



## Guideline 12-10 Version 2

A Quality Initiative of the  
Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO)

# Regional Models of Care for Systemic Treatment: Standards for the Organization and Delivery of Systemic Treatment

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An assessment conducted in November 2025 deferred review of Guideline 12-10 Version 2. This means that the document remains current until it is assessed again next year. The PEBC has a formal and standardized process to ensure the currency of each document ([PEBC Assessment & Review Protocol](#))

Guideline 12-10 Version 2 is comprised of 3 sections. You can access the summary and full report here:

<https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/60086>

Section 1: Model and Standards  
Section 2: Systematic Review  
Section 3: Internal and External Review

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## Table of Contents

Section 1: Model and Standards.....	1
Section 2: Systematic Review .....	14
Section 3: Internal and External Review .....	25
References .....	27
Appendix 1: STP Standards.....	35
Appendix 2: STP Standards Methodology.....	43
Appendix 3: Affiliations and Conflict of Interest Declarations.....	45
Appendix 4: Guideline Methods Overview .....	47
Appendix 5: Literature Search Strategy .....	48
Appendix 6: Guideline Document History.....	49

# Regional Models of Care for Systemic Treatment: Standards for the Organization and Delivery of Systemic Treatment

## Section 1: Model and Standards

### OBJECTIVES

This document presents a practical framework and standards to guide the delivery of systemic treatment Ontario-wide, that is, within cancer-centres, and in facilities beyond the confines of regional cancer centres. The primary goal is to provide safe, evidence-based systemic cancer treatment, maximizing the efficient use of resources and employing the principle of person-centered care with an emphasis on providing care as close to home as possible. Service provision, complexity of care, safety, accessibility, and quality care across all levels defined by the patient, organization, and system perspective, as well as appropriateness, transparency, and accountability have been considered. Both education and research are integral due to their important roles in safety and quality improvement.

### DEVELOPMENT OF THIS DOCUMENT

This document was developed by Cancer Care Ontario's (CCO) Systemic Treatment Program (STP) in collaboration with the Program in Evidence-Based Care (PEBC). It builds on the original 2007 version of this document and introduces revised standards (presented herein as statements) for the delivery of services. The guidance presented here represents the consensus of the members of the Regional Models of Care for Systemic Treatment Guideline Development Group (RMCSTP GDG), informed by the available evidence and information. The content is derived from three sources as outlined below:

- The Regional Model of Care structure and levels of service provision for the Regional Model for Quality Systemic Treatment is retained from 2007 (see Figure 1-1 below). Although there have been many advancements in the safety and quality of systemic treatment, the model-of-care is still relevant and applicable in 2019.
- Some standards have been retained from the 2007 version of this document. Some modifications and additions have been made to reflect technology changes and linkages to the wider community of care providers. In addition, a key set of priority statements has been developed by CCO's STP using a modified Delphi consensus process. The standards provide guidance on policies and procedures, training and education for providers, patient education and patient care, computerized prescriber order entry (CPOE), pumps and equipment and labelling of drug products. A summary checklist has been developed that can be used to assess a program for concordance with this standards document and also guide centres that need to prioritize as they further develop their systemic therapy services ([Appendix 1](#)). For more information on the modified Delphi consensus methodology used by the STP, please see [Appendix 2](#).
- For additional elements related to 1) Safe delivery of systemic treatment, 2) Skills and maintaining competency for health care providers and 3) Roles of health care providers that were not addressed in the original guideline or in the new STP Standards, an updated evidence search was conducted by the PEBC. Additional sources of information relevant to these areas for the purpose of providing guidance are presented in [Section 2](#).

### TARGET POPULATION

All adult patients with cancer who are receiving systemic treatment.

## **INTENDED USERS**

The standards in this guideline apply to the organization and structure of systemic treatment programs in Ontario. They apply to all institutions and programs delivering ambulatory systemic treatment within the province of Ontario.

## **REGIONAL MODELS OF CARE FOR SYSTEMIC TREATMENT**

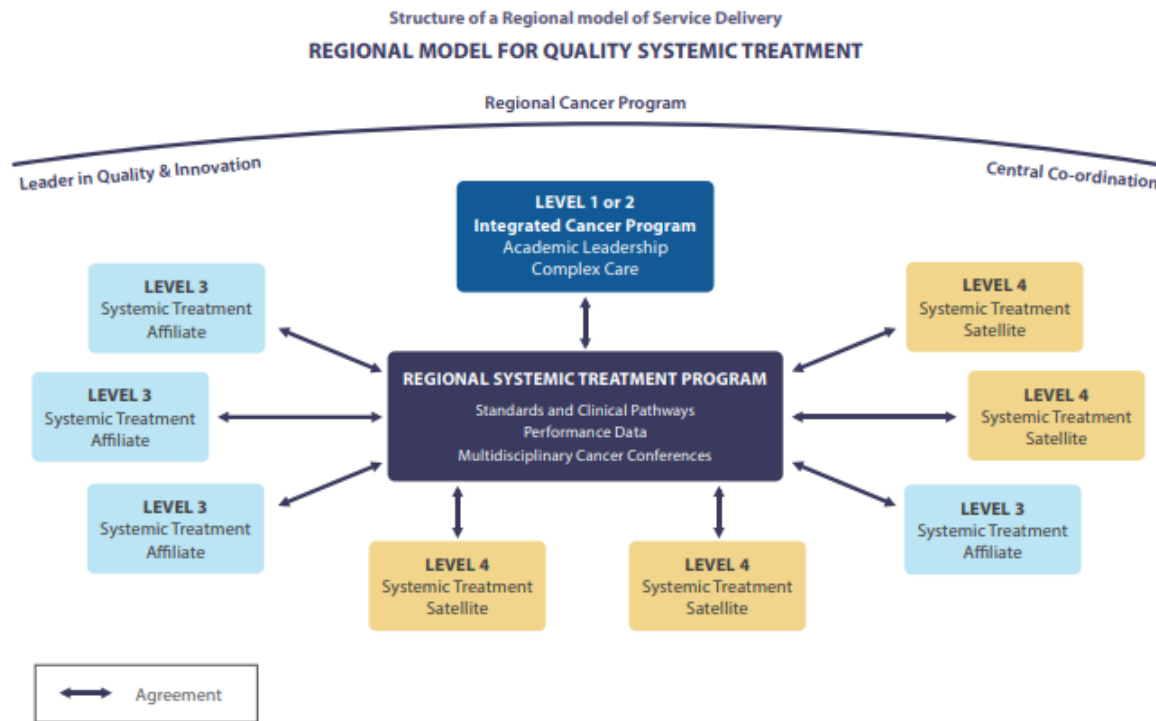
The planning and performance monitoring of cancer services is the responsibility of the Regional Cancer Programs (RCPs) that have been established by CCO. The RCP includes the Integrated Cancer Program (ICP), which is located at one host hospital, other hospitals and healthcare agencies, and health care providers involved in the delivery of cancer services. The RCP includes clinical and prevention programs associated with the various phases of care, each linked to a CCO provincial program. Through the Regional Vice President, the RCP advises CCO as to the appropriate distribution of services and is the primary mechanism through which existing and new CCO quality and access standards for cancer services are implemented and monitored.

One component of each RCP is a Regional Systemic Treatment Program (RSTP), which is linked to the CCO provincial program for systemic treatment. The RSTP is comprised of physicians, pharmacists, nurses and administrative leads from the hospitals that organize the delivery of systemic treatment in the region. Their responsibility is to plan for and facilitate the implementation of the CCO standards outlined in this document. The medical oncologist identified as the lead for the region is a member of the RSTP and is expected to lead or participate in quality improvement initiatives with the RSTP.

The Regional Model for Quality Systemic Treatment (Figure 1-1) consists of a key set of fundamental elements and regional programs designed to implement, monitor, and evaluate quality indicators related to the delivery of safe, evidence-based, and person-centred care. The Model is an organizational framework for the delivery of systemic treatment within a RSTP. The main goal of the Model is to facilitate the provision of the appropriate care in the appropriate setting within the appropriate timeframe for all patients, regardless of where a patient receives systemic treatment. The Model is comprised of three integrated institutional structures each with a defined scope of practice. The structures are ICPs, affiliate institutions, and satellite institutions. The ICPs are multidisciplinary organizations that provide complex cancer care. Affiliate institutions have their own systemic treatment programs, although they are linked through formal agreements with the RSTP. Satellite institutions have fewer oncology-related resources and have a formal linkage to the RSTP for support in delivering systemic treatment.

All regional partner institutions participate in the development of their RSTPs and collaboratively determine the appropriate configuration of their model, including the formal linkages that are required among institutions. The complexity of care delivered in each type of institution may vary; standards encompassing four levels of care (1-4) are recommended for the delivery of systemic treatment in Ontario. It is the level of complexity and the availability of services that differentiate one level from another. The RSTP determines the appropriate level of care for each institution. Levels are hierarchical, with the satellite responsibilities encompassed within the affiliate and ICP levels. As individual institutions expand or focus their services, the configuration of the model and designation of institutional levels may change over time, following consultation between the RSTP and the institution.

Figure 1-1. Regional Model for Quality Systemic Treatment



## LEVELS OF FACILITIES

Each facility will have common expectations for the delivery of quality care. Some facilities may rely on regional networks to achieve access to services.

Level 4 (Satellite)
<ul style="list-style-type: none"> <li>Provides ambulatory facilities, and nursing, pharmacy, and physician support for the administration of intravenous and/or oral systemic treatment under the direction of an oncologist from an ICP or affiliate level 3 institution.</li> <li>Access to onsite physician who could provide support for any urgent medical issues</li> <li>Ideally, patients are stable without significant co-morbidities or organ dysfunction and have a low risk for hypersensitivity. First doses may be administered at the RCP to minimize risk.</li> <li>Requires access to specialized services and providers with a formalized linkage to the RSTP.</li> </ul>
Level 3 (Affiliate)
<ul style="list-style-type: none"> <li>Systemic treatments given under direct supervision of an on-site staff medical oncologist, hematologist, or gynecologic oncologist.</li> <li>May participate in teaching, research and clinical trials</li> <li>Must be part of a partnership for regionalized cancer services including but not limited to hepatobiliary, thoracic, gynecological oncology, and sarcoma</li> <li>Must be part of a network for complex malignant hematology. May participate in shared care for leukemia and day 1 transfer programs for stem cell transplant.</li> </ul>

<b>Level 2 (ICP)</b>
<ul style="list-style-type: none"> <li>• Systemic treatments are given at an ICP with radiation treatment services and capable of providing most complex systemic treatments, including concurrent systemic treatment and radiation and/or radiolabelled conjugates.</li> <li>• May participate in teaching, research, and clinical trials.</li> <li>• Pathology consultation on site.</li> <li>• On-site specialized diagnostic imaging including nuclear medicine, magnetic resonance imaging (MRI), and computerized tomography (CT).</li> <li>• Must be part of a partnership for regionalized cancer services including but not limited to hepatobiliary, thoracic, gynecological oncology, and sarcoma and may host these services.</li> <li>• Must be part of a network for complex malignant hematology. May be a full-service leukemia site or participate in shared care for leukemia and day 1 transfer programs for stem cell transplants</li> </ul>
<b>Level 1 (ICP)</b>
<ul style="list-style-type: none"> <li>• Systemic treatments are given at an ICP with radiation treatment services and capable of providing complex systemic treatments including concurrent systemic treatment and radiation and/or radiolabeled conjugates.</li> <li>• Responsible for training future health professionals including medical students and residents in medical oncology/hematology.</li> <li>• Research and clinical trial programs.</li> <li>• Experimental Investigational New Drug (IND) Program (IND phase 1 and or 2 trials with highly developed clinical trials infrastructure, e.g., participate in the National Cancer Institute of Canada Clinical Trials Group [CCTG] IND program and Princess Margaret Hospital/National Institute of Health [PMH/NIH] new drug consortium)</li> <li>• On site specialized diagnostic imaging including nuclear medicine, MRI, and CT.</li> <li>• Host regionalized services including but not limited to hepatobiliary, thoracic, gynecological oncology, and sarcoma. Establish a partnership with other hospitals in the region to provide services.</li> <li>• A full-service leukemia site and offer stem cell transplant services. Must participate in a network and offer shared care for leukemia and day 1 transfer programs for stem cell transplant with other sites in the region.</li> </ul>
<b>Responsibilities of the ICP</b>
<ul style="list-style-type: none"> <li>• Monitor wait times and other performance metrics</li> <li>• Investigate and report incidents. Share learnings with the RSTP and CCO through the Incident Learning Committee at CCO.</li> <li>• Ensure a mechanism to manage and report drug shortages in collaboration with other hospitals in the region.</li> <li>• Establish or participate in RSTP/communities of practice for the region.</li> </ul>

## STANDARDS FOR SYSTEMIC TREATMENT

The goal of the RSTP is to ensure safe, standardized, evidence-based care across the regions. To ensure equitable access to systemic treatment, the standards described below delineate facility and program supports required to deliver systemic treatment, standards for health care providers and their roles, and standards for quality assurance and safety. Definitions for key terms are provided at the end of this section.

The standards are derived from three sources:

1. Some standards were retained from the original 2007 version guideline. Some modifications and additions have been made by the STP to reflect technology changes and linkages to the wider community of care providers. (indicated as \*)
2. Some standards were developed by the STP modified Delphi consensus process (indicated as +). For more information on the STP modified Delphi consensus process methods, please see [Appendix 2](#).
3. Some standards were developed by the consensus of the RMCSTP GDG with the PEBC, informed by the available evidence and information summarized in [Section 2](#) (indicated as \*\*).

### I. Facility and program supports required to deliver systemic treatment

The facilities should meet minimum requirements for space, service, and administrative supports in order to provide systemic treatment. There are many services that are necessary on site but also several that can be shared within a region to ensure sustainable care close to home.

