

# CLINICAL SERVICES

# **CHEMOTHERAPY**

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# CHEMOTHERAPY

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#### A. INTRODUCTION

Chemotherapy, or systemic therapy, is an integral part of cancer treatment. It has been estimated that more than half of all cancer patients will require chemotherapy during the course of their disease <sup>1</sup>, though the proportion of patients who receive chemotherapy varies across jurisdictions, by type of cancer, and based on the appropriateness and range of available treatments. With the availability of new drugs, this proportion is increasing each year.

This chapter describes the essential elements required to establish and implement a cancer chemotherapy service as part of a cancer centre. Specialized services, such as hematopoietic stem cell transplantation, are covered in brief, with links to additional resources.

#### **B. CLINICAL SERVICES**

# 1. GOALS 2-6

Chemotherapy is an essential treatment for many cancers. In some cases, the goal of chemotherapy is curative; however, when cancer is not treated with curative intent, chemotherapy can induce cancer remission or relieve cancer-associated symptoms, increasing the quality and length of life of the patient. This is termed palliative chemotherapy.

Chemotherapy is often used in combination with other therapies, including:

- Before surgery or radiotherapy, to increase the effectiveness of treatment or decrease the size of tumours prior to resection (i.e., neoadjuvant therapy).
- Concurrently with radiotherapy, to improve local tumour control.
- After surgery or radiotherapy, to lower the risk of cancer recurrence (i.e., adjuvant therapy).

Chemotherapy may also be combined or sequenced with other systemic therapies, such as hormonal therapy or immune targeted agents.

#### 2. SCOPE

A cancer centre should aim to provide a full scope of chemotherapy services, including treatment for highly-complex cancers. Cancer centres should also have the capacity to provide new and innovative treatments, such as targeted agents, cellular therapies, immunotherapy and high-dose chemotherapy followed by hematopoietic stem cell transplantation.

Generally, chemotherapy is provided on an outpatient basis, although inpatient stays may be required depending on the needs of the patient and the treatment being provided. On occasion, chemotherapy may also be provided in the home under the direction of the cancer centre or another hospital. Although chemotherapy drugs are effective against cancer cells, these drugs also affect normal cells. Consequently, chemotherapy is often associated with side-effects. These may present as a variety of short- and long-term symptoms, such as nausea, hair loss, pain, vomiting and neuropathy. They may also cause other toxicities or symptoms related to myelosuppression or mucositis. Patient support and education before, during and after chemotherapy are essential. For more information about support for the

management of symptoms, see the <u>Cancerpedia: Supportive Care</u> and <u>Cancerpedia: Palliative</u> <u>Care</u> chapters.

The type of chemotherapy and the method of chemotherapy delivery used is dependent on the type of cancer being treated, its stage, the patient's characteristics and other factors. The most common way to deliver chemotherapy is intravenously (IV). It can also be given through a subcutaneous, intramuscular injection or intra-arterial infusion, installed directly into an area of the body (e.g., peritoneal cavity, abdomen, chest, central nervous system, bladder), taken orally or applied topically on the skin.

Cancer centres need a critical mass of patients to optimize their use of resources and ensure quality care. The range of chemotherapy drugs and approaches used to treat rare and complex cancers may be expensive and best provided in partnership between two or more centres. One major cancer centre may act as the referral site for other centres that do not have the specialty expertise required to provide more complex treatments. Given that chemotherapy is also provided in conjunction with other therapies (i.e., surgery and radiotherapy), a centre's scope of chemotherapy may be influenced by the need to integrate with other modalities.

Figure 1: Chemotherapy Pathway

#### 3. PATHWAY

The chemotherapy pathway is detailed below and illustrated in Figure 1.

During *consultation*, the patient meets with a medical oncologist for a detailed review of his or her laboratory, pathology, imaging and other healthrelated test results, as well as a general assessment and examination. The oncologist determines whether chemotherapy should be prescribed and develops a treatment plan that is best suited to the patient. The oncologist may involve other members of the interprofessional/multidisciplinary healthcare team (e.g., pathologists, radiologists, surgeons, radiation oncologists) when the treatment plan involves a multimodality approach.

The treatment plan must include the recommended chemotherapy prescription (i.e., drugs, dose,

Consultation

Pre-Treatment
Assessment

Chemotherapy Order
and Preparation

Treatment

Review and Follow-Up

frequency of administration, time period), any pre-medication and tests required, and next steps required for patient care.

Once a patient has been deemed fit for treatment, he or she should be given information on the course of treatment, the drugs to be used and their potential side-effects. Patients are

registered for chemotherapy once they provide informed consent for treatment. The patient is then seen by a chemotherapy nurse or other specialized provider for additional assessments, ongoing education and support.

The patient registration service co-ordinates the timing of a patient's chemotherapy so that it aligns appropriately with other treatments (e.g., surgery, radiotherapy), if applicable. Patient registration also supports checking patients in for their appointments, ongoing patient tracking and retrieving patient files for follow-up. All of the patient's clinical activity – including their treatment plan, appointments, treatments, results and other information – must be entered into the chemotherapy information system and the patient health record.

The *pre-treatment assessment* ideally occurs shortly before treatment and ensures that the patient is fit to receive chemotherapy. Patients are assessed and receive information about chemotherapy, side-effects, the risks of infection and drug interactions, as well as important contacts for ongoing support and follow-up. Assessments also ensure the psychological, emotional, social and spiritual needs of the patient are being addressed. Tests completed at this time may inform the chemotherapy order. If the patient is receiving a number of cycles of chemotherapy over time, blood tests and assessments are repeated before each cycle.

**Chemotherapy order and preparation** are two separate steps, each with multiple checks and balances to ensure that the correct chemotherapy is prepared and delivered.

The medical oncologist and other healthcare team members review the initial treatment plan and the additional information collected in the pre-treatment assessment to determine if chemotherapy can proceed. Healthcare team members work together to develop a detailed order based on the type of cancer, the required drugs and their toxicity.

The chemotherapy order includes the drug regimen, any supportive drugs (e.g., premedications to manage expected side-effects), the method that must be used to administer the chemotherapy and details of the treatment cycle. Details of the treatment cycle should include: i) the duration (i.e., Is the drug received in one day or over more than one day?; Is the drug given in minutes, hours or days?); ii) the frequency (i.e., Is chemotherapy repeated weekly, monthly?); and iii) the number of cycles (i.e., How long does chemotherapy last from start to finish?). The medical oncologist finalizes the chemotherapy order, which is transferred to the pharmacy, and chemotherapy treatment is booked, usually for the next day. The order is reviewed and the chemotherapy is prepared, verified and delivered to the person administering treatment. For more information about chemotherapy preparation, see the *Cancerpedia: Pharmacy* chapter.

**Treatment** begins when chemotherapy is administered, which can be done in an outpatient day service or inpatient service setting. All patients arrive for their appointments at the reception and registration area, where their identity is verified and checks are made to ensure that clinical information is complete. Patients, who may be accompanied by family members or friends, should be directed to a waiting area until they are called for treatment. Patients are typically escorted into the treatment area by clerical or nursing staff. A specialized chemotherapy nurse explains the procedure to the patient, verifies the patient's identity and

checks the patient's chemotherapy drugs, treatment protocol, test results and chemotherapy calculations before beginning treatment. The nurse then closely monitors the patient for any side-effects, responds appropriately and enters information into the patient health record. The level of nursing care required by patients varies, with some patients needing little care, some requiring symptom management and some requiring emergency resuscitation due to allergic reactions, which require physician notification.

Generally, outpatients who receive chemotherapy intravenously sit in reclining chemotherapy chairs or lie in a bed. Chemotherapy treatments may be delivered daily, weekly or monthly, usually at intervals and for several courses.

**Review and follow-up** occur after each chemotherapy administration and at the end of a course of treatment. When a chemotherapy session is finished, the medical oncologist and/or oncology nurse and/or oncology pharmacist must meet with the patient to: review the treatment regimen and any side-effects; identify the need for additional information and support; provide additional medication to manage symptoms, if required; and provide information on the next treatment, follow-up appointments and additional laboratory tests, as required. The clinical team also assesses the patient's response to treatment and considers whether the treatment plan should be modified. If required, supportive or palliative care services may be provided to the patient.

Patient education and support occur throughout the chemotherapy pathway. During the consultation and pre-treatment assessment phases, the patient receives information and educational materials about chemotherapy in general, as well as information specific to their treatment. Over the course of treatment, staff examine the patient, assess symptoms and side-effects, address patient questions and concerns about treatment, and provide ongoing support to patients. Based on individual assessments, patients may be referred to other healthcare providers (e.g. dieticians, social workers, psychologists, psychosexual specialists, spiritual care specialists) to support their needs. Patients may also be provided with a chemotherapy record booklet that includes information about their treatment plan, treatments administered, side-effects and complications, possible infections and other issues, medicines to take at home, 24-hour contact details for the healthcare team and instructions on how to access emergency care. <sup>8</sup>

#### C. RESOURCES

Resources include the facilities and equipment, human resources and information management infrastructure required to provide a comprehensive chemotherapy service. The core resource elements required for chemotherapy are standard; however, various factors may impact the level and configuration of resources required by a specific cancer centre. For example, increased resources may be needed to support higher patient volumes, more sophisticated chemotherapies or innovative ways of administering chemotherapy.

#### 4. FACILITIES AND EQUIPMENT

Chemotherapy facilities must meet quality and safety standards and requirements for inpatient, outpatient and pharmacy services set by the national and subnational regulatory bodies of the jurisdiction in which a cancer centre is located. For example, see the <a href="Canadian Standards">Canadian Standards</a>
<a href="Association">Association</a>. 9 In addition, the overall design of the chemotherapy service should enable the effective, efficient and safe flow of chemotherapy patients and supplies. The number and length of patient transfers from one service area to another should be minimized, where possible. Careful consideration of service area adjacencies can support these goals, including consideration of the areas and departments that should be directly connected to one another versus those that can be separated by a safe distance. In addition, sterile environments must be provided to prepare chemotherapy and infectious diseases must be appropriately managed in areas where chemotherapy is delivered. For more information, see the <a href="Cancerpedia: Inpatient Care">Cancerpedia: Outpatient/Ambulatory Care</a>, <a href="Cancerpedia: Pharmacy">Cancerpedia: Pharmacy</a> and <a href="Cancerpedia: Infection Prevention and Control">Cancerpedia: Infection Prevention and Control</a> chapters.

