

Guidance on Setting Up a Comprehensive Cancer Centre

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IAEA

International Atomic Energy Agency



**World Health
Organization**

GUIDANCE ON SETTING UP
A COMPREHENSIVE
CANCER CENTRE

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GUIDANCE ON SETTING UP A COMPREHENSIVE CANCER CENTRE

JOINTLY PRODUCED BY THE
INTERNATIONAL ATOMIC ENERGY AGENCY
AND WORLD HEALTH ORGANIZATION

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2024

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Publishing Section
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Vienna International Centre
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1400 Vienna, Austria
tel.: +43 1 2600 22529 or 22530
email: sales.publications@iaea.org
www.iaea.org/publications

© IAEA, 2024

Printed by the IAEA in Austria

August 2024

STI/PUB/2070

<https://doi.org/10.61092/iaea.40dy-lc77>

IAEA Library Cataloguing in Publication Data

Names: International Atomic Energy Agency.

Title: Guidance on setting up a comprehensive cancer centre / International Atomic Energy Agency.

Description: Vienna : International Atomic Energy Agency, 2024. | Series: , ISSN ; no. | Includes bibliographical references.

Identifiers: IAEAL 24-01654 | ISBN 978-92-0-145823-0 (paperback : alk. paper) | ISBN 978-92-0-145723-3 (pdf) | ISBN 978-92-0-103024-5 (epub)

Subjects: LCSH: Cancer — Patients — Care. | Cancer — Prevention. | Cancer — Treatment. | Cancer — Research.

Classification: UDC 616-006 | STI/PUB/2070

FOREWORD

Cancer, a disease affecting millions of lives, continues to pose a significant global challenge. In 2022 alone, nearly ten million people lost their lives to cancer, underscoring the urgent need for comprehensive and effective cancer control strategies. The burden of cancer extends far beyond the physical and emotional toll and the impact on individuals and families. It also places a massive strain on societies, economies and health care systems worldwide.

While the impact of cancer is felt universally, it is especially acute in low and middle income countries, where health care resources and infrastructure are often limited. Many such countries face significant challenges in managing the growing cancer burden, resulting in a lack of timely access to high quality diagnosis and essential treatment. However, a proper diagnosis is a crucial initial step in developing appropriate and effective treatment plans, as each cancer type requires a specific therapeutic approach. Treatment typically involves a combination of radiotherapy, chemotherapy and/or surgery, with the primary goals being to cure cancer or significantly prolong life. Equally important is improving the quality of life for patients, which can be achieved through comprehensive support covering their physical, psychosocial and spiritual well-being, including palliative care during the terminal stages of cancer.

Delivering effective cancer care requires a multifaceted approach that involves community empowerment, enhanced health awareness, robust diagnostic and treatment capacity, streamlined referral mechanisms and coordinated access to appropriate treatment. Cancer centres play a pivotal role in providing comprehensive cancer care and can be strategically planned to meet the specific needs of each country. Recognizing the need for guidance in this critical endeavour, the IAEA and the World Health Organization collaborated to develop a framework publication for setting up cancer centres, which was published in 2022. This guide is a companion to that publication, and complements the IAEA initiative Rays of Hope, launched in 2022.

This publication is intended as a resource for countries that wish to enhance their capacity for cancer control. Drawing on the expertise of professionals from around the world, it outlines the fundamental principles of multidisciplinary cancer care and describes the essential infrastructure, human resources and equipment required for various services. This publication will assist national programme managers and planners in expanding cancer care capacity, ultimately improving the lives of countless individuals affected by cancer.

The development of this guide would not have been possible without the dedication and contributions of numerous experts committed to advancing cancer control efforts globally. In particular, the IAEA would like to thank B. Mikkelsen and C. Varghese of the World Health Organization. The IAEA officers responsible for this publication were R.F. Abdelaziz and M. Abdel-Wahab of the Division of Human Health.

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Chapter 1

INTRODUCTION

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1.1. BACKGROUND

The global cancer burden rose to an estimated 20 million new cases and an estimated 9.7 million deaths in 2022 [1.1]. The World Health Organization (WHO) predicts over 35 million new cancer cases in 2025 — a 77% increase from the estimated 20 million cases in 2022 [1.2]. This burden falls disproportionately on low and middle income countries (LMICs), which are facing rapidly rising rates of cancer incidence and mortality [1.2–1.6]. LMICs accounted for 15% of new cancer diagnoses in 1970 and 56% in 2008, and they were projected to account for 70% in 2020 [1.5–1.7]. Five-year net survival in low income countries has been shown to be ten times higher than that in high income countries (HICs) [1.8]. A lack of consistent population based health data in many LMICs means that these statistics may underrepresent the true extent of the growing cancer burden [1.5, 1.7, 1.9]. These concerning trends have been attributed to a number of different factors, among them the reduction in mortality attributable to communicable and cardiovascular diseases, a ‘westernization’ of lifestyle in LMICs that is shifting the profile of common cancer risk factors, and a paucity of resources for cancer prevention, diagnosis and treatment [1.4, 1.5, 1.9–1.11].

There are major inequities within and between countries in the capacity for cancer control. For example, in 2017, more than 90% of HICs reported having publicly available treatment services; among LMICs, fewer than 30% reported having such services [1.12]. Capacity for radiotherapy (or radiation therapy; RT) — a cornerstone of cancer treatment, indicated for approximately 50% of cancer patients [1.13, 1.14] — is markedly inconsistent in LMICs, with the gap between demand and capacity widening [1.15]. Access to cancer medicines is inconsistent; some essential cancer medicines are absent from national medicines lists in LMICs, and others are limited in accessibility owing to prohibitive costs or inadequate infrastructure [1.16]. Capacity for cancer directed surgery is also limited in many LMICs, and surgical care more broadly is inaccessible to over 90% of the population, at least 4.8 billion people [1.17, 1.18]. An overwhelming number of cancer patients simply cannot get the treatment that they need.

In addition to the human cost of cancer, there is a significant economic toll. In 2010, cancer was estimated to cost the global economy approximately US \$1.16 trillion annually [1.19]. Premature mortality leads to a significant loss of productive life years, financially harming individuals, families and communities. As the cancer burden falls disproportionately on LMICs, this acts as a major obstacle to sustainable development in these countries. However, it has been estimated that only approximately 5% of global resources for cancer control and prevention are spent in LMICs [1.20].

In response to this worsening global health concern, health leaders at the 70th World Health Assembly in Geneva in 2017 adopted a resolution entitled ‘Cancer prevention and control in the context of an integrated approach’ [1.21]. This resolution identifies 22 key areas of focus across four domains emphasizing the integration of these efforts as part of country level national cancer control plans. These domains are: (1) the collection of high quality cancer data; (2) early diagnosis programmes; (3) timely and appropriate treatment; (4) supportive and palliative care. The United Nations Sustainable Development Goals include the target of reducing premature mortality from non-communicable diseases (NCDs) such as cancer by one third, underscoring the need for rapid and decisive efforts on a global scale [1.22]. The rising cancer burden is a systemic issue that requires coordinated action.

The need to globally scale up cancer care capacity is urgent. Unfortunately, one of the key factors behind the high mortality rates in LMICs is the lack of capability to make early diagnoses. Patients who present for medical attention with more advanced disease are less likely to be amenable to potentially curative therapies that may be available. Therefore, investment in diagnostic services such as medical imaging is also essential. While the scaling up of surgery, systematic therapy and RT capacities in LMICs would yield the largest survival gains, simultaneous expansion of imaging capacity could result in synergistic benefits, improving the five year survival rates of common cancers tenfold in low income countries and twofold in middle income countries [1.23]. As estimated by the Lancet Oncology Commission, comprehensive global scale-up of treatment, imaging and quality of care would cost US \$232.9 billion, yet produce US \$2.9 trillion in economic benefits, while averting more than 40% of cancer deaths in low income countries and more than 12% of cancer deaths globally [1.23].

It is through collaborative and coordinated efforts that the challenge of scaling up global cancer control capability and delivering high quality cancer care worldwide can be met. These efforts have resulted in two important publications:

- Roadmap Towards a National Cancer Control Programme: Milestones for Establishing Nuclear Medicine, Diagnostic Imaging and Radiotherapy

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- Services [1.24]. This publication draws on expertise from both the IAEA and WHO, bringing together the knowledge and services that countries need when establishing a comprehensive cancer control programme. The IAEA and WHO can assist countries in the different phases of the development of a cancer control programme. This support includes providing guidance to Member States on how to set national priorities for cancer control; on developing, adopting and strengthening nuclear medicine, diagnostic imaging and RT practices; technical advice; training; coordinated research projects; procuring equipment; producing technical publications; developing public information campaigns; and supporting the mobilization of the resources needed to develop national cancer control programmes (NCCPs).
- Setting Up a Cancer Centre: A WHO–IAEA Framework [1.25]. This publication proposes a framework to develop a cancer centre and/or to strengthen the provision of services in an existing cancer centre. This framework is expected to be used as a guide for the implementation of a cancer centre, taking into consideration the local context and resources, while not losing sight of necessary prioritization and planning of the health care and cancer care sectors. Sections related to core cancer services specify human resources and equipment in different domains. The levels of service serve as a guide for incremental improvement in capacity as the local context allows and are not to be taken as predefined conclusions. The publication also provides the context and requirements for specific services in a cancer centre without defining the level of cancer care as a whole. Thus, it can be used as a tool to evaluate and improve the level of services, to help to build them to a level required in an individual cancer centre and to support the planning of new cancer centres.

1.2. OBJECTIVE

Coordination of country level efforts requires that each country establish its own NCCP. Such a programme allows for contextualized responses to locally determined challenges and opportunities. This publication will expand on the concept of the NCCP and on how the IAEA and WHO support Member States in the inception, implementation and evaluation of NCCPs.

Guidance provided here, describing good practices, represents expert opinion but does not constitute recommendations made on the basis of a consensus of Member States.

CHAPTER 1

1.3. SCOPE

The focus of this guide is the cancer centre, which is the nucleus of an NCCP. It is a facility that contains and coordinates the services and human and material resources necessary for achieving a country's goals for high quality cancer care. As such, this publication outlines the fundamental principles of multidisciplinary cancer care and describes the essential infrastructure, human resources and equipment required for various services. Thus, it will assist national programme managers and planners in expanding their cancer care capacity, ultimately improving the lives of countless individuals affected by cancer.

1.4. STRUCTURE

The following eight chapters describe the essential elements of a cancer centre. These include: developing an NCCP; key oncological disciplines (i.e. radiation oncology, medical oncology and surgical oncology) that have to be viewed holistically as interconnected services; ancillary services and their considerations; education, training programmes and research; disease specific service delivery matrices for three common cancers (breast, lung and cervical); and cancer financing. In addition, the publication provides case studies from five countries: India, Ghana, the United Kingdom, the United States of America (USA) and Brazil.

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Chapter 2

DEVELOPING A NATIONAL CANCER CONTROL PROGRAMME

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2.1. BACKGROUND

Addressing the burden of cancer requires complex preventive, diagnostic, therapeutic and supportive care services. This guide outlines the knowledge and services that a country needs when establishing a comprehensive cancer control programme, drawing on expertise from both the IAEA and WHO. This expertise is founded on WHO's leadership in promoting and monitoring global action against NCDs such as cancer, the work of WHO's International Agency for Research on Cancer (IARC), and the IAEA's work to improve access to technology and education in the fields of nuclear medicine, diagnostic imaging and RT, thereby contributing to saving lives and improving the quality of life in Member States.

2.2. WHAT IS A NATIONAL CANCER CONTROL PROGRAMME?

In response to the growing cancer burden, many countries are establishing or scaling up NCCPs — public health programmes designed to reduce the number of cancer cases and deaths and improve the quality of life of cancer patients. On the basis of available resources, NCCPs should be embedded in the health system and supported by effective financing strategies, monitoring systems and quality management programmes. Prior to investing in an NCCP, decision makers have to consider national cancer priorities, as well as the capacity of a country's health system to deliver a sustainable programme within the context of a broader cancer strategy and national health plan.

Under an NCCP, the goals of reducing the number of cancer cases and deaths and improving the quality of life of cancer patients are achieved through systematic, equitable and evidence based strategies at all steps of the cancer care continuum, including prevention, early diagnosis, screening, diagnosis

and staging, treatment, palliative care and survivorship care [2.1]. These are as follows:

- Prevention. Prevention means eliminating or minimizing exposure to the causes of cancer and reducing susceptibility to the effects of such exposures. This approach offers the greatest public health potential and generally the most cost effective interventions. Common priority cancer prevention activities include controlling tobacco use through the Framework Convention for Tobacco Control; reducing alcohol consumption; promoting a healthy diet and physical activity to reduce obesity; and vaccination for hepatitis B and the human papillomavirus (HPV).
- Early diagnosis. This is a priority public health activity that aims to raise awareness of signs and symptoms consistent with cancer, increase access to care, and diagnose and treat cancer at the earliest possible stage. The primary objective of early diagnosis is to improve survival and the quality of life of individuals with cancer by detecting and treating the cancer at its earliest possible, and potentially most curable, stage.
- Screening. The primary objective of cancer screening is to reduce cancer specific mortality at a population level by detecting the cancer at its earliest curable stage. For certain cancers with a detectable pre-cancerous stage (e.g. cervical and colon cancers), screening also has the potential to reduce cancer incidence. These public health programmes should be conducted in an organized manner, including systematic invitations to a defined target population, use of a screening test for asymptomatic individuals, notification of the results, diagnostic examination of the screen positives, and treatment of the screen detected cases.
- Diagnosis and staging. Accurate cancer diagnosis is essential for effective cancer management. This calls for a combination of careful clinical assessment and diagnostic investigations, including endoscopy, medical imaging, histopathology, cytology and laboratory studies, which are selected on the basis of the disease being evaluated. Once a diagnosis has been established, it is necessary to determine the location of the disease and its spread (staging) to help in the selection of the appropriate therapy and to establish the prognosis. Diagnostic techniques are also essential in the follow-up of patients to detect early relapses and evaluate the efficacy of the established treatment. An initial priority, especially in resource limited settings, should be the development of national diagnostic and treatment guidelines to establish a minimum standard of care and promote the rational use of existing resources and greater equity in access to treatment services.
- Treatment. These interventions are intended to cure, prolong life and/or improve the quality of life. Depending on resource availability, treatment

may involve surgery, RT, chemotherapy, hormonal therapy or a combination of these. Supportive care is an essential component of cancer treatment and should include access to psychosocial support, pain management and allied health services (e.g. occupational therapy, physiotherapy and speech therapy).

- Palliative care. Palliative care is an approach that improves the quality of life of patients and their families facing the problems associated with life-threatening illness through the prevention and relief of pain and symptoms. Palliative care services should be available in every country and should be given high priority, especially in resource limited settings, where many patients present with advanced stage disease.
- Survivorship care. This set of services includes surveillance for recurrence or new primary cancers; prevention and detection of new cancers; monitoring and managing long term toxicities of cancer and cancer treatment; and coordination of care to ensure that survivor care needs are met. Survivorship care includes a detailed plan that contains a summary of the patient's treatment and follow-up care. Common activities for survivorship care may include clinical evaluations and medical tests to monitor for cancer recurrence or new cancers, as well as to assess for evidence of long term complications from cancer treatment. Additional survivorship care needs can include services to support the emotional, social, legal and financial needs of the patient.

2.3. HELPING COUNTRIES TO ACHIEVE CANCER CONTROL MILESTONES

The IAEA and WHO can help Member States to set national priorities and devise their NCCP by providing support in the following areas:

- Mobilizing the necessary resources to plan and develop an NCCP;
- Developing, adopting and strengthening nuclear medicine, diagnostic imaging and RT practices;
- Technical advice;
- Training;
- Coordinated research projects;
- Procurement of equipment;
- Technical publications;
- Public information.

In addition, the IAEA and WHO can support Member States in mobilizing resources by facilitating partnerships with prospective donors for the

implementation and evaluation of an NCCP. Table 2.1 sets out key cancer control programme planning milestones and how the IAEA and WHO can help Member States reach them.

2.4. SETTING UP A COMPREHENSIVE CANCER CENTRE

Addressing the growing cancer burden globally requires a multipronged approach that includes population level interventions and sustainable solutions for care delivery. One component of this is the development and implementation of comprehensive cancer centres or programmes that form a nucleus of cancer care delivery at a local, regional and national level [2.2–2.4]. Cancer centres or programmes may be freestanding or form part of a larger organization such as a health science centre, hospital or group of hospitals that share infrastructure and services.

Although the cancer centre may operate as an independent entity, the optimal model is to integrate it into a broader system of health care and cancer control. This allows for a number of synergies and opportunities to enhance care delivery. For example, effective primary prevention and early detection and screening programmes can result in earlier diagnosis, while national regulations and accreditation standards can influence the safe delivery of cancer services.

2.5. CANCER CONTROL CENTRE FRAMEWORK: ESSENTIAL ELEMENTS

This resource provides a system level view of the resources and structures required to establish a cancer centre. The framework used here is comprehensive but not exhaustive, and owing to its breadth, the focus is on essential information only. Although designed for global consumption, there is a bias that reflects evidence from high resource settings. The framework does not address the complex nature of cultural, political, economic and geographical influences on health care, but does provide a comprehensive summary of essential elements that can be adapted to local contexts [2.5]. The essential elements are described below.

2.5.1. Clinical management, decision making and the health care team

Clinical units should develop a consistent and rigorous approach for decision making, which involves implementing evidence based, standardized clinical practice guidelines, multidisciplinary teams (MDTs) and a peer review process. The complexity of cancer requires multiprofessional and multidisciplinary input.

TABLE 2.1. PHASES OF CANCER CONTROL PROGRAMMES, MILESTONES AND SOURCES OF SUPPORT
(*adapted from Ref. [2.1]*)

Phase	Milestone	Support available	Support provider
Phase 1: Pre-planning			
Prepare the planning process:	Decision to devise an NCCP	Help to advocate for the scale-up of cancer prevention and control to achieve the UN Sustainable Development Goals related to NCDs and to advance universal health coverage in Member States	WHO
— Identify cancer control as one of the country's health priorities			
— Establish a nodal officer and a technical working group with national and international experts			
Phase 2: Planning			
Formulate a balanced and realistic plan based on feasibility and capacity. Specify expected deliverables, bearing in mind feasibility and capacity. Observe and learn from progress in similar countries:	NCCP created and costed	— Guidance on setting national priorities for cancer control and assistance, including selecting, prioritizing and costing programmes and interventions across the cancer care continuum (i.e. from prevention to early diagnosis, screening, diagnosis and staging, treatment and palliative care)	WHO
— Step 1: Assess the present state of the cancer burden, and cancer control programmes in your country		— imPACT reviews ^a to assess national capacities in cancer control (IAEA, WHO, IARC)	IARC

TABLE 2.1. PHASES OF CANCER CONTROL PROGRAMMES, MILESTONES AND SOURCES OF SUPPORT
(adapted from Ref. [2.1]) (cont.)

Phase	Milestone	Support available	Support provider
— Step 2: Formulate and adopt a policy specifying the target population, goals and objectives, and priority interventions — Step 3: Identify the steps needed to implement this policy	— Support to establish and scale up cancer registration and research implementation	WHO, IAEA	
	— Support Member States in evidence based planning for cancer control resources and NCCPs	WHO, IARC	
	— Guidance on the planning of national RT, nuclear medicine and diagnostic imaging services	IAEA	
— Guidance on setting up an RT programme, taking into consideration clinical, medical physics, radiation protection and safety aspects — Guidance and support for palliative care programmes	—	IAEA	
	—	IAEA, WHO	

Phase 3: Preparing for implementation

TABLE 2.1. PHASES OF CANCER CONTROL PROGRAMMES, MILESTONES AND SOURCES OF SUPPORT
(*adapted from Ref. [2.11]*) (cont.)

Phase	Milestone	Support available	Support provider	
<p>This phase requires preparatory actions for the implementation of the NCCP and RT plans. Supporting initial education and training of RT professionals, such as medical physicists, RT technologists and radiation oncologists, as well as continuing education and training of previously trained professionals to update or expand their knowledge and skills, are a priority. Begin training different professionals well in advance to ensure their availability one year before beginning operation of the RT centre:</p> <ul style="list-style-type: none"> — Create a steering committee — Perform cost and economic analyses — Perform a risk assessment 	Preparatory work done	<ul style="list-style-type: none"> — Support for financial and economic analyses, including the estimations of cost-effectiveness and impact — Support for development of legal and regulatory nuclear framework — Expert assistance in cancer surgery, RT, nuclear medicine, diagnostic imaging, medical physics, medical oncology, as well as in supportive and palliative care — Assistance with procurement of diagnostic imaging, RT and nuclear medicine equipment 	IAEA, WHO IAEA IAEA, WHO IAEA	

TABLE 2.1. PHASES OF CANCER CONTROL PROGRAMMES, MILESTONES AND SOURCES OF SUPPORT
(adapted from Ref. [2.1]) (cont.)

Phase	Milestone	Support available	Support provider
—	Develop a strategy for implementation	— Guidance on revision of national treatment protocols and guidelines for early detection and treatment of cancer, their revision and adaptation to the national context and implementation	WHO
—	Devise specific project sub-plans	—	
—	Create legal and regulatory nuclear safety and security infrastructure	—	
—	Develop human resources	— Technical support and policy formulation to assess, build and scale up the capacity of the cancer workforce using a labour market approach	WHO
—	Create a logical framework matrix	— Support to train professionals and ensure their continuous development	IAEA
		— Support long term and short term fellowships, education and training workshops, as well as virtual education platforms	IAEA
Phase 4: Implementation			

TABLE 2.1. PHASES OF CANCER CONTROL PROGRAMMES, MILESTONES AND SOURCES OF SUPPORT
(adapted from Ref. [2.1]) (cont.)

Phase	Milestone	Support available	Support provider
Using a phased implementation approach, work on all the NCCP components, including diagnostic capacity such as pathology, diagnostic imaging and nuclear medicine, and radiation physics: ^b	NCCP implemented	Help to ensure that treatment devices can be accurately and safely operated for clinical use in Member States through the dosimetry laboratory services	IAEA
— Step 1 (core interventions): Implement interventions in the policy that are feasible now, with existing resources		Help with calibrating radiation beams in Member States through the IAEA/WHO thermoluminescence dosimetry postal dose quality audit service	IAEA, WHO
		Help to improve accuracy in radiation dosimetry and achieve traceability to national dosimetry standards through the IAEA/WHO Network of Secondary Standards Dosimetry Laboratories	IAEA, WHO

TABLE 2.1. PHASES OF CANCER CONTROL PROGRAMMES, MILESTONES AND SOURCES OF SUPPORT
(adapted from Ref. [2.1]) (cont.)

Phase	Milestone	Support available	Support provider
— Step 2 (expanded interventions): Implement interventions in the policy that are feasible in the medium term, with realistically projected increases in, or reallocation of, resources		— Support for acceptance tests and commissioning of equipment	IAEA
— Step 3 (desirable interventions): Implement interventions in the policy that are beyond the reach of current resources, if and when such resources become available		— Guidance in the elaboration of strong quality management/quality assurance systems in diagnostic radiology, nuclear medicine and radiation oncology	IAEA
		— Help to enhance the safety and quality of diagnostic and therapeutic procedures in radiation medicine	IAEA
		— Help with the revision of the national essential medicines list and procurement planning for cancer priority medical devices and other health goods, enhancing the harmonization with the WHO Essential Medicines List and Essential In Vitro Diagnostics list, and assist in dialogue related to the best practices in price negotiations	WHO

^a The IAEA's Programme of Action for Cancer Therapy (PACT) includes an assessment tool, known as an imPACT Review, which assesses a country's cancer control capacities and needs and identifies priority interventions to effectively respond to those needs.

^b The IAEA develops internationally harmonized codes of practice and guidelines for dosimetry and quality assurance, as well as recommendations for best practices, and provides guidance to Member States for their implementation.

Note: IARC: International Agency for Research on Cancer; NCCP: national cancer control programme; NCD: non-communicable disease; RT: radiotherapy; WHO: World Health Organization.

The cancer team is an essential component of cancer care, involving numerous professions working together.

2.5.2. Clinical services

Diagnostic services involve medical imaging and laboratory medicine and pathology. Treatment services include RT, chemotherapy, systemic therapy and surgery. Supportive care includes palliative care, psychosocial care, medical nutrition therapy (MNT) and cancer rehabilitation and survivorship care. The outpatient or ambulatory care facilities are important care delivery settings. Pharmacy and emergency care are core services that also provide clinical care. It is important to harmonize these services to provide coordinated, efficient care. Each service should have articulated goals, scope, infrastructure, human resources, management, quality and processes. In addition, each service should be aware of and consider imminent and future trends.

2.5.3. Core services and infrastructure

The delivery of cancer care by clinical services depends on the presence of well developed and functioning core services and infrastructure that enable efficient and effective functionality. Many may be invisible to patients but are important for the delivery of care. Among the core services to be considered are infrastructure and information technology (IT), medical records and cancer registry, quality control (QC) and safety, education and training, community participation, service delivery matrix (with disease specific programmes), research, administration and financial sustainability, pharmacy and nursing. These core services and infrastructure may be shared with a broader hospital system beyond the cancer centre.

2.5.4. Governance

Governance and administration functions are crucial to ensuring effective operation of a cancer centre. An overarching formal and informal leadership structure enables planning, decision making, financial and risk management, effective coordination and efficient operations. A robust organizational approach to quality assurance (QA), maintenance and improvement is a vital responsibility of leadership. This includes fostering a culture of quality and implementing a plan to define and enforce quality standards, monitor performance and employ strategies to prevent, analyse and learn from safety incidents.

2.5.5. Education

Progress in cancer care can advance rapidly and cancer control centres or programmes require education programmes to stay abreast of these advances. Cancer centres should commit to supporting and facilitating lifelong learning and are ideal settings for training cancer care professionals. Beyond formal student programmes, health professional education supports the maintenance of competence, continuing education and professional development. Cancer centres should aim to develop continuing educational strategies aimed at all professionals working therein.

2.5.6. Research

The continuous cycle of generating and transferring new knowledge to improve outcomes is integral to the vision and priorities of the cancer centre, making it an ideal place to advance cancer research, and especially to conduct clinical trials. Cancer centres should incorporate research at the outset of planning their programmes and facilities.

2.5.6.1. Strategies to engage patients in their care

Cancer centres should engage and empower their patients. Well designed patient information, navigation, education, and empowerment strategies improve the function of cancer control centres.

2.5.7. Community partnerships

2.5.7.1. Integration with the community

Patients with cancer have health related needs beyond cancer itself, including the impact that their diagnosis and treatment have on finances, employment, family and cultural life. There is a need for integrated health services to improve access, outcomes and patient safety. A variety of providers, organizations and community programmes address the whole spectrum of cancer control. Formalized partnerships at the local, national and international levels can allow the cancer centre to work with external organizations to resolve unmet patient needs and advocate for patient services and support that are outside the scope of the cancer centre, or best delivered in the community.

2.5.8. Integration with the NCCP

A cancer centre is a part of a larger health care system and can serve as a physical and organizational integration point for many key elements of NCCPs. This includes programmes for primary prevention, early prevention, and screening, which can reduce the burden of cancer and optimize outcomes, as described above. Population based cancer registries are important because they can monitor changes in cancer incidence and mortality, thereby guiding cancer centre operations in anticipation of the population's needs. Close communication between the governance and administrative bodies of a cancer centre with those at the NCCP level is necessary to optimize coordination of resources and services.

2.6. BEYOND CANCER CENTRES

2.6.1. Cancer control

Primary prevention, early detection and screening programmes reduce the burden of cancer and optimize outcomes through enabling earlier diagnoses and improved treatment outcomes. Population based strategies for primary cancer prevention aim to address major lifestyle associated risks for cancer. Population based screening programmes address the needs of a broader group of people, and clinical services may engage cancer centres or other health facilities. An important consideration for effective cancer control is the development of population based cancer registries that monitor changes in incidence, mortality and patterns of cancer.

2.6.2. Policy and regulation

National and regional strategies for cancer control can have an effect on the delivery of cancer care services. There are many examples of national cancer control strategies that include licensing, regulation and accreditation bodies related to cancer control and cancer care services.

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Chapter 3

CANCER PREVENTION AND TREATMENT

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3.1. BACKGROUND

Cancer centres provide a wide range of services involved in the diagnosis, treatment and follow-up of cancer patients. The optimal method to deliver these services is a multidisciplinary approach involving the close collaboration of different medical disciplines. Multidisciplinary cancer care needs to include a radiation oncologist, medical oncologist (or clinical oncologist) and a surgical oncologist, if possible (otherwise a general surgeon), as well as radiologists, nuclear medicine physicians, pathologists, palliative care specialists, medical physicists, technologists and nursing staff.

Ideally, multidisciplinary care will be provided in site specific clinics (e.g. breast cancer clinic, gynaecological cancer clinic) [3.1]. In these site specific clinics, new patients will be evaluated collectively by the MDT and an evidence based plan will be developed — keeping in mind the patients' stage at presentation, prognosis and goals of care. This will facilitate an appropriate work-up, diagnosis, staging, treatment and follow-up.

Most cancers require a tissue biopsy to facilitate diagnosis. This needs to be considered in discussion with an MDT, as for some specific cancers a biopsy may be contraindicated and complete resection may be needed instead, following other work-up or initial treatment to facilitate safe complete resection. If indicated, the biopsy specimen would be processed for routine histopathology under the care of the pathology team. Once a diagnosis is made, it is often necessary to consider additional diagnostic testing needed for staging, risk stratification or subclassification of the disease to tailor treatment. This may necessitate procedures (e.g. lumbar puncture, bone marrow aspirate/biopsy) and imaging (standard cross-sectional imaging includes computed tomography (CT) and magnetic resonance imaging (MRI), and for select indications, specialized imaging such as positron emission tomography (PET) scans), ideally planned in collaboration with the MDT.

Once the diagnosis and staging of cancer are complete, then the case of each newly diagnosed cancer patient can be presented for discussion at a multidisciplinary cancer management panel ('tumour board') [3.2]. This panel has to make explicit recommendations, documented in the meeting minutes and included in each patient's medical record, for the optimal combination of treatment modalities and supportive care that will give each patient the best opportunity for definitive therapy and management of symptoms. Innovative solutions, such as web based 'virtual tumour boards', may help smaller centres that lack subspecialists to operate their own multidisciplinary tumour boards [3.3].

This chapter discusses the three primary disciplines involved in cancer treatment — radiation oncology, medical oncology and surgical oncology — as well as oncological imaging/nuclear medicine, pathology/laboratory medicine (key disciplines for cancer diagnosis and survivorship care) and supportive care (involving palliative care, psychosocial care, nutrition and survivorship). Although each of these key oncological disciplines has a unique role in care management for cancer patients, they need to be viewed holistically as interconnected services that work synergistically in providing whole person care. If one of these services is neglected, it can have negative downstream implications for all the other services reliant on it. A balanced approach is therefore needed as cancer centres go through periods of growth.

3.2. RADIATION ONCOLOGY

3.2.1. The rationale for radiation oncology

Radiation oncology is an essential component of multidisciplinary cancer care, as more than half of all cancer patients require RT as part of their treatment course [3.4, 3.5]. In LMICs, that number is closer to 60–70%, as the majority of patients present with advanced disease requiring RT for either cure or palliation. The appropriate use of radiation has been shown to improve disease control and overall survival for many of the most common types of cancer, including lung, breast, colorectal, prostate and cervical cancer [3.6]. RT is a treatment modality that requires capital, operational and staff investments to support each step of the radiation treatment process (see Box 3.1). Additional investments in resources for the specialized needs of paediatric cancer patients is also required. The size of these investments may vary significantly depending on the specific needs and resources of the country.

Despite the significant investment required to open and maintain an effective radiation oncology department, the clinical benefits of RT are clear and justify the investment required. Additionally, the societal and economic

benefits that arise from investing in RT further validate this investment. A recent model developed by the Global Task Force on Radiotherapy for Cancer Control evaluated the costs and benefits associated with investing in RT resources globally to meet the estimated global needs for radiation oncology in 2035 [3.6]. This study reported that a US \$96.8 billion investment was required to meet the growing demand for radiation oncology and that this investment would result in an economic benefit of US \$365.5 billion. In other words, for every US dollar invested in radiation oncology services, there was a US \$3.78 return on investment. In addition, investing in radiation oncology services to meet the anticipated demand would save 26.9 million life years in LMICs between 2015 and 2035. These results were consistent across all regions and income levels — the benefits in terms of lives saved far outweighed the investment costs. This analysis makes a very compelling economic argument for RT to be at the forefront of priorities for cancer control planning in most countries.

BOX 3.1. OVERVIEW OF THE RADIATION ONCOLOGY PROCESS

- (1) *Clinical evaluation of the patient.* Patients need to be evaluated in a multidisciplinary setting, if possible [3.1]. This needs to include assessment and staging of the tumour by a physical examination, evaluation of the available imaging and a decision on whether to prescribe RT.
- (2) *Therapeutic decision making.* Goals of care (curative or palliative) have to be determined according to the clinical context and the patient’s wishes. A decision can then be made as to how RT can be sequenced with other treatment modalities, if they are indicated. A determination needs to be made regarding radiation dose prescription, dose time and volumes to be treated. All patients need to be informed about the benefits and potential adverse effects of RT and asked for their written consent to proceed with treatment.
- (3) *Patient immobilization.* It is necessary to determine if patient immobilization is required and, as appropriate, a reproducible approach to patient immobilization must be used for simulation and treatment.
- (4) *Patient simulation.* The treatment position for the patient must be simulated. An appropriate field arrangement needs to be selected.
- (5) *Target volume determination.* The gross tumour volume must be contoured. The clinical target volume accounting for subclinical disease needs to be determined, as should the potential routes by which it may have spread. In addition, the planned target volume to account for setup uncertainty needs to be determined. Organs at risk need to be identified and contoured.
- (6) *Treatment planning and evaluation.* The radiation technique, fields, modality and treatment energies need to be determined. Custom blocks or

compensating filters need to be developed as required. The dose distribution has to be computed and verified for accuracy. The dose volume histograms need to be evaluated to ensure that the tumour is receiving an adequate radiation dose and that organs at risk are receiving doses below the radiation dose constraints chosen by the treating physician.

- (7) *Simulation of treatment.* Radiographic documentation of shielding blocks and treatment ports is required to verify the fields.
 - (8) *Treatment.* Treatment data need to be transferred to the treatment machine and initial verification of the treatment set-up is required. Verification of the accuracy of repeated treatments, continual assessment of equipment performance, periodic checks of dosimetry and record keeping need to be regularly performed.
 - (9) *Patient evaluation during treatment.* Patients have to be evaluated weekly during treatment to manage any adverse effects of treatment and to assess the treatment response. A standardized grading system (e.g. Common Terminology Criteria for Adverse Events) has to be used to grade toxicities so that side effects can be easily compared from week to week [3.7]. The palliative and supportive therapy teams (e.g. dietician for head and neck cancer patients) have to ensure that patients are well supported and able to complete treatment as planned.
 - (10) *Follow-up evaluation.* Patients need to have routine follow-up after radiation to evaluate treatment response, monitor for recurrence and manage any late toxicity from treatment. Required recurrences need to be discussed in a multidisciplinary setting to determine the best possible treatment plan and to counsel the patient appropriately. Appropriate follow-up will be determined by the tumour type and resources available at the cancer centre (e.g. scheduled follow-up every 3–6 months for the first two years and then every 6–12 months for at least five years).
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3.2.2. Radiation oncology as part of multidisciplinary care

To ensure the appropriate utilization of RT and to provide patients with the highest quality care, it is critical for radiation oncologists to be part of the multidisciplinary care team and be involved in all diagnostic and treatment related decisions, starting from the time when the patient first presents at the cancer centre. Given the interconnected nature of RT with medical oncology and surgical treatments, it is strongly recommended that these treatment decisions be made jointly between these medical specialities, ideally at tumour board

meetings, where the relevant pathology and imaging can also be reviewed [3.2]. A consensus on a specific care plan for each patient can then be made after taking into consideration the stage of disease, the various treatment options and relevant evidence from published clinical trials. Inclusion of radiation oncologists in these multidisciplinary treatment planning discussions will facilitate appropriate radiation treatment planning with regard to the sequencing of treatments and determination of treatment sites, as well as promoting increased coordination of care among the key oncology disciplines [3.1]. External beam RT and brachytherapy are standard RT treatment modalities. They can be incorporated into a multimodality treatment with or without chemotherapy and be delivered prior to surgery, after surgery, as definitive therapy without surgery, or as a palliative treatment course.