<b>Data Collection and Submission</b>
<ul style="list-style-type: none"> <li>• Collect data and monitor provincial indicators (including but not limited to wait times, volumes, unfunded systemic treatment regimens, patient reported outcomes) and other regional indicators as defined by the RCP.*</li> <li>• CCO Activity Level Reporting data book compliant.*</li> </ul>
<b>Systemic Treatment Suite Facilities</b>
<ul style="list-style-type: none"> <li>• Dedicated systemic treatment area adequate for volume of treatment visits with a quiet area for staff to perform checks.* For additional information, please see <a href="#">Appendix 1 #31</a>.</li> <li>• Oxygen available to each systemic treatment infusion chair/stretchers.*</li> <li>• Appropriate equipment for delivery of systemic treatment including tubing, luer-lock syringes and, if needed, elastomeric devices. Consider the use of closed system transfer devices.* For additional information, please see <a href="#">Appendix 1 #14, #33, and #35</a>.</li> <li>• Programmable pumps and the appropriate training/recertification for staff.+ For additional information, please see <a href="#">Appendix 1 #32</a>.</li> <li>• Emergency resuscitation equipment (e.g. crash cart, other emergency supplies, drugs, oxygen and suction) in case of cardiorespiratory arrest or anaphylaxis.*</li> <li>• Supportive drugs and supplies for treatment of hypersensitivity/infusion reactions and extravasation. For additional information, please see <a href="#">Appendix 1 #24</a>.</li> <li>• Additional Policies and Procedures are outlined in <a href="#">Appendix 1 #23-31</a>.</li> </ul>
<b>Clinical Services and Clinic Facilities</b>
<ul style="list-style-type: none"> <li>• A process for patient identification using two patient identifiers such that patients are identified at entry into the system, and then at each step of the treatment process, by the different members of the healthcare team involved in their care+. For additional information, please see <a href="#">Appendix 1 #23</a>.</li> <li>• Information system hardware and support to maintain a secure electronic systemic treatment order entry program and other electronic systems as indicated (e.g., electronic patient record).* For additional information, please see <a href="#">Appendix 1 #1</a>.</li> </ul>



<ul style="list-style-type: none"> <li>• Process to review and check the new regimens in CPOE systems to ensure accuracy and a process for regular review of previously programmed regimens +. For additional information, please see <a href="#">Best Practice Recommendations for Regimen Development and Maintenance</a> and <a href="#">Appendix 1 #1-2</a>.</li> <li>• Adherence to guidelines for CPOE and labelling.* For additional information, please see <a href="#">Computerized Prescriber Order Entry (CPOE) in the Outpatient Oncology Setting</a>, <a href="#">Patient Safety Issues: Key Components of Chemotherapy Labelling</a>, <a href="#">Systemic Treatment Computerized Prescriber Order Entry (ST CPOE: Best Practice Guideline for Intravenous and Oral Chemotherapy)</a> and <a href="#">Appendix 1 #3-5</a>.</li> <li>• Ability to submit e-claims eligibility forms.*</li> <li>• Potential for videoconference, remote web-based teaching as part of multidisciplinary cancer conference (MCC ) or morbidity and mortality rounds.*For additional information, please see <a href="#">Appendix 1 #22</a>.</li> <li>• Collection of near misses and incidents with reporting to National System for Incident Report (NSIR), a component of the Canadian Medication Incident Reporting and Prevention System, as required. For additional information, please see <a href="#">Appendix 1 #21 and #27</a> and <a href="#">Canadian Medication incident Reporting and Prevention System</a>.</li> <li>• Collect adverse events with reporting to Health Canada (or other mechanism) as required.</li> </ul>
<b>Patient Care</b>
<ul style="list-style-type: none"> <li>• All aspects of patient care should be clearly documented.+ For additional information, please see <a href="#">Appendix 1 #13</a>.</li> <li>• All treatment plans are recommended by an oncologist or hematologist and should be distributed to all providers involved in the patient's care. + For additional information, please see <a href="#">Appendix 1 #6 and #17</a>.</li> <li>• Contact information provided to patients so they may review symptoms between appointments with staff trained in triage and systemic treatment side effect management (e.g., Canadian Oncology Symptom Triage and Remote Support [COSTaRS]).+ For additional information, please see <a href="#">Appendix 1 #40</a>.</li> <li>• Patients should be monitored for signs and symptoms of device-related issues and other serious adverse effects.+ For additional information, please see <a href="#">Appendix 1 #16 and #21</a>.</li> <li>• Patient assessments performed by the clinical team prior to systemic treatment including a Best Possible Medication History (BPMH) and document in the chart.+ For additional information, please see <a href="#">Appendix 1 #8</a>.</li> <li>• Collect patient-reported outcomes and have them available for the patient and clinician to review and plan interventions.</li> </ul>
<b>Patient Education</b>
<ul style="list-style-type: none"> <li>• Access to multidisciplinary teaching for patients on systemic treatment provided by nurses, physicians, and pharmacists. For additional information, please see <a href="#">Appendix 1 #11</a>.</li> <li>• Education should include diagnosis, intent of treatment, treatment plan, side effects, and how to manage intravenous and oral treatments in the home including recognizing pump malfunction, disposal, and safe handling. Approach to education should be standardized using validated teaching tools (e.g., Multinational Association for Supportive Care in Cancer (MASCC) Oral Agent Teaching Tool [MOATT]) and developed with patient and family advisors.** For additional information, please see <a href="#">Appendix 1 #9-10, #20, #33, #36, and #39</a>.</li> </ul>
<b>Health Human Resources</b>
<ul style="list-style-type: none"> <li>• Adequate staff numbers to support independent double checks (correct dose, pump programming and other checks as required) for systemic treatment administration. This can occur virtually if required. ** For additional information please see <a href="#">Appendix 1 #12</a>.*</li> </ul>

<ul style="list-style-type: none"> <li>Assigning workload to nurses in the systemic treatment suite is best done with the Nursing Resource Intensity Weight (RIW) tool. **For Nursing RIW for specific regimens, refer to the “Administrative Information” section (section J) of the corresponding <a href="#">regimen monograph</a>.</li> <li>The number of pharmacy technicians should be based on the Pharmacy RIW of the treatments prepared. **For Pharmacy RIW for specific regimens, refer to the “Administrative Information” section (section J) of the corresponding <a href="#">regimen monograph</a>.</li> <li>Ideally there should be access to a minimum of two oncology pharmacists (can be remote or virtual). The number of pharmacists should be based on resource intensity weighting.</li> </ul>
<b>Administrative Support</b>
<ul style="list-style-type: none"> <li>Physician and administrative leads identified with defined roles to manage strategic and operational issues through regional forums.*</li> <li>Incorporate patient and family advisors into leadership discussions and project management*.</li> <li>Nursing and pharmacy administrative leads identified with defined roles to manage strategic and operational issues through the RSTP.*</li> <li>Inventory management for systemic treatment drugs and a defined escalation procedure for drug shortages*.</li> <li>Clerical staff and clinic facilities to support patient scheduling, health record management, and clinic management including clinic and administrative supplies for systemic treatment suites and ambulatory clinic visits.*</li> </ul>
<b>Pharmacy</b>
<ul style="list-style-type: none"> <li>Pharmacy must meet National Association of Pharmacy Regulatory Authorities (NAPRA) Model Standards for Pharmacy Compounding of Hazardous Sterile and Non-Sterile Preparations and Storage as mandated by the Ontario College of Pharmacists (OCP).+ For additional information, please see <a href="#">Appendix 1 #3 and #44</a></li> <li>Biological Safety Cabinet (class II) and external venting, with a preference for type B2. See CCO Safe Handling of Cytotoxics.*</li> <li>Adherence to the guidelines for ordering, mixing, and handling systemic treatment including but not limited to the following: <a href="#">Safe Handling of Cytotoxics</a>; <a href="#">Safe Administration of Systemic Cancer Therapy: Introduction and General Methods</a>; <a href="#">Safe Administration of Systemic Cancer Therapy Part 1: Safety During Chemotherapy Ordering, Transcribing, Dispensing, and Patient Identification</a>; <a href="#">Safe Administration of Systemic Cancer Therapy Part 2: Administration of Chemotherapy and Management of Preventable Adverse Events</a></li> </ul>
<b>Clinical Trials</b>
<ul style="list-style-type: none"> <li>Ensure patients have access to clinical trials on site or with a partner organization</li> <li>If trials are offered on site, the following should be available: <ul style="list-style-type: none"> <li>Specific clinical trial education for patients and health care providers.</li> <li>Adequate space and designated clinical trial data storage.</li> <li>Trials performed under direction of an oncologist with internists or general practitioners able to participate as co-investigators.</li> </ul> </li> </ul>
<b>Medical Support Services</b>
<ul style="list-style-type: none"> <li>Protocols to monitor and manage hypersensitivity/infusion reactions with onsite physician support while systemic treatment is being administered.* For additional information, please see <a href="#">Appendix 1 #15</a>.</li> <li>Emergency department onsite.*</li> <li>Access to inpatient beds for oncology patients.*</li> <li>Access to specialized diagnostic imaging (CT, ultrasound, nuclear medicine), laboratory tests, and pathology.*</li> </ul>

<ul style="list-style-type: none"> <li>• Access to an intensive care unit.*</li> <li>• Ability to insert central venous catheters.*</li> <li>• Establish a network with the other systemic treatment delivery centres within the region and form a RSTP. Regular meetings including the pharmacy leads, nursing, administrative leadership, and the physicians/Regional Quality Lead. Advance the ICP agreement quality improvement projects, incident/near miss discussions through the Systemic Incident Learning (STIL) committee, and participation in the Regional Quality and Safety Network (ReQSN)*.</li> <li>• Establish connections with community pharmacies to enhance safe dispensing of take-home cancer drugs.*</li> <li>• Access to psychosocial oncology care (i.e., social worker, registered dietitian, physiotherapy, occupational therapy, speech language pathologist, and psychology and/or psychiatry).+ For additional information, please see <a href="#">Appendix 1 #19</a></li> </ul>
<b>Drug Access</b>
<ul style="list-style-type: none"> <li>• Provide a drug access navigator/facilitator to help patients navigate funding for drugs.+</li> </ul>

## II. Standards for health care providers and their roles

All health care providers within the systemic treatment program should be working collaboratively to care for patients and also contributing to the quality and development of the program within each centre and across the region. Although the oncologist/hematologist may have the primary role in discussing the treatment plan, several disciplines may have the role of prescribing and supervising systemic treatment. All health professionals should have a role in discussing a patient's goals of care and preferences for palliative care services.

<b>Oncologist/Hematologist</b>
<ul style="list-style-type: none"> <li>• Determine and recommend the treatment plan, prescribe systemic treatment, manage disease status, and discuss patient management issues with the health care team. **</li> <li>• May participate in on-site systemic treatment suite supervision and when supervising, must be available within 15 minutes during drug administration. *</li> <li>• May participate in academic responsibilities including teaching and research.*</li> <li>• Participate in administrative work as required by the centre*.</li> <li>• Mentor family physicians / internists*.</li> <li>• Undertake Continuing Medical Education (CME) as per Royal College of Physicians and Surgeons of Canada.*</li> <li>• Participate in multidisciplinary cancer conferences for their specialized disease sites*</li> <li>• Attend and discuss cases at regular mortality and morbidity rounds (MMRs) including all deaths on systemic treatment within 30 days of treatment.*</li> <li>• Participate as a representative on the RSTP committee, if requested or nominated. +</li> </ul>
<b>General Practitioners in Oncology</b>
<ul style="list-style-type: none"> <li>• Prescribe and supervise systemic treatment administration as defined by the oncologist/hematologist. ** For additional information, see <a href="#">Appendix 1 #7</a></li> <li>• May participate in onsite systemic treatment suite supervision and when supervising, must be available within 15 minutes during drug administration.*</li> <li>• Consult oncologist regarding patient management issues.*</li> <li>• Assess and manage toxicity.*</li> <li>• Complete initial orientation and annual CME.* For additional information, please see <a href="#">Appendix 1 #49</a>.</li> <li>• Mentoring should be available by a medical oncologist/hematologist. *</li> <li>• Have knowledge of CCO regional systemic treatment guidelines and standards and</li> </ul>

<p>regional policies and procedures.*</p> <ul style="list-style-type: none"> <li>• Participate in MCCs. *</li> <li>• Attend and discuss cases at regular MMRs including all deaths on systemic treatment within 30 days of treatment*.</li> </ul>
<p><b>Nurse Practitioners</b></p> <ul style="list-style-type: none"> <li>• Prescribe and supervise patients on treatment as defined by the oncologist/hematologist.* For additional information, see <a href="#">Appendix 1 #7.</a></li> <li>• Manage well follow-up visits.*</li> <li>• Participate in MCCs for their specialized disease sites.+</li> <li>• Attend and discuss cases at regular MMRs including all deaths on systemic treatment within 30 days of treatment*.</li> </ul>
<p><b>Nurses</b></p> <ul style="list-style-type: none"> <li>• All registered nurses (RNs), clinical nurse specialists (CNSs) and nurse practitioners (NPs) working primarily with patients with cancer and their families in the RCPs (Level 1-4 facilities) should obtain and maintain Canadian Nursing Association (CNA) certification as the nationally recognized nursing specialty credential by their 5th year of practice. All registered practical nurses (RPNs) should complete a relevant foundations course.+ <ul style="list-style-type: none"> <li>○ RNs, CNSs and NPs should obtain CNA certification reflective of their main role and practice setting focus (e.g., Certified in Oncology Nursing [CON(C)], and/or Hospice Palliative Care [CHPCN(C)]).</li> <li>○ RPNs should complete a foundations course reflective of their main role and practice setting in oncology or palliative care by an accredited Provincial College, Pallium Canada, Palliative Pain &amp; Symptom Management Consultation Program of Southwestern Ontario, or relevant de Souza course.</li> </ul> </li> <li>For additional information please see <a href="#">Appendix 1 #42 and #52</a></li> <li>• Provide patient education related to planned systemic treatment, in collaboration with pharmacist and physicians*.</li> <li>• Encouraged to participate in MCCs and MMRs *+.</li> <li>• Provide symptom management education.+ For additional information please see <a href="#">Appendix 1 #9 and #20.</a></li> <li>• Participate as a representative on the RSTP committee, if requested or nominated.</li> </ul> <p><b>a) Clinical Nurse Specialist</b></p> <ul style="list-style-type: none"> <li>• May manage selected patient populations independently or inter-dependently with oncologists*</li> </ul> <p><b>b) Nurses involved in the management of outpatients within and between clinic visits</b></p> <ul style="list-style-type: none"> <li>• Monitor and intervene for side effects and reactions, and provide supportive care. Receive standardized training for symptom assessment (e.g., COSTaRS).+ For additional information, please <a href="#">see Appendix 1 #40.</a></li> <li>• Oriented to and practicing according to: CCO Telephone Practice Guidelines (expected date of publication - Summer 2019) and <a href="#">CCO Safe Handling of Cytotoxic Agents Standards*</a></li> </ul> <p><b>c) Nurses involved in the administration of systemic treatment</b></p> <ul style="list-style-type: none"> <li>• All RNs administering systemic parenteral therapy to patients affected by cancer, regardless of setting, should be certified which includes completion of standardized education through the recognized de Souza Provincially Standardized Chemotherapy and Biotherapy course or Oncology Nursing Society (ONS) Chemotherapy/Biotherapy Certificate equivalent course.+</li> <li>• Receive central venous access device management education and selection, certification with annual updates.*</li> <li>• Receive training and recertification on the use of infusion pumps.+ For additional</li> </ul>