Facilities and equipment requirements for each phase of the chemotherapy pathway are described below.

#### Consultation

In terms of facilities, the chemotherapy service should have a reception area to receive patients arriving for consultation. Space is required for patient registration activities, storage and filing. In addition, medical oncologists require clinic space and examination rooms to consult privately with patients.

The registration office should use standardized procedures to register new patients and schedule patient appointments, manage underused or released appointment time, and address instances when scheduled appointments need to be cancelled. Ideally, an electronic patient registration and scheduling system is used to manage patient activity. This system should be linked to, or part of, a chemotherapy information system.

Other requirements include standardized evaluation forms for the chemotherapy team (i.e., medical oncologists, oncology nurses, pharmacists and others), educational and informational materials regarding the chemotherapy process for patients, and information tailored to the needs of individual patients.

# **Pre-Treatment Assessment**

Pre-treatment assessments can occur in the same space used to conduct consultations. Access to diagnostic services and the patient health record are also required.

#### **Chemotherapy Order and Preparation**

Dedicated space is required to enter chemotherapy orders. Chemotherapy orders should ideally be entered electronically to minimize the risk of error associated with written

documentation. This requires software to support computerized provider order entry (CPOE). The chemotherapy order should be part of the patient's health record.

Chemotherapy drugs are prepared in the pharmacy. Personal protective equipment, biological safety cabinets with appropriate venting and safe handling processes should be used for preparing, labelling and storing drugs. A large cancer centre may have a satellite pharmacy located in, or adjacent to, the chemotherapy suite. Regardless of where pharmacy facilities are located, they should meet appropriate design standards for infection prevention and control and occupational health and safety (e.g., sterile work surfaces and counters for the safe preparation of agents; appropriate heating and ventilation systems; sinks; safe mechanisms for the disposal of waste and personal protective equipment; safe storage for drugs and supplies; appropriate electrical systems). In addition, a medication delivery system is needed for the safe transfer of chemotherapy drugs to the treatment area, at the appropriate time and according to protocol (e.g., temperature). For more information, see the *Cancerpedia: Pharmacy* chapter.

#### **Treatment**

Chemotherapy treatment rooms must meet appropriate regulatory standards. Generally, the physical facility and equipment requirements for chemotherapy treatment are fairly low. Equipment requirements include IVs and IV pumps, appropriate medication storage cabinets, resuscitation equipment (e.g., crash cart, drugs, oxygen, suction), and supplies to clean up spills or contamination. Staff should have personal protective equipment and use safe handling processes to administer treatment. Safety precautions should also be taken when storing, handling and disposing of any chemotherapy drugs. <sup>10</sup>

A staff workstation should be centrally located and close to the treatment area, so staff can easily monitor patients. Staff also need workspace beside each patient to verify the patient's identity, conduct final checks prior to treatment, place treatment supplies, and start IVs or oral chemotherapy.

Depending on the condition of the patient and his or her needs, the patient may sit in a reclining chair or lie in a bed during treatment. Provisions should be made for patient privacy (e.g., curtains, dividers). For each patient, sufficient and appropriate space is needed to accommodate a family member or friend, who may stay with the patient during treatment. Ideally, patient treatment areas should be comfortable, relaxed, non-technical environments, with multimedia access, computers and other types of entertainment.

Treatment facilities must meet appropriate standards for: infection prevention and control and occupational health and safety (e.g., walls, ceilings, floors and lighting; sterile work surfaces and counters; heating and ventilation systems and backups; sinks; noise levels; safety cabinets; etc.); layout and flow; electrical systems; and housekeeping services (i.e. to support the efficient and effective turnover of patients, as well as the safe disposal of chemotherapy agents and hazardous waste). For more information, see the <u>Cancerpedia: Physical Facilities</u> <u>Design and Management</u> chapter.

# **Review and Follow-Up**

Review and follow-up can be provided in the same space used to conduct consultations and pre-treatment assessments. Access to the patient health record is required.

# **Patient Education and Support**

Patient education, assessment and support requires sufficient space to provide patient education and store patient education materials.

#### 5. HUMAN RESOURCES

Chemotherapy is provided by an interprofessional/multidisciplinary team that includes medical, nursing and pharmacy expertise. In some jurisdictions, additional expertise may be provided by physician assistants, depending on their scope of practice. The chemotherapy team focuses on meeting the medical and emotional needs of patients, including managing the symptoms and side-effects of chemotherapy.

Generally, the broad functions that must be fulfilled by chemotherapy human resources are standard; however, job titles and who performs specific functions may vary by jurisdiction and scope of practice.

# **Medical Expertise**

Clinical oncologists are physicians trained in both chemotherapy and radiotherapy practice. Generally, medical oncologists focus on treating cancer in solid organs, whereas hematologic oncologists focus on treating hematologic cancers (e.g., lymphoma, leukemia, myeloma). Medical oncologists and hematologic oncologists must be licensed physicians who have specialized in the diagnosis and treatment of cancer using drugs. Although medical oncologists must understand the pathophysiology of cancers of different sites<sup>11</sup> and may cover the full spectrum of cancers, many subspecialize according to tumour type, especially in larger cancer centres. <sup>12</sup>

The European Society for Medical Oncology (ESMO) and the American Society of Clinical Oncology (ASCO) developed joint guidelines in support of a global curriculum for qualified medical oncologists. The curriculum "represents a broad range of recommendations to be adopted by national education and health bodies according to the resources and conditions of their country." <sup>13</sup> According to the global curriculum guidelines, training requirements in medical oncology should be a minimum of five years, with an option for additional subspecialty training in a specific field of care or disease areas.

# Nursing Expertise<sup>14</sup>

Nursing expertise is required in each phase of the chemotherapy pathway, as illustrated in Figure 1.

In the consultation phase, nurses may work with oncologists to develop the patient's treatment plan and provide initial information.

In the pre-treatment assessment phase, nurses assess the patient's physical and psychosocial health, and provide education and information (i.e., about chemotherapy generally and about the individual patient's treatment plan).

In the chemotherapy order and preparation phase, nurses work in partnership with oncologists and pharmacists to review pre-treatment assessment results and determine if the chemotherapy order must be refined. Nurses usually confirm the chemotherapy order and receive prepared chemotherapy from the pharmacy.

In the treatment phase, nurses ensure that the chemotherapy space is appropriate and equipped with the necessary supplies, verify the patient's identity and treatment plan, check that the appropriate chemotherapy has been received, and prepare to administer the chemotherapy (e.g., setting up drug delivery devices). Nurses also administer chemotherapy, monitor the patient, and manage reactions or complications that may arise.

In the review and follow-up phase, nurses answer any questions the patient may have, discuss the patient's supportive care needs and address treatment-related side-effects. In addition, nurses confirm the patient's next appointment and any additional laboratory tests that are required. At the end of a course of treatment, nurses work in partnership with the oncologist and other team members to assess the patient's progress, discuss modifications to the treatment plan and address issues.

In the patient education and support phase – which occurs throughout the chemotherapy pathway – nurses provide information, educational materials and ongoing support, which may include managing symptoms and side-effects.

Cancer centres may have nurses who fulfil additional chemotherapy-related functions. For example, the oncology nurse navigator improves access to services by helping patients, families and caregivers navigate the healthcare system. <sup>15</sup> This may include coordinating care between the cancer centre, community-based care and home.

The specific responsibilities of chemotherapy nurses may vary by jurisdiction, depending on their scope of practice, level of education and experience in relation to other professionals, such as pharmacists and physician assistants. For example, in the United Kingdom, nurses run chemotherapy review clinics for adult patients, where they formally review patients scheduled for chemotherapy who have been assessed by an oncologist. Depending on local circumstances, nurses may modify or delay a chemotherapy cycle within guidelines, manage adverse events and supportive treatments, interpret test results, refer patients directly to other services (e.g., medical imaging, supportive care, palliative care) and other duties. <sup>16</sup>

Chemotherapy nurses in a cancer centre should have formal oncology training; for example, see the <u>Oncology Nursing Certification Corporation</u>. A nationally-recognized oncology nursing qualification may also be required. In addition, chemotherapy nurses should have

subspecialty training and experience in chemotherapy (for example, see Canadian Association of Nurses in Oncology 2011) and be certified to administer chemotherapy (for example, see Vandenberg et al. 2009). <sup>19, 20</sup> Research has highlighted the value of formal, standardized educational preparation in chemotherapy for nurses to support safe and effective practices. <sup>21</sup>

# Pharmacy Expertise<sup>22</sup>

Pharmacy expertise in a cancer centre is provided by oncology pharmacists and oncology pharmacy technicians. The specific responsibilities of oncology pharmacists may vary by jurisdiction, depending on their scope of practice, level of education and experience in relation to other professionals, such as nurses and physician assistants. Generally, pharmacists have evolved from providing traditional drug-oriented services to patient-oriented services. <sup>23</sup> In some jurisdictions, pharmacists take on direct patient care and patient education activities. <sup>24</sup>

Pharmacy expertise is required in several phases of the chemotherapy pathway, as illustrated in Figure 1.

In the chemotherapy order and preparation phase, the oncology pharmacist works in partnership with the healthcare team to assess whether the original chemotherapy order should be modified as a result of the pre-treatment assessment and the patient's medication and treatment history. The pharmacist verifies the final chemotherapy order against the treatment protocol and the patient's medication and health record, oversees the preparation of the chemotherapy by the pharmacy technician, and verifies the final order to ensure that it is correct. The pharmacist also approves the chemotherapy and any other supporting medication for release, and oversees the timely and safe delivery of chemotherapy drugs to the person administering treatment.

Pharmacists have, at a minimum, a university bachelor's degree in pharmacy and may also be trained at a master's or doctoral level. All pharmacists should be licensed to practice through a regulatory organization at a national or subnational level, depending on the jurisdiction. For more information, see the <u>Cancerpedia: Pharmacy</u> chapter.

Pharmacists working in a cancer centre should have post-graduate training in oncology pharmacy and may also have additional subspecialty training in the use of chemotherapy for cancer patients. Cancer centres may require their pharmacists to be formally certified in oncology pharmacy; for example, the board certified oncology pharmacist in the United States. Oncology pharmacists may be assigned to a specific cancer disease site to advance their specialized knowledge.

The oncology pharmacy technician fulfills technical functions in the chemotherapy order and preparation phase of the pathway, including receiving the chemotherapy prescription from the pharmacist, processing and preparing the prescription, and sending the filled prescription to be administered after verification by the pharmacist.

