SOCIÉTÉ INTERNATIONALE D'ONCOLOGIE PÉDIATRIQUE
SIOP
INTERNATIONAL SOCIETY OF PAEDIATRIC ONCOLOGY

STANDARDS FOR PAEDIATRIC ONCOLOGY UNITS

SIOP Guidance Standards Framework for Paediatric Oncology Units in Low- and Middle-Income Countries

SUMMARY

This document provides practical standards to guide the organisation, delivery, and continuous improvement of paediatric oncology services in lower- and middle-income countries.

Developed through international collaboration, the content reflects evidence-informed practices and expert consensus to enhance outcomes and equity in childhood cancer care worldwide.

FOREWARD

It is with great pride and a deep sense of purpose that I present this document on the standardisation of paediatric oncology units for low- and middle-income countries (LMICs). This initiative marks a significant milestone in our collective mission to ensure that every child with cancer, regardless of where they live, has access to safe, effective, and equitable care.

The burden of childhood cancer in LMICs is profound, yet the resources to address it are often fragmented or insufficient. In response, this document provides a practical, evidence-informed framework to guide the development and strengthening of paediatric oncology services in diverse settings.

It is not merely a technical manual—it is a manifesto for equity, grounded in the belief that every child deserves access to the highest attainable standard of care in their context.

What makes this work truly exceptional is the collaborative spirit in which it was created. Experts from all our continental branches—representing paediatric oncology, surgery, nursing, radiotherapy, psychosocial care, nutrition, health systems management, and the voices of those with lived experience of cancer with the guidance of an expert consultant—have come together to contribute their knowledge and expertise. This multidisciplinary approach ensures that the standards proposed are not only clinically sound but also contextually adaptable and sustainable.

This document aligns with the goals of the WHO Global Initiative for Childhood Cancer and the CureAll framework, reinforcing our shared commitment to increasing survival to at least 60% for all children with cancer by 2030.

It is a tool for advocacy, planning, and implementation—designed to empower hospital administrators, and health care teams to build and enhance paediatric oncology units that meet the needs of their populations.

On behalf of SIOP, I extend my deepest gratitude to all contributors and partners who made this work possible. May this document serve as a catalyst for action, a guide for progress, and a symbol of our unwavering dedication to children with cancer everywhere—to fulfil our mission of care for all and cure for more.

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Table of CONTENTS

INTRODUCTION

Key Concepts

The International Society of Paediatric Oncology (SIOP) convened a group of paediatric oncology experts and leaders from across the globe. Over a 12-month period in 2024–2025, this multidisciplinary team collaborated to develop, review, and finalise the recommendations and standards presented in this book.

These standards outline the core infrastructure and clinical processes necessary to deliver safe, equitable, and high-quality care for children with cancer in Paediatric Oncology Units (POUs). Rooted in global evidence and expert consensus, they are practical, adaptable, and suitable for diverse health system settings. Because POUs operate within hospitals and broader health systems—and may not directly oversee all services—the term "hospital" is used throughout. Readers are encouraged to interpret this terminology according to their organisational context. The standards offer a strong foundation for self-assessment, quality improvement, and alignment with best practices.

Paediatric cancer poses a significant global health challenge, particularly in low- and middle-income countries (LMICs), where access to timely diagnosis and effective treatment is often limited. Each year, an estimated 400,000 children and adolescents aged 0 to 19 are diagnosed with cancer worldwide, yet survival rates remain below 20% in many regions. Addressing this disparity is not only a medical necessity—it is a moral imperative.

This publication offers a focused framework for establishing and strengthening POUs through a curated set of standards that cover key elements of care delivery, including clinical services, education, research, and patient-centred approaches. Rather than detailing every operational requirement, these standards prioritise the most impactful areas of practice, based on their relevance to improving outcomes and reducing inequities.

Targeted at medical and nursing leaders and the supportive care team, this resource promotes interdisciplinary collaboration and practical strategies to improve paediatric cancer care. Though care settings and resources vary, all programs can benefit from aligning with standards that are clearly defined, realistic, and scalable. It also serves as a valuable tool for hospital administrators and healthcare policy makers working to strengthen paediatric oncology services within broader health systems. Standardisation reduces unwarranted variation, improves safety and quality, and fosters more equitable care delivery.

By offering standards that are practical, measurable, and adaptive to context, this book supports the global effort to improve outcomes for children with cancer and to close the survival gap between high- and low-resource settings. At the end of each chapter, you will find a set of curated resources specifically chosen to support the implementation of the standards in that section. These may include global guidelines, institutional examples, adaptable tools, or recommended reading to guide improvement efforts. Users are encouraged to review these materials as part of their planning and capacity-building processes.

How to Use the Standards

The standards in this book are not simply aspirational—they are tools for action, improvement, and accountability. Below are suggested ways to apply them:

Assess Gaps in Systems, Processes, and Structures

Conduct a Gap Analysis: Use the standards as a benchmark to evaluate current services. Identify gaps in performance, infrastructure, or clinical processes.

Engage the Team: Involve multidisciplinary staff, leadership, and patients or caregivers to gain a comprehensive understanding of strengths and needs. This fosters shared ownership of the process.

Plan for Short- and Long-Term Improvement

Set Priorities: Use the gap analysis to identify which issues require immediate action and which can be addressed over time.

Develop Action Plans: Create SMART (specific, measurable, achievable, relevant, time-bound) plans to address each priority. This helps track progress and ensures accountability.

Strengthen Internal Quality Improvement

Conduct Regular Audits: Use the standards for ongoing internal review (monthly, quarterly, or annually) to assess compliance and guide improvements.

Establish Feedback Loops: Encourage staff to reflect on performance, share suggestions, and adjust practices based on feedback and outcomes.

Collaborate on External Evaluations

Work with Health Authorities: If supported by a ministry of health or regulatory body, align your efforts with national quality or cancer care frameworks.

Design Improvement Programs: Use baseline evaluations to create structured programs that include training, resource allocation, and process redesign.

Schedule Periodic Reviews: Re-evaluate at regular intervals to maintain momentum and refine strategies as conditions evolve.

As you begin the first chapter, we invite you to explore how these standards can be adapted and applied in your setting to advance care for children with cancer.

ASSESSMENT, TREATMENT AND CONTINUITY OF CARE

Key Concepts

The most effective strategy to reduce the burden of cancer in children and improve outcomes is to ensure early, timely diagnosis followed by effective, evidence-based, and context-adapted treatment regimens with adequate supportive care (Atun et al., 2020; WHO, 2021).

Early diagnosis consists of three key components:

- Awareness of early signs and symptoms by families and primary care providers;
- Timely access to clinical evaluation, diagnostic testing, and cancer staging (i.e., determining the extent of disease);
- Prompt initiation of appropriate treatment.

The primary goal of the POU team is to align the child's healthcare needs with the available services, ensuring coordination of timely, high-quality care within the local health system to maximise patient outcomes. This includes planning for discharge, referral, or transfer, and establishing mechanisms for appropriate follow-up. This approach improves patient outcomes and promotes more efficient use of resources.

Leadership and clinical decision-making related to patient admission, transfer, discharge, referral, and follow-up should consider:

- Prioritisation of patients presenting with urgent or life-threatening conditions;
- Whether the child's clinical and supportive care needs can be safely met by the existing local health system;
- Access to intensive or specialised services, when indicated;
- Expedited and efficient delivery of services;
- Safe and timely referral, transfer, or discharge to home or other care setting;
- Coordination and continuity of care, including monitoring for treatment refusal or abandonment;
- Whether curative treatment is feasible within the available resources; if not, decisions should balance the benefits of transfer to higher-level centres against the option of initiating palliative and supportive care closer to home, considering family circumstances, financial impact, and cultural context.

Assessment for, and Admission to, the Hospital and POU

1. Children with a confirmed or suspected cancer diagnosis are assessed to determine whether their healthcare needs align with the capabilities of the hospital and paediatric cancer care program. This initial assessment may occur through a formal referral or through direct communication between the referring provider and the cancer care team or at the time of diagnosis in the hospital in cases involving their own patients.

2. The hospital evaluates patient clinical needs and informs families if significant delays in diagnostic or treatment services could impact outcomes.

3. The urgency of care is guided by clinical presentation and aims to expedite diagnosis and treatment of childhood cancers, thereby improving outcomes. Patients are assessed and managed based on severity—immediate cases (severe symptoms requiring urgent referral to a hospital with paediatric emergency services) are referred without delay; priority cases (less urgent but still critical) are referred within 48–72 hours; and programmed cases (requiring further diagnostic studies) are scheduled accordingly.

4. Paediatric Oncology Units (POUs) define the age range of patients they serve in alignment with hospital policy and national regulations. Children under 12 years of age are to be managed in a POU, with many units also extending care to patients up to 16 or 19 years of age. Because most cancer registries report data in two groups—0–14 years and 15–19 years—we recommend using these ranges for planning and reporting. Establishing dedicated services for adolescents and young adults (AYA), developed jointly by paediatric and adult oncology specialists, is also encouraged. The hospital has implemented a systematic process to expedite diagnostic studies and interventions for paediatric oncology patients. Turnaround times for urgent diagnostics are monitored and used to drive performance improvement.

5. Clinical criteria and streamlined processes are in place for admission to and discharge from the paediatric cancer care program and inpatient unit.

Assessment, Care planning, Reassessment

1. Clinical care pathways are implemented in the POU to support the coordinated, timely, consistent delivery of care and advanced care planning. These pathways are multidisciplinary in design and operationalise key processes across diagnosis, treatment, supportive care, and follow-up. They help standardise clinical workflows, minimise variation, reduce delays, and improve communication across services. Pathways may be developed or adapted locally to reflect institutional resources, team roles, and care models.

2. The organisation uses evidence-based clinical practice guidelines and protocols to guide the diagnosis, staging, treatment, and supportive care of children with cancer. These resources—such as those from the International Society of Paediatric Oncology (SIOP), Children's Oncology Group (COG), World Health Organization (WHO), or regional or disease-specific cooperative groups—serve as the foundation for clinical decision-making. When necessary, guidelines and protocols are adapted using structured tools, such as the St. Jude Global–SIOP Adaptation Resource and Implementation Application (ARIA) platform, to align with the local context, available resources, and workforce capacity. For staging, disease-specific international guidelines should be used when feasible; however, when certain diagnostic modalities are unavailable, the Toronto staging guidelines provide a practical and standardised alternative (Gupta et al., 2016).

3. Treatment is guided by standardised clinical regimens that specify interventions, medications, dosages, and schedules. Regimen selection is based on the patient's cancer type, risk stratification, service level, available infrastructure, and staff expertise. When optimal resources are not available, adapted regimens are used. These adaptations may include adjustments for comorbid conditions, chemotherapy intensity, staging approaches, or supportive care capacity. Regimens are reviewed and updated periodically.

4. The treatment plan is communicated with the family in a manner that respects their cultural and religious beliefs. This includes sensitivity to family preferences about how much information is disclosed to the child patient or to siblings. Families are supported in making treatment choices, including the option of non-curative treatment, consistent with their values and preferences.

5. The minimum scope and timing of initial patient assessments by all members of the multidisciplinary team are defined by organisational policy, procedure, or required documentation—such as designated fields on digital or paper forms.

6. Medical and nursing assessments are completed within 24 hours of inpatient admission and, for medical assessments, prior to any invasive procedure. The medical assessment includes a complete history and physical examination, incorporating oncology-specific details (e.g., diagnosis, treatment plan, chemotherapy agents, and prior complications). Initial assessments by allied health professionals (e.g., nutrition, social work) are completed within policy-defined timeframes appropriate to the patient's condition.

7. Following initial assessments, the multidisciplinary team develops a treatment and care plan based on applicable clinical care guidelines and treatment protocols. These may include recommendations from the International Society of Paediatric Oncology (SIOP), Children's Oncology Group (COG), World Health Organization (WHO), St. Jude Global ARIA Guide, or nationally adopted paediatric cancer protocols. The plan is then individualised to reflect the patient's specific clinical findings, staging, psychosocial needs, available resources, and patient and family preferences. It incorporates input from all relevant disciplines and is documented in the medical record.

