Organizational Requirements for Acute Leukemia Service Providers in Ontario

Recommendations Report

VERSION 2 | 2024

Ontario Health
Cancer Care Ontario

Executive Summary

In August 2017, Cancer Care Ontario (now part of Ontario Health) released the Acute Leukemia Provincial Plan with standardized clinical care across Ontario as one of its goals. (1) In 2021, the *Organizational Requirements for Acute Leukemia Service Providers in Ontario: Recommendations Report* (the *Report*) was released to support the achievement of this goal by detailing a series of organizational requirements and recommendations for the necessary infrastructure, resources, and capabilities to ensure quality management in the delivery of care at acute leukemia service provider sites across Ontario. The *Report* describes recommended specifications in areas including facility requirements (infrastructure, data management, safety, policies, and procedures), availability of clinical services and service complexity, personnel (roles, responsibilities, ongoing education), patient care, quality management and clinical research. The primary objective of the *Report* is to provide a framework for planning and delivery of consistent, safe and evidence informed care at existing and new acute leukemia service provider sites across the province. The *Report* lays out the vision for the optimal system.

Since the initial version of this *Report* was released in 2021, acute leukemia clinical practice has evolved with the introduction of several new less intensive therapy options targeted toward those individuals who are not ideal candidates for induction chemotherapy or who may otherwise receive palliative care. As of April 1, 2022, public funding for the comprehensive delivery of care of less intensive therapies was made available in Ontario. At the time of this *Report*, less intensive therapies refer to the delivery of subcutaneous azacitidine (monotherapy), azacitidine + venetoclax, azacitidine + tyrosine kinase inhibitor (TKI) and gilteritinib. As a result, this *Report* has been updated to account for the change in clinical practice and include recommendations for two additional levels of acute leukemia service providers: Acute Leukemia Less Intensive Chemotherapy Service Sites and Acute Leukemia Less Intensive Chemotherapy Partner Sites.

Moving forward, Ontario Health (Cancer Care Ontario) will work with acute leukemia service providers in the province to monitor the current state of organizations meeting recommendations outlined in the *Report* and focus improvement efforts in priority areas.

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Part A. Introduction

In August 2017, Cancer Care Ontario (now part of Ontario Health) released the *Acute Leukemia Provincial Plan*. The *Plan* was developed to provide an overview of how adult services are defined and how they should be organized and delivered in Ontario. (1) The *Plan* was created collaboratively by regional, clinical, and patient representatives and facilitated by Cancer Care Ontario, now a part of Ontario Health.

This *Plan* sets the stage to achieve a vision of care in Ontario where there will be strong networks of service providers that deliver coordinated care across the province and is designed to:

- Provide timely access for adults to high-quality, coordinated acute leukemia services as close to home as possible
- Focus on better outcomes and improved patient experience
- Encourage hospitals and providers to work together to form networks of services, which are person-centred, evidence-informed and support evolving clinical practices

One of the goals articulated in the *Plan* is standardized clinical care across Ontario. This standardized clinical care should be evidence-informed to support best outcomes. The development and implementation of the *Organizational Requirements for Acute Leukemia Service Providers in Ontario: Recommendations Report* (the *Report*) is one component that will facilitate implementation of this goal.

Recommended specifications are defined throughout the *Report* for four levels of acute leukemia provider sites based on the scope of service they provide:

- **Acute Leukemia Service Site**
  Provides the full scope of acute leukemia services, including intensive induction therapy and less intensive therapy, with the intent of achieving remission and disease control, as well as post-remission treatment and care. Acute Leukemia Service Site may work in partnership with an Acute Leukemia Shared Care Partner Centre and/or other systemic treatment hospitals to support care closer to home. Acute Leukemia Service Sites may also perform hematopoietic cell therapy (HCT, also known as stem cell transplant) and/or chimeric antigen receptor T-cell (CAR T-cell) therapy. These services must adhere to additional standards (e.g., FACT), which are outside the scope of this report.

- **Acute Leukemia Shared-Care Partner Site**
  Provides a subset of services for patients through a shared-care model. Partner centres work in partnership with an Acute Leukemia Service Site, or a Transplant and Acute Leukemia Service Site, to share portions of care on an ongoing basis and/or accept autologous HCT patients for post-transplant recovery closer to home.

- **Acute Leukemia Less Intensive Chemotherapy Service Site**
  Initiates less intensive chemotherapy for patients with the intent of achieving remission and disease control, as well as post-remission treatment and care. Following initiation of less intensive chemotherapy, patients may be transferred to partner centres to continue receiving subsequent cycles of chemotherapy or supportive care. At the time of this Report, less intensive therapies refer to the delivery of subcutaneous azacitidine (monotherapy), azacitidine + venetoclax, azacitidine + tyrosine kinase inhibitor (TKI) and gilteritinib but is subject to change.

- **Acute Leukemia Less Intensive Chemotherapy Partner Site**

Provides a subset of services for patients through a shared-care model. Acute Leukemia Less Intensive Chemotherapy Service Sites initiate less intensive chemotherapy. Partner sites work in partnership with Acute Leukemia Less Intensive Chemotherapy Service Sites to share portions of care including subsequent cycles of less intensive chemotherapy and provide supportive care closer to home. Partner Sites shall be under the stewardship of the centre initiating the less intensive chemotherapy treatment. Upon patient transfer, the Most Responsible Physician (MRP) at the Partner Site should be established.

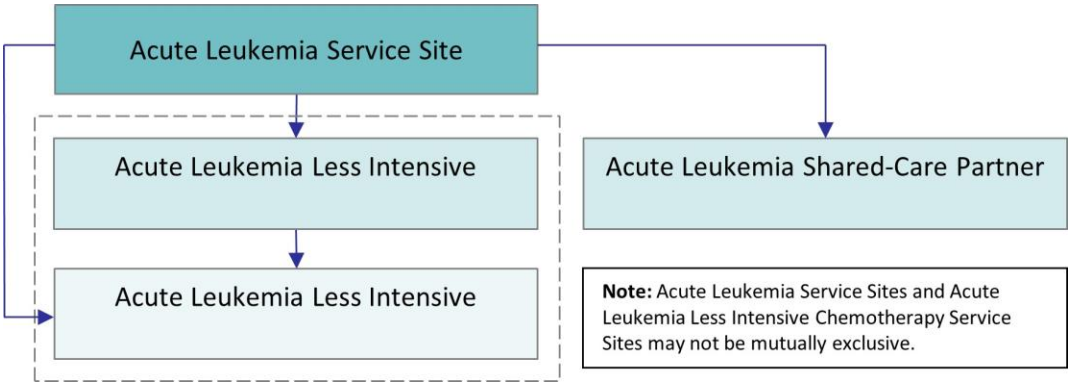


Figure 1. Illustrated relationship between types of sites in Ontario. Arrows indicate the flow of stewardship between sites.

A few specifications in the *Report* identify another type of acute leukemia provider, Systemic Treatment Hospitals. In general, these sites provide supportive care (e.g., transfusion, hydration, palliative care) for acute leukemia patients not on active treatment. Specific requirements for Systemic Treatment Hospitals are not detailed in this *Report*. These sites should provide therapy according to other provincial guidance documents, such as, but not limited to, Forbes *et al*., Regional Models of Care for Systemic Treatment (2019). (2)

Intended Purpose: The purpose of the *Report* is to inform the organizational delivery of care at acute leukemia service providers for patients who are 18 years and older with acute leukemia in Ontario.

The *Report* supports planning for the projected long-term demand for acute leukemia patient care expected over the next decade due to a growing and aging population and evolving therapeutic options. More importantly, this *Report* should support the expectation of increasing accessibility to timely, safe, and high-quality care.

Target Population: This document is targeted to provision of care within the adult setting, defined as patients 18 years and older, in Ontario.

Intended Users: This document has been developed for clinicians, other health care providers, and hospital and system administrators involved in the planning and delivery of adult acute leukemia care at existing Transplant and Acute Leukemia Service Sites, Acute Leukemia Service Sites, Acute Leukemia Shared-Care Partner Centres, Acute Leukemia Less Intensive Chemotherapy Service Sites, and Acute Leukemia Less Intensive Chemotherapy Partner Sites, as well as by those interested in becoming service provider sites. This document would also be useful for Systemic Treatment Hospitals that are providing supportive and palliative care for these patients.

A.1 Rationale for the Report

The primary objective of the *Report* is to provide a framework for the planning and delivery of consistent and safe treatment for acute leukemia patients across the province. Administrators and clinicians participating on the Cancer Care Ontario's Acute Leukemia Advisory Committee and senior leadership at the Regional Cancer Programs in Ontario identified a need to reduce between-centre variability though the standardization of necessary infrastructure, resources and capabilities and ensure quality management at a provider level in the delivery of acute leukemia care. They also recognized the importance of providing this guidance to centres working to become acute leukemia service providers or increasing their existing level of service provision as part of the provincial expansion efforts. As clinical practice evolves, the *Report* may need to be amended to ensure the appropriate delivery of services by the defined service providers. Some aspects of the *Report* may also apply to other cancer types and could be adapted to support standardization in the delivery of care for those disease sites.

Service provision, complexity of care, safety, accessibility, and quality care across all levels defined from the patient, organization, and system perspective have been considered in the development of this *Report*. In addition, transparency and accountability are foundational to these Recommendations. Ongoing education of the care team has been identified as an integral component of high-quality care in the delivery of acute leukemia services and these requirements have been detailed as well. This framework will help support the principle of person-centred care with an emphasis on providing care as close to home as possible while, at the same time, optimizing use of specialized resources.

A.2 Scope of the Report

The specifications included in this *Report* apply to the organizational requirements for the delivery of acute leukemia care in Ontario and address the following elements:

- Facility requirements, including infrastructure, data management, safety, and policies and procedures
- Availability of clinical services and service complexity
- Personnel, including roles, responsibilities and ongoing education
- Patient care
- Quality management
- Clinical research

Activities directed at harmonizing acute leukemia clinical practice in Ontario are being led by Ontario Health (Cancer Care Ontario) and the Acute Leukemia Advisory Committee and are out of scope for this *Report*.

A.3 Ongoing Review of the Report

It is recognized that the treatment and management of acute leukemia is an evolving area of clinical practice and this *Report* should be adapted to meet changes in practice, as needed. This *Report* will be reviewed regularly (at a minimum, every 3 years) under the oversight of Ontario Health (Cancer Care Ontario). The first review of the *Report* was conducted in 2024.

Part B. Methods

The inaugural version of the *Report* was developed by members of the Acute Leukemia Specifications Working Group, consisting of hematologists, nurse practitioners and other clinical specialists in the field, along with health care administrators, under the guidance of Ontario Health (Cancer Care Ontario's) Acute Leukemia Advisory Committee. Conflict of interest declarations for all authors are summarized in **Appendix A** and were managed in accordance with Ontario Health (Cancer Care Ontario)'s Conflict of Interest Policy.