In some jurisdictions – such as the United Kingdom – the scope of practice of pharmacy technicians has evolved to include a clinical role. This role may include providing information to

and advising patients about their medications, reviewing medication charts, identifying medication-related problems for follow-up by the pharmacist and participating in discharge planning. <sup>26</sup>

Generally, pharmacy technicians complete a college-level training program and may need additional training and/or experience in oncology to work in a cancer centre. Depending on the jurisdiction, pharmacy technicians may be regulated, which directly impacts standard education requirements.

# Other: Physician Assistants

Physician assistants (PAs) – who work with and under the supervision of a physician – may provide select chemotherapy-related services (e.g., ordering and interpreting tests, ordering chemotherapy, prescribing medications, helping to manage side-effects, providing education and information), depending on their scope of practice, level of education and expertise.

Background prerequisites, scope of practice, and education and certification requirements for PAs vary by jurisdiction. PAs may have bachelor's, master's or doctoral preparation.

# **Human Resource Requirements**

Table 1 presents an overview of human resource requirements for the chemotherapy service. In all cases, the volume of human resources required depends on the number of patients requiring chemotherapy.

Table 1: Chemotherapy Service Human Resource Requirements

Professional	Goal	Estimated Human Resource Requirements
Medical Oncologist and Hematologist- Oncologist	Lead the provision of chemotherapy	<ul> <li>Medical oncologist to patient ratio: 1 to approximately 200 new patients annually, or 100 to 150 patients for academic medical oncologists <sup>27</sup></li> <li>Hematologic oncologist to patient ratio: 1 to 35 acute leukemia patients; 1 to 25 transplant patients; 1 to 100 myeloma or lymphoma patients with hematological malignancies <sup>28</sup></li> </ul>
Nursing	Participate in treatment planning and ordering; assess the patient; deliver treatments; address care issues; review and follow-up with the patient and healthcare team; inform and educate the patient; and support the patient's care	<ul> <li>Nursing to patient ratio in infusion centre: 1 to 3, dependent on acuity <sup>29</sup></li> <li>Nursing to patient ratio in chemotherapy outpatient clinic: 1 to up to 8.3, dependent on clinic structure and patient acuity <sup>30</sup></li> </ul>

Professional	Goal	Estimated Human Resource Requirements
Pharmacist	Participate in treatment planning and ordering; oversee drug preparation; address drug-related issues; review and follow-up drug-related issues with the patient and healthcare team; inform and educate the patient; and support the patient's drug-related care	Number of pharmacists dependent on expected roles and responsibilities, as well as the number of pharmacy technicians working for the cancer centre
Pharmacy Technician	Prepare chemotherapy order; may fulfil selected clinical duties	Number of pharmacy technicians dependent on expected roles and responsibilities, as well as the number of pharmacists working for the cancer centre
Other: Physician Assistant	Duties depend on scope and level of expertise	Number of PAs dependent on expected roles and responsibilities, as well as the number of pharmacists working for the cancer centre
Chemotherapy Leadership/ Management	Oversee the chemotherapy service	<ul> <li>Lead clinical oncologist, responsible for the delivery of clinical services</li> <li>Head of solid tumour service</li> <li>Head of hematologic oncology service</li> </ul>
	Supervise the chemotherapy service	<ul> <li>Administrative director, responsible for the administrative management of the service</li> <li>Lead chemotherapy nurse manager</li> <li>Lead oncology pharmacist</li> <li>Others, as appropriate</li> </ul>

#### 6. INFORMATION MANAGEMENT

The cancer centre's information management (IM) infrastructure provides an overarching umbrella for the chemotherapy-specific IM infrastructure. Ideally, the centre-wide and function-specific IM infrastructure is electronic and fully integrated.

The chemotherapy-specific IM infrastructure includes a range of interoperable information systems, all of which feed into a chemotherapy information system, as illustrated in Figure 2. The chemotherapy information system is, in turn, connected to the hospital information system and patient health record. This is important for the ongoing care of chemotherapy patients who may need other services.

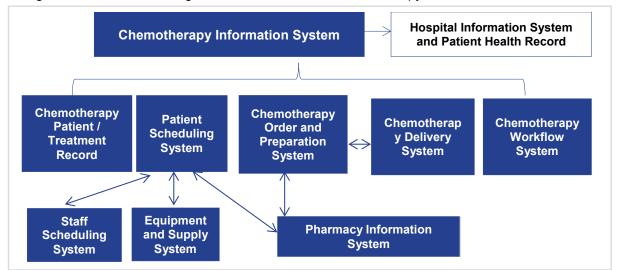


Figure 2: Information Management Infrastructure for Chemotherapy

Major information systems that feed into the chemotherapy information system include the following.

# **Chemotherapy Patient/Treatment Record**

The chemotherapy patient/treatment record includes patient-specific information. Oncologists use the chemotherapy patient/treatment record to document the results of patient examinations and additional tests, the type of chemotherapy to be delivered, the patient's proposed treatment plan and the patient's informed consent. Chemotherapy nurses and pharmacists may also obtain and document some of this information in the chemotherapy patient/treatment record. Schedulers register the patient and document all scheduled patient visits and treatments in the chemotherapy patient/treatment record. Finally, information on all chemotherapy-related patient activities are documented by members of the healthcare team, including the results of all patient assessments, visits and treatments, as well as any education or supportive care provided.

# Patient Scheduling System

The patient scheduling system is used to schedule pre-treatment tests, chemotherapy treatments, supportive care visits, and review and follow-up visits. Chemotherapy must be scheduled to align with a patient's other treatments (e.g., surgery, radiotherapy). Successfully scheduling patients for chemotherapy is only possible if sufficient and appropriate staff, equipment and drug regimens are available. The patient scheduling system is directly linked to the staff scheduling system, the equipment and supply system and the pharmacy information system. As Figure 2 illustrates, there is a two-way information flow between these systems.

#### **Chemotherapy Order and Preparation System**

The process of ordering and preparing chemotherapy is complex and should be supported by an electronic system. Paper-based systems have a greater risk of error due to transcription inaccuracies, illegible handwriting, lack of standardized documentation, the complexity of managing multiple encounters and drug administrations for one patient, and other reasons. <sup>31</sup>

The chemotherapy order and preparation system should include two subsystems:

- A CPOE system, where providers enter prescriptions electronically. CPOEs have been shown to reduce chemotherapy-related medication errors and adverse drug events, improve patient safety, improve clinician workflow practices and decrease medication turnaround time. <sup>1, 32-34</sup>
- A clinical decision support system (CDSS), which aids in clinical decision-making by assessing the characteristics of a patient in relation to a computerized knowledge base of current best practice clinical standards and guidelines. <sup>33</sup> The CDSS should include features that enable real-time clinical decision support. <sup>1</sup> For more information, see the <u>Cancerpedia: Clinical Management</u> chapter.

The chemotherapy order and preparation system should be linked to the pharmacy information system. This ensures that medication orders are transmitted electronically to the pharmacy, which prepares the chemotherapy<sup>31</sup> and conducts and documents safety checks and balances before the therapy is transferred to the treatment area. Barcoded medication administration technology may be used to identify and distribute the medications.<sup>31</sup> For more information, see the *Cancerpedia: Pharmacy* chapter.

# **Chemotherapy Delivery System**

The chemotherapy delivery system links with the chemotherapy order and preparation system and is used to document the medications and treatments delivered to patients.

# **Chemotherapy Workflow System**

The chemotherapy workflow system ensures that the right people and services are available and organized appropriately to support the effective and efficient flow of chemotherapy patients throughout the chemotherapy pathway, as illustrated in Figure 1.

#### D. MANAGEMENT

Effective and efficient chemotherapy management includes a leadership structure with clearly articulated accountabilities and key staff focused on improving quality.

#### 7. LEADERSHIP

The chemotherapy leadership team should reflect both clinical and administrative expertise. Generally, the team should include the lead oncologist and the chemotherapy service administrative director. These co-leads are accountable for the overall chemotherapy service.

The membership of the core leadership team may increase based on the size of the chemotherapy service or the role of the cancer centre as a referral centre. Representatives of the leadership team may include:

- The lead chemotherapy nurse manager
- The lead oncology pharmacist
- Other medical/clinical heads who oversee specialty areas (e.g., leukemia, lymphoma and

myeloma; solid tumours; allogeneic and autologous transplants)

- Quality experts
- Other members with specialized expertise, such as information technology or information management experts or researchers

The leadership team is accountable for planning, managing and improving chemotherapy quality and performance, and is responsible for the smooth functioning of an effective and efficient chemotherapy service. This includes: ensuring compliance with accreditation and operating standards and guidelines; developing and implementing appropriate policies, procedures and processes to operationalize standards and guidelines; overseeing patient flow through the chemotherapy pathway; and ensuring that appropriate systems are in place to decrease wait times and enable proper documentation in the patient health record.

Each member of the leadership team should be responsible for the performance of their respective professional colleagues and area. For example:

- The lead oncologist who serves as the clinical head of medical and hematologic oncology

   is responsible for the performance of the service's medical and other clinical staff, as well
   as the quality and safety of chemotherapy care.
- The lead chemotherapy nurse manager is responsible for nursing professional practice and quality of care, and for ensuring that nursing standards are established and met.
- The administrative director is responsible for the overall management of the service, which
  includes implementing policies, procedures and practices for appropriate, efficient and
  effective chemotherapy.

In addition to the leadership team, cancer centres should consider chemotherapy committees. A chemotherapy quality of care and safety committee can monitor the quality of the chemotherapy service, identify areas for improvement and develop quality initiatives, among other duties.

# 8. OPERATING STANDARDS AND GUIDELINES

Cancer centres must meet accreditation operating standards and guidelines that have been established by their national accreditation body. Many countries have health service accreditation programs, whereas others adopt or adapt the programs of other countries. Accreditation standards and guidelines for hospitals and chemotherapy programs set out operational requirements to support a safe and effective service. Generally, accreditation standards and guidelines relevant to chemotherapy address the following broad areas. 9, 36-39

#### Services

Accreditation standards and guidelines for the chemotherapy service typically include requirements for the following.