8. The minimum scope and timing of patient reassessments by all members of the multidisciplinary team are defined by organisational policy, procedure, or required documentation—such as designated fields in digital or paper medical records. Each patient is reassessed by a physician at least every 24 hours, and more frequently as indicated by the clinical condition. Nursing staff and other clinical team members conduct reassessments in accordance with the individualised care plan and policy. Reassessments reflect the patient's evolving needs and are documented in their medical record.

9. Prior to any clinical intervention, procedure, medication administration, or transfer of care, staff actively verify that the patient's identity matches the order and the care about to be provided. Identity is confirmed using at least two unique identifiers (e.g., full name, date of birth, medical record number).

10. The hospital implements the Universal Protocol to enhance surgical safety, in whatever location the surgery / procedure occurs (bedside, operating room, etc.) and reduce preventable errors. This includes:

- Pre-procedure verification of the correct patient, procedure, and site/side.
- Marking of the surgical site by the clinician performing the procedure (when applicable).
- Documentation of the time-out in the medical record per hospital policy.

11. A postoperative note must be completed promptly after any surgical procedure and entered into the patient's medical record. The timeframe for completion is defined by the institution. This note ensures continuity of care, supports clinical decision-making, and serves as a legal and quality assurance document.

- Date and time of the procedure
- Name(s) of the surgeon and key surgical staff
- Preoperative diagnosis and postoperative diagnosis
- Procedure(s) performed
- Description of the surgical findings
- Any specimens collected for pathological or laboratory analysis, including the type, anatomical source, and the laboratory destination for the specimen, e.g., histopathology, microbiology, or genetic/molecular testing
- Estimated blood loss
- Details of any complications during the procedure
- Postoperative condition of the patient and immediate plan for care
- Instructions for postoperative monitoring, medications, and further investigations

12. Additional standard elements for paediatric cancer surgery operative reports, as applicable to the case:

- Preoperative disease stage
- History of prior tumour biopsy or surgery
- Evidence of preoperative tumour rupture
- Neoadjuvant therapy administered (e.g., chemotherapy or radiotherapy before surgery)
- Surgical access approach (e.g., laparotomy, thoracotomy)
- Type of resection (e.g., partial, total, en bloc)
- Completeness of resection (e.g., gross total, near total, incomplete)
- Tumour margin assessment (e.g., margins free, involved, not assessable)
- Locoregional tumour extension (e.g., invasion into adjacent organs or structures)
- Organs resected in addition to the primary tumour
- Intraoperative tumour spillage (presence and management)
- Vascular involvement (e.g., vessel encasement or resection)
- Lymph node sampling (location, number, and result)
- Anatomical orientation of specimen (clearly marked for pathology)

13. A radiation treatment summary must be completed promptly after any radiotherapy course and entered into the patient's medical record. The timeframe for completion is defined by the institution. This note ensures continuity of care, supports clinical decision-making, and serves as a legal and quality assurance document. The radiation treatment summary includes:

- Name of the radiation oncologist
- Intent of radiotherapy (e.g., curative or palliative)
- Overall dates of radiotherapy
- Duration of radiotherapy (e.g., number of days elapsed)
- For each specific radiation site treated
  i. total dose
  ii. dose per fraction
  iii. radiation modality
- Use of anesthesia
- Use of concurrent chemotherapy
- Toxicity during treatment
- Treatment interruptions

14. All documentation should be clear, legible (if handwritten), and completed according to local policy and within a defined timeframe following the procedure.

15. The patient and family are informed about the clinician who holds overall responsibility for their care.

Orders

1. The hospital develops and implements a uniform process for prescribing and documenting patient orders, including identifying the types of orders and their location in the medical record. When available, electronic ordering systems—such as Computerized Provider Order Entry (CPOE)—are preferred, as they enhance legibility, provide timely access to information, and reduce the risk of medication and communication errors.

2. Where available, standardised order sets are used to support the safe and consistent implementation of clinical practice guidelines, protocols, and care pathways. Qualified staff review them regularly to ensure alignment with current evidence and local resources, with safeguards in place to prevent errors such as duplication or omission.

3. Clinical staff—such as nurses, pharmacists, and radiation oncology technicians—have reliable and effective means of communicating with prescribing providers to verify, clarify, or address any concerns related to patient orders, including the appropriateness, safety, and feasibility of the order based on the patient's clinical condition and available resources. Prescribing providers respond in a timely manner to ensure safe and uninterrupted care.

4. To promote patient safety, verbal or telephone orders are limited to life-threatening emergencies or sterile procedures. When these orders are used, the prescriber verifies their accuracy by having the recipient repeat the order back. Verbal, telephone, or texted orders are documented in the medical record as soon as possible, including sufficient information to identify the ordering provider.

5. Diagnostic imaging and laboratory test orders include clinical indications when necessary for interpretation.

6. Orders for nursing interventions specify the minimum frequency and scope for patient monitoring, tailored to the patient's condition and other relevant clinical factors.

7. A comprehensive nutritional assessment is performed for each paediatric oncology patient at admission and repeated regularly throughout treatment, with a minimum frequency of once every two weeks. Nutritional support is provided in accordance with national or local guidelines. In the absence of such guidelines, WHO recommendations for the management of severe acute malnutrition are followed.

8. Oral nutrition is the preferred and encouraged route of nutritional intake. When oral intake is insufficient or contraindicated, enteral nutrition is initiated promptly, following a standardised protocol adapted to available resources. Parenteral nutrition is reserved for situations in which gastrointestinal feeding is not feasible or effective and is provided where available.

9. Qualified nutrition professionals design meals to meet the nutritional needs of paediatric oncology patients and are prepared under controlled conditions to ensure safety and accommodate treatment-related symptoms. When families are permitted to bring food from home, clinical staff assess whether it meets the prescribed diet and food safety standards. All patient food—whether prepared by the hospital or brought by the family—is stored and reheated under safe temperature conditions to reduce the risk of foodborne illness.

10. All care is delivered according to the orders provided.

Family-Centred Care

1. Psychosocial care must be integral during both treatment and follow-up care.

2. The patient's psychosocial needs are assessed, treated, and monitored, including neuropsychological evaluation for children with brain tumours.

3. Parents should be allowed to stay with their children at all times during hospitalisation.

4. The psychosocial needs of parents and siblings are also assessed by addressing potential financial challenges, with appropriate support provided directly or through referrals to external resources. Interaction with patient organisations is encouraged.

5. The multidisciplinary team implements strategies to support and encourage patient and family engagement in care and decision-making.

6. Patients and families receive education on the patient's condition, diagnosis, treatment plan, associated risks, potential long-term side effects, potential lifestyle restrictions and expected outcomes.

7. Academic and school re-entry needs are addressed, particularly when prolonged treatment or absence is anticipated.

8. Patients and families are supported in navigating the healthcare system by the multidisciplinary team members such as social workers, case managers, psychologists, volunteers, or patient navigators.

9. Referral pathways ensure access to palliative and end-of-life care when needed, in coordination with hospital or external programs.

10. Referral pathways ensure access to bereavement counselling when needed, in coordination with hospital or external programs.

Privacy and Safety/Security

There is an established process to ensure patient privacy and confidentiality of care and information and allow patients/families the right to have access to their health information within the context of existing law and culture.

Paediatric patients are protected from abuse, assault, and neglect through staff training, clear reporting pathways, and vigilant care practices. The organisation ensures all individuals with access to paediatric areas are identified and authorised, and staff are trained to recognise and respond to concerning behaviours by caregivers, visitors, or staff. For examinations or procedures involving the genital, breast, or rectal areas, a caregiver is encouraged to remain present, and the organisation has a process to provide a trained staff chaperone when a caregiver is not available, when the patient or staff requests one, or when required by local policy.

Informed Consent

Patients and their families are provided with information about the risks and expected outcome of interventions/therapies, invasive interventions, blood product administration, and procedures of similar risk. According to institutional procedures, this information may be provided in the form of written consent and/or as a structured conversation with a clinician that is noted in the medical record.

Complaints

The POU has a system to receive complaints and resolve them.

Timeframes have been established for the response to and resolution of complaints.

Response and resolution timeframes are monitored, and deviations are addressed.

Referral, Transfer, Discharge

1. In situations where the hospital is unable to continue care—whether due to lack of clinical capacity, the family's financial constraints, absence of insurance coverage, or at the family's request—the hospital ensures that the patient is promptly referred or transferred to an appropriate facility or service. Every effort is made to support the family in identifying alternative resources and sources of care that can meet the patient's needs, without compromising the continuity, quality, or safety of care. Health authorities provide a referral network for complex paediatric oncology conditions.

2. Prior to transfer, the transferring organisation confirms with the receiving organisation that they accept the patient and operate the services necessary to treat the patient. (This may be through a pre-existing agreement or arranged through a healthcare system/ministry of health). Housing needs for the patient's family are taken into consideration.

3. Upon discharge, referral, or transfer, a complete written summary—either in paper or digital format—is prepared, included in the patient's medical record, and provided to any receiving care team and to the patient's family or caregivers. This summary ensures continuity of care and includes the reason for admission, significant findings, confirmed diagnosis (including cancer stage), procedures performed, medications and treatments administered (e.g., chemotherapy or radiotherapy), and the patient's condition at the time of transfer or discharge. When permitted and feasible, copies of diagnostic studies and biological specimens are also made available. Families are advised to keep this information readily accessible at all times, especially for international referrals.

4. Throughout the patient's stay and as part of the discharge process, families receive education about the patient's health care needs tailored to their language, literacy, and cultural context. Physicians, nurses, and allied health professionals provide verbal and written instructions addressing the care plan, medication administration, signs of complications, follow-up appointments, and when and how to seek urgent care. Education is delivered progressively during the hospitalisation and reinforced at discharge, using teach-back techniques to confirm understanding and empower families to safely continue care at home or in the next care setting.

5. The records of patients requiring complex care, follow-up to an adult institution after treatment in a children's hospital, or with complex diagnoses are made available to the health care practitioners providing care to those patients.

6. The hospital has a process to identify patients at risk of not initiating, discontinuing, or abandoning medically advised cure-directed therapy, and to follow up with patients who have not started treatment, left the care location, or discontinued therapy—whether or not they have notified hospital staff.

7. When cancer treatment is completed, the patient receives regular follow-ups by the POU or is referred to another centre for long-term survivorship care including rehabilitation services when necessary. Follow-up includes the assessment of physical and mental health, with monitoring of specific organ systems—such as cardiac or renal function—based on the treatments received and associated long-term risks.

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Description of Clinical Decision Tools in Paediatric Cancer Care

Tool / Term	Purpose	Example
Clinical Regimen	A treatment plan that specifies a structured sequence of treatment, its schedule, drug dosage and duration of treatment.	ABVD for Hodgkin lymphoma, CHOP for B-cell malignancies, IVA for soft tissue sarcomas, VCE for retinoblastoma
Clinical Practice Guideline	Evidence-based care recommendations that inform national or global standards.	SIOP Umbrella Wilms Tumor Guideline; CCLG Good Practice Guide for Paediatric Radiotherapy
Adaptation Tool	Helps adapt protocols and regimens based on resource levels.	ARIA – St Jude-SIOP Adapted Resource Implementation Application
Clinical Pathway	Institution-wide, time-sequenced plan linking guidelines to care steps.	Paediatric ALL pathway covering diagnosis, risk stratification, and initial treatment
Clinical Protocol	Operational document, usually in the context of a clinical research study, guiding care delivery.. Patients may be formally enrolled in a prospective protocol or treated “as per” a protocol with the standard arm.	iBFM-ALL protocol used in limited-resource paediatric oncology units.

Table 1. Description of Clinical Decision Tools in Paediatric Cancer Care 1

THE PAEDIATRIC ONCOLOGY UNIT (POU) ORGANISATION AND SERVICES

Key Concepts

Paediatric Oncology Units (POUs) are essential to delivering high-quality, specialised care for children with cancer and blood disorders. While the structure and organisation of POUs vary widely across the globe, the core principle remains the same: children with cancer should be managed in settings that are tailored to their unique medical and psychosocial needs.

A POU does not necessarily require a separate, dedicated building. In many resource-constrained environments, care may be delivered within various hospital settings. However, even in these integrated settings, the quality of care must meet the same standards expected in a dedicated paediatric oncology environment. This includes adherence to specialised protocols, infection control practices, supportive care measures, and psychosocial support tailored to the paediatric population.