<p>information, please see <a href="#">Appendix 1 #18 and #32</a>.</p> <ul style="list-style-type: none"> <li>• Receive orientation to and practice according to: <a href="#">CCO Safe Handling of Cytotoxic Agents Standards</a>, <a href="#">Safe Administration of Systemic Cancer Therapy Part 2: Administration of Chemotherapy and Management of Preventable Adverse Events</a></li> </ul>
<p><b>Pharmacists</b></p> <ul style="list-style-type: none"> <li>• Review and verify systemic treatment orders and supervise the preparation and dispensing of systemic treatment.*</li> <li>• ICP pharmacists provide support to allow consultation from other systemic treatment delivery centres in the region.*</li> <li>• Manage or delegate the new drug funding program reimbursement process.*</li> <li>• Provide patient education related to planned systemic treatment using a multi-disciplinary approach with nurses and physicians.</li> <li>• Manage or delegate dispensing and documentation of clinical trials.</li> <li>• Participate as a representative on the RSTP committee, if requested or nominated.+ All pharmacists working primarily with patients and families with cancer in the RCPs (level 1-3) should obtain certification from a recognized program such as the Board of Pharmacy Specialties (e.g., Board Certified Oncology Pharmacist [BCOP]) or the University of Toronto's Oncology Program for Pharmacists (Advanced Oncology program) by their 5<sup>th</sup> year of practice.</li> <li>• All pharmacists working in satellite sites (level 4) should complete the University of Toronto's Oncology Program for pharmacists (Essentials of Oncology and Advanced Oncology Programs) by their 5<sup>th</sup> year of practice or have access to a pharmacist who has oncology certification. For additional information, please see <a href="#">Appendix 1 #43 and #46</a>.</li> <li>• Dedicated oncology pharmacists provide clinical services at levels 1-3 centres with access to a dedicated oncology pharmacist available at level 4 centres.*</li> </ul>
<p><b>Pharmacy Technician</b></p> <ul style="list-style-type: none"> <li>• Prepare systemic treatment under supervision of a pharmacist or compounding supervisor.*</li> <li>• Receive specialized training in the preparation of systemic treatment doses.* For additional information, please see <a href="#">Appendix 1 #43, #44 and #48</a>.</li> <li>• Dispense and document for clinical trials.*</li> <li>• Receive training or certification program for staff involved in the handling of cytotoxic agents with policy on re-training. This may be done at or in collaboration with an ICP or affiliate institution and in compliance with NAPRA Model Standards for Sterile Preparation of Hazardous Drugs.*</li> </ul>

### III. Standards for Quality Assurance and Safety

- Ensure that there is sufficient patient volume at the location to maintain competency and skills of professional healthcare providers to address the acuity and

complexity of the treatment modalities and/or to provide cost-effective use of resources and drugs (e.g., shared care program or collaboration with another program).\*

- Facilities that have staff that see a lower volume of cancer patients should have an education and training plan to ensure competency of nurses, pharmacists and pharmacy technicians.\*\*
- The number of patients that can be treated will be determined by the complexity of treatment regimens.\*
- Staffing resources must be sufficient to provide safe quality care at all times, including during vacation, illness, etc.\*
- Cancer care includes the management of symptoms and complications of therapy and oncological emergencies.\*
- Follow regulatory guidelines and standards for the safe handling and disposal of hazardous drugs including personal protective equipment and training for staff who are handling systemic treatment or waste.\* For additional information, please see [Appendix 1 #25.](#)
- Centres have policies and educational programs available for all staff involved in systemic treatment including storage, transport, spill management, preparation, administration, and waste disposal.\* For additional information, please see [Appendix 1 #26,#28-30, #34-39, #41, and #45.](#)
- Track of incidents and near misses with a review and system improvement process. Share learnings within the RSTP and at provincial forums (e.g., ReQSN, STIL Committee). Consider reporting to provincial and national databases (e.g., NSIR). For additional information, please see [Appendix 1 #27.](#)
- Participate in MCCs as per CCO standards.\* For additional information, please see [Appendix 1 #22.](#)
- Track and actively manage quality indicators including volume of patients treated, wait times, MCC attendance, proportion of non-evidence-informed regimens, patient experience measures, and adherence to guidelines.\*

## DEFINITIONS

**Advanced Practice Nurse** - The Advanced Practice Nurse has a Master's level education (MN, MSc or equivalent) education. Ideally, the graduate program would be focused in oncology nursing, likely with a particular emphasis on a subpopulation or area within cancer control such as prevention, screening, and counselling or a theme within cancer care such as coping, psychosocial care, and counselling. Theoretical knowledge in nursing and other sciences grounds the nurse in the advanced provision of care to patients, their families, and the communities within which cancer care is given. Additional certification as a Registered Nurse (Extended Class), or other levels, may be acquired either within the Graduate Program or through a post-graduate course and certification. The domains of the Advanced Practice Nurse include the following:

- advanced clinical practice
- education
- research
- scholarly/professional leadership
- organizational leadership [1]

**Certification in Systemic Treatment Administration (*Certified in Systemic treatment*)** - No registered nurse in Ontario should administer intravenous systemic treatment until and unless she/he has received additional education and has demonstrated competency in the delivery of these systemic treatment agents. This requirement is specific to the delivery of systemic treatment and is not to be confused with the national examination process for Certification as an Oncology Nurse through the Canadian Nurses Association.

**Complexity** - Determined by the preparation and administration requirements for systemic treatment, risk of immediate grade 3/4 toxicities, medical condition of the patient, or use of investigational agents or new agents just approved for which there are little long-term toxicity data.

**ICP: Integrated Cancer Program** - A multidisciplinary in and out-patient cancer program including medical, radiation, and surgical oncology. The ICP also provides research, education and organizational leadership for the RCP.

**Institutional Facilities** - Hospitals, clinics, or offices as outlined in the facility requirements element.

**Local Health Integration Networks (LHINs)** - The purpose of these regional health districts is to build a system that is focused on the needs of the local community and provides integrated, safe, and high-quality services to meet those needs.

**Regional Cancer Program (RCP)** - Links together cancer providers and organizations across the spectrum of cancer care.

**Regional Systemic Treatment Program (RSTP)** - An agreed-upon relationship among satellites, affiliates, and ICPs.

**Medical Oncologist** - A physician with subspecialty training in the administration of systemic treatment recognized by the Royal College of Physicians and Surgeons of Canada, including medical oncologists, hematologists and gynecologic oncologists.



**Psychosocial Oncology (PSO)** - A specialty in cancer care concerned with understanding and treating the social, psychological, emotional, spiritual, quality-of-life, and functional aspects of cancer, from prevention through bereavement. It is a whole-person approach to cancer care that addresses a range of human needs that can improve quality of life for people affected by cancer. Specialized PSO disciplines include social work, psychiatry, psychology, registered dietitians, physical therapy, occupational therapy, and spiritual care.

**Quality Indicator** - A specific, measurable, attainable, relevant, time-framed outcome from the patient, organizational, or system perspective to assess performance.

**Specialized Oncology Nurse** - A nurse who has a combination of expanded education focused on cancer care and experience such as two years in a setting where the primary focus is cancer care delivery. The Specialized Oncology Nurse might acquire specialty education through a variety of ways, such as enrolment in an undergraduate nursing program, completion of an Oncology Certificate Program, distance specialty education (e.g., Adult and Pediatric Oncology Nursing), or registration in and completion of the certification exam offered by the Canadian Nurses Association and attainment of the distinction Certified in Oncology Nursing Canada CON(C).

The Specialized Oncology Nurse works in a specialized inpatient setting such as an oncology unit or bone marrow transplant unit, an ambulatory setting focused on the delivery of cancer care; a screening program, or a supportive care setting or community setting offering palliative care. There are many environments where the enhanced specialty knowledge and skill of the nurse can be utilized to manage symptoms and side effects of treatment, counsel patients in coping strategies, teach self-care behaviours, and monitor the responses to treatment and interventions. [1]

**Systemic Treatment** - Any oral or parenteral anticancer agent including but not limited to hormonal, biological, immunotherapeutic, or chemotherapeutic, agents.



# **Regional Models of Care for Systemic Treatment: Standards for the Organization and Delivery of Systemic Treatment**

## **Section 2: Evidence Summary**

### **INTRODUCTION**

Cancer is a major cause of morbidity and mortality and the leading cause of potential years of life lost in Canada. It is estimated that 206,200 new cancer diagnoses and 80,800 deaths from cancer occurred in Canada in 2017. In Ontario alone, 80,700 new cases were diagnosed. Increased demands for cancer services are related to annual incidence increases of 2% [2]. Medical oncology consultations are increasing 10% to 20% annually. Systemic treatment has increased at an annual rate of 7% to 10%, a growth related to the continuing introduction of new evidence-based therapies that improve survival and quality of life [3], and newer treatments in development [4]. These new treatments, which are often more complex than those they replace, are delivered for longer periods as the survival time with chronic malignant disease increases. Furthermore, the complexity of care, increased patient expectations, and the influence of information available on the Internet all result in more time being spent with the average patient.

Continuing shortages of clinicians with the required skills contribute to the difficulty of finding and filling new oncology positions [3]. The 2017-2018 Canadian Post-M.D. Education Registry (CAPER) revealed that there are only 82 medical oncology residents for the entire country [1]. Meanwhile, increasing numbers of physicians are reaching retirement age, and retirements are expected to accelerate, particularly in rural areas [5]. Fortunately, this is not predicted to significantly affect physician supply [5]. New and expanded cancer treatment facilities have closed the gap between demand and capacity. Additionally, building and equipping cancer facilities remains one of CCO's primary objectives in order to keep up with the increasing incidence of cancer [6]. The implementation of healthcare restructuring and an increased reliance on alternate healthcare providers such as nurse practitioners and family physicians may pose recruitment problems in some geographic regions. A national report from the Canadian Institute for Health Information [7] suggested that Canada experienced the slowest growth in the nursing workforce in a decade from 2016 to 2017. In the face of these changes, Ontario needs to devise innovative ways to deliver safe and effective systemic treatment for people with cancer. The risks of not pursuing a revised and sustainable model of systemic treatment delivery include the adoption of ad hoc and inconsistent local solutions, the cessation of service in some jurisdictions, and inequalities in access to and standards of care.

Building on the original 2007 version of this document and the new standards that were developed by the STP, additional elements were identified that were not formerly addressed. The RSTP Working Group developed this evidentiary base to identify additional sources of information relevant for the purpose of providing guidance.

### **RESEARCH QUESTION**

What is the best way to organize the delivery of ambulatory systemic treatment in Ontario? Specifically, what has been published or implemented in other jurisdictions that can inform the following aspects of delivery of systemic treatment:

- 1) Safe delivery of systemic treatment
  - Staff numbers to safely deliver systemic treatment (double checks, volumes of oncology patients per nurse, volumes of systemic treatment doses/patients prepared per pharmacy technician, volumes of systemic treatment doses/patients verified per oncology pharmacist)
  - Validated teaching tools for oral systemic treatment
- 2) Requirements of health care providers to be sufficiently skilled and maintain competency (volume of oncology patients per nurse, volume of systemic treatment doses/patients prepared per pharmacy technician, volume of systemic treatment doses/patients verified per pharmacist)
- 3) Health care providers and their roles
  - The role of oncologists/hematologists, general practitioners in oncology, and nurse practitioners in prescribing systemic treatment

## METHODS

This guideline was developed by the RMCSTP GDG - (Appendix 3), which was convened at the request of the Systemic Treatment Program. The project was led by a small Working Group of the RMCSTP GDG, which was responsible for reviewing the evidence base, drafting the guideline recommendations, and responding to comments received during the document review process. The Working Group had expertise in oncology pharmacy, medical oncology, hematology and oncology nursing. Other members of the RMCSTP GDG served as the Expert Panel and were responsible for the review and approval of the draft document produced by the Working Group. Conflict of interest declarations for all GDG members are summarized in Appendix 3, and were managed in accordance with the [PEBC Conflict of Interest Policy](#). Please see Appendix 4 for an overview of the Guideline Methods.

This evidence review was conducted in three planned stages, which comprised searches for existing guidelines, published literature, and environmental scan. The aim was to find evidence for volume numbers to safely deliver systemic treatment, validated teaching tools for oral systemic treatment, requirements for health care providers to be sufficiently skilled and maintain competency, and the prescribing roles of health care providers.

### Search for Existing Guidelines and Standards

A search for existing guidelines is generally undertaken prior to a search for systematic reviews and primary literature. This is done with the goal of identifying current guidelines or standards as a source of information of what other organizations or services are recommending or suggesting. For this project, the following databases were searched for guidelines that addressed the research questions: the Standards and Guidelines Evidence Directory of Cancer Guidelines (SAGE), Agency for Healthcare Research and Quality (AHRQ) National Guideline Clearinghouse, and the Canadian Medical Association Infobase. Websites of the following guideline developers were also searched: National Institute for Health and Care Excellence (NICE), Scottish Intercollegiate Guidelines Network (SIGN), American Society of Clinical Oncology (ASCO), National Health, Medical Research Council - Australia, Australia Clinical Practice Guidelines Portal, and Cancer Council Australia - Cancer Guidelines Wiki. MEDLINE and EMBASE were search for guidelines for the period of 2006 to September 2018 (Appendix 3). Guidelines or standards were considered potentially relevant if they were based on a systematic review and relevant to the guidelines objectives and research questions. Only English language evidence-based guidelines less than five years old were considered. Three guidelines/standards were found: Clinical Oncology Society of Australia (COSA) [8], Spanish Society of Hospital Pharmacy/Spanish Society of Oncology Nursing/the Spanish Society of Medical Oncology [9],

and American Society of Clinical Oncology/Oncology Nursing Society [10]. Endorsement was not feasible as none specifically addressed our research questions however, they were used as a source of information of what other organizations or services in other jurisdictions are recommending or suggesting.