- Consultation: patients are examined and prioritized by the urgency of their condition; appropriate patient information is collected; patient and family rights are respected; informed consent is obtained; an interprofessional/multidisciplinary treatment plan is developed.
- Pre-treatment assessment: patients are assessed and additional tests and investigations

- are completed consistent with clinical practice guidelines.
- Chemotherapy order and preparation: chemotherapy orders are appropriate to the
  patient's needs and meet clinical practice guidelines; chemotherapy is prepared and
  verified according to established protocols; chemotherapy is delivered consistent with best
  practice guidelines and standards.
- Treatment: chemotherapy is provided to the right patient and in a safe and appropriate
  manner; care is evidence-based and informed by clinical best practice guidelines; care is
  documented; patients are monitored.
- **Review and follow-up:** care is reviewed, documented and discussed with the patient and family; care is understood by all, including the patient and the healthcare team; a process for patient monitoring and follow-up care is used.
- **Education, assessment and support:** patients and families receive all necessary information and education throughout the chemotherapy pathway.

**Service co-ordination:** the chemotherapy service is co-ordinated with other patient services (e.g., surgery, radiotherapy, other medical services, supportive care, palliative care).

# **Physical Facilities and Equipment**

Accreditation standards and guidelines for chemotherapy physical facilities and equipment typically include requirements to: meet all planning, design and construction requirements set by subnational, national and international regulatory bodies; provide adequate space and a physical layout that ensures good patient management, workflow, efficiencies, and infection prevention and control; and ensure that necessary chemotherapy equipment and supplies – including medications – are in good condition, safe to use, available and easily accessible.

#### **Human Resources**

Accreditation standards and guidelines for chemotherapy human resources require members of the healthcare team to be fully qualified, licensed and able to meet the responsibilities expected of them, including requirements for continuing education and professional development. Accreditation standards and guidelines may be general or specific, depending on the accreditation body; specific approaches may identify the competencies required of each profession working in the chemotherapy service, as well as the staff number and mix needed for safe and effective care.

# **Quality and Patient Safety**

Accreditation standards and guidelines for quality and patient safety tend to focus on requirements to have:

- A quality improvement plan for the chemotherapy service
- Ongoing staff education on quality and safety
- A performance improvement system that includes collecting and monitoring key indicators, and efforts to improve performance
- Safe practices
- Protocols for ongoing safety, such as infection prevention and control, universal precautions, medical management, and the handling of hazardous waste and substances

Examples of accrediting bodies that have chemotherapy standards and guidelines include, but are not limited to:

- Accreditation Canada, an independent, not-for-profit organization that accredits health organizations across the country. <sup>40</sup> Accreditation Canada also operates the <u>Health</u> <u>Standards Organization</u>, which is international. <sup>41</sup>
- The Australian Council on Healthcare Standards (ACHS), an authorized accreditation agency with the Australian Commission on Safety and Quality in Health Care. <sup>39</sup> ACHS accredits healthcare organizations to the National Safety and Quality Health Service Standards, ACHS also runs ACHS International.
- The <u>Care Quality Commission</u>, which is responsible for hospital accreditation and standards in the United Kingdom. <sup>42</sup>
- The American College of Surgeons' <u>Commission on Cancer</u>, which establishes standards for, and evaluates and accredits, cancer programs, amongst other activities. <sup>43</sup>
- <u>The Joint Commission</u>, an independent, not-for-profit organization in the United States that accredits and certifies healthcare organizations and programs across the country. <sup>44</sup> The Joint Commission also runs Joint Commission International.
- The <u>National Accreditation Board for Hospitals & Healthcare Providers</u> (NABH), a constituent board of the Quality Council of India, set up to establish and operate accreditation programs for healthcare organizations.<sup>38</sup> The NABH also runs NABH International.

For additional healthcare accreditation bodies, see the <u>International Society for Quality in Health Care</u>, which accredits accrediting bodies. <sup>45</sup>

# 9. POLICIES, PROCESSES AND PROCEDURES

Policies, processes and procedures reflect different and interconnected levels of activity.

- Policies are the standards and guidelines of the cancer centre that govern how it operates.
   The cancer centre's operating policies should reflect accreditation operating standards and guidelines.
- Processes set out what the cancer centre will do to achieve its policies. Processes usually
  identify who is responsible for performing a process (e.g., department), and the major
  functions or tasks that will be performed. Processes are high-level actions that drive
  specific procedures.
- Procedures identify the specific steps that will be taken to perform a task, how they will be done, by whom and when.

Cancer centres must establish policies, processes and procedures, and make these readily available to all staff engaged in the chemotherapy service, along with training, as required. Standard operating procedures (SOPs) should be regularly assessed for their relevance and effectiveness, and updated (i.e., annually, at a minimum). Document control is critical to ensure that the most updated versions of policies, processes and procedures are being used. An electronic system is preferable as the number of SOPs increases. Examples of areas in which policies, processes and procedures should be developed for the chemotherapy service include:

• **Scheduling:** scheduling of cases; cancellation of scheduled cases; management of underused or released scheduled time; and scheduling of chemotherapy services.

- Patient assessment and requirements: standard tools for patient assessment and screening; required tests; patient and family education; monitoring and tracking of medications; documentation of allergies; assessment of psychosocial concerns; referral to supportive care.
- **Patient identification:** use of identification bands/allergy bands and MedicAlert<sup>©</sup> bracelets; informed consent for treatment; unsigned or wrong consent; positive patient identification; translation and interpretation services; patient personal property and valuables.
- Ordering medications: who can order medications; standard medication orders (e.g., dose calculation, standard measurement units, use of CPOE with standard content, access to evidence-based best practices); two-plus person medication verification.
- **Preparing and dispensing medications:** who can prepare and dispense medications; standards for preparing and dispensing (i.e., right place at the right time for the right person)<sup>22</sup>; workflow; safety precautions; two-person patient and drug verification; uniform system (e.g., bar coding) for medication labelling and dispensing.
- Administering medications: who can administer medications; patient and drug/dose/route/rate verification; uniform labelling system (e.g., bar coding) for medication administration; safety precautions; appropriate administration.
- **Patient issues:** allergic reactions management; side-effects management; medical emergencies.
- **Personnel:** responsibilities of medical, nursing, pharmacy and other staff; reporting relationships; patient navigation and co-ordination of services; requirements for presence of medical/clinical oncologist; staff scheduling; staff recognition.
- **Documentation:** from consultation to pre-treatment assessment to treatment, review and follow-up.
- **Safety:** safety precautions, including safe working conditions (e.g., personal protective equipment and clothing); infection prevention and control; isolated patients; fire procedures; violence and harassment; safety codes; safe waste and spills management.
- Adverse events: disclosure of adverse events and near-misses; incident reporting; checklist processes; overdose management.
- **Supplies:** standardized equipment (e.g., infusion pumps); equipment and supply availability; drug distribution.
- Infrastructure: electrical failure; light or fan system failure.

#### 10. MANAGEMENT OF PATIENT FLOW

Cancer centres must manage the smooth flow of patients across the chemotherapy pathway, as illustrated in Figure 1. As the chemotherapy patient moves from one phase of care or service to the next, centres must ensure that referral processes are in place and that formal handoffs occur between the most responsible staff at each point of transition.

Table 2 outlines the management of patient flow at each phase of the chemotherapy pathway.

Table 2: Management of Patient Flow by Phase of the Chemotherapy Pathway

Phase	Management of Patient Flow
Consultation	

Phase	Management of Patient Flow
Referral for chemotherapy consultation	<ul> <li>Specialist requests oncology/chemotherapy consultation</li> <li>Oncologist's office assesses request for consultation using a standard process</li> <li>Patient is booked for consultation</li> </ul>
Consultation with oncologist	<ul> <li>Oncologist:         <ul> <li>Examines the patient</li> <li>Reviews diagnostic tests, specimens and other report results, and advises patient</li> <li>Decides on need for additional specialist opinions</li> <li>Develops treatment plan in consultation with team</li> <li>Communicates with the referring physician, other oncologists and the oncology pharmacist, as required, to discuss chemotherapy treatment and timing</li> <li>Co-ordinates with nursing and patient/family support to provide information, education and psychosocial support</li> </ul> </li> </ul>
Registration	<ul> <li>Oncologist's office connects with registration office to schedule pre-treatment assessment and chemotherapy session(s)</li> <li>Registration office schedules pre-treatment assessment visit and chemotherapy session(s)</li> </ul>
Pre-Treatment	
Assessment Pre-treatment	Oncologist and/or oncology nurse examines patient and checks
assessment	that all tests and investigations have been completed; if not, additional tests are ordered and reviewed
Chemotherapy Order and Preparation	
Chemotherapy order	<ul> <li>Oncologist and team members review initial treatment plan and additional test results, and make amendments, if required</li> <li>Oncologist prescribes final chemotherapy order and transfers to pharmacy</li> </ul>
Chemotherapy preparation	<ul> <li>Oncology pharmacist:</li> <li>Reviews the chemotherapy order and all documentation, verifies doses/values, conducts safety checks, and contacts the oncologist and/or oncology nurse to address issues</li> <li>Provides oversight as the pharmacy technician prepares the order</li> <li>Checks the order and approves the transfer of chemotherapy to the treatment area</li> </ul>
Treatment	
Treatment	<ul> <li>Clerical or nursing staff escort the patient to the treatment area</li> <li>Oncology nurse:         <ul> <li>Positively identifies the patient, conducts checks to ensure that clinical information is complete, and prepares the patient for treatment (e.g., information on treatment, instructions)</li> <li>Delivers treatment</li> <li>Monitors the patient for side-effects and allergic reactions, and responds appropriately; this may include notifying the physician on call in an emergency</li> <li>Documents all treatment-related information in the patient health record</li> </ul> </li> </ul>
Review and Follow- Up	

Phase	Management of Patient Flow
Review	<ul> <li>Oncologist and/or oncology nurse examines the patient, reviews the treatment regimen, identifies care needs and addresses treatment side-effects</li> <li>Patient receives information on the next treatment, follow-up appointments and any other tests required</li> <li>Nursing and patient/family support provide psychosocial and other support services on an ongoing basis, as required</li> </ul>
Follow-up	<ul> <li>Oncologist and/or oncology nurse:</li> <li>Meets with the patient after chemotherapy is completed to assess progress and any chemotherapy-related issues</li> <li>Manages complications and side-effects</li> <li>Provides 24 hours a day, seven days a week access to expert advice and assessments</li> </ul>
Patient Education and Support	
Patient education and support	Provided by various staff at all phases of the chemotherapy pathway

#### 11. DOCUMENTATION AND DATA-INFORMED MANAGEMENT DECISIONS

Cancer centres must collect and analyze standard chemotherapy information to ensure that patients receive services consistent with the policies and procedures of the organization, chemotherapy resources are being used effectively and efficiently, and chemotherapy practices are safe.