POUs may be located in various hospital settings, including:

- Dedicated paediatric oncology hospitals
- General paediatric hospitals
- Mixed general adult and paediatric hospitals
- Specialised cancer hospitals for both adults and children

The POU is typically located in a high-complexity hospital with different sources of funding, such as public institutions, university hospitals, private or non-profit facilities, and centres for insured patients. Some POUs focus on specific cancers like CNS, musculoskeletal, ocular, or haematological malignancies.

Each setting offers distinct benefits and drawbacks, such as access to paediatric subspecialties in paediatric hospitals or advanced diagnostic and therapeutic tools in cancer-specific hospitals. POUs are staffed by multidisciplinary teams with paediatric expertise and designed to create a child- and family-friendly environment.

Whenever possible, care should be provided in these specialised units rather than adult oncology wards, where the needs of young patients may be overlooked.

Due to the rarity and complexity of paediatric cancers, in most countries, POUs are located in high-volume public referral centres. Those with comprehensive resources often receive a designation of “National Referral Centre” (NRC). These centres guide national cancer control strategies, train healthcare professionals, and provide expert consultations to smaller facilities.

The denomination of an NRC is basically a decision of the national authorities from each country, city or region. In most cases, they provide the highest standards in the country in an accessible fashion. However, they may not be the only centre providing comprehensive care. The term “Centres of Excellence” has also been proposed by the CureAll document to describe comprehensive centres.

A four-level model of care for children with cancer was proposed by The Lancet Oncology Commission (Atun et al.). Because of overlaps between levels and wide local variation, it is not feasible to adopt a uniform classification in this document.

Instead, each country should stratify POUs according to national guidelines and available resources, with the objective that every child is treated in a hospital best suited to their medical needs. Centralising complex services in well-resourced referral centres, while linking them to peripheral units, promotes efficiency, equity, and better outcomes.

Smaller units in peripheral cities may be important for access when geographical or socioeconomic barriers make it difficult for families to reach a centre of excellence. Patient volume alone should not be the only criterion for stratification; in some settings, smaller but well-resourced centres can deliver high-quality care.

In general, a minimum of 30 newly diagnosed patients per year is recommended for a POU to maintain adequate expertise and activity, although in regions with low population density, a lower number may still be acceptable to ensure access.

POU Organisational Structure and Scope

1. The POU has a written and approved governance structure and paediatric cancer care specific policies.

2. Each POU has at least one designated director or chief responsible for decision-making, the management of staff/personnel, and for implementing hospital and POU specific policies, procedures and guidelines.

3. High-risk, potentially curable patients should have access to the most advanced care available in their settings, while lower-risk cases may be managed in less complex facilities if they can offer a similar outcome based on a track record of efficacy and safety.

4. Collaboration among hospitals with different expertise is ensured. In a shared care model, for instance, when access to a specific component of care—such as a highly specialised surgery—is necessary, the procedure can be performed at a specialised centre, while the rest of the treatment can be provided at a facility where this specialised service is not available.

5. POU leadership participates with the public health authorities in the stratification of POUs based on their capacity to treat different types of paediatric cancers. This allows patients to be managed at the most suitable POU based on their diagnosis and level of complexity.

6. The POU has a written definition of the scope and complexity of care it provides. The definition includes the types of cancer or service lines that the POU treats. The written definition also includes the stages treated, the age range of patients, comorbidities managed, as well as the diagnostic tests and treatments available for each service line.

7. The POU has guidelines for the age limits for accepting patients, which is generally aligned with the hospital where they are located and approved by local authorities in public hospitals. These guidelines should be flexible, fostering collaboration among centres, so that patients may benefit from the best available care in their setting.

8. This definition of the scope of services and complexity or level of care is available to key stakeholders of the hospital, e.g., providers, the community (potential patient families), and to the system/national ministry of health.

9. Information on how to communicate with the POU, provider-to-provider, is readily available and functional.

10. Information on how families can communicate with the POU team to obtain information or an assessment is readily available and functional.

11. For a National Referral Centre (NRC) or “Centre of Excellence” the organisation has:
    - An identifiable organisational entity with clear governance and budget.
    - An innovative multidisciplinary approach using the potential of basic, translational and clinical research and clinical facilities and activities.

- Direct provision of an extensive scope of paediatric cancer care tailored to the individual patient's needs and directed towards improving the quality of care.
- Broad activities in the area of advocacy, national policy, early diagnosis, education, and external dissemination of knowledge and innovation.
- Active training programs preferably with university-endorsed degrees for paediatric oncology fellowships and other related specialties.
- A high patient number with varied paediatric tumours and they should serve as a national or regional referral centre for difficult to manage cases for diagnosis and treatment.
- Comprehensive infrastructure (usually the highest in the country), expertise and innovation experience in the field of paediatric cancer including research.
- An extensive national and international network for advising on the management of all aspects of cancer treatment and research.
- Full integration between hospital care and cancer research, linked to one or more universities or research institutes.

Critical Care and Emergency Support

12. A fully staffed Paediatric Intensive Care Unit (PICU) is readily accessible on campus 24 hours a day, 7 days a week. Paediatric oncology patients requiring critical care—such as for respiratory distress or hypotension—are transferred to the PICU in a timely manner as clinically indicated, following institutional escalation and patient-flow protocols. When PICU access is limited, such as during seasonal surges, prioritisation protocols based on physiological criteria should be in place to guide timely and equitable access to intensive care.

13. The POU has implemented an early warning program for clinical deterioration. A paediatric emergency/code response team is trained and ready to respond to critical situations (e.g., cardiac arrest).

14, Safe intra- and extra-hospital transport are ensured for critically ill paediatric patients. Transport is conducted by trained personnel with appropriate equipment to maintain continuous monitoring and support during transit.

15. Contracted clinical services for paediatric oncology patients—whether provided within the unit by external providers or through temporary transfer to another facility (e.g., radiation oncology, dialysis, specialised imaging)—are the responsibility of POU or hospital leadership when within their scope of authority. Each of these contracted arrangements includes clinical oversight by the POU or hospital leadership to define quality expectations and monitoring—such as credentialing of providers, adherence to treatment protocols, timeliness of care, infection prevention practices, and patient outcomes—along with mechanisms to review performance data, conduct on-site visits, address patient or family complaints, and evaluate compliance with agreed standards.

Diagnostic and Laboratory Services

16. A comprehensive clinical laboratory is available with the ability to monitor tumour markers, and drug levels (antibiotics, immunosuppressants, antineoplastics).

17. A diagnostic imaging department includes: radiography (X-ray imaging); computed tomography (CT); magnetic resonance imaging (MRI); ultrasonography (ultrasound); angiography; and, where available, positron emission tomography (PET) for advanced diagnostic imaging. Radionuclide imaging and imaging under anesthesia—particularly important for younger children—should also be available. A digital archiving system, such as a Picture Archiving and Communication System (PACS), for storing and retrieving imaging studies is recommended.

18. Pathology and haematopathology services provide: immunohistochemistry; cytogenetics; cytomorphology; fluorescence in situ hybridisation (FISH); flow cytometry; and molecular diagnostics (e.g., polymerase chain reaction [PCR]). These services may be available on-site or linked through a formalised, rapid-access network.

Therapeutic Services

19. A blood bank provides irradiated and leukocyte-depleted blood components 24 hours a day, 7 days a week. Transfusion practices and product preparation follow national regulations and internationally recognised guidelines (e.g., WHO, AABB, and Council of Europe).

20. When antineoplastic and investigational medications are prepared on-site, this is done using appropriate environmental controls—such as laminar airflow—and in accordance with safety and monitoring protocols. When these medications are received from another organisation or preparation site, the hospital pharmacy oversees the quality and management of the medications received.

21. Appropriate systems and environmental controls—including safe handling procedures, inventory management, temperature and humidity ranges, clean medication handling surfaces, recall response protocols, and proper labelling of contents, concentrations, volumes, and warnings—are in place to ensure the safe storage, dispensing, and administration of medications.

22. Operating theatres are equipped for a range of paediatric surgical specialties and anesthesia, ideally on campus.

23. Radiation therapy services with paediatric-adapted, up-to-date equipment and anesthesia are accessible, either on campus or through established external partnerships. These services operate under guidelines for good paediatric practice, such as those outlined in the Good Practice Guide for Paediatric Radiotherapy (2nd ed.), developed by the Royal College of Radiologists, the Society and College of Radiographers, the Institute of Physics and Engineering in Medicine, and the Children's Cancer and Leukaemia Group (UK).

24. Stem cell transplantation services are accessible (on-site or through partnerships) and include human leukocyte antigen (HLA) typing—a test used to match donors and recipients based on immune system compatibility—and paediatric-trained professionals, as per national guidelines (if nationally available).

25. Haemodialysis, haemofiltration and therapeutic apheresis services for paediatric patients are available, ideally on-site or in close proximity to support the management of acute or chronic kidney injury, metabolic complications, and other critical conditions requiring extracorporeal therapies.

Specialised Care

26. Dedicated inpatient paediatric oncology beds and appropriate isolation rooms are available. Each patient room must include furniture that allows a parent or caregiver to rest or sleep, such as a comfortable chair or bed. For immuno-compromised patients, air control systems should be functioning. For POUs lacking air control systems, alternatives are utilised, such as portable air purifiers and enhanced protective equipment.

27. An ambulatory infusion care centre is available to provide chemotherapy, transfusions, hydration, other medications and minor procedures for paediatric oncology patients.

28. Where possible, the hospital or health system may establish an ambulatory stem cell transplantation unit to deliver components of the transplant process—such as conditioning chemotherapy, supportive care, and post-transplant monitoring—in an outpatient setting. The unit must meet the same standards of care, safety, and coordination as other transplantation services in the organisation/system.

29. POUs or centres coordinate home-care services to support families in managing their child's treatment and recovery at home. These services may include guidance on medication administration, symptom monitoring, nutritional support, and psychosocial counseling. When available, home-care programs are integrated with hospital-based care to ensure continuity and are adapted to the local context and resources.

30. In settings where home care services are available, the POU is responsible for evaluating the quality of those services when provided to its patients. This evaluation should include, at a minimum, an assessment of the clinical competency of home care providers, adherence to treatment protocols, timeliness and reliability of care delivery, patient and family satisfaction, safety monitoring (including medication administration and infection prevention), and coordination with the POU team to ensure continuity of care.

Supportive and Patient-Centred Services

31. Patient-specific cancer education is provided to patients and caregivers, considering the diagnosis, overall medical condition, socio-economic situation, learning goals, abilities, and preferred methods of learning. To support education tailored to individual learning abilities and preferences, the organisation, often in association with parental groups or other civil society organisations, makes available a variety of resources such as videos, books, mobile applications, and other tools.

32. Language and sign-language interpretation are available to support clear, culturally competent communication of important medical information, such as history and physical exams, treatment decision-making with the family, and informed consents.

33. Sensitive discussions, whether inpatient or in an ambulatory care setting, are conducted in a space and manner that respects patient and family privacy and confidentiality.

34. The hospital uses psychosocial screening tools to assess the emotional and mental health needs of paediatric oncology patients and, when appropriate, their caregivers and family members. Staff are trained to recognise signs of distress and to initiate basic supportive communication. Trained personnel or partners provide counseling or peer support, and referral pathways are established for access to mental health professionals for more complex needs.

35. Fertility preservation counseling and access to fertility preservation resources (on-site or via referral) are provided when appropriate and available.

36. Patients, caregivers, and families traveling from outside the local area are provided with information and support to access housing accommodations and other logistical resources, which are ideally available at no-cost or at a cost accessible to them based on their resources. Parental groups usually support these activities.

37. Spaces where paediatric patients receive care—whether ambulatory or inpatient—are designed to be child-friendly and safe (e.g., electrical outlets are protected). When play areas are available, policies are in place to ensure that only patients who can safely share the space based on their immune status use them, and that toy and surface cleaning is included in the organisation's infection prevention and control program.

38. Scholastic support services are provided for continued instruction for hospitalised children and adolescents.

39. A long-term follow-up program is provided for multidisciplinary care and rehabilitation for survivors, including transition to adult care as appropriate.