3.2.3. Human resources and equipment

Key features for a radiation oncology service include human resources and training, infrastructure and equipment, a monitoring and evaluation framework, QA and management processes. A core radiation oncology team consists of radiation oncologists, oncology nurses, RT technicians (RTTs) and medical physicists. The team also includes equipment maintenance engineers and other health professionals involved in multidisciplinary cancer management. The core team members need to have received a formal academic education and structured, practical, competency based training. The IAEA has produced education and training guides, including syllabi, for all professional team members involved in radiation oncology [3.8] (see Table 3.1). The education and training of radiation oncology professionals takes several years, so careful planning is needed to ensure that a sufficient number of radiation oncology professionals are being trained to meet the anticipated growing demand for RT services in the future. Professionals providing paediatric radiation oncology services will require specialized training for the treatment, anaesthesia and psychosocial needs of paediatric patients. The IAEA has extensive publicly accessible guidelines on the appropriate staffing of an RT centre.

3.2.3.1. Radiation oncologist

Radiation oncologists need to have a deep knowledge of the aetiology, pathophysiology and natural history of cancer, as well as be able to appropriately work up, diagnose and stage cancer patients, deliver RT effectively and safely, manage complications associated with radiation, and interpret and implement clinical advances and research into their practice. Additionally, radiation oncologists need to have at least a basic familiarity with medical and surgical

oncology practices. At least one radiation oncologist has to be hired for every 200–250 patients treated annually [3.18].

To acquire this skill set and knowledge base, the IAEA recommends a minimum three year, full time training period for radiation oncologists following medical school graduation. During these years, trainees will be residents in clinical radiation oncology departments and participate in seminars, conferences, teaching assignments, interdepartmental clinics and external beam and brachytherapy procedures under the supervision of practicing radiation oncologists. The IAEA provides extensive guidance on the education and training of radiation oncologists (including requirements for training institutes, training programmes, curriculum, as well as systematic evaluations for trainees) in Ref. [3.8]. It has to be noted that some countries utilize clinical oncologists trained in radiation oncology and medical oncology. These physicians represent a distinct professional group capable of delivering treatment with radiation and chemotherapy.

3.2.3.2. Radiation oncology nurse

Radiation oncology nurses have to have sufficient training to have informed discussions with patients regarding the purpose of radiation, educate patients and families on the process of radiation treatment delivery and possible related adverse effects, evaluate patients undergoing RT to identify and assist in the management of any radiation related side effects, and assess the psychosocial impact of cancer on patients and their families in order to connect them with the relevant supportive services. Reference [3.9] recommends that oncology nurses undergo 12–16 weeks of radiation oncology nursing training after a baccalaureate degree in nursing. Topics covered in this 16 week IAEA radiation oncology nurse curriculum range from effectively assessing a patient to multidisciplinary collaboration. Approximately one nurse has to be hired for every 300 patients treated annually [3.18].

3.2.3.3. Radiotherapy technician

RTTs have to be proficient in the following aspects of practice: comprehending and interpreting radiation treatment prescriptions; treatment preparation; treatment delivery and patient set-up; treatment verification; treatment documentation and IT; and radiation protection. The IAEA provides extensive guidance on the education of radiation therapists in Ref. [3.10]. In brief, the IAEA recommends a two year programme after at least secondary school education for the training of RTTs. Year one needs to be focused on the basic medical sciences and medical radiation physics, while year two needs to

be based in the clinic and involve clinical rotations. When possible, a four year degree programme could offer an opportunity to participate in advanced treatment planning and QA. Details of the curriculum, requirements for training institutions/programmes, accreditation process, and student teaching and evaluation methods are available in Ref. [3.10]. In general, at least two RTTs have to be in attendance at each treatment machine and an additional two RTTs have to be hired for every additional 25 patients treated on that machine or shift. Two RTTs need to be hired for every 500 patients simulated annually [3.18].

3.2.3.4. *Medical physicist*

Clinically qualified medical physicists specialized in RT help to ensure the quality, safety and effectiveness of RT. The IAEA defines the roles and responsibilities of clinically qualified medical physicists in Ref. [3.11]. Generally, medical physicists play a central role in the technical, physical, safety and dosimetric aspects of radiation oncology, including treatment planning, equipment specification, commissioning, acceptance testing and QC. After installation, medical physicists are further involved in overseeing equipment maintenance, as well as calibration and verification of the RT units and the relevant QC and dosimetry instruments. A comprehensive list of the tasks of clinically qualified medical physicists in RT are available in Ref. [3.11]. Generally, at least one medical physicist has to be hired for every 400 patients treated annually [3.18].

Despite the inclusion of medical physics as a health profession according to the International Standard Classification of Occupation of the International Labour Organization [3.19], in many countries this profession lacks recognition, entailing limited access to suitable academic education [3.12, 3.20] and, in particular, to structured and supervised clinical training [3.13, 3.20] — this last being necessary to achieve adequate levels of competency. International guidelines describing the roles and responsibilities of clinically qualified medical physicists were issued in 2013 by the IAEA and endorsed jointly by the American Association of Physicists in Medicine and the International Organization for Medical Physics [3.11].

The pathway towards becoming a clinically qualified medical physicist encompasses post-graduate level academic education in medical physics [3.10], followed by a structured and supervised hospital based training programme for acquiring practical competencies. Ideally, clinically qualified medical physicists are then recognized nationally through a system of certification and re-certification, typical of health professionals [3.12, 3.13].

In some cases, the need for supervised clinical training — essential to allow the medical physicist to reach the needed competencies — is overlooked or dealt with inadequately. Consequently, the IAEA has issued guidelines [3.14] that

provide tools to ensure the quality of clinical training programmes and, at the same time, may be used as a guide to establishing clinical training programmes.

3.2.3.5. *Dosimetrist or physics assistant*

Dosimetrists, under the supervision of the medical physicist, are responsible for computerized dose calculations, preparation of low dose rate sources for patient treatments, maintenance of source inventory and creation of RT treatment plans, which are reviewed and approved by the radiation oncologist. In order to master these skills, a dosimetrist has to have a university degree, followed by clinical training. Many dosimetrists may have a background in radiation oncology from previously working as an RTT. At least one dosimetrist has to be hired for every 300 patients treated annually [3.18].

Staffing levels are dependent on the complexity of the RT procedures and the number of patients being treated. Therefore, decisions regarding staffing levels have to begin with an analysis of the population that the cancer centre is serving and a review of the local cancer epidemiology. The proportion of patients with cancers that will need radiation, as well as the modalities of radiation that would be indicated, can then be estimated to inform staffing decisions and the equipment needed [3.21]. Decisions regarding staffing and investment in equipment need to be made in tandem, as investing in equipment without a concomitant investment in trained human resources can be dangerous.

3.2.3.6. *Equipment*

Radiation oncologists and medical physicists have to be involved in all decisions related to the acquisition and implementation of new RT equipment. The equipment required for the comprehensive cancer centre RT facility will vary depending on the services offered. A cancer centre would typically have external beam and brachytherapy treatment units, as required; imaging required for treatment planning and simulation; computerized treatment planning systems; dosimetry, QC and safety equipment; mould room equipment; positioning and immobilization devices; and consumable equipment [3.22–3.24] (see Table 3.2). Examples of radiation treatment equipment and modalities are as follows:

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TABLE 3.1. PUBLICATIONS ON CAPACITY BUILDING RELATED TO HUMAN RESOURCES

Field	Topic/title	Reference	Average duration ^a
Radiation oncologist	IAEA Syllabus for the Education and Training of Radiation Oncologists	[3.8]	~4–5 years
Radiation oncology nurse	A Syllabus for the Education and Training of Radiation Oncology Nurses	[3.9]	12–16 weeks
Radiotherapy technician	A Handbook for the Education of Radiation Therapists	[3.10]	~2 years
Medical physicist	Roles and Responsibilities, and Education and Training Requirements for Clinically Qualified Medical Physicists	[3.11]	
	Guidelines on Professional Ethics for Medical Physicists	[3.15]	
	Clinical Training for Medical Physicists Specializing in Radiotherapy	[3.13]	~2 years
	Guidelines for the Certification of Clinically Qualified Medical Physicists	[3.16]	
	Postgraduate Medical Physics Academic Programmes	[3.12]	~3–6 years
	Audit Methodology for Medical Physics Clinical Training Programmes	[3.14]	
Staffing	Staffing in Radiotherapy: An Activity Based Approach	[3.17]	

^a For completion of the minimum competencies to work independently in the clinic (considering the starting point).

- Cobalt-60 (^{60}Co) units utilize a ^{60}Co source, which has a half-life of 5.27 years. Cobalt-60 units can produce stable dichromatic beams of 1.17 MeV and 1.33 MeV for an average beam energy of 1.25 MeV.
- Linear accelerator (LINAC) units do not have a radioactive source and therefore avoid the need for source replacement and decommissioning. A LINAC instead accelerates electrons, which then strike a target, producing photons of varying energies. LINACs can also be used without a target to produce electron beams to treat more superficial sites.
- Orthovoltage X ray units produce X rays with a peak energy ranging from approximately 100 keV to 300 keV. Similar to a LINAC, orthovoltage units do not require a radioactive source.
- Proton therapy units utilize protons, rather than photons or electrons, to produce the therapeutic effect of RT. Protons differ from photons or electrons in how they deposit radiation, allowing for greater protection of distal organs at risk [3.40]. Proton therapy requires specialized expertise from the medical physicist and radiation oncologist and is cost prohibitive at most cancer centres.
- Brachytherapy is an RT treatment that involves placing a sealed radioactive source (common sources include iridium-192, iodine-125, palladium-103 and cobalt-60) [3.24] in or near a tumour permanently or for a predefined period of time. Brachytherapy can be subclassified as being high dose rate or low dose rate. Brachytherapy can be performed using moulds/plaques for superficial lesions, as an interstitial implant or as an intracavitary application.

3.2.3.7. *Examples of modalities*

- Intensity modulated RT (IMRT) is an external beam treatment modality that modulates the intensity and shape of the radiation beam during treatment using multileaf collimators or a compensator. This can allow a radiation oncologist to make the radiation more conformal to the target and decrease the dose to nearby organs at risk or to intentionally deliver different doses of radiation to different anatomical sites simultaneously. IMRT has been shown to reduce the side effects of radiation in a number of settings [3.41].
- Image guided RT (IGRT) can be incorporated into any radiation treatment modality, as it involves using imaging before and/or during treatment to ensure that the patient is positioned correctly and the tumour is being targeted accurately. This can allow for adaptive radiation plans to be created based on how patients respond to radiation during their treatment course or to account for other unanticipated anatomical changes [3.42]. IGRT can

consist of various imaging modalities, such as ultrasound, MRI, X rays and CT scans.

- Volumetric arc therapy is a form of IMRT that delivers conformal radiation using one or more modulated arcs. This can shorten the time required to deliver a dose of radiation and uses fewer monitor units [3.43].
- Stereotactic radiosurgery (SRS) is a type of external beam RT that uses specialized equipment such as a 3-D coordinated system/stereoaxis, and a head frame at some institutions, to enable radiation oncologists to deliver a high dose of conformal radiation to a precise target in a single fraction. SRS is non-invasive and does not involve a surgical procedure, but commonly involves a neurosurgeon in addition to a radiation oncologist. SRS is used to treat tumours of the central nervous system such as brain metastasis.
- Stereotactic body RT (SBRT) is a type of external beam RT that delivers high doses of conformal radiation, similar to SRS, but treats sites outside the brain. It also requires specialized immobilization devices, image guidance and medical physics expertise. It is commonly used to treat cancers of the lung, liver and spine over one to five treatments.
- Total body irradiation is a form of external beam RT that treats the entire body. This can be used in preparation for a bone marrow transplant for haematological malignancies or other haematological conditions.

TABLE 3.2. PUBLICATIONS ON CAPACITY BUILDING RELATED TO EQUIPMENT

Modality	Topic/title	Reference
External beam RT	Selecting Megavoltage Treatment Technologies in External Beam Radiotherapy	[3.25]
Brachytherapy	The Transition from 2-D Brachytherapy to 3-D High Dose Rate Brachytherapy	[3.26]
	Implementation of High Dose Rate Brachytherapy in Limited Resource Settings	[3.27]
Immobilization	Basic Positioning and Immobilization in Radiotherapy: A Training Video	[3.28]
Treatment planning systems	Commissioning of Radiotherapy Treatment Planning Systems: Testing for Typical External Beam Treatment Techniques	[3.29]

TABLE 3.2. PUBLICATIONS ON CAPACITY BUILDING RELATED TO EQUIPMENT (cont.)

Modality	Topic/title	Reference
Proton therapy	Minimum requirements and challenges in setting up a particle therapy facility	[3.23]
QA and safety	Regulatory Control of the Safety of Ion Radiotherapy Facilities	[3.30]
Equipment	Determining essential equipment	[3.31]
	Radiotherapy equipment specifications	[3.32]
	IMRT commissioning	[3.33]
	Patient safety	[3.33]
	Transitioning from 2-D Radiation Therapy to 3-D Conformal Radiation Therapy and Intensity Modulated Radiation Therapy: Training Material	[3.34]
	Stereotactic body RT patient safety	[3.35]
	Quality requirements to implement SRS	[3.36]
	Introduction of Image Guided Radiotherapy into Clinical Practice	[3.37]
General	Setting Up a Radiotherapy Programme: Clinical, Medical Physics, Radiation Protection and Safety Aspects	[3.18]
	Radiation Protection and Safety of Radiation Sources	[3.38]
	Radiotherapy Facilities: Master Planning and Concept Design Considerations	[3.39]

Note: 2-D: two dimensional; 3-D: three dimensional; IMRT: intensity modulated radiation therapy; QA: quality assurance; RT: radiotherapy; SRS: stereotactic radiosurgery.

One common decision that needs to be made is whether to invest in a ^{60}Co machine or a LINAC. Each RT unit has unique advantages, and one machine is not necessarily superior to the other. Generally, ^{60}Co machines are less expensive, require less preventative maintenance and are less likely to undergo downtime. However, they involve a radioactive source, which will decay, lengthening the necessary treatment times, and which will require appropriate security, storage and decommissioning. LINACs enable clinicians to create complex treatment plans more easily but require more infrastructure, shielding, personnel training, staffing and maintenance, have a higher risk of downtime and are more expensive over the expected lifetime of the machine. A decision on which RT unit to acquire will depend on the resources available, clinic needs and local infrastructure [3.22, 3.44].

An RT facility requires specialized construction and design to ensure that public and clinical personnel are not exposed to radiation. Information regarding the structure and design of RT facilities can be found in Section 5.1.3.5.

3.2.4. Teaching, research and clinical trials

3.2.4.1. Training programmes in radiation oncology

A cancer centre needs to be able to sustainably train its own workforce, evaluate its own outcomes and share expertise with others in the region. Training additional radiation oncologists has to be prioritized at cancer centres, as the number of practicing radiation oncologists in LMICs is only a small fraction of what is required to provide optimal access to RT services. With the anticipated increase in the incidence of cancer in the coming decades, the need for trained radiation oncologists will only increase without the establishment of new training programmes [3.45] (see Table 3.3).

Prior to developing a training programme, it is prudent to perform a survey of patient case numbers and the number of faculty capable of teaching trainees to ensure that a trainee will have sufficiently broad clinical exposure and depth of experience to meet the objectives of a training programme. Additionally, evaluations with respect to the capability of ensuring sustainability and quality management of training programmes are of crucial importance [3.14].

To ensure quality and sustainability, preconditions may also need to be defined. For instance, in the USA, the Accreditation Council for Graduate Medical Education requires that a radiation oncology training programme have at least four full time equivalent radiation oncologists and that the number of trainees not exceed the number of practicing radiation oncologists [3.46].

Where sustainability of a full clinical training programme cannot be ensured, consideration should be given to collaborating with other centres

TABLE 3.3. RADIATION ONCOLOGY SERVICE LEVELS AND REQUIREMENTS SPECIFIC TO TECHNOLOGY AND TRAINING

Level of cancer centre	Technologies needed	Human resources needed	Radiation oncologist competencies needed
Level 1	Plain radiography (X ray), Co-60 RT unit or single photon energy LINAC, brachytherapy, mould room	General radiation oncologist, medical physicist, RTT	Planning using X ray and bone anatomy, manual calculation of dose distribution
Level 2	2-D and 3-D planning using CT simulation, multi-energy LINAC, brachytherapy with remote afterloader	In addition to Level 1, radiation oncologists with specialized training in specific disease sites. In-house medical equipment engineer	2-D and 3-D planning
Level 3	Six degree of freedom couch, motion management systems such as 4-D CT and respiratory gating, MR-LINAC	In addition to Level 2, radiation oncologists and physicists with training in advanced treatment modalities	IMRT, volumetric modulated arc therapy (VMAT), SRS, SBRT, image guided RT, proton therapy, etc.

Note: 2-D: two dimensional; 3-D: three dimensional; 4-D: four dimensional; CT: computed tomography; IMRT: intensity modulated radiotherapy; MR-LINAC: magnetic resonance guided linear accelerator; RT: radiotherapy; RTT: RT technician; SBRT: stereotactic body RT; SRS: stereotactic radiosurgery; VMAT: volumetric modulated arc therapy.

nationally or regionally to establish a joint clinical training programme. In the framework of such programmes, residents collect different competencies in different centres [3.14]. The IAEA has been supporting the provision of clinical training in the framework of an international initiative, as well as the national and regional establishment of such programmes.

Overall, it is important that clinical training programmes are aligned to international best practices to provide the necessary competencies to work in alignment with harmonized professional standards. The IAEA has provided several syllabi for radiation medicine professionals [3.13, 3.47, 3.48]. These may be tailored to local needs, for instance, through regional approaches (e.g. the Latin American Association of Medical Physicists, Regional Cooperation Agreement

for the Promotion of Nuclear Science and Technology in Latin America and the Caribbean [3.49] and the African Regional Cooperative Agreement for Research, Development and Training related to Nuclear Science and Technology [3.50]). In some cases, a clinical training programme might be approved in writing by local health and professional societies to ensure that the training programme's objectives, curriculum, time frame and practicum will produce competent clinical personnel who can safely perform their responsibilities.

Typically, the professional competence of a health care professional is then verified through a system of certification and re-certification, sustained by continuing professional development (CPD) [3.16].

3.2.4.2. *Research*

A critical part of initiating a research programme is to set up a cancer registry and a follow-up/death registry for all cancer patients. There are various resources available through the IARC to assist in this endeavour. A cancer registry needs to include basic information about a patient's age, stage, cancer diagnosis and treatment delivered so that clinical outcomes can be appropriately assessed. As a research programme gains experience and expertise through collaborations and training, further clinical studies and eventually clinical trials can be developed to answer specific questions relevant to the cancer centre's patient population. Research programmes focused on questions relevant to a specific country's local radiation oncology researchers need to be established as part of the national cancer control plan and incorporated into radiation oncology training programmes. Research requires funding, infrastructure, and staff with the expertise and skill set necessary to develop relevant research questions, design an appropriate research methodology, analyse the results and publish the outcomes. These skills need to be taught at all radiation oncology training programmes.

An example of how research could advance the interests of a cancer centre is implementation research [3.51]. This focuses on effectively incorporating evidence based research and changes in health care policy into clinical practice. For instance, research within the field of radiation oncology has led to significant progress in the development of hypofractionated treatment regimens. These treatment courses can significantly shorten radiation treatment courses and can be utilized in some of the most common cancers, such as prostate, breast and rectal cancer [3.52–3.55]. Finding a way to safely and effectively implement these treatment courses into clinical practice will improve clinic efficiency by freeing up machine time and resources, particularly in settings where the number of treatment machines may not be sufficient to meet the needs of the local population [3.56]. Implementation research is needed so that advances that can have a significant impact on treatment delivery in low resource settings, such as

hypofractionation, can be safely and effectively implemented or modified to meet local needs. However, research programmes have to also focus on answering questions that are directly applicable to the local population and providing innovative solutions to address the challenges being faced.

3.2.5. Quality assurance

QA in radiation oncology is essential because of the potentially serious, possibly lethal, consequences of the misadministration of ionizing radiation. It is mandatory to comply with national or international regulatory requirements, particularly radiation protection and safety protocols. As a result, significant resources need to be invested to ensure safe, high quality and effective services. The entire core RT team needs to be involved in QC activities. However, in a facility containing radiation emitting equipment, medical physicists are usually responsible for managing the radiation safety and protection aspects of patients, staff and the general public who have access to the premises.

A main point of emphasis for radiation oncology QC is ensuring that the machines used to deliver radiation are appropriately and consistently calibrated. Recommendations for QA programmes for each of the different treatment modalities have been developed; for instance, the American Association of Physicists in Medicine has produced several reports with established protocols that can be used as a reference [3.57–3.61]. The IAEA and WHO also run a postal dose audit programme that allows RT centres to verify their external beam machine calibration.

One of the most effective tools for continuous quality improvement (QI) is a comprehensive clinical audit. Such an audit involves a systematic assessment of clinical management and infrastructure, patient related and technical procedures, education and research. Reference [3.62], published by the IAEA, includes a guide to performing an internal audit, as well as data collection sheets for the rapid generation of reports that can serve as a model for radiation oncology facilities wishing to improve the quality of their service. Additionally, institutions can request an external audit from the IAEA Quality Assurance Team for Radiation Oncology (QUATRO) [3.63], which involves a team of external auditors (radiation oncologist, medical physicist and radiation therapist) sent to the institution. QUATRO audits are performed as requested by individual institutions and change in range from comprehensive audits of a department to partial audits concentrated on specific aspects of treatment delivery. A comprehensive audit consists of interviews of staff members; documentation review, dosimetric measurements and infrastructure; and observation of RT practices. The goal of a comprehensive audit is to confirm the appropriateness of diagnosis, treatment

and follow-up of patients, dosimetry, medical radiation physics, calibration of machines, staffing, infrastructure and training programmes.

3.3. MEDICAL ONCOLOGY

3.3.1. The rationale for medical oncology

Medical oncology is an integral component of multidisciplinary cancer care. It is estimated that the need for adequately trained medical oncologists will continue to grow, as it is estimated that there will be an increase of 53% for first course chemotherapy between 2018 and 2040 [3.64]. In LMICs, the proportion of patients needing chemotherapy is higher and is estimated to increase from 63% of all cancer patients in 2018 to 67% of all cancer patients by 2040 [3.64]. This is largely driven by patients with lung, breast and colorectal cancer [3.64]. Systemic therapy is an essential curative and palliative treatment for many haematological and solid tumour diagnoses, such as lung, breast and colorectal cancer. Systemic therapy is of particular importance for patients diagnosed at locally advanced stages, which is more common in low resource settings.

Medical oncology requires investments in capital, operational processes and staff training to deliver quality care and support each step of the medical oncology treatment process (see Box 3.2). Additional investments are required to meet the specialized needs of children with cancer. The resources and investment required to implement medical oncology services will differ significantly between countries, but basic requirements include adequately trained personnel, infrastructure, consistent access to medicines, essential devices and equipment, blood banking, monitoring and evaluation tools, and QA and management processes. Inpatient and outpatient oncology need to be addressed within a medical oncology budget as well as the costs of required peripheral services, such as emergency/acute and intensive care, rehabilitation and palliative care.

BOX 3.2. OVERVIEW OF THE MEDICAL ONCOLOGY PROCESS

- (1) *Clinical evaluation of the patient.* All patients should optimally be evaluated in a multidisciplinary setting, if possible [3.1]. This can include assessment and staging of the tumour through a physical examination; evaluation of all available imaging; and a decision on whether to prescribe systemic therapy.
- (2) *Therapeutic decision making.* Targets of cancer care (curative or palliative) need to be determined according to the clinical context and the patient's wishes. A decision needs to be made as to how systemic therapy can be

sequenced with other treatment modalities, if they are indicated. A systemic therapy prescription including dose, frequency, duration and route of administration needs to be selected. All patients have to be informed about the benefits and potential adverse effects of systemic therapy and asked for their consent to proceed with treatment.

- (3) *Oncology pharmacy/medication preparation.* An oncology pharmacist (or equivalent profession) generally prepares the prescription as prescribed and clarifies any aspects with the prescribing medical oncologist as appropriate. Safe handling of all medications has to be assured.
 - (4) *Pre-treatment assessment.* Relevant laboratory results, including a pregnancy test for indicated women, need to be ordered to ensure that the patient is fit to receive chemotherapy. The patient's weight, height and body surface area need to be confirmed as being consistent with the intended prescription. Appropriate access for the indicated route of administration needs to be confirmed (e.g. intravascular, intrathecal, port).
 - (5) *Treatment delivery.* Treatment delivery may be carried out on an inpatient or outpatient basis, as indicated. Prior to the administration of systemic therapy, the patient's identification, drug name, drug dose, drug volume, rate of administration, route of administration and dose calculation need to be confirmed by two providers. Chemotherapy and any indicated supportive medications can be administered by an oncology nurse. The patients have to be observed during treatment delivery in case of any unexpected side effects.
 - (6) *Evaluation of patients during treatment.* All patients need to be evaluated during treatment to manage adverse effects of treatment, as well as to estimate the response to treatment when possible. A standardized grading system (e.g. Common Terminology Criteria for Adverse Events) needs to be used to grade toxicities so that side effects can be easily compared over the course of treatment [3.7]. When needed, the palliative and supportive therapy teams (e.g. dietician for head and neck cancer patients) have to be involved to ensure that patients are well supported and able to complete treatment as planned.
 - (7) *Follow-up evaluation.* All patients need to have routine follow-up after completion of systemic therapy to evaluate treatment response, monitor for recurrence and manage any late toxicity from treatment. The appropriate follow-up will be determined by the tumour type and resources available at the cancer centre.
-

3.3.2. Medical oncology as part of multidisciplinary care

Systemic therapy can be delivered alone, concurrently or as induction/consolidation with RT, or in a neoadjuvant or adjuvant fashion with surgery. Medical oncologists, or relevant professionals, are tasked with guiding patients through these complex treatment courses and coordinating care among the various oncological disciplines, reinforcing the need for a multidisciplinary treatment approach and the essential role of medical oncologists on multidisciplinary care teams. Additionally, the administration of chemotherapy requires plans for close follow-up, supportive care, scheduled bloodwork and other diagnostic tests (depending on the chemotherapy regimen), and rapidly accessible emergency care in the case of an adverse event or clinical deterioration. Close collaboration with nursing, pathology and laboratory medicine (PALM), radiology and pharmacy professionals is necessary to facilitate this process for chemotherapy patients.

3.3.3. Human resources

A core medical oncology team is required at a comprehensive cancer centre or a multispeciality tertiary care facility with a functional medical oncology unit. This team includes medical oncologists; nurses trained in administration and monitoring of systemic therapy; pharmacy staff trained in preparing and monitoring systemic therapy; multidisciplinary staff, including psychosocial, nutrition and palliative specialists; and other support staff, such as administrators and ward clerks. For paediatric oncology services, the core team members are as noted above, with specific personnel, including paediatric oncologists. In many settings, paediatricians join the roster of providers to support continuity of care, and it is helpful for nurses and multidisciplinary providers to receive dedicated training in the management of children with cancer. Access to specialist paediatric providers (e.g. paediatric anaesthesiologists) can help to ensure safe and effective care during intravenous therapy administration and procedures (e.g. bone marrow aspirates/biopsies) [3.65]. Medical oncology and paediatric oncology training involves both practical, competency based training and formal academic education, ideally with continuing medical education (see Table 3.4).

3.3.3.1. Medical oncologist

The discipline of medical oncology requires an ability to accurately diagnose, stage and treat cancer and other co-morbid or related health conditions. The selection and delivery of appropriate systemic therapy prescriptions (such as chemotherapy, endocrine therapy, immunotherapy and targeted therapy),

supportive care, and monitoring of symptoms and outcomes during and after treatment are essential activities for trained providers in medical oncology, who are generally medical oncologists or paediatric oncologists. Where potential cure, overall survival and quality of life gains are the main goals, the choice of treatment needs to be based on medicines that confer meaningful clinical benefit, follow institutional guidelines and national medicine lists and are tiered according to resources [3.65]. To perform these tasks safely and effectively, at least one medical oncologist has to be hired for every 250 patients treated annually [3.66].

To acquire the skill set of a medical oncologist requires a minimum of four years of specialized training after graduation from medical school. This process involves training as a resident in a medical oncology department, performing relevant medical procedures under the supervision of a licensed medical oncologist, participation in research and involvement in seminars, conferences, teaching assignments and interdepartmental clinics. The American Society of Clinical Oncology (ASCO) and the European Society for Medical Oncology (ESMO) provide extensive guidance on the education and training of medical oncologists (including requirements for training institutes, training programmes, curriculum, etc.) [3.66]. It has to be noted that some countries utilize clinical oncologists trained in radiation oncology and medical oncology. These physicians represent a distinct professional group capable of delivering treatment with both radiation and chemotherapy.

3.3.3.2. Medical oncology nurse

The role of a medical oncology nurse is similar to what was previously described for a radiation oncology nurse, but with an emphasis on systemic therapy. Oncology nurses have to undergo a 12–16 week medical oncology nursing training after a baccalaureate degree in nursing. This specialized training needs to include safe administration of systemic therapy and addressing side effects related to systemic therapy.

3.3.3.3. Oncology pharmacist

Oncology pharmacists are responsible for compounding and dispensing systemic therapies, ensuring appropriate handling and disposal of systemic therapy agents, and maintaining an adequate supply of systemic therapy agents and their associated supportive medications. They can also serve as a resource when reviewing medication pharmacology, drug interactions and other issues that arise from the use of systemic therapy agents. Oncology pharmacists require an additional one–two years of specialized training after completing a Doctor of Pharmacy degree.

CANCER PREVENTION AND TREATMENT

TABLE 3.4. PUBLICATIONS ON CAPACITY BUILDING RELATED TO HUMAN RESOURCES

Field	Topic	Title	Reference	Average duration ^a
Medical oncologist	Training requirements	ESMO/ASCO Recommendations for a Global Curriculum in Medical Oncology	[3.66]	~3 years
Medical oncology nurse	Reproductive health in adolescent and young adult cancer patients	Reproductive Health in the Adolescent and Young Adult Cancer Patient: An Innovative Training Program for Oncology Nurses	[3.67]	12–16 weeks
	Implementing an ambulatory oncology nursing peer preceptorship programme	Designing and Implementing an Ambulatory Oncology Nursing Peer Preceptorship Program: Using Grounded Theory Research to Guide Program Development	[3.68]	12–16 weeks
	Description of a blended teaching approach to oncology nurse training	Oncology Nursing Training: A Blended Teaching Approach in Resource-limited Countries	[3.69]	12–16 weeks
Oncology pharmacist	Oncology pharmacist training curriculum	Cancer Care Expert Professional Practice Curriculum: Professional Curriculum for Advanced Pharmacy Practice in Cancer Care	[3.70]	~2–4 years

^a For completion of the minimum competencies to work independently in the clinic (considering the starting point).

Note: ASCO: American Society for Clinical Oncology; ESMO: European Society for Medical Oncology.

3.3.3.4. *Equipment*

Staffing levels are dependent on the local cancer epidemiology, which needs to inform decisions regarding planned medical oncology facilities. These facilities typically include inpatient and outpatient services. Inpatient medical oncology services include an assigned unit for oncology patients to enable hospital admission for expedited work-up, management of oncological emergencies and administration of systemic therapies that require close clinical management and observation. Outpatient clinics are best utilized for initial patient consultation, non-emergent diagnostic work-up and for follow-up appointments. Lastly, many inpatient and outpatient facilities include chemotherapy administration areas, which are designated for the administration and observation of patients receiving systemic therapy. Additional facilities are also needed for the oncological pharmacy, which requires areas for medication compounding and secure storage.

The major medical oncology treatment equipment and modalities and their clinical relevance are as follows (Table 3.5 [3.31, 3.71–3.77]):

- Chemotherapy represents a broad category of systemic medications that preferentially affects rapidly dividing cells and is used to stop the growth of or kill cancer cells. It may be delivered as a single drug agent or as a combination of drugs. There are multiple methods of administration, including oral, intravenous, intra-arterial and intrathecal. Chemotherapy represents the backbone of many cancer treatments, given its ability to treat microscopic disease throughout the body.
- Targeted therapies leverage the differences between cancer cells and normal cells to preferentially target and kill cancer cells. Potential differences that are targeted include metabolic pathways, cell signalling, genetic markers and hormone receptor expression.
- Immunotherapy is a form of targeted systemic therapy that utilizes antibodies, vaccines and molecular pathways related to the immune system to treat cancer. Immunotherapy can be used alone or in combination with chemotherapy and has improved survival and disease free survival in various cancers [3.78]. One of the best known examples of immunotherapy is rituximab, which is an antibody directed against the CD20 molecule on B-cell malignancies.
- CAR T-cell therapy is a form of immunotherapy that involves genetically engineering T-cells, which are modified to target and kill tumour cells for conditions such as refractory or high risk lymphomas and leukaemias. In many settings, these therapies are currently available only for the very few who have the resources or appropriate insurance.

- Bone marrow transplant is a procedure that involves depleting a patient's diseased bone marrow in order to replace it with healthy bone marrow from the same patient or a donor. This procedure is commonly done for patients with haematological malignancies and blood/immune system diseases. These procedures may be performed by a medical oncologist or a specialized bone marrow transplant team.

3.3.4. Teaching, research and clinical trials

3.3.4.1. Training programmes

As previously mentioned, it is important that cancer centres devise a plan to reach sufficient numbers of adequately trained clinical personnel to meet their current and future needs. Meeting this demand in medical oncology is essential, given the already significant shortage of medical oncologists. This shortage has led to some countries having a greater than 1000:1 ratio of new cancer diagnoses a year per trained medical oncologist compared with a ratio of less than 150:1 in some HICs [3.79]. This discrepancy between the number of oncology patients and medical oncologists may contribute to worse cancer outcomes in some LMICs with a shortage of trained physicians. For this reason, establishing a medical oncology training programme that produces well trained medical oncologists has the potential to save lives (Table 3.6).

The creation of a training programme has to start with a formal assessment to ensure that a cancer centre has the resources, expertise and patient case numbers to meet the objectives of a training programme. If this analysis shows that a training programme can be set up using one of the above factors, then a plan needs to be put in place to meet the requirements that would enable a cancer centre to establish a training programme. Following this, a structured curriculum has to be created. There are a number of tools and resources that can be used as a basis for this curriculum. Examples of curricula for the speciality of medical radiation oncology have also been provided by professional societies including the ESMO and ASCO, which have published a joint guide [3.66]. This curriculum may be adapted to meet local needs and can be supplemented with international partnerships [3.80]. A specialized training programme needs to be created for paediatric oncologists.