To develop this *Report,* the Working Group was responsible for searching for evidence, conducting an environmental scan, and reviewing available literature regarding the organization and delivery of acute leukemia care, across Ontario, Canada, the United States, the United Kingdom, Australia and France. The evidence review was conducted in two stages, including a search for guidelines, followed by a search of primary literature. These stages are described in subsequent sections. Due to the lack of available guidelines and evidence, these recommendations are largely based on expert opinion informed by the endorsement and adaptation of existing standards and recommendations from other jurisdictions, especially publications from Ontario Health (Cancer Care Ontario), National Institute for Health and Care Excellence (NICE) (3) and the Foundation for the Accreditation of Cellular Therapy (FACT) at the University of Nebraska Medical Centre. (4)

B.1 Search for Guidelines

A search was conducted for existing guidelines. The search terms 'acute leukemia' or 'hematolog*', and 'recommendation*' or 'standard*' or 'guideline*' were used to search Guidelines International Network, National Guidelines Clearinghouse, Standards and Guidelines Evidence Inventory for Cancer Guidelines, Clinical Practice Guidelines Infobase and Trip guideline databases. Guidelines and relevant literature were also searched for on the websites for the National Health System, including NICE, Scottish Intercollegiate Guidelines Network and Health Improvement Scotland, FACT, American Society of Clinical Oncology, American Society of Hematology, European Society for Medical Oncology, Alberta Health Services, Cancer Care Nova Scotia, British Columbia Cancer Agency, Cancer Care Manitoba, the Hospital for Sick Children, Pediatric Oncology Group of Ontario, Western Australian Department of Health, National Comprehensive Cancer Network, Belgian Health Care Knowledge Centre, European LeukemiaNet, Health Quality Ontario (now apart of Ontario Health), Agency for Healthcare Research and Quality and Cancer Care Ontario. Results of the guideline literature search can be found in **Appendix B**.

All guideline databases and webpages were searched using the search terms and the titles of all results were reviewed. Where titles appeared relevant, the abstracts were reviewed. The full text publication was reviewed when the abstract was deemed relevant. A flow chart of the guideline literature search and primary literature can be found in Figure 1.

B.2 Search for Systemic Reviews, Primary Literature and Grey Literature

Following the Ontario Health (Cancer Care Ontario) Program in Evidence Based-Care's Handbook[a], a search was conducted for existing systematic reviews, and primary and grey literature. The Ovid interface was used to search MEDLINE and EMBASE for existing systematic reviews and primary literature relating to this topic. The full search strategy is available in **Appendix B**.

The titles of all identified literature were reviewed. Where titles appeared relevant, the abstracts were reviewed. The full text was reviewed where the abstract was deemed relevant. A flow chart of the guideline literature search and primary literature search can be found in Figure 2.

[a] Ontario Health (Cancer Care Ontario) Program in Evidence-Based Care's Handbook (2020) is available at: https://www.cancercareontario.ca/sites/ccocancercare/files/assets/CCOPEBCHandbook.pdf

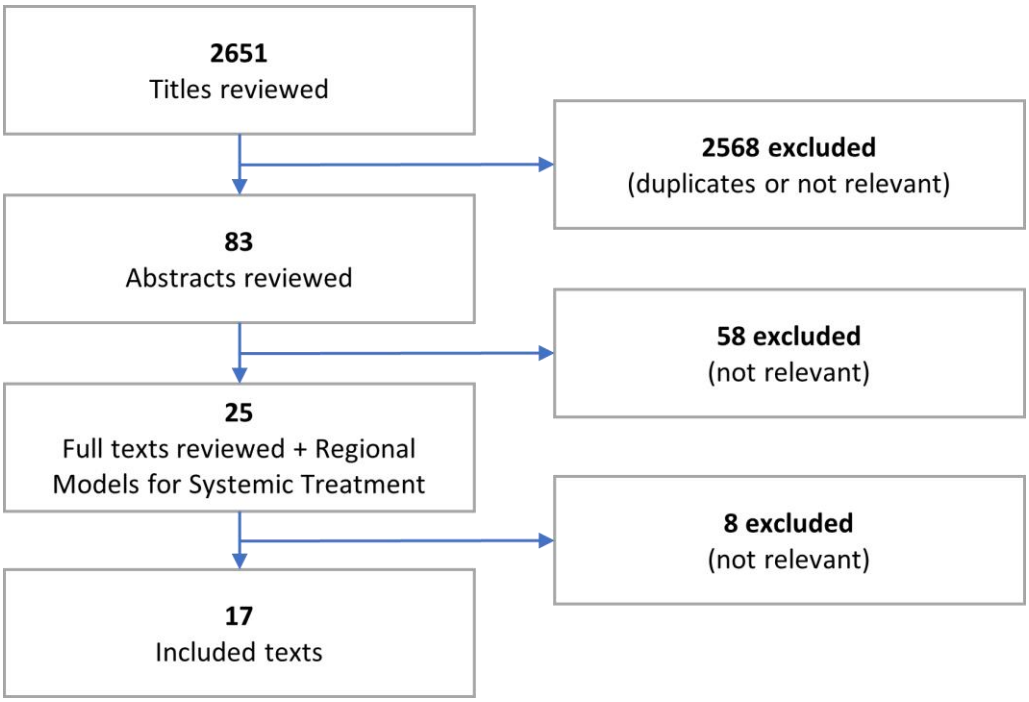


Figure 2. Results of literature search for relevant guidelines, primary literature and grey literature.

B.3 Data Extraction and Synthesis

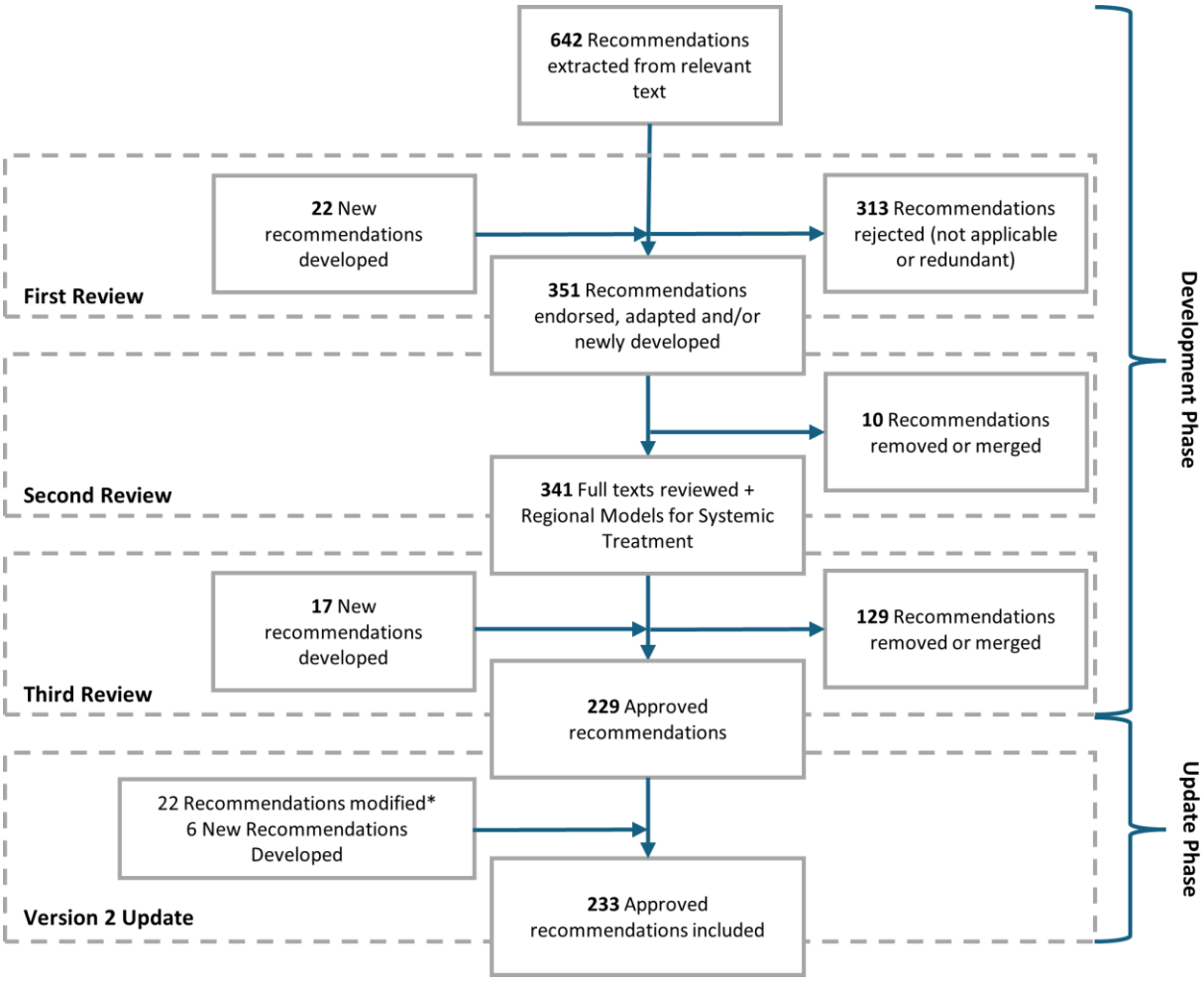
The recommendations from relevant guidelines, systematic reviews and primary literature were extracted from the source. The Working Group members assessed recommendations and determined if they should be:

1) Endorsed as is;
2) Adapted to meet the needs of adult patients with acute leukemia in Ontario; or
3) Rejected.

Endorsed and adapted recommendations were compiled. Based on consensus of the Working Group members, additional recommendations were created in areas where the Working Group thought there was a gap that should be addressed. Recommendations were consolidated and grouped according to themes.

The recommendations were further refined through a second and third round of reviews which involved members of the Working Group, the Acute Leukemia Advisory Committee, and relevant Ontario Health (Cancer Care Ontario) Program administrators, Provincial Program Heads, senior leadership, as well as external clinical and administrative expert reviewers. As part of these rounds of review, recommendations that were identified as being a responsibility of the hospital, rather than specific to the Acute Leukemia Program, were removed.

In the end, 229 recommendations were included in this *Report* to inform the Ontario cancer system. Results are detailed in Figure 3.



*n=2 recommendations split into multiple recommendations, n=7 recommendations collapsed into one recommendation, n=11 recommendations with wording changes, n=2 recommendations removed

Figure 3. Flow chart showing the results of the data extraction and synthesis used to identify and develop recommendations throughout the development and version update phases of this *Report*.

B.4 Update

In May 2023, Ontario Health (Cancer Care Ontario) convened an Acute Leukemia Less Intensive Chemotherapy Working Group to advise on the update of the *Report* (**Appendix A**). The Working Group worked in collaboration with members of the Ontario Health (Cancer Care Ontario) team to review and recommend which organizational requirements in the *Report* should be applicable to Acute Leukemia Less Intensive Chemotherapy Service Sites and Acute Leukemia Less Intensive Chemotherapy Partner Sites.

Ontario Health (Cancer Care Ontario) developed documents listing all recommendations from the previous version of the *Report* for the Working Group to review. Working Group members were divided into groups of two, paired by clinical expertise, when possible. Sections of the recommendations were assigned to the pairs to independently review. Recommendations were assigned to reviewers with the relevant clinical expertise, when possible. For example, those with laboratory expertise reviewed recommendations addressing laboratory requirements. Working Group members were asked to determine if each of the recommendations should be relevant to Acute Leukemia Less Intensive Chemotherapy Service Sites, or alternatively, should not be relevant to these sites. Working Group members also provided suggestions for wording amendments as required.

Once completed, Working Group members returned their independent review document to the Ontario Health (Cancer Care Ontario) team to create a consensus document. Recommendations that reached automatic consensus were included in the report. All disagreements were presented at the working group meetings and discussed to reach consensus.

All Working Groups members, as well as the Acute Leukemia Advisory Committee members reviewed and approved the final report.

Part C. Terminology

For purposes of this *Report*, the term *shall* means that the specification is to be complied with at all times and is noted in bold text throughout **Part D** of this *Report*. The term *should* indicates that a specification is recommended or advised, but for which there may be appropriate alternatives. The term *may* is permissive and is used primarily for clarity.