40. Children with life-limiting or life-threatening conditions and their families receive comprehensive, developmentally appropriate care that addresses needs during the illness and dying process. This care prioritises the effective relief of pain and other distressing symptoms, together with psychosocial and spiritual support. Shared decision-making is encouraged with the child and family, and communication is conducted in a culturally sensitive and respectful manner. Palliative and end-of-life care must be accessible in all appropriate settings, including the hospital, home, paediatric-appropriate hospice facilities, and, when necessary, through coordinated referral to external services.

41. Following a child's death, the bereaved family receives compassionate, culturally responsive support. Legal and administrative processes such as death certification are completed accurately and promptly, and the child's body, body parts, or tissues are handled, stored, viewed, and released with dignity and respect. Families are offered opportunities, consistent with local law and cultural practice, to participate in decisions regarding autopsy and organ or tissue donation, and they are provided with bereavement information and follow-up support. Viewing of the body is facilitated in a private setting—such as the ward, a designated viewing area, or the hospital morgue—ensuring culturally appropriate access at no cost to the family; if unavoidable fees for storage or release are required, they must be set at a level that is financially accessible and does not obstruct grieving, cultural or religious practices. Whenever possible, support for repatriation of the body to the child's home community is also offered.

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MULTIDISCIPLINARY TEAM

Key Concepts

The shortage of trained paediatric oncologists, nurses, and pharmacists in LMICs contributes to treatment delays and inadequate symptom management. Focusing on workforce development and enhancing training opportunities for healthcare professionals can improve the quality of care. Addressing these workforce shortages is crucial to reducing the risk of misdiagnosis and medication errors.

SIOP adheres to the International Atomic Energy Agency (IAEA) and the World Health Organization (WHO) recommendation that "an optimal approach to cancer planning is the 'multidisciplinary clinic' in which patients with newly diagnosed cancer are seen by surgical, paediatric oncology and radiation oncology specialists. When multidisciplinary collaboration is not facilitated by co-location of services or in difficult to manage cases, multidisciplinary team (MDT) meetings are used to coordinate care. The MDT reviews the clinical, histological and staging findings and makes consensus recommendations alongside an optimal treatment and care plan for each individual patient.

An MDT is composed of healthcare providers specialising in different areas of cancer care. A paediatric oncology MDT may comprise surgeons, radiation oncologists, paediatric oncologists-haematologists, pathologists, radiologists, oncology nurses, palliative care specialists and other professionals, such as pharmacists, social workers, psychologists, and nutrition specialists, basic and translational researchers among others, may be included. MDTs are crucial in ensuring quality in cancer care and improving patient outcomes. POUs should establish a standard procedure for MDTs and ideally, all major treatment decisions should be discussed in the context of an MDT.

In some settings, paediatric haemato-oncologists manage all the aspects of care of their patients, whereas, especially in busy hospitals, the responsibility for patient care is shared with general paediatricians or hospitalists, especially for supportive care. Therefore, it is not possible to give an exact estimate for the ideal number of paediatric oncologists per newly diagnosed patient for the different settings. This number is between one every 15 to 50, according to the roles taken in the complexity of the POU, the care of patients with benign haematology and the availability of stem cell transplantation for example.

It is important to highlight that the resources listed below must be present and effectively available for an adequate functioning POU. Centres having less capabilities should expeditiously refer patients for treatment to those POUs with adequate resources if available.

Multidisciplinary Team and Services

1. One qualified professional leads paediatric cancer care. This person's qualifications are demonstrated by education, training and experience in both paediatrics and oncology.

2. Professionals in each discipline (medical, medical specialties, nursing, support services, etc.) providing care to paediatric oncology patients have the training, certifications and competencies to do so.

3. The POU/hospital has written descriptions of the scope of care and services provided by each specialty and discipline.

Human Resources and Competencies

4. All licensed, registered, or certified clinical and technical personnel—including physicians, nurses, pharmacists, laboratory professionals, and allied health staff that care for paediatric oncology patients—have their credentials verified before providing patient care, in accordance with national regulatory standards. Verification confirms that qualifications are current, valid, and appropriate for their defined scope of practice. Verification is repeated as credentials expire or require renewal.

5. Paediatric oncology care is provided by licensed physicians who are certified in paediatric oncology or paediatric haematology-oncology by a recognised national or international board and who have completed formal subspecialty training, typically through a fellowship program of at least two years. Where board certification is not available, equivalent qualifications—such as postgraduate training in paediatric oncology, verified clinical experience, and formal recognition by the national medical authority or professional body—are accepted. In settings where paediatric oncology is not formally recognised or subspecialty training is unavailable, care may be provided by general paediatricians who meet national criteria for prescribing chemotherapy and have received basic training in haematology-oncology. Especially in these cases, a continuing medical education program should be offered to support and complement their training.

6. Each POU includes at least two qualified paediatric haematologists/oncologists who meet the standards described above. In high-volume centres, these professionals work full-time on a permanent contract or are available on call 24 hours a day, 7 days a week. They are responsible for managing patients within the POU and leading the delivery of care.

7. Adult medical oncologists or adult haematologists are not responsible for the management of children with developmental tumours or haematopoietic malignancies who are younger than 12 years if a paediatric specialist is available. Only in settings where a paediatric oncologist is not available and the patients cannot be referred to a centre with such capabilities, adult specialists (with the support of a trained paediatrician) may manage paediatric oncology patients.

8. In settings where training specifically in haematology is available, medical doctors with training in adult haematology manage paediatric patients (with the support of a trained paediatrician) only if there is not locally available board-certified or equivalent paediatric haematology/oncology trained physician and it is not possible to refer these patients to a centre with such capabilities.

9. In both circumstances, a paediatrician with complete residency training should work in collaboration for managing differential diagnoses and supportive care especially for managing paediatric patients under 12 years. In all cases, children should be managed in paediatric services.

10. In many locations and settings, training in both benign and malignant paediatric haematology and oncology is offered in the same subspecialty program, and appointed professionals take care of patients with cancer and benign haematology disorders. However, in some settings a separate training program may be available, and services may be separated.

11. A minimum of 2 years of general paediatric training in a residency program is mandatory plus an additional of 2-3 years of subspecialty training in a formal academic program, to complete 4-5 years minimum of training is encouraged. National board certification and periodic re-accreditation for continuous education are mandatory when nationally available.

12. Paediatricians with training in internal and/or emergency paediatrics participate in the supportive care of children with cancer.

13. Paediatric oncology nurses are professional nurses trained and competent. These are nurses certified in chemotherapy, knowledgeable about paediatric protocols and experienced in the management of complications of therapy. Certification from the Association of Paediatric Haematology/Oncology Nurses and-or national certification bodies is recommended.

14. A nurse staffing plan based on patient acuity levels is utilised. A minimum safe nurse to patient ratio is 1:5 for general paediatric oncology units and 1:2 for critical care and transplant units.

15. Nurses with experience of oncology should remain within the service and not rotate between specialties.

16. All nursing staff new to paediatric oncology receive structured induction. Evidence of successful completion, demonstrable knowledge, skills and competencies should be obtained before new nurses provide direct patient care. Minimum content should include: review of paediatric cancers treated, administration of chemotherapy and management of side effects, management of venous access (central and peripheral), use of equipment specific to the unit, control and prevention of infections, administration of blood products, management of neutropenic sepsis, early detection and treatment of oncology emergencies, assessment and management of pain, nutritional support, education for patients and families, palliative care including death and dying and spiritual and psychological issues.

17. Nurses receive continuing education and training to maintain and increase their paediatric oncology clinical skills and knowledge. A minimum of 10 hours continued education and training per year is recommended.

18. Nurses are included as core members of the multidisciplinary paediatric oncology team, as evidenced by participation in patient rounds and key meetings with patients and parents/caregivers such as when the diagnosis and treatment plan are discussed.

19. Only when a pharmacist is unavailable, chemotherapy is prepared by nurses with appropriate training. Preparation occurs in a dedicated, well-ventilated room equipped with a Class II Biological Safety Cabinet, along with appropriate personal protective equipment (PPE). The organisation conducts periodic health screenings of staff to monitor for potential adverse effects, including secondary cancers related to exposure to antineoplastic agents.

20. Evidence-based paediatric oncology nursing policies and procedures are available, in place and up-to-date to guide the delivery of quality nursing care.

21. Board-certified or equivalent radiologists with specific expertise—as evidenced by certification and training in the diagnostic imaging and radiologic interventions of infants, children, adolescents, and young adults—are available.

22. Board-certified or equivalent paediatric surgeons, or those with demonstrated expertise in paediatric surgery, are available.

23. Specialised professionals must be available for the management of certain tumour types. For example, retinoblastoma. For conservative eye therapy, ophthalmologists with documented training in ocular oncology must be available. If intra-arterial chemotherapy is provided, interventional neuro-radiologists or neurosurgeons with appropriate expertise are required. Access to an ocularist is also recommended. Management of Central Nervous System (CNS) tumours requires paediatric neurosurgeons with documented training and ongoing clinical practice in paediatric CNS tumour surgery, supported by the necessary equipment and a 24/7 intensive care unit. Pathologists with expertise in CNS tumours must be on site or reliably available.

24. Centres treating musculoskeletal tumours have a trained paediatric orthopedic surgeon and wide access to radiotherapy, rehabilitation services, and limb salvage capabilities.

25. Centres treating liver tumours have a liver surgery program, usually including liver transplantation when nationally available.

26. Paediatricians or paediatric haemato-oncologists with training in palliative care are responsible for the palliative care of children with cancer. Palliative care is available at any stage of the disease and throughout treatment. Different models of palliative care may be used, and each centre adopts one consistent with national guidelines, resources, and patient needs.

27. A board-certified or equivalent radiation oncologist with special expertise as evidenced by certification and training in the treatment of infants, children, and adolescents is in charge of the radiation treatment of children with cancer.

28. Board certified or equivalent pathologists with special expertise as evidenced by certification and training in the pathology of haematologic malignancies, tumours of the central nervous system, and solid tumours in children, adolescents, and young adults are available.

29. Board-certified or equivalent paediatric medical subspecialists—including anesthesiology, critical care, infectious diseases, cardiology, neurology, endocrinology and metabolism, genetics, gastroenterology, child and adolescent psychiatry, nephrology, pulmonology, adolescent medicine, and behavioural and developmental specialists—are available.

30. Nutrition experts with paediatric training determine the patient's nutritional requirements and select appropriate formulations for both enteral and parenteral nutrition. When commercial products are unavailable or unsuitable, they develop individualised recipes or compounding formulas according to standardised algorithms. They oversee processes for preparation, compounding, administration, and ongoing monitoring of each POU patient's biochemical parameters—such as electrolytes, glucose, liver and renal function, and serum proteins—to ensure nutritional adequacy.

31. Pharmacist(s) with experience and training in preparing and dispensing chemotherapy and supportive care medicines for paediatric patients with cancer are available. A board-certified clinical pharmacologist, where available, may be helpful in patient management.

32. Paediatric physical and mental rehabilitation services, including paediatric physiatry and paediatric psychiatry, are available.

33. Social workers with experience in paediatric oncology are integral members of the multidisciplinary team.

34. Care coordinators for coordination of family-centred services including home health, pain management, palliative, and end-of-life care and treatment plan compliance.

35. Continued active involvement by the primary care paediatrician is facilitated by the POU because of its importance for the provision of patient- and family-centred supportive care.

36. Additional professionals recommended to be available, either in-hospital, through a healthcare system network, by formal referral or through community resources are:

- paediatric psychologists
- child life specialists
- play therapists
- school reintegration specialists
- adult psychologists with expertise in family and group support
- chaplaincy personnel who provide spiritual care
- dentists with additional training in paediatric dentistry, and oral care of immunosuppressed children.
- in some settings, experts with knowledge in complementary and alternative therapies.

Competencies for Paediatric Cancer Specialist Providers/ Physicians

1. Board certification or equivalent, when nationally available, is renewed periodically and is mandatory for POU specialists.

2. In cases where that certification does not exist, scientific societies and national-local regulatory offices should consider initiating the process for board certification and propose mechanisms for awarding certification for professionals practicing the specialty without formal certification.