### Search for Published Literature

A literature search strategy (Appendix 5) was developed and conducted using Cochrane Library, MEDLINE, EMBASE and HealthStar databases for the period of June 2006 to November 2018. The search included guidelines, systematic reviews, and primary studies. Systematic reviews were evaluated based on their clinical content and relevance prior to screening the primary studies. Systematic reviews published as components of practice guidelines) were also considered. Systematic reviews and primary studies were included if they met the following criteria: (i) addressed one of the objectives of the guideline and (ii) published between June 2006 and November 2018. Article reference lists were also searched for evidence relevant to this guideline.

### Environmental Scan

The environmental scan involved reviewing sources related to the objectives of the guideline. In addition to searching within Canada, organizations in the United Kingdom (UK), Australia, and New Zealand were also searched as those countries have health care systems that most closely reflect those in place in Canada. The following Web sites were searched:

***Other provincial cancer agencies in Canada:*** Alberta Cancer Board, British Columbia (BC) Cancer Agency, Cancer Care Manitoba, Cancer Care Nova Scotia (CCNS), Newfoundland Cancer Treatment and Research Foundation, and Saskatchewan Cancer Agency.

***National cancer agencies (United Kingdom, Australia, and New Zealand):*** The Cancer Council Australia, The Collaboration for Cancer Outcomes Research and Evaluation, National Cancer Control Initiative , New Zealand Cancer Control Strategy, New Zealand Cancer Control Trust, Regional Cancer Centre Waikato Hospital, State Government of Victoria (Australia), Peter MacCallum Cancer Centre, Medical Oncology Group of Australia, Cancer UK, Cancer Services Collaborative, Avon Somerset and Wiltshire (UK), Cancer Services Collaborative National Health Service, Modernisation agency, and UK National Health Service.

***Canadian Organizations:*** The Canadian Association of Provincial Cancer Agencies, Canadian Association of Medical Oncologists, Canadian Intravenous Nurses Association, Canadian Association of Nurses in Oncology, Canadian Society of Surgical Oncology, Canadian Patient Institute , Institute for Safe Medication Practices Canada, Ontario College of Pharmacists , Ontario Pharmacists Association, Canadian Pharmacists Association, Neighbourhood Pharmacy Association of Canada, Canadian Cancer Society, CanCertainty Coalition, Canadian Society of Hospital Pharmacists, Canadian Association of Pharmacy in Oncology, Canadian Association of Pharmacy Technicians, Institute for Safe Medication Practices Canada, CCO (Systemic Treatment Program & PDRP), and Canadian Council on Continuing Education in Pharmacy

***Ontario Public Drug Programs:*** Patients for Patient Safety Canada, Ontario Hospital Association, College of Physicians and Surgeons of Ontario, Innovative Medicines Canada and Health Quality Ontario

References from identified documents were also searched. Given the breadth of the information identified by this approach, the selection of documents focused on reports from

jurisdictions that were generalizable to Ontario. These included jurisdictions having a government-funded universal health care system with regional rather than hospital-based models of systemic treatment delivery.

### **Study Selection Criteria and Process**

A review of the titles and abstracts and subsequent full-text review (if warranted) was conducted by one reviewer (LDDA). If uncertainty existed, a second reviewer (LF) reviewed the studies. Studies, reports and standards published between June 2006 and November 2018 were included if they provided evidence on safe delivery of systemic treatment (e.g. staff numbers to safely deliver systemic treatment; teaching tools for oral systemic treatment); health care providers requirements to be sufficiently skilled and maintain competency; and the role of oncologist/haematologist, general practitioners in oncology, and NPs in prescribing systemic treatment). Articles were excluded if they were published in a language other than English, as translation services were not available.

### **Data Extraction**

All included reports/studies underwent data extraction by LDDA with all extracted data and information audited subsequently by an independent auditor.

### **Synthesizing the Evidence**

Due to the nature of the evidence and heterogeneity of data, a meta-analysis was not planned.

## **RESULTS**

An overview of the documents deemed eligible for inclusion is presented in Table 2-1. Documents were categorized by the research question to which they pertained and are described in further detail below.

A total of 2875 studies were identified in the published literature search. Thirty-two were selected for full-text review. Of those, five met the pre-defined eligibility criteria for this systematic review [8,10-13]. A total of 58 reports were identified through the environmental scan. Thirty-one were selected for full-text review. Of those, seven documents from six institutions and regions met the inclusion criteria [14-20]. The majority of excluded articles were ineligible because they did not address a study question. Overall, the quality of evidence was low to moderate as no randomized controlled trials and few systematic reviews or primary studies were found. The majority of documents consisted of reports providing standards on how to safely and effectively deliver cancer services in the community. Few of the documents reported on the evidence found and limited information was provided in standards documents.

Table 2-1: Documents eligible for inclusion.

	Published Literature		Environmental Scan							
			Canada		United Kingdom		Australia		New Zealand	
	Number	Ref ID	Number	Ref ID	Number	Ref ID	Number	Ref ID	Number	Ref ID
Staff number to safely deliver systemic treatment	1	[8]	2	[14,16]	1	[18]	1	[20]	0	
Teaching tools for oral systemic treatment	2	[11,12]	1	[19]	0		0		0	
Health care providers requirements to be sufficiently skilled and maintain competency (volumes per pts)	0		1	[16]	0		0		0	
Health care providers and their prescribing roles	3	[8,10,13]	4	[14-17]	0		0		0	

## Outcomes

### *1. Staff numbers to safely deliver systemic treatment (double checks, volumes of oncology patients per nurse, volumes of systemic treatment doses/patients prepared per pharmacy technician, volumes of systemic treatment doses/patients verified per oncology pharmacist).*

One guideline systematic review and two reports described double checks and the safe delivery of systemic treatment (Table 2-2). The COSA guideline recommends that at point of administration, two independent RNs with appropriate training and skills should check the medication order and systemic treatment, targeted therapy, and related medications [8]. Cancer Care Eastern Health also states that two clinicians (nurses, physicians or pharmacists) are to independently verify information on the label at the start and once again verify the final product label [14]. In Nova Scotia, the basic level hospital (i.e. systemic treatment with minimal risks) should have at least one chemotherapy-certified RN available during the administration of systemic treatment and a sufficient number of staff for appropriate double checking [16]. In intermediate level hospitals (i.e., systemic treatment with moderate risks), there must also be sufficient professional staff available for appropriate double checking [16].

One report described volumes of oncology patients per nurse and the safe delivery of systemic treatment (Table 2-2). CCNS reported that at the basic and intermediate-level hospitals, there should be at least two chemotherapy-certified RNs to safely deliver systemic treatment and they should not be assigned to other responsibilities [13]. At the advanced level (i.e., higher risk associated with administration), there should be adequate numbers of chemotherapy-certified RNs to support all order verification and drug needs. There should also be adequate numbers of oncology nurses and CNSs/nurse educators to provide full nursing services for inpatients and outpatients.

One guideline systematic review and three reports described volumes of systemic treatment doses/patients verified per oncology pharmacist and the safe delivery of systemic treatment (Table 2-2). CCNS specified that at the basic and intermediate-level hospitals, there should be at least one hospital pharmacist with oncology training, at least one other hospital pharmacist with basic oncology pharmacy training, and a minimum of two staff for additional coverage who have successfully completed the chemotherapy preparation course [16]. At advanced level hospitals, there should be at least one oncology pharmacist and adequate hospital pharmacists with oncology training to provide full clinical service for both inpatients and outpatients [16]. In order to support all chemotherapy order verification and drug preparation, there should also be adequate numbers of oncology pharmacists and hospital pharmacists with oncology training at the advance level hospitals [16]. Similarly, the COSA guideline indicated that adequate staffing resources should permit a pharmacist to verify all orders and prescriptions without distractions and interruptions [8]. When supported by adequate staffing resources, a second pharmacist with appropriate training and competence should perform independent checks [8]. The British Oncology Pharmacy Association (BOPA) reported that there should be a minimum of 1.2 whole time equivalent (WTE) oncology-trained pharmacists per 25 inpatient oncology beds or 15 inpatient level II-IV hematology beds [18]. Another report mentioned that for hematology/medical oncology related group/bed types, there should be one full time equivalent (FTE) pharmacist for clinical pharmacy service (5 days/week) per 15 beds and for chemotherapy services, one FTE pharmacist for clinical pharmacy service (5 days/week) per 20 beds [20].

Table 2-2. Staff numbers to safely deliver systemic treatment

Report (reference)	Double Checks	Nurses	Pharmacy Technician	Oncology Pharmacist
<b>Published Literature</b>				
Clinical Oncology Society of Australia [8]	At administration, 2 independent RNs with appropriate training and skills should check medication order			When staffing resources allow, 2 pharmacists with appropriate training and competence should verify all orders and perform independent check.
<b>Environmental Scan</b>				
BOPA [18]			Min. of 1.2 WTE oncology accredited pharmacy technician per 30 ambulatory SACT attendances	Min. of 1.2 WTE oncology trained pharmacists per 25 inpatient oncology beds or 15 inpatient level II-IV hematology beds
Cancer Care Eastern Health [14]	At administration, 2 clinicians (nurses, physicians, pharmacists) are to independently verify info on the label and also verify final product label against original label.			
Cancer Care Nova Scotia [16]	<i>Basic level:</i> If only 1 chemo certified RN is available, there must be sufficient staff available for chemo double checking <i>Intermediate level:</i> there must be sufficient professional staff available for appropriate chemo double-checking	<i>Basic level:</i> Min 2 chemo certified RNs. During administration, RN will not be assigned to other responsibilities. <i>Intermediate level:</i> Min 2 chemo certified RNs in chemo unit at all patient care times. <i>Advance level:</i> Adequate numbers of chemo certified RNs to support all chemo order verification and drug needs. Adequate number of oncology nurses/clinical nurses/ nurse educators for inpatient/outpatient nursing services	<i>Advanced level:</i> Adequate number of pharmacy technicians (who have successfully completed the Chemo Preparation Course) to support all chemo order verification and drug preparation	<i>Basic/Intermediate level:</i> Min 1 oncology trained hospital pharmacist and min 1 other hospital pharmacists with basic oncology training. Min 2 staff that completed chemo prep course for coverage. <i>Advanced level:</i> Adequate numbers of oncology pharmacist and oncology trained hospital pharmacists to support all chemo order verification, drug preparation and to provide full clinical service for inpatients/ outpatients. <i>Specialized level:</i> Min 1 oncology pharmacist to provide full clinical service for appropriate sub specialty areas
Society of Hospital Pharmacists of Australia [20]				For hematology /medical oncology service-related group/bed type, 15 beds to 1 FTE pharmacist for clinical pharmacy services 5 days/wk. For chemo services, 20 beds to 1FTE pharmacist for clinical pharmacy services 5 days/wk.

Abbreviations: BOPA: British Oncology Pharmacy Association; chemo: chemotherapy; FTE: Full time equivalent; info: information; min: minimum; prep: preparation; RN: registered nurse; SACT: Systemic Anti-Cancer Therapy; WTE: whole time equivalent. Wk: week

Two reports described volumes of systemic treatment doses/patients prepared per pharmacy technician (Table 2-2). The CCNS suggested that an adequate number of pharmacy technicians should be available to support chemotherapy order verification and drug preparation [16]. BOPA reported that there should be a minimum of 1.2 WTE oncology accredited pharmacy technicians per 30 patients receiving systemic treatment [18].

## ***2. Validated teaching tools for oral systemic treatment***

Three reports on one validated teaching tool for oral systemic treatment were included [16,18,19]. Kav et al. developed the MOATT for patients receiving oral agents for cancer [12,19]. The aim of this tool is to assist healthcare providers worldwide to assess and teach patients about oral cancer treatment [12]. In a recent quasi-experimental study at two hospitals, patients receiving oral agents for cancer treatment were educated using the MOATT and were found to have increased medication adherence and self-efficacy [11].

## ***3. Requirements for health care providers to be sufficiently skilled and maintain competency (volume of oncology patients per nurse, volume of systemic treatment doses/patients prepared per pharmacy technician, volume of systemic treatment doses/patients verified per pharmacist)***

Many reports provided general information that a provider in the health care setting should be educated, trained and receive an annual competency validation, however, no reports were found that provided information on volume of systemic treatment doses/patients prepared per pharmacy technician, or volumes of systemic treatment doses/patients verified per pharmacist.

## ***4. The role of oncologists/hematologists, general practitioners in oncology, and nurse practitioners in prescribing systemic treatment***

In total, seven reports described healthcare providers' roles in prescribing systemic treatment (Table 2-3). Five reports mentioned that the oncologist/hematologist may prescribe systemic treatment, indicating that the treatment order should be written/signed by the oncologist/oncologist delegate [14,16] and in accordance with the plan developed by the most responsible physician [15]. General practitioners in oncology who are appropriately qualified and competent may also prescribe systemic treatment [10,13-15]. Few of the reports specified that a general practitioner in oncology should only prescribe under the supervision of a medical oncologist/hematologist for systemic treatment orders [8,17], oral therapy specifically [8] or in accordance with the plan developed by the most responsible physician [15,17]. Responsible physicians with a special interest in oncology could also prescribe under the direction of an oncologist, but only after completion of education/orientation as defined by Oncology Education for Physician Working Group [14]. In BC, associates in oncology, and medical oncology/hematology residents and fellows in training may also prescribe in accordance with the treatment plan [15]. Few reports also mentioned that nurse practitioners may prescribe systemic treatment under the supervision of an oncologist [16,17] or with a collaborative practice agreement that allows for prescribing [16]. BC Cancer specified that an NP who has completed the General Practitioner in Oncology course (didactic and practicum) may prescribe medications within the scope, limitations, restrictions, and conditions for prescribing set by the College of Registered Nurses of BC and federal or provincial regulation [15]. An NP may prescribe the second and subsequent cycles for cancer drug treatments of a BC cancer chemotherapy protocol [15].