Table 1. Acronyms and Abbreviations

Abbreviation	Definition
CAR T-cell	Chimeric antigen receptor T-cell
FACT	Foundation for the Accreditation of Cellular Therapy
FTE	Full time equivalent
HCT	Hematopoietic cell therapy
ICU	Intensive care unit
NICE	National Institute for Health and Care Excellence
SOPs	Standard operating procedures
TKI	Tyrosine kinase inhibitor

Table 2. Key Terms

Term	Definition
Access to	Refers to a centres ability to access services or products, either directly on-site or off-site through an agreement or partnership with another facility.
Clinical Program	A multidisciplinary medical team, including a clinical program director, physicians, quality manager, nurses, pharmacists, etc., that provide care for a defined population of patients (for the purpose of this document, patients with acute leukemia) within the facility. Care should be provided in accordance with protocols, SOPs, and quality management systems.
Clinical Program Medical Director	Physician leader responsible for the clinical program within a facility. The Director may be responsible for services beyond acute leukemia. An individual who may not have the title of 'Director' at service provider site, may be the physician leader that is identified for this role/position.
Clinical Unit	Location within a facility where care is provided.

Term	Definition
Critical	Any element that, if removed, would potentially impact the quality and/or outcome of therapy. Example: Cytogenetic testing is considered a critical service as it informs the treatment plan for the patient. Critical elements are those defined by the clinical program's medical director.
Electronic decision-making tools	Electronic tools developed either internally or externally to assist with decision making (i.e., treatment algorithm, dosage calculator).
Electronic Record System	The electronic health record and other electronic systems and programs used to capture and store patient information, guide treatment decisions and perform calculations. These may be a substitute for, or in adjunct to, paper records.
High Acuity Unit	A unit managing patients with life-threatening or serious medical issues that require 24-hour attention by a team of appropriately trained medical staff.
Quality Manager	Individual responsible for the quality management of the clinical program. May be a clinical or administrative role with the right expertise (including quality management training) and responsibilities.

Part D. Organizational Requirements for Acute Leukemia

Through this section of the document, there are recommendations that apply to each of the levels of acute leukemia provider sites as indicated. Sites are encouraged to meet, or strive toward meeting, the recommendations as appropriate.

The following terminology is used to recommend the implementation of each recommendation:

- ***shall*** means that the specification is to be complied with at all times
- ***should*** indicates an activity that is recommended or advised, but for which there may be appropriate alternatives
- ***may*** is permissive and is used primarily for clarity

D.1 General

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Site
1.1	The Centre **shall** have a clearly defined organizational structure. (3)	Yes	Yes	Yes	Yes
1.2	The Clinical Program **shall** consist of an integrated medical team housed in a defined location(s), including a Clinical Program Medical Director(s), who is responsible for the medical aspects of the operation of the service, in collaboration with appropriate facility administrators. This includes the design of the diagnostic pathway, resource use, and reporting standards. (3)	Yes	Yes	Yes	Yes
1.2.1	The Centre **should** consider the organization of current services to allow the development of disease-specific clinics where patient numbers are sufficient. (5)	Yes	Yes	Yes	Yes
1.3a	The Centre **shall** work to implement the current version of Complex Malignant Hematology Models of Care Recommendations. (6)	Yes	Yes	No	No
1.3b	The Centre **should** work to implement the current version of Complex Malignant Hematology Models of Care Recommendations. (6)	N/A	N/A	Yes	Yes
1.4	The Clinical Program **shall** be located in a facility that is licensed, registered, or accredited by Accreditation Canada. (7)	Yes	Yes	Yes	Yes
1.5	The Centre **shall** comply with the current versions of the Ontario Health (Cancer Care Ontario) standards for the delivery of systemic treatment, including but not limited to, the Regional Models of Care for Systemic Treatment: Standards for the Organization and Delivery of Systemic Treatment, as appropriate to their designated level of service. (2)	Yes	Yes	Yes	Yes

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Site
1.6	The Centre **shall** comply with the current version of the Ontario Health (Cancer Care Ontario) guidelines for the safe administration of systemic therapy, including but not limited to, the following reports: • Safe Administration of Chemotherapy: Safety During Chemotherapy Ordering, Transcribing, Dispensing, and Patient Identification. (7,8) • Safe Administration of Systemic Cancer Therapy Part 2: Administration of Systemic Treatment and Management of Preventable Adverse Events. (7,8)	Yes	Yes	Yes	Yes
1.7	The Centre **shall** participate[b] as part of a Provincial Acute Leukemia Network developed by the Regional Cancer Programs in partnership with Ontario Health (Cancer Care Ontario). (1,7)	Yes	Yes	Yes	Yes
1.7.1	The Centres **shall** have clear and reliable systems (e.g., processes, tools) for communicating with relevant healthcare professionals at other service sites. (3)	Yes	Yes	Yes	Yes
1.7.2	The Acute Leukemia Service Sites **shall** provide mentorship (e.g., onsite training, sharing resources, availability to respond to questions, etc.) to affiliated Acute Leukemia Shared-Care Partner Centres, Systemic Treatment Hospitals, Acute Leukemia Less Intensive Chemotherapy Partner Sites and other centres, as appropriate. (1)	Yes	N/A	N/A	N/A
1.8	The Clinical Program **shall** have a designated acute leukemia team that includes a Clinical Program Medical Director, a Quality Manager, and a total of at least three (3) full time attending hematologists[c], providing 24-hour coverage (including by phone). (1,3,4)	Yes	No	Yes	No
1.8.1	Non-Acute Leukemia Service Sites **shall** have access to acute leukemia expertise through an Acute Leukemia Service Site. (7)	N/A	Yes	Yes	Yes
1.9	The Centre **shall** collaboratively participate in provincial capacity management activities, as needed to ensure access to timely care. (1,7)	Yes	Yes	Yes	Yes
1.10	The Centre **should** provide clinical services for patients with hematological cancers delivered by multidisciplinary hemato-oncology teams. (3)	Yes	Yes	Yes	Yes

[b] May include involvement in committees or willingness to refer and accept patients as appropriate. Variation is dependent upon type of centre and capacity.
[c] May include the Clinical Program Medical Director if the Clinical Program Medical Director is a hematologist.

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Site
1.11	The Centre **should** provide intensive induction chemotherapy (including induction therapy following remission and subsequent relapse) or less intensive chemotherapy with the intent of remission to a minimum of 10 patients with acute leukemia per year and who are at risk of more than 7 days of neutropenia (absolute neutrophil count of 0.5×10^9/litre or lower). (3,7)	Yes	No	Yes	No

N/A: not applicable

D.2 Clinical Unit

Inpatient Unit

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Site
2.1	The Centre **shall** have an ICU or readily available access to an ICU. (1,4)	Yes	Yes	Yes	Yes
2.2	The Centre **shall** provide patients who have acute leukemia and are at risk of more than 7 days of neutropenia (absolute neutrophil count of 0.5×10^9/litre or lower) with an inpatient room with an occupancy of no greater than two (2) patients in keeping with appropriate Canadian Standards Association guidelines. (9) The room should be equipped with its own bathroom. (3,7)	Yes	Yes	Yes	Yes
2.2.1	If patients require isolation in accordance with local infectious disease practices, the patient **shall** be isolated in a private room with a private bathroom. (7)	Yes	Yes	Yes	Yes
2.3	The Centre **shall** have a designated inpatient unit that minimizes airborne microbial contamination, in keeping with the Guideline for the Implementation of Air Standards in Ontario. (10)	Yes	Yes	Yes	Yes
2.4	The Centre **shall** ensure there are beds available in a dedicated ward within the hospital with the capacity to treat the planned volumes of patients. (3,6)	Yes	Yes	Yes	Yes
2.4.1	The Centre **shall** ensure the availability of a flex bed to allow for the direct, urgent admission of patients being managed on an outpatient basis.	Yes	Yes	No	No

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Site
2.4.2	The Centre **should** ensure the availability of a flex bed to allow for the direct, urgent admission of patients being managed on an outpatient basis.	N/A	N/A	Yes	Yes
2.5	The Centre **should** have the level of staffing required for febrile neutropenia patients that is equivalent to that in a high acuity unit, as per hospital policies. (3)	Yes	Yes	N/A	N/A

N/A: not applicable

Outpatient Unit

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Site
2.6	The Centre **shall** provide monitoring following leukemia therapy in an ambulatory setting and ensure that there is an area for outpatient care that provides the following:	Yes	Yes	Yes	Yes
2.6.1	Reasonably protects the patient from transmission of infectious agents and minimizes risk of airborne microbial contamination	Yes	Yes	Yes	Yes
2.6.2	Allows for confidential examination and evaluation	Yes	Yes	Yes	Yes
2.6.3	Provides, as necessary, an area for patient isolation, administration of intravenous infusions, multiple medications, and/or blood component transfusions. (3,4)	Yes	Yes	Yes	Yes
2.7	The Centre **should** consider ambulatory care for patients who have hematological malignancies that are in remission and other clinically appropriate patients, who are at risk of more than 7 days of neutropenia (absolute neutrophil count of 0.5×10^9/litre or lower) (i.e., outpatient consolidation chemotherapy, other less intensive therapies). (3,6)	Yes	Yes	Yes	Yes
2.8.	The Clinical Program **should** have a checklist to account for the following when assessing patients to determine if ambulatory care is appropriate: • Access to appropriate and timely transport • Accommodation and communication facilities (e.g., translation services) • Availability of caregiver to provide support • Comorbidities	Yes	Yes	Yes	Yes

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Site
	• Distance and travel times to treatment in case of neutropenic fever and other toxicities • Patient's and/or caregiver's understanding of the safety requirements of ambulatory care and other individual treatment plan • Patient preference. (3)				

Supportive Services

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Sites
2.9	The Centre **shall** have an on-site blood bank with ability to deliver packed red blood cells and platelet transfusions, as well as plasma and factor concentrates, without delay. (1,3)	Yes	Yes	Yes	Yes
2.9.1	The Centre's blood bank **should** have a record of patient transfusions that is accessible to the members of the multidisciplinary Clinical Program. (7)	Yes	Yes	Yes	Yes
2.10	The Centre **shall** have 24-hour access to irradiated blood products needed for the care of acute leukemia patients as per National Advisory Committee on Blood and Blood Products - Recommendations for use of Irradiated Blood Components in Canada, 2018, or as updated. (11)	Yes	Yes	Yes	Yes
2.11	The Clinical Program **shall** have dedicated pharmacists with oncology/hematology training involved in the inpatient and outpatient care of leukemia patients. (1,4)	Yes	Yes	Yes	Yes
2.12	The Centre **shall** have 24-hour availability of medications needed for the care of acute leukemia patients. (4)	Yes	Yes	Yes	Yes
2.13	The Centre **shall** have appropriate diagnostic services to care for the acute leukemia patient population and complications of therapy, including, but not limited to, bronchoscopy, cross-sectional imaging, endoscopy, and renal support. (3,7)	Yes	Yes	Yes	Yes
2.14	The Centre **shall** have access to expertise and supporting technologies for image-guided biopsy and interventional radiology/oncology. (7)	Yes	Yes	Yes	Yes
2.15	The Centre **may** have access to leukapheresis therapy. (12)	Yes	Yes	No	No

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Sites
2.16	The Centre **should** have expertise in vascular access for central venous catheter insertions. (3)	Yes	Yes	Yes	Yes

D.3 Personnel

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Sites
3.1	The Clinical Program **shall** include members of multidisciplinary care team (which may include clinical associates, nurse practitioners, physician assistants, registered nurses and other providers) with the appropriate training and oversight of care by a hematologist/oncologist. (6)	Yes	Yes	Yes	Yes
3.1.1	The scope of responsibility of the multidisciplinary care team members **shall** be defined. (4)	Yes	Yes	Yes	Yes
3.1.2	The Clinical Program Team (physicians/ physicians assistants/ clinical associates/ nurse practitioners/ pharmacists) **shall** participate in a minimum of ten (10) hours of educational activities (e.g., self-directed education, rounds, webinars, meetings, conferences), annually, related to acute leukemia care or management. (4)	Yes	Yes	Yes[d]	Optional

Clinical Program Medical Directors

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Sites
3.2	The Clinical Program Medical Director **shall** have at least two (2) years of experience as an attending physician responsible for the direct clinical management of acute leukemia patients in the inpatient and outpatient settings or additional training in acute leukemia. (4)	Yes	No	Yes	No

[d] At Shared-Care Partner Centres, Physicians/ Pharmacists/ Nurse Practitioners/ Physicians Assistants/ Clinical Associates should (rather than shall) participate in a minimum of ten (10) hours of educational activities (e.g., self-directed education, rounds, webinars, meetings, conferences), annually, related to acute leukemia care or management.