3. In all cases, paediatric training is mandatory. In all instances, paediatric oncologists, haemato-oncologists must demonstrate knowledge, training or certification regarding:

- The biology of normal cells and the basic processes of carcinogenesis with a specific focus in developmental tumours and paediatric haematopoietic malignancies.
- The structure, organisation, expression and regulation of the genes involved. They must be familiar with molecular techniques, chromosomal analysis and other molecular biology or immunology techniques used to characterise tumour cells.
- Recognise the criteria for morphological diagnosis, imaging and phenotypic or genomic confirmation and the evaluation of treatments for haematologic and oncologic diseases with the techniques available in their setting.
- Proficient in the use of studies necessary for adequate staging and risk assignment of paediatric patients with oncologic diseases.
- Communicate to the patient and family the nature of the disease, therapeutic possibilities, adverse effects of treatments and eventual need for prolonged follow-up.
- Develop anticipatory strategies to manage family and patient stressful situations in the face of the impact of a diagnosis or the end-of-life period working in a multidisciplinary group.
- Design and implementation of a treatment strategy with evidence-based medicine standards and following national standards when available for each of the malignant tumours and blood diseases of the paediatric age group, recognising the indications, limitations, and adverse effects of surgical, radiation, and haematopoietic tissue transplant treatments.
- Have skills for interdisciplinary work in collaboration with multiple related specialists.
- Perform techniques required for the diagnosis of haematological-oncological diseases such as bone marrow aspiration and biopsy or fine-needle aspiration of tumours or fluids and interpret laboratory results related to the specialty. Independently interpret the morphology of peripheral blood and bone marrow smears.
- The prescription and safe administration of chemotherapy by all routes, including intrathecal and intravenous catheter management.
- Recognise the biological mechanisms of the pathogenesis of haemato-oncological diseases.
- Become familiar with data management for statistical processing and critical analysis of the results of clinical studies being conducted.
- Implement basic supportive care, including the different nutritional therapy options for haemato-oncological patients, recognising and treating the adverse effects of the treatments administered usually in a context of a multidisciplinary team.

- Manage haemato-oncological emergency situations.
- Manage infections in immunocompromised hosts and infection prevention measures in the context of a multidisciplinary team.
- Know symptom control measures in patients with haemato-oncological diseases and properly implement a palliative care plan in association with paediatric palliative care specialists.
- Assist families of haemato-oncological patients in emotional support by developing skills for adequate communication, including basic knowledge of genetics and hereditary predisposition to the diseases they manage.
- Implement treatments respecting moral and legal guidelines regarding clinical research in human beings, respecting the rights of minors involved.
- Effectively present oral communications in scientific sessions, multidisciplinary tumour board discussions, and publication of case studies or treatment results.
- Know the epidemiological distribution of paediatric tumours and their local variations, participate in early diagnosis and awareness activities as well as report data to national or international registries and legally authorised research protocols.
- Assess and correctly treat the long-term sequelae that may develop after oncological treatment and/or haematopoietic progenitor cell transplantation in survivors and establish an adequate transfer program to an adult institution for follow-up when necessary.
- To maintain care for the quality of life of patients regardless of the stage of treatment they are in.
- To have the tools to manage an independent paediatric haematology-oncology service in the region, through adequate interaction with other specialists and directors, parents' associations, advocacy events and efficient and honest use of public and private resources.

Research

Important considerations:

- Research is an essential component of POUs. The complexity and organisation of the research program varies according to the characteristics of the POU.

- Research in children is a highly regulated activity and all POUs should undertake research activities based on international principles and under the national law that regulates them but at the same time maximise the opportunities for children with cancer to participate in clinical research.

- Valid informed consent is a critical component of clinical research and national regulations govern the need for informed consent and assent according to age. Research in paediatric oncology covers a wide range of disciplines from basic and translational research to clinical research, but also includes epidemiology, social sciences research, implementation research, health economics, among others. The WHO defines clinical trials as any research study that prospectively assigns human participants or groups of humans to one or more health related interventions to evaluate the effects on health outcomes. Clinical research in LMIC usually includes implementation studies or pragmatic research programs but examples of sponsored early phase clinical trials are present. Research in paediatric oncology is collaborative by nature, but the complexity of research activities may vary according to the size of the POU. All centres are encouraged to be members of, or affiliated with, cooperative clinical trial groups—whether national, international, or regional—to gain access to state-of-the-art clinical trials. Additionally, centres should have support systems in place to coordinate research activities, track patient progress, and maintain clinical trial data. For National Referral Centres (NRCs) and centres of excellence, both affiliation with cooperative groups and the availability of coordination and data management support are mandatory.

- Smaller size POUs may have limited capacity to lead clinical research projects, but they may participate in national research protocols or undertake retrospective studies, institutional research projects, when available, or participate in research projects where patient numbers are not critical. On occasion, small size POUs exist in an academic institution with good resources for research.

- NRCs and designated Centres of Excellence are expected to support a robust research program that includes clinical research and, where possible, translational research. While opportunities for translational research may be more limited in LMIC, POUs, through their affiliated institutions, are encouraged to collaborate with local or international universities and research centres to undertake context-relevant studies. Translational research not only contributes to the generation of new knowledge but also promotes multidisciplinary collaboration—bringing together basic scientists and clinical teams to exchange perspectives and inform care. Ideally, translational research teams participate in the clinical diagnostic evaluation of tumours under study, helping to optimise the use of available expertise and laboratory infrastructure. In addition to basic and clinical research, POUs and affiliated institutions are encouraged to engage in implementation science and improvement science, which support the adaptation and sustained use of evidence-based practices within real-world health systems.

- POUs and their institutions are encouraged to participate in multicentric studies, but POUs should have a procedure for participating in these studies, especially when patient data and specimen transfer are involved which should be aligned with national regulations.

- Cancer registries provide essential epidemiological data. Participation in national or regional registries strengthens research capacity by capturing survival and morbidity outcomes, helping to benchmark progress and inform the adaptation of context-specific treatment protocols in LMICs.

- Human resources dedicated to research may vary across different centres. Some centres have a dedicated clinical trial unit with appointed research support staff. Depending on the complexity of the POU and the robustness of their research program, it may be worth designing a three-year strategic plan for research activities.

Competencies for Paediatric Cancer Specialist Providers/ Physicians

1. Research in children is a highly regulated activity and all POUs adhere to international research principles and national laws and regulations, including those related to processes and documentation for consent and assent according to age.

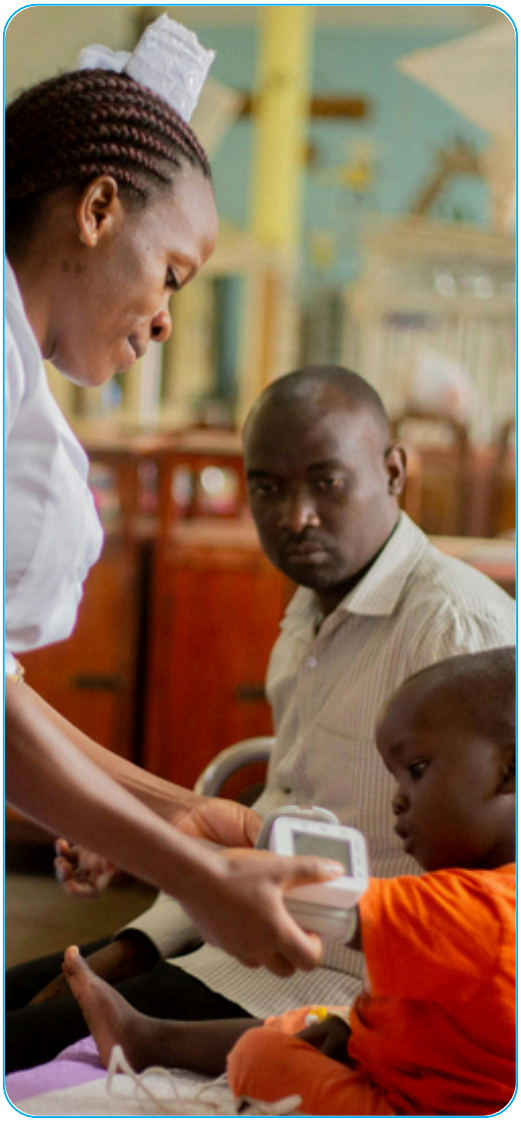
2. Professionals participating in clinical research should receive specific and continuous training in Good Clinical Practice (GCP).

3. Centres are nationally accredited for early phase clinical trials where such accreditation is available.

4. The POU participates in collaborative research projects.

5. Institutions should have an institutional research board (IRB) or an independent ethics committee (as denominated in many countries) governing the research activities in each centre, complying with national regulations. This committee may be external to the institution, but national referral centres are expected to have an in-house IRB.

6. Patients/families are informed of opportunities for children with cancer to participate in clinical research.



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MEDICATION MANAGEMENT

Key Concepts

Medications are vital to the care of paediatric cancer patients, supporting diagnostic, symptomatic, preventive, curative, and palliative treatments. In high-risk environments such as POUs, robust medication management involves clear and coordinated steps across all stages of medication use, including selection, procurement, storage, ordering, prescribing, transcribing, distribution, preparation, dispensing, administration, documentation, monitoring of therapies, and disposal.

Challenges such as restricted access to essential cancer medications and chemotherapy drugs can result in improper dosing and treatment-related toxicity. Addressing stock shortages, improving pharmacy management, and ensuring a reliable supply of authentic drugs can significantly enhance both medication availability and safety. This, in turn, helps prevent under-treatment and toxic overdosing, which can severely affect patient outcomes.

Additionally, poor regulation of the pharmaceutical supply chain in LMICs increases the risk of substandard or counterfeit medications, further compromising patient safety. Strengthening quality control measures and improving oversight of the supply chain are crucial steps in ensuring that medications are safe, effective, and available when needed. Incorporating medication safety best practices, adhering to clinical practice guidelines, and following cancer treatment protocols can further improve patient outcomes by reducing medication errors and misuse. In paediatric oncology, where precise dosing is critical, these practices are particularly important to maximise treatment efficacy and safety.

Oversight and Standard Operating Procedures for Medication Management

A licensed pharmacist, or a professional with equivalent training and experience, oversees the hospital's medication management processes. This includes coordination with medical and nursing staff to ensure safe, effective, and context-appropriate practices in the selection, storage, preparation, dispensing, administration, monitoring, and disposal of medications.

Hospitals maintain up-to-date Standard Operating Procedures (SOPs) for all aspects of the medication-use process, including ordering, dispensing, transport, storage, administration, waste disposal, and management of medications, including high-risk medications and hazardous drugs. All personnel involved in medication processes are trained in the use of these SOPs and demonstrate competence in their application.

Formulary

The hospital maintains an updated list of all medications available by prescription to patients.

This list is periodically reviewed by qualified personnel or a formally designated committee, with active participation from healthcare professionals involved in prescribing, dispensing, administering, and monitoring patients. The review incorporates new medications as needed and removes obsolete or discontinued ones.

Evidence-based guidelines and recommendations from recognised national organisations guide the selection of medications. The national list should include at least all the WHO Essential Medicine List (EML) or the WHO Essential Medicines List for Children (EMLc).

Medications in the formulary are available and if not readily available, alternative sources are identified to meet these needs.

When patients/families are required to pay for their essential medicine, this information is provided up front.

Safe Ordering, Dispensing and Administration of Medications and Blood and Blood Components

1. Before placing medication orders, medication reconciliation is conducted to ensure that prescribed medications are appropriate for the patient's current condition and treatment plan. A complete history of substances used—including prescription and non-prescription drugs, traditional or complementary remedies, vitamins, nutraceuticals, vaccines, diagnostic agents, and other therapeutic products—is obtained to identify items that may be inappropriate to continue and to avoid unintentionally discontinuing essential medications.

2. Essential information about each drug in the formulary, such as indications, contraindications, dosing guidelines, and potential side effects is readily available to those professionals who order, prepare, dispense and administer medications. Ordering providers, pharmacists and nursing staff have access to, and are trained in, the interpretation and application of this information to ensure safe practice.

3. There are written procedures that outline steps to be taken in cases of incomplete, illegible, or unclear prescriptions, including measures to prevent the recurrence of such errors.