Table 3-3. Health care providers and their prescribing roles

Report (reference)	Oncologist/Hematologist	General Practitioner in Oncology	Nurse Practitioners
<b>Published Literature</b>			
Clinical Oncology Society of Australia [8]	Clinicians with appropriate skills, training, and qualifications in the management of care	Should only prescribe under the supervision of a medical oncologist/hematologist and should not prescribe oral therapy unless directed by the patient's oncologist or hematologist	
Neuss et al. [10]		Orders for chemo are signed manually or by using electronic approval by licensed independent practitioners who are determined to be qualified by the health care setting	
Scottish Government (NHS)[13]		Appropriately qualified, competent practitioner, as defined by local policy may prescribe	
<b>Environmental Scan</b>			
BC Cancer [15]	Medical oncologists, hematologists, gynecological oncologists, associates in oncology, GPO, and medical oncology or hematology residents and fellows in training may prescribe cancer treatments in accordance with the plan developed by the most responsible physician. Similarly within the Community Oncology Network, medical oncologists, hematologists, and GPOs may prescribe in accordance with the treatment plan.		If completed the GPO course (didactic and practicum), may prescribe medications within the scope, limitations, restrictions and conditions for prescribing set by the College of Registered Nurses of BC and federal or provincial regulation. For cancer drug treatments, may prescribe for second and subsequent cycles of a BC Cancer chemo protocol.
Cancer Care Eastern Health[14]	May prescribe chemotherapy	Cancer Care Program GPO may prescribe. Responsible physicians with a special interest in Oncology may prescribe under the direction of Oncology, only after they complete education/orientation as defined by Oncology Education for Physicians Working Group.	
Cancer Care Nova Scotia [16]	At basic and intermediate level hospital, systemic therapy should be ordered only by or in documented consultation with an oncologists.		At basic/intermediate/advanced level hospitals, nurse practitioner (or clinical associate) from the consultant oncologist's practice may prescribe, if practicing under oncologist supervision and with a collaborative practice agreement that allows for prescribing.
Cancer Care Nova Scotia [17]	Orders are written and signed by an Oncologist/Community Specialist /Oncologist Delegate	Can be designated as oncologist delegate and can prescribe under the supervision of an oncologist.	Can be designated as oncologist delegate and can prescribe under the supervision of an oncologist.

Abbreviations: chemo: chemotherapy; GPO- general practitioner in oncology; NHS: National Health Service

## DISCUSSION

In 2007, the original version of this guideline provided a framework to integrate the delivery of systemic treatment services and ensure all patients and families receive the same standard of care. This structure allowed centres to share best practices and has been pivotal in elevating the quality of care across the province. The purpose of this update is to include new elements of best practice and also to provide a list of the quality recommendations published over the past several years. The updated guideline builds upon the original 2007 version and introduces revised standards for the delivery of services from two sources. The STP produced a consolidated list of standards through a modified Delphi consensus process and the RMCSTP GDG Working Group (PEBC) used an evidence based search and expert opinion to advise on questions related to optimal volumes for safety and competency, teaching tools, and provider roles.

Additional elements were identified that were not addressed in the original guideline or in the STP standards. These included the staff numbers to safely deliver systemic treatment; validated teaching tools for oral systemic treatment; the requirement for health care providers to be sufficiently skilled and maintain competency; and the roles of oncologists/hematologists, general practitioners in oncology, and NPs in prescribing systemic treatment. An updated evidence search was conducted by the PEBC to identify additional sources of information relevant to these areas for the purpose of providing guidance. The RMCSTP GDG examined the modest evidence that was available from the published literature and an environmental scan in conjunction with expert opinion to reach consensus.

With respect to staff numbers to safely deliver systemic treatment, the area of double checks was investigated. From the modest evidence, it was stated that there must be at least two independent RNs [8] or clinicians (nurses, physicians or pharmacist) with appropriate training and skills for appropriate double checking[14], or if only one RN is available there should be sufficient staff for appropriate double checking [16]. We acknowledge that it may be difficult to have multiple chemotherapy-trained RNs at one site for double checks. In such cases, checks could be accommodated with one non chemotherapy-trained RN or by virtual independent checks.

No high quality evidence was found to indicate optimal numbers of patients or treatments per nurse. There was one report that indicated there should be at least two RNs with chemotherapy certification present during treatment delivery [16]. There was consensus within the Working Group that there is no clear evidence or standard on a specific ratio of nurse to patient but this may change over time as systemic treatment becomes more complex. The Working Group recommended considering a RIW, which was developed for use in quality based procedures for systemic treatment in Ontario. Similarly with pharmacy technicians and pharmacists, there is no specific recommendation pertaining to numbers of patients to provider volumes or of systemic treatment doses. As treatments become more complex or shift to more oral therapies and pharmacy technology evolves, the tasks involved in preparing treatments will change and a ratio of health care professional to number of treatments will become less relevant. We also recommend using an RIW tool in this setting.

Patient education is a crucial element of treatment safety. A search for evidence identified three reports on one validated teaching tool (MOATT) specifically for patients receiving oral therapies [11,12,19]. We have included recommendations for the elements of patient education as well the recommendation for a standardized tool with MOATT as a reasonable option.

We wanted to address concerns about how healthcare professionals can remain skilled and maintain competency. We searched for information on volumes of oncology patients per nurse, volume of systemic treatment doses/patients prepared per pharmacy technician, and volumes of systemic treatment doses/patients verified per pharmacist. There were no reports found that provided minimum volumes for competency and there was no general consensus among Working Group members how this might be quantified. As there was no evidence base or expert consensus, we elected to recommend an education plan to ensure competency in centres where there may be lower volumes of treatments.

Lastly, we examined the roles of oncologists/hematologists, general practitioners in oncology and NPs in prescribing systemic treatment. Five reports mentioned that oncologists/hematologists may prescribe systemic treatment, indicating that the prescription or order should be written/signed by the oncologist/oncologist delegate [8,14,16,17] and in accordance with the plan developed by the most responsible physician [15]. General practitioners in oncology who are appropriately qualified and competent may also prescribe systemic treatment [10,13-16]. Several reports mentioned that a general practitioner in oncology should only prescribe under the supervision of a medical oncologist/hematologist for systemic treatment orders [17] [8] or oral therapy specifically [8] or in accordance with the plan developed by the most responsible physician [15,16]. A few reports also mentioned that NPs may prescribe systemic treatment under the supervision of an oncologist [15,17] or with a collaborative practice agreement that allows for prescribing [16]. We have recommended that the medical oncologist/hematologist must recommend the treatment plan but that there are several practitioners that can prescribe the treatment.

In conclusion, the original 2007 guideline was essential in helping shape a network of quality care in the province. These updated guidelines provide additional evidence and information to support the standards of practice. Our expectation is that all people living with cancer will receive the same high quality of care and that centres across the province will continue to collaborate to provide those services. It is our hope that this document will serve as a tool to help our providers reach those goals.

#### RELATED PEBC GUIDELINES

- [Safe Handling of Cytotoxics](#)
- [Safe Administration of Systemic Cancer Therapy: Introduction and General Methods](#)
- [Safe Administration of Systemic Cancer Therapy Part 1: Safety During Chemotherapy Ordering, Transcribing, Dispensing, and Patient Identification](#)
- [Safe Administration of Systemic Cancer Therapy Part 2: Administration of Chemotherapy and Management of Preventable Adverse Events](#)
- [Computerized Prescriber Order Entry \(CPOE\) in the Outpatient Oncology Setting](#)
- [Patient Safety Issues: Key Components of Chemotherapy Labelling](#)

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# Regional Models of Care for Systemic Treatment: Standards for the Organization and Delivery of Systemic Treatment

## Section 3: Internal and External Review

### INTERNAL REVIEW

The guideline was evaluated by the GDG Expert Panel and the PEBC Report Approval Panel (RAP) (Appendix 3). The results of these evaluations and the Working Group's responses are described below.

### Expert Panel Review and Approval

Of the five members of the GDG Expert Panel, five members cast votes for a total of 100% response in March 2019. Of those that cast votes, five approved the document (100%). The main comments from the Expert Panel and the Working Group's responses are summarized in Table 3-1.

**Table 3-1. Summary of the Working Group's responses to comments from the Expert Panel.**

Comments	Responses
1. Concern with Appendix 1, pumps and equipment #32 falling under "very high" due to the definition of must be in place immediately at time of evaluation. This will have a potentially large impact to centres that are not currently doing this but following the independent double check process using nursing and pharmacy, but not IDC at time of administration.	We have decided to leave it as "very high" as these are accreditation standards.
2. Suggest changing wording (highlighted in italics) of Appendix 1 #35 to : "Spiking of bags and priming of tubing should occur before the addition of the hazardous drug if a closed system <i>transfer device is not being used</i> or unless the clinical protocol requires otherwise. The use of a closed system transfer device may reduce contamination. A risk assessment should be performed if deviating from this practice. If priming occurs <i>at the location of administration</i> , prime intravenous tubing with a fluid that is compatible to but does not contain the systemic treatment <i>medication</i> or by using the backflow method	We have revised it to: "Spiking of bags and priming of tubing should occur before the addition of the hazardous drug if a closed system cannot be established or unless the clinical protocol requires otherwise. The use of a closed system transfer device may reduce contamination. <i>Attaching the tubing to the spike port is acceptable after the hazardous drug has been added. A risk assessment should be performed if deviating from this practice.</i> If priming occurs outside of a closed system environment, prime IV tubing with a fluid that is compatible to but does not contain the systemic treatment <i>medication</i> or by using the backflow method."
3. Patient Education Standard Point 1: Can this also be provided by electronic means (iPad presentation) when resources require?	We have left it as it. 'Written' encompasses electronic presentations.
4. Medical Support Services Point 8: This might be practical when a 3 <sup>rd</sup> party pharmacy is in place within a medical campus but is far less practical when we consider mid-large size cities. At that level, it is a provincial project/mandate.	We have left it as it. This is future work that will be done to improve the quality and safety of take home cancer drugs.
5. Medical Oncologist/Hematologist Point 6 - Consider deleting, because it is redundant.	Prefer original wording.

6. Medical Oncologist/Hematologist Point 8 and General Practitioner in Oncology Point 9:- Consider changing to “curable patients within 30 days of treatment”. Patients unfortunately die of their disease frequently while on treatment and we need to be practical.	Prefer original wording.
7. General Practitioners in Oncology (GPO): Point 3- consider changing example “dose alteration” to “changes in regimen”. For dose alterations, many trust the experience of the GPO. If the GPO is to be an extender of the oncologist, we need to consider trust and ability, just as we work to add other health care members (eg APN’s).	We have removed the example of dose alteration.
8. Appendix 1: Rather than repeating so much of what was done above, is it not possible to code priority and simply embed it in the above recommendations?	Prefer original wording. This was a separate process.
9. STP Standards #43: This should include language around the “delegation of compounding with appropriate education and training where resources don’t exist	We have added the delegation statement to the beginning of Appendix 1.
10. There are many references regarding physician support when chemotherapy is administered. Some standards states that the physician should be on-site and other areas state available within 15 minutes. This should be consistent in the document.	Prefer original wording.
11. Standards on M&M Rounds-these rounds are challenging within the regional centres along with the collection of patient survival/outcome data as the regional centre is not always notified when a patient has died.	Prefer original wording.
12. Pharmacist, Point 1: Within our centre and other centre this would be the compounding supervisor not the pharmacist.	We have modified the statement to include compounding supervisor.
13. Pharmacy technician Point 1: This would be under the supervision of the compounding supervisor within our centre and some other centres.	Prefer original wording.

### RAP Review and Approval

Three RAP members, including the PEBC Director, reviewed this document in March 2019. The RAP approved the document on April 10<sup>th</sup>, 2019. The main comments from the RAP and the Working Group’s responses are summarized in Table 3-2.

**Table 3-2. Summary of the Working Group’s responses to comments from RAP.**

Comments	Responses
1. The reviewer provided feedback on how to make document more concise, particularly as it relates to the representation of the scarce and poor quality evidence base.	We have considered the reviewers feedback on how to make the document more concise and have made such changes.

2. Consider removing * + and ** to simplify things from standards table in section 1. Also, when it says please see Appendix X and it's the exact same thing, consider removing them.	We have considered your suggestion but have decided to leave the * + and ** for transparency. We have removed duplicate references to Appendix X.
3. The core of the document is very focused on the term "oncologist" except for in Section 1 Part 2 Standards for health care providers; where the term medical oncologist/hematologist is used. Consider changing to oncologist. A stronger document would recommend the gynecological oncologist and others like them at any committees making decisions for chemotherapy delivery locally and provincially.	We have removed "medical".
4. Standards do not discuss "written consent for treatment"	This is an accreditation standard and this document is not meant to be comprehensive to include all
5. Page 7 - Administrative support: Should there be a statement that the leads should be given "protected time to deal with the tasks of these roles".	Prefer original wording.
6. Page 7 under clinical trials as it pertains to Pharmacy: does there need to be a comment about storage, labelling, tracking, etc., of investigational products.	Prefer original wording.
7. In all the listed health care personnel there is no comment about clerical staff or janitorial staff. Consider adding special training about disposal and cleaning of the chemotherapy suite and pharmacy for clerical/janitorial staff. It is sort of alluded to at the top of page 11 but this could be just referring to nursing and pharmacy.	Please refer to standards #25 and #41.

## EXTERNAL REVIEW

### External Review by Ontario Clinicians and Other Experts

#### *Targeted Peer Review*

Three targeted peer reviewers from Ontario who are considered to be clinical and/or methodological experts on the topic were identified by the Working Group. Three agreed to be the reviewers (Appendix 3). Two responses were received. Results of the feedback survey are summarized in Table 3-3. The main comments from targeted peer reviewers and the Working Group's responses are summarized in Table 3-4.