3.3.4.2. Research

Oncology research, like clinical care, is often a multidisciplinary effort. The establishment of a research programme requires starting a cancer registry, which requires obtaining clinical and treatment information from various

CHAPTER 3

TABLE 3.5. PUBLICATIONS ON CAPACITY BUILDING RELATED TO EQUIPMENT

Modality	Topic	Title	Reference
Equipment	Determining essential equipment	WHO List of Priority Medical Devices for Cancer Management	[3.31]
Immunotherapy	Immuno-oncology	ESMO Handbook of Immuno-Oncology	[3.71]
Targeted therapies	Implementing a targeted therapy programme	Strategies for Clinical Implementation: Precision Oncology at Three Distinct Institutions	[3.72]
Bone marrow transplant	Establishing a bone marrow transplant service	Setting Up and Sustaining Blood and Marrow Transplant Services for Children in Middle-Income Economies: An Experience-driven Position Paper on Behalf of the EBMT PDWP	[3.73]
	Establishing a bone marrow transplant service	How to setup a successful transplant program for hemoglobinopathies in developing countries: The Cure2Children approach	[3.74]
	Establishing a bone marrow transplant service	The EBMT Handbook: Haematopoietic Stem Cell Transplant, Chapter 4	[3.75]
Research	Forming a research consortium	Establishing a Cancer Research Consortium in Low- and Middle-Income Countries: Challenges Faced and Lessons Learned	[3.76]
	Strengthening research capacity	Seven Principles for Strengthening Research Capacity in Low- and Middle-Income Countries: Simple Ideas in a Complex World	[3.77]

Note: ASCO: American Society for Clinical Oncology; EBMT: European Society for Blood and Marrow Transplantation; ESMO: European Society for Medical Oncology; PDWP: Paediatric Diseases Working Party.

TABLE 3.6. MEDICAL ONCOLOGY SERVICE LEVELS AND REQUIREMENTS SPECIFIC TO TECHNOLOGY AND TRAINING

Level of cancer centre	Technologies needed	Human resources needed	Medical oncologist competencies needed
Level 1	Ability to deliver single agent chemotherapy, perform and monitor blood counts	Medical oncologist, staff nurses, health care assistants	Administration of single agent chemotherapy, monitoring of patients on oral chemotherapy
Level 2	Palliative care	In addition to Level 1, palliative care teams	Management of treatment toxicity, such as febrile neutropenia
Level 3	Blood bank	In addition to Level 2, bone marrow transplant team	Bone marrow transplant unit

oncological medical disciplines, forming an institutional review board (IRB) or ethics committee to review project proposals, obtaining statistical support and conducting training programmes for new and early career investigators [3.81]. When the resources or expertise needed to establish a research programme within a clinical cancer centre are insufficient, then a multi-institution approach can be beneficial. Multiple studies have outlined the process for establishing an oncology research programme and multi-institution research consortiums [3.76]. Generally, this process includes identifying collaborators, forming a research team, scaling up research infrastructure and finding sources of funding.

3.3.5. Quality assurance

QA is essential in medical oncology, given the potentially serious (debilitating to lethal) consequences of misadministration of systemic therapy and supportive care products (including inappropriately dosed cytotoxic agents with narrow therapeutic ratios, or non-cross-matched blood products). Consequently, significant resources have to be invested to ensure safe, high quality and effective delivery of systemic therapy; point of care monitoring before, during and after therapy; and documentation and review of adverse events affecting patients, families or providers. The core medical oncology team needs to be engaged in QC activities. Patient involvement in QA processes can improve service delivery and may require committing institutional resources for patient education, engagement and feedback

[3.65]. All chemotherapy protocols being used need to be reviewed and signed off by the appropriate clinical authorities, such as the chief medical oncologist or clinical review committee. Where possible, treatment roadmaps are documented and integrated into an electronic system to facilitate accurate dose calculations, safe treatment delivery and monitoring.

At the bedside or point of care, standard policies and processes need to be established to ensure that appropriate patient identification and secondary checks are performed prior to delivery of systemic therapy (including cytotoxics and blood products). Continuous audits of treatment toxicity and outcomes are essential, and all adverse reactions, including extravasation, need to be recorded using Common Terminology Criteria for Adverse Events to ensure safety and assess the appropriateness of treatment regimens in the local context to guide evidence based treatment adaptations [3.7]. Safety systems should continuously be improved to prevent and mitigate adverse events (such as unintended exposure) affecting families or providers by utilizing equipment and resources for the safe disposal of hazardous medications and materials, including sharps. National or international regulatory requirements should be noted and referenced in the development and implementation of local requirements, including for personal protective equipment (PPE) and safe handling, prescribing and disposal of systemic therapy agents [3.82]. Sample resources are available to assist in creating protocols for the safe handling of chemotherapy drugs in different resource settings [3.83].

3.4. SURGICAL ONCOLOGY

3.4.1. The rationale for surgical oncology

Surgery plays an important role in the diagnosis and treatment of cancer. The tissue obtained during surgery can aid in the diagnosis and staging of cancer and inform whether adjuvant therapies are indicated. Surgery can also function as a stand-alone curative therapy or as part of multimodality cancer treatment in combination with neoadjuvant or adjuvant therapies. The clinical benefits of curative surgery are best seen in some of the most common cancers, including breast and colorectal cancer, where surgery is estimated to improve the five year overall survival rate by 56% in breast cancer patients and the three year overall survival rate by 36% in colorectal cancer patients [3.84].

Finally, surgery can be used palliatively to address symptoms due to cancer progression or symptoms secondary to prior cancer treatments. Examples of palliative surgery include reconstructive surgery to improve the function and quality of life, operative management of intestinal obstruction or creation of a tracheostoma for airway management. Even in resource constrained settings,

where many patients present with advanced disease and may not be candidates for curative surgery, palliative surgery can play an important role in minimizing suffering. In HICs, approximately 14–20% of palliative care cases require surgical intervention [3.84]. Given the higher rate of patients presenting with advanced disease in LMICs, the need for palliative surgery is probably higher. An overview of the surgical oncology process is given in Box 3.3.

Given the numerous potential roles that surgery can play in cancer care, it is estimated that in 2030 an estimated 17.3 million patients, or 80% of all cancer patients, will need surgery as part of their care [3.84]. In LMICs, the most common indications for surgery will be breast, head and neck, oesophagus, stomach, lung, cervix and prostate cancer. Many of these patients will need more than one surgical procedure, leading to an estimated 45 million procedures that will need to be performed in 2030. However, less than 5% of patients in low income settings and only approximately 22% of patients in middle income countries have access to safe, affordable and timely oncologic surgery [3.84]. Owing to this lack of access, it has been estimated that in 2015–2030 undertreated surgical cancers will result in a cumulative gross domestic product loss of US \$12 trillion globally, which correlates with an annual gross domestic product loss of 0.5–1.5% [3.85]. Given the vast chasm between the need for and availability of oncologic surgery, it is imperative that cancer centres establish a surgical oncology service.

BOX 3.3. OVERVIEW OF THE SURGICAL ONCOLOGY PROCESS

- (1) *Clinical evaluation of the patient.* All patients have to be evaluated in a multidisciplinary setting, if possible [3.1]. This has to involve assessment and staging of the tumour by a physical examination, evaluation of the available imaging and a decision on whether surgical intervention is indicated.
- (2) *Therapeutic decision making.* Goals of care (curative or palliative) have to be determined according to the clinical context and the patient's wishes. If surgery is indicated and desired, a decision needs to be made as to how surgery can be sequenced with other treatment modalities, if they are indicated. All patients have to be informed about the risks and benefits of surgery and asked for their consent to proceed with treatment.
- (3) *Patient optimization.* All reasonable efforts need to be made to optimize the patient prior to surgery to reduce the risk of surgical complications [3.86–3.88]. This may include tobacco cessation, weight loss, nutrition and management of co-morbid conditions such as diabetes, hypertension or anaemia.
- (4) *Pre-operative work-up.* Relevant pre-operative testing, which may include a complete blood count (CBC), coagulation studies, blood cross-matching,

metabolic panel, pregnancy test, chest X ray and electrocardiogram, needs to be ordered, as appropriate.

- (5) *Anaesthesia.* The anaesthesiologist has to review the patient's medical history, allergies, current medication list, prior experience with anaesthesia, etc., to identify any potential anaesthesia risk factors. The patient's airway has to be assessed. The patient's weight, height and body surface area need to be confirmed as being consistent with the intended anaesthesia dosing.
 - (6) *Pre-operative checklist.* Confirm the patient identity, planned procedure, surgical site, anaesthesia plans, patient allergies, antibiotic prophylaxis and any other patient specific concerns.
 - (7) *Surgery.* Everyone present in the operating room has to follow appropriate sterile techniques. The patient is positioned and draped appropriately for the planned procedure. Surgery is performed by the cancer surgeon and any other subspecialists, as indicated.
 - (8) *Pathology.* A plan is needed for any anticipated surgical specimens and whether intra-operative pathology consults will be needed. Surgical specimens need to be enclosed in an appropriate container with the indicated media/fixative and labelled with the patient identification, date, specimen source, specimen site, etc. Appropriate pathological and molecular testing need to be ordered and the specimen needs to be transported to the pathology department.
 - (9) *Post-anaesthesia care.* The patient has to be observed in a post-anaesthesia care unit. Fluids and medications need to be given as needed to minimize any post-anaesthesia side effects or post-operative pain. Once patients have recovered from the anaesthesia, they may be transported or discharged from the post-anaesthesia care unit, as appropriate.
 - (10) *Post-operative care.* Patients have to be educated about wound care, new medications and any relevant post-operative restrictions. Follow-up needs to be scheduled with the operating surgeon and multidisciplinary care team, as appropriate.
 - (11) *Rehabilitation:* Patients have to be scheduled for physical therapy, occupational therapy and other supportive services, as indicated.
 - (12) *Follow-up evaluation.* All patients need routine post-operative follow-up with the operating surgeon to evaluate post-operative wound healing, monitor for recurrence and manage any late toxicity from treatment. All recurrences need to be discussed in a multidisciplinary setting to determine the best possible treatment plan and to counsel the patient appropriately. Appropriate follow-up will be determined by the tumour type and resources available at the cancer centre.
-

3.4.2. Surgical oncology as part of multidisciplinary care

Surgical oncologists have to be integrated effectively into multidisciplinary care teams and be involved in the screening, diagnosis, staging and treatment of cancer patients to reduce the interval between patient presentation and surgical intervention [3.1]. Shortening this interval can improve the possibility of delivering curative therapy and reduce the risk of disease progression and its associated complications. For this reason, oncological surgeons have to play a role in the development of cancer screening programmes. These programmes for common cancers, such as breast cancer and colorectal cancer, may lead to patients presenting with early stages of cancer, when definitive surgical management is feasible, thus increasing the need for surgical oncology services. This multidisciplinary integration requires close coordination of medical services, as simple things, such as a diagnostic biopsy, need organized planning and communication between surgery, imaging and anatomical pathology.

Many medical services are needed to perform safe and effective surgery [3.89]. For instance, accurate pre-operative care may include a registered dietician or physical therapist who can assist in optimizing the cancer patient's overall health, functional status and nutrition prior to surgery [3.86–3.88]. Pre-operative planning involves radiology and anatomical pathology services, which provide information on tumour involvement based on imaging and/or endoscopy, as well as an understanding of the tumour biology from the pathology review. Peri-operative care relies on safe anaesthesia tailored to the operation, as well as nursing care responsive to the potential complexities of an operation and the potential co-morbidities of individual patients. Safe blood products need to be available for safe surgery [3.65]. Speciality nursing, physical therapy, occupational therapy and nutritional support have a great impact on peri-operative outcomes and recovery. Given the interconnectedness of surgery with other specialities, it is paramount that oncology surgeons be involved in multidisciplinary care teams.

3.4.3. Human resources

The core surgical oncology team consists of a surgical oncologist (or an equivalently trained, accredited surgical professional), an anaesthesiologist, a scrub nurse and a surgical technologist. This team is further supported by radiologists, pathologists, pharmacists, physical therapists, occupational therapists and dieticians. To deliver safe and effective cancer surgery, a country's educational and health care systems have to train and retain adequate numbers of these key individuals, as well as the relevant technicians for these fields (Table 3.7 [3.90–3.93]). Retention requires an adequate salary, supportive

working conditions and opportunities for professional development that enhance specialized training. Specialized training in cancer surgery generally requires dedicated time at tertiary referral hospitals, either in-country or at regional or global cancer centres.

Surgeons and other health care providers involved in cancer surgery have to receive evidence based medical training in professional educational institutions and post-graduate settings. Additional training is necessary for surgeons operating on children with cancer. There is currently significant unmet need for paediatric cancer patients, as 80% of paediatric cancer patients live in LMICs. Approximately 20% of all paediatric cancer patients admitted to these hospitals need surgery at some point during their inpatient care. However, many of these patients are unable to get the surgeries that they need because of a lack of specialized care [3.84, 3.94].

TABLE 3.7. PUBLICATIONS ON CAPACITY BUILDING RELATED TO HUMAN RESOURCES

Field	Topic	Title	Reference	Average duration ^a
Surgical oncologist	Global surgical oncology curriculum	Global Curriculum in Surgical Oncology	[3.90]	~10 years
	Research literacy	Global Curriculum in Research Literacy for the Surgical Oncologist	[3.91]	~10 years
	Designing a surgical oncology curriculum	Designing a National Curriculum to Advance Surgical Oncology in Mozambique: A Delphi Consensus Study	[3.92]	~10 years
Anaesthesiologist	Creating an anaesthesia curriculum	Anesthesia Curriculum: Design for the Global Setting	[3.93]	~4 years

^a For completion of the minimum competencies to work independently in the clinic (considering the starting point).

3.4.3.1. *Surgical oncologist*

Surgical oncologists are responsible for all aspects of a surgical procedure, including the pre-operative assessment, determination of whether and what kind of operative management is indicated, intra-operative decision making, maintaining a sterile field, post-operative care and post-operative follow-up. This requires a detailed knowledge of human anatomy and imaging, mastery of relevant surgical procedures and the ability to manage a team inside and outside an operating room. At least one surgical oncologist has to be hired for every 200–250 surgical procedures performed annually [3.84].

In order to develop the knowledge base and procedural proficiency needed to safely operate on cancer patients, most surgical oncologists undergo a minimum of ten years of surgical training. The Lancet Oncology Commission has identified 277 procedures relevant to a surgical oncologist and has graded these procedures on the basis of complexity level, as well as which procedures can be performed by a general surgeon and which procedures require specialist training [3.84]. These procedures range from a simple needle biopsy to more complex procedures, such as a Whipple procedure. Surgical oncologists have to practice within their training and actively seek out opportunities to gain additional experience through fellowships and by visiting tertiary care centres.

3.4.3.2. *Anaesthesiologist*

An anaesthesiologist is a physician with specialized training in critical care and the administration of anaesthesia. Anaesthesiologists assess a patient prior to a procedure, administer medications enabling a surgical procedure to be performed, continually assess the patient during the procedure and manage the patient during recovery from anaesthesia. Additionally, anaesthesiologists may have specialized clinics focused on the management of cancer related pain. Anaesthesiologists generally require four years of speciality training, and approximately 20 anaesthesiologists are needed for every 100 000 people in a given community served by a cancer centre. Resources related to anaesthesiology training are offered by the International Anaesthesia Research Society and the World Federation of Societies of Anaesthesiologists.

The World Federation of Societies of Anaesthesiologists has outlined three levels of training through which different centres can progress with regard to anaesthesia capabilities [3.95]. The lowest level is called Category A, followed by Category B, and finally the highest level, Category C. At Category A centres, anaesthesiologists can deliver anaesthesia for common ‘Bellwether’ procedures such as a laparotomy and a much wider range of emergency and essential operations. Category B centres can provide anaesthesia for relatively

uncomplicated patients and have some subspeciality training, such as paediatric anaesthesia, pain management and training in non-clinical areas, such as research and teaching. Finally, Category C centres have specialized anaesthesiologists capable of managing complicated cases and delivering peri-operative and critical care. Some cancer centres may have teams composed of physician anaesthesiologists and non-physician anaesthesia providers.

3.4.3.3. *Scrub nurse*

Scrub nurses are trained to assist in ensuring that the appropriate sterile technique is used in the operating room, preparing the operating room for surgical procedures and ensuring that the appropriate tools and resources are available for a procedure, and perform other duties under the guidance of the surgical oncologist. Scrub nurses may also assist in the peri-operative management of patients or in the post-anaesthesia care unit. Scrub nurses do not frequently receive oncology specific training.

3.4.3.4. *Surgical technologist*

Surgical technologists share many of the same responsibilities as scrub nurses. However, they do not assist in the peri-operative management of surgical patients.

Surgical oncology encompasses a variety of surgical procedures that require different surgical training and infrastructure according to the complexity of the procedures performed. A publication of The Lancet Oncology Commission identified 277 different surgical procedures, 222 of which were considered major resections requiring a specialist or gynaecological surgeon, required to treat cancer across six complexity levels [3.84]. Ideally, a cancer centre needs to be able to perform basic curative and palliative surgical procedures, such as lumpectomy, mastectomy, hysterectomy and wide local excision of various lesions.

At facilities with minimal surgical capacity, surgeons and obstetricians/gynaecologists must have the appropriate training and resources to perform biopsies of abnormal masses, including lesions of the skin, breast, oral cavity, uterine cervix and enlarged lymph nodes [3.84]. Histological materials need to be preserved appropriately, processed swiftly and analysed by pathologists promptly. The individual performing the biopsy needs to ensure that the specimen is handled correctly and that follow-up care has been arranged as indicated. Additionally, these lower level facilities may be able to perform basic palliative procedures, such as tracheostomy, drainage of pleural effusions and repair of non-functioning colostomies. More complex surgical care, such as pancreaticoduodenectomy, oesophagectomy and lung resections,

may be restricted to higher volume facilities with appropriately trained surgeons and more extensive capacity for imaging, critical care, peri-operative nurses, interventional radiology, symptom management and post-operative rehabilitation services. Generally, cancer centres that perform a higher volume of oncological surgeries and provide specialized training for members of the multidisciplinary care team have been associated with more favourable cancer outcomes [3.96].

3.4.3.5. *Equipment*

The anticipated volume and complexity of surgeries performed at a cancer centre are important aspects in planning for a cancer centre's surgical capacity and which accompanying services need to be provided. Several of the medical services listed in the preceding sections (e.g. imaging, anaesthesia, blood banking) need to be in place to ensure that cancer surgery is safe and effective. Additionally, a reliable supply chain for the supplies and instruments necessary for surgery, anaesthesia and hospital care, such as those listed in Ref. [3.31], is required (see Table 3.8).

The organization of a region's cancer care system — namely, how hospitals capable of basic, intermediate and highly complex surgical procedures are distributed throughout a region — has to aim to make access as easy as possible for cancer patients and their families. Multiple studies have demonstrated that increases in distance to diagnostic and treatment facilities are associated with delays in cancer care and abandonment of cancer treatment. To counteract this, the cancer care system needs to consider provision for transportation, lodging and meals for patients and family members, and may include a modest stipend to replace income lost from time away from normal employment. In addition, the use of mobile phone technology, effective communications between different hospitals/clinics regarding individual patients, and patient navigators can help to ensure timely diagnosis and treatment for cancer patients.

Given the extensive list of potential oncological surgical procedures, only a few broad categories of surgical intervention are presented below:

- Open surgery is the traditional approach to surgery and involves making incisions to expose a relatively large aspect of the body to facilitate the intended surgical procedure.
- Minimally invasive surgery is a technique that does not utilize a large incision with the aim of reducing the recovery time. Minimally invasive surgical techniques frequently involve creating small incisions through which a small flexible tube can be inserted; the tube contains a light and can accommodate various surgical instruments that facilitate the intended

surgical procedure. Examples of minimally invasive surgery include laparoscopy, endoscopy and bronchoscopy.

- Robotic surgery involves using a mechanical arm consisting of various surgical instruments and a camera, which are controlled by the surgeon. Robotic surgeries are often considered a type of minimally invasive surgery and share the same goal of reducing recovery time.
- Debulking surgery is performed with the aim of removing a portion of a cancerous tumour. This can be done palliatively or as part of a definitive treatment course with radiation and or chemotherapy.
- Palliative surgery involves a surgical procedure with the aim of improving a patient's quality of life but not necessarily extending the patient's life or curing the cancer. Examples of palliative surgery include creation of a stoma, fixation of a pathological fracture or palliative mastectomy.
- Restorative surgery is performed to improve a patient's function or cosmesis. One of the most common restorative surgeries is breast reconstruction after mastectomy.
- Diagnostic/staging surgery is performed to get tissue to facilitate a diagnosis and/or assess the extent of a patient's cancer so the patient can be accurately staged.
- Cryosurgery uses extremely cold temperatures to kill cancer cells. Cryosurgery has been utilized to treat skin, prostate, liver and cervical cancers.
- Laser ablation uses beams of light to kill small cancers while causing minimal damage to surrounding tissue. Laser ablation has been used for prostate cancer, intracranial metastasis and various other cancers.

3.4.4. Teaching, research and clinical trials

3.4.4.1. Training programmes

Training programmes play an important role in basic and advanced surgical centres, as even common procedures, such as fine-needle aspiration biopsies, can be improved with the use of directed training programmes. Such programmes have previously been shown to reduce the likelihood of missing the target lesion during a fine-needle aspiration biopsy from 25% to 2% [3.100]. It is recommended that all surgical oncologists undergo advanced training in surgical oncology following their general surgical training and be certified or accredited as a surgical oncologist, whenever possible. Training and certification requirements vary between countries across the globe. The Society of Surgical Oncology and the European Society of Surgical Oncology have jointly published guidelines for a global curriculum of surgical oncology [3.101, 3.102]. This curriculum

TABLE 3.8. PUBLICATIONS ON CAPACITY BUILDING RELATED TO EQUIPMENT

Modality	Topic	Title	Reference
Equipment	Determining essential equipment	WHO List of Priority Medical Devices for Cancer Management	[3.31]
Quality assurance	WHO guidelines for safe surgery	WHO Guidelines for Safe Surgery: Safe Surgery Saves Lives	[3.89]
General	Resource stratified approaches for developing cancer services and building capacity	Cancer: Disease Control Priorities, 3rd edn, Chapter 13: Surgical Services for Cancer Care	[3.97]
Robotic surgery	Implementing a robotic surgery service	Best Practices for Robotic Surgery Programs	[3.98]
	Robotic surgery training	Utilising the Delphi Process to Develop a Proficiency-based Progression Train-the-trainer Course for Robotic Surgery Training	[3.99]

includes a focus on general oncology, pre-, peri- and post-operative surgical care, management of specific malignancies and core competencies ranging from holistic patient care to operative skills.

Because there is a dearth of surgical oncology specialists in many LMICs, general surgeons and gynaecologists who do not have formal training in oncology can participate in shortened training programmes to gain the skills needed to carry out diagnostic and basic and intermediate level surgical procedures. There is a direct relationship between national income level and the presence of locally available fellowships for specialized cancer training, and many LMICs need to rely on international collaboration for such specialized training. A national workforce strategy linked to a labour market analysis needs to be used to ensure that an adequate number of cancer health care professionals are trained to the full scope of their practice and retained in order to scale up treatment capacity at cancer centres (Table 3.9 [3.84]). In addition, Fig. 3.1 shows the framework for scaling up surgical and gynaecological cancer services in cancer centres.

3.4.4.2. *Research*

Only 1.3% of the annual global cancer research budget supports cancer surgery despite the significant role that it plays in cancer care [3.103]. Despite this lack of funding, surgeons and other health care providers involved in cancer care need education in professional schools and post-graduate settings on the principles of clinical research and evidence based medicine. Cancer surgeons have to also have the opportunity to pursue additional training in designing, conducting and analysing clinical research, including health services research, implementation science and prospective clinical trials. The health care system, both public and private, has to support clinical research in the public's interest across the cancer continuum. Surgeons have to play an active role in clinical research, whether addressing surgical questions, questions on optimal multidisciplinary care for cancer patients or questions on symptom management and cancer care delivery.

3.4.5. **Quality assurance**

Providing high quality surgery not only benefits patients but also lowers health care costs, as inadequate surgeries, such as incomplete resections, may require reoperation or surgical revision. QA requires prospectively collecting standardized quality metrics, as well as an evaluation of how clinical practice adheres to guidelines for cancer diagnosis, treatment and symptom management. Guidelines may be national, international or developed by medical professional societies. Commonly tracked metrics include the time from biopsy to pathological diagnosis, the time from diagnosis to definitive surgical treatment and the time from surgery to the initiation of adjuvant therapy [3.65]. Metrics evaluating the quality of cancer specific surgeries may include lymph node evaluation, tumour margins, success in removing all gross tumours, success of organ sparing procedures and incidence of post-operative infections. Standards of synoptic reporting have been developed for imaging, pathology and surgery.

QA needs to be introduced through routine conferences on morbidity and mortality that allow for review of any peri-operative complications as well as provide an opportunity to identify system and process factors that contributed to surgical complications. It may also take other forms, such as using checklists for standardized surgical procedures or clinical audits. Within a surgical department, it is necessary to identify a surgeon responsible for promoting QA measures and implementing evidence based quality standards, such as a safety timeout before and after an operation [3.65]. Cancer centres have to routinely assess quality of cancer care prospectively and retrospectively through audits.

TABLE 3.9. SURGICAL ONCOLOGY SERVICE LEVELS AND REQUIREMENTS SPECIFIC TO TECHNOLOGY AND TRAINING

Level of cancer centre	Technologies needed	Human resources needed	Surgical oncologist competencies needed
Level 1	Imaging, laboratory medicine, anaesthesia, blood banking, pre- and post-operative care, critical care, nursing, anatomical pathology, symptom management and rehabilitation	General surgeons, obstetricians and/or gynaecologists, anaesthesiologists, nurses	Biopsies of abnormal masses (e.g. skin, breast, oral cavity, uterine cervix, lymph nodes), basic palliative procedures (tracheostomy, drainage of pleural effusions, repair of non-functioning colostomies) [3.84]
Level 2		In addition to Level 1, palliative care teams and peri-operative nursing services	Intermediate complexity surgeries such as lumpectomy, mastectomy, hysterectomy and wide local excision [3.84]
Level 3	Advanced imaging modalities, minimally invasive surgery, advanced critical care services, interventional radiology, post-operative rehabilitation services	In addition to Level 2, specialized physician anaesthesiologists, specialized radiologists, specialized pathologists, rehabilitation services, critical care services and peri-operative nursing services	Advanced surgeries such as pancreaticoduodenectomy, oesophagectomy and lung resection [3.84]

3.5. ONCOLOGICAL IMAGING AND NUCLEAR MEDICINE

3.5.1. Rationale for oncological imaging and nuclear medicine

Medical imaging and nuclear medicine are integral to the diagnosis, accurate staging, medical decision making and overall clinical management of cancer patients. Oncological imaging is of particular importance for the delivery of RT, given that it enables identification of treatment targets, and for surgical planning so that surgeons can accurately visualize patient anatomy and the extent of disease before a surgical intervention. Given the key role that imaging plays in the management of cancer patients, it is not surprising that some reports describe

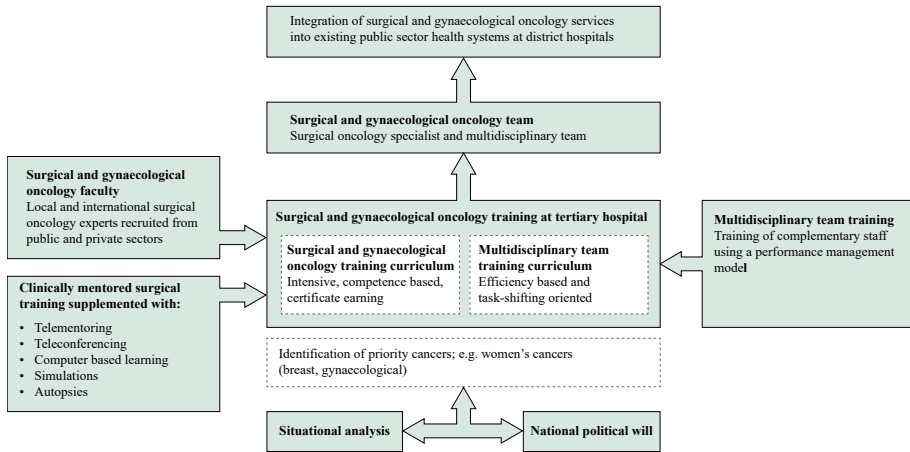


FIG. 3.1. Conceptual framework for scaling up surgical and gynaecological cancer services in resource limited settings (adapted with permission from Ref. [3.84]).

that in certain countries, up to 23% of all CT scans are performed for oncological indications. This reliance on oncological imaging makes it a crucial building block in the multidisciplinary infrastructure of a cancer centre [3.104].

Although it is impossible to quantify the myriad of clinical benefits associated with cancer imaging, key statistics exist. For example, clinical trials have shown that mammography screening programmes can reduce the relative risk of breast cancer mortality by approximately 20% when implemented in countries with strong health systems [3.105]. Similarly, the National Lung Screening Trial, also conducted in a country with a strong health system, showed that low dose CT screening of individuals at high risk for lung cancer reduces the relative risk of lung cancer specific mortality by 20% and all-cause mortality by 6.7% [3.106]. While these studies in high income countries illustrate the benefits of screening modalities requiring medical imaging in patients without a known cancer diagnosis, there is also a role for surveillance imaging in patients who have completed their cancer treatment or have metastatic disease. In the United Kingdom for example, 75% of patients diagnosed with colorectal cancer could be expected to enter a surveillance programme. This surveillance programme may include liver imaging, since identification of isolated hepatic metastases allows patients to undergo a resection of these metastases, which is associated with an improved five year survival rate [3.107].

In addition to these clinical benefits, a recent model that assessed the cost of a global scale-up of imaging revealed that a US \$6.84 billion investment would be required between 2020 and 2030, but that this would yield an economic benefit of US \$1.23 trillion [3.108]. That yields a net return of US \$179.19 for

every US dollar invested in imaging. This same report also modelled how up-scaling global radiology services would impact the mortality rates of 11 cancers and found that it would avert 3.2% (2.46 million) of all cancer deaths between 2020 and 2030. Similar benefits were seen when investments were made in treatment and imaging for paediatric cancers [3.94].

3.5.2. Oncological imaging and nuclear medicine as part of multidisciplinary care

Medical imaging and nuclear medicine are pillars in evidence based clinical management and critical to achieving the best outcomes for each patient. Clinical cancer management algorithms feature imaging centrally throughout the care continuum, including screening, work-up and diagnosis, staging, treatment planning, assessment of treatment response, image guidance for interventions and evaluation of complications or co-morbidities. For example, image guidance renders biopsies not only safer, but also more accurate and more cost effective. Imaging guides the placement of central venous catheters, which are required for the administration of essential medicines such as antineoplastic agents. Imaging can similarly be used to direct minimally invasive tumour ablations (e.g. via radiofrequency). Moreover, molecular imaging has progressed rapidly, making the diagnostic and therapeutic applications of nuclear medicine commonplace in high resource settings.

The National Comprehensive Cancer Network (NCCN) of the USA has published evidence based, algorithmic guidelines for the management of cancer by anatomical site and pathology. For 19 of the most common cancer indications, the NCCN has formulated resource stratified guidelines for a variety of contexts, namely those with either ‘basic’, ‘core’ or ‘enhanced’ resources available [3.109]. Taking the example of breast cancer and the NCCN directives, the ‘basic’ setting recommends diagnostic mammography and ultrasound, while the highest resource settings can include the options of CT, MRI, PET/CT and bone scans [3.109].

3.5.3. Human resources and equipment

The core imaging team consists of radiologists, nuclear medicine physicians, medical physicists and various imaging technologists with training specific to the imaging modality or modalities that they handle. Additionally, IT specialists contribute to the management of the imaging infrastructure and vast amounts of patient data collected within an imaging department (see Table 3.10).

TABLE 3.10. PUBLICATIONS ON CAPACITY BUILDING RELATED TO HUMAN RESOURCES

Field	Topic/Title	Reference	Average duration ^a
Radiologist	Quality improvement training/ Implementing a Radiology Residency Quality Curriculum to Develop Physician Leaders and Increase Value for Patients	[3.110]	~3–5 years
Nuclear medicine physician	Training Curriculum for Nuclear Medicine Physicians	[3.111]	~3–5 years
Medical physicist	Clinical training for medical physicists specializing in diagnostic radiology	[3.12, 3.47]	~2 years
	Clinical training for medical physicists specializing in nuclear medicine	[3.48]	~2 years

^a For completion of the minimum competencies to work independently in the clinic (considering the starting point).

3.5.3.1. Radiologist

Radiologists are responsible for interpreting medical imaging and performing or assisting in image guided procedures. To accomplish this, they need to have extensive knowledge of human anatomy and of the imaging presentation of various disease processes. A cancer centre needs to have well trained radiologists, ideally with specialized training in the different subspecialized fields of radiology. Board certified radiologists generally undergo a minimum of three years of radiology training (average three–five years) after medical school, which emphasizes conventional general radiology including plain X ray, fluoroscopy, breast imaging, ultrasound, CT and MRI. An additional one–two years of specialized training (fellowship) may be beneficial for radiologists subspecializing in, for example, breast imaging, musculoskeletal imaging, interventional radiology, chest imaging, abdominal imaging and neuroradiology. Radiologists have to be trained at tertiary care centres where they are exposed to a broad variety of disease pathology and imaging modalities. Each country has different rules regarding the licensing and certification of general and specialized radiologists. Therefore, in settings with a scarcity of trained radiologists, it

is important to take into account the time required to train a radiologist when considering future staffing needs.

3.5.3.2. *Nuclear medicine physician*

Nuclear medicine physicians specialize in the use of radioactive materials, often called radiopharmaceuticals, to diagnose and treat disease. This requires the same skill set and knowledge base described in Section 3.5.3.1, as well as specialized training in nuclear medicine. At present, there is a wide variety of training paths available worldwide for physicians practicing nuclear medicine, ranging from a three month rotation as part of their general radiology training to an additional one–two years of specialized fellowship training in nuclear medicine. In some countries, nuclear medicine residency entails a separate three year programme (averaging three–five years). This lack of standardization among training programmes leads to significant heterogeneity in the quality of training received by nuclear medicine specialists worldwide. Consequently, a recommended basic minimum training requirement for nuclear medicine as a medical speciality is needed to ensure the safety and quality of clinical practice.

One effort to standardize the training of nuclear medicine physicians was led by the IAEA through Ref. [3.111], which illustrates the competencies that a nuclear medicine trainee needs to master, as drawn from the European Union of Medical Specialists syllabus for post-graduate specialization in nuclear medicine, the American Board of Nuclear Medicine, the Royal Australasian College of Physicians, the Joint Royal Colleges of Physicians and the Asian Board of Nuclear Medicine, among others. The goal of the curriculum presented in Ref. [3.111] is to create an international training standard for nuclear medicine physicians.

3.5.3.3. *Imaging technologist*

Imaging technologists are responsible for assisting in positioning the patient and performing or assisting in diagnostic imaging procedures. They usually acquire the images. Imaging technologists may undergo specialized training for a specific imaging modality or, more commonly, multiple imaging modalities. However, they do not undergo oncology specific training alone, but learn protocols for certain oncological imaging applications as part of overall imaging to evaluate a spectrum of pathologies not limited to cancer. Nuclear medicine technologists represent a specialized group of imaging technologists. They may prepare or administer radiopharmaceuticals in addition to performing the same functions as an imaging technologist.

The training required for imaging technologists and nuclear medicine technologists varies between countries. The IAEA has created a distance

assisted training for nuclear medicine professionals on-line, which can be used by nuclear medicine technologists and emphasizes the practical application of nuclear medicine procedures in a clinical setting. It consists of a comprehensive on-line set of training materials, available in English and Spanish, providing easy to understand descriptions of nuclear medicine procedures and the science that underlies them. These materials are available either as an open access course or as part of instructor led courses (which include a formal assessment and certification).