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Sites
3.3	The Clinical Program Medical Director **shall** have oversight of the medical care provided by all members of the Clinical Program. (4)	Yes	Yes	Yes	Yes
3.4	The Clinical Program Medical Director or designate **shall** be responsible for verifying the knowledge and skills of members of the Clinical Program multidisciplinary care team, including nurses, pharmacists, physicians, and other providers once every three (3) years. (4)	Yes	Yes	Yes	Yes
3.5	Working in partnership with hospital administration, the Clinical Program Medical Director **shall** be responsible for administrative and clinical operations, including compliance with these recommendations and applicable laws and regulations. (4)	Yes	Yes	Yes	Yes
3.6	Working in partnership with hospital administration, the Clinical Program Medical Director **shall** be responsible for all elements of the design of the Clinical Program including quality management as per Section D.4, whether internal or contracted services, which may be part of a broader malignant hematology program. (4)	Yes	Yes	Yes	Yes

Clinical Program Medical Directors and Attending Physicians

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Sites
3.7	Clinical Program Medical Directors and Attending Physicians **shall** have received specific training in each of the following areas as applicable to the Clinical Program's services:	Yes	Yes	Yes	Yes
3.7.1	Applicable regulations and reporting responsibilities for adverse events and reactions, as required by Health Canada. (4)	Yes	Yes	Yes	Yes
3.7.2	Documentation and reporting for patients on investigational protocols and completion of Good Clinical Practice training as recognized by their institution. (13)	Yes	Yes	Yes	Yes

Attending Physicians

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Sites
3.8	Attending Physicians **shall** have received specific training in each of the following areas as applicable to the Clinical Program's services in order to ensure holistic and comprehensive care and to recognize complications of prescribed therapies.	Yes	Yes	Yes	Yes
3.8.1	Administration of acute leukemia therapy	Yes	Yes	Yes	Yes
3.8.2	Blood transfusion management	Yes	Yes	Yes	Yes
3.8.3	Cardiac dysfunction	Yes	Yes	Yes	Yes
3.8.4	Prevention, diagnosis and management of fungal disease	Yes	Yes	Yes	Yes
3.8.5	Prevention, diagnosis and management of infectious and non-infectious complications of acute leukemia therapy, including but not limited to:	Yes	Yes	Yes	Yes
3.8.5.1	Appropriate antimicrobial prophylaxis	Yes	Yes	Yes	Yes
3.8.5.2	Hemophagocytosis	Yes	Yes	Yes	Yes
3.8.5.3	Hypersensitivity reactions	Yes	Yes	Yes	Yes
3.8.5.4	Management of neutropenia and neutropenic fever	Yes	Yes	Yes	Yes
3.8.5.5	Management of mucositis, nausea, and vomiting	Yes	Yes	Yes	Yes
3.8.5.6	Management of thrombocytopenia and bleeding, including recognition of disseminated intravascular coagulation	Yes	Yes	Yes	Yes
3.8.5.7	Monitoring and management of pain	Yes	Yes	Yes	Yes
3.8.5.8	Neurologic toxicity	Yes	Yes	Yes	Yes
3.8.5.9	Renal dysfunction	Yes	Yes	Yes	Yes
3.8.5.10	Respiratory distress	Yes	Yes	Yes	Yes
3.8.5.11	Tumour lysis and cytokine release syndrome	Yes	Yes	Yes	Yes
3.8.6	Evaluation of post-leukemia therapy outcomes and late effects	Yes	Yes	Yes	Yes

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Sites
3.8.7	Serious Illness Conversations and Goals of Care	Yes	Yes	Yes	Yes
3.8.8	Indications and appropriateness of leukemia therapy, including appropriate selection of suitable candidates for HCT or cellular therapy referral	Yes	Yes	Yes	Yes
3.8.9	Palliative and end of life care	Yes	Yes	Yes	Yes
3.8.10	Survivorship care	Yes	Yes	Yes	Yes
3.8.11	Use of irradiated blood products, where appropriate. (4,7)	Yes	Yes	Yes	Yes
3.9	Attending physicians **shall** each have had a minimum total of one (1) year of supervised training in the management of acute leukemia patients in both inpatient and outpatient settings. (4)	Yes	No	Yes	No

Physicians Assistants, Clinical Associates, Nurse Practitioners and Registered Nurses

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Sites
3.10	Physicians Assistants, Clinical Associates, Nurse Practitioners and Registered Nurses **shall** have received specific training and maintain competence in the acute leukemia-related skills that they routinely practice within their respective role including:	Yes	Yes	Yes	Yes
3.10.1	Administration of acute leukemia therapy	Yes	Yes	Yes	Yes
3.10.2	Administration of blood products, growth factors, and other supportive therapies	Yes	Yes	Yes	Yes
3.10.3	Care interventions to prevent and manage acute leukemia therapy-related complications, including, but not limited to:	Yes	Yes	Yes	Yes
3.10.3.1	Cardiac dysfunction	Yes	Yes	Yes	Yes
3.10.3.2	Cytokine release syndrome	Yes	Yes	Yes	Yes
3.10.3.3	Disseminated intravascular coagulation	Yes	Yes	Yes	Yes
3.10.3.4	Hypersensitivity reactions	Yes	Yes	Yes	Yes

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Sites
3.10.3.5	Infectious processes	Yes	Yes	Yes	Yes
3.10.3.6	Mucositis	Yes	Yes	Yes	Yes
3.10.3.7	Nausea and vomiting	Yes	Yes	Yes	Yes
3.10.3.8	Neurologic toxicity	Yes	Yes	Yes	Yes
3.10.3.9	Neutropenic fever	Yes	Yes	Yes	Yes
3.10.3.10	Pain management	Yes	Yes	Yes	Yes
3.10.3.11	Renal and hepatic failure	Yes	Yes	Yes	Yes
3.10.3.12	Respiratory distress	Yes	Yes	Yes	Yes
3.10.3.13	Tumor lysis syndrome	Yes	Yes	Yes	Yes
3.10.4	Palliative and end of life care	Yes	Yes	Yes	Yes
3.10.5	Survivorship care. (1,4,7)	Yes	Yes	Yes	Yes
3.11	The Clinical Program **shall** have a sufficient number of nurses appropriately trained in the care of patients with acute leukemia. (4,14,15) For inpatient units where patients are receiving specialized care, nursing ratios may vary based on setting and changing acuity of patients. (15)	Yes	Yes	Yes	Yes
3.12	The Clinical Program **should** have specialized oncology nurses with national certification in oncology through the Canadian Nurses Association and additional knowledge, clinical skills and clinical decision making in leukemia (such as courses through the de Souza institute and Lymphoma Society). (2,16)	Yes	Yes	Yes	Yes

Pharmacists

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Sites
3.13	Clinical pharmacists, or designate, **shall** work with the multidisciplinary team to perform medication reconciliation, monitor for side effects, including medication side effects, and provide supportive care and manage symptoms. (1)	Yes	Yes	Yes	Yes
3.14	Training and knowledge of designated pharmacists **shall** include:	Yes	Yes	Yes	Yes
3.14.1	Requirements detailed in the Regional Models of Care for Systemic Treatment: Standards for the Organization and Delivery of Systemic Treatment, as appropriate to their designated level of service. (2,7)	Yes	Yes	Yes	Yes
3.14.2	Hematology/oncology patient care, including the role of administration of and complications of systemic therapy for acute leukemia patients. (4)	Yes	Yes	Yes	Yes
3.14.3	Therapeutic drug monitoring, including, but not limited to, anti-infective agents, immunosuppressive agents, anti-seizure medications, and anticoagulants. (4)	Yes	Yes	Yes	Yes

Other Specialists

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Sites
3.15	The Clinical Program **shall** have access to certified or trained consulting specialists and/or specialist groups from key disciplines capable of assisting in the management of acute leukemia patients, including, but not limited to:	Yes	Yes	Yes	Yes
3.15.1	Cardiology	Yes	Yes	Yes	Yes
3.15.2	Dentistry	Yes	Yes	Yes	Yes
3.15.3	Dermatology	Yes	Yes	Yes	Yes
3.15.4	Gastroenterology	Yes	Yes	Yes	Yes

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Sites
3.15.5	Infectious Disease	Yes	Yes	Yes	Yes
3.15.6	Intensive Care	Yes	Yes	Yes	Yes
3.15.7	Nephrology	Yes	Yes	Yes	Yes
3.15.8	Neurology	Yes	Yes	Yes	Yes
3.15.9	Obstetrics/Gynecology	Yes	Yes	Yes	Yes
3.15.10	Ophthalmology	Yes	Yes	Yes	Yes
3.15.11	Pain and Symptom Management	Yes	Yes	Yes	Yes
3.15.12	Palliative and End of Life Care	Yes	Yes	Yes	Yes
3.15.13	Pathology and Hematopathology (including molecular diagnostics and genetics)	Yes	Yes	Yes	Yes
3.15.14	Physiatry/Rehabilitation Medicine	Yes	Yes	Yes	Yes
3.15.15	Psychiatry	Yes	Yes	Yes	Yes
3.15.16	Pulmonary Medicine	Yes	Yes	Yes	Yes
3.15.17	Radiology, including relevant subspecialty expertise related to:	Yes	Yes	Yes	Yes
3.15.17.1	Cross-sectional Imaging	Yes	Yes	Yes	Yes
3.15.17.2	Interventional Radiology	Yes	Yes	Yes	Yes
3.15.18	Radiation Oncology	Yes	Yes	Yes	Yes
3.15.19	Surgical services that includes general surgery, thoracic surgery, neurosurgery, and ears, nose, and throat (ENT) surgery	Yes	Yes	Yes	Yes
3.15.20	Transfusion Medicine. (1,4,7)	Yes	Yes	Yes	Yes
3.16	The Clinical Program **shall** have access to a multidisciplinary care team, including designated staff with appropriate training and education to assist in the provision of pre-treatment evaluation, treatment, and post-treatment follow-up and care. Designated staff/roles **shall** include:	Yes	Yes	Yes	Yes

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Sites
3.16.1	Data management staff sufficient to comply with Section D.8 and D.9	Yes	Yes	Yes	Yes
3.16.2	Decision-support resources to collate and analyze quality indicators	Yes	Yes	Yes	Yes
3.16.3	Dietitian	Yes	Yes	Yes	Yes
3.16.4	Interpretative/translation services	Yes	Yes	Yes	Yes
3.16.5	Patient care coordinator	Yes	Yes	Optional	Optional
3.16.6	Physical therapy and occupational therapy	Yes	Yes	Yes	Yes
3.16.7	Psychology	Yes	Yes	Yes	Yes
3.16.8	Social work	Yes	Yes	Yes	Yes
3.16.9	Speech language pathology	Yes	Yes	Yes	Yes
3.16.10	Spiritual care[e]. (1,4,7)	Yes	Yes	Yes	Yes

Quality Managers

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Sites
3.17	There **shall** be a Clinical Program Quality Manager to establish and maintain systems to review, modify, and approve all policies and SOPs intended to monitor compliance with these recommendations or the performance of the Clinical Program. (4)	Yes	Yes	Yes	Yes
3.18	The Clinical Program Quality Manager **shall** participate in a minimum of ten (10) hours of educational activities (e.g., self-directed education, rounds, webinars, meetings, conferences), annually, related to acute leukemia therapy and/or quality management. (4)	Yes	Yes	Yes	Yes

[e] Although spiritual care is not included as part of the Acute Leukemia Funding Model, access should be provided as requested by patients.