**Table 3-3. Responses to nine items on the targeted peer reviewer questionnaire.**

Question	Reviewer Ratings (N=2)				
	Lowest Quality (1)	(2)	(3)	(4)	Highest Quality (5)
1. Rate the guideline development methods.				1	1

2. Rate the guideline presentation.		1		1	
3. Rate the guideline recommendations.			1		1
4. Rate the completeness of reporting.				2	
5. Does this document provide sufficient information to inform your decisions? If not, what areas are missing?			1		
6. Rate the overall quality of the guideline report.				1	1
	Strongly Disagree (1)	(2)	Neutral (3)	(4)	Strongly Agree (5)
7. I would make use of this guideline in my professional decisions.			1		
8. I would recommend this guideline for use in practice.			1		1
9. What are the barriers or enablers to the implementation of this guideline report?	<p>Barriers: The extent of the recommendations may be a challenge but hard to avoid; lack of companion document to provide to the field which could codify the exact standards to be used in each organizations; not easy to navigate</p> <p>Enabler: document is laid out well and logical; very high, high, and medium priorities</p>				

\* One respondent did not respond to question 5 and 7.

**Table 3-4. Summary of the Working Group's responses to comments from targeted peer reviewers.**

Comments	Responses
1. Recommend that the standards be compared with other legal/regulatory/standards document to ensure that the recommendations and standards meet these legal and accreditation requirements. This would include but not be limited to Accreditation Canada, Ontario College of Pharmacists regulations, Ontario labour and safety laws, environmental laws etc. For example, ISMP (p. 36) is not a regulatory or accrediting agency. Accreditation Canada should be the reference point.	We have compared with other documents. For example, Standard 6.5 in Accreditation Canada (v12, 2018): "An organizational standard format is followed when ordering, labeling, and administering systemic cancer therapy medications. A format that is detailed, accurate, and intuitive to the process is used. Tallman lettering is used for look-alike/sound-alike medications. For an example, see ISMP guidelines." We have referenced ISMP as they recommend strategies based on best practices documented in the literature and learned via ISMP medication error reporting programs
2. Recommendations do not specify the different requirements for L1, 2,3,4 centres.	Recommendations apply to all levels
3. The standards interpose words like should or ideally instead of must. If these are standards then the authors should use directive statements.	The words "ideally" or "should" in the context of this document provides direction on best practice.
4. The document is not clear if the scope includes inpatients	These standards apply to any area where systemic treatment is administered
5. Page 1 scope - this does not relate to all patients receiving chemotherapy. This relates to Adult patients receiving chemotherapy	Changed to adult.
6. Page 6 - HHR section - assigning work is best done with some workload tool. Can this be	We have referenced the RIW tool for both nurses and pharmacists. We prefer to leave the standards

combined into one standard instead of various standards for professions? Nothing is noted about competence of staff	separate for the professions, where appropriate. Competence is addressed under training and education for providers.
7. Standard 38 - Suggested rewording for clarity: Each corporation must develop and maintain a list of hazardous drug products in compliance with Ontario College of Pharmacy regulations.	We prefer the original wording.
8. Standard 8 - BPMH. This should be done in context with what the AC standards say. BPMH and Med Rec currently is not needed for all chemotherapy patients. For our last accreditation (Nov 2018 with 2017 Standards) we were able to define when and for whom med rec is provide. We chose changes in chemo regimens as an important time of risk; but not every chemo administration.	Med rec may only be targeted to patients receiving selected ambulatory care that are at most risk and likely to benefit from it; however, BPMH should be done at every single visit for systemic treatment patients. Prefer original wording. Please refer standards 15.5.1, 15.5.2, and 15.5.3 in Accreditation Canada (v12, 2018): Upon or prior to admission, a Best Possible Medication History (BPMH) is generated and documented in partnership with clients, families, caregivers, and others, as appropriate; the BPMH is used to generate admission medication orders OR the BPMH is compared with current medication orders and any medication discrepancies are identified, resolved, and documented; and a current medication list is retained in the client record.
9. Standard 19 - is this a standard for all hospitals regardless of level? Level 4 centres are only defined as providing chemo administration and their scope does not include this	Patients should have access to all services but this may be a shared responsibility between sites.

### ***Professional Consultation***

Feedback was obtained through a brief online survey of healthcare professionals and other stakeholders who are the intended users of the guideline. All medical oncologists, haematologists, nurses, nurse practitioners, advanced practice nurses, and professionals with an interest in systemic treatment or chemotherapy in the PEBC database were contacted by email to inform them of the survey. Forty-two (26.6%) responses were received. Twelve stated that they did not have interest in this area or were unavailable to review this guideline at the time. The results of the feedback survey from thirty people are summarized in Table 3-5. The main comments from the consultation and the Working Group's responses are summarized in Table 3-6.

**Table 3-5. Responses to four items on the professional consultation survey.**

	<b>N=30</b>				
<b>General Questions: Overall Guideline Assessment</b>	Lowest Quality (1)	(2)	(3)	(4)	Highest Quality (5)
<b>1. Rate the overall quality of the guideline report.</b>			3	13	14
	Strongly Disagree (1)	(2)	(3)	(4)	Strongly Agree (5)
<b>2. I would make use of this guideline in my professional decisions.</b>	1		3	10	16
<b>3. I would recommend this guideline for use in practice.</b>			3	11	16
<b>4. What are the barriers or enablers to the implementation of this guideline report?</b>	Barriers: lack of a universal region-wide or province-wide CPOE system; lack of funding				



	<p>for required infrastructure e.g. NAPRA-compliant pharmacy production facilities; very small satellites are challenged with striking a balance between having enough staff to run the program and cover any absences/vacation and having enough work for the staff to maintain competency; resource limitations and support for oncologist and nurses.</p> <p>Enablers: strong linkages between ICP's and regional satellites are key to success; classifying standards as very high priority, high and medium;</p>
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**Table 5-6. Summary of the Working Group's responses to comments from professional consultants.**

Comments	Responses
1. Please remove mention of NCIC and update it with CCTG	We have updated it to CCTG.
2. It would be helpful if the Appendix links in the body of the report led directly to the number in the Appendix instead of the start of the Appendix.	We have modified the Appendix links in the body of the report to lead to the subheading associated with the number in the Appendix instead of the start of the Appendix.
3. The planned Ontario Health Teams changes could impact the loco-regional models that evolve, as consolidation of agencies and provincial services and programs would be expected to impact the organization of oncology services. Should a rider or special section be included, or should the guideline be held until implications of the new processes are known?	We do not have enough information at this time. The model should stay intact but the regions may change. We have removed references to CCACs/LHINs.
4. Which level includes pediatric cancer?	None. The target population for this document is adult patients with cancer who are receiving systemic treatment
5. P.4 - Level 1 (CCP) - radiotherapy techs? Isn't specific pathology/pathologists mandated for Level 1 CCPs eg. Hemato-pathologists expert in lymphoma	The focus of this document is systemic treatment.
6. P.8 - Should Home Care or Home Support be part of Access to psychosocial oncology care (and spiritual/religious counsel)	Home care services are separate to psychosocial oncology services
7. P.12 - Paragraph 1 needs to be changed - No ACNP now - just RN(EC) Adult - or RN(EC) Pediatrics vis-à-vis RN(EC) Primary Care. As well, - should 'pediatric' be assumed or added?	Changed to Registered Nurse (Extended Class), "RN(EC), The target population for this document is adults with cancer who are receiving systemic treatment.
8. Standard 52. "...obtain (AND maintain) CNA certification." Similarly for Pharmacists.	"Maintain" has been added to standard 52.
9. There is no reference to non-same day chemotherapy administration in the policy section. I would have thought this might be a recommended policy, at least for level 1 facilities	We have no comment, as this practice is a local process issue.

10. "Discussion of cases at regular mortality and morbidity rounds (MMRs) including all deaths on systemic treatment within 30 days of treatment."-- is this feasible? Should it just be patients with death attributable to systemic treatment?	Prefer the original language
11. Description of Level 1 facility is missing components of medical oncology/radiation oncology as in level 2	It has been added to Level 1.
12. Advanced Oncology Nurse is not a common term in nursing. Are you referring to Advanced Practice Nurse which is an umbrella term for CNSs and NPs? I would refer you to Canadian Nurses Association for more clarity.	Changed to Advanced Practice Nurse
13. There are many references to CNA certification however we live in a multicultural province with many people working that were prepared internationally with international credentials that are often superior to what you have referenced. I would add (or equivalent) these to be more inclusive of our diversity.	We recommend CNA certification because it is our national standard and it does require re-certification every 5 years. CNA may have exceptions based on international certifications and it could be explored. Our statement should not be viewed as 'non-inclusive' but rather it meets Canada's standards based on our laws and treatments available here. Also the wording is "should" not "must" and thus, a hiring organization can choose to recognize other national certifications if they choose.
14. The chemo maintenance expectation for chemo certified staff is not clearly addressed.. One issue that's often raised is the staffing challenges in regard to oral chemo-biologic administration and whether or not it should be administered by chemo-certified nurses only.	This applies to systemic treatment administration only because of many complex principles and guidelines for administration. All nurses are required to have knowledge of any medication they administer and potential side effects, etc. This is not unique to oral cancer drugs. Principles of safe handling are taught by the organization. While nurses in clinic settings provide education to patients who will start oral treatments, they are not dispensing and administering. This mostly happens at home although it can happen in hospital. There is less complexity; however safety issues still exist and pharmacists play a large role with oral cancer drugs. Prefer original wording.
15. There is nothing said about GP oncologists, not even a definition. The need for GPOs in this model needs to be addressed. This includes the requirement for GPO education and staffing models as has been made for nursing and pharmacy.	Please refer to page 8

## CONCLUSION

The final guideline recommendations contained in Section 1 reflect the integration of feedback obtained through the external review processes with the document as drafted by the GDG Working Group and approved by the GDG Expert Panel and the PEBC RAP.

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## Appendix 1: STP Standards

The standards have been prioritized into the following categories through a modified Delphi process as described in the methodology:

**Very high priority:** must be in place immediately at time of evaluation. Systemic treatment should be halted until criteria are met, or interim strategy must be developed in partnership with facility and CCO.

- For immediate evaluation
- All standards in this category have the potential to significantly impact patient and provider safety
- Facilities must re-confirm that these standards are met on an ongoing basis and new facilities must confirm that these are in place prior to starting a new program

**High priority:** must be in place within 6 months of evaluation.

- For immediate evaluation
- Standards in this category have potential to impact patient safety/quality of care
- Facilities must re-confirm that these standards are met on an ongoing basis and new facilities must confirm that these are in place within 6 months of starting a new program

**Medium priority:** strongly recommended that standards/guideline statements be implemented as soon as possible. Timelines for evaluation are to be determined. However, facilities must have an action plan in place to state when implementation will be complete.

Please note that in circumstances where individuals with appropriate training are not available, controlled acts can be delegated. There must be an individual willing to accept the delegation and they must receive appropriate training and evaluation of their skills. There must also be an individual willing and able to supervise the delegate who has competence in performing the delegated task. Please click on the following links for more information - The [OCP Policy](#) and the [FHRCO Policy](#).

### Computerized Physician Order Entry (CPOE)

Very High

1. Computerized Physician Order Entry (CPOE) systems should be used in the inpatient and outpatient systemic treatment delivery setting to decrease systemic treatment-related medication errors. Where CPOE is not available, standardized, regimen-level pre-printed forms should be used to improve consistency and readability and to avoid prescription error. Handwritten orders are not acceptable. [21]

High

2. Implementation, oversight, monitoring and sustainability of CPOE systems should be done through multi-disciplinary teams. These teams should conduct regimen review, quality evaluation, and risk assessment. [22,23]

### Labelling of Drug Products

Very High

3. In addition to regulatory requirements, including the National Association of Pharmacy Regulatory Authorities (NAPRA) Standards, labels affixed to final drug products should contain the following information (EBS #12-11) [24]:

- a) Two unique identifiers consistent with the patient record
- b) Drug name
- c) Amount of drug per container
- d) In those circumstances in which overfill is required, the overfill volume (in mL) should be printed on the label separately from the dose information
- e) If a product contains two or more active ingredients, they should all appear in the generic name field
- f) The route of administration
- g) The volume of fluid to be administered
- h) Duration of infusion
- i) Rate of administration expressed in mL/hour or as a duration in minutes in the case of medications given by intravenous (IV) push
- j) Number of medication containers, when the drug is to be administered sequentially (e.g., bag 1 of 3)
- k) Relevant auxiliary information should be included on auxiliary labels. Examples of auxiliary labels include “AVOID EXTRAVASATION” and “FOR INTRAVENOUS USE ONLY - FATAL IF GIVEN BY OTHER ROUTES”
- l) Use the complete generic drug name rather than an abbreviated version
- m) Use lower case or mixed case lettering for generic drug names as appropriate. Use current TALL man lettering to differentiate between look-alike/sound-alike drug names [25].

4. When drug name, strength, dosage form, and dosage units appear together, provide a space between them [24].

Very High

5. Follow Institute for Safe Medication Practices (ISMP) guidelines for abbreviations and dose expressions and the United States Pharmacopeia (USP) standards for dosage units and standard units for weight and measures. Alternative abbreviations and dose expressions should be avoided [24,26]

#### **Patient Care**

Very High

6. All treatment plans are recommended by an oncologist or hematologist [27].

7. Satellite sites (Level 4) have access to oncologists and hematologists from level 1, 2 or 3 hospitals in addition to other healthcare professionals such as General Practitioners in Oncology (GPOs) and nurse practitioners who are required to manage disease status, and to discuss patient management issues with the healthcare team. [27]

8. A patient assessment prior to systemic treatment administration is the responsibility of the clinical team [21]. The assessment for systemic treatment administration should include, but may not be limited to, the following:

- a) Baseline observations, specific to the protocol
- b) Patient history (e.g., comorbidities)
- c) Best Possible Medication History (BPMH) including alternative therapies
- d) Presence of allergies or other hypersensitivity reactions
- e) Patient performance status and physical findings that may impact on the treatment process
- f) Patient weight, height, and body surface area
- g) Laboratory results
- h) Response to previous treatment and previous toxicities that may impact on treatment

- i) Compliance with home pre-medication treatment
- j) Assessment for and maintenance of access devices required for administration
- k) Presence of psycho-social concerns

9. Patients who are going to receive or who are already receiving systemic treatment should be provided with information (ideally oral and written) that enables them to comprehend the intended aims, plans, effects, and outcomes of the proposed or ongoing treatment [21]. Information should cover the following, at a minimum:

- a) Diagnosis
- b) Intent of Treatment
- c) Treatment plan (e.g., drugs, schedule, follow-up)
- d) Short and long-term effects, management of side effects

10. Patients should be educated about the risk of vesicant extravasation that can occur during administration and actions that they can take in managing their care after administration, or after extravasation has been identified. [28]

11. Provide patient education related to planned systemic treatment using a multi-disciplinary approach which may include nurses, physicians and pharmacists [27].