3.5.3.4. Medical physicist

Medical physicists have previously been discussed under the radiation oncology key discipline subheading, but radiology and nuclear medicine also need medical physicists specialized in these areas [3.11]. Briefly, medical physicists have expertise in the physical and technical requirements of installing and utilizing medical imaging instruments, as well as radiation safety and protection. Medical physicists also serve a vital role in QC and QA measures in nuclear medicine, such as verifying that appropriate radiation doses are administered to patients and monitoring personnel radiation exposure. Having trained medical physicists is essential to the proper functioning and QA of radiation technologies in a cancer centre that offers medical imaging, nuclear medicine services and RT. The training of a medical physicist involves post-graduate academic education in medical physics, followed by a structured and supervised hospital based training programme for developing practical competencies [3.12, 3.47, 3.48].

3.5.3.5. Information technology specialist

IT specialists, or data managers, manage all the information generated in an imaging division. This includes the storage and delivery of data to patients and referring physicians in a secure and proper way. The necessity for, and training of, IT specialists is dependent on the complexity of the digital system used. Digital Imaging and Communications (DICOM) format images are memory intensive. A detailed description of Radiology Information Systems (RIS), Picture Archiving and Communications Systems (PACS) and hospital information systems (HISs) can be found in Chapter 5 (see Section 5.3); these are essential, interlinked IT technologies in modern comprehensive health care, including in cancer centres.

Running an imaging department requires planning for future personnel needs, including medical doctors specialized in radiology and nuclear medicine. The IAEA can provide consultations and training fellowships for Member States (if needed) in compliance with the countries' policies to ensure that

these specialized physicians are being trained at a rate required to meet future demand. The sophistication of such training programmes varies according to the complexity of the planned cancer centre and the expected patient base. Although residency curriculums in radiology and nuclear medicine vary by country, minimum training periods after medical school are, respectively, three years and two to three years.

As the field of radiology has grown dramatically, it is now also common to see subspecialized imaging physicians, such as body radiologists, neuroradiologists, musculoskeletal radiologists, breast radiologists and others. However, for less complex facilities, a general radiologist and nuclear medicine physician with comprehensive training will be capable of handling an imaging division broadly, but perhaps not uniquely, devoted to cancer imaging. At more advanced cancer centres, the aforementioned imaging and nuclear medicine specialists will serve as members of a trained MDT to meet the needs of a cancer centre, in concert with radiographers/technologists, sonographers/ultrasound technologists, nurses, medical physicists, engineers and IT personnel.

3.5.3.6. *Equipment*

When establishing or increasing the capacity of a radiology and nuclear medicine department at a cancer centre, it is crucial to accurately plan for future needs. Existing guidelines help to develop more accurate action plans (Table 3.11) that can help to define the path and timeline for capacity building of radiation medicine professionals. While the complexity and sophistication of new imaging equipment will depend on the resources available, it is also important to account for the local epidemiological cancer landscape by performing a needs assessment. Mapping this epidemiological landscape and calculating the estimated number of patients that the cancer centre will serve is the first step towards planning a comprehensive imaging facility. These estimates can help to determine the number and types of imaging instruments that are needed to best serve the population.

The IARC, which is part of WHO, publishes data from national cancer registries and fact sheets for each Member State in the Global Cancer Observatory (GLOBOCAN)¹. If such data indicate that a particular country has a higher incidence of, for example, breast cancer compared with other types of cancer, specific breast imaging tools (e.g. mammography) in that country need to be prioritized. However, some of these imaging resources will also be needed for patients without cancer. Cancer patients may derive minimal benefit from a cancer centre's radiology service if there are unreasonable wait times for necessary

¹ <https://gco.iarc.fr/>

scans owing to imaging resources being overburdened by the combined needs of oncological and non-oncological patients. For this reason, non-oncological imaging indications need to be considered when determining what imaging resources are needed. Tools have been developed to perform a needs assessment, such as a radiology readiness assessment questionnaire developed by RAD-AID International [3.112]. After each survey and resulting facility improvement, the assessment is repeated to plan logical subsequent steps and to learn from the victories and challenges of prior steps.

It is imperative to match the number and types of imaging modalities to be procured to the budget available and the qualifications of trained staff. The budget allocated also has to address other aspects, such as customized construction (including space structuring, air conditioning, IT infrastructure, quality and safety assurance equipment, etc.). The simpler the chosen imaging modality unit to be installed, the easier licences and the lower the costs will be. Another consideration is to reserve some long term funds for maintenance and continued QA, especially for after the end of the equipment warranties and software licenses. This task needs to be performed by an administrative team capable of formulating a detailed business plan of the minimal investments needed to meet estimated clinical demands. The cost of equipment for a particular imaging method needs to match the needs and budget of the centre. For example, a basic analogue (as opposed to digital) X ray unit could be a reasonable purchase for a very low income setting. A four or six slice CT may work in certain resource constrained settings for all-purpose applications, with no need for immediate acquisition of a 64 or greater slice CT. However, such decisions depend on the business plan of a particular imaging division. For example, the centre could use its imaging modalities for the provision of diagnostic services beyond the realm of oncology, especially if the centre is in a region where there is little or no business competition and patients have limited access to imaging services. This approach would help to reduce costs and generate additional revenues to support maintenance and upgrades of the division.

Given the risk of unexpected post-procurement costs, not every technology needs to be implemented upfront and, according to the budget available, administrators could start with basic investments and leave space for growth. For example, starting with one X ray unit, as well as ultrasound, mammography and CT equipment, could be a basic, economical starting point for a lower budget cancer centre. However, if the budget allows, it would be advisable to install MRI and basic to more sophisticated nuclear medicine services. As it becomes feasible, interventional radiological facilities and other advanced imaging modalities can be introduced to better serve the needs of a growing cancer centre.

The main types of imaging are plain or conventional radiography (X ray), mammography, ultrasound (also known as sonography or echography), CT, MRI,

angiography, and nuclear medicine and molecular imaging (see list of major imaging modalities below). The footprints of these imaging modalities usually depend on the extent and level of instruments to be installed and need to take into consideration the space available and the changing needs of a cancer centre due to expected growth in the future. The imaging health care companies in the market normally give full support for proper site planning to ensure the proper functioning of the imaging instruments sold by them. Nevertheless, it is prudent to have a qualified team of local clinical engineers to supervise all construction, if possible. The major imaging modalities and their clinical relevance are as follows:

- Plain radiography (X rays) units generally cost less than other imaging modalities and are necessary at every cancer centre. They are relatively cost effective for hospitals and for third party funders (especially in cases where a CT scanner is not needed), have a relatively small structural footprint and do not require complex planning. X ray units can assess various anatomical sites such as bones, chest/lungs and the abdominopelvic region. They are easily operated but are less accurate than ultrasound and CT in some settings.
- Fluoroscopy uses plain X rays to acquire real time images in a moving, video clip type fashion. A simple fluoroscope has an X ray source and a fluorescent screen, between which the patient is placed. Fluoroscopy is a key modality for many image guided procedures performed by interventional radiologists.
- Mammography is key to breast cancer screening programmes, assessment of palpable breast masses and for guiding stereotactic biopsies of suspicious masses in resource appropriate settings. Mammography units have a small footprint and do not require complex construction. A basic cancer centre would benefit from at least one unit and anticipate more according to local demand.
- Ultrasound, sonography or echography is used in oncology for screening, staging, monitoring for recurrence, biopsy guidance and treatment interventions. It uses sound waves, rather than ionizing radiation, to image. A wide range of instruments and transducers are available, from very basic low cost systems to more sophisticated devices. Ultrasound has proven clinical value for many cancer subtypes, including, but not limited to, breast, thyroid, kidney, pancreatic, uterine, ovarian, adrenal, gallbladder, spleen and liver cancers. While ultrasound has a small footprint and simple infrastructure, it nonetheless requires skilled physicians and ultrasound technologists/sonographers.
- CT is essential for cancer screening, as well as for diagnosis, staging, assessing treatment response, guiding therapy and biopsies, and monitoring

for recurrent disease. Sophisticated multidetector CT (MDCT) scanners can have from a few detectors to 320 detectors. For the majority of oncological applications, a lower cost unit with at least 16 detectors will be sufficient to cover imaging indications for brain, head and neck, chest, abdomen, pelvis, extremities and bone and soft tissue tumours. The number of CT units will depend on the size of the cancer centre, its complexity and the number of patients (including outpatients) to be covered. One MDCT scanner can perform at least 1500 to 2000 examinations per month when using extended business hours for running time. CT (including MDCT) has a larger footprint than X rays, mammography and ultrasound [3.65].

- MRI and CT imaging complement each other and have different indications, benefits and downsides. MRI scans take longer to acquire compared with a CT scan and require a patient to remain still. Therefore, patients who are very young, claustrophobic or experiencing pain or other bothersome symptoms may not be able to tolerate an MRI scan. This type of scan uses magnetism, rather than ionizing radiation, to acquire images. This makes MRIs a preferred imaging modality in paediatric patients under certain circumstances owing to the decreased radiation exposure. However, the magnetism involved in an MRI scan means that some patients with implanted medical devices/metal cannot undergo this type of imaging. MRI scans provide better visualization of soft tissue and thus may be preferred when imaging the central nervous system, head and neck, joints, abdomen and pelvis. For this reason, they are often used to evaluate brain, breast, prostate and gynaecological tumours, in addition to being used to guide biopsies and other procedures performed at these sites. In general, MRI units require a larger footprint and more complex infrastructure, and therefore have a higher cost. The minimum advised magnetic field strength for these machines is 1.5 T. A single state of the art MRI unit can perform approximately 800–1200 examinations a month.
- Angiography is the imaging of the lumen of vessels or organs, often performed using injected contrast. Today, conventional angiography is commonly used for guiding therapy, such as embolization or chemoembolization, catheter placement and special interventional radiology procedures, such as cryoablation and radiofrequency ablation of tumours in complex health systems. Angiography can guide surgery and hybrid therapies in real time. Most diagnostic angiography applications are now addressed by ultrasound, CT and MRI [3.65].
- Nuclear medicine and molecular imaging utilize radiopharmaceuticals that are introduced into patients' bodies prior to image acquisition to generate images or provide treatment. Nuclear medicine and molecular imaging have proven clinical value for image guided procedures such as biopsies,

staging, treatment planning, assessing treatment response and post-treatment surveillance. These techniques use radiation and require complex infrastructure. The footprint is larger than all other imaging modalities owing to the specialist personnel, protected areas for radioactive waste disposal, hot lab (radiopharmacy laboratory to manipulate radioactive materials), clinic rooms for radiopharmaceutical administration, and other designated spaces that are required. The level of sophistication can range from a basic single photon emission computed tomography (SPECT) camera to digital hybrid systems. For nuclear medicine, it is possible to import technetium generators and other radiopharmaceuticals, as long as the local regulatory agencies support it. One SPECT system performs at least 400–500 examinations per month. A single state of the art PET/CT unit can perform about 400–600 examinations per month when using an extended after hours running time and faster acquisition protocols. The IAEA has published guides on establishing a comprehensive nuclear medicine and PET/CT service, including Ref. [3.113], which includes information on the infrastructure and space required, as well as recommended layouts of a comprehensive nuclear medicine and PET/CT service (see Table 3.11).

3.5.4. Teaching, research and clinical trials

3.5.4.1. Training programmes

Training and retaining the personnel necessary to run a radiology service safely and effectively is of the utmost importance, given the reliance of medical, surgical and radiation oncology on imaging for nearly all aspects of patient care. This training may take many forms, including post-graduate training for physicians, local and international fellowships, or on-line lecture series and workshops. Cancer centres have to be involved in training radiologists and nuclear medicine physicians. There are two main challenges to consider before designing a nuclear medicine training programme: first, trainees have different levels of prior knowledge and experience; and second, the training programme needs to involve active clinical practice of nuclear medicine in which a wide variety of procedures are performed. To address these challenges, frequent formative and summative assessments are required. These assessments are based on daily observations, review of reports and other methods of periodical assessments of performance. This type of approach can enable the training programme team to cater to the individual needs of trainees on the basis of their different starting points. Regarding the second challenge, an appropriate duration of the training needs to be set to ensure the inclusion of all essential training

CHAPTER 3

TABLE 3.11. PUBLICATIONS ON CAPACITY BUILDING RELATED TO EQUIPMENT

Modality	Topic/Title	Reference
CBCT	Safe implementation of CBCT	[3.114]
PET	Planning a Clinical PET Centre	[3.113]
	Standard Operating Procedures for PET/CT: A Practical Approach for Use in Adult Oncology	[3.115]
Nuclear medicine	Nuclear Medicine Resources Manual	[3.116]
	Guided Intraoperative Scintigraphic Tumour Targeting (GOSTT): Implementing Advanced Hybrid Molecular Imaging and Non-imaging Probes for Advanced Cancer Management	[3.117]
	QUANUM 3.0: An Updated Tool for Nuclear Medicine Audits	[3.118]
Equipment	Determining essential equipment WHO List of Priority Medical Devices for Cancer Management	[3.31]
Quality assurance	Quality Management Audits in Nuclear Medicine Practices	[3.118]
	PET/CT Atlas on Quality Control and Image Artefacts	[3.119]
	Quality Assurance for SPECT Systems	[3.120]
	Quality Assurance for PET and PET/CT Systems	[3.121]
	Radiation Protection and Safety in Medical Uses of Ionizing Radiation	[3.122]
	Implementation of a Remote and Automated Quality Control Programme for Radiography and Mammography Equipment	[3.123]
	SPECT/CT Atlas of Quality Control and Image Artefacts	[3.124]

TABLE 3.11. PUBLICATIONS ON CAPACITY BUILDING RELATED TO EQUIPMENT (cont.)

Modality	Topic/Title	Reference
	Quality Assurance Programme for Computed Tomography: Diagnostic and Therapy Applications	[3.125]
	Quality Assurance Programme for Screen Film Mammography	[3.126]
	Quality Assurance Programme for Digital Mammography	[3.127]
	Comprehensive Clinical Audits of Diagnostic Radiology Practices: A Tool for Quality Improvement	[3.128]
	COVID-19 Technical Specifications for Imaging Devices: Portable Ultrasound; Mobile Radiographic Digital Equipment; Computed Tomography (CT) Scanning System ^a	[3.129]

^a These specifications, produced by an IAEA–WHO working group on imaging technologies, were multipurpose, not just for COVID-19 but for the most common clinical reasons for imaging referral, including cancer.

Note: CBCT: cone beam CT; CT: computed tomography; PET: positron emission tomography; SPECT: single photon emission CT.

elements, including physics, radiochemistry and relevant pathophysiology for the entire field of nuclear medicine.

A radiologist’s training can be complemented by educational materials available through various global radiology societies. For example, the Radiological Society of North America has created on-line ‘essential courses’ in distinct areas of radiology². The European Society of Radiology (ESR) supports e-learning courses through the European School of Radiology. The ESR’s Education on Demand programme has courses geared for radiologists with varying backgrounds and training levels, including Level 1 (up to three years of training), Level 2 (four–five years of training in general radiology) and Level 3 (subspeciality training), as well as for radiographers (R Level). Other professional societies with on-line educational resources include the Society of

² <https://education.rsna.org>

Nuclear Medicine and Molecular Imaging, European Association of Medicine and the World Federation of Paediatric Imaging.

3.5.4.2. Research

Of particular importance for radiologists and nuclear medicine physicians is participation in implementation research. Currently, most of the research in radiology is performed in HICs. Given the differences in patient populations, cancer aetiologies, molecular markers, average stage of presentation, etc., the data from HICs may not always be applicable to LMICs. Implementation research allows radiologists and nuclear medicine physicians who practice in different settings to translate those findings into their own clinical practice.

3.5.5. Quality assurance

From the first day of establishing an imaging division, QA and monitoring need to be prioritized. One quality metric of particular importance is how well evidence based guidelines are followed with regard to the utilization of the varying imaging modalities. This requires not only training the imaging staff, but also educating referring physicians on the role of the various imaging modalities within the framework of clinical management. There are data to support QA programmes focused on the appropriate use of imaging in cancer patients, leading to reductions in the cost of care while simultaneously improving medical management [3.130–3.132]. These benefits are in part due to a reduction in the number of inappropriate or redundant tests performed, allowing for discontinuation of ineffective therapies and improved treatment planning.

Protocols to guide clinical imaging practices are based on internationally published guidelines. Section 2.3.4 of the WHO Priority List of Medical Devices for Cancer Management lists relevant links [3.31]. MDT meetings to discuss the optimal care of individual patients, particularly complex cases, can also promote education and best practices in the institution. This also applies to routine ‘tumour boards’, where patient cases are regularly presented and discussed, inclusive of pathology slides and relevant medical imaging [3.2].

Often undervalued, but also critical in providing high quality evidence based care, is educating patients and the population that the cancer centre serves about the role of medical imaging in maintaining and improving health. Without appropriate community driven demand, even the most high tech, well intentioned centre cannot achieve its desired health targets. Additionally, patient satisfaction with the services provided will bring prior patients back and attract new patients (Table 3.12).

Clinical audits have been introduced as a QC measure for medical imaging; in Europe, these are mandated by the European Commission (Council Directive 97/47/EURATOM). Comprehensive clinical audits focus on clinical management and infrastructure, patient related and technical procedures, and education and research. ESR published Ref. [3.133] to help to guide centres in performing these audits. Additionally, the IAEA published Ref. [3.128], which includes a structured set of standards, an audit guide to clinical review and data collection sheets for the rapid generation of reports. This publication serves as a guide for imaging facilities wishing to improve their provision of service. Multiple complementary, open access IAEA publications are listed in Table 3.12. As for RT equipment, the American Association of Physicists in Medicine has published documents and protocols to assist in calibrating and performing QA for different imaging modalities [3.134, 3.135].

3.6. PATHOLOGY AND LABORATORY MEDICINE

3.6.1. Rationale for pathology and laboratory medicine

The first step in the management of cancer patients is making an accurate diagnosis. For this reason, all cancer patients benefit from the services provided by a high quality PALM department. PALM represents a group of highly technical medical disciplines that are essential for the screening, diagnosis, staging and surveillance of cancer patients. PALM plays an important role in screening for some of the most common cancers, such as cervical and prostate cancer. Cervical cancer screening involves a Pap smear, which requires the cytology services of a PALM department, and HPV molecular testing. A study from the United Kingdom reported that if everyone in their health care system underwent appropriate cervical cancer screening, cervical cancer specific mortality would decrease by 50%, which highlights the significant impact that PALM services can have on a population [3.136]. Box 3.4 provides an overview of the PALM process.

Although data regarding the overall economic benefit of an investment in PALM are limited, the clinical benefit to patients is clear, as an estimated 65–70% of all medical decisions are made based on PALM testing [3.137, 3.138]. Nevertheless, a report from WHO found that only approximately one in four low income countries have PALM services generally available in-country (defined as being accessible in 50% or more public health care facilities) [3.139]. This limited access to PALM resources has resulted in some hospitals in low income countries performing less than 12% of the diagnostic tests performed by hospitals in middle income countries and HICs [3.140]. This underutilization of critical PALM services may have downstream effects on patient care.

In those LMICs that do have accessible PALM services, these departments may lack the necessary expertise and resources to provide high quality and reliable testing for cancer patients. This can lead to cancer centres having to send tissue and laboratory specimens to an outside centre, potentially delaying the diagnosis and initiation of treatment for patients, which can compromise oncological outcomes. Additionally, if PALM services are available but not

TABLE 3.12: RADIOLOGY SERVICE LEVELS AND REQUIREMENTS SPECIFIC TO MEDICAL IMAGING

Level of cancer centre	Technologies needed	Human resources needed	Radiologist competencies needed
Level 1	Plain radiography (X ray), mammography, single slice CT scan (refurbished) or MDCT with four–six detectors	General radiologists, radiographers, medical physicists qualified in diagnostic radiology	General radiologists capable of interpreting plain radiographs, general ultrasound, CT and possibly MRI
Level 2	Plain radiography, mammography, MDCT (6–64 detectors), MRI, conventional nuclear medicine (SPECT), basic interventional radiology	In addition to Level 1, nuclear medicine physician and medical physicist clinically qualified in all imaging areas	Radiologists with specialization in breast imaging, chest and abdominopelvic, neurological, musculoskeletal and basic interventional radiology
Level 3	Plain radiography, mammography, MDCT (16–320 detectors), MRI, basic and advanced interventional radiology, nuclear medicine including hybrid imaging (PET/CT and PET–MRI).	In addition to Level 2, interventional radiologists qualified to perform a broad spectrum of image guided interventions, nuclear medicine physicians, or radiologists specialized in hybrid imaging and physicians with special qualifications in therapy with non-sealed radioactive probes	Radiologist capable of performing advanced applications in CT, MRI and ultrasound, advanced interventional radiology and hybrid imaging (e.g. PET/CT and PET–MRI)

Note: CT: computed tomography; MDCT: multidetector CT; MRI: magnetic resonance imaging; PET: positron emission tomography; SPECT: single photon emission CT.

reliable, a patient may be misdiagnosed and receive inappropriate treatment, which may cause harm without providing a meaningful benefit, lead to worse outcomes and constitute a waste of limited health care resources.

BOX 3.4. OVERVIEW OF THE PALM PROCESS [3.141]

- (1) *Specimen collection.* Physicians responsible for performing procedures or surgeries collect relevant pathological specimens using the appropriate sampling method and collection protocol.
- (2) *Specimen fixation.* Fixation is a technique that allows the physician who has collected a specimen to preserve it in a state that will enable PALM testing to be performed accurately.
- (3) *Specimen labelling.* After fixation, the specimen needs to be placed in an appropriate container or slide and labelled. This labelling needs to include patient identification (name, date of birth, unique medical identifier number), the date and time of specimen collection and the site of specimen collection.
- (4) *PALM test ordering.* The desired testing needs to be ordered through the appropriate channels, stating the patient identifiers, specimen information, relevant clinical details and test being requested. Physicians can consult with the PALM team to ensure that the appropriate tests are ordered to meet the desired clinical goal.
- (5) *Specimen transportation.* Transportation of specimens will depend on whether there is a PALM services at the cancer centre or they will need to be sent to another testing facility. The specimen will need to be processed and transported according to the testing facilities protocol and in compliance with local regulations.
- (6) *Receipt of specimen.* The receiving testing facility will assess each specimen to ensure that it has not been compromised in a way that could impact testing results (e.g. loss of patient identifying information, broken container, delays in delivery, inappropriate tissue preservation).
- (7) *Accessioning.* The specimen is given a unique identifying code (often a bar code) to enable tracking of the specimen through the PALM system.
- (8) *Specimen processing.* The specimen is processed on the basis of the specimen type and intended test/analysis. For example, a surgical specimen may require gross dissection, tissue processing, embedding, sectioning and staining.
- (9) *Testing and analysis.* After the specimen has been processed, the requested testing or evaluation can be performed. Other pathology specialists available locally or remotely may provide input on whether additional testing has to be performed or assistance is needed in the analysis of specimens.

- (10) *Reporting*. Standardized synoptic reports need to be utilized to ensure that relevant data are consistently reported and to facilitate interpretation of results.
 - (11) *Specimen retention and disposal*. Processed specimens may need to be stored in case additional testing is needed. Specimens need to be retained in compliance with and for the time period specified by local regulating agencies.
-

3.6.2. Role of pathology and laboratory medicine in multidisciplinary cancer care

Although pathologists rarely interact with patients face to face in multidisciplinary clinics, their role on a multidisciplinary cancer care team is indispensable, given the role of PALM in informing medical decision making. A PALM department is composed of multiple specialized subdisciplines that perform distinct tests. The subdisciplines relevant for oncology patients are outlined as follows:

- Haematopathology is responsible for running tests involving the haematopoietic system (e.g. blood cells, bone marrow). Examples of testing performed in the haematology laboratory unit include CBC, cytochemistry and bone marrow biopsies.
- Clinical chemistry is a service concerned with the analysis of bodily fluids for diagnostic and therapeutic purposes. Tests performed in this unit include metabolic testing, protein electrophoresis and immunofixation, assessment of tumour markers and urinalysis. Depending on the technical sophistication of a cancer centre, there may be different levels of automation involved in these tests to best accommodate the unit's workload. However, automated tests are closely monitored and QC measures are in place.
- Histopathology is responsible for preparing and analysing under the microscope tissues and cells that were removed via biopsy, surgery or other procedures. This involves tests such as cytopathology, chromosome pathology and immunohistochemistry. Histopathology units may also perform autopsies.
- Molecular biology services involve diagnostic testing to identify alterations in genes and chromosomes. This can facilitate the diagnosis and prognostic stratification of patients, as well as create opportunities for personalized/precision medicine. Relevant tests performed by a molecular biology unit include polymerase chain reaction (PCR), quantitative reserve

transcription PCR, genomic DNA, RNA sequencing electrophoresis and fluorescent in situ hybridization.

- Microbiology is a service responsible for performing tests to identify infectious disease. This includes testing for bacteria, viruses, fungi and parasites. This is relevant to oncology patients, as a number of cancers have an infectious aetiology (e.g. HPV, Epstein–Barr virus).
- Blood banking may fall under the purview of the haematopathology. This unit is responsible for blood typing and testing for various antibodies. Blood banking is an essential subdivision, as many cancer patients may undergo aggressive surgeries or receive cytotoxic therapies that may cause different types of cytopenia, necessitating supportive blood transfusions.

A cancer centre will likely be composed of all or most of these subdivisions, which may have their own varying levels of technical expertise. However, cancer patients may also suffer from other common health conditions secondary to their cancer diagnosis or as an unrelated co-morbidity. A cancer patient's general health has to be maintained to complete the recommended cancer treatment. This will require that PALM services provide oncology specific services and non-oncological services, such as testing blood, urine and other specimens for evidence of clinically relevant deviations, which may represent organ dysfunction. These services necessitate accurate collection, processing, analysis and interpretation of pathology and laboratory specimens and timely communication of findings. This process from specimen collection to the reporting of results can be organized into three distinct phases: the pre-analytical phase (specimen collection, labelling, preparation and transportation), the analytical phase (specimen processing and performance of tests/analysis) and the post-analytical phase (interpretation, documentation and communication of results). These phases require multidisciplinary collaboration from various oncological disciplines.

3.6.3. Human resources and equipment

Key features of a PALM service include human resources, infrastructure and equipment, a monitoring and evaluation framework, QA and management processes (see Tables 3.13 and 3.14). The core members of the PALM team include general and specialized pathologists, laboratory directors, technical supervisors, clinical consultants, general supervisors, laboratory technicians and testing personnel. Additionally, biomedical engineers help to maintain testing equipment, and IT specialists help to maintain the vast amounts of patient data/information collected in a PALM department.

3.6.3.1. *Pathologist*

Pathologists are physicians trained in anatomical and clinical pathology. This enables a pathologist to oversee various laboratory techniques that incorporate microbiology and molecular biology, haematology, chemistry and immunology. Additionally, pathologists examine tissue and cells under the microscope to determine whether cells are benign or malignant, and they often run further tests to determine the exact cancer diagnosis. This requires a broad knowledge of anatomy, pathophysiology and the presentation of various illnesses. Pathologists generally undergo four years of training after medical school and may undergo an additional one–two years of specialized training to gain expertise in subspecialties such as cytopathology, blood banking, haematological histopathology, immunopathology and neuropathology. Pathologists may also assist other physicians in determining the most appropriate test to assist in making a diagnosis.

3.6.3.2. *Laboratory director*

A laboratory director is a position that may be filled by a pathologist, PhD scientist with a relevant background or someone with an alternative advanced degree in a related scientific field. The laboratory director has to ensure the following:

- The testing systems in the laboratory provide quality services that are appropriate for the patient population.
- The physical and environmental conditions of the laboratory are adequate and appropriate for the testing performed.
- The environment for employees is safe from physical, chemical and biological hazards, and safety and biohazard standards are followed.
- There is adequate staffing with the appropriate education, experience and training for their specified task.
- New test procedures are reviewed, included in a standard operating procedure (SOP) manual, and followed by personnel.

3.6.3.3. *Technical supervisor*

A technical supervisor has to have an advanced degree in a relevant science and needs to have at least two years of experience working in one of the PALM subdisciplines. The technical supervisor is responsible for choosing

the appropriate methodology, instrumentation and reagents for each test. The technical supervisor's responsibilities include the following:

- Selecting an appropriate testing methodology to guarantee the accuracy, precision and reproducibility of the test.
- Enrolment of the laboratory in a proficiency testing programme for the tests performed and remedial action in case of failure. Alternative options to proficiency testing include reaching out to the test kit providers who can facilitate retesting of patient samples or splitting samples with other laboratories in the area to verify the accuracy of results.
- Establishing and maintaining QA and QC programmes.
- Establishing and maintaining acceptable analytical test performance for each test system.
- Taking and documenting remedial action when significant deviations from the laboratory's established performance characteristics are identified, and ensuring that patient test results are reported only when the system is functioning properly.
- Confirming that personnel have been appropriately trained and demonstrate competency prior to testing patient specimens and establishing policies and procedures for monitoring personnel competency in all phases of testing (pre-analytical, analytical and post-analytical).
- Ensuring that remedial training or continuing education needs are identified and training is provided.
- Creating an approved procedure manual that is available to all personnel (analyser instruction manuals or package inserts are not sufficient).

3.6.3.4. *General supervisor*

A general supervisor has to have an advanced degree in a relevant science and needs to have at least two years of experience working in one of the PALM subdisciplines. The general supervisor is responsible for the day to day operation of the laboratory; making sure that QC levels are within normal ranges before running patient testing; performing daily, weekly and monthly maintenance; and making sure that preventative maintenance is done on time, including the following:

- Remedial action is taken when test systems deviate from the laboratory's established performance specifications.
- Patient test results are not reported until all corrective actions have been taken and the test system functions properly.
- Orientation is provided to all testing personnel.

- Annual personnel performance evaluations are made, and testing personnel performance competency is documented.

3.6.3.5. *Clinical consultant*

The clinical consultant is responsible for ensuring that test reports include pertinent information for test interpretation. The role also involves consulting with the other ordering clinicians when questions arise concerning test results and the interpretation of those results as they relate to specific patient conditions.

3.6.3.6. *Technical consultant*

The role of a technical consultant is similar to that of technical supervisor; the only difference is that they work with testing analysers and kits that are closed systems with prepared QC and calibrators that require less experience than those assessed by the technical supervisor. Technical consultants have to make sure that instructions are strictly followed for all tests.

3.6.3.7. *Testing personnel*

While laws and regulations differ between countries, laboratory personnel need to have proper education and experience to fulfil their positions and responsibilities. Some countries require specific licensing, certification, fellowship training or residency training, and the facility needs to understand and follow local requirements (Table 3.13).

Human resources are the most important factor in producing reliable results. As discussed previously, a variety of specially trained personnel are required for a PALM service to function appropriately. However, in many countries there is a significant shortage of PALM care team members. Given this shortage, PALM departments have to search for qualified PALM care team members in advance of when they will be needed, owing to anticipated growth. As laws and regulations differ between different countries, the required qualifications for each of the PALM care team members cannot be quantified. In general, PALM personnel need to have the relevant educational background and practical experience to perform their job reliably, as well as any required licensing, certification or prior residency/fellowships training.

Cancer centres with understaffed PALM services can devise innovative approaches to maximize the efficiency of PALM care team members. This may include task shifting/sharing, which involves distributing specific skilled tasks, with appropriate oversight and QC measures, to less specialized health care personnel to allow pathologist and PALM clinicians to use their time more

effectively and efficiently. An example includes teaching nurses or technologists to process specific pathology specimens [3.156].

3.6.3.8. *Equipment*

Like other key oncological disciplines, PALM is an infrastructure intensive service, which requires specialized instruments, physical laboratory space, IT services and a reliable supply chain. Additionally, a PALM information system

TABLE 3.13. PUBLICATIONS ON CAPACITY BUILDING RELATED TO HUMAN RESOURCES

Field	Topic	Title	Reference	Average duration ^a
Pathologist	Molecular biology curriculum	A Suggested Molecular Pathology Curriculum for Residents: A Report of the Association for Molecular Pathology	[3.142]	~4-6 years
	Genomics curriculum	A Curriculum for Genomic Education of Molecular Genetic Pathology Fellows: A Report of the Association for Molecular Pathology Training and Education Committee	[3.143, 3.144]	~4-6 years
	Molecular/cytogenetic curriculum	Molecular/Cytogenetic Education for Hematopathology Fellows	[3.145]	~4-6 years
	Haematopathology curriculum	Recommended Curriculum for Teaching Hematopathology to Subspecialty Hematopathology Fellows	[3.143]	~4-6 years

^a For completion of the minimum competencies to work independently in the clinic (considering the starting point).

is a unique resource that requires investment to monitor current supply levels, decrease the risk of errors in the recording and reporting of test results, and assess a number of quality metrics to ensure that high quality care is being delivered [3.157]. Depending on the complexity of the cancer centre and the in-house PALM expertise, it may be prudent to invest in telepathology services. This will allow development of PALM departments to gain access to remote PALM experts who can assist in the analysis of pathology specimens in real time or allow advanced PALM departments to assist regional hospitals. A list of various equipment and testing modalities required in PALM departments is provided below (see also Table 3.14):

- Coagulation analyser. This equipment is used to perform routine coagulation tests such as prothrombin time (PT), international normalized ratio (INR) and activated partial thromboplastin time, which are essential prior to surgery.
- Haematology analyser. This unit is utilized for common tests such as a CBC and white blood cell differential, which can inform whether a patient is fit for surgery, chemotherapy or radiation.
- Clinical chemistry analyser. This equipment is used for tests such as basic metabolic panel, liver function testing and cardiac markers. This is particularly important for patients undergoing chemotherapy.
- Point of care testing. This method uses equipment to perform specific tests outside a laboratory setting, typically by a nurse or medical assistant using a small mobile testing device. Examples of point of care testing include faecal occult blood analysis, blood glucose monitoring, urine pregnancy test and even portable ultrasound. Point of care testing blood/urine tests are usually available within minutes, unlike other laboratory tests, where specimens need to be sent to a laboratory and results may not be available for hours to days.
- Tissue processing. This process is used for preparing tissue for analysis. This often requires a microtome (which can cut extremely thin sections of tissue within a cryostat, which maintains a low temperature), manual staining equipment or an autostainer, embedding cassettes/moulds, mounting blocks, slide drying bench, etc. Automated processing units are available.
- Immunohistochemistry. This process involves immunostaining thin sections of previously prepared and processed tissue on a glass slide. The immunostaining can help in diagnosing and stratifying a patient's tumour, as certain stains are associated with different tissue types or reveal specific characteristics of the tumour, such as the receptor status of a breast cancer. Following staining, the tissue architecture and cell characteristics can be visualized using light or fluorescence microscopy.

CANCER PREVENTION AND TREATMENT

TABLE 3.14. PUBLICATIONS ON CAPACITY BUILDING RELATED TO EQUIPMENT

Modality	Topic	Title	Reference
Histopathology	Minimum requirements for a histology laboratory	A Minimum-Requirement Model to Start Up a Histology Laboratory in a Developing Country	[3.146]
Microbiology	Establishing a molecular and microbiology laboratory	Establishing Molecular Microbiology Facilities in Developing Countries	[3.147]
Bloodbanking	Establishing a blood bank	Design Guidelines for Blood Centres	[3.148]
General	Establishing a pathology laboratory	Guide for Establishing a Pathology Laboratory in the Context of Cancer Control	[3.141]
Equipment	Determining essential equipment	WHO List of Priority Medical Devices for Cancer Management	[3.31]
	Essential in vitro diagnostics	Selection and Use of Essential In Vitro Diagnostics	[3.149]
QMS	Laboratory QMS	Laboratory Quality Management System: Handbook	[3.150]
Quality assurance	Laboratory assessment tool	WHO Laboratory Assessment Tool	[3.151]
National health laboratory system	Establishing a national health laboratory system	Establishing a National Health Laboratory System	[3.152]
Accreditation	Strengthening laboratory management towards accreditation	The SLMTA Programme: Transforming the Laboratory Landscape in Developing Countries	[3.153]
	Approaches to improving QMSs and accreditation	Improving Quality Management Systems of Laboratories in Developing Countries	[3.154]
	Guide for PALM accreditation in Africa	WHO Guide for the Stepwise Laboratory Improvement Process Towards Accreditation in the African Region	[3.155]

Note: PALM: pathology and laboratory medicine; QMS: quality management system.