Documentation is required throughout the chemotherapy patient care pathway, as illustrated in Figure 1. Given that the amount of data collected can be overwhelming, management should develop a minimum data set, with clearly defined key indicators to monitor activities and processes and improve performance. Indicators should be analyzed to support data-informed management decisions, and management tactics should be implemented to mitigate risks and make improvements. Improvements can be assessed in various ways; for example, the centre can focus on internal performance improvements, compare its performance in relation to external standards or compare its performance in relation to external peer group benchmarks.

Table 3 presents a suite of chemotherapy management indicators that may be considered for a cancer centre's minimum data set. Additional indicators depend on local circumstances. Table 3 also presents potential management analyses targeted at improving performance.

Table 3: Examples of Chemotherapy Indicators and Management Analysis

Area	Indicators	Management Analysis
Patient	<ul><li>Number of chemotherapy patients</li><li>Patient demographics</li></ul>	Profile of patients by age, gender, location of residence and analysis of variation over time
Consultation	<ul> <li>Number of initial consultations for which all relevant information has been provided (e.g., tests, reports)</li> <li>Number of consultations that require additional specialist input</li> </ul>	<ul> <li>Rate and analysis of incomplete information provided to make a decision, and improvement tactics</li> <li>Rate of consultations that require additional specialist input</li> </ul>

Area	Indicators	Management Analysis
Alea	Number of initial consultations where chemotherapy is recommended     Number of patients and families who are educated about the chemotherapy process and their care	Rate of education compared to target, and improvement tactics
Pre-Treatment Assessment	<ul> <li>Number of patients with incomplete tests and investigations</li> <li>Time the order is complete to when it is received by the pharmacy</li> </ul>	<ul> <li>Rate of incomplete tests and investigations, and improvement tactics</li> <li>Analysis of time the order is completed to when it is received by the pharmacy, compared to target</li> </ul>
Chemotherapy Order and Preparation	<ul> <li>Number and type of chemotherapy orders</li> <li>Number of issues identified by the pharmacist that need resolution</li> <li>Number of chemotherapy orders that are incorrectly prepared</li> <li>Time the order is received by the pharmacy to when it is sent to the treatment area</li> </ul>	<ul> <li>Profile of chemotherapy orders and analysis of changes over time</li> <li>Rate and analysis of issues that need resolution, and improvement tactics</li> <li>Rate of chemotherapy orders that are incorrectly prepared, and improvement tactics</li> <li>Analysis of time the order is received by the pharmacy to when it is sent to the treatment area, compared to target</li> </ul>
Treatment	Time patient enters and exits the chemotherapy suite Scheduled start time of treatment and actual start time Start time and finish time of treatment Hours scheduled for chemotherapy and hours actually used Number of treatments that cannot proceed as scheduled	<ul> <li>Analysis of time in the chemotherapy suite compared to targets (e.g., total time from entry to exit; time between in-chair and treatment start; duration of treatment time), and tactics to address variations</li> <li>Analysis of time discrepancies (e.g., scheduled and actual start; scheduled and actual duration of treatment), and tactics to address variations</li> <li>Number of treatment delays and cancellations, and reasons why: i.e., patient action (e.g., late arrival); provider action (e.g., late arrival); clinical causes (e.g., patient ill); non-clinical causes (e.g., wrong chemotherapy, no chair, equipment issues), plus causal analysis and improvement tactics</li> </ul>

Area	Indicators	Management Analysis
Safety Best Practices	<ul> <li>Compliance with verification and safety protocols</li> <li>Complete, detailed and accurate documentation of consultation, pretreatment assessment, chemotherapy order and preparation, treatment, and review and follow-up</li> <li>Compliance with quality and safety regulations and requirements</li> </ul>	<ul> <li>Rate of compliance with verification and safety protocols compared to target, and improvement tactics</li> <li>Rate of complete and accurate documentation, and improvement tactics</li> <li>Rate of compliance with quality and safety regulations and requirements, and improvement tactics</li> </ul>
Use of Chemotherapy Resources	Volume of drugs, equipment and supplies used in the chemotherapy service in relation to activity	Tracking of volumes, resource utilization and costs (i.e., financial, human, capital, operating), and identification of resource gaps and opportunities for improved efficiencies that do not compromise the chemotherapy service

#### 12. SPECIAL CONSIDERATIONS FOR HEMATOPOIETIC STEM CELL TRANSPLANTATION

Hematopoietic stem cell transplants (HSCTs, or bone marrow transplants) are used to treat leukemia, lymphoma and myeloma. Very high doses of chemotherapy are given with or without total body irradiation to kill cancer cells and stem cells. Following this treatment, healthy stem cells are returned to the body intravenously. The following section provides a high-level overview of the HSCT service. More detailed information is available in the references provided.

# The HSCT Pathway

Most HSCTs occur within the context of the chemotherapy service along a pathway, as illustrated in Figure 3 and described in further detail below.

# Confirming Eligibility for Treatment

HSCTs leave patients temporarily, but severely immunocompromised and carry risks. A full physical and psychosocial examination, blood tests, imaging tests and other functional tests may be required to confirm a patient's eligibility for this treatment. In addition, risks and possible complications must be discussed with the

Confirming Eligibility
for Treatment

Procuring Stem Cells

V

Preparing for Treatment

V

Treatment

V

Follow-Up

Figure 3: The HSCT Pathway

patient to ensure informed consent for the procedure.

When resources permit, an HSCT co-ordinator should be assigned to the patient to organize these tests and support patient navigation throughout the pathway.

# **Procuring Stem Cells**

Once a patient has been deemed eligible for HSCT, healthy and viable stem cells must be procured before treatment can proceed. Stem cells may be obtained in two ways:

- Directly from the patient (i.e., autologous)
- From a donor (i.e., allogenic)

An allogenic stem cell donation must be a "match" for the patient. A greater match lowers the likelihood of complications post-treatment. The extent of a match between a donor and a patient is determined through a histocompatibility antigen blood test. Access to a specialized cell processing laboratory and other appropriate laboratory facilities and expertise are required for this testing. For more information about the requirements for a cell processing laboratory, refer to Leemhuis et al. 2014. For more information about other laboratory facilities, see the *Cancerpedia: Laboratory Medicine and Pathology* chapter.

Matched allogenic stem cells may come from a known person (e.g., a sibling or relative) or from an anonymous donor. Anonymous donors are located through stem cell registries, such as the international registry <u>World Marrow Donor Association</u>. <sup>47</sup> Certain patient groups are currently underrepresented in stem cell registries, including those of African and Asian descent. <sup>48</sup> Many cancer centres offer the services of a donor search co-ordinator to support the search for an allogenic stem cell match.

Stem cells may be harvested from the bone marrow or the peripheral blood of an autologous or allogenic donor. Stem cell harvesting from bone marrow occurs under general anaesthesia. Access to surgical suites and expertise are required for this procedure. In addition, a surgical day unit must be available for post-procedure observation. For more information, see the *Cancerpedia: Surgery* chapter.

Stem cell harvesting from peripheral blood occurs on an outpatient basis and may take place over the course of several days. Donors may be given advance injections of a hematopoietic growth factor drug to promote the proliferation of stem cells and their release into the blood stream. Once ready, donor blood is taken intravenously and cycled through an apheresis machine, which collects stem cells. Access to a specialized HSCT outpatient clinic equipped with patient beds or chairs and appropriate expertise is required. As above, a specialized laboratory is also required to support stem cell mobilization and collection, photopheresis and plasmapheresis. For more information about the requirements for this laboratory, refer to Leemhuis et al. 2014.<sup>46</sup>

# **Preparing for Treatment**

Regardless of their source, stem cells must be prepared for use in HSCT. As above, a specialized cell processing laboratory is required to support stem cell cryopreservation and

thawing, CD34+ enumeration, the determination of cell viability and other cell manipulation. For more information about the requirements for this laboratory, refer to Leemhuis et al. 2014.<sup>46</sup>

Treatment planning for HSCT typically involves a wide range of physicians and other health professionals, which may include oncologists, respirologists, gastroenterologists, dermatologists, critical care specialists, infectious disease specialists, palliative care specialists and psychosocial supports, depending a patient's condition and individual needs. This interprofessional/multidisciplinary approach serves to minimize risk to the patient and ensures that appropriate supports are in place for the treatment and post-treatment period. It is imperative that any healthcare providers who are primarily responsible for the care of HSCT patients receive special training. This includes hematologists, medical oncologists, radiation oncologists, pharmacists and nurses.

#### **Treatment**

Once preparation for treatment is complete, HSCT can begin. The treatment is a two-step process, beginning with a preparation of the body for transplant followed by the transplant itself. Treatment begins with high-dose chemotherapy and sometimes total body irradiation to kill both cancer cells and stem cells. This may occur over a period of days. Following a short break, treatment continues with an HSCT, in which donor stem cells are given intravenously to the patient. Patients must be closely monitored during treatment for side-effects. Following treatment, allogenic transplant patients may be given anti-rejection drugs to minimize their reaction to mismatched donor cells

Autologous bone marrow transplant patients may receive treatment on an outpatient basis. Access to a specialized HSCT outpatient clinic equipped with patient beds or chairs and appropriate expertise is required, as above. Allogenic HSCT patients usually receive treatment in an inpatient setting, given their higher risk for complications. Specialized inpatient rooms equipped with patient beds, high efficiency particulate air (HEPA) systems and positive / negative pressure systems (i.e., depending on the patient and the circumstances) are required. For more information, see the *Cancerpedia: Inpatient Care* chapter.

#### Follow-Up

HSCT patients may experience complications following treatment, ranging from infection to graft versus host disease. Allogenic HSCT patients, in particular, should receive frequent monitoring post-treatment, typically attending follow-up appointments twice per week for two to three months. Access to a specialized HSCT outpatient clinic equipped with appropriate expertise is required, as above.

