the Planning Committee for their dedication, commitment, and timeliness in organizing this event.

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Appendices

Appendix A Speakers' Biographical Sketches

Venetia Bourrier

Ms. Venetia Bourrier is the Director of the Provincial Oncology Drug Program at CancerCare Manitoba (CCMB). After practising as a staff and clinical pharmacist at St. Boniface General Hospital, in 1990, Ms. Bourrier became the director of pharmacy at the Manitoba Cancer Treatment & Research Foundation (now known as CCMB). Over the next 20 years, she developed a comprehensive oncology pharmacy program for that organization. In 2006, a Provincial Oncology Drug Program was established for Manitoba and, as its director, Ms. Bourrier focused on escalating oncology drug costs, provincial purchasing of oncology drugs, outcomes analysis and managing the appropriate use of these drugs within existing funding. Since then, Ms. Bourrier has also been involved in provincial and national safety initiatives related to IV chemotherapy, and she currently serves as the Vice Chair of the Canadian Association of Provincial Cancer Agencies' Systemic Therapy Safety Committee. In 2011, she was honoured with the College of Pharmacists of Manitoba's first Patient Safety Award.

Larry Broadfield

Mr. Larry Broadfield is the Systemic Therapy Program Manager with Cancer Care Nova Scotia. He is also Clinical Co-ordinator for Oncology Pharmacy at Capital Health in Halifax and an adjunct professor at Dalhousie University. Previously, Mr. Broadfield practised in oncology pharmacy for over 30 years, including at the Hamilton Regional Cancer Centre (now the Juravinski Cancer Centre). Mr. Broadfield is also active in professional groups at the national and international levels.

Carole Chambers

Ms. Carole Chambers, BScPhm, MBA, FSCHP, FSIOP is the Pharmacy Director of Cancer Services with Alberta Health Services, and the author of over 50 peer-reviewed publications. She serves on the provincial advisory group for the pan-Canadian Oncology Drug Review and the pan-Canadian Pharmaceutical Alliance (formerly, the pan-Canadian Pricing Alliance).

Ms. Chambers has received a Distinguished Service Award (2005) from the Canadian Association of Pharmacy in Oncology and an Achievement Award (2006) from the International Society of Oncology Pharmacy Practitioners (ISOPP) for her long-standing commitment to oncology pharmacy practice through sustained excellence in providing oncology pharmacy services, leadership in innovative oncology pharmacy, related research and ongoing contributions to ISOPP.

Scott Gavura

Mr. Scott Gavura, BScPhm, MBA, has been Director, Provincial Drug Reimbursement Programs, at Cancer Care Ontario (CCO) since 2007. In this role he is responsible for coordinating CCO's advice to the Ministry of Health and Long-Term Care on cancer drugs, and for the management and delivery of several

funding programs including the New Drug Funding Program, which reimburses hospitals for the costs of new and expensive injectable cancer treatments. He also currently serves as the vice-chair of the pan-Canadian Oncology Drug Review advisory group.

Mr. Gavura is the former director of the Drug Information and Research Centre at the Ontario Pharmacists Association, where he led a large team of pharmacists to support appropriate medication use. Other roles include government (Manager, Drug Submissions at the Ministry) and hospital pharmacy practice (Clinical Pharmacist at Mount Sinai Hospital). He is a licensed pharmacist in Ontario.

Kathy Gesy

Ms. Kathy Gesy is the Director of Oncology Pharmacy Services for the Saskatchewan Cancer Agency. In this role, she is responsible for the agency's oncology pharmacy program, which includes operational oversight of two oncology pharmacies and the provincial management of oncology drug resources. After working for many years as a pharmacist at Royal University Hospital in Saskatoon and holding faculty appointments at the University of Saskatchewan's College of Pharmacy, in 1987 Ms. Gesy's hospital pharmacist assignment moved to the Saskatoon Cancer Centre, which began her career in oncology pharmacy. In 2001, she became directly employed by the Saskatchewan Cancer Agency to manage the increasing need for systemic therapy policy, safety and drug budget management throughout the province. Ms. Gesy is also Saskatchewan's representative to the pan-Canadian Oncology Drug Review and the pan-Canadian Pharmaceutical Alliance (formerly the pan-Canadian Pricing Alliance).

Leonard Kaizer

Dr. Leonard Kaizer is the Provincial Program Head of CCO's Systemic Treatment Program. Dr. Kaizer was the first medical oncologist recruited to the Credit Valley Hospital, where he has played an important role in the significant growth and development of systemic treatment services in what is now the Carlo Fidani Regional Cancer Centre. From 2004 to 2009, Dr. Kaizer served as director of medical oncology at the centre and from 2007 to 2009, he was the physician lead in the Mississauga Halton / Central West Regional Systemic Treatment Program.

Vishal Kukreti

Dr. Vishal Kukreti is a hematologist working at the Princess Margaret Cancer Centre, and also an assistant professor in the Department of Medicine at the University of Toronto. In addition, he is the Clinical Lead, eTools and Technology, at CCO. Dr. Kukreti's research focuses on how information technology supports quality of care and patient safety.

Carol Sawka

Dr. Carol Sawka is a medical oncologist, an independent healthcare consultant, as well as an Adjunct Clinical Professor in the University of Toronto's Department of Medicine and a senior fellow with the university's Institute of Health Policy, Management and Evaluation. Her research focuses on cancer-system health services and policy related to the cancer system. From 1999 to 2005, Dr. Sawka was Regional Vice President of Sunnybrook Health Science's Odette Cancer Centre, and from 2005 to 2013, she served as CCO's vice-president, Clinical Programs and Quality Initiatives. In that role, Dr. Sawka worked with clinical leaders across the province to improve the quality and coordination of the full spectrum of cancer care.

Michael Sherar

Mr. Michael Sherar is President and CEO of Cancer Care Ontario. From 2006 to 2011, he was the provincial agency's Vice-President, Planning and Regional Programs, leading the development of Regional Cancer Programs, including capital planning for cancer services across the province. He was previously Regional Vice-President, Cancer Services, London for Cancer Care Ontario and Vice-President, London Regional Cancer Program, London Health Sciences Centre. Michael received a BA in physics from Oxford University in 1985 and his PhD in medical biophysics from University of Toronto in 1989.

Susan Walisser

Ms. Susan Walisser is the Provincial Pharmacy Professional Practice Leader at the British Columbia Cancer Agency (BCCA). She is also a member of the Provincial Systemic Therapy Program Committee and its Strategic Advisory Group, and serves as the Director of the BCCA Pharmacy Residency Program in addition to representing the BCCA at the pan-Canadian Oncology Drug Review. Ms. Walisser's interests include medication safety, and she is a member of the Canadian Association of Provincial Cancer Agencies, Systemic Therapy Safety Council. Ms. Walisser is also a member of the National Cancer Institute of Canada's Audit and Monitoring Committee and of the Canadian Association of Pharmacy in Oncology (from which she received a Distinguished Service Award).

Appendix B

Summary of Select Provincial Models for Take-Home Cancer Medications

Reimbursement

The public drug reimbursement system in Canada is composed of 13 provincial and territorial programs, plus several federal programs. Reimbursement for outpatient prescription drugs is not mandated by the Canada Health Act or any other federal or provincial legislation.^{1,2} Consequently, each jurisdiction administers its own program for cancer drug funding.

There may be significant differences in:

- types and numbers of drugs covered
- patient eligibility (e.g., plan restrictions based on age and income)
- patient out-of-pocket costs

Studies have found differences in public funding of the same cancer drug across the country due to interprovincial variances.^{3,4,5} Access to benefits may differ due to patient eligibility, drug utilization restrictions, or high out-of-pocket costs.^{6,7}

Public plans for the western provinces (British Columbia, Alberta, Saskatchewan, Manitoba), offer universal coverage for both take-home cancer medications and hospital-administered cancer drugs with no associated out-of-pocket costs to the patient. In Ontario (and similarly, Atlantic provinces), cancer drug coverage is dependent on patient eligibility factors (e.g., age and income) and is typically associated with out-of-pocket costs. For all of these provinces, cancer drugs covered under the provincial plan are not necessarily covered for all patients. Patients must still meet drug specific clinical criteria to obtain funding. In terms of supportive care drugs, most patients still need to rely on coverage through either provincial drug benefit programs, private insurance, and self-pay.⁶

The following summary compares the characteristics of Ontario's existing programs against those provinces with cancer agencies that administer and offer universal coverage for take-home cancer medications:

Table 1.0: Overview of Provincial Plans for Take-Home Cancer Medications

Province	Plan	Eligible Patients	Coverage Restrictions		
			Drugs and Indications Covered ^a	Hospital-Administered Drugs Covered?	Supportive Care ^b Drugs Covered?
AB	Outpatient Cancer Drug Benefit Program (OCDBP)	<ul style="list-style-type: none"> Covered under Alberta Health Care Insurance Plan Registered with Cancer Registry with a disease classified in the International Classification of Diseases for Oncology Requires drugs to treat cancer 	<ul style="list-style-type: none"> Listed on Outpatient Cancer Drug Benefit Program Formulary Approved by Director's Privilege Program 	NO ^c	NO
BC	British Columbia Cancer Agency (BCCA)	<ul style="list-style-type: none"> BC resident Registered with the cancer agency 	<ul style="list-style-type: none"> Listed on BCCA Benefit Drug List Approved by Compassionate Access Program 	YES	NO (May be covered under Pharmacare plan)
SK	Saskatchewan Cancer Agency (SCA)	<ul style="list-style-type: none"> SK resident Registered with the Cancer Agency 	<ul style="list-style-type: none"> Designated "Formulary" status on the SCA Drug Formulary Approved by the SCA Treatment Evaluation Program (STEP) Case-by-case approval by the Exceptional Drug Coverage (EDC) program 	YES	SOME ^e (Majority funded under the Saskatchewan Prescription Drug Plan)

Province	Plan	Eligible Patients	Coverage Restrictions		
			Drugs and Indications Covered ^a	Hospital-Administered Drugs Covered?	Supportive Care ^b Drugs Covered?
MB	Home Cancer Drug Program	<ul style="list-style-type: none"> Registered with Pharmacare Registered on the Home Cancer Drug (HCD) Program 	<ul style="list-style-type: none"> On HCD formulary 	YES	SOME ^e (Majority funded via Manitoba Pharmacare)
ON	Ontario Drug Benefit Program	<p>Ontario resident with a valid Ontario health card and at least one of the following:</p> <ul style="list-style-type: none"> 65 years or older Residents of long-term care facilities Residents of homes for special care People receiving professional services under the Home Care program Receiving social assistance through Ontario Disability Support Program or Ontario Works Registered in the Trillium Drug Program 	<ul style="list-style-type: none"> Listed on ODB Formulary Prior approval through the Exceptional Access Program 	NO ^d	YES ^e

AB = Alberta; BC = British Columbia; MB = Manitoba; SK = Saskatchewan; ON = Ontario

^aThe majority of cancer drugs listed on provincial formularies are not covered for all patients. Patients must meet drug-specific clinical criteria.