- Fluorescence in situ hybridization (FISH). This is a molecular cytogenetic technique that utilizes fluorescent probes (DNA/RNA) that bind to specific nucleic acid sequences. These probes can then be localized with fluorescence microscopy, which can identify where the fluorescent probe is bound on chromosomes. The equipment required includes a fluorescent microscope, appropriate filters, RNA/DNA probes, and the appropriate chemicals and equipment for tissue processing.
- Genomic DNA/RNA extraction. Methodologies for high quality DNA and RNA extraction from biological samples are essential for molecular biology analysis, involving PCR, RTPCR, genotyping, Sanger sequencing (short fragments of the genome), next generation sequencing (NGS) (full genome) and messenger RNA expression analyses.
- PCR. This method is used to amplify short segments of DNA/RNA. It involves three key steps: denaturing, annealing and extension/elongation, which are repeated to create millions of copies of a target DNA/RNA sequence. There are many PCR systems of varying complexity and automation. PCR is a critical feature of identifying targetable mutations, gene expression and castPCR technology for detecting somatic mutations for cancer research [3.158], thereby delivering personalized medicine.
- Electrophoresis. This is a process that can be used to measure specific proteins/nucleic acids in the blood, urine or cerebrospinal fluid by separating proteins by their electrical charge. An example of this is using electrophoresis to quantify the presence of different proteins in the blood, which can help in cancer diagnoses. Electrophoresis requires a power supply, specific dyes, trays, electrodes, cables, gel mixtures and other chemicals.
- Enzyme-linked immunoassay (ELISA) kit. ELISA kits are used to measure tumour markers such as prostate specific antigen and carcinoembryonic antigen. The tumour markers/antigens are immobilized on a surface (microplate) and then bound by antibodies that are linked to a reporter enzyme, which can be detected. The reporter enzyme's activity is then quantified to determine how much of the tumour marker/antigen is present. To perform this test, appropriate microplates, antibodies and buffers are needed. There are multiple detection units that can be used to quantify the reporter enzyme's activity, such as colorimetric, fluorescence or chemiluminescence detectors. Tests kits that include all needed supplies can be purchased.
- NGS. This is a process of high throughput DNA/RNA sequencing using massive parallel processing. There are multiple platforms commercially available for NGS that generally go through the same process of generating a DNA sequence library by clonal amplification via PCR, DNA sequencing by synthesis (rather than through chain termination chemistry) in a massively

parallel fashion, and finally analysis of sequenced DNA. NGS can be utilized to identify targetable mutations, gene expression, epigenetics and methylation analysis, immune system and inflammation research, targeted transcriptome sequencing, whole exome sequencing, liquid biopsy clinical research, immuno-oncology solutions and targeted sequencing for oncology research to deliver personalized medicine.

- Flow cytometry. This is a test that measures the physical and chemical characteristics of a population of cells by passing the cells through a laser and measuring the scattered light. Flow cytometry plays an important role in the diagnosis and prognostic stratification of haematological malignancies. The required equipment includes a flow cytometer and flow cytometry analyser.
- Digital pathology slide scanner. This unit allows scanning of pathology slides to create images that can be uploaded to a network for remote access and collaboration. This can help with telepathology services.
- Laboratory information system (LIS). This is computer software that processes, stores and manages data in a PALM department. This software can manage inpatient and outpatient medical testing and track specimens throughout the PALM process. Use of an LIS can decrease human error and allow a PALM department to run more efficiently.

3.6.4. Teaching, research and clinical trials

3.6.4.1. Training programme

Insufficient human resources and workforce capacity have been identified as one of the four key barriers to PALM services in LMICs. This is illustrated by the fact that in some LMICs in sub-Saharan Africa, there is only approximately one anatomical pathologist per one million patients compared with one anatomical pathologist per 20 000 patients in some HICs [3.159]. While there are many causes of this diminished workforce capacity, there is evidence that insufficient post-graduate training opportunities, as well as a lack of programmes for continued professional development or skill enhancement, are major contributors [3.160]. This is complicated by the fact that PALM clinicians face heavy workloads due to understaffing, which inhibits clinicians from participating in ongoing education endeavours themselves and from teaching and mentoring future PALM clinicians.

Given the competing interests that PALM care team members face, cancer centres have to facilitate and encourage the participation of PALM team members in programmes to enhance their knowledge base and skill set. This may include participation in international fellowships, spending time at a tertiary care centre

or participating in workshops and professional conferences. To accomplish this, cancer centres can provide funding for educational endeavours, create partnerships with regional and international centres, and create short term visitor programmes, which invite experts in the field to spend time at the cancer centre for lectures and workshops and to establish mentor–mentee relationships. Task shifting and sharing is also an approach that may provide PALM team members with more time to pursue additional training or to mentor new and potential PALM clinical team members [3.160].

Cancer centres have to play a leading role in training additional PALM care team members to help to meet the growing demand for PALM services. An integrated educational system that trains pathologists and PALM technologists in tandem is preferred, so that as additional pathologists enter the workforce, they are surrounded by an adequate number of trained care team members.

3.6.4.2. Research

Pathology plays a unique role in clinical research across multiple specialities. The results of tests performed by PALM services often determine whether a patient is eligible for a given clinical trial or whether an investigational drug has been effective. Pathology also has a unique role in that the vast amount of data that the department collects can fuel research across multiple scientific disciplines. For this reason, clinical registries with detailed PALM test results have to be maintained when feasible. Population level research on mortality rates from various causes, including cancer, also rely on an efficient autopsy service, as identification of the cause of death is often inaccurate without these services [3.161].

3.6.5. Quality assurance

Reliable and reproducible results in PALM services can only be achieved through the implementation of quality management systems (QMSs). A comprehensive QMS has three main components: QA, QC and QI.

A dedicated QA programme has to be created with the goal of ensuring that policies/procedures are effective and comply with laboratory laws/regulations; tests are performed in a safe environment for patients and staff; the PALM services being offered meet the needs of physicians in assisting with the diagnosis and treatment of patients; and there is accurate, reliable and efficient testing and reporting of results. This programme has to include representatives from laboratory, clinical, administrative and public relations staff, who will meet at least monthly to discuss QA standards for all aspects of test performance (i.e. the pre-analytical, analytical and post-analytical phases) and ensure that

they are appropriate for the respective patient population. The QA programme also needs to focus on resolving known, identified or suspected problems that may have a negative effect on the quality and delivery of laboratory services. This needs to be accomplished through an organized systematic process that includes the following:

- (a) Identifying, prioritizing, monitoring, evaluating, acting on and resolving issues in the laboratory that impact procedures, test management, test performance and patient care;
- (b) Evaluating personnel to assess their competence and create plans to maintain their skill and knowledge levels;
- (c) Communicating with staff regarding ongoing QA initiatives and results;
- (d) Following up on all corrective actions to ensure that improvements have been made;
- (e) Coordinating all laboratory QA activities to promote cooperation and to prevent duplication;
- (f) Reviewing and updating the QA plan of the laboratory on an annual basis.

Particular attention needs to be paid to critical indicators, which are processes or events that reveal how well the laboratory is functioning. Monitoring critical indicators results in the identification of problems significant enough to require review, analysis and implementation of appropriate corrective action. The chosen critical indicators need to be reviewed periodically. The review of these critical indicators needs to include a review and documentation of the frequency and/or trends of identified problems related to the respective clinical indicator. Data regarding clinical indicators can be collected through chart audits, laboratory test log reviews, etc. Examples of critical indicators in each phase of PALM testing include the following:

- (a) Pre-analytical phase: Appropriateness of tests ordered, specimen rejection rate, and appropriate specimen labelling, preservation, transportation and storage;
- (b) Analytical phase: Number of machines up to date with preventive maintenance, machine downtime and frequency of running out of required supplies/reagents;
- (c) Post-analytical phase: Use of standardized synoptic reporting, completeness of test reports, turnaround time for test results, regulatory compliance, appropriate storage and retrieval of test results.

Once the criteria to be monitored and the method of data collection have been determined, the QA programme can be initiated. This process needs to be

well documented for future review. Rigorous QA measures have been shown to decrease the discordance between low volume and high volume laboratories [3.162]. Once there is confidence that high quality services are being provided by the PALM department, the focus can shift to QC.

QC involves the monitoring of all inputs for the tests being performed to ensure accurate and reproducible results. Given the varying requirements of the different reagents and materials used within PALM, it is essential to maintain centralized and thorough documentation of these requirements (storage temperature, reagent shelf life, appropriate instrument calibration, etc.), which can be referenced. This can be accomplished through a comprehensive bench-top standard operation manual. A standard operating manual is a written document containing the specific requirements for the various tests that a PALM department performs (Table 3.15). These requirements need to be followed exactly to ensure that test results are comparable over time. This manual may also contain guidelines that are more flexible and general in nature to inform PALM care team members how to manage any issues that arise throughout the testing process. A standard operation manual has to include details regarding the following:

- Sample handling for each test, including preservative, temperature, stability, storage and transportation, if applicable;
- Reagents and supply part numbers, where and how to order, minimum inventory for supplies, storage conditions for each item, etc.;
- Turnaround time for each test;
- Steps for preparing to run a given test — for example, washing techniques, adding fluorescent antibodies, fixation on slides and biopsy handling;
- Detailed steps for processing and analysing the samples with current methodology;
- Daily QC and calibration intervals for analysers;
- Reference values for each test;
- Panic/critical values for each test, and delta values if applicable.

The standard operation manual needs to be reviewed by the laboratory director at least once per year, any retired protocols need to be marked as such and any new protocol approved for implementation needs to be added. Additionally, daily logs confirming that these requirements and standards have been met need to be maintained (e.g. keeping a log of the temperature for a temperature controlled storage unit). Using automated detection protocols, which alert personnel when standards are not being met, may decrease the monitoring burden on personnel. However, automated processes have to function in conjunction with proactive daily, weekly and monthly preventive maintenance and testing to ensure that high quality services are being maintained.

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TABLE 3.15. PALM SERVICE LEVELS AND REQUIREMENTS

Level of cancer centre	Technologies/ equipment needed	Skilled human resources needed	Pathologist competencies needed
Level 1	CBC analyser with automated 3-part and 5-part differential haematology analysers, chemistry analyser, coagulation analyser, automated immunoassay analyser, urine analysis, microscope with phase contrast, spectrophotometer, electrophoresis, manual DNA extraction and PCR	General laboratory tests such as comprehensive metabolic panels and their components of electrolyte, kidney function, liver function, and basic metabolic, etc.; CBC with automated differential; assessment of therapeutic drug levels; coagulation studies (PT/INR); hormones; vitamin levels; urine analysis; and some limited automated oncological diagnostics such as tumour markers (CEA, AFP, CA15.3, CA125, CA 19-9, NSE, PSA< B-HCG)	General pathologist, laboratory technicians, pathology assistants
Level 2	In addition to Level 1, flow cytometer, automated immunohistochemistry system, automated PCR extraction, fluorescent microscope, digital pathology slide scanner, FISH slide cycler, PCR microtube cycler	In addition to Level 1, immune phenotyping, FISH, DNA tumour markers, autopsy, frozen section, ability to prepare samples for Level 3 laboratories	In addition to Level 1, clinical scientists

TABLE 3.15. PALM SERVICE LEVELS AND REQUIREMENTS (cont.)

Level of cancer centre	Technologies/ equipment needed	Skilled human resources needed	Pathologist competencies needed
Level 3	In addition to Level 2, DNA extraction and liquid handling, PCR, genetic analyser and sequencing reactions, image analysis system with software for chromosome pathology and haematopathology, super-resolution microscope, single molecule localization biplane nanoscope, confocal microscope, image analysis and tracking software, binding studies, X ray crystallography structure, fixing/staining equipment and microtome	In addition to Level 2, molecular diagnostics, regular and fluorescent histopathology, assessment of chromosome pathology	In addition to Level 2, pathology subspecialists

Note: CBC: complete blood count; FISH: fluorescence in situ hybridization; INR: international normalized ratio; PALM: pathology and laboratory medicine; PCR: polymerase chain reaction; PT: prothrombin time.

QI is the natural next step in a QMS through which QA or QC has identified weaknesses in the structure or process of the PALM department. QI needs to be thought of as a system put in place to ensure that the services being provided are improving over time to better meet the future needs of the PALM department. Examples of QI initiatives include upgrading equipment to manage increasing test volumes or implementing an LIS and bar coding samples to reduce medical errors. This process has to be overseen by the technical supervisor and laboratory director, given the complexity of instituting such changes.

PALM care team members also have other general responsibilities regarding QA. For instance, pathologists play an important role in educating other clinicians about the indications and interpretation of the various tests that they perform. This is of particular importance when new tests are implemented to replace or complement other tests within a PALM services portfolio. Additionally, all PALM departments need to have a goal of gaining accreditation through regional

or international accreditation agencies. There are tools that can assist with this process, including the Stepwise Laboratory Improvement Process Towards Accreditation, Strengthening Laboratory Management Toward Accreditation and the Laboratory Quality Stepwise Implementation tools. These tools help PALM departments to become compliant with the ISO-15189 accreditation, which focuses on improving testing processes from collection through reporting and disposal. It is important to comply with national or international regulatory requirements, including mandatory reporting of infectious diseases and adherence to confidentiality regulations (Table 3.15).

3.7. PALLIATIVE AND SURVIVORSHIP CARE

3.7.1. Rationale for palliative and survivorship care

Cancer and its treatment can cause physical side effects as well as emotional, social and financial side effects. Comprehensive cancer care needs to address these holistic needs of patients during and following active treatment. This is best done through a dedicated palliative and survivorship care team [3.163]. Palliative and survivorship care represents a treatment approach that focuses on improving the quality of life of patients and their families through the prevention, early identification and treatment of pain and other physical, psychosocial and spiritual suffering. This palliative treatment approach does not need to be used exclusively for patients who are dying, as all cancer patients, regardless of prognosis, can benefit from the services provided by a palliative and survivorship care team. However, an estimated 14% of patients who need palliative care receive it [3.164]. An overview of the palliative and survivorship oncology process is listed in Box 3.5.

Integrated palliative and survivorship care improves patients' quality of life, promotes treatment adherence, increases the likelihood of patients completing recommended treatments and, in certain settings, has been shown to improve survival [3.165]. However, the biggest benefit of accessible palliative and survivorship care is the alleviation of serious health related suffering (SHS), which is defined as physical, emotional or social suffering due to an illness or injury, which cannot be relieved without medical intervention. A Lancet Commission reported that cancer is the second leading cause of SHS and that 80% of the people who died in 2015 from SHS were from developing regions that lacked access to palliative care and pain relief [3.166]. Additionally, almost 98% of children who die from SHS come from developing regions, where they account for 30% of all deaths associated with SHS. This burden could be alleviated by accessible palliative and survivorship care expertise. The need for this expertise is increasing, and currently more than 40 million people require palliative care every

year. However, there are significant disparities in the availability of palliative care services across different countries.

The disparities in the availability of palliative care in LMICs are best illustrated by the fact that the amount of morphine equivalent opioids distributed in these settings is approximately 5–10 mg per patient in need of palliative care per year compared with 55 000 mg per patient in the USA [3.166]. Opioids have limited availability, despite morphine representing an inexpensive, essential and effective medical intervention for moderate to severe pain. The lack of access to effective opioids has led to 99% of palliative pain control needs being unmet, causing a significant and unnecessary amount of physical, emotional and social suffering. For instance, in 2012 alone, about 425 million days of cancer pain could have been relieved with effective access to opioids in LMICs.

This gap between the need and availability of opioids could be closed if LMICs had access to the lowest retail prices available, as opioids would constitute only 0.009% of LMIC health expenditures, according to 2015 data [3.166]. Although this represents a relatively minor cost, there are other costs associated with establishing a palliative care team. These may be offset by savings associated with the implementation and early integration of palliative care into a patient's treatment course. For instance, patients who are managed by an outpatient palliative team are more likely to have adequate pain control, leading to a 25–35% reduction in end of life hospital admissions [3.167–3.171]. The Lancet Commission estimated that this reduction in health care costs from reduced hospital admissions would offset not only the cost associated with acquiring the necessary pain medications but also the cost of offering an essential package of palliative care services.

3.7.2. Palliative care as part of multidisciplinary cancer care

Patients with cancer have complex physical, psychosocial and spiritual needs that evolve throughout their disease trajectory. For paediatric patients, their physical, emotional and cognitive developmental needs, as well as their need for continued education and play, need to be considered. Patient centred palliative services encompassing these dimensions are feasible in all resource settings. When these needs are addressed, the quality of care improves, costs decrease and goals are aligned between the medical care provider, the patient and the patient's family. One of the best ways to address these needs is to ensure that comprehensive care for cancer patients includes palliative care specialists as active participants on multidisciplinary care teams. Palliative care can be concurrently delivered with curative disease directed therapy and is not synonymous with end of life care. Palliative care can be delivered in various settings (hospital based, home based and community based) and often involves palliative treatment using surgery, radiation or chemotherapy.

BOX 3.5. OVERVIEW OF THE PALLIATIVE AND SURVIVORSHIP ONCOLOGY PROCESS

(a) *Clinical evaluation of the patient.* If possible, all patients have to be evaluated in a multidisciplinary setting [3.1]. Palliative care team members have to seek to understand the patient's goals of care, performance status, cultural/spiritual background and current symptom burden through a physical examination and compassionate discussion. Current medications being used for symptom management need to be reviewed.

(b) *Triage.* On the basis of the initial evaluation, patients have to be referred to supportive services, as indicated (physical therapy, dietician, psychologist/psychiatrist, fertility preservation, pain clinic, home hospice, etc.). Patients may be referred for consideration of palliative surgery, radiation or chemotherapy.

(c) *Symptom management.* A written plan needs to be prepared for the management of individual symptoms. For example, a prescription for a non-opioid or opioid pain medication can be given with a plan to increase the dose/frequency or add an additional medication in the event that pain is not well controlled. A home visit may be needed to assess compliance with this plan and ensure that the patient has a safe home environment, including safe storage of opioid medications.

(d) *Patient health maintenance.* Before or during treatment, a patient has to be regularly assessed to ensure that symptoms and the side effects of treatment are well controlled. The goal of these visits is to decrease the likelihood of the patient being deconditioned and unable to continue or complete the planned treatment course.

(e) *Follow-up evaluation.* At the conclusion of treatment, the patient may be seen in a survivorship clinic or may transition to hospice care. Survivorship clinics perform anticipatory assessments, promote wellness, monitor for long term treatment toxicity and support patient integration into schools, workplaces and communities. Hospice care may be delivered in the patient's home, at an outpatient clinic or on an inpatient basis according to available resources.

Palliative care specialists play an important role in maintaining and improving the patient's quality of life and performance status so that the patient is well enough to undergo any treatments recommended by the multidisciplinary care

team. Following active treatment, there continues to be a role for ongoing palliative and/or survivorship care to help patients reintegrate into their communities while managing any lingering symptoms or side effects related to their cancer diagnosis or cancer treatments. Survivorship care focuses on the anticipatory management of physical and functional morbidities and late effects secondary to a diagnosis of cancer or its treatment and early recognition of cancer recurrence or secondary malignancies. For those patients with a poor prognosis, palliative care is an essential component of multidisciplinary care, as an estimated 80% of patients dying from cancer in low income countries experience moderate to severe pain lasting an average of 90 days [3.166]. Alleviating this pain through compassionate care is important for maintaining a patient's dignity during end of life care. Palliative care needs to be integrated as an essential component of cancer programmes across the life course and care continuum [3.172, 3.173]. Policies and resources need to reinforce the appropriate integration of upstream palliative care and ensure access to pain medications (including opioids).

3.7.3. Human resources and equipment

Although minimal specialized physical equipment is required for the delivery of palliative and survivorship care, the required human resources and training are unique (Tables 3.16 and 3.17 [3.174–3.195]). The core members of a palliative and survivorship care team include: a palliative care physician; palliative care nurse; community health workers; caregivers; a psychosocial care team (psychiatrists, psychologist, counsellors, social workers, chaplains); volunteers; and a dietician. This team is further supported by surgeons, medical oncologists, radiation oncologists, physical therapists, occupational therapists and speech therapists. Paediatric palliative care teams will also include paediatricians, child psychologists, child life specialists and teachers. All staff involved in the care of patients with cancer can benefit from at least basic training in palliative care.

3.7.3.1. Palliative care physician

A palliative care physician has specialized training in hospice and palliative medicine. This may require an additional year of training following completion of training in another medical discipline, such as internal medicine. Palliative care physicians are responsible for discussing a patient's goals of care, assessing and managing current symptoms, assisting in coordinating care between medical teams and overseeing end of life care. Given the complex medical issues that can arise in patients with cancer, a palliative care physician has to have a

strong understanding of psychosocial care, pathophysiology, pharmacology and prognostic stratification, as well as experience in counselling patients.

Given the shortage of physicians who specialize in palliative care, this role may be filled by primary care physicians of various specialities who have undergone basic palliative care training. This training may range from one to six weeks, depending on the resources available. This training needs to include communication skills, the appropriate use of non-opioid and opioid medications for the management of pain, management of common symptoms and side effects from cancer and its treatment (e.g. nausea, emesis, anorexia, fatigue, shortness of breath, sleep loss, altered mentation, depression) and end of life care. Physicians with training in palliative care can assist in the training of nurses and community health workers.

3.7.3.2. *Palliative care nurse*

Palliative care nurses may have the same scope of care and responsibilities as nurses in other settings. Preferably, they can deliver care in a patient's home rather than in the standard setting of a hospital or clinic. In a patient's home the nurse may represent the main caregiver who calls in additional resources as needed. Nurses can play a key role in educating caregivers in the home as well as assisting in the preparation of a written plan for medications/dosing if a patient is having specific symptoms. Palliative care nurses often receive additional specialized training focused on communication skills, end of life care and pain management. Nurses with training in palliative care can assist in the training of community health workers and supervise community health workers while providing care.

3.7.3.3. *Community health worker*

Community health workers can play an essential role by visiting patients frequently in their home when in-home palliative services are not available. This will allow them to offer emotional support, identify symptoms that may require medical intervention, ensure that basic needs are being met and that medications are being used as prescribed. When appropriate, community health workers can also assist in transporting the patient to and from medical facilities. If community health workers have prior experience in health care, then a supplemental one day/16 hour training can prepare them for the challenges involved in delivering palliative care. Additional training of up to three months/400 hours can be given to enable community health workers to perform the tasks and responsibilities assigned to them.

3.7.3.4. *Caregiver*

A caregiver may represent a family, friend or community volunteer who is assisting with the daily needs of the patient. This may involve bathing, toileting, feeding, administration of medications or emotional support. Caregivers may be required 24 hours per day and can incur significant financial costs owing to lost work or withdrawing from educational pursuits to fulfil their role as a caregiver. They are also at risk of physical, psychological, social or spiritual suffering and are unique in that they are a part of the palliative medicine care team while also having their needs addressed by this same team. Additionally, caregivers may need training on how to provide wound care, how to manage patient oxygen requirements, medication management or other practical medical skills.

3.7.3.5. *Psychosocial care team*

A psychosocial care team can be composed of psychiatrists, psychologists, counsellors, child life specialists, chaplains and social workers. Psychosocial care for patients with cancer includes assessment and anticipatory management of patients' and families' needs, from diagnosis and throughout the disease trajectory, encompassing needs across emotional, spiritual, interpersonal and material/financial domains. This can include patient and family education and counselling, provision of resources and support (e.g. financial, housing, transportation, meal support), support for family members/caregivers, consultation services involving legal and ethics experts, and support for reintegration into schools and workplaces. Given the sustained duration of many treatments for cancer, support to reduce patient and family distress and to promote treatment adherence is vital. Special attention needs to be paid to patients and family members experiencing depression and anxiety related to their diagnosis and treatment course. When psychiatric needs exceed the expertise of palliative care physicians, a psychiatrist has to be consulted. Where possible, paediatric psychosocial providers have to have specialized training and education and be credentialled to provide developmentally appropriate care for children with cancer and their families [3.174]. Spiritual and social suffering can impact the effective delivery of palliative care and may need to be addressed by palliative care team members as a complement to medical interventions. Local and national partnerships have to be established to assist in managing the spiritual and social needs of patients.

3.7.3.6. *Dietician*

Dietitians are professionals with expertise in identifying and treating patients with malnutrition, undernutrition and obesity, which have a high prevalence among cancer patients. Training to become a dietitian varies but generally requires a university degree followed by one year of clinical training. The care provided by dietitians is critical, as the short term consequences of malnutrition may include decreased treatment tolerance, increased treatment delays and increased hospitalization and treatment cost. Cancer patients who are malnourished have lower survival rates and face other long term consequences, such as reduced functional capacity, decreased bone density and increased risk of metabolic syndrome. To avert these complications, dietitians perform nutritional screening and assessment for cancer patients, followed by management as needed, which can include nutrition counselling, oral supplementation, enteral/parenteral nutrition or drug therapy. MNT is generally a mandatory component of supportive care for all cancer centres.

3.7.3.7. *Paediatric palliative care team*

Palliative care for children involves care of the child's body, mind and spirit, while recognizing their age appropriate developmental needs, distinct disease trajectories and treatment needs in children and adolescents [3.65]. Although the first priority of paediatric palliative care is providing for the needs of the child, it is also essential to provide support to the family. While paediatric palliative care builds on general palliative care principles and practices, it also utilizes distinct competencies, alongside different assessment tools, pharmacological and non-pharmacological management approaches for children and adolescents with cancer. The minimum workforce required for paediatric palliative care services includes a nurse and a doctor, supported by community health care workers, all of whom require at least basic paediatric palliative care knowledge and competence. In settings with more resources, a team would ideally include providers with specialist training in paediatric palliative care, including paediatricians, paediatric nurses, psychologists, social workers and other allied health therapists, such as child life workers, music and art therapists, and rehabilitation specialists. In addition to facilitating discussion of goals of care with families and age appropriate assessment and management of symptoms, providers of paediatric palliative care can often facilitate care coordination and access to other therapies as needed [3.65].

The core palliative care team members will work across various clinical settings. Palliative care needs to be accessible at all levels of the health care system (Table 3.18) and can be delivered as hospital, community or home based care.

CHAPTER 3

TABLE 3.16. PUBLICATIONS ON CAPACITY BUILDING RELATED TO HUMAN RESOURCES

Field	Topic	Title	Reference	Average duration ^a
Palliative care physician	Implementing palliative care services	Planning and Implementing Palliative Care Services: A Guide for Programme Managers, Annex 5	[3.175]	One week
Psychologist, psychiatrist, counsellor	Paediatric psychosocial care	Standards for the Psychosocial Care of Children with Cancer and Their Families: An Introduction to the Special Issue	[3.174]	Variable
	Communication, documentation and training	Communication, Documentation, and Training Standards in Paediatric Psychosocial Oncology	[3.176]	Variable
Community health worker		Planning and Implementing Palliative Care Services: A Guide for Programme Managers, Annex 4	[3.175]	16 h/400 h
Paediatric palliative care provider	Management of pain in paediatric patients	WHO Guidelines on the Pharmacological Treatment of Persisting Pain in Children with Medical Illnesses	[3.177]	~2–3 years
	Cancer survivorship	ReCAP: ASCO Core Curriculum for Cancer Survivorship Education	[3.178]	~2–3 years
General	General guide for all members of the clinical care team	Clinical Practice Guidelines for Quality Palliative Care	[3.179]	Variable

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TABLE 3.16. PUBLICATIONS ON CAPACITY BUILDING RELATED TO HUMAN RESOURCES (cont.)

Field	Topic	Title	Reference	Average duration ^a
	Guidelines for care team members and instructions on how to start a palliative care service	International Association for Hospice and Palliative Care Manual of Palliative Care	[3.180]	Variable
	Treatment guidelines	NCCN Guidelines Insights: Palliative Care, Version 2.021	[3.181]	Not applicable
Survivorship	Establishing a survivorship service	Developing a Quality of Cancer Survivorship Care Framework: Implications for Clinical Care, Research, and Policy	[3.182]	Not applicable
	Personalized survivorship care pathways	Building Personalized Cancer Follow-up Care Pathways in the United States: Lessons Learned from Implementation in England, Northern Ireland, and Australia	[3.183]	Not applicable
	Personalized survivorship pathways	Implementing Personalized Pathways for Cancer Follow-up Care in the United States	[3.184]	Not applicable
Palliative care	Case study of how to implement palliative care services in low and middle income countries	Oncology-Based Palliative Care Development: The Approach, Challenges, and Solutions from North-East Region of India. A Model for Low- and Middle-Income Countries	[3.185]	Not applicable

^a For completion of the minimum competencies to work independently in the clinic (considering the starting point).

3.7.3.8. *Hospital based palliative care*

A hospital based service facilitates the discussion of the patient's values, diagnosis, prognosis and goals of care and enables a smooth transition to care in the community, where appropriate. A hospital based palliative care service can include an outpatient palliative care clinic, a palliative care consultation service for hospital inpatients, a palliative care respite service, an inpatient palliative care unit and a palliative care outreach/home care service [3.65]. The outpatient palliative care clinic can offer low cost care to a large number of patients and, when included with an inpatient consultation service, can be a particularly effective model where resources are limited. An inpatient palliative care unit has dedicated palliative care beds with staff trained in palliative care available 24 hours a day [3.65]. This unit may also serve as a demonstration unit and training centre for the rest of the hospital. The professionals required include doctors and nurses with at least basic training in palliative care, ideally supplemented with consistent access to team members with specialist palliative care training, and a full complement of multidisciplinary providers to serve the holistic needs of patients and families [3.65]. This MDT may include psychologists, pharmacists, physiotherapists, spiritual care providers, dieticians and volunteers, each of whom has a role in strengthening the team and the service offered. Access to medical treatment options such as interventional radiology, RT and salvage surgery, which can alleviate oncological symptoms, has to be part of hospital based care [3.65].

3.7.3.9. *Community based palliative care service*

Community based palliative care services are typically provided by health care professionals and community health workers and/or lay volunteers. Palliative care services at a community health centre (CHC) can include outpatient services offered during defined hours, home based support and, in some cases, inpatient services. Health care professionals based at a CHC can offer outpatient services for assessment and management of more advanced symptoms while also providing a respite for family caregivers. Community based health care professionals can also support home based services by supervising community health workers or volunteers, visiting patients at home when needed and keeping in touch with patients and family members via mobile telephone. In addition, CHCs that have inpatient beds can manage more complex symptoms, provide short term respite for family caretakers and deliver uncomplicated end of life care for a few inpatients at any one time to better support the preferences and needs of patients and families, often in a more home-like environment than a hospital inpatient setting. Training needs to be provided to members of the

CHC health care team include basic palliative care training appropriate for the level of care that they provide and in alignment with national and international recommendations. The nurses and doctors can then participate in training community health workers or volunteers. Community health workers or lay volunteers, supported by health care professionals, can be trained to provide or to support community based services in continuity with home based services.

3.7.3.10. Home based palliative care

Many patients feel more comfortable in their home than in a health care setting, especially during treatment or towards the end of their life. A home based approach provides advice and support to family members serving as caregivers and can facilitate referrals for additional services. Resources for transportation and communication are vital to continuity of care. A dedicated vehicle, for example, can facilitate team visits to patients' homes or the transfer of patients and families between appointments (ideally accommodating wheelchairs and other equipment). Patients and their caregivers have to be able to contact the home care team around the clock, with team members having access to mobile telephones at scheduled intervals to answer urgent calls after hours. An MDT of nurses, doctors, psychologists/counsellors, social workers and trained volunteers or community health workers is preferred [3.65]. A health record system needs to be maintained for each patient, ideally integrated with hospital based and community based service records. Records of prescriptions and medications administered (especially morphine and other opioids) need to be maintained in compliance with local laws and regulations. Minimum basic training in palliative care for doctors, nurses, community health workers and lay volunteers, along with access to staff with speciality training in palliative care, is essential to provide home care services [3.65].

Mobilizing financial and organizational resources to ensure the availability of palliative and survivorship care is critical to operating a cancer centre across these three settings. This can further be supported by local/national policies, financing and partnerships (including non-governmental organizations (NGOs)) to create demand, enable and sustain development, enable the strengthening of human resources, medicines and equipment, and apply QA for integrated palliative, psychosocial, nutritional and survivorship care.

3.7.3.11. Equipment and infrastructure

As previously mentioned, the physical equipment that is needed to provide palliative care and survivorship care is similar to the equipment that would generally be required to operate a medical centre. However, to aid in the palliative

care of cancer patients, a sample list of essential equipment has been created by WHO and by a Lancet Commission [3.166]. This package is not specific to oncology patients, but has been created to identify the lowest cost medications and equipment required to provide a basic level of palliative care across different resource settings for 20 of the most common global illnesses. To accomplish this, off-patent formulations and low cost medications were prioritized.

All medications and equipment were required to meet the following three criteria:

- (1) They have to prevent or treat symptoms associated with 20 of the most common health conditions (including cancer);
- (2) The expertise required for these medications and equipment needs to be widely available in a primary care setting if augmented by basic training in palliative care;
- (3) Medications and equipment need to balance accessibility on the world market with clinical effectiveness, safety, ease of use and minimal cost.

The essential package includes the following:

- Medicines: Amitriptyline, bisacodyl (senna), dexamethasone, diazepam, diphenhydramine, fluconazole, fluoxetine (or other selective serotonin reuptake inhibitor), furosemide, hyoscine butylbromide, haloperidol, ibuprofen (naproxen, diclofenac, meloxicam), lactulose (sorbitol or polyethylene glycol), loperamide, metoclopramide, metronidazole, morphine (oral immediate release and injectable), naloxone parenteral, omeprazole, ondansetron, paracetamol and petroleum jelly.
- Equipment: Pressure reducing mattress, nasogastric drainage or feeding tube, urinary catheters, opioid lock box, adult diapers (or cotton and plastic if in extreme poverty) and oxygen.

This package is meant to represent a minimum standard for palliative care services and needs to be expanded to address local population needs and specialized paediatric care as a cancer centre's budget and technical expertise increase. Additional equipment could include ambulatory assisting devices (wheelchairs, canes, crutches, etc.), hearing aids, eyeglasses, etc. To ensure that the lowest price and highest quality medicines and equipment can be acquired, it may be prudent to work with local or regional health care facilities to establish regional purchasing and procurement funds. Other lists of essential medications and equipment for palliative care services have been created by WHO and can be referenced when making budgetary decisions [3.175].