D.4 Quality Management[f]

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Sites
4.1	Centres **shall** have a Quality Management Program that allows the Clinical Program Medical Director and all members of the care team to maintain their competency as internally assessed by the Clinical Program Medical Director or designate. The clinical competency of the Clinical Program Medical Director should be assessed by another identified staff member. (4)	Yes	Yes	Yes	Yes
4.1.1	The Clinical Program Medical Director or designate **shall** have authority over and responsibility for ensuring that the overall Quality Management Program is effectively established and maintained. (3,4)	Yes	Yes	Yes	Yes
4.1.2	The Clinical Program Medical Director or designate **shall** review the Quality Management activities with representatives in key positions in all elements of the Clinical Program, at a minimum, quarterly. (4)	Yes	Yes	Yes	Yes
4.1.2.1	Key performance data and review findings **shall** be reported to staff. (4)	Yes	Yes	Yes	Yes
4.1.2.2	Meetings **should** have defined attendees, documented minutes, and assigned actions. (4)	Yes	Yes	Yes	Yes
4.1.2.3	In the course of their regular meetings, the Clinical Program **should** annually review patient feedback of the acute leukemia care and any actions implemented, and improvement programs. (17)	Yes	Yes	Yes	Yes
4.1.3	The Clinical Program Medical Director or designate **shall** annually review the effectiveness of the overall Quality Management Program. (4)	Yes	Yes	Yes	Yes
4.1.4	The Clinical Program Medical Director or designate **shall not** have oversight of his/her own work if this person also performs other tasks in the Clinical Program. (4)	Yes	Yes	Yes	Yes
4.2	The Clinical Program **shall** establish and maintain a written Quality Management Plan. (4)	Yes	Yes	Yes	Yes
4.2.1	The Clinical Program Medical Director or designate **shall** be responsible for the Quality Management Plan. (4)	Yes	Yes	Yes	Yes

[f] Depending on the size of the site, the quality management requirements may be part of existing Regional Cancer Program operations.

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Sites
4.2.2	The Quality Management Plan **shall** include, or summarize and reference, a comprehensive system for document control. (4)	Yes	Yes	Yes	Yes
4.2.2.1	There **shall** be policies or SOPs for the development, approval, implementation, distribution, review, revision, and archival of all critical documents. (4)	Yes	Yes	Yes	Yes
4.2.3	The Quality Management Plan **shall** include, or summarize and reference, policies and SOPs for the establishment and maintenance of written agreements. (4)	Yes	Yes	Yes	Yes
4.2.3.1	Agreements **shall** be established with external parties (who are accredited, as appropriate) providing critical services that could affect the quality and safety of care for patients in the Clinical Program. (4)	Yes	Yes	Yes	Yes
4.2.3.2	Agreements **shall** be dated and reviewed on a regular basis. (7)	Yes	Yes	Yes	Yes
4.2.4	The Quality Management Plan **shall** include, or summarize and reference, policies and SOPs for occurrences including near misses, errors, accidents, deviations, adverse events, adverse reactions, and complaints. This maybe the same as existing policy at the centre. If not already available at centre **(Appendix C)**. (4)	Yes	Yes	Yes	Yes
4.2.5	The Quality Management Plan **shall** include, or summarize and reference, policies and SOPs for actions to take in the event the Clinical Program's operations are interrupted. (4)	Yes	Yes	Yes	Yes
4.2.6	The Quality Management Plan **shall** include, or summarize and reference, policies and SOPs for the qualification of critical manufacturers, vendors, equipment, supplies, reagents, facilities, and services. (4)	Yes	Yes	Yes	Yes
4.2.6.1	Qualification plans, results, and reports **shall** be reviewed and approved by the Quality Manager and Clinical Program Medical Director or designate. (4)	Yes	Yes	Yes	Yes
4.2.7	The Quality Management Plan **shall** include, or summarize and reference, policies and SOPs for the evaluation of risk in changes to a process to confirm that the changes do not create an adverse impact or inherent risk elsewhere in the operation. (4)	Yes	Yes	Yes	Yes
4.2.8	The Quality Management Plan **shall** include, or summarize and reference, an organizational chart of key positions and functions within the Clinical Program (governance structure). (4)	Yes	Yes	Yes	Yes

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Sites
4.2.8.1	The Quality Management Plan **shall** include a description of how these key positions interact to implement the quality management activities. (4)	Yes	Yes	Yes	Yes
4.2.8.2	The Quality Management Plan **shall** include, or summarize and reference, policies and SOPs addressing personnel requirements for each key position in the Clinical Program. Personnel requirements shall include at a minimum:	Yes	Yes	Yes	Yes
4.2.8.2.1	A current job description for all staff. (4)	Yes	Yes	Yes	Yes
4.2.8.2.2	A system to document the following for all staff: • Initial qualifications • New employee orientation • Initial training, competency, and retraining when appropriate for all procedures performed • Continued competency for each critical function performed, assessed annually at a minimum • Continuing education. (4)	Yes	Yes	Yes	Yes
4.2.9	The Quality Management Plan **shall** include key performance indicators and outcome analysis. (7)	Yes	Yes	Yes	Yes
4.2.9.1	The Clinical Program **should** work with Ontario Health (Cancer Care Ontario) to meet Provincial Acute Leukemia Program benchmarks, including:				
4.2.9.1.1	Consult Wait Times	Yes	No	Yes	No
4.2.9.1.2	Length of stay	Yes	Yes	Yes	Yes
4.2.9.1.3	Mortality	Yes	Yes	Yes	Yes
4.2.9.1.4	Survival Outcomes	Yes	Yes	Yes	Yes
4.2.9.1.5	Treatment Utilization	Yes	No	Yes	No
4.2.9.1.6	Treatment Wait Times and	Yes	No	Yes	No
4.2.9.1.7	Other indicators, as established. (7)	Yes	Yes	Yes	Yes

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Sites
4.2.9.2	In addition to the Ontario Health (Cancer Care Ontario) recommended metrics, review of outcome analysis **shall** include at a minimum:	Yes	Yes	Yes	Yes
4.2.9.2.1	Central venous catheter infection and/or thrombosis	Yes	Yes	Yes	Yes
4.2.9.2.2	Complete remission	Yes	Yes	Yes	Yes
4.2.9.2.3	Hospital-acquired infections	Yes	Yes	Yes	Yes
4.2.9.2.4	ICU admissions. (4,7)	Yes	Yes	Yes	Yes
4.2.10	The Quality Management Plan **shall** include, or summarize and reference, policies and SOPs for, and a schedule of, audits of the Clinical Program's activities to verify compliance with elements of the Quality Management Program and policies and SOPs, applicable laws or regulations, and these Specifications. (4)	Yes	Yes	Yes	Yes
4.2.10.1	The results of audits **shall** be used to recognize problems, detect trends, identify improvement opportunities, and implement corrective and preventive actions, when necessary, and follow-up on the effectiveness of these actions in a timely manner. (4)	Yes	Yes	Yes	Yes
4.2.10.2	Audits **shall** be conducted by an individual with sufficient expertise to identify problems, but who is not solely responsible for the process being audited. (4)	Yes	Yes	Yes	Yes

D.5 Policies and Procedures

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Site
5.1	The Centre **shall** have SOPs that are detailed, as per hospital's policy, to allow qualified staff to follow and complete the procedures successfully. (7)	Yes	Yes	Yes	Yes
5.2	The Clinical Program **shall** have SOPs defining local protocols for patient eligibility and selection for care (including performance status, prognostic factors, comorbidities) and consent. (3,4)	Yes	Yes	Yes	Yes
5.3	There **shall** be written SOPs or guidelines, including, but not limited to:	Yes	Yes	Yes	Yes

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Site
5.3.1	All clinical procedures	Yes	Yes	Yes	Yes
5.3.2	Administration of systemic therapy	Yes	Yes	Yes	Yes
5.3.3	Central venous access device care	Yes	Yes	Yes	Yes
5.3.4	Management of complications with systemic therapy:	Yes	Yes	Yes	Yes
5.3.4.1	Nausea, vomiting, pain, and other discomforts	Yes	Yes	Yes	Yes
5.3.4.2	Monitoring of blood counts and transfusion of blood products	Yes	Yes	Yes	Yes
5.3.4.3	Monitoring and management of infections and use of antimicrobials	Yes	Yes	Yes	Yes
5.3.4.4	Monitoring of organ dysfunction or failure	Yes	Yes	Yes	Yes
5.3.5	Prophylaxis, management and care of immunocompromised patients. (3,4,7,18)	Yes	Yes	Yes	Yes
5.4	The Centre **shall** have policies addressing safe administration of patient-specific radiation therapy. (19)	Yes	Yes	No	No
5.5	The Clinical Program **shall** have policies or SOPs in place for planned discharges and provision of follow-up care post-systemic therapy care, including transfer of patient, if required. (4)	Yes	Yes	Yes	Yes
5.6	The Clinical Program **shall** have a SOP for inter-institutional patient transfer that specifies clinical criteria for eligibility to transfer the patient and information transferred with the patient. (7)	Yes	Yes	Yes	Yes
5.7	The Clinical Program **shall** have an SOP for electronic decision-making tools used by the Clinical Program documenting the tool's development, validation and auditing. (7)	Yes	Yes	Yes	Yes
5.8	Staff training and, if appropriate, competency **shall** be documented before performing a new or revised SOP or guideline. (4)	Yes	Yes	Yes	Yes
5.9	Planned deviations from SOPs **shall** be pre-approved by the Clinical Program Medical Director, or designate, and reviewed by the Quality Manager. (4)	Yes	Yes	Yes	Yes
5.10	The Centre **should** have a SOP for the recognition of systemic therapy-related complications and emergencies requiring rapid notification of the Clinical Program. (4)	Yes	Yes	Yes	Yes

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Site
5.11	The Centre **should** have an institutional SOP for direct admission of patients to the hematology ward or other facilities equipped to rapidly assess and manage potentially life-threatening complications of systemic therapy (such as neutropenic sepsis or bleeding), where appropriate. (3)	Yes	Yes	Yes	Yes
5.12	The Clinical Program **should** have an established framework or policies for the transfer of patients to the ICU, as appropriate. The framework/policies should include written guidelines for communication, patient monitoring, and prompt triage or transfer of patients to an ICU when appropriate. (4,20)	Yes	Yes	Yes	Yes
5.13	The Centre **should** have written policies for communication with the person's primary care physician and other teams involved in treatment. (3)	Yes	Yes	Yes	Yes

D.6 Patient Care

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Site
6.1	The Clinical Program **shall** obtain patient informed consent, as per Accreditation Canada, for systemic therapy, which is documented in the patient's medical record by a licensed health care professional familiar with the proposed systemic therapy. (2,7)	Yes	Yes	Yes	Yes
6.1.1	The Clinical Program **shall** provide information regarding the risks, benefits, and alternatives of the proposed systemic therapy. (4)	Yes	Yes	Yes	Yes
6.1.2	The Centre **shall** provide the patient with access to information regarding the impact of treatment on fertility and information, including contact information, about fertility preservation. (7)	Yes	Yes	Yes	Yes
6.2	Centres **should** be versed in Goals of Care discussions as per the Ontario Health (Cancer Care Ontario) Goals of Care Toolkit for Oncology Settings.	Yes	Yes	Yes	Yes
6.3	The Centre **shall** provide the patient with access to holistic palliative care, and end of life care. (21) In accordance with patient and family's wishes, this care could be provided at centres at and beyond the acute leukemia service provider sites and can be offered closer to home. (1)	Yes	Yes	Yes	