^bDrugs used to manage cancer-associated complications (e.g., medications to treat or prevent nausea, vomiting, pain, infections or blood clots).

^cHospital budget covers IV chemotherapy.

^dHospital-administered drugs covered under the New Drug Funding Program and hospital budget.

^eSelective supportive drugs are covered. Patients may need to meet specific clinical criteria.

Table 1.1: Out-of-Pocket Costs for Take-Home Cancer Medications Covered on Public Plans

Province	Plan	Deductible	Copayment
AB	Outpatient Cancer Drug Benefit Program	\$0.00	\$0.00
BC	British Columbia Cancer Agency	\$0.00	\$0.00
SK	Saskatchewan Cancer Agency	\$0.00	\$0.00
MB	Home Cancer Drug Program	\$0.00	\$0.00
ON	Ontario Drug Benefit Plan	\$0.00 - \$100.00 [*]	\$2.00 - \$6.11 ^{**}
	Trillium Drug Program	4% of net household income	\$2.00 [†]

^{*} High income seniors are subject to a \$100 deductible.

^{**} Dispensing pharmacies may charge a lower copayment or waive the copayment.

[†] Once the deductible has been paid, pharmacies may charge up to \$2.00 copayment per prescription.

Quality & Safety Practices

CCO consulted with four provincial cancer agencies regarding current practices on prescribing, dispensing, and monitoring of take-home cancer medications.

Prescribing

Table 2 compares the prescribing practices amongst provinces. The majority of western provinces have prescriptions written by cancer specialists. Computerized prescriber order entry (CPOE), which is considered the safest method of prescribing chemotherapy has been implemented in several provinces. In Manitoba and Alberta the majority of prescriptions for take-home cancer medications are generated using CPOE. For provinces that do not have CPOE, pre-printed orders have been established. In Saskatchewan, approximately 80% of take-home cancer medications are prescribed using pre-printed orders.

Table 2.0: Provincial Prescribing Practices for Take-Home Cancer Medications

Province	Prescribing Restricted to Cancer Specialists ^a	CPOE Implemented	Pre-Printed Orders in Use	Handwritten Prescriptions
AB	✓	✓	✓	✗/✓ ^d
BC	✓	✗	✓	✗/✓ ^e
SK	✓	✗	✓	✗/✓ ^e
MB	✗/✓ ^f	✓	✓	✗/✓ ^d
ON	✗	✗/✓ ^b	✗/✓ ^c	✓

CPOE = Computerized Physician Order Entry

^a Prescribing of cancer medications is restricted to cancer specialists (e.g., oncologists, hematologists, etc.).

^b In Ontario, CPOE is used in a minority of hospitals/cancer centres.

^c In Ontario, pre-printed orders are in use at several hospitals. CCO is also introducing its own pre-printed orders.

^d Prescriptions are primarily generated by CPOE.

^e The majority of prescriptions are written on pre-printed orders.

^f Older cancer medications may be prescribed by non-cancer specialists.

Dispensing

In the majority of western provinces, dispensing of publicly funded therapies is restricted to specialized oncology pharmacies (Table 3). Pharmacists in these pharmacies are able to access the patient's medical records for the purpose of safe dispensing. In Manitoba, similar to Ontario, take-home cancer medications can be dispensed from community pharmacies. Community pharmacists cannot access patient records in the hospitals/cancer centres and the community pharmacy and hospital information

systems are not integrated. Of note, in Saskatchewan, if take-home cancer medications are dispensed by community pharmacies, patients must pay upfront and subsequently they are reimbursed at the formulary cost of the cancer agency.

In terms of safe handling procedures, Alberta, British Columbia and Saskatchewan reported that their dispensing pharmacies do have guidelines, policies or procedures on the safe-handling of oral chemotherapy by healthcare providers.

Table 3.0: Provincial Dispensing Practices for Take-Home Cancer Medications

Province	Cancer Centre Pharmacy	Community Pharmacy	Option for Prescription Delivery by Mail	Comments
AB	✓	✗	✓	Cancer centre pharmacies can mail medications to patients Drug coverage not provided if dispensed outside of a designated cancer centre pharmacies.
BC	✓	✗	✓	Dispensed from either BCCA pharmacies (six locations) or Community Oncology Network pharmacies (34 locations). Medications may be couriered to remote locations.
SK	✓	✗	✓	There are two cancer centre pharmacies which can mail medications to patients.
MB	✗/✓*	✓	✗	*Select oral cancer drugs dispensed from the agency.
ON	✓	✓	✓	Can be dispensed from any pharmacy (e.g., community pharmacy, cancer centre pharmacy).

Monitoring

Provinces were asked whether they have established standardized monitoring programs to assist patients with adherence (i.e., taking their medication as prescribed) and side-effect management. Similar to Ontario, the majority of provinces did not have standardized programs in place. Alberta has developed a specific oral chemotherapy multidisciplinary monitoring program, which is administered by the pharmacy team. In British Columbia, take-home cancer medication monitoring programs are in place, and the need for standardization and tailoring of programs (to be therapy specific) have been identified as future enhancements.

In terms of error reporting, three provinces reported that they routinely report medication incidents related to take-home cancer medications. Electronic reporting and learning systems are used to facilitate this activity.

Table 4.0: Provincial Monitoring Practices for Take-Home Cancer Medications

Province	Standardized Monitoring Programs	Medication Errors Routinely Reported
AB	✓	✓
BC	✗	✓
SK	✗	✓
MB	✗	Unsure if routinely reported
ON	✗	Unknown

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Appendix C

Backgrounder: Quality and Safety

Introduction

The *Excellent Care for All Act* (2010) was enacted to put Ontario patients first by strengthening the focus of healthcare organizations in the delivery of high-quality patient care.¹ High-quality care is evidence-based, patient-centred, safe and timely.²

The growing use and therapeutic importance of take-home cancer medications has introduced new challenges to providing high-quality care. While patients may prefer take-home cancer medications due to convenience, they are not necessarily safer than intravenous treatments, as commonly perceived.³ Patients and providers are faced with new risks in prescribing and dispensing, as standards, protocols and guidelines are not equivalently established or implemented to the same degree as for hospital-administered (injectable) cancer medications. With the growing use of take-home cancer medications, improving the quality is a priority.⁴

For the purpose of cancer care delivery, Ontario is divided into 14 Regional Cancer Programs. In these programs, there may be regional variations in prescribing, dispensing, administration, and monitoring practices. Take-home cancer medication introduces further variation, as dispensing is not limited to cancer centre/hospital pharmacies that prepare intravenous chemotherapy. Take-home cancer medication can be dispensed from specialized oncology pharmacies located in cancer centres or hospitals (cancer centre pharmacies) or retail pharmacies. Retail pharmacies, also referred to as drug stores, are typically located in the community (community pharmacies) and sometimes in an outpatient area of a hospital.

This backgrounder outlines the current challenges to the quality and safety of take-home cancer medication in Ontario, and the opportunities that exist to enhance the current model.

Two Canadian surveys provide insight into the Ontario system:

- **CCO survey:** In 2012 Cancer Care Ontario (CCO) conducted a survey of 13 of 14 Regional Cancer Programs to identify current practices relating to oral chemotherapy including prescribing, dispensing, patient education, and adherence.
- **Abbott et al. survey:** In 2010, researchers conducted a cross-country survey of Canadian community pharmacists regarding the safety of oral chemotherapy. There were 352 respondents of which 41% (n=139) were Ontario pharmacists. Recognizing the date of the survey and the limited sample size, this survey provides the most detailed description of challenges facing Ontario community pharmacies.

Understanding the Treatment Pathway

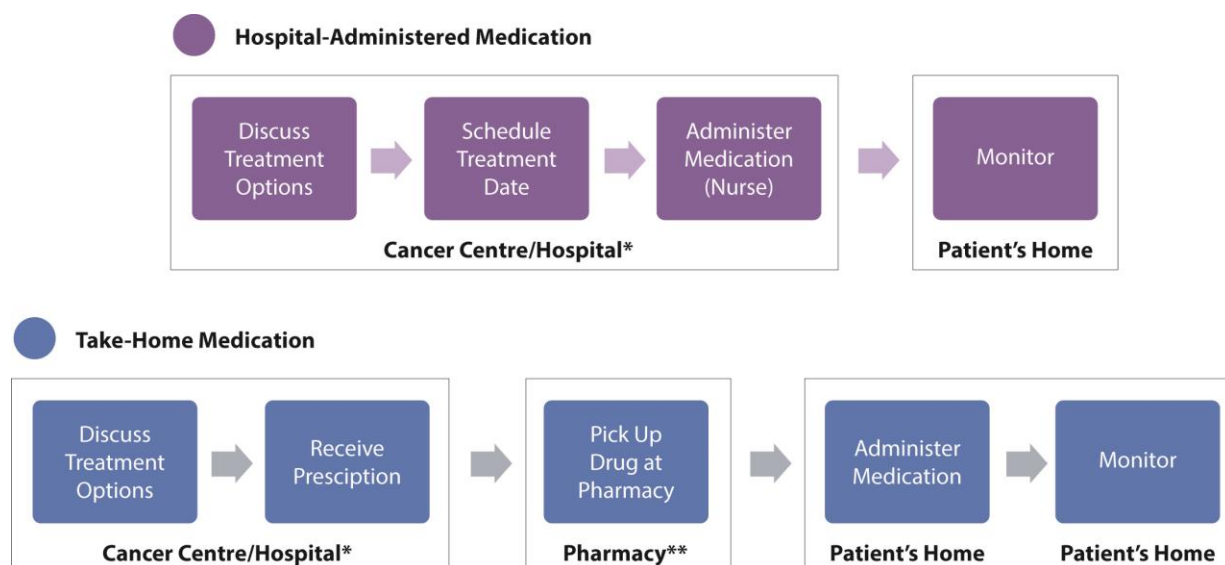
The key components (Figure 1) of the patient's treatment journey are: the treatment decision to select the therapy, prescribing the medication, dispensing the medication by the pharmacy, administering the medication, and monitoring of therapy to evaluate the patient's response to treatment and possible side-effects. Patient education regarding their disease, treatment options, potential side-effects and their role in safe administration, including safe handling and disposal, is required every step along the way.