CANCER PREVENTION AND TREATMENT

TABLE 3.17. PUBLICATIONS ON CAPACITY BUILDING RELATED TO EQUIPMENT

Modality	Topic	Title	Reference
Palliative care	Establishing hospital, community and home based palliative care services	Planning and Implementing Palliative Care Services: A Guide for Programme Managers	[3.175]
	Planning a palliative care centre	Cancer Control Knowledge into Action: WHO Guide for Effective Programmes	[3.186]
	Establishing a palliative care programme	The Central Role of Provider Training in Implementing Resource Stratified Guidelines for Palliative Care in Low-Income and Middle-Income Countries: Lessons from the Jamaica Cancer Care and Research Institute in the Caribbean and Universidad Católica in Latin America	[3.187]
	Establishing a palliative care programme	Building Integrated Palliative Care Programs and Services	[3.188]
	Resources stratified palliative care guidelines	Palliative Care in the Global Setting: ASCO Resource-Stratified Practice Guideline	[3.189]
Paediatric Services	Pain management in adult and adolescent cancer patients	WHO Guidelines for the Pharmacological and Radiotherapeutic Management of Cancer Pain in Adults and Adolescents	[3.190]
General	Establishing a palliative care service	Guidelines and Suggestions for Those Starting a Hospice/Palliative Care Service	[3.191]

TABLE 3.17. PUBLICATIONS ON CAPACITY BUILDING RELATED TO EQUIPMENT (cont.)

Modality	Topic	Title	Reference
	Resource stratification	Supportive and Palliative Care for Metastatic Breast Cancer: Resource Allocations in Low- and Middle-Income Countries. A Breast Health Global Initiative 2013 Consensus Statement	[3.192]
	Model for increasing palliative care capacity	Project ECHO: An Effective Means of Increasing Palliative Care Capacity	[3.193]
	Model for increasing palliative care capacity	Developing Community Palliative Care Programs Using a Capacity Building Approach: The Northwestern Ontario Experience	[3.194]
	Models of palliative care delivery	Models of Palliative Care Delivery for Patients with Cancer	[3.195]

3.7.4. Teaching, research and clinical trials

3.7.4.1. Training programmes

Like other key oncological disciplines, the accessibility of palliative and survivorship care is limited by insufficient human resources and workforce capacity. As all clinical staff who interact with oncology patients at a cancer centre need to have at least basic palliative care training, cancer centres need to have an in-house palliative care training programme, with opportunities for additional training at outside institutions as needed. This training needs to cover compassionate and effective communication, pain management strategies (non-pharmacological and pharmacological), management of common symptoms associated with cancer and its treatment, and end of life care. Additionally, all clinical staff need to have sufficient training to identify and support the psychosocial needs of patients and families directly or by connecting them with the appropriate resources. There are a number of institutions that provide educational material for palliative care team members [3.196, 3.197].

3.7.4.2. *Research*

Research into innovations to improve access to palliative care services and palliative care delivery in resource constrained settings is an urgent need. This research may include basic, clinical, implementation science [3.198] and health systems related studies aimed at developing palliative care treatment guidelines across varying resource settings or palliative care practice models that can be scaled up as needed. Palliative care research also presents an opportunity to explore the ethical dimensions of cancer care in a way that is rarely addressed in other oncology disciplines. There are unique research opportunities at all cancer centres, as different communities have different cultural beliefs regarding death, which alter the dynamics and conversations regarding the trade-offs between treatment efficacy and toxicity, as well as end of life care. Although the cultural beliefs vary, the principles of compassionate humanism that imbue these conversations with meaning are universal and can provide insight into how conversations between clinicians, patients and families can be conducted in a way that provides patients with dignity and control in their cancer care.

3.7.4.3. *Quality assurance*

QA in palliative care needs to be approached in a similar standardized fashion as has been discussed for other oncological disciplines. This includes establishing and implementing clinical guidelines and SOPs adapted to the local context to ensure that high quality, evidence based care is delivered. An additional point of emphasis for QA that is unique to palliative care is the safe utilization of opioid medications. The essential role of opioids in the management of cancer patients needs to be balanced with the harms resulting from non-medical opioid use. However, access to medicines for the relief of pain is increasingly being viewed as a human right, which needs to not be unduly sacrificed in the pursuit of minimizing the potential illicit use of these substances [3.166, 3.199]. Reasonable requirements include ensuring secure storage of morphine in a locked and well anchored location; maintaining records of opioid supply at all points through the supply chain, including amount prescribed and wasted or returned; and careful documentation of opioids administered in clinics and in patients' homes (Table 3.18).

TABLE 3.18. PALLIATIVE CARE SERVICE LEVELS AND REQUIREMENTS

Level of cancer centre	Technologies/ equipment needed	Skilled human resources needed	Competencies needed
Level 1	Outpatient emergency care, home care, immediate release morphine (oral and injectable) sufficient to meet the needs of all patients with moderate to severe pain or terminal dyspnoea that cannot be relieved adequately by other means	At least one physician and one nurse with basic training in palliative care; general physicians, nurses, pharmacists, counsellors, community health workers, social worker, chaplain	MNT, basic palliative care training in pain and symptom management, palliative radiotherapy, surgery, and chemotherapy
Level 2	In addition to Level 1, inpatient palliative care, enteral nutrition, extended release opioids, off-patent morphine formulations, patient controlled anaesthesia, wheelchairs, canes, crutches, hearing aids, programmes for financial support (housing, food, transportation, etc.)	In addition to Level 1, dietician, psychologist, physical therapists, occupational therapists	In addition to Level 1, nurses and physicians with specialized palliative care training
Level 3	In addition to Level 2, parenteral nutrition, advanced body composition assessment techniques	In addition to Level 2, full time doctor and nurses with specialized cancer qualifications, multidisciplinary team of psychologists, counsellors, pharmacists, physiotherapist, spiritual care providers, dieticians specializing in cancer care, social workers and trained volunteers	In addition to Level 2, specialized paediatric palliative care, legal/ethical expertise

3.8. PREVENTIVE ONCOLOGY

3.8.1. Rationale

Prevention of cancer has become one of the most significant public health challenges. It has an essential role in the fight against cancer. Building on the

current scientific evidence, 30% to 50% of cancer cases could be prevented by effective primary prevention measures, and further mortality can be reduced by early detection/diagnosis of tumours [3.200, 3.201]. Cancer prevention activities need to be selected on the basis of the country's cancer burden and contextual cost effectiveness, ensuring equity and acceptability. Population wide interventions generally have a greater potential impact. Individual interventions need to be part of a broad integrated national strategy and not be implemented in isolation. Comprehensive cancer centres have a significant role in cancer prevention. Cancer centres may provide cancer prevention services, positively influencing the status of a comprehensive cancer centre. A preventive oncology unit can lead and coordinate the work in the cancer centre along with activities in the wider community. This unit could be set up with a separate entrance to make it easier and welcoming for walk-in clients. Staff trained in public health or preventive and community medicine with skills in cancer prevention and screening can lead and provide such services. All departments will have a role in prevention, especially cancer epidemiology and cancer registry.

3.8.2. Services to be provided and human resources

Preventive oncology covers preventive and promotive activities that can be provided at cancer centres of all levels. Screening needs to be offered to asymptomatic individuals, while early diagnostic tests need to be provided to those who are symptomatic. In both situations, those with suspected cancer need to be followed by diagnostic confirmation and initiation of treatment. A WHO guide for early cancer diagnosis has more details and can be used as a resource in planning services. The scope of preventive oncology services is provided in Box 3.6 (adapted from Ref. [3.65]).

3.8.3. Public awareness

The general public needs a good understanding of cancer, its risk factors and prevention possibilities. Cancer centres are well placed to provide the content for such programmes and can engage various channels, including print, electronic and social media for their propagation.

In addition, individual and group activities can be taken up in various settings like schools, the workplace and health facilities. The involvement of community champions, volunteers and community based organizations can help to emphasize and sustain the messages. Cancer detection camps are another avenue for offering services closer to the community.

In addition to the generation of awareness and screening activities, it is important that health teams mobilize community support to address the

BOX 3.6. SCOPE OF PREVENTIVE ONCOLOGY IN A COMPREHENSIVE CANCER CENTRE

- (a) Development and dissemination of information related to cancer risk factors and identification of ‘red flag’ symptoms of cancer;
- (b) Technical support for local and national government cancer control programmes;
- (c) Tobacco cessation programme;
- (d) On-site cancer detection and screening services;
- (e) Cancer related health check-up, screening services for walk-in clients;
- (f) Outreach programmes;
- (g) Early cancer detection centres in peripheral hospitals;
- (h) Training and utilization of community health workers to support cancer awareness and services in the community;
- (i) Facilitating linkage to pathology and diagnostic services;
- (j) Facilitating patient support groups.

non-medical needs of cancer patients. Examples include linking the community to the cancer centre; social work, including financial welfare and family support; bereavement support; social support for people coming to cancer centres; patient navigator support; and patient follow-up during all cancer treatment.

3.8.4. Opportunistic screening and early detection

In many parts of the world, common and detectable cancers present in late stages. Cancer centres can offer a service through the preventive oncology unit for screening and early detection. The facilities of the cancer centre can make this more feasible and almost all services can be provided ‘under one roof’.

3.8.5. Counselling and support for survivorship care

Patients and their relatives attending the cancer centre will need psychosocial support and counselling, and these can be organized through the preventive oncology unit. This will be a big help to the clinical care providers and will ease the journey of patients and their carers in the cancer centre.

3.8.6. Contribution to national programme and policies

Specialists working in a cancer centre are also expected to provide technical support for local and national government cancer control programmes. They can guide the development and local adaptation of global recommendations, norms and standards; supportive supervision of population based activities; and support in capacity building for all cadres of health personnel involved in cancer prevention.

3.8.7. Preventive oncology services in cancer centres

Preventive oncology units are needed at all levels of the cancer centre. Table 3.19 provides an illustration of the services provided and the human resources with required skills to provide these services. These can be contextualized when cancer centres are organized in countries. Examples provided are for general cancer awareness and for breast, cervical, oral and colorectal cancer. Requirements for other cancers can be found in IARC and WHO resource materials [3.31, 3.208, 3.209].

At all levels, linkages with diagnostic facilities and treatment centres have to be clearly established to facilitate patient navigation through the system. Patients have to be offered support at every step until confirmation of diagnosis and initiation of treatment. Follow-up of diagnosed cases is important and community involvement will be crucial for achieving proper follow-up throughout the entire cancer care continuum.

3.8.7.1. Quality assurance

QA in preventive services and cancer care have to be observed, given the laboratory and radiological procedures involved in screening and early diagnostic tests. This would include establishing standard guidelines and SOPs adapted to the local context. Supportive supervision from higher levels would go a long way in establishing and delivering high quality, evidence based care.

CHAPTER 3

TABLE 3.19. SERVICES, ACTIVITIES AND HUMAN RESOURCES REQUIRED FOR CANCER SCREENING AND EARLY DETECTION IN CANCER CENTRES OF DIFFERENT LEVELS

Services	Activities	Human resources needed
General cancer awareness		
Population awareness initiatives and general cancer awareness	Organization and management of cancer awareness activities Mobilization of community support Settings: workplace, health facility, schools, community	Persons trained in PH or PO; nursing professionals, community health workers, social workers and trained volunteers
Breast cancer [3.31, 3.202, 3.203]		
Breast examination	Clinical breast examination	Surgeon, PH/PO; nursing professional
Breast imaging	Screening mammography; breast ultrasound	Radiologist; radiographer
Breast pathology	Fine needle aspiration cytology	Surgeon; cytotechnologist
Cervical cancer [3.31, 3.204, 3.205]		
Preventive immunization	HPV vaccination	PH/PO; health worker; nursing professional
HPV testing	HPV testing	Gynaecologist; PH/PO; nursing professional
Screening of precancerous lesions	Visual inspection with acetic acid test; colposcopy (with or without biopsy); LEEP/LLETZ; cryotherapy	PH/PO; gynaecologist; nursing professional; laboratory technician; cytotechnician; cytotechnologist
Oral cancer [3.31, 3.206]		
Physical examination	Oral visual examination	PH/PO; dental surgeon; ENT surgeon; dental assistant; nursing professional

TABLE 3.19. SERVICES, ACTIVITIES AND HUMAN RESOURCES REQUIRED FOR CANCER SCREENING AND EARLY DETECTION IN CANCER CENTRES OF DIFFERENT LEVELS (cont.)

Services	Activities	Human resources needed
Oral pathology	Fine needle aspiration cytology	Oncologist; dental surgeon; ENT surgeon; pathologist;
	Immunohistochemistry	cytotechnologist; dental assistant; nursing professional
Imaging	Fluorescence imaging	Oncologist; dental surgeon; ENT surgeon; dental assistant; nursing professional
Colorectal cancer [3.31, 3.207]		
Stool based tests for occult blood	Guaiac test, faecal immunochemical test	Laboratory technician
Endoscopy	Proctoscopy, sigmoidoscopy colonoscopy	Gastroenterologist; surgeon; nursing professional
Imaging	CT colonography	Radiologist; radiographer; nursing professional

Note: CT: computed tomography; ENT: ear, nose and throat; HPV: human papillomavirus; LEEP/LLETZ: large loop excision of transformation zone; PH: public health; PO: preventive oncology.

3.8.8. Research in preventive oncology

There is an ongoing need for research in the prevention of cancer. With the changing pattern of risk factors such as obesity, dietary habits or environmental factors, a decrease in exposure to such risk factors could lead to a reduction in cancer incidence. The emergence of new screening and diagnostic techniques can add to early detection and improvement in prognosis. Well designed epidemiological studies can provide valuable information about causal factors, new preventive methods and the cost effectiveness of various treatment modalities. In recent years, there has been an increasing focus on qualitative research, which can provide valuable insights into the determinants of high risk

behaviour such as tobacco and alcohol use, which are strongly influenced by human behaviour, psychosocial and cultural factors.

3.9. PAEDIATRIC ONCOLOGY

3.9.1. Rationale for paediatric oncology

It is estimated that every year about 400 000 children aged 0–14 years around the world are newly diagnosed with cancer [3.210]. Cancers are among the leading cause of death among children aged 0–14 years in HICs, and the ninth leading cause of childhood disease burden globally [3.211, 3.212].

Childhood cancers have some unique characteristics that warrant a different approach to strategizing services compared with adult cancer management (Table 3.20). First, childhood cancers are generally not preventable. Thus, the only means of reducing the burden is early detection and treatment. Second, the vast majority of children with cancers can achieve high rates of survival with effective treatment, which can be achieved by multimodality therapy using conventional chemotherapeutic agents, unlike adult cancers; in HICs about 85% of children with cancer survive the disease [3.213]. Third, setting up facilities for management of the most common types of childhood cancer requires relatively fewer resources compared with cancers in adult age groups [3.214]. An overview of the paediatric oncology process is given in Box 3.7.

Some estimates show that globally about 43% of children with cancer remain undiagnosed, with the highest figure being 57% for Western Africa [3.210]. The global five year survival rate for childhood cancer has been estimated to be 37.4%, which ranges from 8.1% in Eastern Africa to 83% in North America [3.213]. These facts clearly reflect the disparity both in access to and quality of care available in different regions of the world.

To address this gap, the WHO Global Initiative on Childhood Cancer was launched in 2018, which aims to achieve a global survival rate of 60% for childhood cancer by 2030. The initiative has identified six of the most common childhood cancers with high curability and relative ease of treatment as the index cancers. These include acute lymphoblastic leukaemia (ALL), Burkitt lymphoma, Hodgkin lymphoma, Wilms' tumour, retinoblastoma, and low grade glioma, which together comprise 50–60% of all childhood cancers [3.215].

3.9.2. Paediatric oncology as part of multidisciplinary care

Treatment in childhood cancer is carried out in tertiary level care facilities for children that provide expertise in multiple disciplines. Treatment of a child

BOX 3.7. OVERVIEW OF THE PAEDIATRIC ONCOLOGY PROCESS

- (a) Making a diagnosis. Cancer diagnosis is usually made in a primary/secondary or tertiary level health facility as part of an evaluation of some specific or persistent symptoms or signs. Making or confirming a diagnosis of leukaemia usually involves examination of blood and bone marrow. Other tumours are usually suspected by radiological imaging and frequently confirmed with a biopsy/tumour markers.
- (b) Work-up and planning before treatment. This involves further tests to classify the subtype of cancer or identify the risk category (using tests such as additional immunohistochemistry, flowcytometry, cytogenetics and molecular genetics) or to determine the stage of the disease (through further imaging tests, including nuclear imaging) and assess the general condition of the patient. This is best done by engaging an MDT, which makes an appropriate plan based on standard treatment regimens, taking into consideration the particular characteristics of the patient.
- (c) Starting treatment. For ALL, this usually involves starting induction chemotherapy, which lasts for four–five weeks. For all other childhood malignancies, the initial treatment usually involves starting the first cycle of chemotherapy, or upfront surgery in some specific types of cancer. Chemotherapy is usually provided in cycles, allowing time for the child to recover from the severe adverse effects of the medicines while the cancerous cells have still not had time to grow back to their previous size/extent. The standard doses and regimens are guided by multicentre clinical trials, which have been conducted over the years by many collaborations. However, these standard guidelines may need to be adapted to the local context. Surgery and RT may be required for some tumours at various points during chemotherapy. RT is to be avoided whenever possible, especially in very young patients and in situations where the outcome is not significantly compromised, in view of the long term toxicities.
- (d) The treatment for most cancers, including ALL, is intensive, involving high doses of chemotherapy in relatively short spaced cycles. This intensive phase lasts from two to eight months, depending on the type of cancer. Children may need to be admitted for certain types of chemotherapy, while some other types can be provided in day care. Frequently, adverse effects, such as neutropenia and infections, will warrant multiple admissions and, on occasions, need for intensive care. Treatment for most cancers ends with completion of the intensive phase.
- (e) Maintenance phase of treatment. In some childhood cancers, the intensive phase is followed by a subsequent phase with low intensity chemotherapy. This

is specifically relevant in the management of ALL, where the intensive phase is followed by a prolonged maintenance phase that entails low dose chemotherapy for two to three years.

- (f) Shared care model. In the maintenance phase, the child is expected to have an otherwise normal routine, and it is preferred that the child stays at home and goes to school and visits hospital once a month for maintenance phase treatment/evaluation. This can be achieved more comfortably via a shared care model in which health facilities with general paediatric services are provided with some capacity building/training to enable the delivery of maintenance phase treatment. Since the shared care or satellite centre is nearer the child's home, this model is expected to significantly reduce the burden on families due to the child's cancer treatment. This approach is being tried in some countries and the final outcome is yet to be seen [3.216]. This model also offers the opportunity to further strengthen the capacity of shared care centres for early diagnosis and for delivery of post-treatment follow-up and palliative care.
 - (g) Follow-up and survivorship care. Completion of treatment is followed by post-treatment evaluation, usually after around six weeks, and regular follow-up every three–six months, where the child is monitored for adverse outcomes (late effects) due to treatment or for recurrence of the disease. The frequency of follow-up is gradually reduced to yearly or less. Structured follow-up guidelines for each childhood cancer are available, which may need to be adapted to local settings. These guidelines include surveillance strategies for disease recurrence, as well as monitoring for late effects of therapy.
 - (h) Palliative care. This is provided as part of curative intent treatment or as end of life care. In the latter, it is preferred that the services be delivered from primary health care closer to the patient's home.
-

with cancer may require one of the following approaches, depending on the diagnosis and staging:

- Systemic chemotherapy alone;
- Neo-adjuvant chemotherapy, surgery (and/or RT) and adjuvant chemotherapy;
- Surgery and adjuvant chemotherapy;
- Surgery alone;
- Chemotherapy and RT;
- Chemotherapy, surgery and RT.

Systemic therapy, including chemotherapy, is the mainstay of treatment for the most common types of childhood cancer. However, solid tumours — such as Wilms' tumour, hepatoblastoma, neuroblastoma and germ cell tumours — require surgery as an integral part of treatment. A large number of cancers in children require RT. The need, timing and approach of surgery and RT are best decided by an MDT meeting; inputs are also provided by the nursing team, dieticians and pharmacists. Wilms' tumour, retinoblastoma, osteosarcoma and soft tissue sarcomas are typical diseases in which treatment is not possible without engagement of MDTs, which achieve excellent outcomes.

3.9.3. Human resources

Since paediatric oncology is part of a multidisciplinary approach, human resources with the capability to treat cancers in adults are also capable of caring for children. However, some expertise in paediatric oncology is needed, as described below.

3.9.3.1. Paediatric oncologist

The paediatric oncologist has a central role in delivering care for a child with cancer and usually coordinates the care to be provided by experts in other disciplines. Paediatric oncologists are involved in making the diagnosis, initial evaluation and staging; counselling the family and child; planning the treatment; delivering the treatment; directing the coordination of care; and managing complications, follow-up and survivorship care.

Paediatric oncologists are trained in paediatric oncology after their specialization in general paediatrics. This training ranges from one–two years of fellowships to three years of a formal subspeciality degree of Doctorate of Medicine.

3.9.3.2. Paediatric oncology nurse

Nurses in the paediatric oncology unit are responsible for general nursing care of children with cancer. In LMICs, the nurses in the paediatric oncology unit are also responsible for the preparation and administration of chemotherapy. Some of the nurses build expertise in the care of central lines and in infection prevention and also offer psychological support. Paediatric oncology nurses can have some form of formal diploma or fellowship training in paediatric oncology, usually provided after a graduate nursing degree. The availability of such training programmes in LMICs is, however, very limited. Most of the childhood cancer treatment centres depend on nurses with training in general nursing who acquire

skills by experience through working in paediatric oncology. In such instances, it is recommended that new nursing staff joining the unit are given induction training, followed by supervised co-work, and then annual training for updating knowledge and skills [3.217].

3.9.3.3. *Pharmacist*

Pharmacists are required to prepare the chemotherapy medication. However, in many centres in LMICs, this task is carried out by nurses in the paediatric oncology unit.

3.9.3.4. *Paediatric surgeon*

Many childhood cancers, such as Wilms' tumour, neuroblastoma, hepatoblastoma and osteosarcoma, need surgery as an integral part of treatment. In most countries, a paediatric surgeon requires three years of training after specialization in general surgery. There are some programmes that provide five–six years of training directly after a medical degree.

3.9.3.5. *Radiation oncologist*

Ideally, RT needs to be delivered by someone with specialized training in paediatric RT. While most HICs have such expertise available, it is not commonly available in LMICs. In such a situation, special in-service training needs to be provided to the radiation oncologists treating children.

3.9.3.6. *Paediatric anaesthesiologist*

Paediatric anaesthesiology services are required for children with cancer for carrying out surgeries, during RT and also during procedures such as lumbar puncture, bone marrow aspiration and tissue biopsies. While formal fellowships and university degree programmes are available in many countries, anaesthesiologists with such subspeciality training are not commonly available in LMICs. Hence, some form of in-service training is needed.

3.9.4. Equipment

Much of the equipment required for the management of childhood cancer is similar to that used for the management of adult cancers. However, special consideration needs to be given to the size of specific equipment for paediatric age groups. Details of the equipment required for childhood cancer are available

in the WHO list of priority medical devices for the management of cancer [3.31]. Some of the minimum equipment required or of special importance for childhood cancer is listed below:

- (a) Bone marrow aspiration and biopsy set and accessories;
- (b) Lumbar puncture and intrathecal chemotherapy administration set and accessories;
- (c) Flow cytometric immunophenotyping equipment;
- (d) Biosafety cabinet;
- (e) PPE;
- (f) Venous access devices, including a 'port-a-cath', peripherally inserted central catheter (PICC) line, Hickman lines, etc.

All other equipment relevant for systemic administration of chemotherapy and adult oncology is applicable for paediatric oncology as well.

3.9.5. Research in paediatric oncology

Research in paediatric oncology has led to significant achievements in the field of cancer treatment, such as the first use of chemotherapy by S. Farber in 1947 [3.218]. Continuing research and application of findings has led to the attainment of up to 85% survival rates in childhood cancers in HICs. The duration and adverse effects of treatment, however, warrant that further basic and translational research be continued so as to develop simpler treatment modalities with minimal or more acceptable adverse effects. When specific cancer types are considered, childhood cancers, in general, are rare diseases. This makes it necessary that research efforts are collaborative, with the involvement of multiple centres, and are usually multinational. Some examples of large collaborative research groups include the Children's Oncology Group (USA) and the Children's Cancer and Leukaemia Group (United Kingdom).

Research in LMICs is required to find answers to the unique challenges posed by resource constraints. Examples include studies conducted on the safety of administering high dose methotrexate in the absence of a facility for monitoring the drug level [3.219]. The feasibility of larger collaborative research in LMIC settings has been demonstrated in some countries. Research in paediatric oncology needs to have proportionate focus on research in paediatric oncology nursing. Implementation research is important for objective identification of hurdles in implementing interventions to improve the quality and accessibility of childhood cancer care.

3.9.6. Quality assurance

Efforts have been made to define consensus quality indicators in paediatric cancer care in the areas of general childhood cancer care, outpatient settings, nursing care and critical care, among others [3.220–3.222]. Some of the proposed indicators include the following:

- Five year survival rates;
- First therapeutic intervention wait time;
- Drug availability;
- MDT meetings;
- Chemotherapy certification of nursing staff;
- Drug/dose errors;
- Infection control measures;
- Central venous line infection rate;
- Early warning score system for patient deterioration;
- Timely transfer to paediatric intensive care unit;
- Abandonment rates.

Further work on the identification of the most useful consensus indicators, their application and validity are required from the broader paediatric oncology community (Table 3.20).

TABLE 3.20. PAEDIATRIC ONCOLOGY SERVICE LEVELS AND REQUIREMENTS SPECIFIC TO TECHNOLOGY AND TRAINING

Level of cancer centre	Technologies needed	Skilled human resources needed	Paediatric oncologist competencies needed
Shared care centre	Blood counts, renal and liver function tests and other basic tests Medicines for maintenance phase treatment Biosafety cabinet PPE	Paediatrician, nurse with some training in shared care for maintenance phase of ALL, or adjuvant chemotherapy in Wilms' tumour and similar level of care	Paediatrician and nurses trained in relevant aspects of childhood cancer care to ensure delivery of maintenance phase treatment, including supportive care

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TABLE 3.20. PAEDIATRIC ONCOLOGY SERVICE LEVELS AND REQUIREMENTS SPECIFIC TO TECHNOLOGY AND TRAINING (cont.)

Level of cancer centre	Technologies needed	Skilled human resources needed	Paediatric oncologist competencies needed
Level 1	<p>Blood counts, peripheral blood smear examination, bone marrow aspiration cytology and biopsy examination, flow cytometry, tissue biopsy examination, cerebrospinal fluid evaluation and cytology, X ray, ultrasonography, CT scan</p> <p>In-house or dependable arrangement with third parties for immunohistochemistry, cytogenetic studies and nuclear imaging</p> <p>Standard treatment regimens with local adaptation</p> <p>Central venous access technology, chemotherapy preparation, medicines for supportive care, common surgeries for childhood cancers, paediatric intensive care facility, dedicated rooms for neutropenia and for possible contagious illnesses</p> <p>In-house or shared care arrangement for RT</p>	<p>Laboratory technicians, pathologists, radiologists, radiology technicians, paediatric oncologists, pharmacists or trained nurses for chemotherapy preparation and handling, general paediatricians, nursing staff trained in paediatric oncology, paediatric intensivists, paediatric surgeons, dietician</p>	<p>Making diagnoses of cancer in children, providing counselling to the child and family, planning treatment based on standard regimens, leading and coordinating treatment from multiple specialities, identifying and managing complications of treatment</p> <p>Leading the team and supporting learning and growth for all team members</p>

TABLE 3.20. PAEDIATRIC ONCOLOGY SERVICE LEVELS AND REQUIREMENTS SPECIFIC TO TECHNOLOGY AND TRAINING (cont.)

Level of cancer centre	Technologies needed	Skilled human resources needed	Paediatric oncologist competencies needed
Level 2	In addition to Level 1: MRI, in-house immunohistochemistry, cytogenetics In-house nuclear imaging and RT preferred SOPs for chemotherapy preparation and administration Surgeries for complex and late stage tumours; orthopaedic surgery and rehabilitation	In addition to Level 1: Oncopharmacist, orthopaedic surgeon, other subspeciality surgeons Infectious disease specialist Physiotherapist, play therapist, social worker, counsellor, teacher	Convene MDT meetings Develop/conduct training/education programmes Implement QA measures
Level 3	In addition to Level 2: Nuclear imaging, Haematopoietic stem cell transplantation, CAR T-cell therapy	In addition to Level 2: Nuclear physician and technicians, transplant physician and nurse	Haematopoietic stem cell transplant Management of complications such as graft versus host disease and cytokine storm with the MDT

Note: ALL: acute lymphoblastic leukaemia; CT: computed tomography; MDT: multidisciplinary team; MRI: magnetic resonance imaging; PPE: personal protective equipment; QA: quality assurance; RT: radiotherapy; SOP: standard operating procedure.

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Chapter 4

CANCER CENTRES: KEY SUPPORTIVE SERVICES

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4.1. ONCOLOGY NURSING

4.1.1. Rationale for oncology nursing

Specialist oncology nurses are crucial in the delivery of quality oncology services and are critical participants in cancer control and treatment worldwide [4.1]. When caring for patients with cancer, they apply specialized knowledge across the continuum of patient care, from community care to intensive care, and in a variety of roles, from point of care to administrative leadership [4.2]. Global oncology nursing societies support the contributions of oncology nurses in the delivery of holistic cancer care across the cancer continuum to complex patients, tailoring care to the person, family, population, setting and available resources [4.1–4.3].

4.1.2. Oncology nursing as part of multidisciplinary care

As members of multidisciplinary cancer care teams, oncology nurses provide direct care to patients in acute, ambulatory and community settings to improve cancer outcomes and reduce the burden of the disease on patients, families and countries. They may serve as direct care providers after surgery or as care coordinators between the hospital and community settings, in roles such as community health nurses and nurse navigators. Oncology nurses can hold a variety of roles, including the following:

- Cancer prevention and screening. Public health and community nurses are involved in community education to reduce cancer risk, promote healthy behaviours, develop and administer vaccination programmes (e.g. HPV vaccination), screening programmes (e.g. cervical cancer screening), and navigation through cancer care system community education.

- Cancer treatment. Oncology nurses are involved in delivering chemotherapy and immunotherapies, assessment and management of the treatment of specific symptoms from chemotherapy, immunotherapies and RT.
- Supportive care and symptom management.
- Follow-up and survivorship care.
- Palliative and end of life care.

4.1.3. Human resources

While there are no specific numbers on the oncology nursing workforce globally, there are disparities between higher and lower resource settings that impact delivery of cancer care and the burden of this disease. Table 4.1 lists the nursing requirements that ideally should be present in the three facility levels providing cancer services, while Table 4.2 outlines the suggested nursing roles, levels, education and competencies for each of the three levels of cancer centre.

Generalist nurses are trained to diploma, baccalaureate, master's or doctoral level. Diploma and baccalaureate nursing education is general and basic, preparing the nurse to become a registered nurse and function as a novice in a health care area [4.3]. In contrast, graduate and doctoral programmes enable nurses to assume roles in advanced practice as nurse practitioners or clinical nurses specializing in leadership, education and research to advance best practice [4.14].

Safe and effective oncology practice requires the professional nurse to have a knowledge base specific to cancer and clinical expertise beyond the fundamental skills learned in a basic programme¹. There are subspecialty oncology nursing roles, such as radiation oncology, palliative and hospice care, clinical research, and oncology nurse navigators (see Table 4.2). Both novice and experienced generalist nurses new to oncology have to acquire the necessary skills and competencies through supervised practical training to deliver safe, high quality care [4.2].

4.1.4. Quality assurance

To achieve quality patient outcomes in a cancer centre, it is important to organize nursing service divisions or programmes according to best practices in service performance. Health service accreditation bodies and professional associations have developed standards and guidelines that can serve as guides for organizing nursing service departmental structures and policies based on best practices and evidence [4.2, 4.3]. Additionally, nursing leaders have described

¹ <https://www.oncc.org/>

what is needed within health care facilities to support nursing staff and patient safety, including essential medications for cancer treatment, supportive care and symptom management, and priority medical devices such as infusion pumps [4.15, 4.16].

Ultimately, practice environments need to be organized so that they enable nurses to practice to the full scope of their capabilities and quality patient outcomes can be achieved. Policies are needed that establish and support the growth of such a work environment. The types of policy that will facilitate the development and growth of this type of practice environment are those that aim to achieve the goals described below.

TABLE 4.1. NURSING REQUIREMENTS IN LEVEL 1, 2 AND 3 CANCER CENTRES

Level 1	Level 2	Level 3
Community based	Middle level (e.g. a cancer ward in a general, acute care hospital or a palliative unit in a nursing home)	Comprehensive cancer centre or multispeciality tertiary care facility
Generalist nurses Additional preparation through certification or advanced skills Senior nurses as mentors, access workshops and use of tertiary cancer centre as a resource	Mix of generalist and specialized oncology nurses on the ward Generalist nurses, trained through certification Presence of a clinical educator Senior nurses as mentors, supported to take certificate programmes, either on-site or at another site; ongoing education provided Access to other specialized nurses (e.g. wound care, palliative care)	Mix of generalist, specialized oncology and palliative care nurses Mandatory developmental pathway to specialization for generalist nurses Advance practice nurses: educators, clinically specialized and nurse practitioners Nurses in specialized programmes (e.g. wound care, geriatrics, adolescent and young adults, survivorship, palliative care) On-site specialized training, supported specialized training (on- or off-site), ongoing education provided and supported if off-site (e.g. conferences, workshops)

TABLE 4.2. CANCER CARE NURSING ROLES

Role	Education	Responsibilities	Certification and competencies
Generalist nurse	Basic nursing education	Assessment Nursing care delivery Cancer risk assessment Community education Primary care	Licensed as a registered nurse in country/state of practice
Nurse with expertise in oncology	May have advanced education after generalist training	Educate patient/family Treatment administration Coordinate care Provide supportive care Provide psychosocial support Referral to specialized services	Chemotherapy training and certificate (country specific) Certification as oncology certified nurse [4.4] Advanced oncology certified nurse [4.5] Certified oncology nurse, specialized in haematology, solid tumours (Canadian Association of Nurses in Oncology) [4.6]
Radiation oncology nurse	Advanced training after generalist training	Educate patient/family about RT Assess and manage side effects and symptoms Coordinate care Provide psychosocial support Referral to specialized services	ONS, Radiation Oncology Certificate Course [4.7] Canadian Association of Nurses in Oncology, specialized radiation nurse [4.6]
Palliative and hospice care nurse	Oncology specialized nurse with advanced training in palliative and end of life care	Assess and manage cancer related symptoms Provide psychosocial support to patient and family/carers Provide end of life care	Hospice and Palliative Care Nurse certification (country specific) [4.8] Canadian Association of Nurses in Oncology, palliative cancer nurse [4.6]

TABLE 4.2. CANCER CARE NURSING ROLES (cont.)

Role	Education	Responsibilities	Certification and competencies
Oncology nurse navigator	Oncology specialized nurse with advanced training in navigation	Bridge community screening and diagnosis and treatment Identify and help overcome barriers to access care Coordination of care across speciality and primary care settings	Competencies developed (ONS) [4.9] Certification being developed
Clinical research nurse	Training as an oncology specialized nurse with additional training in clinical trials	Coordinate clinical trials to ensure patient safety, assessment and adherence to protocols Educate patient/family Coordinate care/tests Collaborate with clinicians and research team	Competencies developed (ONS) [4.10] IACRN Scope and Standards (2016) [4.11]
APN/nurse practitioner ^a	Master’s degree/DNP	Symptom management Pre-treatment/diagnosis assessment Follow-up care Survivorship Direct patient care	Licensure as APN Speciality certification, advanced oncology certified nurse practitioner [4.12] May have faculty appointment May have prescriptive authority
APN/clinical nurse specialist ^a	Master’s degree/DNP	Provide nursing education Bridge evidence to practice unit based education Patient and family clinical care QI	Licensure as APN May have certifications such as: — Advanced Oncology Certified Nurse Practitioner [4.12] — Canadian Nurses Association 2014 [4.13] May have faculty appointment May have prescriptive authority

TABLE 4.2. CANCER CARE NURSING ROLES (cont.)