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Site
6.3.1	The Clinical Program **should** conduct a comprehensive assessment of the patients needs across all domains of care early in their disease trajectory, to support early access to palliative care services.	Yes	Yes	Yes	Yes
6.4	If radiation is used, the centre **shall** document a final report with details of the radiation therapy administered in the patient's medical record that is accessible to the acute leukemia team. (4)	Yes	Yes	Yes	Yes
6.5	The Clinical Program **shall** provide access to services for adolescents and young adult patients and a process describing the transition and acceptance of adolescents and young adult patients to adult care, as appropriate. (4,5)	Yes	Yes	Yes	Yes
6.6	The Centre **should** have access to formal Multidisciplinary Case Conferences (MCC), where acute leukemia cases may be presented and discussed, attended by individuals detailed in the Cancer Care Ontario's MCC Standards. (3,22)	Yes	Yes	Yes	Yes
6.7	The Clinical Program **should** provide acute leukemia patients with access to a designated contact person, as part of a multidisciplinary team, throughout the duration of their care. (23)	Yes	Yes	Yes	Yes
6.8	The Centre **should** provide care in alignment with Cancer Care Ontario's Person-Centred Care Guidelines (24), in effort to meet the Person-Centred goals and objectives detailed in the most recent version of the Ontario Cancer Plan. (18)	Yes	Yes	Yes	Yes

D.7 Clinical Research

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Centre	Less Intensive Service Site	Less Intensive Partner Site
7.1	The Centre **shall** conduct and/or provide access to clinical trials and consider available clinical trials when assessing patient treatment options, (1,17)	Yes	No	Yes	No
7.2	The Centre **shall** inform other centres of available clinical trials for patients with acute leukemia. (7)	Yes	No	Yes	No

D.8 Data Management

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Sites
8.1	The Centre **shall** be compliant with laws and regulations regarding storage and use of personal health information as detailed by the Information and Privacy Commissioner of Ontario. (7)	Yes	Yes	Yes	Yes
8.2	The Centre **shall** be compliant with Cancer Care Ontario Data Book. (1)	Yes	Yes	Yes	Yes
8.3	The Clinical Program **shall** collect all the data necessary to complete data submission requirements of Ontario Health (Cancer Care Ontario), as detailed in the Funding Agreement with Ontario Health (Cancer Care Ontario). (7)	Yes	Yes	Yes	No
8.4	The Clinical Program **should** have an IT system that allows:	Yes	Yes	Yes	Yes
8.4.1	Specimen booking and registration at source	Yes	Yes	Yes	Yes
8.4.2	Input and update of clinical information	Yes	Yes	Yes	Yes
8.4.3	Integrated/synoptic reporting	Yes	Yes	Yes	Yes
8.4.4	Secure internal and external two-way communication between health care professionals. (3)	Yes	Yes	Yes	Yes
8.5	Defined data management staff **should** participate in continuing education annually. (4)	Yes	Yes	Yes	Yes

D.9 Laboratory Services

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Sites
9.1	The Centre **shall** ensure patients have access to all required pathology and molecular diagnostic tests as listed in the most recent version of the Consensus Pathology Recommendation for Complex Malignant Hematology Report. (25)	Yes	Yes	Yes	Yes
9.1.1	Testing sites **shall** meet all relevant Institute for Quality Management in Healthcare requirements and maintain Institute for Quality Management certification. (26)	Yes	Yes	Yes	Yes

#	Recommendation	Acute Leukemia Service Site	Shared-Care Partner Site	Less Intensive Service Site	Less Intensive Partner Sites
9.1.2	All testing performed for clinical management should be licensed and performed by accredited labs. (7)	Yes	Yes	Yes	Yes
9.1.3	Testing sites performing cytogenetics and molecular diagnostics **shall** meet provincial turnaround time targets. (25)	Yes	Yes	Yes	Yes
9.2	The Centre **shall** report an acute leukemia classification or classification differential according to a standard classification system recognized and supported by established hematopathology and hematology societies and Ontario Health (Cancer Care Ontario) Synoptic Reporting[g,h]. (3,25,27)	Yes	Yes	Yes	Yes
9.2.1	The Centre **shall** procure the appropriate biospecimens necessary for classification, prognostication and assessment of eligibility (where applicable) for targeted acute leukemia therapies; this minimally requires the Centre to expedite molecular and cytogenetic specimen delivery to CMH-laboratory testing facilities whenever acute leukemia is suspected.	Yes	Yes	Yes	Yes
9.2.2	The Centre **shall** integrate or reference into a final report the morphologic/ immunohistochemical blast count, acute leukemia phenotype/lineage and results of molecular and cytogenetic testing or acknowledge these results through an acute leukemia classification (see 9.2).	Yes	Yes	Yes	Yes

[g] Examples of established professional hematopathology and hematology societies may include Society of Hematopathology (SH), European Association of Hematopathology (EAHP), American Society of Hematology (ASH) and/or European Hematology Association (EHA)).

[h] Examples include the World Health Organization (WHO) Classification of Haematolymphoid Tumours 4th ed. Revised (34), 5th ed (35) and the International Consensus Classification (36). Should a harmonized international classification standard become universally recognized by established professional hematopathology and hematology societies, this new system shall be applied to render final classifications.

Part E. Moving Forward

Ontario Health (Cancer Care Ontario) will work with centres in Ontario providing acute leukemia services to assess and monitor progress towards implementation of the specifications within the *Report*. In February 2023, Ontario Health (Cancer Care Ontario) surveyed acute leukemia provider sites to review the current state of implementation for recommendations deemed to be highest priority for ensuring high quality care. Future Ontario Health (Cancer Care Ontario) initiatives will look to address common gaps in meeting the organizational requirements for Acute Leukemia Service Sites. The intent of this work is not to penalize centres, but rather to support service providers as they work to meet the recommendations in the *Report* and deliver high quality, standardized clinical care to patients in Ontario.

The *Report* should be reviewed regularly (every 3 years, at a minimum) to incorporate the impact that changes in practice and therapy may have on these recommendations. The *Report* should also be updated and adapted to consider other guidance released by Ontario Health, including guidance related to health equity and the provision of culturally appropriate care.

Acknowledgements

Ontario Health (Cancer Care Ontario) would like to acknowledge the Acute Leukemia Less Intensive Chemotherapy Working Group (**Appendix A**) and the Acute Leukemia Advisory Committee for their efforts and contributions to the review and update of the *Report*.

In addition, Ontario Health (Cancer Care Ontario) continues to acknowledge the efforts and contributions of the Acute Leukemia Specifications Working Group (**Appendix A**), the external reviewers (listed below), and the Ontario Health Library Services, in particular, Jessie Cunningham, former Medical Librarian, whose valuable input and expertise supported the provision of the inaugural report.

External Reviewers of inaugural report:

- Dr. Andrew Daly, Head, Section of Hematology, Alberta Health Services – Calgary Zone, and Clinical Assistant Professor, Cumming School of Medicine, University of Calgary
- Dr. C. Fred LeMaistre, Senior Vice President, Market Operations and Physician-in-Chief, Hematology, Sarah Cannon, Nashville, United States of America
- Dr. Matt Seftel, Hematologist, BC Cancer, and Clinical Professor, Division of Hematology, Department of Medicine, University of British Columbia

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Appendices

Appendix A: Committee Memberships

Table A1 | Acute Leukemia Specifications Working Group

Member	Affiliation(s)	Conflict of Interest Declarations
Dr. Christopher Bredeson	Chair, Clinical Lead, Quality Care and Access, Complex Malignant Hematology, Ontario Health (Cancer Care Ontario) Hematologist, The Ottawa Hospital	No relevant conflicts of interest to declare.
Dr. Rena Buckstein	Hematologist, Sunnybrook Health Sciences Centre	Research funding from Celgene/BMS, TAIHO, Honoraria from BMS, TAIHO and Abbvie.
Kardi Kennedy	Regional Systemic Program Lead, Kingston General Hospital	No relevant conflicts of interest to declare.
Dr. Tom Kouroukis	Provincial Head, Complex Malignant Hematology, Ontario Health (Cancer Care Ontario) Hematologist, Hamilton Health Sciences Corporation	No relevant conflicts of interest to declare.
Lia Kutzscher	Nurse Practitioner, Royal Victoria Regional Health Centre	No relevant conflicts of interest to declare.
Dr. Janet MacEachern	Hematologist, Grand River Hospital	No relevant conflicts of interest to declare.
Kit McCann	Lead Nurse Practitioner, Windsor Regional Hospital	No relevant conflicts of interest to declare.
Dr. Mitchell Sabloff	Hematologist, Director of Leukemia Program, The Ottawa Hospital	Research support from Sanofi Canada (2016/17). Honoraria from Pfizer Canada (Oct 2018), Celgene (Jun 2018), Jazz Pharmaceuticals (Apr 2018), and Novaritis (Feb 2017/18).
Dr. Karen Yee	Hematologist, Princess Margaret Cancer Centre – University Health Network	Ad board and research funding from various pharmaceutical companies.
Sherrie Hertz	Former Group Manager, Specialized Services Oversight Program, Ontario Health (Cancer Care Ontario)	No relevant conflicts of interest to declare.

Member	Affiliation(s)	Conflict of Interest Declarations
Cassandra McKay	Former Lead, Specialized Services Oversight Program, Ontario Health (Cancer Care Ontario)	No relevant conflicts of interest to declare.
Amanda Wong	Former Lead (Acting), Specialized Services Oversight Program, Ontario Health (Cancer Care Ontario)	No relevant conflicts of interest to declare.
Suzanna Apostolovski	Former Coordinator, Specialized Services Oversight Program, Ontario Health (Cancer Care Ontario)	No relevant conflicts of interest to declare.

Table A2 | Acute Leukemia Less Intensive Chemotherapy Working Group

Member	Affiliation(s)	Conflict of Interest Declarations
Dr. Christopher Bredeson (Co-chair)	CMH Quality Lead Ontario Health (Cancer Care Ontario) The Ottawa Hospital	No relevant conflicts of interest to declare.
Lauren Chun	Lead, Ontario Health (Cancer Care Ontario)	No relevant conflicts of interest to declare.
Dr. Erica DiMaria	Hematologist, Royal Victoria Hospital	No relevant conflicts of interest to declare.
Dr. Jai Jayakar	Hematologist, Southlake Regional Health Centre	No relevant conflicts of interest to declare.
Dr. Dina Khalaf	Medical Oncologist, Hamilton Health Sciences Centre	No relevant conflicts of interest to declare.
Dr. Sahar Khan	Hematologist, Windsor Regional Hospital	No relevant conflicts of interest to declare.
Dr. Tom Kouroukis (Co-chair)	CMH Provincial Health Ontario Health (Cancer Care Ontario) Hamilton Health Sciences Centre	No relevant conflicts of interest to declare.
Dr. Nicole Laferriere	Hematologist, Thunder Bay Regional Health Sciences Centre	No relevant conflicts of interest to declare.
Dr. Kit McCann	Nurse Practitioner, Windsor Regional Hospital	No relevant conflicts of interest to declare.
Cassandra McKay	Manager, Ontario Health (Cancer Care Ontario)	No relevant conflicts of interest to declare.
Dr. Guillaume Richard-Carpentier	Hematologist, Kingston Health Sciences Centre	No relevant conflicts of interest to declare.
Dr. Mitch Sabloff	Hematologist, The Ottawa Hospital	No relevant conflicts of interest to declare.

Dr. Lalit Saini	Hematologist, London Health Sciences Centre	No relevant conflicts of interest to declare.
Dr. Hubert Tsui	Hematopathologist, Sunnybrook Health Sciences Centre	No relevant conflicts of interest to declare.
Leslie Verville	Specialist, Ontario Health (Cancer Care Ontario)	No relevant conflicts of interest to declare.
Dr. Karen Yee	Hematologist, Princess Margaret Cancer Centre – University Health Network	Ad board and research funding from various pharmaceutical companies.