As the delivery of care differs for take-home cancer medications and hospital-administered drugs in Ontario (Figure 1), there are concerns that there may be significant differences in the ultimate quality of care and overall patient safety.

Figure 1: Patients' Treatment Journey



Figure 2: Patients' Treatment Journey: Hospital-Administered vs. Take-Home Cancer Medication



* Refers to an outpatient area of the hospital (e.g., chemotherapy suite, infusion clinic).

** Prescriptions may be filled at a cancer centre pharmacy or a community pharmacy.

Challenges

1. Patient Education

As with other medications, patients considering take-home cancer medications require education about their disease, and the risks and benefits of available treatment options. For take-home cancer medications, additional counselling is required regarding safe handling, disposing of medication, the management of missed doses, and drug-food or drug-drug interactions.

Educating patients starting take-home cancer medication requires a considerable amount of time by the provider (e.g., nurse or pharmacist). Dedicated space for counselling, using specialized staff, is essential.³

Existing patient education practices are sub-optimal. Patient education needs to be provided throughout the patient's treatment journey, but currently it is often only provided at the start of treatment. Patients may also receive non-standardized information from different healthcare providers.

Based on the CCO survey, patient education is not consistent or adequate across Ontario:⁵

- Only 23% of regions provide extensive patient teaching through a multi-disciplinary and coordinated approach where education is provided initially by the prescribing physician, then by the primary nurse and thirdly by dispensing pharmacist in an organized fashion. Only 38% of the regions routinely instruct patients to bring unused medication back to the pharmacy.

2. Method of Prescribing

Computerized prescriber order entry (CPOE) systems have been shown to reduce errors for prescribed chemotherapy regimens from 15 % to nearly zero.⁶ For chemotherapy administered in the hospital, CPOE is a recommended provincial standard. Handwritten prescriptions are not acceptable and if CPOE is not available, the use of standardized, regimen-level pre-printed order (PPO) forms is advised.⁷

Without the use of standardized PPOs or CPOE, key prescription information such as diagnosis, regimen name, cycle number, start and stop date, and reasons for dose reduction may be omitted.⁸ Both PPOs and CPOE can ensure correct spelling and legibility of drug names, administration instructions, and laboratory monitoring parameters. However, PPOs still require physicians to perform complex dosing calculations.⁹ The dose for cancer medications is often weight-based and may require a body surface area (BSA) calculation. In a CPOE system, the BSA calculation is automated. A CPOE system also allows the prescriber to verify if they are selecting the most appropriate treatment for the patient as it contains decision support tools that can flag drug interactions or drug allergies, and allow the prescriber to make clinical decisions at the point of care.¹⁰ CPOE also provides safety features by alerting the prescriber to incorrect doses or the need for dose reductions if the CPOE integrates with the laboratory information systems.

Approximately 90% of chemotherapy prescribed in Ontario hospitals is via a CPOE system. However, most systems are not optimally configured to allow the prescriber to print a prescription for take-home cancer medications. Based on a 2012 survey of oral chemotherapy practices in Ontario, the majority of prescriptions for take-home medications may not be routinely prescribed using CPOE or PPOs. At that time, 23% of Regional Cancer Programs reported routinely using CPOE for oral chemotherapy prescriptions. Eight per cent of regions only used handwritten prescriptions while 69% of regions used a combination of both a CPOE system and handwritten prescriptions.⁵

3. Dispensing

At the point of dispensing, the pharmacist must verify that the prescription is complete, accurate and appropriate (e.g., right drug, right dose, no drug-drug interactions), prepare and label the product, and counsel the patient on proper administration and side-effect monitoring. Key issues include:

i. Prescription Verification

Once a prescription is written for intravenous chemotherapy, it must be independently double-checked by at least a pharmacist and a registered nurse to minimize errors.⁷ While provincial guidelines exist to guide safe dispensing and prescription verification processes for hospital-administered chemotherapy, such standards do not exist for take-home cancer medications. In the CCO survey, Regional Cancer Programs noted that prescription verification was less rigorous for take-home cancer medications.⁵

At this time, routine and standardized prescription verification process for cancer medications is unlikely to be widespread amongst Ontario community pharmacies based on findings in other jurisdictions:

- An Irish study found that 64% of community pharmacists (147 respondents) did not have enough information to safely dispense oral chemotherapy.¹⁰
- In the Abbot et al. survey of 352 Canadian community pharmacists, only 10% of respondents re-calculated the dose based on body surface area (BSA). However, only 2.3% of respondents received prescriptions that included the patient's height, weight, and BSA.¹¹

Prescription verification is likely difficult for Ontario community pharmacists due to the lack of access to required patient information. The current information systems infrastructure does not support information transfer between hospital and community healthcare providers. In order to check for appropriate dosing and drug interactions, the pharmacist needs to confirm the patient's diagnosis and obtain an accurate list of the patient's current medication. However, community pharmacists cannot directly access a hospital or cancer centre health records and there is often limited communication with the prescribing physician.

ii. Safe Labelling

Cancer medications must be appropriately labelled so that the patient's name, drug, dose and directions for administration are easily identifiable to the patient and provider. Additionally, warning labels may be needed to advise that the drug is cytotoxic and safe handling precautions are required.

For hospital-administered cancer medications, policies and procedures are in place for standardized labelling. CCO has published guidelines on the safe labelling of intravenous chemotherapy. A similar guideline for take-home cancer medications is lacking.¹² In the CCO survey, seven out of 13 (54 %) regions reported that when oral chemotherapy is dispensed at their hospital, the practice of labelling as “chemotherapy” is inconsistent and is often left to the discretion of the individual pharmacist.⁵ In Ontario community pharmacies, the extent of safe labelling practices specific to chemotherapy is not known.

iii. Community Pharmacy Expertise

With the use of take-home cancer medication, there is a shift in responsibilities from the hospital team to the community pharmacist who may lack oncology-specific training. Pharmacists require cancer-specific knowledge and experience to safely dispense, educate, and monitor patients on take-home cancer medication. Ontario pharmacists and pharmacies are not mandated to obtain specialized training or certification to dispense cancer medications.

In the Abbot et al. survey of 352 Canadian community pharmacists, only 14% felt they had adequate oncology education during university, 24% were familiar with common doses for oral cancer medications, and only 9% felt comfortable providing patient education.¹¹

4. Adherence

Patients who fail to take their medication as prescribed can be considered non-adherent.¹³ For example, the patient may miss doses, take the wrong dose, take additional doses or take the dose at the wrong time.¹⁴ Patients may be non-adherent for a variety of reasons including fear of side-effects, lack of drug coverage or individual health beliefs. Non-adherence is associated with treatment failure, increased toxicity, and may result in increased healthcare costs.^{14,15}

For drugs administered in the hospital, healthcare providers can easily monitor adherence by direct observation. Additionally, medication administration details such as time of administration or dose administered can be electronically captured. With take-home cancer medications, monitoring adherence is much more challenging for the healthcare team, as measuring adherence is based on patient self-report or other less reliable, indirect methods. Pharmacy or insurance databases can provide information on rates of prescription refills but cannot decipher whether the right dose at right time was administered.^{3,14}

In Ontario, standardized methods of monitoring adherence to take-home cancer medications are lacking:

- In the CCO survey, tools identified to track adherence and dose changes to take-home cancer medications included calendars, patient diaries, blister packs, and manual pill counts but these are limited and used infrequently.⁵
- In the Abbott et al. survey of community pharmacists, 46 % (163 respondents) had a process to monitor compliance but only 8 % (27 respondents) used a scheduled call-back program.¹¹

5. Toxicity Management

For both hospital-administered and take-home cancer medications, patients must be counselled on how to self-monitor for side-effects. They require a communication protocol with the oncology team when issues arise – no matter what time of day they occur. Patients on take-home cancer medications may be afforded the convenience of fewer clinic visits, but still need comprehensive patient education about side-effects and adequate instruction on when to hold doses for toxicity.¹⁶ In a U.S. study on patients' perceptions of oral chemotherapy, patients desired more detailed information at the time of prescribing and at follow-up on the type and severity of side-effects to expect.¹⁶ Ontario patients may be facing a similar situation, as there is a lack of standardized education for patients on take-home cancer medications. Patient information on after-hours support, describing who to call, or where to go if toxicities are experienced, may be insufficient.

6. Safe Handling

Take-home cancer medications can be cytotoxic (harmful to cells in the body) and require special handling and disposal precautions. Accidental exposure to take-home cancer medications can occur at the point of transport, unpacking, storage, handling, or disposal. Patients, families, and providers must be knowledgeable and careful to avoid unnecessary or accidental exposure.⁴

In hospitals, providers follow policies and guidelines for handling cytotoxic drugs. Personal protective clothing (e.g., gowns, gloves) and separate areas and equipment to prepare and administer cytotoxic drugs may be required. Additionally, written emergency plans for handling cytotoxic spills are mandatory.