Role	Education	Responsibilities	Certification and competencies
PhD nurse researcher	PhD	Generate evidence Have faculty appointment Train graduate level nurses and researchers	Programme of research Faculty at academic institution

^a Roles of APNs are merged into one role in some settings.

Note: See Annex I for the International Council of Nurses (ICN) definition of a nurse and details on oncology nursing professional organizations.

Note: APN: Advanced practice nurse; DNP: Doctor of Nursing Practice; IACRN: International Association of Clinical Research Nurses; ONS: Oncology Nursing Society; RT: radiotherapy.

- Promoting a patient/client centred philosophy. The provision of care is respectful of, and responsive to, individual patient/family preferences, needs and values and ensures that those values guide all clinical decisions. For nurses and other health care professionals, this means consciously seeking, as a priority in their interactions, an understanding of the patient’s perspective about what is important, working *with* individuals rather than *for* them.
- Fostering a learning environment. This includes placing value on continuous lifelong learning; cultivating a culture of questioning, openness and flexibility; rewarding critical thinking, problem solving and innovation; and focusing on continuous QI.
- Ensuring that procedures and programmes are evidence based. This means adopting perspectives and strategies that reward the use of research evidence to inform decision making in daily practice and designing processes to incorporate evidence into clinical policies/programmes; and introducing approaches to implement evidence based programmes and policies in clinical settings.
- Maintaining appropriate nurse–patient ratios. Having appropriate numbers of suitably qualified nurses has been strongly linked with patient safety, quality patient outcomes, staff satisfaction, quality of working life and financial savings for institutions.
- Offering a system of accountability. For nurses, such a system includes clarity of roles and responsibilities, clearly stated expectations for performance, and being held responsible for not just tasks but also interactions (how to communicate) and patient outcomes under the nurse’s control. Having documentation or a record system and specified ways in which staff members

receive constructive feedback on a regular basis helps to support a system of accountability. Additionally, having a system for measuring quality of care within the facility is critically important.

- Fostering the professional development of nurses. With the rapidly changing nature of knowledge and its potential to influence practices, nurses will need access to education at both a generalist and a specialized level. Career pathways need to be clearly laid out for nurses, together with the available mentorship and fellowship programmes.
- Supporting the development of nursing leadership. This is an issue of central importance because leaders have the responsibility for embracing the vision of an empowering practice environment and bringing that vision to life. Leadership is vitally important within the hierarchy of an institution, but it also needs to be clearly evident at the point of patient care. The voice of nursing needs to be present and strong throughout the health care system. Patients and families need strong nurses.

Nurses are critically important members of the health care team and can make a significant difference in the lives of patients and families. However, to have such an impact, nurses need to be able to work to the full scope of their education and in accordance with evidence based standards of professional practice and care. Only then will quality patient outcomes be achieved. Strong nursing leadership will be needed to implement policies that facilitate the breadth of practice performance for which nurses are capable.

4.1.5. Training oncology nurses

Cancer control centres can support nursing development by outlining minimum expectations for oncology nursing practice on the basis of recognized oncology nursing standards [4.1–4.3, 4.17]. In addition, certain countries, such as Canada and the USA, have developed specialization designations, competencies and certifications through oncology nursing societies in partnership with nursing governing bodies, including chemotherapy/immunotherapy administration courses [4.2, 4.3]. These standards and competencies can be used to develop educational programmes in specific countries within the context of that country. Training may range from hospital based certification to diploma level and beyond, depending on the programme of study.

In addition to supporting specialization designation, oncology nursing standards and competencies inform basic expectations for oncology nursing practice. At minimum, nurses should receive an oncology focused orientation, be trained to achieve mandatory certification in the safe administration of chemotherapy/immunotherapy and management of side effects, and receive

continuing education to augment clinical practice and maintain quality care [4.2, 4.3, 4.18, 4.19].

Once trained, oncology specialized nurses have advanced skills in patient and family education on cancer disease and treatments, can safely administer systemic therapy, manage side effects of treatments and disease, and provide supportive care. Oncology APNs, such as nurse practitioners and clinical nurse specialists, usually have completed a post-graduate or master's degree programme. Doctoral education at the Doctor of Nursing Practice or PhD level is necessary for nurse scientists and faculty. The Canadian Nurses Association has developed educational pathways for speciality nurses.

It is also important to develop long term strategies to sustain oncology nursing training and specialization. Very few countries have developed standards for the defined scope of practice for oncology nurses, and this may lead to potential confusion when formulating training curriculums for oncology nurses [4.19]. Oncology nursing curricula have been developed by the ONS, European Oncology Nursing Society, the Association of Pediatric/Hematology Oncology Nurses and WHO [4.20–4.23]. These curricula, when adopted and contextualized to individual settings, create the foundation for evidence based oncology nursing education. In addition, it is important to consider faculty development and to have partnerships between teaching hospitals and schools of nursing to develop an oncology faculty. Expert oncology faculty can enhance oncology nursing training, carry out and support contextually relevant research to support regional best practice and contribute to the development of advanced oncology practitioners with graduate degrees.

The need for oncology nursing education will continue to grow as treatment advances continue and survivorship and palliative care become more complex. It is crucial to align the educational system to meet these demands, facilitate the transition from formal education systems to care settings and support lifelong learning [4.24]. This can only be achieved through a collaborative approach involving health care, regional oncology nursing societies and academia through a long term sustained plan to develop specialized oncology nurses. Table 4.3 sets out the training qualifications necessary for nursing professionals at each level of a centre providing cancer care.

TABLE 4.3. NURSING EDUCATION, TRAINING AND CERTIFICATION BY CANCER CENTRE LEVEL

Level 1	Level 2	Level 3
Community based hospital	Middle level hospital, urban based	Comprehensive cancer centre or multispeciality tertiary care hospital
Diploma or baccalaureate qualified registered nurse	Specialized oncology nurses if hospital has a dedicated cancer ward	RT:
Generalist nurse		— Basic knowledge
Oncology specific training (dependent on area of work):		— Patient preparation
— Screening for breast and cervical cancer		— Management of side effects
— Intravenous access: central and peripheral		— Therapeutic communication
— Chemotherapy:		Specialized, programme based education:
• Administration		— Bone marrow transplant
• Safe handling		— Wound care
• Management of side effects		— Geriatric oncology
— Therapeutic communication		— Adolescent and young adult oncology care
		— Survivorship
Palliative care:		Expanded practice roles (master's degree qualified):
— Symptom assessment and management		— Advance practice nurse educator
Therapeutic communication		— Clinical nurse, specialized
		— Nurse practitioner
		Nurse researcher (doctoral qualification)

TABLE 4.3. NURSING EDUCATION, TRAINING AND CERTIFICATION BY CANCER CENTRE LEVEL (cont.)

Level 1 Community based hospital	Level 2 Middle level hospital, urban based	Level 3 Comprehensive cancer centre or multispeciality tertiary care hospital
<p>Generalist nurses will need additional training and preparation to provide cancer care</p> <p>Oncology specific training options:</p> <ul style="list-style-type: none"> — Diploma in Oncology Nursing — Diploma in Palliative Care (Nursing) — Certificate training: <ul style="list-style-type: none"> • Cancer screening • Intravenous access • Chemotherapy • Therapeutic communication 	<p>Oncology specific training options:</p> <ul style="list-style-type: none"> — Diploma in Oncology Nursing — Diploma in Palliative Care (Nursing) — Certificate training: <ul style="list-style-type: none"> • Cancer screening • Intravenous access • Chemotherapy • Therapeutic communication 	<p>Oncology specific training options:</p> <ul style="list-style-type: none"> — Specialization training for oncology and palliative care nursing as mandated by the employing institution

TABLE 4.3. NURSING EDUCATION, TRAINING AND CERTIFICATION BY CANCER CENTRE LEVEL (cont.)

Level 1	Level 2	Level 3
Community based hospital	Middle level hospital, urban based	Comprehensive cancer centre or multispeciality tertiary care hospital
<p>Nurses in this setting should ideally have:</p> <ul style="list-style-type: none"> — Mentorship from trained senior nurses — Access and sponsorship to attend certificate or diploma level training from urban, tertiary teaching hospitals — Access and sponsorship to take on-line certificate courses <p>Ongoing education (e.g. in-service) at the work site or access/sponsorship to attend continuing professional development programmes at other accredited sites</p>	<p>Nurses in this setting should ideally:</p> <ul style="list-style-type: none"> — Be specialized oncology nurses, having met the requirements set by the nursing regulatory body for the country — Have access to an oncology clinical educator (baccalaureate or master's degree qualified) — Have access to other, specialized nurses (e.g. stoma wound care, intravenous access nurses) — Receive mentorship from senior specialized oncology nurses — Be sponsored to obtain oncology nursing specialized designation recognized by the regulatory body of the country 	<p>Nurses in this setting should ideally:</p> <ul style="list-style-type: none"> — Have access to an advanced practice oncology clinical educator (master's degree) — Have access and sponsorship to complete certification training from an employer designated, accredited provider — Receive ongoing education (e.g. in-service) at the work site or access/sponsorship to attend continuing professional development programmes at other accredited sites — Receive support to carry out nursing research

TABLE 4.3. NURSING EDUCATION, TRAINING AND CERTIFICATION BY CANCER CENTRE LEVEL (cont.)

Level 1	Level 2	Level 3
Community based hospital	Middle level hospital, urban based	Comprehensive cancer centre or multispeciality tertiary care hospital
<ul style="list-style-type: none"> — Have access and sponsorship to attend certificate or diploma level training from tertiary teaching hospitals or other sites (e.g. university or college extension programmes) — Have access and sponsorship to take on-line certificate courses — Receive ongoing education (e.g. in-service) at the work site or access/ sponsorship to attend continuing professional development programmes at other accredited sites — Sponsorship to attend continuing professional development programmes at other accredited sites (e.g. Level 3 sites or continuing professional development programmes at training centres or universities) 		

4.2. SAFE HANDLING AND ADMINISTRATION OF CANCER TREATMENT

4.2.1. Chemotherapy

Chemotherapy and other drugs used in cancer treatment may pose adverse health effects for health care workers delivering treatment. The IARC lists more than 20 antineoplastic agents that are carcinogenic or probably carcinogenic to humans [4.25]. In addition to their mutagenic and carcinogenic properties, many of the antineoplastic agents have been associated with adverse reproductive and developmental effects that have been observed both in animals and in treated male and female patients [4.26]. Adverse reproductive and developmental effects in health care workers, similar to those observed in patients, have been due to exposure to antineoplastic agents at much lower doses than those administered to patients [4.27–4.29]. This includes mixing, administering or disposing of treatments and supplies such as tubing and intravenous bags. The IARC has identified 11 antineoplastic drugs and several combination regimens as known human carcinogens [4.25]. Because of occupational exposure, including surface contamination, oncology nurses and other health care workers, such as pharmacists, are at increased risk for cancers. To decrease exposure, nurses require access to supplies to protect themselves, patients and other health care workers from hazardous effects, including adequate PPE (e.g. gloves, masks, gowns) and disposal containers. The hierarchy of hazard controls to reduce exposure includes, in order of priority: engineering controls, such as biosafety cabinets; administrative controls, such as safe handling policies and procedures, work practices, education and training; and PPE (gowns, gloves, masks) [4.30]. These individuals also require specialized training in the handling of spills and disposal of equipment used in delivering treatment.

In addition, oncology nurses need to advocate for access to essential medications for antidotes, infusion reactions, as well as symptom management and supportive care. Essential medicines include medicines for supportive care for chemotherapy, such as antiemetics and steroids, and medications for infusion reactions, such as diphenhydramine, prednisolone and epinephrine.

4.2.2. Antineoplastic agents

Cancer centres need to create a culture of safety for both patients and health care workers. The ONS and PAHO/WHO provide position statements, courses and textbooks on the safe handling of hazardous drugs [4.30–4.32]. PAHO/WHO [4.33] and ONS [4.34] have created safe handling guidelines to inform policies

for safe handling, mixing/compounding, administration, disposal and spill management of hazardous drugs [4.33, 4.34].

Specialized training of nurses in administering cancer treatment is essential for patient and staff safety. Didactic courses and competency validation are needed to ensure competent administration of antineoplastic agents, use of PPE, administration and disposal of drugs and equipment, and management of spills [4.30, 4.33, 4.34]. Problem solving when resources are limited or unavailable, or when essential policies are being developed, is also necessary to provide the safest environment possible.

The requirements for all care settings where anticancer drugs are being administered include the following:

- Identification of hazardous drugs used in the facility.
- Tracking the use of hazardous drugs in the setting.
- Limiting hazardous drug administration to trained personnel and restricted areas.
- Training specialized staff to provide care and administer treatment.
- Educating staff: didactic education with clinical experience to establish competency, continuing education in the following:
 - Types, classifications and routes of administration;
 - Pharmacology of agents used in this setting;
 - Molecular biomarkers;
 - Safe preparation, storage, labelling, transportation and disposal of hazardous drugs;
 - Safe administration procedures;
 - Use and disposal of PPE;
 - Assessment, monitoring and management of patients receiving therapy in the care setting, including short and long term side effects;
 - Patient and family education;
 - Follow-up and survivorship care.
- Developing and maintaining policies and procedures to support the safety of patients and staff regarding drug administration.
- Educating patients and families on hazardous drug exposure and how to minimize exposure to body fluids.
- Developing and implementing procedures for cleaning of equipment and disposal of drugs.
- Considering alternative duties for nurses who are pregnant, breastfeeding or trying to conceive.

4.2.3. Radiotherapy

All nurses require an awareness of the radiation signage and its meaning. Especially in low resource countries, both generalist and oncology specialized nurses need to have awareness of the principles of time, distance and shielding regarding their own safety while handling of radiation sources and caring for patients receiving brachytherapy on a general unit. Nurses should ensure that they work in safe environments, with radiation treatment units built with sufficient lead and concrete shielding. RT nurses require additional safety training regarding the indications and side effects of RT as a treatment for cancer [4.35, 4.36].

A subspeciality of oncology nursing, RT nurses require an understanding of the principles of RT. The Radiation Oncology Nursing Knowledge and Skills (RONKAS) framework was developed in New South Wales, Australia, to educate nurses on patient education, assessment and management in radiation oncology [4.36]. Training is essential for all nurses involved in the care of patients undergoing brachytherapy with radiation sources and educating those receiving radioactive iodine treatment. If nurses are responsible for delivering RT, they need additional training, comparable to that of radiation technologists. This extended training ensures proficiency in all aspects of RT. Specifically, RT nurses play a crucial role in educating patients and families on protection measures, focusing on the principles of time, distance and shielding. This education is particularly vital after brachytherapy, injection of radioactive iodine, or implantation of seeds for prostate cancer. Furthermore, they should be well versed in addressing the potential absence of patient radioactivity following low dose rate/high dose rate treatments.

4.2.4. Supportive care and symptom management

4.2.4.1. *Oncology nurses and symptom management*

Oncology nurses play a key role in symptom management in advanced or metastatic disease situations. They teach patients and family members about self-care related to symptoms and side effects while at home. Nurses need to be well prepared to engage successfully in these activities in busy clinical environments, whether they work in inpatient, outpatient or community settings.

The needs of individuals with cancer have been well documented in many countries [4.37, 4.38]. Consistently, cancer brings fear and distress to patients, in addition to the physical concerns surrounding the disease and its treatment, and has a profound and negative impact on quality of life, mental health and overall experience of cancer treatment and care for patients and families [4.39–4.41]. Tables III–1 and III–2 (see Annex III to this publication) outline the most

common symptoms after surgery, chemotherapy, immunotherapy and RT, along with assessment, evidence based interventions and resources.

4.2.4.2. *Symptom assessment*

Regardless of the actual treatment and resource availability, oncology nursing has a key role in symptom and side effect management, patient and family support, and patient education for self-care. Conducting a comprehensive initial assessment is imperative to have a baseline against which to compare the patient's status once treatment is under way. The baseline assessment includes all body systems and establishes the patient's health status prior to beginning treatment. Additionally, it helps to understand the person and the environment (including social and behavioural determinants of health, such as relationships, employment and education, where a person lives and the genetic makeup) or the context of patients' lives [4.42]. Should symptoms become severe (graded at 4 on medical grading tools, e.g. NCCN, Common Terminology Criteria for Adverse Events, Radiation Therapy Oncology Group) or unanticipated, they are referred to as toxicities. Specific effects will vary depending on the type of treatment (i.e. surgery, chemotherapy, RT, immunotherapy, etc.), on whether it is a local or systemic modality, and on the intensity/dose of the therapy. Subsequently, the nurses develop a plan to monitor the patient's status routinely and reassess any aspect in depth, if required.

4.2.4.3. *Patient reported outcomes*

Recently, there has been a movement to incorporate patient reported outcomes into routine assessment. Patient reported outcomes are a good example of patient centred care, gathering data on health status directly from the patient, usually using a standardized (validated) tool (e.g. Edmonton Symptom Assessment System, MD Anderson Symptom Inventory and appropriate format (e.g. paper, telephone, iPad, Internet). Incorporating patient reported outcomes into the daily interactions with clinical staff facilitates the identification of patient issues or concerns that may not be revealed through the clinician's assessment alone. Use of patient reported screening and assessment tools quickly identifies patient concerns and is useful in prioritizing and addressing needs [4.43].

4.2.4.4. *Plan of care for symptom management*

A plan for interventions to manage symptoms needs to be crafted on the basis of a particular symptom or side effect, or cluster of symptoms, identified by the nurse as concerning or by the patient as troublesome [4.44, 4.45]. Overall,

the most common side effects reported by patients on treatment are fatigue, pain, nausea/vomiting and diarrhoea [4.46–4.48]. Ideally, the plan incorporates patient reported outcomes and evidence based approaches for the particular symptom or symptom cluster, as well as education of the patient and family for self-care away from the clinical setting. The actual implementation will depend on the available resources.

Clearly, all oncology specialized nurses need to be well versed in assessment and effective interventions for commonly experienced symptoms or side effects. The plan of care assessment, intervention and follow-up needs to be tailored to the unique aspects of the person and his/her situation.

A nurse who has specialized in cancer care will have the knowledge and skill to conduct a deeper assessment and will be well versed in the management of a wide range of side effects, toxicities and rare symptoms. In addition, nurses have the capacity to intervene when situations are complex and unstable. In many cancer centres, oncology nurses are assigned to care for specific patient populations (e.g. paediatric patients; specific cancers, such as breast or lung cancer; specific treatments, such as RT) and can develop a highly specialized knowledge about the needs of that patient group.

4.2.4.5. *Psychosocial issues*

Dealing with the symptoms of psychosocial distress (i.e. anxiety and depression) is a primary responsibility of the oncology nurse. Over the past two decades, there has been increased recognition of the impact of unmet emotional needs [4.37, 4.48–4.52] and an emphasis on utilizing standardized tools to identify individuals who are distressed, in addition to clinical assessment. Once identified, interventions can be offered, including both community based and professional support. The factors that contribute to a cancer patient's anxiety and/or depression can be varied, and astute communication skills will be required by the nurse to uncover the sources of concern. Oncology nurses are expected to be able to assess psychosocial distress and identify when additional resources (and referral) are required and need to be able to offer basic emotional support.

Patient and family education about symptoms, side effects and toxicities are an important intervention to help individuals to manage at home. Nurses need to be prepared to teach patients using principles of adult education and patient centred learning to achieve the most beneficial outcomes [4.53]. Assessment of health literacy and willingness to learn are important initial steps in this process. The actual teaching may be conducted on an individual or group basis, depending on resources.

4.3. PHARMACY

4.3.1. Rationale for a cancer centre pharmacy

The pharmacy service is critical for safe, cost effective and appropriate procurement; prescription verification; and preparation and dispensing of systemic anticancer therapy (SACT). This includes cytotoxic chemotherapy, biological therapy and targeted therapy and associated supportive medicine in accordance with legislative requirements, adhering to professional and national standards and local policy.

Some clinical cancer pharmacists may subspecialize in solid tumour oncology or haemato-oncology, bone marrow transplantation, paediatrics or palliative care. However, for simplicity they are referred to as cancer pharmacists in this section.

Many cancer pharmacists apply their clinical knowledge to participate in policy and procedure development, create treatment guidelines and give advice on clinical and medication related issues. This knowledge is crucial in developing collaborative institutional guidelines and supporting practice based decisions.

4.3.2. Role of pharmacy in multidisciplinary cancer care

Given the complexity of caring for patients with cancer (including the cost of systemic anticancer medicines, the potential for severe toxicity or medication error, and the requirements for safe preparation, administration and disposal of cytotoxic agents), pharmacists are critical members of the health care team. Pharmacists assume extended clinical roles, assessing and reviewing patients on treatment, and adjusting or prescribing medication as required, where permitted in their national setting. These services are particularly valuable in settings with limited medical coverage, allowing this resource to focus on new patients and complex cases.

Heads of pharmacy services ensure that policies and procedures are in place for training, continuing education and assessment of the competency of cancer pharmacists [4.54–4.57]. Pharmacist prescribers may require additional training, according to country regulatory requirements. Pharmacists who provide medication and pharmaceutical care to patients with cancer need to be equipped with the appropriate skills and competencies to ensure the safe use of these medicines.

4.3.3. Human resources

The cancer pharmacy workforce is diverse, consisting of a range of professionals. This should include not only pharmacists but also support staff (technicians, technologists and assistants) for both clinical and non-clinical tasks. There needs to be a sufficient number of pharmacists and technical pharmacy staff for all aspects of the service, including, but not limited to, the dispensing and checking of prescriptions, reconstitution and delivery of medicines.

There is no internationally endorsed competency framework for specialist cancer pharmacists. Published standards consider realities from both resource rich and resource poor settings. These standards address key issues for pharmacy personnel preparing and administering chemotherapy with respect to sterile preparation, PPE, waste/spill management, medicines management and checking procedures to prevent medication errors. Competency standards and assessment tools are available to describe and estimate the skills, attitudes and attributes essential to a practicing pharmacist [4.58, 4.59]. Frameworks can be used to inform the development and provision of training, professional development for cancer pharmacists and the commissioning of pharmacy cancer services [4.60]. Moreover, a key set of competencies for the pharmaceutical delivery of cancer care has been developed [4.55]. Standards of practice and guidelines that define the appropriate training, knowledge and skills in cancer chemotherapy treatment are available [4.54–4.56, 4.60–4.63].

4.3.4. Quality assurance and safety

A dedicated cancer pharmacist/pharmacy service may be involved in the development of standards related to patient safety, including clinical governance [4.56, 4.57, 4.62–4.66]. These standards establish written policies and procedures for the training of staff, ensuring that SACT orders are safe and accurate, and the preparation and administration of hazardous medications. The cancer pharmacist may also be responsible for updating these policies and procedures as needed according to current literature.

The cancer pharmacist can provide patient directed education and tools to improve adherence to medication with complicated regimens. The pharmacist alerts the patient to potential drug interactions and anticipated toxicities and how to manage symptoms or side effects. The pharmacist also educates patients and family members on how to handle chemotherapy safely at home [4.67].

Cancer pharmacists may also be involved not only in the development of clinical guidelines, such as the prevention and treatment of nausea and vomiting, but also in other aspects of safe medication use and oncology practice. Many cancer pharmacists are members of their institutional Pharmacy and Therapeutics

Committees and make formulary recommendations on the efficacious, safe and cost effective use of SACT [4.67].

4.3.5. Clinical pharmacy

The term clinical pharmacist describes a pharmacy role that focuses on patient care and optimization of medicines. There are a variety of areas where clinical pharmacy skills are required within the cancer setting [4.68–4.79], as detailed below.

4.3.5.1. Hospital outpatient services

Pharmacists and pharmacy support staff (technicians, technologists and assistants) play a vital role within the outpatient setting. All chemotherapy prescriptions that are prescribed by a clinician should be clinically verified by a pharmacist for appropriateness, accuracy and safety. By working alongside the MDT, they are able to promptly intervene during the prescription verification process. In outpatient clinics, pharmacists and pharmacy support staff can counsel patients on their chemotherapy and supportive medicines, ensuring that they are assisted to understand their treatment and remain compliant.

4.3.5.2. Hospital inpatient services

A full medication history should be taken, ideally within 24 hours of a patient's admission to hospital. This should include all current medicines (both prescribed and bought in a community pharmacy), complementary and alternative medicines, allergies, alcohol or illicit drug consumption and smoking status. This can be completed by either a pharmacist or suitably trained pharmacy support staff, but the information should preferably be obtained from two sources, one being the patient where possible. Pharmacists should review patients receiving chemotherapy in the inpatient setting on a daily basis. Patients for review and pharmacy input should be prioritized according to clinical need. All medicine requests should have the prescription verified by a pharmacist prior to supply and administration. Pharmacy support staff and pharmacists should be responsible for ensuring that the ward stock medicines are appropriate and available.

Pharmacist presence within the MDT at ward level has been shown not only to improve patient safety and satisfaction but also to provide cost savings through effective prescribing and medicine optimization. The pharmacy ward team has a significant impact on reducing length of stay, reducing prescribing errors and improving patient benefits.

4.3.5.3. Advanced clinical practitioner and prescribing roles

Many pharmacists are qualified as non-medical prescribers (pharmacist prescribers) and may have undertaken additional physical assessment training. They work closely with their clinicians to assess and treat patients in outpatient and inpatient settings. Pharmacists are able to undertake the routine prescribing or modification of SACT treatment and supportive care medicines, usually within an agreed protocol or guideline. These services can release medical capacity for the review of more complex cases.

4.3.5.4. Community pharmacy services

The input of community pharmacists to cancer patient care varies according to local regulations. In some settings, secondary care pharmacists have strong links with the community pharmacists within their patient population to provide them with a support network for cancer patients. Secondary care can provide guidance on what medicines, including palliative and end of life medicines, the community pharmacist should stock in the pharmacy. Some community pharmacists specialize in palliative and end of life care.

Other community pharmacy services can include early detection of cancer and supporting people living with and beyond cancer. There are several examples of community pharmacy services; for example, lifestyle interventions to improve cardiovascular health in people living with prostate cancer.

4.3.5.5. Specialist services

In addition to traditional roles, pharmacists can provide specialist services. These include home delivery of oral anticancer medicines, chemotherapy administration at home or in satellite units and personalized medicine involving genomic testing, acute oncology services and ambulatory care.

4.3.5.6. Patient information

Whenever possible, patients should have access to a helpline to contact the centre should they require advice about their medicines and/or associated adverse events. It is recommended that the staff who manage this helpline are from mixed disciplines to ensure that the skills of each professional benefit the patient. The telemedicine helpline can be available through a variety of technologies, such as by telephone and smartphone applications.

4.3.5.7. *Training*

A comprehensive education and training programme should be in place for pharmacists and pharmacy support staff for any centre that treats cancer patients. The training programme needs to provide assurance that a pharmacist or pharmacy support staff member, regardless of level of training, is competent to complete the tasks set out in their job plan. The training programme should involve elements of direct learning linking to the SOPs, shadowing, supervision and completion of national or international competencies, as well as an assessment. The member of staff participating in the training should be supported throughout and provided with protected time away from other duties to facilitate completion.

4.3.5.8. *Workforce*

To determine the pharmacy workforce required to establish a proficient clinical cancer pharmacy service, the demand for the service should be assessed. This includes looking at the number of inpatient wards and the number of patients per ward, the number of outpatient clinics and the number of patients treated at the day unit. Ideally, a pharmacist should be present in each area where medicines are prescribed and administered. There needs to be a clear management structure to support those pharmacists working operationally and to allow for the service to strategically improve and develop using new policies and international guidance.

4.3.5.9. *Equipment*

An electronic system for reporting all patient records, prescriptions and laboratory results is crucial. This should be the goal for all cancer centres, even if it is not currently possible. Electronic health care systems can support the work of pharmacists by having in-built drug interaction checks and alerts for allergies (see Section 4.3.10).

4.3.5.10. *Quality assurance and safety*

Each SOP needs to be updated according to locally or nationally agreed time frames to ensure that it is current and provides the trainee with the required level of skill. Each chemotherapy regimen that is administered by the cancer centre should have a validated protocol providing details of the indication, the dosing and blood parameters.

4.3.5.11. Governance

Each cancer centre should have a pharmacy governance team to support new medicine/indication implementation. Once approved, the new medicine or indication should be added to a medication formulary detailing all the medicines approved for use in the institution.

4.3.6. Out of hospital delivery of systemic anticancer treatments

Administration of SACT is an integral part of the cancer treatment pathway. The context in which these treatments are delivered poses significant implications for patients in terms of the socioeconomic burden and impact on their quality of life [4.80–4.86].

SACT has traditionally been delivered in chemotherapy day units in hospitals on an outpatient basis. Where the regimen is clinically suitable for out of hospital (OOH) delivery, provision of SACT at a convenient location for patients has the potential to relieve them of logistical commitments and financial burdens, in view of improving their quality of life. On a different front, the advent of novel anticancer treatments and targeted therapies has meant that the repertoire of available treatments and the patients eligible to receive them has expanded significantly in a short space of time. This, in turn, has placed increasing pressures on the current infrastructure (outpatient clinics, IT systems, chemotherapy day units), resources (workforce, staff training, governance framework, supportive services) and capacity (chair time, staff to patient ratio, aseptic services) available to deliver these treatments. The economic burden of consistently delivering high quality cancer care in the face of rising pressures has acted as a driver for finding new, innovative and cost effective ways for delivering SACT.

4.3.6.1. Models of out of hospital systemic anticancer therapy delivery

A range of SACT treatments can be safely administered in a community setting. Community based SACT delivery models are being adopted by health services worldwide. Patients receiving treatments classified as low risk would be eligible to receive treatment at locations close to home or work, which would allow minimal disruption of their day to day activities. Examples of OOH SACT provisions currently available are as follows:

- Community/district hospitals, hospices or in general practitioner practices. SACT is mainly available as a ‘hub and spoke model’, whereby a large/regional cancer centre usually serving a large geographical area

provides SACT delivery in a community or in district hospitals as a new service or acquisition of an established service.

- Community pharmacies. SACT is delivered via a service level agreement with a private community pharmacy, pharmacy chain or privately owned subsidiary pharmacy.
- Mobile care units. These are especially designed, transportable units conveniently located in community locations. They are operated by a cancer centre or third party specialist clinical service.
- Home care service. This involves delivery of SACT in the patient's home. This can be operated by the cancer centre or a third party specialist clinical service.

It is recommended for cancer centres to use benchmarking to gauge the performance of new service care models.

4.3.6.2. *Quality assurance and safety*

The literature base evaluating the different models for the provision of OOH SACT is limited in scope and quantity. Therefore, it is essential to formulate robust measures for the evaluation of pilot schemes or changes to service delivery to ensure that this is a true representation of patient experience, clinical treatment and cost effectiveness. They can then be utilized to formulate/inform long term plans for service provision.

SOPs and clinical guidelines detailing the processes involved in the delivery of OOH treatments, staff training, equipment/resource provisions and patient involvement/engagement will need to be devised, validated and approved through the agreed (local or regional) governance pathways. These will then need to be rolled out to all relevant stakeholders in a comprehensive approach. The delivery of SACT on an OOH basis needs to be clearly outlined on the appropriate regimen protocols.

4.3.6.3. *Governance*

Plans for the development of in-service delivery encompassing expected benefits, proposed changes, criteria for regimen selection, risk assessment/important considerations, financial considerations, action planning and timeline for implementation should be submitted to the Drugs and Therapeutics Committee for final approval. Selection of a specific regimen will need to be approved by an appropriate clinical group.

4.3.7. Dispensary services

The purpose of a pharmacy dispensary is to obtain, store and distribute medicines [4.87]. For a cancer centre, this includes oral SACT as well as supportive medicines such as antiemetics and granulocyte colony stimulating factor. Pharmacists and pharmacy support staff (technicians, technologists and assistants) have to ensure that all medicines dispensed by the pharmacy are stored, handled and distributed reliably and safely. This needs to be standardized across all dispensary areas. Satellite pharmacies work well to provide specific areas with timely medication supply.

4.3.7.1. Training

Pharmacists and pharmacy support staff working in the dispensary require training specific to this role. The training programme should be competency based and include supervised dispensing and checking logs, in addition to underpinning theory and knowledge of local and national policy and legislation. Revalidation should take place at agreed intervals and following any break in practice to ensure that competency is maintained.

4.3.7.2. Workforce

A pharmacy dispensary can be led by support staff, as appropriate to national, regional or local legislation, where the prescriptions are clinically verified by a pharmacist outside the dispensary, such as on the ward or in an outpatient clinic. There should be at least one pharmacist present in the dispensary for clinical advice. The staff member who dispenses an item should be different from the person who provides a final item check. Owing to the increased risk posed by oral SACT medicines, additional safeguards should be in place to avoid dispensing errors; for example, including a second check before release. When developing a pharmacy dispensary workforce for a cancer centre, the following factors should be considered: number of prescriptions or discharge letters to be processed each day; complexity of prescriptions; delivery location; and whether the prescriptions will be clinically verified prior to arrival in the dispensary.

4.3.7.3. Equipment

Automated or robotic dispensing machines provide a safe and efficient dispensing process and can be considered best practice where capacity warrants this need. They can also save space, as the robot can be stored in a different

location from the dispensary and chutes can be utilized to deliver the dispensed item to the staff member labelling the medication.

Dispensing software is required for ordering, locating, labelling and stock management purposes. Each computer terminal requires its own labelling printer and should be connected to the robot (if applicable). A prescription tracking system will assist nursing and pharmacy staff during the inpatient discharge process.

Cytotoxic medicines should be stored separately from other medicines and be dispensed using dedicated equipment, e.g. a counting triangle labelled 'cytotoxic only'. Appropriate PPE needs to be provided for dispensing staff, e.g. nitrile gloves and cytotoxic waste bins, to ensure that contaminated waste is disposed of appropriately.

4.3.7.4. Quality assurance and safety

The pharmacy procurement team should be responsible for ensuring that licensed, approved medicines are supplied. Computerized systems can be employed to detect counterfeit medications. Use of SOPs ensures that all staff are dispensing, labelling and checking each medicine to the same minimum standard.

There should be a pathway set up for the safe disposal of medicines waste from the hospital. The dispensary pharmacy team should monitor the medicine inventory to ensure that stock levels are correct and any expired stock is removed.

Systems should be in place to ensure that a medicine recall is acted on in a timely manner. This includes providing a separate area where recalled medicines can be quarantined, preventing distribution.

4.3.7.5. Governance

All SOPs and patient information should be approved for use by the pharmacy governance committee or equivalent. Each procedure should have a review date. Staff members should have their own login when accessing patient details and participating in the dispensary process. This will ensure an audit trail and provide information governance.

4.3.8. Purchasing pharmaceuticals for cancer treatment

Where medicines or medical devices are used in health care systems, these need to be purchased from appropriate and trusted sources to ensure that the quality and integrity of products is maintained and to minimize the risk of defective or counterfeit medicines entering the system. Manufacturers, suppliers or wholesalers have to hold the required licences to operate in the relevant

countries; these licences should be checked for authenticity. National bodies should hold lists of approved suppliers to allow health care professionals to confirm the supplier's licence to operate in their health care system [4.88–4.97].

WHO formulated a policy mechanism, the Essential Medicines List [4.98], to provide a list of medicines that “satisfy the priority health care needs of the population”, in an effort to help to guide decisions regarding procurement and coverage of essential medicines. There have been 36 updates in recent years regarding the inclusion of additional antineoplastic medicines.

It is important that the whole supply chain is validated, as there are several stages and operators involved in the procurement and supply of medicines or devices. This process is important for the procurement of systemic agents used in cancer treatment and also for therapeutic agents used for the supportive care of patients receiving chemotherapeutic agents. Ideally, pharmacy procurement specialists should always be part of the process to provide advice on sourcing potential new medicines, identify alternatives when dealing with medicine shortages and deal directly with suppliers to procure identified therapies.