### **Management and Quality**

The oversight of HSCT is typically aligned to existing chemotherapy management and quality assurance structures. For information on important standards, guidelines and policies associated with HSCT, see the Foundation for the Accreditation of Cellular Therapy (North

America)<sup>49</sup> or the <u>Joint Accreditation Committee – International Society for Cellular Therapy & European Society for Blood and Marrow Transplantation</u> (Europe).<sup>50</sup>

#### E. QUALITY

Quality performance in chemotherapy is critical, given that approximately half of all cancer patients need chemotherapy as a treatment. 1 It is also critical given the complexity of chemotherapy, which increases the opportunities and potential for error. Chemotherapy drugs have a low therapeutic (i.e., safety) index; that is, a small window in which the amount of chemotherapy is therapeutic as opposed to toxic. 34, 51-53 Treatments are highly personalized based on multiple factors, including: patient characteristics; the type, site, stage and genetics of the tumour; the treatment goal; the timing of treatment in relation to other treatments; sideeffects; the need for supportive medications, and so on. 1, 7, 34, 51, 52 Methods of administering chemotherapy also present risks, including complications associated with the use of access devices (e.g., infections, thrombosis, occlusion and extravasation) that can lead to high morbidity, mortality and increased costs.<sup>54</sup> Finally, the chemotherapy pathway involves multiple steps and healthcare providers, and usually includes multiple chemotherapy treatments over time. 34 These processes and people must be well integrated and co-ordinated, with clear roles, responsibilities and communication. This is true both within the cancer centre as well as between the cancer centre and external organizations, which may be responsible for some aspects of chemotherapy (e.g., outsourcing of treatment preparations). 7,55

The following section describes strategies and tools for preventing chemotherapy errors and improving the quality of chemotherapy-related care.

# 13. STANDARDS, GUIDELINES AND BEST PRACTICES

The standards, guidelines and best practices used by a cancer centre may originate from different sources, such as international, national or subnational organizations and bodies. Although cancer centres may develop local best practices, these should align with the national and subnational standards and guidelines of the jurisdiction in which the cancer centre is located.

# **Clinical Management**

Clinical practice guidelines for chemotherapy are based on evidence or expert consensus, and are generally developed or recommended by larger health bodies. In addition, a number of organizations make available a wide range of cancer-related standards and guidelines, including those for chemotherapy.

Examples of selected chemotherapy-specific clinical guidelines include:

- BC Cancer's chemotherapy protocols (Canada) <sup>56</sup>
- European Society for Medical Oncology's clinical practice guidelines 57
- European Oncology Nursing Society's clinical practice guidelines and recommendations 58
- National Institute for Health and Care Excellence's guidance (United States) 59
- National Comprehensive Cancer Network's <u>guidelines</u> <sup>60</sup> and <u>chemotherapy order</u> templates (United States) <sup>61</sup>

For more information about evidence- and consensus-based clinical guidelines, see the <u>Cancerpedia: Clinical Management</u> chapter.

#### **Human Resources**

All healthcare professional groups develop professional care standards and recommended practices for their members. Examples of professional bodies that develop chemotherapy human resource practices include the following.

# Medical/Clinical Oncology

- Australia: Medical Oncology Group of Australia 62
- Canada: Canadian Association of Medical Oncologists 63
- Europe: European Society for Medical Oncology 64; European Hematology Association 65
- Latin America / the Caribbean: <u>Latin American and Caribbean Society of Medical Oncology</u>
- United States: <u>American Society of Clinical Oncology</u> <sup>67</sup>; <u>American Society of Hematology</u>

# Nursing

- Australia: <u>Clinical Oncology Society of Australia</u>, whose COSA Guidelines for the Safe Prescribing, Dispensing and Administration of Systemic Cancer Therapy describe the nursing role <sup>22</sup>
- Canada: <u>Canadian Association of Nurses in Oncology</u>, which offers Standards and Competencies for Cancer Chemotherapy in Nursing Practice and an associated toolkit and self-assessment tool <sup>69</sup>
- Europe: <u>European Oncology Nursing Society</u>, which offers a cancer nursing curriculum <sup>70</sup>
- United States: American Society of Clinical Oncology <sup>67</sup>, Oncology Nursing Society<sup>71</sup> and The US Oncology Network <sup>14</sup>, whose Chemotherapy Administration Safety Standards, Chemotherapy and Biotherapy Guidelines and Recommendations for Practice and The Role of the Oncology Registered Nurse In Outpatient Medical Oncology <sup>72</sup> describe the nursing role

# Pharmacy

- Australia: <u>Pharmaceutical Society of Australia</u> <sup>73</sup>; Clinical Oncology Society of Australia, whose COSA Guidelines for the Safe Prescribing, Dispensing and Administration of Systemic Cancer Therapy describe the pharmacy role <sup>22</sup>
- Canada: <u>Canadian Association of Pharmacy in Oncology</u> <sup>74</sup>; <u>The Pharmacy Examining</u> <u>Board of Canada</u> <sup>75</sup>
- Europe: <u>European Society of Oncology Pharmacy</u> <sup>76</sup>
- International: <u>International Pharmaceutical Federation</u> <sup>77</sup>; <u>The International Society of</u> Oncology Pharmacy Practitioners <sup>78</sup>
- United Kingdom: General Pharmaceutical Council 79; British Oncology Pharmacy Association 80
- United States: <u>Board of Pharmacy Specialties</u> <sup>81</sup>; <u>American College of Clinical Pharmacy</u> <sup>82</sup>; <u>American Society of Health-System Pharmacists</u> <sup>83</sup>; <u>Hematology/Oncology Pharmacy</u>

# Association 84

# Pharmacy Technicians

- Canada: <u>National Association of Pharmacy Regulatory Authorities</u> <sup>85</sup>; <u>Canadian Association of Pharmacy Technicians</u> <sup>86</sup>; <u>The Pharmacy Examining Board of Canada</u> <sup>75</sup>; <u>Canadian Council for Accreditation of Pharmacy Programs</u> <sup>87</sup>
- United Kingdom: General Pharmaceutical Council 79
- United States: Pharmacy Technician Certification Board 88

### Physician Assistants

- Australia: <u>Australian Society of Physician Assistants</u> <sup>89</sup>
- Canada: Canadian Association of Physician Assistants 90
- India: Indian Association of Physician Assistants 91
- United States: American Academy of Physician Assistants 92

# **Chemotherapy Practices**

Cancer centres must implement quality chemotherapy practices that inform patient care in the following areas.

# Up to and Including the Decision to Proceed with Chemotherapy

# Multidisciplinary Cancer Conferences

The majority of cancer patients require a number of different clinical services from a range of healthcare providers. The multidisciplinary cancer conference (MCC) – also known as a multidisciplinary meeting – is a quality practice that guides complex, evidence-based, shared decisions about treatment. For more information, see the <u>Cancerpedia: Clinical Management</u> chapter.

### Priority Rating System

Cancer centres should adopt a priority rating system to help guide decisions about timely access to chemotherapy, based on clinical need. The system should:

- Define what is meant by chemotherapy wait (e.g., date of decision to treat with chemotherapy to the date when the chemotherapy is provided)
- Establish standard priority levels (e.g., immediate to least urgent, based on the type of cancer, complexity of the patient and the extent to which the cancer has spread)
- Develop standard clinical assessment criteria and recommended wait time targets for each priority

Cancer centres may be required to use chemotherapy rating systems that have been developed at a national or subnational level. A number of chemotherapy priority rating systems are available, including the following.

 In the United Kingdom, the Joint Collegiate Council for Oncology (1993) 93 has recommended wait time targets by patient urgency, from the date of first oncology

- consultation to the start of chemotherapy.
- At the Peter MacCallum Cancer Centre in Melbourne, Lingaratnam et al. (2013) <sup>94</sup> have developed a performance data suite to support a chemotherapy service improvement project. The suite includes prioritization criteria based on clinical need, as illustrated in Table 4.
- In Ontario, Canada Cancer Care Ontario (2006)<sup>95</sup> has recommended target wait times for systemic therapy by patient priority.

Table 4: Target Wait Times for Systemic Therapy 94

Priority	Treatment to Commence	Patient at Imminent Risk of Significant Complications or Deterioration if Chemotherapy Not Started
1	Within two days	For example: imminent airway obstruction or superior vena cava obstruction
2	Within seven days	For example: rapidly progressive disease or advanced disease with risk of critical organ/structure compromise
3	Within 14 working days	All other groups of patients not meeting the above category criteria

### Patient Education and Information

Providing patient information and education throughout the chemotherapy pathway is a key quality practice. Patients require comprehensive information that is both generic and specific. Generic information includes, but is not limited to, overviews of the cancer centre and the chemotherapy process, the chemotherapy experience (i.e., how to prepare and what to expect), possible side-effects, and general post-chemotherapy planning and care. Patient-specific information includes, but is not limited to, details on the patient's disease, the expected outcomes of chemotherapy, how to address side-effects, details of after care and contact information.

In addition to providing information and education, there must be dialogue with, and support for, the patient and his or her caregivers to address ongoing needs and concerns.

For more information, see the <u>Cancerpedia: Patients</u> chapter.

# Throughout the Chemotherapy Pathway

Quality issues can occur at multiple points along the chemotherapy pathway. For example: 31, 96

- Chemotherapy prescribing and ordering e.g., wrong medication, wrong dose, wrong patient
- Chemotherapy preparation e.g., wrong labelling, ordering mistakes, wrong medications, wrong dose
- Chemotherapy administration e.g., wrong drug, wrong patient, wrong rate and time of treatment, wrong administration route, wrong treatment duration

Lennon (2013)<sup>97</sup> notes that using a simple mnemonic of the five Rs can be highly effective: right patient, right drug, right dose, right time and right administration route. Ulas et al. (2015)<sup>53</sup> further adds right registration, right form, right sequence and right administration duration. There are many resources that outline how to prevent chemotherapy errors through quality practices; for example, see Schulmeister (2006)<sup>96</sup>.

#### Process Standards and Guidelines

Numerous organizations have developed comprehensive standards and guidelines for the entire chemotherapy pathway. Effective implementation of these standards and guidelines can reduce the risks of errors <sup>98</sup>, enhance the safety of chemotherapy administration<sup>52</sup> and protect staff from harm.