4. The prescription and administration of certain high-risk medications, such as chemotherapy agents, is limited to personnel authorised to do so by law, regulation, certification or training. Orders for these medications are reviewed for accuracy and appropriateness according to the patient's clinical status and organ function studies by two health professionals trained to do so.

5. For high-risk medication treatment, patients/families are provided with information needed to provide informed consent according to the content and format required by local regulations and best practice.

6. Each newly prescribed medication must be reviewed by trained staff (e.g., prescriber, clinical pharmacist, trained nurse, etc.) for its appropriateness for the patient. The process includes evaluation of drug, dose, frequency, route, interactions, allergies, and patient-specific factors.

7. If medication samples, patient-brought medications, or medications from sources other than the hospital's pharmacy are permitted for use in the organisation, standardised procedures are in place to evaluate and manage their safety and register use in the medical record.

8. Safe medication practices are followed, such as appropriate storage temperatures and clean procedures, expiration date monitoring, in preparing and administering medications regardless of where they are stored, prepared, or administered.

9. Prior to administration, two nurses—each trained in hazardous medication handling, including the use of personal protective equipment (PPE) and spill management—independently verify the chemotherapy order and prepared product against the patient's identifiers. This verification confirms the correct drug, dose, route, timing, and patient to ensure safe administration.

10. Prior to administration, patients/families are informed of the name and type of medication to be administered, its purpose, and any anticipated side effects.

11. The hospital ensures the safe administration of blood and blood component transfusions for paediatric oncology patients. This includes accurate patient identification, double verification of patient and product, weight-based verification of orders, type and crossmatch confirmation, careful monitoring during and after transfusion, and prompt recognition and management of transfusion reactions. Additional precautions—such as the use of irradiated, leukoreduced, or CMV-negative blood products—are followed when clinically indicated. Standardised paediatric protocols guide each step of the process. Staff involved in transfusions receive formal training in transfusion safety, including documentation, the use of personal protective equipment (PPE), and timely reporting of adverse events.

12. To prevent accidental misconnections, devices used for enteral nutrition administration—including breast milk—are physically incompatible with intravenous or parenteral systems. Where enteral-specific connectors are not available, the organisation implements alternative safety mechanisms to mitigate the risk of enteral products entering the bloodstream. These include clear labelling, staff training, and separation of preparation and administration areas.

13. Each dose of medication is administered as prescribed, on a timely basis, and documented in the patient's medical record.

14. Physicians, nurses, and other healthcare practitioners collaborate to monitor medication effects—evaluating symptoms, lab results, and potential adverse reactions—especially after initiating new medications.

15. Patients receiving intravenous medications are monitored for signs of infiltration and extravasation through a defined process for assessment and response. Nurses are trained to recognise early signs, initiate appropriate protocols, and document findings promptly. Ready-to-use extravasation and spillage kits are available in clinical areas to support timely and effective management.

16. A mechanism is in place for timely reporting of adverse effects and adverse medication events. The use of standardised tools, such as the Common Terminology Criteria for Adverse Events (CTCAE), improves consistency and accuracy in the documentation of cancer treatment–related adverse events. In alignment with pharmacovigilance principles, systems should also support the identification and reporting of suspected poor-quality or counterfeit medicines to appropriate regulatory or procurement authorities.

High-Risk and Look-Alike Sound-Alike Medications

17. High-risk medications—such as anticoagulants, opioids, chemotherapy agents, and concentrated electrolytes—are managed using defined policies and safety procedures. The hospital maintains a list of high-risk medications and applies safeguards such as double-checking protocols, auxiliary labels, secure storage, and preparation according to standard operating procedures. Special precautions are taken for hazardous therapies, including high-dose methotrexate and intrathecal chemotherapy.

18. The organisation implements safety measures to prevent wrong-route medication administration. Medications with route-specific risks—such as vincristine—are clearly labelled with standardised warnings (e.g., "FOR IV USE ONLY – FATAL IF GIVEN BY OTHER ROUTES") and are stored, prepared, and administered using distinct processes and dedicated equipment. Equipment includes infusion devices, connectors, syringes, and administration sets that are specifically designed or designated for intravenous or intrathecal use. When available, route-incompatible connectors (e.g., devices conforming to ISO 80369 standards) are used to physically prevent misconnections. Intrathecal medications are prepared and administered separately from intravenous medications, and handling is guided by specific protocols aligned with international safety recommendations.

19. The organisation maintains a list of look-alike, sound-alike medications, which are clearly identified and managed with strategies such as tall-man lettering, physical separation, distinct labelling, and electronic or manual alerts to promote safe prescribing, ordering, dispensing, and administration.

Alternative Preparations and Treatments

1. The hospital pharmacy or other qualified services prepare and dispense medications in a clean and safe environment, adhering to legislation, regulations, and professional quality standards.

2. Personnel involved in the compounding/preparation of sterile products or using multi-dose vials are trained and competent in medication preparation principles and aseptic techniques.

3. The pharmacy ensures that alternative preparations, such as compounded medications or those used off-label, meet the same safety and efficacy standards as commercially available products. (Off-label use: using a drug for a different disease, age group, dosage or administration route than what was originally tested and approved.)

Vaccines

1. The hospital follows documented protocols for vaccine management, including storage, preparation, and administration. Joint storage of vaccines and chemotherapy products is not recommended. Live vaccines are not administered during cancer treatment, and live oral polio vaccine is contraindicated for household contacts. Vaccination resumes per national guidelines after treatment and immune reconstitution.

2. Documentation of vaccine administration includes the patient's identity, vaccine type, dose, lot number, and any observed reactions.

Medication Security

1. Medications are securely stored in specially designated areas, such as pharmacies, patient care units, or nursing stations, to prevent loss or theft.

2. Emergency medications, including contrast reaction medications, are readily available, stored in controlled locations, such as in a locked location or under continuous direct supervision, and procedures are in place to monitor and replace them promptly after use or when they are expired or damaged.

3. The hospital implements documented procedures for the identification, receipt, labelling, storage, control, distribution, and safe disposal of specific types of medications such as radiopharmaceuticals, controlled medications, for example, opioids, those used for research, or other similar medications.

4. Processes are in place for promptly identifying, reporting, investigating, and managing suspected diversion of controlled substances. This includes secure storage and access controls, staff education on recognising signs of diversion, and clear internal reporting pathways. All suspected cases are reviewed by designated personnel or committees and reported to appropriate regulatory authorities in accordance with national laws. Corrective actions and preventive measures are implemented to address identified vulnerabilities and protect patient safety.

Investigational Drugs

1. The hospital / POU has procedures for the secure storage, accurate documentation, and controlled distribution of investigational drugs.

2. All personnel involved in the handling of research medications must be trained in the specific requirements of these protocols and the associated regulatory standards.

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ENVIRONMENT OF CARE

Key Concepts

- Health care organisations work to provide safe, functional, and supportive facilities for patients, families, staff, and visitors. To reach this goal, the physical facility, medical and other equipment, and people must be effectively managed striving to:
    - reduce and control hazards and risks;
    - prevent falls, accidents and injuries; and
    - maintain safe conditions.
- The physical infrastructure of a Paediatric Oncology Unit (POU) directly impacts the safety, efficiency, and effectiveness of cancer care delivery. Facility planning must prioritise essential elements that enable consistent clinical workflows, reduce risks, and support infection prevention.

Facilities Management

1. The hospital and POU comply with applicable national laws and regulations related to occupational safety and hazardous exposures.

2. The hospital has written standard operating procedures (SOPs) for, and staff are trained in, safe practices related to environmental and occupational risks, including radiation protection and exposure monitoring, personal protective equipment (PPE), and emergency procedures.

3. The hospital takes reasonable measures to prevent and address the presence of pests and stray animals in indoor patient care areas. This includes securing care, medication, and food preparation and storage spaces against access by insects, rodents, and stray animals and responding promptly and safely to any identified animal intrusions or infestations.

4. Safety precautions are implemented for the handling, storage, and disposal of hazardous medications (such as chemotherapy), radioactive materials, and biological waste.

5. The unit ensures that hazardous materials, including cleaning chemicals and medications, are secured and clearly identified to prevent accidental injury or ingestion. Cleaning supplies are labelled with their contents, stored in locked or restricted-access areas, and never transferred into food or beverage containers. Medications are stored in locked medication rooms, cabinets, or carts, or are under constant supervision by authorised staff, to prevent unauthorised access.

6. The POU maintains a safe and functional environment by protecting children, families, and staff from electrical, structural, equipment and furniture-related hazards. Electrical outlets are tamper-resistant and properly grounded. Regular environmental safety rounds verify that outlets, equipment, and furniture are intact, clean, and free from rust, breakage, or other hazards. Medical gas cylinders are secured.

7. The facilities team inspects and performs routine preventive maintenance of duct and filter systems. Positive and negative pressure rooms are monitored for proper pressures.

8. The facilities team ensures dust mitigation measures are utilised during all construction activities.

9. Water systems are monitored for water quality and alternative potable water sources are provided when the system water is compromised.

Security and Safety

10. The facility implements measures to address security and safety risks specific to the paediatric population. These include staff and visitor identification, use of constant companions, provision of chaperones during sensitive procedures, visitor screening and restriction when necessary for the child's safety or legal reasons, monitoring with cameras, secured entryways, and a defined security response action plan.

11. Staff are trained in identifying early signs of aggression and in using de-escalation techniques appropriate to paediatric oncology settings.

12. Procedures are in place for reporting and responding to incidents involving aggression or violence from patients, families, or others.

13. Access to institutional or external support resources such as security personnel, crisis response teams, and psychosocial support is readily available.

Imaging and Radiation Safety

14. The hospital's radiation safety program adheres to the ALARA principle ("As Low As Reasonably Achievable") by minimising radiation exposure while maintaining diagnostic or therapeutic effectiveness. This includes using paediatric-specific protocols, limiting high-dose procedures (e.g., computerised tomography (CT) scans) to those that are clinically justified, and selecting alternative imaging modalities (e.g., ultrasound or MRI) when appropriate.

15. The program includes protective measures such as the use of personal dosimeters, protective equipment for staff and patients, appropriate shielding, and procedures to identify pregnancy in patients of childbearing age. During portable imaging procedures, staff follow safety protocols to inform others nearby, maximise distance from the radiation source, and use shielding to protect individuals not directly involved. A qualified medical physicist conducts periodic reviews to ensure compliance with safety standards and equipment performance.

16. Cumulative radiation exposure in paediatric patients is tracked over time when systems and infrastructure allow to inform care planning and minimise repeat or unnecessary imaging.

17. Procedures are in place to monitor radiation doses delivered during diagnostic or therapeutic procedures. When exposure exceeds defined thresholds or local diagnostic reference levels, appropriate clinical and safety personnel review the event. Internal reporting is encouraged or required depending on national policy, and external reporting to regulatory authorities is conducted when mandated.

18. Entry into the MRI area is strictly controlled by specially trained MRI staff. All individuals—including paediatric patients, family members or caregivers, and healthcare personnel—are screened for MRI safety. This includes checking for external objects, implants, or any other conditions that may pose a risk in the MRI environment. Furniture, equipment, medical devices, and supplies are classified as MRI-safe, MRI-unsafe, or MRI-conditional based on their compatibility with MRI systems.

19. Standard operating procedures are in place to manage situations where individuals do not pass MRI safety screening or when the safety status of an object is uncertain. All MRI personnel are trained in emergency procedures, including immediate evacuation, activating emergency stop controls for equipment in the room, notifying appropriate clinical and technical staff and reporting incidents.

Supplies

20. Medications and supplies are not expired, and single-use supplies (disposables) are only reprocessed if this has been approved by the infection control team and aligns with national regulations.

21. Instruments and equipment requiring high-level-disinfection or sterilisation are processed and stored according to manufacturer instructions and national and international standards.

Equipment Management

22. There is an effective program for preventive maintenance and repair or replacement of medical equipment and patient care furniture such as gurney's, beds and wheelchairs, electronic or not. The program categorises equipment by level of criticality to prioritise maintenance, replacement, and backup planning.

23. Critical equipment, such as defibrillators or patient telemetry monitors, has functional backups available in case of device failure. For example, if a defibrillator malfunctions, a second device is readily accessible. In addition, when such equipment is in use, it is connected to electrical circuits that are supported by an emergency power supply—such as a red outlet linked to a backup generator or uninterruptible power supply (UPS)—to ensure continued operation during power outages.