For take-home cancer medications, studies have reported a lack of safe handling by patients. An Asian study noted that patients were not routinely washing their hands, wearing gloves when handling cytotoxic medications, or returning unused medication to the pharmacy.¹⁷ Sub-optimal practices may also be occurring in Ontario putting patients and providers at risk:

- Provincial and institutional policies for safe handling and disposal specific to take-home cancer medications are lacking. In 2013, CCO published an updated guideline on the safe handling of cytotoxic medications to include oral chemotherapy; however, the guidelines do not address dispensing in community pharmacies.¹⁸
- In the CCO survey, eight out of 13 regions reported that their cancer centre pharmacies have tools and methods in place to ensure safe handling and dispensing of oral cytotoxics, however only two regions have formal policies and procedures in place.⁵
- In the Abbott et al. survey of 352 Canadian community pharmacists, the majority of respondents did not use personal protective equipment (e.g., gloves, mask) or a separate counting tray. Additionally, only 17% of pharmacists labelled prescriptions with a hazardous medication label.¹¹

7. Error Reporting

A system of reporting medication errors is a necessary tool for ensuring patient safety. A medication error is described as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient or consumer. The Institute of Safe Medicine Practices (ISMP) considers chemotherapy to be high-alert drugs that are more likely to cause patient harm when an error occurs.¹⁹ Examples of medication errors associated with oral chemotherapy include the wrong dose, the wrong drug, a missed dose, or the wrong number of days supplied.²⁰

In hospitals, an error reporting system is typically a requirement for hospital accreditation.²¹ Medication error reporting may occur at the institutional, provincial or national level.²² In Ontario, the *Excellent Care for All Act* mandates that hospitals must establish a system for reporting and analyzing critical incidents (i.e., an incident resulting in death or significant harm to the patient that is unrelated to a patient's underlying disease). Hospitals are required to report all critical incidents related to medication and intravenous fluids through the National System of Incident Reporting (NSIR) system. The NSIR is a free and secure web-based tool that allows providers to report incidents anonymously.²³

Within the community, medication error-reporting practices are not as well cultivated. As such, the rate of error reporting for take-home cancer medications is expected to be much lower. In 2010, the ISMP Canada created the Community Pharmacy Incident Reporting program to enable and improve error reporting in the community pharmacies.

Opportunities

To improve the current state, CCO and its stakeholders recognize that the current quality and safety gaps need to be addressed. Opportunities to enhance existing processes include the following:

- **Create a Provincial Strategy**

CCO and its regional stakeholders are currently developing the second Systemic Treatment Provincial Plan (2014-2019) with two areas of focus related to this topic: oral chemotherapy and community pharmacy practices. To enable the development of the plan, working groups of key stakeholders including physicians, nurses, pharmacists (hospital and community) and administrators are developing recommendations to address challenges in safe prescribing, dispensing, patient education, monitoring and adherence of oral chemotherapy.

Recommendations considered in this plan may include:

- Targeting a provincial goal of zero handwritten and verbal prescriptions by June 30, 2015.
- Developing standardized, high-quality education for patients and families with consistent messaging on safe handling, storage, monitoring, adherence, administration and disposal of oral chemotherapy.
- Establishing standardized, person-centred monitoring and adherence tools for all patients on oral chemotherapy.

- Implementing standards for prescription verification to ensure safe dispensing. For example, oral chemotherapy prescriptions would have to be clinically verified by pharmacists with expertise in oncology.
- Developing a strategy to improve communication between the hospital oncology care team and community pharmacists.

- **Establish Regional Quality Improvement Initiatives**

In 2013/14 each region in Ontario initiated a quality improvement project focused on oral chemotherapy with funding support from CCO. Table 1 summarizes these initiatives:

Table 1: Summary of Regional Quality Improvement Initiatives for 2013/14

Area of Focus	Number of Regions with Initiatives
Patient Education/Self-Management	10
Patient Adherence	8
Safe Prescribing	7
Community Pharmacy Engagement	4
Other*	3
Total Ongoing QI Initiatives	32

* Refers to disposal initiatives, audit of local oral chemotherapy practices, toxicity or adherence monitoring.

- **Adapt National Quality Guidelines**

The Canadian Association of Provincial Cancer Agencies is finalizing a set of national recommendations to address the safety and quality concerns with oral chemotherapy. The recommendations propose revisions to the national pre-printed order guidelines to include information on oral chemotherapy.

- **Support Continuing Education for Pharmacists**

CCO collaborated with the Ontario Pharmacists Association to develop an online education program for pharmacists with a specific focus on oral chemotherapy. This program launched in 2014. CCO is also partnering with the University of Toronto to establish an online and classroom curriculum with a focus on oral chemotherapy. This program is expected to launch in late 2015 or early 2016.

- **Engage in Knowledge Transfer and Exchange**

In early 2012, CCO launched the Regional Quality and Safety Network which now has over 200 members. Regional and hospital teams collaborate on projects focused on enhancing the safety and quality of systemic treatment in Ontario. Oral chemotherapy is a standing agenda item at monthly meetings. Ongoing email discussions and a SharePoint site support continued

knowledge sharing between the regions. In February 2014, CCO held its second annual Systemic Treatment Safety Symposium where approximately 100 stakeholders from across all Regional Cancer Programs participated in a full-day event focused entirely on safety and quality issues with oral chemotherapy.

Conclusion

There is considerable variation in take-home cancer medication practices across the province, which leads to potential safety and quality gaps. Despite the extensive work underway, there remain substantial opportunities to align the quality of delivery for take-home cancer medications with hospital-administered therapies. It is anticipated that the challenges of quality and safety will continue to grow as new take-home cancer drugs enter the market and the overall number of cancer patients continues to rise. With the recommendations from the soon-to-be-launched second Systemic Treatment Provincial Plan and the expected recommendations from Canadian Association of Provincial Cancer Agencies, there will need to be broad, system level support for change across the health system to maximize the quality of take-home cancer medications in Ontario.

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Appendix D

Backgrounder: Reimbursement and Drug Distribution

Introduction

Over the past two decades, the delivery of systemic cancer therapy has expanded from primarily intravenous treatment, delivered in cancer centres and hospitals, to include take-home cancer medications (e.g., oral, subcutaneous or other self-administered chemotherapies). This trend is expected to continue, as a Canadian survey of 25 drug manufacturers estimated that 44% of the new cancer therapies under development in 2013 were oral cancer medications.¹

There are growing demands on public health systems to fund all cancer drugs, regardless of where the treatments are administered. The lack of first dollar and universal coverage for take-home cancer medications in Ontario has been cited as a significant barrier to some cancer patients, given the increasing availability and use of these products in cancer regimens. This document outlines the context, the current reimbursement model and the challenges and opportunities that exist.

Cancer Drug Funding in Ontario

The cost of cancer treatments used in non-hospitalized patients (i.e., the outpatient setting) are not defined as insured services under the *Canada Health Act*. They are additional benefits provided by provinces and territories.² This has resulted in interprovincial differences with respect to the extent and types of drug coverage offered, and the out-of-pocket costs that patients may be required to pay.

Ontario has a single decision-making process for determining which cancer drugs will be eligible for public funding. However, once a funding decision has been made, the extent to which a cancer drug will be publicly funded is based on where the treatment will be administered. There are a variety of programs offered. The Ministry of Health and Long-Term Care (Ministry) directly manages public reimbursement for take-home cancer drugs dispensed through pharmacies. Cancer Care Ontario (CCO) administers (on the Ministry's behalf) funding for expensive hospital-administered injectable cancer medications. While provincial cancer reimbursement programs are integrated at a policy level, at the point of care the programs operate separately.

Several different payment sources exist for Ontario patients depending on the type of medication and where it is administered (Table 1). The major programs and sources of funding are:³

Hospital-Administered Injectable Cancer Drugs

- **Hospital Budget:** covers costs of inexpensive cancer drugs in the episode-based systemic treatment funding model that now supports the delivery of chemotherapy in Ontario in the outpatient setting.
- **The Evidence Building Program (EBP):** seeks to resolve uncertainty around clinical and cost-effectiveness data related to the expansion of cancer drug coverage within Ontario. For a cancer drug to be included in Ontario's EBP there must be evolving, but incomplete evidence of benefits. It provides funding only to hospital-administered treatments.
- **New Drug Funding Program (NDFP):** funds new and often very expensive cancer drugs that are administered in cancer centres or hospitals. The program was created in 1995 to ensure that Ontario patients have equal access to high-quality intravenous (IV) cancer drugs.
- **Private pay:** may be the method patients elect to use for drugs not funded publicly. Patients may choose to use private insurance or will self-pay in some cases.

Take-Home Cancer Medications

- **Ontario Drug Benefit Program (ODB):** provides drug benefits for Ontarians who are:
 - 65 years of age and older
 - residents of long-term care homes and homes for special care
 - enrolled in the home care program
 - recipients of social assistance through either Ontario Works or Ontario Disability Support Program
- **Exceptional Access Program (EAP):** facilitates patient access to take-home cancer medications not listed on the ODB Formulary, or where no listed alternative is available. To receive coverage, patients must be eligible to receive benefits under the ODB program.⁴
- **Trillium Drug Program:** provides drug benefits to Ontario residents who face high drug costs in relation to their household income. Residents might not have private insurance or their private insurance does not cover 100% of their prescription drug costs.⁵

Any Ontario resident that does not qualify under another ODB Program can apply for coverage under Trillium. This program provides coverage for all drugs listed on the ODB Formulary or considered through the EAP.

Table 1: Overview of Major Ontario Public Plans for Cancer Drugs⁶

Type of Medication	Benefit Programs	All Ontario Residents Eligible? [*]	Patient Out-of-Pocket Costs	Costs Reimbursed by Payer	Administrator
Hospital-Administered Injectable Cancer Drugs	New Drug Funding Program	YES	None	<ul style="list-style-type: none"> Drug cost for doses <u>administered</u> 	Cancer Care Ontario, Provincial Drug Reimbursement Programs
	Evidence Building Program	YES			
Take-Home Cancer Medications	Ontario Drug Benefit Program	NO	Copayments/Deductibles	<ul style="list-style-type: none"> Drug cost for doses <u>dispensed</u> Mark-Up (up to 8%) Dispensing Fee 	The Ministry, Ontario Public Drug Programs
	Exceptional Access Program [†]	NO			
	Trillium Drug Program	YES			

^{*} Persons who live in Ontario and have a valid Ontario Health Card.