12. Systemic treatment preparation and delivery should include the following [21]:

- a) Verification of the systemic treatment order and preparation.
- b) Verifying a systemic treatment order should include a systematic check of all the components of the systemic treatment order and its preparation and dispensing.
- c) Verification and independent double checking processes should be regulated by oncology-specific policies and procedures and training and certification programs to maintain accuracy and quality.
- d) Independent double checking at various points of the systemic treatment preparation process including the order and preparation of product.
- e) Independent double checking during the systemic treatment preparation process is completed by a second pharmacist, by a pharmacy technician (Verification procedure where one technician checks the order-filling accuracy of another), or by another healthcare professional with appropriate knowledge, skills and training to perform this function.

13. Clearly document:

- Systemic treatment administration and verification including independent double checks to maintain accuracy and quality and relevant safety issues (e.g., allergies, reactions) as per oncology-specific policies, procedures, training and certification programs [e.g., Provincial Standardized Chemotherapy and Biotherapy Course (PSCB) by the de Souza Institute, Canadian Association of Pharmacy in Oncology (CAPHO) Standards of Practice for Oncology Pharmacy in Canada]. Independent double checking may still be required when CPOE is in place because of the possibility of major variations or deviations in protocol, protocols that are new or not yet built into the CPOE program, or complex calculations involved in systemic treatment preparation (EBS #12-12-1).
- A systemic treatment plan that is readily available (in the patient's medical record). The plan should reference all treatment modalities (e.g., surgery, radiation therapy) as well as involvement with other healthcare professionals such as nursing and allied healthcare staff. The plan should be available to everyone in the circle of care.
- Any change in treatment (i.e., a new protocol is initiated or a medication dose is changed)
- All patient education
- Assessment of toxicities and adverse reactions [21].



14. Luer-Lock connectors and needleless administration systems should be employed in the administration of intravenous medications [29].

15. Drugs with a high risk of hypersensitivity/infusion reaction require a physician to be available during administration. [28]

16. Healthcare professionals and where applicable patients and/or caregivers should monitor for early signs and symptoms of:

- Access device-related partial or total occlusion
- Local and systemic catheter-related infections on insertion, during infusion and maintenance of the access device
- Venous thrombosis [28]

High

17. A copy of the treatment plan should be distributed to all facilities involved in the patient's care as well as to the patient's primary healthcare provider [21].

18. Treatment factors are the primary consideration in the selection of an access device, as they may dictate the need for a particular device or class of devices. Clinical factors, patient informed decision-making, resource concerns and catheter-related complications may further direct or guide selection. [28]

19. Patients should have access to supportive care services to address specific patient needs (e.g., psycho-social support) [27].

Medium

20. Education on self-management should be encouraged for persons receiving systemic treatment (e.g., on prevention, management and reporting of side effects and adverse events). [28]

21. Surveillance programs should be in place to monitor for device-related complications and conduct systematic error analyses on incident events. [28]

22. There should be the potential for video conferencing, remote web-based teaching, as part of multi-disciplinary case conferences (MCC) at each site [27].

### **Policies and Procedures**

Very High

23. There should be a process for patient identification (using two patient identifiers) such that patients are identified at entry in the system, and then at each step of the treatment process, by the different members of the healthcare team involved in their care [21].

24. There should be a complete description of precautions that need to be taken when starting and when monitoring intravenous treatment including standardized procedures for managing hypersensitivity/infusion reactions, allergic reactions, and extravasation [28].

25. Follow regulatory standards for the safe handling of hazardous drugs (E.g., EBS #16-3), including drug receiving, storage, preparation, packaging, transportation administration and disposal as well as personal protection equipment, spill management, waste disposal (used equipment and unused medication) and hand decontamination. [29]

26. There should be policies and procedures in place to address accidental worker exposure to hazardous drugs [29].

27. There should be a policy to track incidents electronically and to review all critical medication events in a multidisciplinary approach [27].

High

28. There should be policies for all major processes involved in prescribing, dispensing, handling, and administering systemic treatment (i.e., how systemic treatment is prescribed, the use of standardized protocols, a process for order verification and independent double-checking; preparation and dispensing; pre-treatment assessment, catheter selection, maintenance and removal; monitoring; patient education and discharge documentation). [28]

29. There should be policies to address prevention, early detection, and the management of complications related to the catheter/device use and to the drug administered. [28]

30. All sites should have a procedure to continue delivery of systemic treatment during downtime. [30]

Medium

31. The systemic treatment area should accommodate the volume of treatment visits, which includes:

- Adequate space to accommodate patients and equipment in an appropriate environment which meets infection control standards.
- Adequate slots to minimize day of treatment wait times.
- Adequate bookings to ensure access within wait times. [27]

### **Pumps and Equipment**

Very High

32. For elastomeric or volumetric pumps, ensure the following are in place:

- a) User-specific education materials for pharmacy staff, nurses and patients
- b) Instructions on how to identify a pump failure, and appropriate interventions in case of failure
- c) Collaboration with the vendors to improve educational materials.
- d) Administration of systemic treatment via volumetric or elastomeric pumps should only be performed by registered nurses trained and certified in their use
- e) The number of different brands or models of pumps in one institution should be minimized to reduce the risk for incorrect use or programming
- f) Pumps in a hospital should all be programmed using the same units that are included in the labeling of systemic treatment. Standardize pump technology within an institution or at least use pumps with a common format. The use of pumps programmed in mL/hour is strongly recommended over the use of pumps programmed in mL/24 hour. Refer to Cancer Care Ontario (CCO) guidelines (EBS #12-11) for appropriate labeling of systemic treatment products [24]
- g) Pump programming should be independently double checked by two registered nurses with the appropriate training for the particular brand and model of volumetric pump
- h) Prior to systemic treatment administration, a final check of patient and drug information should be performed independently by two registered nurses with appropriate training and skills
- i) Administer continuous systemic treatment via a central venous access device
- j) Only Luer-Lock fittings should be used with administration sets
- k) Devices should be checked for leakage or contamination prior to use and throughout the

infusion period. If the infusion is occurring at home, the patient should be educated on periodically performing this check

l) Where patients are receiving the infusion at home, they must be supplied with a spill kit and be educated on how to recognize and manage a spill

m) Unused or remaining systemic treatment drug and its devices should be returned to the systemic treatment suite or community/home care provider for disposal

n) Hazardous precautions (i.e., prevention of contact with systemic treatment drugs or bodily fluids of patients who received such drugs) should be taken according to the recommendations in EBS #16-3[29]

33. Patients who are going to be sent home with an ambulatory pump (e.g., volumetric or elastomeric) should understand who to contact for issues/concerns and before leaving the site, should be observed to ensure:

- Volumetric: The pump is functioning correctly
- Elastomeric: The site is intact and the patient has information about how to recognize when the pump is not functioning properly.
- There are no allergic or hypersensitivity/infusion reactions after the pump is connected.

[28]

### **Safe Handling**

Very High

34. Hazardous drugs should be handled in a manner that avoids skin contact or contact with mucous membranes, the liberation of aerosols or powdered medicine into the air, and cross-contamination with other medicines[29].

35. Spiking of bags and priming of tubing should occur before the addition of the hazardous drug if a closed system cannot be established or unless the clinical protocol requires otherwise. The use of a closed system transfer device may reduce contamination.

Attaching the tubing to the spike port is acceptable after the hazardous drug has been added. If priming occurs outside of a closed system environment, prime IV tubing with a fluid that is compatible to but does not contain the systemic treatment medication or by using the backflow method.[29].

36. Patients/caregivers involved in administering hazardous drugs in the home should be provided with a process for the appropriate disposal of hazardous waste, including left-over drugs. A spill kit should be readily available in the home in case of accidental spills. There should be a clear process in place to address the disposal of hazardous waste from patients in their homes, in compliance with municipal or local hazardous waste rules. [29]

37. All staff should be fully informed of the potential reproductive risks of hazardous drugs. [29]

38. A list of hazardous drugs should be maintained at the site and updated on a regular basis. [29]

Very High

39. Patients should be informed of, and be provided with, written instructions for the safe handling of hazardous drugs in the home as well as contact information should they require any assistance. [29]

### **Training and Education for Providers**

Very High

40. Educational programs and skills development should be available to establish competence in caring for persons receiving systemic treatment and in operating any equipment required to provide this care. Elements could include but are not limited to the following:

- Preventing, managing and reporting of side effects and adverse events using standardized tools, where available
- Healthcare professionals working in systemic treatment administration settings should receive training related to care of, and identification of complications including extravasation, phlebitis, infiltration, flare reaction, hypersensitivity/infusion and allergic reactions which are monitored in collaboration with the patient. [28]

41. Training and/or certification programs should be available for staff involved in the handling of hazardous agents and have a policy on re-training. This may be done at or in collaboration with an Integrated Cancer Program (ICP), Affiliate or satellite institution. [27]

42. All registered nurses administering systemic parenteral therapy to patients with cancer, regardless of setting, should maintain certification which includes the completion of standardized education through the recognized de Souza Cancer Chemotherapy Maintenance Course (CCMC) or ONS Chemotherapy/Biotherapy Renewal Course. [27]

43. Only pharmacists or pharmacy technicians with appropriate training and assessment will compound chemotherapy, immunotherapy and targeted therapy. [27]

44. All pharmacy technicians preparing systemic parenteral therapy, regardless of setting, should receive specialized training and maintain certification in the preparation of systemic treatment doses. This may be done at or in collaboration with an ICP, Affiliate or satellite institution. Training programs should incorporate the NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations. [27]

45. Educational programs and skills development should be available for all staff involved in systemic treatment including receiving, storage, transport, spill management, environmental cleaning, preparation, administration, and waste disposal. [27]

#### High

46. Dedicated oncology pharmacists should provide clinical services at level 1, 2, and 3 hospitals. Pharmacists who rotate through oncology should have a minimum exposure to maintain competence. [27]

47. There should be sufficient patient volume or a process at the site to maintain competency and skills of professional providers to address the acuity and complexity of the treatment modalities and/or to provide cost-effective use of resources and drugs (e.g., shared care program or collaboration with another program). [27]

#### Medium

48. All pharmacy technicians handling hazardous agents should complete training that may include continuing education programs or courses (CAPHO Fundamentals Day for Pharmacy Technician), oncology pharmacy review courses (e.g., American Society of Health-System Pharmacists (ASHP) Oncology Review) or preceptorship programs. [27]

49. Family physicians/internists/physician assistants participating in supervising oncology care in partnership with an oncologist should participate in education programs related to the management of patients receiving systemic treatment. [27]

50. All registered nurses (RNs), clinical nurse specialists (CNSs) and nurse practitioners (NPs) working primarily with patients and families with cancer in the Regional Cancer Programs (RCPs) (Level 1-4 facilities) should obtain and maintain Canadian Nursing Association (CNA) certification as the nationally recognized nursing specialty credential by their 5th year of practice. All registered practical nurses (RPNs) should complete a relevant foundations course.

a. RN's, CNSs and NPs should obtain CNA certification reflective of their main role and practice setting focus (E.g., Certified in Oncology Nursing (CON(C)), and/or Hospice Palliative Care (CHPCN(C)))

b. RPN's should complete a foundations course reflective of their main role and practice setting in Oncology or Palliative Care by an accredited Provincial College, Pallium Canada, Palliative Pain & Symptom Management Consultation Program of Southwestern Ontario or de Souza Institute course

51. All registered nurses administering systemic parenteral therapy to patients affected by cancer, regardless of setting, should be certified which includes completion of standardized education through the recognized de Souza Provincially Standardized Chemotherapy and Biotherapy course or Oncology Nursing Society (ONS) Chemotherapy/Biotherapy Certificate equivalent course.

52. Nurses working in practice settings that less frequently encounter patients and families affected by cancer should have access to CNA certified nurses to support their care OR complete a foundations course in Oncology/Palliative care, OR obtain and maintain CNA certification CON(C) or CHPCN(C).

53. All pharmacists working primarily with patients and families with cancer in the Regional Cancer Programs (Level 1 - 3) should obtain certification from a recognized program such as the Board of Pharmacy Specialties (e.g., Board Certified Oncology Pharmacist (BCOP)) or the University of Toronto's Oncology Program for Pharmacists (Advanced Oncology program) by their 5th year of practice.

54. All pharmacists working in satellite sites (Level 4) should complete the University of Toronto's Oncology Program for Pharmacists (Essentials of Oncology and Advanced Oncology programs by their 5th year of practice) OR have access to a pharmacist who has oncology certification.

## Appendix 2: STP Standards Methodology

### Participants

CCO leadership sought to identify representatives from across the province. The approach was to ensure that all relevant disciplines (Pharmacy, Nursing, Medical Oncology/Hematology, and Management) had a voice at the table. Each Regional Vice-President/Director (14) was asked to nominate up to four representatives from different disciplines who could provide subject matter expertise. A Participation Agreement including a Conflict of Interest (COI) Declaration was required upon joining the group.

### Three-Step Modified Delphi Process

The modified Delphi method is a structured method for soliciting expert opinion about a topic with a series of questionnaires and controlled feedback as well as a consensus meeting. The Delphi process does not create new knowledge but rather collects expert opinion from the group. The technique is a widely used and accepted method for gathering data from respondents within their domain of expertise.

Systemic treatment standards from leading national and international authorities were extracted, compiled into an excel spreadsheet and synthesized by the leadership team into 65 statements. A Delphi survey was created to generate consensus on the inclusion or exclusion of those statements (indicated by agree or disagree) in the RSTP standards as well assign a priority level should they be included. The leadership group defined the priority level and it is as follows:

•**Very high priority:** must be in place immediately at the time of evaluation. Systemic treatment should be halted until criteria are met, or an interim strategy must be developed in partnership with the facility and CCO.

- For immediate evaluation
- All standards in this category have the potential to significantly impact patient and provider safety
- Facilities must re-confirm that these standards are met on an ongoing basis and new facilities must confirm that these are in place prior to starting a new program

•**High priority:** must be in place within 6 months of evaluation.