Cancer centres should develop, implement and monitor the use of comprehensive standards and guidelines for the entire chemotherapy pathway. Examples that can be adopted and/or adapted include the following:

- Australia: Clinical Oncology Society of Australia's <u>COSA Guidelines for the Safe</u> Prescribing, Dispensing and Administration of Systemic Cancer Therapy <sup>22</sup>
- Canada: Canadian Association of Nurses in Oncology's <u>Standards and Competencies for Cancer Chemotherapy in Nursing Practice</u> and associated toolkit <sup>69</sup>; Cancer Care Ontario's <u>Safe Administration of Systemic Cancer Therapy: Administration of Chemotherapy and Management of Preventable Adverse Events</u> <sup>99</sup>
- United States: American Society of Clinical Oncology / Oncology Nursing Society's <u>Chemotherapy Administration Safety Standards Including Standards for the Safe</u> <u>Administration and Management of Oral Chemotherapy</u> 37

#### Standard Systems and Tools

Standard systems and tools should be used to help support the implementation of best practice standards and guidelines. Some of these tools and systems are regarded as best practices and are included in the standards and guidelines noted above.

Standard templates and order sets (i.e., that eliminate the use of free text), CPOE and electronic patient health records support safe practice, improve compliance with guidelines, and mitigate the chance of errors reaching patients and causing harm. <sup>32, 34, 100, 101</sup> Ideally, cancer centres should use CPOE as the standard for protocols and orders. CPOE incorporates electronic order sets along with best practice guidelines to standardize practice, incorporate clinical decision support, improve interdepartmental communication, and capture data for management, research and quality monitoring. <sup>34</sup> The use of CPOE or pre-printed orders as opposed to handwritten orders can significantly reduce rework, confusion and the incidence of errors; however, these measures will not eliminate all errors, which means that ongoing vigilance is needed to ensure quality. <sup>102</sup> Best practice guidelines for establishing a CPOE system for systemic treatment can be found at Cancer Care Ontario (2012).<sup>32</sup>

Standard checklists help prevent errors of omission and can be used throughout the chemotherapy administration process. <sup>103</sup> Checklists are best applied to multiple, complex,

mechanistic tasks, rather than tasks that require critical thinking. <sup>103</sup> Checklists with explicit step-by-step instructions appear to be more effective than abstract general reminders in helping healthcare providers detect errors. <sup>104</sup> Matching the sequence of items on a checklist with workflow has a positive impact on the ease of use and efficiency of the checklist. White et al. (2010) recommend steps to develop a checklist for detecting errors. <sup>104</sup>

In addition to checklists, the use of validated tools helps ensure a standard approach to measuring critical aspects in the chemotherapy process. For example, many validated tools exist for standard patient screening and assessment (see Leung et al. 2012). 103

Various checking and tracking processes can also be used to help reduce the risk of error. Examples include:

- Drug dose checks.<sup>101</sup>
- Error management surveillance systems, to detect and correct medical and administrative errors. 52
- Bar coding systems, which can generate alerts in such instances as a missing order, wrong dose, wrong route, wrong schedule and so on.<sup>31</sup> Bar coded technology has been shown to significantly reduce the rate of dispensing errors and associated potential adverse drug events, and decrease administration-related errors. <sup>105</sup>

#### After Treatment

To advance quality chemotherapy performance, cancer centres should hold regular quality of care conferences (QCCs) after treatment is finished. QCCs – also known as morbidity and mortality rounds or morbidity and mortality conferences – are usually held monthly, or more often if certain patient care issues need to be discussed. Everyone involved in the treatment of the patient whose care is being examined should attend. Discussions should be detailed, with open and frank examinations of the quality of care that was provided. Complications, deaths and adverse events should be fully examined, with the goal to identify policies and processes to help prevent recurrence, staff education opportunities and required practice changes. For more information, see the <u>Cancerpedia: Clinical Management</u> chapter.

Along with QCCs, cancer centres should require the completion of standard incident reports for any adverse events that have occurred, so that quality can be monitored, mitigating actions taken and performance improved.

#### Flow

The chemotherapy pathway is complex, as illustrated in Figure 1. A great deal of effort is required to plan, prepare and co-ordinate chemotherapy services so that patients receive safe, high-quality and timely treatment, and so that resources (i.e., human resources, financial resources, equipment and facility infrastructure) are optimized. Poor chemotherapy flow results in the poor use of resources, delayed or cancelled treatments, increased wait times, and high levels of patient and staff stress.

Examples of quality performance within each phase of the chemotherapy pathway are illustrated in Figure 4.

The use of process improvement methodology is a major tactic for improving chemotherapy quality and efficiency. One common approach is lean methodology, which was pioneered by Toyota and has since been adopted by the manufacturing, service and healthcare industries. Using this approach, front line staff use a structured process to define value, map work steps, and identify and remove unnecessary steps in their work. 106 A second common approach is Six Sigma, which was pioneered by Motorola and has also been adopted by other industries, including healthcare. Six Sigma uses quantified value targets and identifies and removes the cause of defects or errors to eliminate these defects and errors and minimize variability. 107 Aspects of both approaches can be used for quality improvements. 108 For more information, see the Cancerpedia: Quality chapter. Outlining the

chemotherapy pathway is

Figure 4: Examples of Quality Performance

#### Consultation and Pre-Treatment Assessment

- · Patient arrives on time
- Oncologist has sufficient patient information to conduct a chemotherapy consultation
- Patient receives information and is educated about their chemotherapy and care
- · Patient provides consent
- Additional tests are ordered and completed as part of pre-treatment
- Interprofessional/multidisciplinary treatment plan is developed and updated, subject to additional test results

#### Chemotherapy Order and Preparation

- Detailed order for chemotherapy complete
- Final chemotherapy order transferred to pharmacy in a timely manner
- Chemotherapy order correct from a clinical perspective
- Chemotherapy order prepared using efficient practices
- Prepared order matches the original order
- Prepared chemotherapy order transferred to treatment area in a timely manner

#### **Treatment**

- · Patient arrives in treatment room on time
- Treatment staff arrive on time
- Treatment area is prepared and supplied appropriately
- Sufficient time is scheduled for the chemotherapy treatment
- Treatments are scheduled using efficient practices (e.g., appropriate number of patients for day, etc.)
- Excellent communications and teamwork

#### Review and Follow-up

- Patient assessed after each treatment and issues addressed
- Next treatment, follow-up appointments and additional laboratory tests scheduled
- Follow-up conducted after treatment finished

helpful for understanding each healthcare team member's role and scope of practice, and for highlighting bottlenecks and issues that need to be addressed.<sup>97</sup> Studies have shown that process improvements can have significant positive impacts, including: reduced wait times; reduced waste relating to expired drugs and pharmacy rework; and reduced staff resources required to deliver the chemotherapy service. <sup>94, 109, 110</sup>

Initiatives to improve flow that directly impact patients should consider the patient population as well as the environment of the cancer centre and its geographic challenges.<sup>54</sup> For example, scheduling a patient's pre-treatment and treatment on the same day may reduce the number of

patient visits for care, but tends to result in long patient waits at the hospital, high staff workload pressures (e.g., if treatment protocols are long, if orders need to be clarified), less than optimal use of nursing and treatment capacity in the early hours of the day, and other issues. <sup>30, 54</sup>

Programs are available to help hospitals improve the quality and efficiency of the chemotherapy service. For example, the <u>Western & Central Melbourne Integrated Cancer Service</u> offers a guide to chemotherapy day unit redesign measures that includes detailed process maps and improvement measures. <sup>111</sup>

#### 14. Performance Monitoring, Reporting and Quality Improvement

The chemotherapy service must establish a system for quality and performance management and continuous quality improvement. Quality improvement includes the following.

# **Quality Framework**

The cancer centre's chemotherapy quality framework should include broad domains for performance improvement, such as patient safety, staff satisfaction, and care that is timely, efficient, patient-centred, effective, accessible, equitable and appropriate. <sup>112</sup> These broad domains should align with the cancer centre's priorities and reflect the particular priorities of the chemotherapy service. The selection of domains may also be influenced by the external priorities of national or subnational health ministries or organizations that focus on quality in cancer chemotherapy. Examples include the following:

- Agency for Healthcare Research and Quality 113
- American Society of Clinical Oncology <sup>67</sup> and its Quality Oncology Practice Initiative (QOPI®) and QOPI Certification Program™ <sup>114</sup>
- Cancer Quality Council of Ontario <sup>115</sup>
- European Society for Medical Oncology 64
- The Joint Commission 44

A wide range of clinicians and managers should have input into selecting the domains.

#### **Quality Performance Indicators**

The cancer centre's chemotherapy service should select quality performance indicators within each broad domain. As with the selection of domains, the selection of indicators should align with the cancer centre's objectives, reflect the priorities of the chemotherapy service and may be influenced by the priorities of external bodies. A wide range of clinicians and managers should have input into selecting the indicators, and should have confidence in both the process used to select the indicators and the indicators themselves.

Quality performance measures that are most useful to clinicians include appropriate groupings of meaningful indicators, high-quality data obtained using a valid methodology and results that are published in a timely manner. Indicator definitions may be adopted or adapted from other reliable sources. Indicators must be clearly defined, measurable and reliable, incorporate

the use of evidence or benchmarks, and be used to manage and improve the quality of chemotherapy.

Generally, quality performance indicators should consider structures, processes and outcomes. <sup>117</sup> For chemotherapy:

- Structures are the settings where care takes place and the related supports (e.g., registration office, consultation office, laboratory medicine and pathology, pharmacy, treatment room, equipment and supplies, human resources, administrative structures, program operations and policies).
- Processes refers to the full range of chemotherapy-related services the patient receives and how they are provided (e.g., in a way that is appropriate, complete, technically competent, guideline-based, safe, co-ordinated, acceptable).
- Outcomes refer to the patient's recovery, restoration of function and survival.

Numerous chemotherapy performance indicators can be selected. The chemotherapy service should select a manageable number of indicators to track. Table 5 presents examples of quality performance domains and indicators for chemotherapy.