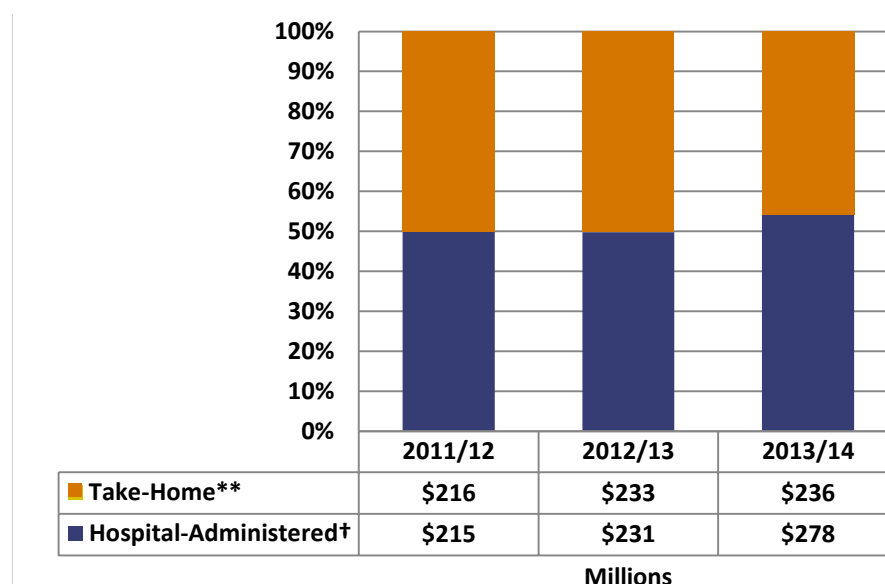
[†] The Exceptional Access Program considers funding requests for drugs that are not listed on the Ontario Drug Benefit (ODB) Formulary. Patients must be eligible for ODB benefits to receive coverage.⁷

Public and Private Expenditures

New cancer medications are increasingly costly. Eleven of 12 cancer medications approved in the United States in 2012 were priced above \$100,000 per year.⁸ In 2007, imatinib (Gleevec), an oral cancer drug, was estimated to cost between \$3,000 to \$4,000 per month for Ontario patients who required treatment for chronic myelogenous leukemia.⁹ In comparison, pomalidomide (Pomalyst), a new oral drug for the treatment of multiple myeloma, is estimated to cost approximately \$10,000 per month.¹⁰ These potentially unsustainable pricing trends place heavy financial burden on payers and patients alike.^{11,12}

- **Public payers:**
 - In 2012/13, public drug plans covered an estimated 46% of costs for cancer drugs dispensed from community pharmacies in Ontario.¹³
 - In the last fiscal year (2013/14), public payers spent slightly over \$500 million on active cancer treatments, with 46% of this allocated to take-home medications (Figure 1).
- **Private payers:**
 - In 2012/13, private insurance covered an estimated 39% of costs for cancer drugs dispensed by Ontario community pharmacies.¹³
 - Based on IMS Brogan data, an estimated \$120 million of take-home cancer medications and supportive treatments listed under the ODB Formulary or covered by EAP were funded in-part or wholly by private insurers in 2012.

Figure 1: Public Payer Costs for Outpatient Cancer Medications *



* Total drug expenditures for medications used in the active treatment of cancer (Some drugs are also used for non-cancer conditions). Supportive care drugs were excluded.

** Total drug expenditures reported by the Ontario Drug Benefit Program.

† Total drug expenditures reported by the New Drug Funding Program.

Cost Burden to Patients

Despite a mix of private and public funding sources, patients cite a personal financial burden as a barrier of access to take-home cancer medications.^{14,15} Not all patients have private insurance to cover unfunded drugs. Even with private coverage, deductibles and copays can be considerable to overcome. The average copayment for patients with private insurance has been cited as 20% which would be more than \$500 per month for a patient requiring oral chemotherapy priced at \$3000 per month.¹² Additionally, some insurers have implemented lifetime or annual coverage caps.¹²

The scope of this problem was illustrated in a recent survey of 183 Canadian cancer specialists, half of whom were from Ontario. This study found that Canadian physicians employed various strategies to overcome funding barriers including enrolling patients in clinical trials, using compassionate access programs, falsifying claims on eligibility forms, shipping drugs from other countries and using leftover supplies. Physicians felt that being unable to prescribe the preferred drug due to these funding barriers had a negative impact on their patients' outcome (56%) and quality of life (73%).¹⁶ Researchers have also found that prohibitive costs of medications results in patients not taking their medications as prescribed or being "nonadherent".^{17,18} A U.S. study of 164 cancer patients reported that 45% of patients were nonadherent due to cost. Twenty-two percent had taken less than their prescribed dose, 25% partially filled prescriptions and 27% did not fill a prescription.¹⁷ Cost barriers affecting adherence are a major concern, as non-adherence is known to compromise the effectiveness of the treatment and increase healthcare costs.¹⁹

Ontario's Reimbursement & Distribution Process

Access to Cancer Medications

Outpatient cancer drug medications follow different distribution practices based on place of delivery. Patients can receive take-home cancer medications from the pharmacy of their choice:

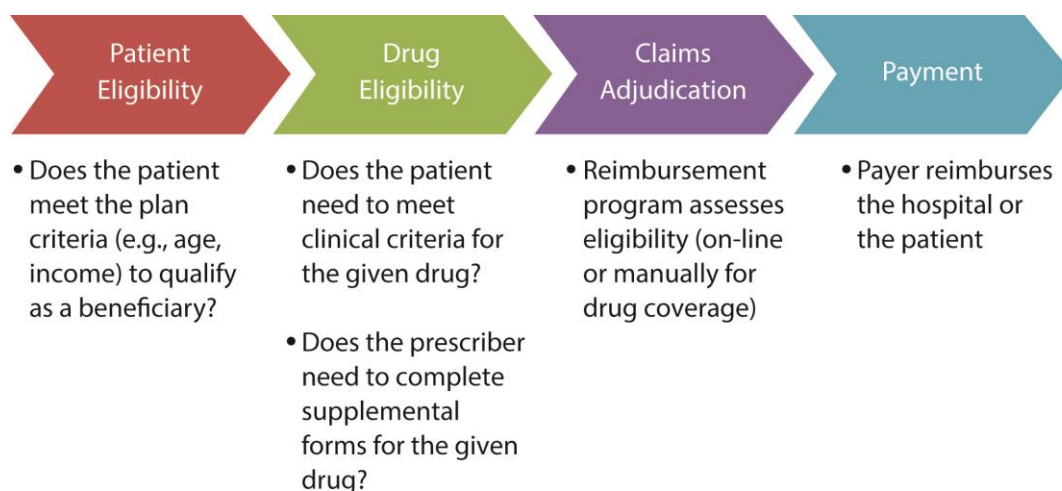
Specialized oncology pharmacies located in cancer centres or hospitals ("cancer centre pharmacies") or retail pharmacies. Retail pharmacies, also referred to as drug stores, are typically located in the community (community pharmacies) and sometimes in an outpatient area of a hospital. In Ontario, pharmacies are not mandated to follow safety guidelines or standards specific to the dispensing and handling of cancer medications.

Patients requiring hospital-administered cancer medications may need to travel to specific hospitals outside of their local community. Hospitals must meet specific standards to prescribe, dispense and administer cancer medications. In the current Ontario model, treatment centres are assigned different levels based on the complexity of cancer care delivered. Complex chemotherapy is restricted to regional cancer centres while community hospitals are able to administer less complex chemotherapy regimens.²⁰

Access to Public Drug Coverage Benefits

For a patient to obtain drug coverage, the prescriber should confirm eligibility requirements (both patient and drug specific) prior to writing a prescription. For drugs not funded on the plan's formulary, the prescriber may be required to submit additional information or complete a supplemental application. Once funding is confirmed, the prescription can be issued to the patient (for take-home cancer medications) or the pharmacy (for hospital-administered drugs). The key components of a reimbursement process are described in Figure 2 and differ for hospital-administered and take-home cancer medications.

Figure 2: Components of the Reimbursement Process



Reimbursement Process for Take-Home Cancer Medications

Obtaining drug coverage for take-home cancer medications can be a multi-step process. As the ODB plan is not universal, the prescriber must first confirm patient eligibility and subsequently drug eligibility. The ODB Formulary is available online, so prescribers can check drug eligibility at the point of care. Not all cancer drugs are listed on the Formulary and this may require the prescriber to apply to the EAP. Once drug coverage is confirmed, the patient is given a prescription to take to a pharmacy of their choice. Upon receipt of a prescription, the pharmacist submits an electronic claim to the Ministry's online adjudication system, the Health Network System, which processes the claim, confirms eligibility and the amount owing by the patient for copayments or deductibles. The pharmacy's reimbursement is calculated in real-time via the online system. Pharmacies are reimbursed twice monthly.

Supplemental applications are required of patients and/or providers in the following scenarios:

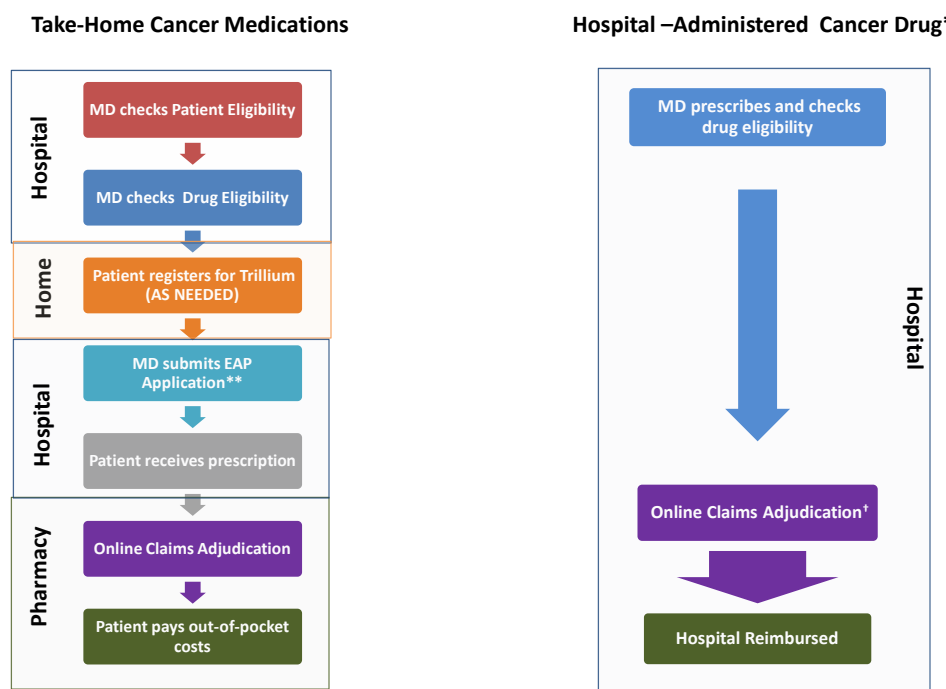
- *Home Care/Social Assistance Beneficiaries:* Patients must first enroll in these programs and then obtain a drug benefit card to present to the pharmacy each month.^{21,22}
- *Low Income Seniors:* Patients must complete a copayment application to qualify for a lower copayment.
- *Patients < 65 years and ODB ineligible:* Patients must register with Trillium, where they must mail in an application.⁵
- *Off-formulary drugs:* Prescribers must complete and fax an application to the EAP to determine if coverage could be obtained under EAP.