- For immediate evaluation
- Standards in this category have the potential to impact patient safety/quality of care
- Facilities must re-confirm that these standards are met on an ongoing basis and new facilities must confirm that these are in place within 6 months of starting a new program

•**Medium priority:** strongly recommended that standards/guideline statements be implemented as soon as possible. Timelines for evaluation are TBD however, facilities must have an action plan in place to move towards implementation.

### Round 1

The questionnaire was circulated by email to the participants. Each participant was asked to give a two-part answer for each standard; that is inclusion/exclusion and priority level assignment. Participants were also given the opportunity to provide comments and suggest additional items that may not have been included when developing the initial list of statements.

Response frequencies for each statement were calculated and entered anonymously into a database. Seventy percent agreement was required to include a statement in the final list of standards. Statements that required more discussion or did not receive consensus, along with accompanying comments, were retained for discussion in Round 2.

### Round 2

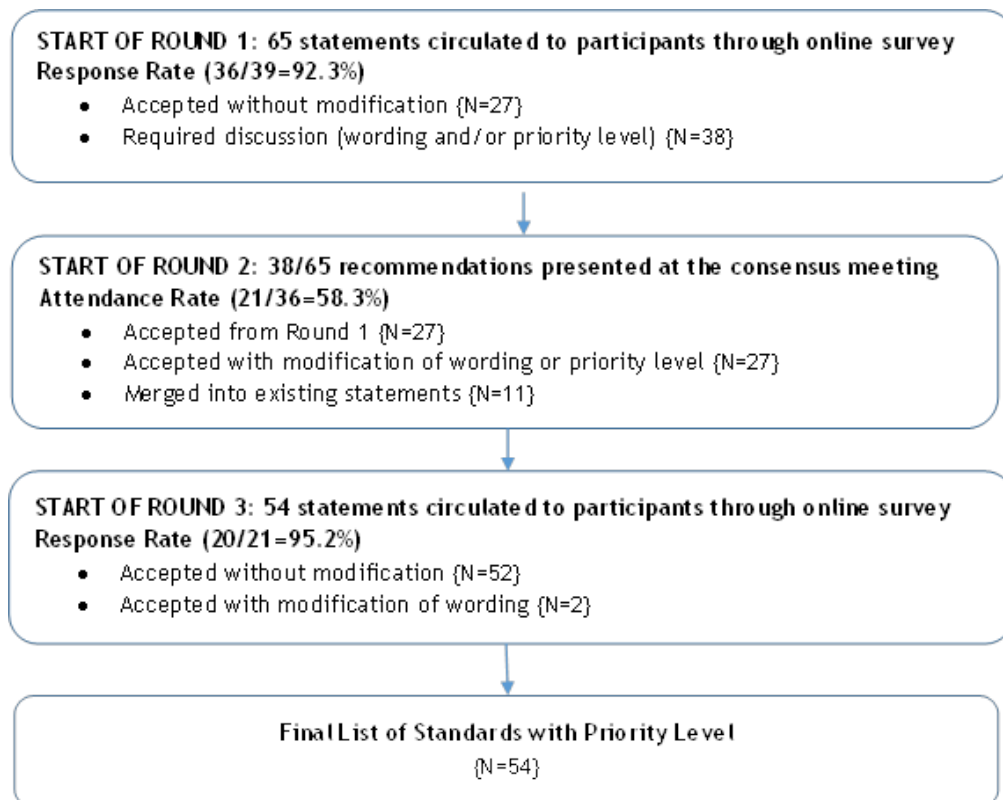
In a teleconference, participants were provided with the opportunity to refine their views based on the knowledge of group results and comments. Participants were encouraged to discuss the list of statements and/or priority levels that did not receive consensus until agreement was reached to retain, modify, or exclude from the final list. Seventy percent agreement was still used to determine acceptance or rejection of a statement however, anonymity was not retained.

### Round 3

Statements with priority levels that were added, retained and/or modified in Round 2, were re-circulated to members in a second electronic survey. Participants used the same voting method as described for Round 1 to gauge agreement on the statements and the priority level that would be accepted in the final list of standards.

Following Round 3, there was final editing by the leadership group on the statements for accuracy of content, development of ideas, organization and clarity of expression and opportunity for the participants to review the final list of standards with the priority level.

## Results



**Appendix 3: Affiliations and Conflict of Interest Declarations**

<b>Working Group Members</b>		
<b>Name</b>	<b>Affiliation</b>	<b>Declarations of interest</b>
Leta Forbes Working Group Chair	Provincial Head of Systemic Treatment Program (CCO) and Medical Oncologist, Lakeridge Health	None declared
Daniela Gallo-Hershberg Working Group Member	Group Manager, Systemic Treatment Program (CCO) and Assistant Professor (status) at the Leslie Dan Faculty of Pharmacy at the University of Toronto	Has received funding of \$500 or more in honorarium expenses from Boehringer Ingelheim in 2016 to moderate a presentation and discussion on Timely Management of Side Effects with TKIs and Toxicity Management with Afatinib: Developing Tools.
Kardi Kennedy Working Group Member	Program Operational Director & Regional Director, Cancer Services	None declared
Jennifer Newton Working Group Member Nurse Educator	Nurse Educator- Cancer Program	Has received an honourarium of \$500 or more in a single year for speaking at a Bristol Meyers Squibb sponsored educational event and was on the afivory board for Hoffman LaRoche
Aliya Pardhan Working Group Member	Team Lead, Systemic Treatment Program (CCO)	None declared
Lacey Pitre Working Group Member	Regional Quality Lead	Has received funding of \$500 or more for Novartis RIBBON program, honoraria -Sept/Oct 2018; Merck Oncology - Speaker honoraria Dec 2017 - Merck Oncology speaker honoraria May 2017; Astellas Oncology Advisory Board (prostate cancer); - FUSE Health - Targeting BRCA-Mutated Solid Tumours: Ovarian Cancer - honorarium
Dana Root Working Group Member	Lead Oncology Pharmacist, Oncology Pharmacy Department	Has received funding of \$500 as advisory board member (BM, Roche, One Education, Pfizes)
Kathy Vu Working Group Member	Clinical Lead, Systemic Safety (CCO) and Director Pharm D for Pharmacists Program, Leslie Dan Faculty of Pharmacy, University of Toronto	Has RRSP stocks in Incyte, was an author on consensus guideline for the safe use and handling of oral anticancer drugs in community pharmacy



Lisa Durocher-Allen Health Research Methodologist	Program in Evidence-Based Care McMaster University Hamilton, Ontario	None declared
<b>Expert Panel</b>		
<b>Name</b>	<b>Affiliation</b>	<b>Declarations of interest</b>
Mona Abdallah Expert Panel Member	Oncology, Pharmacist, Grand River Regional Cancer Centre	None declared
John Goffin Expert Panel Member	Dept. of Oncology, McMaster University CCO Regional Quality Lead, Systemic Treatment, LHIN 4 Juravinski Cancer Centre	Has received Honorarium from Amgen (2014), Boehringer Ingelheim (2015), BMS (2015), and Merck (2019). Conference support from AZ (2017). Speaking fee from Amgen (2018).
Darrilyn Lessels Expert Panel Member Nursing Lead	Durham Regional Cancer Centre, Lakeridge Health Oshawa, Ontario	None declared
Susan Rieger Expert Panel Member	London Health Sciences Centre London, Ontario	None declared
Karen Roberts Expert Panel Member	Thunder Bay Regional Health Sciences Thunder Bay, Ontario	None declared
<b>Report Approval Panel</b>		
<b>Name</b>	<b>Affiliation</b>	<b>Declarations of interest</b>
Melissa Brouwers	Director of School of Epidemiology and Public health Faculty of Medicine, University of Ottawa	None declared
Laurie Elit	Juravinski Cancer Centre Hamilton, Ontario	None declared
Jonanthan Sussman	Chair, Department of Oncology, Juravinski Cancer Centre, Hamilton, Ontario	None declared
<b>Targeted Peer Reviewers</b>		
<b>Name</b>	<b>Affiliation</b>	<b>Declarations of interest</b>
Neil Johnson	Regional Vice President, London Health Science Centre,	Received \$500 or more in a single act in a consulting capacity from Sunnybrook Health Sciences Centre not related to this guideline.
Marrianne Taylor	British Columbia Cancer Agency	None declared

## **Appendix 4: Guideline Methods Overview**

### **THE PROGRAM IN EVIDENCE-BASED CARE**

The Program in Evidence-Based Care (PEBC) is an initiative of the Ontario provincial cancer system, Cancer Care Ontario (CCO). The PEBC mandate is to improve the lives of Ontarians affected by cancer through the development, dissemination, and evaluation of evidence-based products designed to facilitate clinical, planning, and policy decisions about cancer control.

The PEBC supports the work of Guideline Development Groups (GDGs) in the development of various PEBC products. The GDGs are composed of clinicians, other healthcare providers and decision makers, methodologists, and community representatives from across the province.

The PEBC is a provincial initiative of CCO supported by the Ontario Ministry of Health and Long-Term Care (MOHLTC). All work produced by the PEBC and the Systemic Treatment Program (STP) is editorially independent from the MOHLTC.

### **GUIDELINE DEVELOPMENT METHODS OVERVIEW**

The PEBC produces evidence-based and evidence-informed guidance documents using the methods of the Practice Guidelines Development Cycle [31,32]. This process includes a systematic review, interpretation of the evidence by the Working Group and draft recommendations, internal review by content and methodology experts and external review by Ontario clinicians and other stakeholders.

The PEBC uses the AGREE II framework [33] as a methodological strategy for guideline development. AGREE II is a 23-item validated tool that is designed to assess the methodological rigour and transparency of guideline development.

### **GUIDELINE REVIEW AND APPROVAL**

#### **Internal Review**

For the guideline document to be approved, 75% of the content experts who comprise the GDG Expert Panel must cast a vote indicating whether or not they approve the document, or abstain from voting for a specified reason, and of those that vote, 75% must approve the document. In addition, the PEBC Report Approval Panel (RAP), a three-person panel with methodology expertise, must unanimously approve the document. The Expert Panel and RAP members may specify that approval is conditional, and that changes to the document are required. If substantial changes are subsequently made to the recommendations during external review, then the revised draft must be resubmitted for approval by RAP and the GDG Expert Panel.

#### **External Review**

Feedback on the approved draft guideline is obtained from content experts and the target users through two processes. Through the Targeted Peer Review, several individuals with content expertise are identified by the GDG and asked to review and provide feedback on the guideline document. Through Professional Consultation, relevant care providers and other potential users of the guideline are contacted and asked to provide feedback on the guideline recommendations through a brief online survey. This consultation is intended to facilitate the dissemination of the final guidance report to Ontario practitioners.

## Appendix 5: Literature Search Strategy

1. exp Neoplasms/ or exp tumor/ or exp cancer/ or (cancer: or neoplasm: or tumor: or carcinom: or malignan: or oncolog:).mp.
2. exp chemotherapy/ or exp immunotherapy/ or exp systemic therapy/ or exp Antineoplastic Agents/ or (chemotherap: or chemoradio: or radiochemo: or immuno: or vaccin: or adjuvant or neoadjuvant).mp.
3. 1 and 2
4. (abstract\* or conference abstract\* or note or letter or comment or commentary or editorial).pt.
5. 3 not 4
6. limit 5 to yr=2007-current
7. exp practice guideline/ or exp consensus development conference/ or guideline.pt. or practice parameter\$.tw. or practice guideline\$.mp. or (guideline: or recommend: or consensus or standards).ti. or (guideline: or recommend: or consensus or standards).kw.
8. Limit 7 to yr=2013-current
9. exp meta analysis/ or exp "meta analysis (topic)"/ or exp meta-analysis as topic/ or exp "systematic review"/ or exp "systematic review (topic)"/ or ((exp "review"/ or exp "review literature as topic"/ or review.pt.) and ((systematic or selection criteria or data extraction or quality assessment or jaded scale or methodologic\$ quality or study) adj selection).tw.) or meta-analysis.mp. or (meta-analy: or metaanaly: or meta analy:).tw. or (systematic review or systematic overview).mp. or ((cochrane or medline or embase or cancerlit or hand search\$ or hand-search\$ or manual search\$ or reference list\$ or bibliograph\$ or relevant journal\$ or pooled analys\$ or statistical pooling or mathematical pooling or statistical summar\$ or mathematical summar\$ or quantitative syntheses\$ or quantitative overview\$ or systematic) adj2 (review\$ or overview\$)).tw.
10. 6 and (8 or 9)
11. safety/ or Safety Management/ or Patient Safety/ or Patient Harm/ or patient risk/ or (safe: adj2 (prescrib: or prescription: or deliver: or administ: or dispens:)).mp.
12. 10 and 11
13. (volume\$ adj2 (patient\$ or dose\$)).ti,ab.
14. Pharmacist/ or hospital pharmacy/ or (pharmac: adj2 (volume\$ or workload\$ or experience\$ or train\$ or standard\$ or requirement\$ or guideline\$ or quality\$)).ti,ab.
15. (nurs: adj2 (volume\$ or workload\$ or experience\$ or train\$ or standard\$ or requirement\$ or guideline\$ or quality\$)).ti,ab.
16. ((organization\$ or resource\$ or train\$ or education:) adj2 (requirement\$ or standard\$ or guideline\$ or volume\$ or workload\$ or experience\$)).ti,ab. Or (practice adj2 (requirement\$ or volume\$ or workload\$)).mp.
17. Clinical Competence/
18. 9 and (or/13-17)
19. exp practice patterns, physicians'/ or medical oncologist.tw. or oncology physician.tw. or family nurse practitioner\$.tw. or medical oncology/ma or drug prescriptions/
20. 9 and 17
21. drug prescriptions/ or ((medical oncologist\$ or oncology physician\$ or oncologist\$ or general practitioner\$ or nurse practitioner\$) and (prescrib: or prescription:)).tw.
22. 9 and 19
23. administration, oral/ or patient compliance/ or patient education as topic/ or self administration/ae, mt, nu
24. 9 and 21
25. 11 or 16 or 18 or 20 or 22
26. remove duplicates from 23

**Appendix 6: Guideline History**

Guideline Version	Search Date	Data	Publications	Notes and Key changes
Original Version May 2007	1996-June2006	Full Report	Web publication, Journal publication	N/A
Version 2	June 2006- October 2018	Full Report	Web publication, Journal publication	N/A