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INFECTION PREVENTION AND CONTROL

Key Concepts

Effective infection prevention and control (IPC) is critical in paediatric oncology due to the high risk of infection-related morbidity and mortality among immunocompromised patients. In LMICs, even basic IPC lapses can have severe consequences, making adherence to core practices and environmental hygiene a fundamental priority.

Hand Hygiene

1. The POU has adopted and adheres to the WHO's or a comparative evidence-based hand hygiene program (WHO Multimodal Hand Hygiene Improvement Strategy).

2. The hand hygiene program provides guidance for:
   - care providers and visitors who either wash hands with soap and water or use alcohol-based hand rub in moments such as before and after patient contact, before cleaning/aseptic procedures, after body fluid exposure, after contact with the patient's surroundings;
   - when to wear gloves and perform hand hygiene before and after glove use; and
   - hand hygiene for invasive procedures.

Personal Protective Equipment (PPE) and Isolation Precautions

3. Standard and transmission-based precautions are used in accordance with national guidelines and include hand hygiene, use of PPE, environmental cleaning, injection and medication safety, minimising potential exposures, and reprocessing of reusable equipment.

4. When patients are on special precautions, healthcare providers, family members, and patients themselves use PPE such as gloves, gowns, and masks, based on the patient's condition and the specific precautions in place. For example, patients may wear a mask when being transported within the hospital. All healthcare providers and family members are informed about required precautions and receive instruction or training on the correct use of PPE to ensure consistent adherence and to protect immuno-compromised patients.

5. Standard immunocompromised precautions are defined and applied to neutropenic patients (ANC < 500 x 10^6/L) on the haematology/oncology service who do not meet criteria for strict precautions.

6. A standard operating procedure (SOP) for the management of children with cancer and febrile neutropenia is available and consistently implemented by clinical staff.

7. Strict immunocompromised precautions are defined and utilised for all BMT patients from the day of admission through discharge, patients with acute myeloid leukemia (AML), patients with acute lymphoblastic leukemia (ALL) not in remission, patients with severe or combined immune deficiency, and those on significant immunosuppressive therapy such as for severe graft-versus-host disease (GVHD).

Immunisations and Prophylaxis

8. Prophylactic antimicrobials, including antibiotics, antivirals, and antifungals, are available and prescribed as appropriate for cancer patients with compromised immune systems. These are managed in accordance with the organisation's antimicrobial stewardship program.

9. Live vaccines are contraindicated during cancer treatment, and the live oral polio vaccine is absolutely contraindicated for both patients and household contacts. Immunisation of healthcare workers and household members is recommended to reduce risk of transmission. Patients are vaccinated according to national immunisation schedules after treatment is completed and immune reconstitution is confirmed.

Line and Device Care

10. Central venous catheter (CVC) and other line and device care follows infection control best practices. These include strict aseptic techniques during insertion and access, routine flushing, dressing and cap changes, appropriate hygiene, and continuous monitoring for signs of infection. Insertion and maintenance are performed only by physicians, or by nursing or other clinical staff with documented training and demonstrated competence. Invasive procedures, the use of lines and devices, and their duration (such as urinary catheterisation or intravenous access) are minimised whenever possible to reduce infection risk.

Environmental Cleaning and Facility Requirements

11. The hospital has written procedures and schedules for the regular cleaning and disinfection of patient care areas, medication preparation spaces, and high-touch surfaces. These include schedules and protocols for terminal cleaning of procedural areas and rooms upon patient discharge, as well as procedures for spill response. Cleaning procedures follow national infection control guidelines and are adapted to meet the needs of immunocompromised paediatric oncology patients.

12. Cleaning personnel and clinical teams receive appropriate training in these procedures, and compliance is routinely monitored.

13. Disinfectants used are readily available, suitable for healthcare settings and are effective against common pathogens and hazardous drug residues.

14. Shared clinical equipment—such as infusion pumps, vital sign monitors, thermometers, stethoscopes, and other reusable devices—is cleaned and disinfected between each patient use, in accordance with manufacturer instructions and organisational policy. Disinfectants used are appropriate for healthcare settings, effective against known pathogens and hazardous drug residues, and suitable for the type of surface or equipment being cleaned.

15. Patients requiring strict immunocompromised precautions recover in single occupancy rooms equipped with a handwashing sink and private bathroom. When available, these rooms are HEPA-filtered to provide enhanced environmental protection.

16. Rectal temperature measurements (and rectal examinations) are avoided during neutropenia to prevent colonising gut organisms from entering the surrounding mucosa.

17. Food preparation, handling, and storage practices follow strict hygiene standards, including proper temperature control and sourcing from safe, approved food suppliers, to minimise the risk of foodborne illness. When the hospital permits food to be provided by the family or visitors, nutrition or nursing staff inspect its quality, storage requirements and its appropriateness for the patient's diet.

18. Healthcare workers with acute infections are restricted from patient care or, if they work, are required to wear appropriate protective equipment such as masks and limit direct contact with patients to prevent transmission.

Surveillance and Staff Education

19. The infection surveillance program includes tracking of febrile neutropenia in patients with ANC < 500, central line-associated bloodstream infections (CLABSIs), respiratory infections, and opportunistic infections such as fungal (e.g., Aspergillus, Candida) and viral (e.g., CMV, EBV) pathogens. Surveillance for multidrug-resistant organisms (MDROs) is also conducted, including screening for methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistant enterococci (VRE), and extended-spectrum beta-lactamase (ESBL)–producing organisms, as well as other organisms identified as priorities within the infection prevention program.

20. POU staff receive regular infection prevention training tailored to the risks and needs of paediatric cancer patients and the complex interventions they receive.

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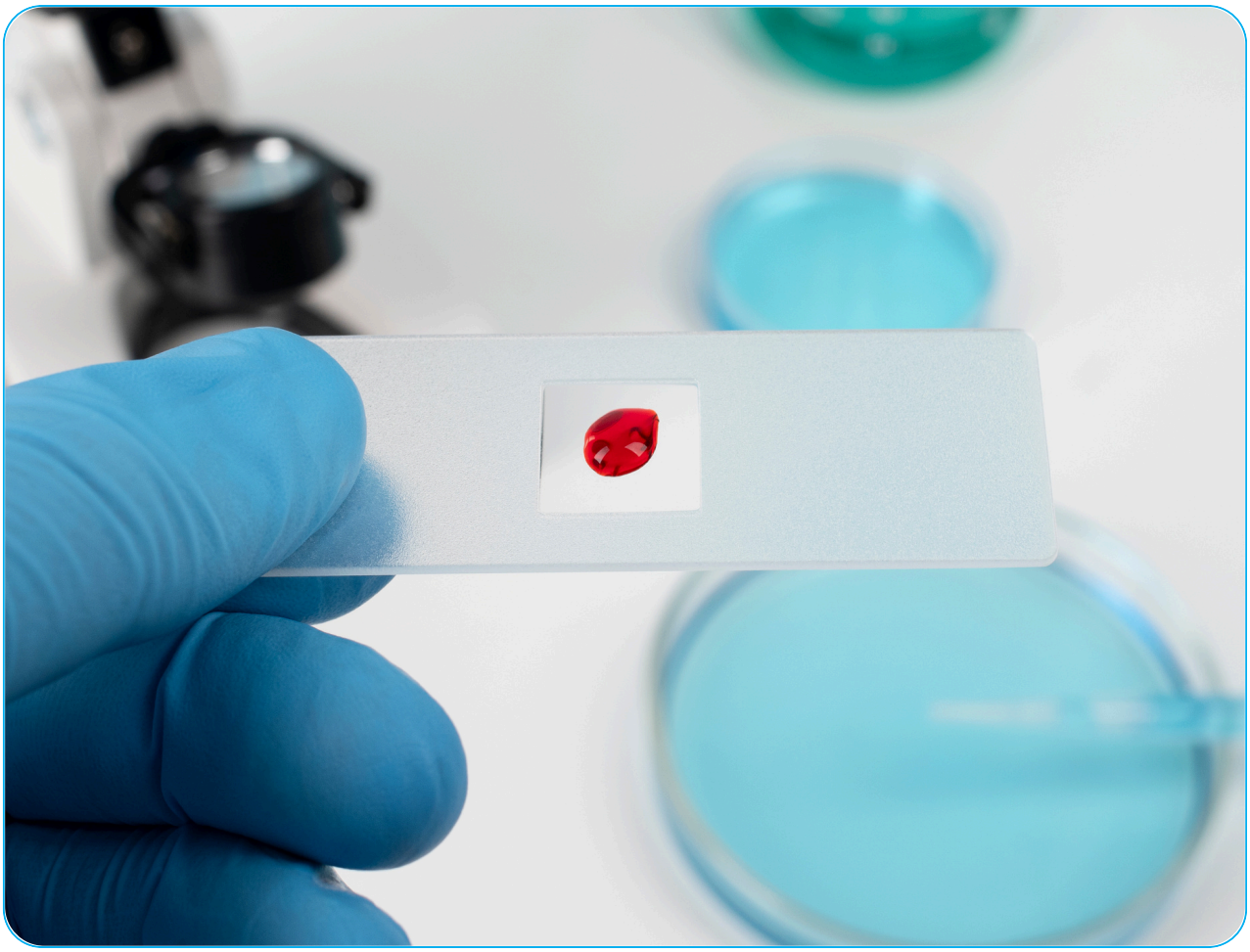
Definition

Absolute Neutrophil Count (ANC): The measure of the number of neutrophil granulocytes (also known as polymorphonuclear cells, PMN's, polys, granulocytes, segmented neutrophils or segs) present in the blood. Neutrophils are a type of white blood cell that fights infection. The ANC is calculated from measurements of the total number of white blood cells (WBC), usually based on the combined percentage of mature neutrophils (sometimes called "segs," or segmented cells) and bands, which are immature neutrophils. ANC = (% neutrophils + % bands) x WBC. The unit of ANC is cells per microliter (abbreviated µL; a microliter is equal to one cubic millimeter) of blood. A normal ANC is 1,800 or more cells per microliter. An ANC less than 500 cells/µL is defined as significant neutropenia and increases the risk of infection.



QUALITY MANAGEMENT & MEDICAL RECORD/INFORMATION SYSTEMS

Key Concepts

- Data helps hospitals and POUs make the right decisions. POUs measure, analyse, and validate their performance data. When data are analysed and become information, the reasons for certain outcomes become more visible.

- By participating in databases, a POU can compare itself to that of other similar units locally, nationally, and internationally. Comparison is an effective tool for identifying opportunities for improvement. Hospitals and paediatric cancer programs may be required by laws or regulations to contribute to some external databases such as tumour registries. In all cases, the security and confidentiality of data and information are maintained.

- Cancer registries are essential to quality management. At a minimum, registries should systematically capture mortality and morbidity data, enabling hospitals and POUs to monitor outcomes, benchmark progress nationally and internationally, and identify areas where adapted treatment protocols may be required. Registry data are particularly critical in LMICs, where survival outcomes and treatment-related complications may differ from those reported in high-income countries. Strengthening national or regional registries ensures that quality improvement and policy decisions are guided by reliable evidence.

- The patient's medical record documents their care journey across all phases of treatment. Timeliness, accuracy, and security of record entries are essential to ensuring its integrity and reliability and for providing a reliable source for data abstraction.

Information Management (Medical Record)

1. Medical record content facilitates informed clinical decision-making and care and facilitates communication of vital information such as chemotherapy orders and doses administered.

2. All orders and episodes of care are captured in the medical record.

3. Each view or printed page of the patient's medical record—whether electronic or paper-based—as well as labels (for example, those on medications and blood or blood products prepared for the patient), reports, images, studies (e.g., electrocardiograms, laboratory results), orders, and prescriptions must clearly display these two identifiers to ensure accurate matching of the right patient to the intended care.

4. The medical record must be readily accessible to authorised staff throughout all transitions of care, including changes in the care team, shifts in the level of care, hospital transfers, and movement to procedural or treatment areas. When care is transferred to another hospital or healthcare facility outside the same system, a detailed summary of the patient's medical course, including diagnostic study results is provided to the receiving team. Additionally, the patient's diagnostic study results and treatment plan should be available upon request to any new care team, ensuring seamless continuity of care and minimising delays in treatment.