For patients who require registration to Trillium and an application to the EAP, accessing benefits is more complicated. These two programs operate independently, which requires providers and patients to complete and submit two paper-based application forms where the timeframe for decisions in each in program may be in the order of days to weeks.²³ The EAP does not verify the patient's ODB eligibility status, thus patients may receive funding approval from EAP, but need to wait until they are registered with Trillium to initiate therapy if they are not already eligible for benefits under the ODB Program. In 2012/13, the usual processing time for Trillium was cited as 17 days.²³

Reimbursement Process for Hospital-Administered Cancer Drugs

Obtaining drug coverage for hospital-administered injectable cancer drugs is less complex than for take-home cancer medications (Figure 3). As coverage is universal for Ontario residents with a valid Ontario health card, the prescriber must only confirm drug eligibility prior to prescribing. Providers in the hospital must submit funding requests online via eClaims, a CCO-developed application that tracks and adjudicates claims. For the majority of requests, funding eligibility is assessed automatically by the system software and the provider is notified of the funding decision the same day. Funding requests for some cancer drugs require the provider to submit supplementary information that is manually reviewed by CCO program staff. In many centres, the prescribing software (e.g., an outpatient oncology computerized prescriber order entry system) has been integrated with CCO's online adjudication system (eClaims). In this setting, providers can confirm their patients' drug eligibility at the time of prescribing (or at least prior to the patient's scheduled visit). CCO directly reimburses hospitals monthly for doses administered.

Figure 3: Reimbursement Process for Cancer Medications Publicly Funded in Ontario



EAP = Exceptional Access Program; Trillium = Trillium Drug Program

* For injectable drugs administered in the outpatient setting.

** Some take-home cancer medications require approval through the EAP.

† The majority of funding requests are automatically adjudicated by CCO's online system, eClaims.

Challenges

1. Disparities in Universal Coverage

The *Canada Health Act* is the legislation that mandates publicly funded insurance across the nation where the primary objective includes “to facilitate reasonable access to health services without financial or other barriers.”²⁴ Universality is a core principle of the Act which means that provincial public plans must entitle all insured persons to health insurance coverage on uniform terms and conditions.²⁵ However, the Act excludes coverage for drugs prescribed for use in the outpatient setting (e.g., take-home cancer medications, outpatient hospital clinics, cancer centres). Only patients who are admitted to the hospital (i.e., inpatients) are required to receive full drug coverage with no out-of-pocket costs.

For outpatient cancer medications, universal coverage is provided for hospital-administered drugs where patient eligibility criteria is based on proof of Ontario residency and a valid Ontario health card. In general, public programs for take-home cancer medications provide more limited financial support, where plans are age and income dependent.²⁶ These programs are largely for seniors, patients on social assistance or who have drug costs that represent a significant portion of their

income. Coverage is not universal for Ontario residents, and many cancer patients must rely on private insurance or self-pay for all or part of their take-home cancer drug costs.

2. Lack of First Dollar Coverage

In Ontario, first dollar coverage is provided for hospital-administered cancer therapies. For take-home therapies, public funding is often associated with out-of-pocket costs in the form of copayments and deductibles. Dispensing pharmacies may choose to waive copayments associated with public plans, creating further variations in out-of-pocket costs. Patients with a mix of public and private benefits may not have any out-of-pocket costs.

Table 2 summarizes the out-of-pocket costs associated with the take-home cancer medications which can be significant for patients. In the 2013/14 fiscal year, patients paid an estimated \$6.7 million in out-of-pocket costs associated with active and supportive treatments for cancer.²⁷ The average copayments associated with private plans has been estimated to be 20%, and in 2009 was estimated to be approximately \$13,000 for an average course of treatment with a new cancer drug.²⁸

Table 2: Summary of Out-of-Pocket Costs for Outpatient Cancer Medications

	Deductible	Maximum Copayment
Hospital Administered (CCO-Funded)	\$0.00	\$0.00
Take-home cancer medications (ODB-Funded)		
Low Income Senior *	\$0.00	\$2.00
High Income Senior **	\$100.00	\$6.11
Social Assistance/Home Care	\$0.00	\$2.00
Trillium Drug Program	4% net household income	\$2.00 [†]

* A senior (aged 65 or older) whose yearly net income is lower than \$16,018 or a senior couple whose combined yearly net income is less than \$24,175.

** A single senior (aged 65 or older) with a yearly net income of \$16,018 or more or a senior couple with a combined yearly net income of \$24,175 or more.

[†] Once the deductible has been paid, pharmacies may charge up to \$2.00 copayment per prescription.

3. Two Pharmacy Compensation Frameworks

The Ministry provides public funding for both hospital-administered drugs and take-home cancer medications but with distinct compensation structures:

- For hospital-administered drugs, the Ministry (via CCO) reimburses hospitals for the cost of drug for doses administered (usually on a per-milligram basis) based on the current NDFP price.
 - Costs of administering the drug are covered through CCO's Systemic Treatment Funding Model as part of overall regimen funding.²⁹
- For take-home cancer medications, the Ministry reimburses pharmacies for doses dispensed at the ODB or EAP list price, plus an eight per cent markup on the acquisition cost, and a dispensing fee (e.g., typically \$8.83) for each prescription filled.³⁰

In the current model, the Ministry is paying additional costs for take-home therapies that are based only on the cost of the drug, and not on the actual cost of providing the drug. In 2013/14, pharmacies charged approximately \$22 million in markup and \$6 million in dispensing fees for ODB-funded treatments.²⁸ In contrast, hospital-administered drugs are not associated with dispensing fees or mark-ups. Profit on the provision of therapies is not allowed, and the systemic treatment funding model provides overall funding for the delivery of treatments.

4. Lack of Systems Integration

Increasingly, the management of cancer involves a mix of hospital-administered and take-home cancer medications, either issued as part of the same regimen or given at different points in the patient's care. As a result, for one treatment regimen, patients may need to apply to multiple reimbursement programs and visit both their hospital and community pharmacy to obtain their medications.

Two models for the reimbursement and distribution of outpatient cancer drugs not only affects the quality of patient care but limits the overall effectiveness of the cancer system. Neither administrator can easily conduct comprehensive drug utilization reviews, audit appropriate use, or evaluate the overall appropriateness of cancer treatments, compared with a more integrated system.

Opportunities

A public cancer system has dual responsibilities: delivering high-quality care to patients, and spending healthcare dollars wisely to produce the greatest value for patients and society. Given the high and growing costs of cancer therapies, any evaluation of funding and equity issues for cancer drugs in Ontario mandates a careful consideration from both of these perspectives.

One approach that has been proposed is a simple one: Increase public funding for take-home cancer medications by reducing the current funding eligibility requirements, while eliminating copays and

deductibles. This approach would more closely align Ontario's funding scheme with cancer programs in some other Canadian provinces. However, the performance of the cancer system is not solely evaluated on access. If this approach were implemented in Ontario, it would not address important issues of data quality or treatment quality, both of which are a product of Ontario's current cancer drug funding and distribution system. Both the Ministry and CCO would continue to lack access to program administration and management tools that are part of more integrated cancer funding systems.

Given the challenges identified, potential areas for system change that would enhance quality, safety, effectiveness, safety, equity include:

1. Change WHO is eligible for public benefits

- **Provide universal coverage for take-home cancer medications to align with the funding model for hospital-administered cancer drugs.**
 - Elimination of current eligibility criteria such as age and income would expand access to more Ontario residents who require take-home cancer medications.
 - Modifying eligibility requirements for take-home cancer medications would move more patients from the private system to the public system.
 - Changing financial thresholds for Trillium would maintain, but lessen the role of private insurance, and would ease the financial burden for cancer patients without access to private insurance.
 - Moving to universal coverage would allow for the elimination of the current qualification and registration process for programs like Trillium, increasing overall administrative efficiency.
 - Any changes would require close consideration of the incremental financial public cost, recognizing that any approach would have the net effect of shifting costs away from not only patients, but from private insurance providers.

2. Change HOW MUCH patients are charged

- **Reduce out-of-pocket costs to patients by modifying the copayment/deductible structure.**
 - Changing the extent to which patients are directly responsible for the cost of care, which could occur by varying the extent of a personal (direct) cost burden.
 - The overall cost burden could be shifted by reducing the out-of-pocket costs for eligible recipients.
 - There are arguments in favor of maintaining a modest copayment cost-sharing component within public drug funding programs.³¹ The merits should be considered from both the cancer system and overall health system perspective.

3. Change HOW patients access benefits

- **Streamline and improve the process for determining coverage eligibility.**
 - In the current system, the reimbursement processes for hospital and take-home cancer medications are operationally distinct. Moving towards a single claims adjudication system that is integrated with hospital prescribing systems and pharmacy dispensing systems could:
 - Reduce time to reimbursement decisions through increased administrative efficiencies.
 - Ensure appropriate use as medication orders (or modifications) are tied to regular patient assessment and monitoring.

- Ensure value for money by validating that treatments are used according to established funding criteria.
- Improve quality and safety if medication orders are also integrated into a single distribution system, where the care team has access to the full patient history and treatment information.
- Enhance pharmacists' role in monitoring medication adherence for take-home cancer medications.
- Enhance the ability for post-treatment and post-payment verification of funding eligibility.
- Allow for the introduction of new quality indicators for systemic therapy, placing greater responsibility onto regional cancer programs to ensure that all therapies (hospital-administered or take-home) are being prescribed optimally.

4. Change WHERE patients access take-home cancer medications

- **Restrict dispensing of take-home cancer medications to specialized oncology pharmacies**
 - The current model allows take-home medication to be dispensed by pharmacies with a varying scope of oncology expertise. Patients can have prescriptions filled at cancer centre pharmacies, community pharmacies or drug stores located in the hospital.
 - Restricting the provision of take-home cancer medications to pharmacies located in cancer centres or hospitals that deliver cancer care could enhance safety and quality.

5. Change HOW pharmacies are reimbursed for providing take-home cancer medications.

- **Align pharmacy compensation structure for take-home cancer medications therapies with hospital-administered injectable drugs.**
 - In the current models, pharmacies profit on the dispensing of take-home cancer medications, as the Ministry pays an 8% mark-up on the cost of the drug. For hospital-administered drugs, compensation has been de-coupled from the cost of the drug and no profit is permitted.
 - A new compensation model could consider paying pharmacies on the quality and extent of services provided, rather than linking compensation to the acquisition cost of the drug.