Appendix B: Literature Search

Table B1. | Guideline Search Results

Database	Search Date	Additional Search Criteria	Search Results	Applicable Titles	Applicable Abstracts	Full Text Reviewed	Text included in Recommendations
Guidelines International Network	Nov 9, 2017	Language: English Publication: guideline	523	0	0	N/A	N/A
National Guidelines Clearinghouse	Nov 9, 2017	Clinical Speciality: Hematology	88	0	0	N/A	N/A
Standards and Guidelines Evidence (SAGE) Inventory for Cancer Guidelines	Nov 9, 2017	Disease type: Hematologic; Document type: Organizational/ Professional	8	1	0	N/A	N/A
CPG Infobase	Nov 9, 2017		0	0	0	N/A	N/A
TRIP	Nov 9, 2017	Acute Leukemia + Guidelines	147	14	1	Dohner *et al*. (2017) - Diagnosis and Management of AML in Adults (27)	Dohner *et al*., 2017. Diagnosis and Management of AML in Adults (27)
ASCO	Nov 9, 2017		0	0	0	N/A	N/A
NICE	Nov 9, 2017	Document Type: Guidance; Guidance Category: Medicines practice guidelines, NICE guidelines, Public Health guidelines, safe staffing guidelines Status: Published	270	2	2	NICE (2016) -Haematological cancers: improving outcomes (NG47) (3) NICE (2017) - Hematological Cancers: Quality Standard – QS150) (28)	NICE (2016) -Haematological cancers: improving outcomes (NG47) (3)
FACT-JACIE	Nov 9, 2017		94	3	2	FACT (2018) - 7th Edition Standards for Hematopoietic cellular Therapy Accreditation Manual (4)	FACT (2018) - 7th Edition Standards for Hematopoietic Cellular Therapy (4)

Database	Search Date	Additional Search Criteria	Search Results	Applicable Titles	Applicable Abstracts	Full Text Reviewed	Text included in Recommendations
						FACT (2018) - 7th Edition Standards for Hematopoietic Cellular Therapy (4)	
Cancer Care Ontario	Nov 10, 2017	Type of Content: Guidelines and Advice	34	10	6	Cancer Care Ontario (2017) - Acute Leukemia Provincial Plan (1) Cancer Care Ontario (2012) - Adult Acute Leukemia Services Plan for the Greater Toronto Area-Recommendations Report (29) Good *et al.* (2014) - Best Practices for Pathology Secondary Review: Hematological Cancers (30) Cancer Care Ontario (2016) - Consensus Pathology Recommendations for Complex Malignant Hematology (25) **Other Reports to be Reviewed:** Forbes, *et al.* (2019) - Regional Models of Care for Systemic Treatment (2) Leung M, *et al*. (2012) - Safe Administration of Chemotherapy: Safety During Chemotherapy Ordering, Transcribing, Dispensing, and Patient Identification (8) Leung M, et al. - Safe Administration of Systemic Cancer Therapy Part 2: Administration of Systemic Treatment and Management of Preventable Adverse Events (31) Cancer Care Ontario (2017) - Recommendations for changes in the roles and composition of multidisciplinary team and the setting of care to improve access for patients in Ontario (6)	Cancer Care Ontario (2017) - Acute Leukemia Provincial Plan (1) Cancer Care Ontario (2016) - Consensus Pathology Recommendations for Complex Malignant Hematology (25) Forbes, *et al.* (2019) - Regional Models of Care for Systemic Treatment (2) Leung M, et al. (2012) - Safe Administration of Chemotherapy: Safety During Chemotherapy Ordering, Transcribing, Dispensing, and Patient Identification (8) Leung M, et al. (2018) - Safe Administration of Systemic Cancer Therapy Part 2: Administration of Systemic Treatment and Management of Preventable Adverse Events (31) Cancer Care Ontario (2017) - Recommendations for changes in the roles and composition of multidisciplinary team and the setting of care to improve access for patients in Ontario (6)
American Society of Hematology	Nov 27, 2017		1055	5	1	Ketterer *et al.* (2014) - Conventional Hospital Room Is as Safe as Sterile Unit for High-Dose Chemotherapy and Peripheral Blood Stem Cells Transplantation (32)	N/A

Database	Search Date	Additional Search Criteria	Search Results	Applicable Titles	Applicable Abstracts	Full Text Reviewed	Text included in Recommendations
Other identified articles	Jan 19, 2018	Identified by working group members	2	2	1	National Advisory Committee on Blood and Blood Products (2016) - Recommendations for use of Irradiated Blood Components in Canada (11)	National Advisory Committee on Blood and Blood Products (2016) - Recommendations for use of Irradiated Blood Components in Canada (11)
Total	**N/A**	**N/A**	**2219**	**35**	**12**	**15**	**11**

Table B2 | Grey Literature Search Results (performed by Cancer Care Ontario Library Services)

Webpages Searched	Search Date	Keywords	Search Results	Applicable Titles (duplicates removed)	Applicable abstracts	Full text reviewed	Texts included in Recommendations
• Alberta Health Services • Cancer Care Ontario • ESMO • Cancer Care Nova Scotia • BC Cancer Agency • Cancer Care Manitoba • Hospital for Sick Children (Sick Kids) • POGO • NCCN • Western Australian Department of Health • Belgian Health Care Knowledge Centre • NHS evidence (includes NICE, SIGN, Health Improvement Scotland, etc) • Trip database • European LeukemiaNet • HQO • AHRQ • Canadian Partnership Against Cancer/Cancerview • NGC	Nov 13, 2017	Acute leukemia hematolog* Haematologic Malignancy recommend* Hospital service(s) Minimum requirements Standards Personnel Organization and administration Facilities Guidelines Service delivery Utilization/utilisation Inpatient Model(s) of care Care pathway Quality improvement Quality measures	35	16	4	Western Australia Cancer and Palliative Care Network (2009) - Hematologic Malignancy Model of Care (5). Leukaemia CARE (2013) - Defining high quality care for haematological cancer patients (23) NHS National Peer Review Programme (2013)- Manual for Cancer Services Haemato -oncology Cancer Measures (17) NHS National Cancer Action Team (2012) - Additional best practice commissioning guidance for developing haematology diagnostic services (33)	Western Australia Cancer and Palliative Care Network (2009) - Hematologic Malignancy Model of Care (5) Leukaemia CARE (2013) - Defining high quality care for haematological cancer patients (23) NHS National Peer Review Programme (2013)- Manual for Cancer Services Haemato - oncology Cancer Measures (17)
Total	**N/A**	**N/A**	**35**	**16**	**4**	**4**	**3**

Primary Literature Search (Performed by Cancer Care Ontario Library Services)

Subject: Development of organizational standards for acute leukemia
Date range: 10 years
Language(s): English
Database(s): Medline, Embase

Medline Search Strategy:
Set 1 Acute Leukemia/Hematology
exp Leukemia, Myeloid, Acute/ or exp Leukemia, Erythroblastic, Acute/ or exp Leukemia, Myelomonocytic, Acute/
or
(Acute adj leuk?emia$ adj2 (granulocytic or megakaryocytic or monocytic or myeloblastic or myelomonocytic or myeloid or myelocytic or myelogenous or nonlymphoblastic or non-lymphoblastic or nonlymphocytic or non-lymphocytic or erythroid or monoblastic or basophilic or erythroid or monoblastic or nonlymphoid or non-lymphoid)).ti,ab,kw.
or
(AML not (angiomyol: or amylose or amlodipine)).ti,ab
or
*Hematology/ or (hematology or haematology or haematologic or hematologic).ti,ab
Not
(Cord blood or Venous Thromboembolism or lupus* or prostat*).ti,ab,kw
And
Set 2 Guidelines/Recommendations/Standards
*Practice Guidelines as Topic/ or guideline.pt.
or
(organizational standard$ or organisational standard$ or practice parameter$ or practice guideline$).tw or (guideline or guidelines or recommended or recommendation or recommend or consensus or standards).ti. or (guideline or guidelines or recommended or recommendation or recommend or consensus or standards).kw

Medline search history as run

Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to Present>

#	Searches	Results
1	exp phase 3 clinical trial/ or exp "phase 3 clinical trial (topic)"/ or exp clinical trial, phase iii/ or exp clinical trials, phase iii as topic/ or exp phase 4 clinical trial/ or exp "phase 4 clinical trial (topic)"/ or exp clinical trial, phase iv/ or exp clinical trials, phase iv as topic/ or exp randomized controlled trial/ or exp "randomized controlled trial (topic)"/ or exp controlled clinical trial/ or exp randomized controlled trials as topic/ or exp randomization/ or exp random allocation/ or exp double-blind method/ or exp single-blind method/ or exp double blind procedure/ or exp single blind procedure/ or exp triple blind procedure/ or exp placebos/ or exp placebo/ or ((exp phase 2 clinical trial/ or exp "phase 2 clinical trial (topic)"/ or exp clinical trial, phase ii/ or exp clinical trials, phase ii as topic/ or exp clinical trial/ or exp prospective study/ or exp controlled clinical trial/) and random$.tw.) or (((phase II or phase 2 or clinic$) adj3 trial$) and random$).tw. or ((singl$ or double$ or treple$ or tripl$) adj3 (blind$ or mask$ or dummy)).tw. or placebo?.tw. or (allocat: adj2 random:).tw. or (random$ control$ trial? or rct or phase III or phase IV or phase 3 or phase 4).tw. or (random$ adj3 trial$).mp. or "clinicaltrials.gov".mp.	1084306
2	exp meta analysis/ or exp "meta analysis (topic)"/ or exp meta-analysis as topic/ or exp "systematic review"/ or exp "systematic review (topic)"/ or ((exp "review"/ or exp "review literature as topic"/ or review.pt.) and ((systematic or selection criteria or data extraction or quality assessment or jaded scale or methodologic$ quality or study) adj selection).tw.) or meta-analysis.mp. or (meta-analy: or metaanaly: or meta analy:).tw. or (systematic review or systematic overview).mp. or ((cochrane or medline or embase or cancerlit or hand search$ or hand-search$ or manual search$ or reference list$ or bibliograph$ or relevant journal$ or pooled analys$ or statistical pooling or mathematical pooling or statistical summar$ or mathematical summar$ or quantitative synthes?s or quantitative overview$ or systematic) adj2 (review$ or overview$)).tw.	253662
3	(Acute adj leuk?emia$ adj2 (granulocytic or megakaryocytic or monocytic or myeloblastic or myelomonocytic or myeloid or myelocytic or myelogenous or nonlymphoblastic or non-lymphoblastic or nonlymphocytic or non-lymphocytic or erythroid or monoblastic or basophilic or erythroid or monoblastic or nonlymphoid or non-lymphoid)).ti,ab,kw.	346
4	(AML not (angiomyol: or amylose or amlodipine)).ti,ab.	28421
5	Leukemia, Myeloid, Acute/ or Leukemia, Erythroblastic, Acute/ or Leukemia, Myelomonocytic, Acute/	44563
6	*Hematology/ or (hematology or haematology or haematologic or hematologic).ti,ab.	65399
7	*Practice Guidelines as Topic/ or guideline.pt.	56520
8	(organizational standard$ or organisational standard$ or practice parameter$ or practice guideline$).tw.	23269
9	7 or 8	73074
10	9 not (1 or 2)	65123
11	(Cord blood or Venous Thromboembolism or lupus* or prostat*).ti,ab,kw.	333463
12	6 not 11	63249
13	exp Leukemia, Myeloid, Acute/ or exp Leukemia, Erythroblastic, Acute/ or exp Leukemia, Myelomonocytic, Acute/	55074
14	3 or 4 or 13 or 12	127320
15	14 and 10	398
16	limit 15 to (english language and yr="2007 -Current")	173

Embase Search Strategy:

*acute myelomonocytic leukemia/ or *erythroleukemia/ or *acute myeloid leukemia/
or
(Acute adj leuk?emia$ adj2 (granulocytic or megakaryocytic or monocytic or myeloblastic or myelomonocytic or myeloid or myelocytic or myelogenous or nonlymphoblastic or non-lymphoblastic or nonlymphocytic or non-lymphocytic or erythroid or monoblastic or basophilic or erythroid or monoblastic or nonlymphoid or non-lymphoid)).ti,ab,kw
or
(AML not (angiomyol$ or amylose or amlodipine)).ti,ab
or
*Hematology/ or (hematology or haematology or haematologic or hematologic).ti,ab
Not
(Cord blood.or Venous Thromboembolism or lupus* or prostat*).ti,ab,kw
And
*practice guideline/
or
(organizational standard$ or organisational standard$ or practice parameter$ or practice guideline$).tw or (guideline or guidelines or recommended or recommendation or recommend or consensus or standards).ti. or (guideline or guidelines or recommended or recommendation or recommend or consensus or standards).kw
not
exp phase 3 clinical trial/ or exp "phase 3 clinical trial (topic)"/ or exp clinical trial, phase iii/ or exp clinical trials, phase iii as topic/ or exp phase 4 clinical trial/ or exp "phase 4 clinical trial (topic)"/ or exp clinical trial, phase iv/ or exp clinical trials, phase iv as topic/ or exp randomized controlled trial/ or exp "randomized controlled trial (topic)"/ or exp controlled clinical trial/ or exp randomized controlled trials as topic/ or exp randomization/ or exp random allocation/ or exp double-blind method/ or exp single-blind method/ or exp double blind procedure/ or exp single blind procedure/ or exp triple blind procedure/ or exp placebos/ or exp placebo/ or ((exp phase 2 clinical trial/ or exp "phase 2 clinical trial (topic)"/ or exp clinical trial, phase ii/ or exp clinical trials, phase ii as topic/ or exp clinical trial/ or exp prospective study/ or exp controlled clinical trial/) and random$.tw.) or (((phase II or phase 2 or clinic$) adj3 trial$) and random$).tw. or ((singl$ or double$ or treple$ or tripl$) adj3 (blind$ or mask$ or dummy)).tw. or placebo?.tw. or (allocat: adj2 random:).tw. or (random$ control$ trial? or rct or phase III or phase IV or phase 3 or phase 4).tw. or (random$ adj3 trial$).mp. or "clinicaltrials.gov".mp.
or
exp meta analysis/ or exp "meta analysis (topic)"/ or exp meta-analysis as topic/ or exp "systematic review"/ or exp "systematic review (topic)"/ or ((exp "review"/ or exp "review literature as topic"/ or review.pt.) and ((systematic or selection criteria or data extraction or quality assessment or jaded scale or methodologic$ quality or study) adj selection).tw.) or meta-analysis.mp. or (meta-analy: or metaanaly: or meta analy:).tw. or (systematic review or systematic overview).mp. or ((cochrane or medline or embase or cancerlit or hand search$ or hand-search$ or manual search$ or reference list$ or bibliograph$ or relevant journal$ or pooled analys$ or statistical pooling or mathematical pooling or statistical summar$ or mathematical summar$ or quantitative synthes?s or quantitative overview$ or systematic) adj2 (review$ or overview$)).tw.

Embase <1974 to 2017 December 07>

#	Searches	Results
1	*acute myelomonocytic leukemia/ or *erythroleukemia/ or *acute myeloid leukemia/	5632
2	(Acute adj leuk?emia$ adj2 (granulocytic or megakaryocytic or monocytic or myeloblastic or myelomonocytic or myeloid or myelocytic or myelogenous or nonlymphoblastic or non-lymphoblastic or nonlymphocytic or non-lymphocytic or erythroid or monoblastic or basophilic or erythroid or monoblastic or nonlymphoid or non-lymphoid)).ti,ab,kw.	442
3	(AML not (angiomyol$ or amylose or amlodipine)).ti,ab.	49396
4	*Hematology/ or (hematology or haematology or haematologic or hematologic).ti,ab.	172805
5	(Cord blood or Venous Thromboembolism or lupus* or prostat*).ti,ab,kw.	424873
6	4 not 5	164462
7	1 or 2 or 3 or 6	203160
8	*practice guideline/	55866
9	(organizational standard$ or organisational standard$ or practice parameter$ or practice guideline$).tw.	29091
10	(guideline or guidelines or recommended or recommendation or recommend or consensus or standards).ti. or (guideline or guidelines or recommended or recommendation or recommend or consensus or standards).kw.	165050
11	or/8-10	201965
12	exp phase 3 clinical trial/ or exp "phase 3 clinical trial (topic)"/ or exp clinical trial, phase iii/ or exp clinical trials, phase iii as topic/ or exp phase 4 clinical trial/ or exp "phase 4 clinical trial (topic)"/ or exp clinical trial, phase iv/ or exp clinical trials, phase iv as topic/ or exp randomized controlled trial/ or exp "randomized controlled trial (topic)"/ or exp controlled clinical trial/ or exp randomized controlled trials as topic/ or exp randomization/ or exp random allocation/ or exp double-blind method/ or exp single-blind method/ or exp double blind procedure/ or exp single blind procedure/ or exp triple blind procedure/ or exp placebos/ or exp placebo/ or ((exp phase 2 clinical trial/ or exp "phase 2 clinical trial (topic)"/ or exp clinical trial, phase ii/ or exp clinical trials, phase ii as topic/ or exp clinical trial/ or exp prospective study/ or exp controlled clinical trial/) and random$.tw.) or (((phase II or phase 2 or clinic$) adj3 trial$) and random$).tw. or ((singl$ or double$ or treple$ or tripl$) adj3 (blind$ or mask$ or dummy)).tw. or placebo?.tw. or (allocat: adj2 random:).tw. or (random$ control$ trial? or rct or phase III or phase IV or phase 3 or phase 4).tw. or (random$ adj3 trial$).mp. or "clinicaltrials.gov".mp.	1372494
13	exp meta analysis/ or exp "meta analysis (topic)"/ or exp meta-analysis as topic/ or exp "systematic review"/ or exp "systematic review (topic)"/ or ((exp "review"/ or exp "review literature as topic"/ or review.pt.) and ((systematic or selection criteria or data extraction or quality assessment or jaded scale or methodologic$ quality or study) adj selection).tw.) or meta-analysis.mp. or (meta-analy: or metaanaly: or meta analy:).tw. or (systematic review or systematic overview).mp. or ((cochrane or medline or embase or cancerlit or hand search$ or hand-search$ or manual search$ or reference list$ or bibliograph$ or relevant journal$ or pooled analys$ or statistical pooling or mathematical pooling or statistical summar$ or mathematical summar$ or quantitative synthes?s or quantitative overview$ or systematic) adj2 (review$ or overview$)).tw.	358181
14	11 not (12 or 13)	179644
15	7 and 14	1089
16	((Animal Experimentation or animal model or animal* or nonhuman or non human or rat or rats or mouse or mice or rabbit or rabbits or pig or pigs or porcine or swine or dog or dogs or hamster or hamsters or fish or chicken or chickens or sheep) not (Humans or human)).ti,ab,kw.	3534882
17	(conference abstract or editorial or comment or letter or newspaper article).pt.	4362938
18	15 not (17 or 16)	693
19	limit 18 to (english language and yr="2007 -Current")	348

Table B3 | Primary Literature Search Results

Database	Search Date	Additional Search Criteria	Results	Applicable Titles	Applicable Abstracts	Full Text Reviewed	Text included in Recommendations
Medline and Embase	Dec 7, 2017	See search strategy above.	395	30	8	Pratt G, Morris TC. Review of the NICE guidelines for multiple myeloma. International Journal of Laboratory Hematology. 2017;39(1):3-13. Huang XJ, Liu K, Ritchie D, Andersson B, Lu J, Hou J, et al. Hematology oncology practice in the Asia-Pacific APHCON survey results from the 6th international hematologic malignancies conference: Bridging the gap 2015, Beijing, China. Oncotarget. 2017;8(25):41620-41630. Neuss MN, Gilmore TR, Belderson KM, Billett AL, Conti-Kalchik T, Harvey BE, et al. 2016 updated American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards, including standards for pediatric oncology. Journal of Oncology Practice. 2016;12(12):1262-1271. Turner A, Stephenson M. Documentation of chemotherapy administration by nursing staff in inpatient and outpatient oncology/hematology settings: a best practice implementation project. JBI Database Of Systematic Reviews And Implementation Reports. 2015;13(10):316-334. Yaur, J. Automated testing in hematology: the role of rules in setting a standard. MLO: medical laboratory observer. 2015;47(11):44. Hayward CP, Moffat KA, George TI, Proytcheva M. Assembly and evaluation of an inventory of guidelines that are available to support clinical hematology laboratory practice. International Journal of Laboratory Hematology. 2015;37 Suppl 1:36-45. Gavin A, Rous B, Marcos-Gragera R, Middleton R, Steliarova-Foucher E, Maynadie M, et al. Towards optimal clinical and epidemiological registration of haematological malignancies: Guidelines for recording progressions, transformations and multiple diagnoses. European Journal of Cancer. 2015;51(9):1109-1122. Malak S, Sotto JJ, Ceccaldi J, Colombat P, Casassus P, Jaulmes D, et al. Ethical and clinical aspects of intensive care unit admission in patients with hematological malignancies: Guidelines of the ethics commission of the French society of hematology. Advances in Hematology. 2014;2014 (no pagination) (704318) (Malak, et al., 2014).	Malak S, Sotto JJ, Ceccaldi J, Colombat P, Casassus P, Jaulmes D, et al. Ethical and clinical aspects of intensive care unit admission in patients with hematological malignancies: Guidelines of the ethics commission of the French society of hematology. Advances in Hematology. 2014;2014 (no pagination) (704318) (Malak, et al., 2014).
Total	**N/A**	**N/A**	**395**	**30**	**8**	**8**	**1**

Appendix C: Policy for Occurrences

As described in Recommendation 4.2.4, the Quality Management Plan **shall** include, or summarize and reference, policies and SOPs for occurrences including near misses, errors, accidents, deviations, adverse events, adverse reactions, and complaints. This may be the same as existing policies at the centre. If not already available at centre, the quality management plan should include the following details:

- Detection
- Investigation
    - Investigations **shall** identify the root cause and a plan for short- and long-term corrective and preventive actions as warranted.
- Documentation:
    - Documentation **shall** include a description of the occurrence, date and time of the occurrence and the involved individuals, when and to whom the occurrence was reported, and the immediate actions taken.
    - All investigation reports **shall** be reviewed in a timely manner by the Clinical Program Medical Director or designate and the Quality Manager.
    - Cumulative files of occurrences **shall** be maintained.
    - Cumulative files **shall** include written investigation reports containing conclusions, follow-up, corrective and preventive actions.
- Reporting according to governance at institution.
- Corrective and preventative action.
    - Appropriate action **shall** be implemented if indicated, including both short-term action to address the immediate problem and long-term action to prevent the problem from recurring.
    - Follow-up audits of the effectiveness of corrective and preventive actions **shall** be performed in a timeframe as indicated in the investigative report. (4)

Appendix D: Funding

This *Report* was conducted with the support of Ontario Health (Cancer Care Ontario) through funding provided by the Ontario Ministry of Health. Funding to assist with open access publishing fees was provided by the Ontario Health (Cancer Care Ontario) Research Office.

Appendix E: Copyright

Appendix F: Disclaimer

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Appendix G: Contact Information

For further information about this report, please contact the Specialized Services Oversight Program (OH-CCO_SSOInfo@ontariohealth.ca). For information about Ontario Health (Cancer Care Ontario) and the most current version of all reports, please visit the Ontario Health (Cancer Care Ontario) website.

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