5. Access to the medical record is secure and limited to authorised staff.

6. Patients and families are provided access to the patient's medical records—including diagnostic findings, treatment history, and follow-up care—in a timely and organised manner, in accordance with applicable laws and regulations. Permanent access to a complete medical history is encouraged, particularly for paediatric oncology patients and survivors, to support informed long-term follow-up and management of treatment-related toxicities. In settings where national law or regulation may limit full or permanent access, the organisation takes reasonable steps to ensure patients receive essential documentation of their diagnosis and treatment course in a format that can be retained and used over time.

7. Electronic systems and paper records are securely maintained. Back-up systems and procedures exist for failures of electronic systems or loss of paper records.

8. Clinical practice guidelines and clinical protocols, when referred to with a reference or link in the medical record for purposes of diagnosis, decision-making, orders, and treatments, are continuously validated and readily accessible to support informed, consistent, and timely clinical decision-making.

Quality Management

1. The hospital maintains a structured, accessible, and confidential system for reporting adverse events, near-misses, and safety incidents. All healthcare workers are trained and encouraged to report incidents promptly and without fear of blame or retaliation, fostering a culture of safety. Reports are reviewed in a timely manner to identify contributing factors and implement corrective and preventive actions. The organisation regularly analyses incident data to detect patterns, update procedures, strengthen staff competencies, and reduce harm. Findings are shared with relevant staff to promote continuous learning and system-wide improvement.

2. Information from the reporting system and analysis of events specifically related to paediatric oncology care is reviewed in depth by POU leadership. Targeted actions to improve the safety and quality of care for POU patients are implemented, monitored, and sustained—such as through direct observation or clinical audits. For example, analysis of recurring medication errors may lead to changes in prescribing workflows, pharmacy labelling, staff training, or administration protocols to prevent recurrence and enhance safety.

3. The hospital and POU maintain an integrated quality and patient safety program. This program includes processes to abstract, validate, and aggregate data related to clinical care, patient outcomes, and safety events. Aggregated data serves as the foundation for performance monitoring and continuous improvement efforts.

4. Collected data are reviewed regularly by hospital and clinical leadership. These data are used to identify trends, inform decision-making, prioritise improvement areas, and implement actions that strengthen the quality and safety of patient care. In addition to supporting clinical practice and operational management, aggregated data are used for professional performance reviews and system-wide quality initiatives.

5. Data and information are shared with external agencies when required by national laws or regulations. Security and confidentiality are maintained at all times.

6. The hospital and POU contribute to and utilise internal or external quality databases and registries that follow structured formats and uniform coding systems. Participation in such systems supports data comparability, benchmarking, and the identification of opportunities for improvement based on national, regional, or international best practices.

7. The POU maintains survival statistics by tumour type and stage. A hospital-based cancer registry is maintained—ideally linked to the electronic health record—and reports to a National Paediatric Cancer Registry, if one exists in the country or region.

Useful Metrics

The following indicators are useful for evaluating the performance of the POU and should be ideally used over periods of time.

1. **Paediatric cancer patients newly treated in the index year**

Definition (adapted from the Organisation of European Cancer Institutes [OECI]): The number of patients with a diagnosis of cancer who are treated for the first time in the POU in the index year for a particular cancer, regardless of the date and place of the initial diagnosis. Treated means that the patient has gone through cancer directed treatment, regardless of type. Newly treated means the patient has never been treated before in the POU for the same cancer. According to this definition: a patient with a new (second or subsequent) cancer should be counted again; but a patient with a recurrent disease previously treated in the POU should not be counted. The number of patients is counted, not the number of visits.

2. **30-day mortality data**

Definition: Mortality occurring from the date of diagnosis to 30 days afterwards. Date of diagnosis in this case should be considered from the time when the biopsy was taken in cases with a presumed diagnosis of cancer (or when cancer is diagnosed by imaging when biopsy is not mandatory such as retinoblastoma and diffuse intrinsic pontine glioma). The denominator is: Paediatric cancer patients newly treated in the index year. It may be preferable to report for haematopoietic malignancies, CNS tumours and extracranial solid tumours separately.

3. **Abandonment rate**

Definition: Percentage of patients with a confirmed diagnosis of cancer that drop out from medical treatment and are presumably not being treated at another institution. This includes the failure to start or complete curative therapy (except when such treatment is contraindicated for medical reasons) and is defined by missed therapy for 4 or more consecutive weeks. The denominator is: Paediatric cancer patients newly treated in the index year. It may be preferable to report for haematopoietic malignancies, CNS tumours and extracranial solid tumours separately.

5. **Treatment-related mortality**

Definition: Percentage of patients dying for causes not related to tumour progression but likely related to treatment received. This includes deaths in neutropenic episodes, those caused by cardiological, neurological or other toxicities. In cases when the neoplasm is in the induction phase like in haematopoietic malignancies, it may be difficult to ascertain the actual cause of mortality. In solid tumours it is more straightforward, and this becomes a “cleaner” metric when chemotherapy-related deaths are considered. Surgical deaths should be included here (catheter-related, bleeding, organ rupture leading to death, post-surgical sepsis, etc.) as well as radiotherapy related death (CNS necrosis, pneumonitis, etc.)

Other Indicators

1. The percentage of patients receiving treatment with intention to cure dying at the general ward (not being admitted to the PICU) may be used also as a useful indicator for general quality of care since it will include all causes and give an estimate of the access to PICU either because the patient was not recognised as having an imminent life-threatening condition or when there was no bed available in the PICU. The denominator is: Paediatric cancer patients newly treated in the index year, but it may also consider the cases treated at relapse or segregated by tumour or treatment (e.g., stem cell transplant).

2. The percentage of patients receiving intention to cure treatment or in follow-up dying at home or on the way to the hospital may also be used as an indicator for access to care. In these cases, the time of the last visit to the hospital should be recorded, the date of the following scheduled appointment and socioeconomic factors. The denominator is: Paediatric cancer patients newly treated in the index year, but it may also consider the cases treated at relapse or segregated by tumour or treatment (e.g., stem cell transplant).

3. **All cancer patients seen or treated in the index year**
Definition: The number of unique patients with a diagnosis of cancer who are seen in person in the POU in the index year, regardless of the date and place of initial diagnosis. This includes all patients seen, including for follow-up. The number of patients is counted, not the number of visits.

Disease-Specific Mortality

1. For this estimation, patients in first-line therapy should be considered.

2. This figure should be provided ideally by disease, and the minimum required metric should include the 6 index cancers by the WHO.

Overall Survival

1. Overall survival data should include assessments at 1,2,3,5 and 10 years.

2. When patient numbers allow, specific 3–5-year survival data that could be used as quality indicators since they include populations with high survival rates (usually over 90%) and they can provide an estimation of the overall results in a POU. In all cases, crude and abandonment-sensitive Kaplan-Meier curves should be provided.

Essential Measures of Performance

This list includes tumours with a 3-year overall survival greater than 90-95%, so any deviation from this figure should be evaluated at the POU and actions should be implemented. In cases of low patient numbers, results may be analysed together.

1. Overall survival of stage I-II Wilms tumours
2. Overall survival of stage I-IIa Hodgkin's lymphoma
3. Overall survival of IRSS stage I retinoblastoma
4. Overall survival of stage I-II Burkitt lymphoma
5. Overall survival of Low-Grade Glioma
6. Overall survival of CNS germinoma

Optional Measures of Performance

7. Overall survival of low-risk neuroblastoma
8. Overall survival of stage I germ cell tumours

Indicators for Access

Waiting Times

Each POU should keep a record of different metrics related to waiting times as an indicator of access and quality of care with a periodical evaluation to improve these figures. Metrics include:

1. Waiting time from 1st contact to 1st visit (mean, days).
This indicator is of use in POU that receives patients with a proven or suspected diagnosis of cancer from other institutions. It should separate patients seen in other institutions from those seen in the same institution. In the later, the referral may come from another specialty. This only includes new patients. Visit means a face-to-face consultation with a physician in the POU. It should also identify those patients coming from distant centres who have already contacted the centre, needing time to reach the facility. Each centre should give a figure of maximum waiting time: Ideally: less than 48 hours.

2. Waiting time from 1st consultation at the hospital to 1st definitive diagnosis: Definitive diagnosis may be the date of pathology, immunocytology or other lab-result OR the date of Multidisciplinary Team Meeting in which the decision was taken (for cases not documented by biopsy such as retinoblastoma or DIPG). Each centre should give a maximum waiting time from the time the diagnostic procedure is performed (it may be reported separately for haematopoietic malignancies and solid tumours): Ideally: less than 14 days for solid tumours, 5 days for haematopoietic malignancies.

3. Waiting time for specific treatments like surgery, radiotherapy or diagnostic procedures like bone marrow aspiration.

4. Waiting time from definitive diagnosis to start of treatment. Definitive diagnosis may be the date of pathology, immunocytology or other lab-result OR the date of Multidisciplinary Team Meeting in which the decision was taken.

Other Indicators of Access to POU

1. Annual number of patients whose referral was not accepted (according to haematopoietic versus solid tumours)

2. Annual number of patients diagnosed in the POU that opt for treatment elsewhere (not including abandonment)

General Quality Indicators

1. Hospital-acquired infection rates
2. Mortality in fever and neutropenia episodes
3. Central line related infections
4. Extravasation of chemotherapy drugs
5. Falls with Injury
6. Hospital-acquired stage 3, 4 or unstageable pressure injuries
7. Complaints
8. Time to antibiotics (TTA) administration (Golden hour programs and similar)
9. Percentage of POU inpatients discussed in MDTs
10. Percentage of paediatric cancer patients enrolled onto front-line treatment clinical trials at the hospital

Institutions participating in early diagnosis initiatives collect data on the time from first symptom recognition to initial healthcare presentation, from presentation to confirmed diagnosis, and from diagnosis to start of treatment. They also document the number of consultations, referrals, and diagnostic procedures involved. Data is collected using standardised definitions, consistent with national guidelines or program-specific protocols, and often aligned with WHO's early diagnosis framework.

Other Measures

1. Which of the following services do NGOs/NPOs provide for paediatric patients with cancer and their parents/caregivers in your facility? Check all that apply.
    - Provides health information for patients and families
    - Raises community and professional awareness about signs/symptoms of cancer
    - Fundraises
    - Advocates for children with cancer and their families
    - Assists in ward/department development
    - Lobbies government ministries / other funders
    - Purchases chemotherapy
    - Provides food for parents/caregivers
    - Provides transportation for patients/parents/caregivers
    - Provides housing (free or subsidised accommodation) for parents/caregivers

Research Metrics (Adapted From OECI)

Publications

1. Number of international peer-reviewed publications (in the year specified) with first, second or last author from the POU
2. Total Number of international peer-reviewed publications per year (in the year specified)
3. Number of publications with impact factor 5 - 10 with first, second or last author from the POU
4. Total number of publications with impact factor 5 - 10
5. Number of publications with impact factor > 10 with first, second or last author from the POU
6. Total number of publications with impact factor > 10 Impact factor cumulative

Clinical Research

1. Total number of accruing multi-centre trials with international participation
2. Total number of accruing multi-centre trials with Principal Investigator (coordinating) from the POU
3. Number of new investigator-initiated multi-centre trials started in the year with PI coordination from the POU
4. Number of accruing prospective studies sponsored by industry
5. Number of accruing prospective studies academically initiated
6. Total number of trials in follow up (closed to recruitment)
7. Is the centre certified for early phase clinical trials?
8. Does the centre have a Biobank? Is it nationally certified?

Human Resources

1. Total number of senior (independent) researchers (FTE)
2. Total number of postdocs (FTE)
3. Total number of PhDs (FTE)
4. Total number of technical staff (FTE)
5. Total number of administrative staff (FTE)
6. Total FTEs of medical doctors' time in oncology/haematology/surgery /radiotherapy with a formalised allocation to research
7. Total number of allied health professionals (FTE)
8. Total FTEs of MD pathologists and radiologists with a formalised allocation

Funding

1. Number of research grants
2. Total cancer research funding from internal resources of the centre/institute
3. Total number of competitive grants
4. Overall value/amount

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