Conclusion

Cancer treatment regimens are becoming more complex, and take-home cancer medications now play an essential role in the treatment of many cancers. There are increasing calls to fund all drugs in a manner similar to hospital-administered therapies. Several areas in the current reimbursement framework could be evaluated and reassessed. The most effective cancer system will not only address funding issues but ensure quality, safety and a responsive, integrated system.

Table 3: Summary of Major Public Plans for Outpatient Cancer Medications

Plan Component	Hospital-Administered Drugs	Take-Home Cancer Medications
Plan Name	<ul style="list-style-type: none"> New Drug Funding Program 	<ul style="list-style-type: none"> Ontario Drug Benefit Program
Patient Eligibility	<ul style="list-style-type: none"> Ontario resident with a valid health card 	<ul style="list-style-type: none"> Ontario resident with a valid health card Age, income and other factors
Drug Eligibility	<ul style="list-style-type: none"> Plan only covers cancer drugs Must meet clinical criteria for NDFP drugs 	<ul style="list-style-type: none"> Plan covers cancer and non-cancer drugs Must meet clinical criteria on the ODB Formulary as required
Funding for Off-Formulary Drugs	<ul style="list-style-type: none"> None 	<ul style="list-style-type: none"> EAP considers funding requests through a prior approval process
Registration Process	<ul style="list-style-type: none"> Patient presents valid health card at the hospital visit Hospital enrolls patient in eClaims 	<p><i>Patients >65 years:</i></p> <ul style="list-style-type: none"> Present health card at pharmacy on the first day of the month after turning 65 years of age Complete copayment application to qualify for a lower payment per prescription if required <p><i>Patients <65 years:</i></p> <ul style="list-style-type: none"> Drug Benefit Cards must be obtained for those in home care or on social assistance (i.e., Ontario Works, Ontario Disability Support Program) Applications must be completed and manually submitted to register for the Trillium Drug Program

Plan Component	Hospital-Administered Drugs	Take-Home Cancer Medications
Claims Submission and Adjudication	<ul style="list-style-type: none"> Hospital submits claim online (via eClaims) Immediate adjudication of clinical criteria (for most claims) 	<p><i>General ODB funding:</i></p> <ul style="list-style-type: none"> Pharmacy submits claim online via HNS <p><i>Drugs requiring EAP approval:</i></p> <ul style="list-style-type: none"> Physician completes and faxes EAP application Physician is notified of approval via a faxed letter Patient presents prescription at the pharmacy; claim is processed as per HNS above
Reimbursement Process	<ul style="list-style-type: none"> Hospital directly reimbursed at the NDFP list price for doses administered No costs incurred by the patient No administrative work required by patient 	<ul style="list-style-type: none"> Patient directly reimbursed at the point the prescription is filled for doses dispensed at the ODB list price Patient may be required to pay copays/deductibles Patients with private drug insurance must manually submit prescription receipts to the Trillium Drug Program for reimbursement

EAP = Exceptional Access Program; HNS = Health Network System; NDFP = New Drug Funding Program, ODB = Ontario Drug Benefit Program

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Appendix E

Backgrounder: Information Management and Information Technology

Introduction

Information systems and technology that support integrated cancer care and treatment can improve quality of care, patient safety, coordination among the different healthcare providers, and the overall efficiency of delivering health services.¹ In Ontario, existing information management (IM) and information technology (IT) systems for outpatient cancer medications were primarily designed to serve the delivery of intravenous chemotherapy in the outpatient hospital setting. While the use of take-home cancer medications has dramatically increased, the IM/IT infrastructure has not evolved to respond to the increased demand. IM/IT infrastructure is required to:

- **Enable optimal patient care:** Technological solutions are required to assist patients and providers. IT solutions are needed to facilitate continuity of care, improve patient safety and improve provider practices (e.g., dispensing, prescribing, medication administration as well as inter-professional communication) to be more efficient and effective.
- **Support reimbursement delivery:** Drug coverage decisions need to be made quickly and ideally at the point of care.
- **Strengthen cancer system planning and performance management:** Comprehensive data collection from all points of care (e.g., prescribing, dispensing, reimbursement) is required for system oversight and quality improvement initiatives.

Current IM/IT infrastructure

Table 1 summarizes the variations in technology used for outpatient cancer medications depending on whether it is a hospital-administered cancer drug (e.g., intravenous chemotherapy) or a take-home cancer medication. Different information systems are used for prescribing, dispensing, reimbursement and patient monitoring.

Table 1: Overview of IM/IT Infrastructure for Outpatient Cancer Medications

Process		Hospital-Administered Cancer Drugs	Take-Home Cancer Medications
Prescribing	Treatment Decision	<ul style="list-style-type: none"> • CPOE* (standalone or with an EMR) • Clinical Decision Support Software 	<ul style="list-style-type: none"> • CPOE* (standalone or with EMR) • Clinical Decision Support Software
	Method of Prescribing	<ul style="list-style-type: none"> • ~ 90 % of cancer centres use an outpatient oncology CPOE.² • Comprehensive CPOE* guidelines 	<ul style="list-style-type: none"> • CPOE use is highly variable and not routinely used • There is a lack of CPOE guidelines that are focused on take-home cancer therapies
Dispensing	Prescription Verification	<ul style="list-style-type: none"> • Cancer centre pharmacy can access hospital medical records • CPOE* with clinical decision support software 	<ul style="list-style-type: none"> • Community pharmacies cannot access hospital medical records
	Labelling	<ul style="list-style-type: none"> • CPOE can be used to generate medication labels 	<ul style="list-style-type: none"> • Community pharmacies must re-enter handwritten or computer-generated prescriptions
Administration	Medication Administration Record	<ul style="list-style-type: none"> • Nurse documents dose administered electronically in real-time. in real-time (e.g., CPOE or EMR) 	<ul style="list-style-type: none"> • Patient may document dose taken electronically or on paper • Pharmacy database captures doses dispensed
Monitoring	Adherence	<ul style="list-style-type: none"> • n/a 	<ul style="list-style-type: none"> • Variable and may be pharmacy-specific
Reimbursement	Claims Processing**	<ul style="list-style-type: none"> • eClaims can be used to check funding eligibility at point of care (eClaims is integrated with some CPOE systems) 	<ul style="list-style-type: none"> • Pharmacy system linked to private insurance adjudication systems and the Ministry's HNS adjudication system for ODB claims
	Reimbursement	<ul style="list-style-type: none"> • Invoices are generated in eClaims based on the treatment data that hospitals submit • Hospitals reimbursed monthly by CCO 	<ul style="list-style-type: none"> • ODB claims are adjudicated in real-time; pharmacies paid twice monthly • Patients may need to manually submit receipts for private or public reimbursement

CPOE = Computerized Prescriber Order Entry; EMR = Electronic Medical Record; HNS = Health Network System; ODB = Ontario Drug Benefit Program.

* Cancer centres/hospitals may use an outpatient oncology CPOE system (e.g., OPIS) to order cancer medications for outpatients. Hospitals may also have a separate CPOE system to prescribe medications for inpatients.

** Claims processing: process of determining whether the patient meets funding criteria to obtain drug coverage.

Challenges

In the current state, hospital-administered drugs follow different prescribing (or ordering), dispensing, and reimbursement processes. Consequently, IM/IT solutions are often distinct and not integrated between the hospital and community environment. Challenges to adapting the current systems to enhance the delivery of take-home cancer medications include:

1. Transition to Computer-Generated Prescriptions

Prescribers in hospitals may order medications through a computerized prescriber order entry (CPOE) system. In Ontario, hospitals may have different CPOE systems, one for prescribing inpatient medications and another for prescribing cancer medications for outpatients (i.e., outpatient oncology CPOE). In Ontario, approximately 90% of chemotherapy provided in hospitals or cancer centres is ordered through an outpatient oncology CPOE system.² However, these systems were designed for use with hospital-administered drugs and have not been widely used or specifically adapted for the prescribing and dispensing of take-home cancer medications. Based on oral chemotherapy practices in Ontario, the majority of prescriptions for take-home medications are likely handwritten without the use CPOE or PPO forms. A CCO survey on oral chemotherapy found only 23% routinely used CPOE.³

Computerized drug ordering systems have been shown to reduce errors for prescribed chemotherapy regimens from 15% to nearly zero.⁴ For chemotherapy administered in hospital settings, CPOE is recommended as the standard by provincial guidelines. Hand written prescriptions are not considered acceptable from a safety perspective, and if CPOE is not available, the use of standardized, regimen-level PPO forms is advised.⁵ A CPOE system can eliminate errors in transcription, provide decision support tools that can flag drug-drug interactions or drug allergies, and allow the prescriber to make clinical decisions at the point of care.² Specifically for oral chemotherapy, a U.S. study reported a 69% reduction in prescribing errors six months after implementing CPOE in the inpatient setting.⁶ Studies have also shown that CPOE can generate new errors which will have to be monitored when adapting to take-home cancer medications.⁷

2. Prescription Transmission to Community Pharmacies

Take-home cancer medications can be dispensed from cancer centre pharmacies, or retail pharmacies located in the hospital or community (community pharmacies). Presently, patients typically present a handwritten or computer-generated prescription. Prescriptions are not directly transferred from the hospital or cancer centre to the community pharmacy, in part due to the lack of technological capability. ePrescribing offers one such solution. ePrescribing is the process of generating, authorizing and securely transmitting prescriptions from the doctor (or other prescriber) directly to the pharmacist (or another dispenser).⁸ It eliminates handwritten prescriptions by physicians, enables and facilitates the electronic delivery of prescriptions directly to the pharmacy and facilitates communication between healthcare providers. In Ontario, ePrescribing has yet to be implemented across the province but pilot projects have been initiated.

3. Integration between Prescribing and Reimbursement Systems

Linking prescribing and reimbursement systems allows drug coverage determination at point of care. Additionally, payers may be able to adjudicate claims more accurately if there is sufficient clinical information in the prescribing system.

For hospital-administered drugs, prescribing and reimbursement systems are integrated at the point of care. eClaims, an electronic adjudication system developed by CCO, is actively used by approximately 90 hospitals to adjudicate claims for hospital-administered cancer drugs. eClaims is integrated with outpatient oncology CPOE systems to allow drug coverage determinations to occur at the point of care. A similar integrated system does not exist for take-home cancer medications. Outpatient oncology CPOE systems located in hospitals/cancer centres are not integrated with community pharmacies or the Ministry's systems that adjudicate funding requests for take-home medications.