Table 5: Examples of Quality Performance Indicators for Chemotherapy

Domains	Examples of Quality Performance Indicators
Accessible	<ul> <li>Wait time for chemotherapy within priority rating target</li> <li>Cancelled chemotherapy and reasons why</li> <li>Unplanned chemotherapy suite closures and reasons why</li> <li>Availability of chemotherapy to the population</li> </ul>
Appropriate	<ul> <li>Patients tests done prior to treatment</li> <li>Use of priority rating scale</li> <li>Appropriate number and mix of staff for the chemotherapy</li> <li>Appropriate medications, equipment and technologies for the chemotherapy</li> <li>Number of chemotherapy suites</li> </ul>
Effective	<ul> <li>Same-day and alternate day pre-treatment and treatment</li> <li>Use of evidence-based chemotherapy guidelines and standards</li> <li>High-level team performance</li> <li>Equipment functioning appropriately</li> </ul>
Efficient	<ul> <li>Flow between pre-treatment assessment, treatment, and review and follow-up phases, and reasons for delays</li> <li>First patient and subsequent patient on-time start accuracy, and reasons for delays</li> <li>Late chemotherapy finish and reasons why</li> <li>Time from patient arrival to beginning of treatment, compared to benchmarks</li> <li>Length of chemotherapy treatment compared to benchmarks</li> <li>Chemotherapy time booked compared to chemotherapy time used</li> <li>Turnover time of chemotherapy suite</li> <li>Per cent chemotherapy suite utilization</li> <li>Distribution of treatments across defined time (e.g., day, week)</li> <li>Total patients</li> <li>Average cost per case</li> <li>Average cost per chemotherapy hour</li> </ul>
Patient-Centred	Patient satisfaction levels     Provision of patient education and information

Domains	Examples of Quality Performance Indicators
Safety	<ul> <li>Compliance with accepted chemotherapy checklists</li> <li>Adverse events</li> <li>Near misses (e.g., unplanned event without injury, illness or damage, but with the potential for any or all of these adverse outcomes)</li> <li>Sterility break</li> <li>Complications and side-effects</li> <li>Injuries in the chemotherapy suite</li> </ul>
Staff Work Life	Staff satisfaction     Staff absenteeism     Staff efficiency     Staff turnover     Overtime hours

# **Quality Infrastructure**

A quality infrastructure with the following elements is needed to measure, monitor and improve chemotherapy performance.

First, information management support is needed to collect, analyze and report on indicators. The timing of indicator collection may vary from just-in-time to weekly, monthly, quarterly, semi-annually or annually. Regular access to chemotherapy data and the ability to develop customized reports is critical to driving improvements. Customized performance reports may focus on particular chemotherapy service areas, groups of staff or individual staff. It is best to provide performance feedback quickly and frequently, so that care and process improvements can be made. <sup>118</sup>

Second, a chemotherapy performance accountability team – made up of key chemotherapy leaders (e.g., medicine, nursing, pharmacy and others) – should review the indicators in relation to evidence- and consensus-based benchmarks and best practice standards and guidelines. The team should engage staff to identify areas for improvement, establish improvement targets with associated timelines, develop action plans, support the implementation of change and track improvements.

Members of leadership have the power and responsibility to drive patient safety, personally lead and be accountable for ongoing patient safety programs, set expectations for superior performance, model the way and mobilize efforts. <sup>100</sup> Market et al. (2009) note that a quality assurance team dedicated to detecting and preventing medical errors is needed to enhance the safety of chemotherapy administration. <sup>52</sup>

Third, chemotherapy staff should receive ongoing training in quality improvement and patient safety, including best practices, adverse events (i.e., recognize, respond, report, disclose) and human factors. The latter includes factors that can influence people and their behaviour. In the cancer centre, these are environmental, organizational and job factors, and individual characteristics that influence behaviour at work.<sup>119</sup>

Finally, to promote transparency and continuous quality improvement, performance information should be communicated to those working in the chemotherapy service and, more broadly, to everyone in the cancer centre. Communication should include commentary on the data, expected plans of action and successes improving performance.

#### F. THE FUTURE

There have been significant advancements in the treatment of cancer with chemotherapy. Patients are living longer, treatment options have increased dramatically and the use of targeted therapies is becoming more commonplace. <sup>97</sup> Complex treatments are usually delivered for longer periods of time. <sup>20</sup> In addition, chemotherapy is now being provided beyond larger cancer centres, in multiple settings. These trends impact facility infrastructure and design, as well as equipment, human resources and training requirements.

#### 15. INNOVATIVE TRENDS

Several major trends have, and will continue to, influence the evolution of chemotherapy.

# **Innovations in Chemotherapies**

Chemotherapy is evolving from simple drug regimens that kill spreading cancer cells as well as healthy cells to more complex drug regimens that target cancerous cells as they develop, are personalized to the individual and are used with other therapies. The rapid expansion of the "pharmaceutical armamentarium" <sup>30</sup> and different drug indications and combinations are fueling the evolution and growth of chemotherapy. Three future trends in chemotherapy – which are not mutually exclusive – are explored in greater detail below.

# Targeted Therapies

Targeted cancer therapies interfere with the specific molecules involved in the growth and spread of cancer cells, and reduce damage to healthy cells. Targeted therapies differ from standard chemotherapy in the following ways:

- They act on specific molecular targets associated with cancer, rather than all quickly dividing normal and cancerous cells
- They are cytostatic, rather than cytotoxic <sup>120</sup>

Targeted cancer therapies approved for use against specific cancers include: signal transduction inhibitors; anti-angiogenesis drugs; apoptosis-inducing drugs; immunotherapies; and agents that deliver toxic drugs to cancer cells.<sup>120, 121</sup>

Research has, and will continue to, develop targeted therapies approved for use in cancer treatment for a wide range of indications. For example, significant progress has been made in the area of antibody drug conjugates for the selective delivery of cytotoxic drugs to tumours. 122

Targeted therapies are enablers of personalized medicine, described below.

#### Personalized Medicine

Personalized medicine – also known as precision medicine – tailors the treatment plan to a person's unique clinical, genetic, genomic, biologic and environmental information. <sup>7</sup> Personalized medicine is enabled by new imaging and electronic health technologies, molecular and companion diagnostics, multiplex testing and next generation sequencing. <sup>123</sup> Chemotherapy will continue to play a critical role in personalized medicine.

# **Combination Therapies**

Chemotherapy is often used with other therapies to treat cancer. Traditionally, chemotherapy has been combined with surgery and radiotherapy. Increasingly, it is being coupled with other treatments. For example, an innovative approach to treating pancreatic cancer uses the patient's immune system to help fight disease by combining chemotherapy and immunotherapy. <sup>124</sup> This approach may also be used for melanoma, breast cancer and hepatocellular carcinoma.

#### **HSCT**

As HSCT advances, new opportunities are emerging. Evolving technologies and pharmaceutical supports are helping to minimize HSCT complications, thereby creating the potential for a larger and less matched donor pool. In some cases, haplo or half matches have been used successfully. A decreased risk of complications also means that some allogenic HSCTs can occur safely on an outpatient basis. Finally, HSCTs are increasingly being offered to an older age group, in which blood cancers tend to be more prevalent.

# **Evolving Chemotherapy Delivery Settings**

Traditionally, chemotherapy was provided in large cancer centres and hospitals. Increasingly, less complex chemotherapy is being provided in smaller community hospitals and in the home. Depending on the clinical needs of the patient, some may receive chemotherapy in all three settings. In the future, there will be increasing devolution of chemotherapies to settings outside of cancer centres. This trend is described in more detail below.

# Chemotherapy in Community Hospitals and Clinics

Community hospitals and clinics ranging in size and location (i.e., urban, rural, remote) are now providing chemotherapy due to increased demands for cost containment, advances in technology, improvements in managing side-effects, a desire for more consumer choice, and consumer preference for cancer care and treatment closer to home. These community hospitals and clinics must be connected into a larger chemotherapy network at a subnational or national level, with each network including a cancer centre. Each setting that provides chemotherapy should have clearly defined roles and responsibilities, which include: the appropriate range of chemotherapy for the setting; delivery standards; responsibility for patient treatment plans and continuity of care; provider and patient education and information;

prevention of, and response to, side-effects and adverse events; follow-up care; and quality assurance.

For a consensus-derived, integrated regional systemic treatment model, see Vandenberg et al. (2009) <sup>20</sup>. The team noted that the network-related roles of large, integrated cancer programs could include: providing complex cancer care; conducting cancer site-specific multidisciplinary care conferences; providing leadership for the development of local guidelines for the region; collecting and assisting in the analysis of outcome measures and quality indicators (e.g., funding, patient safety, program organization and efficiency); and providing academic leadership, including educational support and access to research.

# Chemotherapy in the Home

Increasingly, chemotherapy is being received in the home under specific conditions that take into account the treatment prescribed, caregiver availability, motivation and training, the home environment and location, and patient characteristics. Hethods of home-based chemotherapy delivery are similar to those used in outpatient settings; that is, intravenous and subcutaneous injections, as well as oral medications and topical preparations.

Depending on the method of chemotherapy delivery, a healthcare provider may need to visit the home to oversee one or more treatments. For example, continuous low-dose chemotherapy – which typically involves the use of a portable infusion pump – may be started in the hospital or by a healthcare provider in the home. All patients receiving chemotherapy at home must remain connected to a cancer centre or hospital for review, follow-up, and additional blood and other tests.

There is evidence to suggest that home chemotherapy can be delivered safely, with few serious complications or accidents; however, patients receiving this treatment must be carefully selected and trained. The cancer centre has an important role to play in helping to establish safe chemotherapy practices at home. Developing and implementing these practices can be resource intensive and require the ongoing support of a well-integrated, collaborative team of healthcare providers. 125

#### 16. THE IMPACT OF INNOVATIVE TRENDS

Infrastructure must be designed to accommodate evolving chemotherapy treatments. For example, chemotherapy units were traditionally designed for relatively short-duration treatments. Today, chemotherapy treatments are more complex and may involve multiple therapies that can take much longer to infuse.<sup>30</sup> These changes necessitate an effective physical set-up, which many include additional space to accommodate patients.

Given that the preparation of more complex chemotherapies requires increased vigilance to minimize error, examples of equipment for the future include: advanced bar-coded technologies, linked to electronic records and other information systems; radiofrequency identification that supports multiple and simultaneous scanning; smart infusion pumps, with dose error reduction systems that include built-in dosing limits and clinical advisories; and robotic technologies that prepare chemotherapy medications.<sup>105</sup> Other technologies to support

future trends include electronic tablets that support e-prescribing, mobile, hand-held devices that support CPOE, and access to electronic patient health records and patient assessment and education. <sup>105</sup>

In terms of human resources, everyone working to provide chemotherapy must be trained in current, specialized techniques and safe practices. The roles and scope of practice of healthcare providers may evolve as treatments become more complex. For example: the core competencies of medical oncologists will expand to include more molecular-based cancer subtypes, as well as the management of comorbidities, combination therapies, and short- and long-term side-effects <sup>123</sup>; more direct nursing care will be required to support more complex therapies <sup>30</sup>; and pharmacists will increasingly be called upon as members of the integrated clinical care team to contribute specialized knowledge to treatment decisions. <sup>126</sup>

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