4. Optimizing IT tools to support patient education, monitoring, and self-management

Person-centred applications can facilitate communication between providers, patients, and caregivers to ensure procedures and decisions consider patient needs and preferences. Tools may include internet-based applications, mobile devices, and telehealth applications. These types of applications have been used in managing chronic diseases like asthma and could be adapted to the oncology setting.^{9,10}

In Ontario, there is limited experience with IM/IT solutions to assist in patient education and monitoring. Methods of patient education vary regionally but typically include verbal counseling at the cancer centre, paper-copies of chemotherapy education sheets and paper calendars to help with adherence. However, disseminating masses of printed information to patients at the time of diagnosis can often be overwhelming and confusing. Web-based patient education sites can provide access to information at the patient's convenience.⁹

CCO has launched several mobile applications (mobile apps) to support patient and provider education. For example, the Drug Formulary app is an information-only resource for Ontario cancer drug and regimen monographs and symptom management information. The Symptom Management Guide app allows healthcare providers to quickly find and use best practices for symptom assessment and control at the patient's bedside.

Mobile apps that allow patients and providers to directly interact to adjust treatment regimens or manage side-effects are lacking. Mobile apps for improving adherence are available. Patients can log doses taken and set notification alarms to remind them of their next dose or refill.¹¹ However, not all patients have access or are comfortable with using such tools.

5. Comprehensive and integrated data collection

Ideally, cancer care providers and administrators would like access to all data in a patient's health record to provide high-quality care and system oversight. Ontario is moving toward an electronic health record which can bring together patient information from different healthcare providers (e.g., family doctors or oncologists), hospital information systems, and community pharmacy systems.¹² However, a complete electronic health record is not available at this time.

Currently, data is collected at multiple points along the patient's treatment journey and is not yet integrated at single source:

- Separate information systems exist with the hospital (e.g., inpatient systems are not linked to outpatient cancer clinics).
- Community pharmacies are not connected to hospital information systems.
- Provincial reimbursement systems for take-home and hospital-administered drugs are operationally distinct and not integrated:
 - Take-home cancer medications reimbursed by the Ministry link to community pharmacy computer systems via the Health Network System (HNS). The HNS supports claims adjudication. Data is collected by the community pharmacies and submitted to the HNS at the point of dispensing and claims adjudication.
 - For hospital-administered drugs, data is collected by the hospital at the time of prescribing, ordering and administration. Additionally, CCO collects reimbursement data through its eClaims adjudication software.

Opportunities

The appropriate approach to enhancing existing information systems is dependent upon the design of the take-home delivery system. Variables to consider are listed in Table 2.

Table 2: Core Components of the Take-Home Cancer Therapy Model

Component	Key Questions	Comprehensive and Integrated Option
Drug Plan Eligibility	<ul style="list-style-type: none"> • Who will be covered? • What is the extent of coverage? 	<ul style="list-style-type: none"> • All Ontario residents will have first dollar coverage (to align with the plan for hospital-administered injectable cancer drugs).
	<ul style="list-style-type: none"> • Which drugs will be covered? 	<ul style="list-style-type: none"> • Take -home cancer therapy is covered for drugs required for both the active treatment of cancer or supportive care.
Adjudicators	<ul style="list-style-type: none"> • Who will assess eligibility of plan beneficiaries? 	<ul style="list-style-type: none"> • Consolidate the adjudication process for publicly funded cancer drugs into a single process.
Payers	<ul style="list-style-type: none"> • Who will be reimbursed? • Who administers reimbursement? 	<ul style="list-style-type: none"> • Consolidate all reimbursement for publicly funded cancer drugs into a single process.
Distribution Centres	<ul style="list-style-type: none"> • Where can patients access the drug? 	<ul style="list-style-type: none"> • Specialized oncology pharmacies that are located either on or off the premises of hospitals/cancer centres.

Based on the variables outlined in Table 2, the following would need to be addressed:

1. Prescribing:

- Modify existing outpatient oncology CPOE systems to generate prescriptions for take-home cancer medications. To accomplish this task, areas to address include:
 - Define the optimal functionality to support take-home cancer medications, including decision support systems such as interfaces with laboratory systems and an up-to-date drug databases.
 - Define standards for the key elements that should be included on a take-home chemotherapy prescription. Currently, CCO and the Canadian Association of Provincial Cancer Agencies are working on this initiative.
 - Automate dosing calculations for safe dispensing.
 - Implement outpatient oncology CPOE in all Ontario hospitals. Four systemic treatment facilities, which account for approximately 5% of chemotherapy orders, lack this CPOE system.

2. Dispensing:

- Most cancer centre pharmacies can use an outpatient oncology CPOE system as a dispensing system (e.g., OPIS). Restricting dispensing to cancer centre pharmacies may simplify integration challenges between hospital, cancer centre, and community pharmacy information systems. One challenge that would still exist is the integration between CPOE and pharmacy inventory systems. Currently, some cancer centre pharmacies must re-enter CPOE generated prescriptions for inventory purposes due to lack of integration.
- For scenarios requiring dispensing from community pharmacies, ePrescribing offers a potential solution but will require an understanding of the requirements and functionality between hospital and pharmacy systems. Implementing ePrescribing is complex due to the variety of hospital and community pharmacy IT systems. There are several thousand community pharmacies in Ontario each with variations in their IT systems. Additionally, there are a variety of CPOE systems used by hospitals and cancer centres that currently prescribe intravenous chemotherapy.

3. Adjudication/Reimbursement:

- For scenarios where CCO is the adjudicator, eClaims can be extended to support the inclusion of take-home cancer medications.
- Integrating the eClaims application with community pharmacy systems would be problematic due to variations in the systems used by public and private payers. Community pharmacies currently coordinate benefits between multiple parties (e.g., Ontario Drug

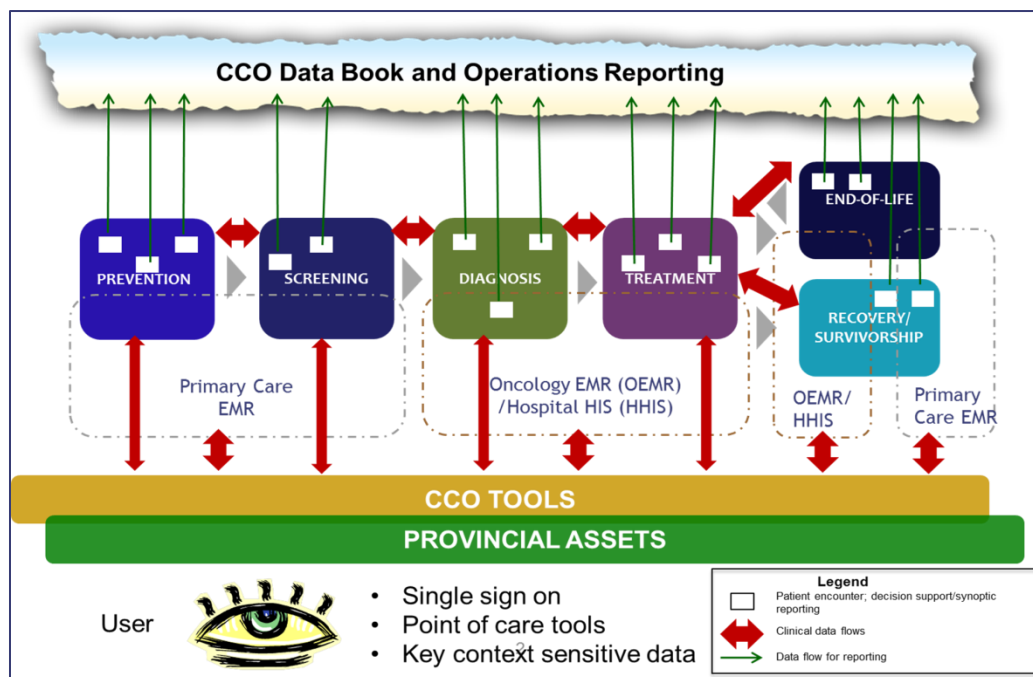
Benefit Program, private insurers). Adding CCO as another payer will require further examination if it is felt to be a potential option for consideration.

- The cost of deploying eClaims to 80 hospitals was approximately \$500,000. Deploying eClaims to all or the majority of community pharmacies would cost several million over the span of approximately four years. Developing interfaces between eClaims and community pharmacy systems would add significant costs.

4. Reporting:

- Regardless of the delivery model chosen, the cancer system should be designed to allow data sharing between CCO, community pharmacies, cancer centres and inpatient hospital information systems. Figure 1 depicts an ideal model of data flow along the patient journey developed by CCO. Community pharmacies, which are not shown in this diagram, would be integrated into this model as well. However, this type of solution would require several years to implement.

Figure 1: “Putting it All Together” - Data Flow Along the Patient Journey



Comprehensive and Integrated Solution

The optimal solution that could be adapted to various reimbursement and distribution models is a full medication management system. A medication management system would allow integration between primary care providers, hospitals, cancer centres and community pharmacies. This system could integrate inpatient and outpatient CPOE systems, ePrescribing and dispensing in the community. eHealth Ontario undertook some initial work on a primary care medication management system in 2013. A solution to support the needs of chemotherapy would likely be more complex, and would require significant modifications to CPOE systems. Possible costs for such a system are hard to estimate but it seems probable that the cost of implementing such a solution would exceed hundreds of millions of dollars. Even under this scenario, costs for deploying some sort of reimbursement and reporting framework would also be incurred.

Conclusion

From an IM/IT perspective, expanding the use of outpatient oncology CPOE systems within systemic treatment facilities may offer a simple integration approach. While this restriction may be less convenient for patients, these facilities must meet specific standards to prescribe, dispense, and administer cancer medications. As such, patient safety and quality of care should be enhanced by limiting to specialized facilities.

Using an outpatient oncology CPOE for prescribing with dispensing activity outside of the existing systemic treatment facilities would also be feasible, though the design and deployment strategies would be significantly more complex, time consuming and expensive.

Extending the use of technology beyond prescribing using printed orders to ePrescribing and adherence monitoring would be ideal and pilot activities could be undertaken to work through a feasible strategy for take-home cancer medications.

A full provincial solution would enable effective communication between cancer care providers and enhance the efficiency and quality of the overall delivery model, but would depend on a provincial medication management system with support and direction from the Ministry.

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