Although many medicines are licensed and come from a suitable supplier, when multiple brands or preparations of the same medicine exist, there may often be differences in the presentation. A risk assessment should be undertaken regarding the use of a particular product, which needs to consider all aspects of the use of that medicine to ensure that it is suitable for use.

4.3.8.1. *Licensing*

Before a medicinal product can be marketed by a pharmaceutical company, a marketing authorization, also known as a product licence, is required. The relevant national body coordinates the assessment of the quality, safety and efficacy of medicinal products before a decision to grant authorization is made. The pathway to obtaining registration approval for medicines in individual countries can often be lengthy. The individual regulatory agencies have their own unique set of regulations and requirements that need to be followed.

While many SACT agents are used according to the specifications in the medical authority, they may also be used outside these specifications; this is referred to as ‘off-label’ use. For example, where the medicine is used for a different indication, in an age group outside the licensed range (e.g. children) or in a different dose or presentation to that stated in the marketing authorization. Medicines may also be available as ‘unlicensed’ products, where the product holds a licence in another country, but not the host country, and has to be imported. A medicine may sometimes have no licence at all. This is commonly the situation in the treatment of rare diseases, or in the use of a manufacturers’ ‘special’, where the medicine is reformulated — for example, in a liquid formulation for patients

unable to swallow the licensed solid dosage form. In the treatment of cancer, many medicines are accessible prior to the licensing stage from manufacturers through schemes referred to as either ‘named patient’, ‘compassionate use’ or ‘expanded access’ schemes. Pharmacy procurement specialists and relevant regulatory authorities are required to provide advice on the procurement and purchasing process for unlicensed medicines. In some cases, this may involve liaising with specialist medicine importers.

4.3.8.2. *Outsourcing of compounded cancer medicines*

To cope with the ever increasing demand on cancer services for the provision of SACT, in-house aseptic services could be replaced by a third party specialist aseptic manufacturing company for products already compounded in a ready to administer format. Advice on the outsourcing of SACT is provided in a ‘how to’ guide produced by the United Kingdom’s National Health Service (NHS) Pharmaceutical Assurance Committee [4.97]. The publication gives guidance on both understanding the risks in the outsourcing and supply process and on ways of ensuring that the necessary control measures are in place to minimize these risks.

4.3.8.3. *Principles of the medicine management process and procurement*

WHO provides guidance on the essential components of the medicine management process as follows [4.90]:

- Appropriate medicine selection. Selection of medicines for procurement by the public sector should be based on the national essential medicines list.
- Quantification of medicine requirements. To avoid waste through overstocking or stock-outs of pharmaceuticals, a reliable system of quantification of medicine needs is required.
- Procurement. Procurement can be undertaken through various methods such as tenders, competitive negotiations or direct procurement. The aim is to provide quality medicines at the lowest possible cost when needed.
- Storage and distribution. Correct storage of medicines to avoid deterioration and waste is essential, as is a proper stock inventory control system that can be computerized. Medicines should be available when needed. A system that enables coordination between medication needs and supply will ensure adequate distribution from the central source to the health facilities.
- Medicine use reviews. In addition to being available in the required quantities when needed, medicines need to be used rationally. If not, they can be ineffective or even harmful. In addition to serious health consequences,

irrational medicine use leads to waste, thus increasing the cost of running a medicine supply system.

- Monitoring and improving the medicine management cycle. The medicine management cycle is a continuous process that needs to be monitored with the aim of improving all its elements.
- QA in the medicine management cycle. QA measures should be included in each of the abovementioned steps of the cycle. The following issues should be addressed:
 - Selection of well documented quality products from reliable manufacturers;
 - Certificate of analysis of delivered products;
 - Use of the WHO certification scheme;
 - Quality assessment of medicines upon receipt;
 - Inspection of shipments;
 - Laboratory testing;
 - Appropriate storage and transport;
 - Appropriate dispensing and use;
 - Monitoring of product quality/reporting system.

4.3.9. Aseptic preparation and technical services

Cytotoxic chemotherapy and some other SACT agents are designated as hazardous by the US National Institute for Occupational Safety and Health and by other related authorities [4.97] and should be made in a controlled environment. Some, but not all, monoclonal antibodies used in the treatment of cancer have been designated as hazardous medicines and therefore the risk of each medicine should be assessed individually to determine the most appropriate setting for preparation, taking into account capacity and practical considerations such as shelf life [4.99]. If cytotoxic and non-cytotoxic products are made in the same facility, measures need to be put in place to avoid cross-contamination between product types [4.100].

The following guidelines apply to the aseptic reconstitution of hazardous anticancer medicines in a hospital setting.

4.3.9.1. Facilities for aseptic reconstitution and PPE

Aseptic preparation needs to take place in a controlled and monitored environment to prevent exposure of the operator to hazardous medicines and to prevent microbial or particulate contamination of the product. Preparation should be either centralized within the pharmacy department or in a designated satellite

area under the supervision of a pharmacist. Cytotoxic medicines should never be reconstituted by staff in clinical areas [4.101].

Reconstitution of hazardous medicines should be carried out in a designated room (clean room) that complies with the requirements of the International Organization for Standardization (ISO) 14644-1 standard [4.102], which defines air quality in terms of maximum levels of particulate contamination. A similar grading system is used by WHO and in the European Union and defined in Ref. [4.103]. Access to this room must be granted only to trained and validated pharmacy staff. Room surfaces need to be smooth and easily cleaned, with recessed lighting and clear of any items not essential for the preparation process. The room must be equipped with a cytotoxic spillage kit and emergency eye wash facilities. Consideration should also be given to the installation of an emergency shower. The clean room should not be accessible directly from an uncontrolled area. Access need to be gained via an anteroom providing an airlock, in which the operator removes outer clothing and wears suitable clean protective clothing, including gloves, before entering the clean room [4.62, 4.101]. The requirements for clean room clothing are set out in Ref. [4.103].

The use of closed system drug transfer devices should be considered as an extra level of protection during the preparation of cytotoxic chemotherapy and other SACT [4.101, 4.104].

Ideally, the clean room should be designed to have a positive pressure compared with surrounding uncontrolled areas (10–15 Pa difference), with a standard minimum air change rate provided by the air handling unit. Lighting, temperature, humidity and ventilation should also be considered in the design [4.62, 4.101, 4.102].

Aseptic manipulation of a product needs to take place in an ISO Class 5 environment [4.102] (equivalent to Eudrallex Grade A [4.103]), which can be provided by a HEPA filtered, vertical laminar airflow hood or a pharmaceutical isolator. The laminar airflow hood allows the operator a greater range of movement but needs to be situated in a higher grade clean room; the isolator affords greater operator and environmental protection. Further information on the choice and use of these devices can be found in the International Society of Oncology Pharmacy Practitioners standards of practice [4.62], and specifications for design, installation, testing and maintenance are given in ISO 14644–7 [4.105]. Additional equipment is required to produce labels for the finished product, which should be sealed in a leakproof outer wrapper before being transported to the administration area.

4.3.9.2. *Workforce*

Typically, technical tasks, such as cleaning, environmental monitoring, worksheet preparation and labelling, are carried out by an appropriately trained pharmacy assistant, technician or technologist. Clinical screening or verification of the prescription before preparation and the final check of the prepared product are carried out by a pharmacist. In-process checks, such as worksheet checks, raw material checks and volume checks, are completed by the most appropriate grade of staff, depending on the work system set-up.

4.3.9.3. *Education and training*

All personnel should be aware of the principles of good manufacturing practice that affect them and receive initial and continuing training, including hygiene instructions, relevant to their needs [4.100]. There is no internationally recognized standard training for staff carrying out the aseptic preparation of medicines. Ideally, staff will possess a nationally recognized qualification of have undertaken training in accordance with local regulations. The International Society for Oncology Pharmacy Practitioners recommends that basic training should include the following [4.62]:

- The potential risks of exposure to cytotoxic agents;
- Basic pharmacology of cytotoxic agents;
- Theory of aseptic technique;
- Use of PPE;
- Theory of containment devices and barriers;
- Theory of hierarchy of protection measures;
- Handling of cytotoxic waste;
- Cytotoxic spills and accidental exposure;
- Prescribing of cytotoxic agents;
- Validation of cytotoxic prescriptions;
- Hospital policies and procedures on cytotoxic management;
- Cytotoxic medicine use processes (medicine selection, prescription validation, preparation, dispensing, medicine administration and medication use evaluation).

An assessment of the practice should be undertaken on a regular basis for all personnel preparing hazardous medicines and should include validation of the aseptic technique using accepted methods such as media fill tests (known as ‘broth tests’), hand washing validation and finger dabs. It is recommended that the education programme be repeated on a regular basis to maintain competence

and keep up to date with new medicines and technological innovations introduced into practice. Additional training should be given whenever any major change in practice occurs [4.100].

4.3.9.4. *Good manufacturing practice*

All aseptic preparation services need to maintain robust SOPs for every aspect of that service, including cleaning, maintenance and monitoring of the facilities and equipment, staff training, prescription verification, worksheet and label production, aseptic technique, final product checking and release [4.67]. Detailed information on these procedures, including environmental monitoring (from temperature, pressures, contact and settle plates, finger dabs, microbiology, air sampling and monitoring logs) can be found in the guidelines of EudraLex [4.103] and the Pharmaceutical Inspection Co-operation Scheme [4.101].

4.3.9.5. *Quality assurance*

The quality of an aseptically prepared product depends on human operators and, because of the high risk nature of the medicinal products prepared, the consequences of an error can be severe. It is therefore essential to have a QMS in place to ensure that all aspects of the service are run to the required standards. In resource constrained settings, the Cyto-SAT self-assessment tool can be used to identify gaps in practice and areas where improvements can be made to reduce risks to patients, personnel and the environment [4.106].

4.3.10. Electronic prescribing

SACT agents are associated with a narrow therapeutic window, severe medicine related toxicity and occupational health risks to staff, as well as high medication costs. Sources of error include miscalculation and misinterpretation of prescriptions, exceeding single or cumulative dose limits and miscalculation of patient body surface area. Experience has shown that errors may evade detection by clinicians, nurses and pharmacists [4.67].

SACT regimens (a combination of one or more SACT agents typically used to treat patients) are complex, and their prescribing is a specialized process. Even simple regimens, such as those used in outpatient practice, frequently require intravenous administration of several different SACT medicines. These medicines require individualized doses according to patient size and toxicity from previous treatments, together with the administration of both intravenous and oral antiemetics. Some other regimens, especially those used in haemato-oncology, are complex and involve the administration of medicines in sequence

over many days. This sometimes involves more than one intravenous line and elaborate calculations of fluid requirements. Furthermore, many chemotherapy patients receive lines of treatment separated by months or years; however, some SACT agents have lifelong cumulative toxicities [4.67].

The complexity of SACT regimens, the narrow therapeutic window of the medicines themselves and the intermittent nature of treatment makes the implementation of computerized SACT ePMA (electronic prescribing and medicines administration) or electronic prescribing packages a vital component of a modern and efficient service [4.107–4.111]. It is therefore essential that the technology be employed to enhance patient safety and increase the data quality for future service planning.

Where IT systems are in place in the health care setting, it is important that SACT ePMA is carried out on a system that is designed for this purpose (Table 4.4). Where IT systems are not in place in the health care setting, paper proforma prescriptions should be available, with sufficient governance structures to allow safe prescribing of recommended treatments for the specific cancer type, namely to facilitate standardization and prevent errors [4.67].

4.3.10.1. Governance

The implementation of SACT ePMA is considered to be a high risk endeavour. Incorrect doses or prescribing errors (human or electronic) can potentially lead to lethal consequences. In addition, setting up this complex software system could result in other errors and harmful consequences. It is therefore imperative that the implementation of SACT ePMA is properly managed by suitably trained individuals who understand SACT, pharmacy services, local cancer services and the relevant computer system (Table 4.5).

4.3.10.2. Use of electronic prescribing and medicines administration

Although ePMA systems are known to improve the safety of SACT prescribing, their introduction does not eliminate prescribing errors and may introduce their own specific risks. To reduce the risk of errors arising at different stages of the operation of ePMA systems, including the set-up, validation, prescribing, clinical verification, ordering/preparation and administration of SACT, it is recommended to follow the relevant national and local recommendations and standards [4.113].

It is important to consider how the ePMA system is used in the organization and not just how the system is set up. Processes and local/regional policy detailing how to use the system should be in place and regularly reviewed to ensure a continuing process of improvement with regard to efficacy and patient safety.

TABLE 4.4. BENEFITS OF ELECTRONIC PRESCRIBING AND MEDICINES ADMINISTRATION SYSTEMS FOR SYSTEMIC ANTICANCER THERAPY

Increased patient safety	<ul style="list-style-type: none"> — Minimized prescribing errors [4.108, 4.111] — Easy access to previous treatment history (last cycle) — Legible and completed medication orders — All changes recorded in one centralized record accessible to all relevant staff — Reducing adverse medication events [4.108] — Improved safety through the ability to standardize treatment regimens/ protocols [4.110]
Improved efficiency	<ul style="list-style-type: none"> — No paper processes, which are laborious and have high potential for error (manual transcriptions, duplication of data input, manual calculations) — Potential integration with other computer systems, so as not to rely on a manual system of checking (such as blood results) — Reduced administrative burden on qualified health care staff
Improved clinical governance and audit	<ul style="list-style-type: none"> — Access to a full record of all chemotherapy prescribed and administered — Supply information about patient outcomes — Real time and prospective medicine usage and expenditure information — Clear and concise management reports on chemotherapy medicine and regimen prescribing practice — Access to a complete audit trail of any dose changes, etc. — Ability to standardize treatment regimens/protocols
Improved communication	<ul style="list-style-type: none"> — Improved communication in the entire health care team, such as doctor, nurse and pharmacist — All notes recorded in one centralized record that is accessible to all relevant staff

4.3.11. Clinical trials

If a clinical trial involves an investigational medicinal product (IMP), there will be a need for clinical trial support within the cancer pharmacy service [4.106]. The pharmacy should be involved in the trial review process and consulted before an organization issues an approval to run a trial.

CHAPTER 4

TABLE 4.5. RECOMMENDATIONS FOR IMPLEMENTATION OF ELECTRONIC PRESCRIBING AND MEDICINES ADMINISTRATION SYSTEMS FOR SYSTEMIC ANTICANCER THERAPY [4.112]

Recommendation	Detail
Robust project plan	<p data-bbox="352 384 1006 524">Include in the project plan all dates at which the system will be implemented for each tumour site/stage. Have a final date of all relevant patients to be in the software system (i.e. no paper prescribing). Keep this realistic but as short as possible, considering the resources available and other demands on time for staff.</p> <p data-bbox="352 560 988 644">Build into the project plan protected time for key staff to supply information. Consider the cost of backfilling posts into the project budget to ensure that the work can be done and on time.</p> <p data-bbox="352 680 960 735">Build into the project plan protected time for key staff to attend training sessions.</p>
Purchase the right system	<p data-bbox="352 771 1010 826">Ensure that the vendor has a long term plan for the development and continuous improvement of the software.</p> <p data-bbox="352 862 1020 971">Ensure that the project budget has considered long term management of the system and edits to the system as the prescribing needs change, with a designated system administrator as an additional permanent member of staff.</p> <p data-bbox="352 1008 1023 1062">Ensure that the software that is purchased can demonstrate acceptable functionality in the local health care system.</p> <p data-bbox="352 1099 1022 1183">Ensure adequate and extensive testing of the system prior to implementation. The external vendor should supply a user acceptance test to guide the trust.</p> <p data-bbox="352 1219 1011 1335">Ensure procurement of a system from a company with sufficient resources and infrastructure to support the trust during and after implementation. Ensure that a dedicated project manager is assigned to the organization from the company.</p>
Communicate	<p data-bbox="352 1372 1014 1395">Ensure that all end users are aware of the benefits of the new system.</p> <p data-bbox="352 1432 980 1456">Communicate with all end users regularly throughout the project.</p> <p data-bbox="352 1492 1006 1547">Listen to the concerns of end users and address them. Communicate how you have addressed them to end users.</p>

TABLE 4.5. RECOMMENDATIONS FOR IMPLEMENTATION OF ELECTRONIC PRESCRIBING AND MEDICINES ADMINISTRATION SYSTEMS FOR SYSTEMIC ANTICANCER THERAPY [4.112] (cont.)

Recommendation	Detail
	<p>The project team has to be approachable.</p> <p>Ensure that the whole organization is aware of changes occurring in the cancer services.</p> <p>Ensure that the extent of work required by the team is communicated to all outside cancer services.</p> <p>Ensure that there is a contingency plan in place before implementation as part of the organization’s governance framework and include all managers of all departments.</p> <p>Make sure that end users are aware of the contingency plan procedure before implementation.</p>
<p>Get the right project team</p>	<p>Ensure that the IT department has sufficient skills and time to build and test the interface with clinical staff and the external vendor.</p> <p>Ensure that the management team (at a high enough level to strategically influence the health care organization) supports the project from the first stages. Ensure that a member of the management team is on the electronic prescribing project board.</p> <p>Ensure that the person responsible for building the system has extensive knowledge of what is being built. To build the oncology regimes in the system, a cancer pharmacist should be employed. To set up the system, a person with knowledge of the working practices in the pharmacy, IT and clinical areas should be used. In some cases, this will not be one person but a core team of people working closely together.</p> <p>Ensure that a dedicated project manager is assigned to the project from IT. Ideally, this person should have pharmacy or clinical knowledge.</p> <p>Ensure that an IT department manager is included in the project team, as well as other key members of the team.</p>

TABLE 4.5. RECOMMENDATIONS FOR IMPLEMENTATION OF ELECTRONIC PRESCRIBING AND MEDICINES ADMINISTRATION SYSTEMS FOR SYSTEMIC ANTICANCER THERAPY [4.112] (cont.)

Recommendation	Detail
Ensure good training	<p data-bbox="353 384 986 407">Training packages have to be developed for each level of security.</p> <p data-bbox="353 475 1004 529">Training should take place as close to implementation as possible to retain information.</p> <p data-bbox="353 566 1008 620">Provide post-implementation training sessions to cement knowledge of the system.</p> <p data-bbox="353 657 982 711">Communicate the training plans to staff from an early stage in the project to alleviate concerns.</p> <p data-bbox="353 748 976 829">Ensure correct and accurate training of the system by sufficiently qualified people to confirm that clinical staff uses the system appropriately.</p> <p data-bbox="353 866 986 920">Ensure that adequate training is given to each staff member. Some staff will require more individual effort than others.</p> <p data-bbox="353 957 1016 1011">Follow up with a refresher session after initial implementation and at regular intervals.</p>
Set the right budget	<p data-bbox="353 1048 1004 1130">Include in the project budget funds for upgrades of hardware or purchasing of additional computers and printers. Workflow changes need to be predicted as soon as possible to determine this.</p> <p data-bbox="353 1166 946 1221">Ensure that the person responsible for building the system has sufficient experience and knowledge of what is being built.</p>

4.3.11.1. Facilities

Pharmacies need to be able to store IMPs separately from normal pharmacy stock or in a way that they can be easily distinguishable. There needs to be a designated area to store any patient returns/quarantined medication separately, and this should be clearly identified.

Temperature monitoring systems will be required so that each specific storage area (i.e. refrigerator/freezer and ambient room temperature) can be temperature logged using calibrated systems regularly. There should be a process

in place for identifying when storage temperature limits have been breached and subsequent management of the affected medicines is needed.

4.3.11.2. Staff and training

Clinical trial pharmacy staff should receive training in their national legal requirements and agreed local procedures as well as specific training in the IMP handling requirements for each trial they will be working on.

For IMP management, the clinical trial pharmacy department should have written clinical trial SOPs to cover the following essential processes [4.54]:

- Pharmacy approval of a clinical trial;
- Receipt and recording of the safe delivery of IMPs;
- Safe handling and storage of IMPs;
- Temperature monitoring and reporting of temperature deviations;
- Risk assessment of storage areas for IMPs outside the pharmacy;
- Quarantine of IMPs;
- Expiry date relabelling;
- Unblinding of the trial;
- Preparation and dispensing of IMPs as per professional standards (including dispensing against an appropriate prescription, maintaining medication accountability records and ensuring that all IMPs are labelled with the appropriate pharmacy label);
- Return and disposal of unused IMPs;
- Reconciliation of IMPs;
- Medication alerts and recalls of IMPs;
- Maintaining a pharmacy study file;
- Training of clinical trial pharmacy staff;
- Archiving of clinical trial documentation;
- Division of the clinical trial set-up into three main stages.

4.3.11.3. Study feasibility review

The goal of this stage is for the pharmacy to assess the feasibility, capability and capacity to support the study. The pharmacy should estimate the cost for the work undertaken and assess the impact on the delivery of the study via the pharmacy. The correct equipment (e.g. cabinets or refrigerators) must be available for storage of the clinical trial medicine at the correct temperature and humidity.

The pharmacy should review the following documents at a minimum:

- Clinical trial protocol. The goal of the review is to understand the background of the investigational compound, trial design, safety and toxicity management, and the details of the administration of the treatment.
- Pharmacy manual. The review should include the medicine supply and distribution mechanism, stability monitoring and the process for dealing with excursions. It may also contain details of dispensing and administration, if not contained within the protocol, and equipment and facilities required.
- Label. The review needs to confirm that the product is labelled according to regulatory requirements.
- Investigator's brochure (if the product is unlicensed) or summary of product characteristics (if licensed), providing detailed information about the medicine.
- Medication accountability forms, prescriptions or worksheets. These should be assessed for suitability.

These documents may have different names depending on each trial and each jurisdiction.

4.3.11.4. Study set-up

Pharmacy staff should be trained in the specific requirements of the study. This is done formally through a site initiation visit. The pharmacy should have a system in place, either on paper or electronically, agreed with the sponsor to keep study related documents. This should contain the reference documents, such as protocols, pharmacy manuals, investigators brochure or the manufacturer's summary of product characteristics, a copy of the ethics documents and/or regulatory approvals as per each jurisdiction. The contents can vary according to the legal, sponsor and local requirements.

IMPs should be shipped to the site only once all regulatory approvals are in place and the pharmacy is ready to receive the stock. The pharmacy needs to ensure that trial stock is stored in accordance with the sponsor's requirements.

When the IMP arrives at the department, verification of the packaging and transport conditions, quantities received, batches, retest date, general condition and release statements is essential.

4.3.11.5. *Disclaimer*

Clinical trial legislation will vary according to the laws and legislation of each country/jurisdiction. Since some terms used may differ, national or regional legislation and laws should be consulted first.

4.3.12. Finance and sustainability

Finance departments play a crucial role in ensuring that there are resources available for meeting the comprehensive cancer centre's objectives — from the setting up of the centre to the point at which it becomes sustainable (typically four–five years). It is imperative to have a strong finance team from the outset, so that cash flows are estimated regularly to make funds available. There should be a detailed budgeting exercise followed by a cash flow mechanism to ensure a viable project, including inputs regarding clinical planning, medical and non-medical equipment, design and from the building contractor.

Sustainability requires a thorough analysis and adequate calculation for funds to pay salaries, purchase consumables, maintain and replace equipment in due time, maintain and expand the existing infrastructure, and train current and new workforce. Some important features include the following:

- (a) Planning to be efficient. This involves answering questions such as: how many beds, intensive care units (ICUs) and operating theatres are required; the technology that will be used, etc.
- (b) Innovative financing mechanisms/identifying multiple donors. It is the sole responsibility of the organization setting up the cancer centre (government, non-governmental or private) to make financial resources available. There are several ways to achieve this, as follows:
 - Vendor financing. This includes various modes of partnership with equipment manufacturers, including mechanisms such as the following:
 - Deferred payment over eight–ten years;
 - Vendor financed complementary equipment, where the vendor lends certain expensive equipment to a hospital, which purchases their inventory of services or consumables (e.g. laboratory reagents, scans).
 - Lease finance. This can be adopted in cases where vendor financing is not possible. Cancer centres can reach out to finance companies to help them to lease equipment. This permits the use of equipment by the centre without obtaining ownership rights.

- (c) Maximizing revenues. This can be achieved as follows:
 - Empanelment with government insurance schemes;
 - Staggered recruitment of human resources according to occupancy;
 - Bulk procurement of drugs and consumables;
 - Policy and advocacy.
- (d) Philanthropic support. Many cancer centres seek and receive philanthropic support, which has the potential to transform the future of cancer care and comprehensive cancer centres. The centre may work with donors and/or foundations to generate funds for strategic investments.

Lastly, financial systems should be used to record basic data for analysis, such as consumption subcategories, risk categorization of patients and norms. The finance team should have analytics capabilities to provide insights on deviations for ensuring timely measures for sustainability.

4.4. NUTRITION

4.4.1. Rationale for nutritional services

Malnutrition may significantly affect outcomes in cancer patients. To ensure comprehensive care for cancer patients, MNT needs be considered when planning a cancer centre. All components of MNT (nutrition screening, assessment and management) can be offered over the three levels of an MNT module and customized according to the staff, funds and nutritional resources available. There are many nutritional resources available, and cancer centres should consult with national, regional or international nutrition and dietetics organizations, as well as available consensus guidelines, when establishing an MNT module.

4.4.2. Role of medical nutrition therapy in multidisciplinary cancer care

Malnutrition — both undernutrition and obesity — is prevalent in cancer patients. Malnutrition in cancer patients may result from treatment induced effects on oral intake (such as nausea, vomiting, constipation, diarrhoea, xerostomia, mucositis, dysphagia and loss of appetite) or from site specific, tumour induced effects on energy balance (including hypermetabolism, malabsorption, dysmotility and obstructions). The short term consequences of malnutrition may include decreased treatment tolerance, increased treatment delays, fatigue, susceptibility to infections and increased hospitalization and treatment cost. Cancer patients who are malnourished have lower survival rates and face other long term consequences, such as reduced functional capacity, decreased

bone density and increased risk for metabolic syndrome. The awareness of the importance of nutritional support in treating cancer patients is growing and cancer centres need to plan to incorporate MNT, either as an MNT unit or as integrated resources, considering the level of complexity of the planned cancer centre.

MNT should therefore be a mandatory component of supportive care for all cancer centres and there needs to be a multidisciplinary approach. SOPs for all levels of cancer centres should be centre specific on the basis of evidence and available guidelines, resources and capacities. Procedures should cover the continuum of MNT, from screening to management and from diagnosis to survivorship. Resources needed for MNT can be tailored to the level of the cancer centre, and all phases of MNT can be covered in cancer centres of Level 1 to Level 3.

A Level 1 MNT unit is the minimum level of providing nutritional support to cancer patients. To implement a Level 1 MNT, the minimum staff requirement is a nurse or clinician who has undergone some training in nutrition management of cancer patients. For a Level 1 programme, nutrition screening should be undertaken for all patients and a review of nutritional intake and nutrition symptoms can be performed using a checklist. For nutrition management, printed materials can be provided to patients as nutrition education, and basic oral nutritional supplements can be provided or locally produced.

A Level 2 MNT unit should have access to a dietician and, in addition to the Level 1 assessment, it should assess body composition using simple methods. At a Level 2 MNT unit, enteral nutrition should be made available.

A Level 3 MNT unit, which would be found in a comprehensive cancer centre, should have full time dieticians with specialized cancer qualifications. Advanced body composition assessment methods, such as dual energy X ray absorptiometry or isotope dilution, should be used to monitor nutritional status throughout treatment and guide interventions in a Level 3 unit. This unit provides individualized nutritional counselling and access to all available nutrition interventions, including parental nutrition, as well as drug therapy to support the nutritional needs of cancer patients.

4.4.3. Components of nutrition services

Nutrition services involve the following components:

- (a) Nutrition screening. This is the first step in identifying patients who may be malnourished or who are at risk of developing malnutrition. It prevents nutrition related problems when risks are identified and allows prompt intervention when malnutrition is identified. All oncology patients should be screened at the time of diagnosis and throughout treatment into

survivorship. Screening tools should be used to combine parameters that are known to contribute to malnutrition in patients, such as nutritional intake, weight changes and nutrition related symptoms, and then to categorize malnutrition risk. There are many malnutrition screening tools available for cancer patients, and the tools chosen need to be validated in the setting in which they are intended for use [4.114–4.119]. Nutrition screening is a simple, cost effective and quick process that can be carried out by any clinical staff, who will then direct the next steps in providing nutritional support. There are no limitations to providing nutrition screening at all levels of cancer centre.

- (b) Nutrition assessment. This should be undertaken for all cancer patients who are identified by nutrition screening as being at high risk of malnutrition. The nutritional assessments should justify, inform and guide the MNT. There are several aspects to nutrition assessment that require varying levels of assessment tools and capacities:
- (i) Nutritional intake. The dietary intake of the patient should be assessed to investigate whether the energy intake is meeting the patient's energy needs. There are many tools available to evaluate the nutritional intake of cancer patients, including 24 h dietary recall, three day food diaries or chart reviews, and the depth of the evaluation can be modified for the level of cancer centre.
 - (ii) Nutrition impact symptoms. Patients should be observed and should report if they are experiencing any symptoms that may affect their dietary intake and nutrient absorption. These symptoms may include xerostomia, changes in smell and taste, nausea, vomiting, mucositis or constipation. There are nutritional impact symptoms checklists available for cancer patients to ensure that all cancer centres can evaluate nutrition impact symptoms [4.120, 4.121].
 - (iii) Body composition. Malnutrition is reflected in altered body composition (fat and lean tissues). Body composition assessment is vital in cancer patients, as altered hydration and tumour mass will affect weight, and body composition assessments are required to look beyond the weight and understand the clinically significant changes in fat and lean tissues. There are many body composition methods that can be used for cancer patients, and their limitations and advantages should be considered before choosing the method to be used in the cancer centre. While Level 1 cancer centres may rely on simple methods, such as circumferences and skinfolds, Levels 2 and 3 cancer centres should provide more advanced assessments, such as dual energy X ray absorptiometry and isotope dilution.

- (c) Nutritional management. This should be provided at some level to all patients identified with reduced dietary intake, nutrition related symptoms and body composition changes. The goals of nutrition management are to preserve lean mass, prevent fat mass gain, prevent nutrient deficiencies, minimize nutrition related complications, boost immune function and treatment tolerance, maintain functional capacity and maximize quality of life.
- (i) Nutrition counselling. All patients at cancer centres should receive information about maintaining good nutrition during treatment, food safety and symptomatic management of nutrition related side effects. Available nutrition guidelines include those of the National Cancer Institute [4.122], and all cancer centres should provide access to information that is relevant to the tumour site and culturally appropriate.
 - (ii) Oral nutrition supplements. Ensuring adequate oral intake to meet energy requirements is the preferred method of nutrition support for cancer patients. The oral nutrition supplements available will depend on the level of the cancer centre and may range from commercially available protein and energy dense liquid supplements in Level 3 cancer centres to locally made shakes and ready to use therapeutic foods in Level 1 cancer centres.
 - (iii) Enteral versus parent nutrition. Maintaining an adequate oral intake to meet energy requirements may be difficult in cancer patients owing to nutrition related side effects. The enteral route is the safest way of providing nutrition to patients with a functional gastrointestinal tract, and Level 2 cancer centres should have the capacity to provide enteral nutrition to their patients. Parental nutrition is restricted to Level 3 cancer centres.
 - (iv) Drug therapy. To combat nutrition impact symptoms and systemic inflammation, medications such as antiemetics, antimicrobials, corticosteroids and antisecretory agents may be prescribed. Algorithms can be developed to prioritize interventions based on the emetogenic potential of chemotherapy. While some medications may be prohibitively expensive for Level 1 and 2 cancer centres, more economical alternatives can be considered while also advocating for the inclusion of antiemetics in essential medicine lists for cancer patients.

4.5. PSYCHOSOCIAL CARE

4.5.1. Rationale for psychosocial care

Cancer is often a life changing illness. From diagnosis through active treatment and extending into survivorship or end of life care, cancer imposes significant mental, emotional, social and financial challenges for patients and families. These may be consequences of the cancer itself or of cancer directed treatments. In addition to biomedical support, there is therefore a need for psychosocial support for cancer patients. Holistic psychosocial support is multidisciplinary, viewing the patient as a whole person and addressing the psychological, social, emotional and functional needs of patients and their families. The needs of individual patients may vary according to the details of their diagnosis and treatment plans, socioeconomic factors and cultural values.

4.5.2. Psychosocial care as part of multidisciplinary care

Psychosocial care for patients with cancer includes assessment and anticipatory management of patients' and families' needs, from diagnosis and throughout the disease trajectory, encompassing needs across emotional, spiritual, interpersonal and material/financial domains. Given the long duration of many treatments for cancer, support to reduce patient and family distress and to promote treatment adherence is vital. Common elements of psychosocial care include supportive counselling or psychotherapy, social work and spiritual care.

4.5.3. Types of psychosocial care

4.5.3.1. *Hospital based psychosocial services*

Hospital based psychosocial services have the following features:

- Services can be provided by trained social workers and psychosocial professionals, starting with part time staff (staff that have responsibilities for other patient populations or are available for consultation), including added training and peer support to manage serious chronic illness.
- Services can also be complemented by lay volunteers and support staff.
- Core services include patient and family education and counselling, including group education; needs assessment and provision of resources and support, including for financial burden, housing, transportation and meal support; procedural preparation and support; and assessment and support for treatment adherence.

- Expanded services can also include efforts to provide individualized psychoeducation and counselling, assessment and management; psychosocial follow-up in survivorship; child life, social interaction, recreation and respite support; support for siblings of children and adolescents with cancer; consultation services involving legal and ethics experts; and support for reintegration into schools and workplaces.
- In many settings, services are often provided in conjunction with palliative services.
- Where possible, paediatric psychosocial providers should have specialized training and education and be credentialled to provide developmentally appropriate assessment and management for children with cancer and their families [4.123].

4.5.3.2. *Community based psychosocial services*

Community based psychosocial services have the following features:

- Services can be provided by or with NGOs, and with support from parent/family advocacy groups or councils.
- Core services include patient and family education and counselling, including group education, needs assessment and provision of resources and support, including for housing, transportation and meal support.
- Expanded services can also include those linked to school programmes or community based legal/health services; vocational programmes for families; integrative health services and linkages with traditional and complementary medicine providers and services, as appropriate according to the local context; and recreation and respite support.

4.5.3.3. *Relevant standards*

Standards that apply to psychosocial services are as follows:

- Psychosocial care is a universal human right [4.124].
- Evidence based psychosocial standards have been established for the care of children with cancer and their families, spanning diagnosis through to survivorship care [4.123].

4.5.4. **Community participation**

Recognizing that cancer affects an increasing number of people globally and that appropriate cancer control can save lives, the global health community

has embraced efforts for collective action and joint efforts to improve cooperation and coordination to maximize the use of available resources. An important contribution to these efforts is made through civil society engagement.

Civil society organizations (CSOs), sometimes called the ‘third sector’ after government and commerce, refer to the private and family sphere and encompass a wide array of bodies, including community groups, NGOs, labour unions, indigenous groups, charitable organizations, faith based organizations, professional associations and foundations aiming for collective action around shared interests, purposes and values. When mobilized, civil society, as a non-state actor, has the power to influence the actions of elected policy makers and businesses and play critical and diverse roles in societal development.

CSOs can be engaged to do the following:

- Support a cancer centre in ensuring that patient experience and outcomes are of central focus in the design and daily services of the centre.
- Help to drive the vision of the first cancer centre in the country in its role beyond that of a stand-alone treatment clinic to that of a ‘reference cancer centre’ for the country and community.
- Contribute to realizing that vision in a multifaceted manner, holding institutions to account and promoting transparency; raising awareness of consumer and societal issues; delivering services to meet public information, education and health needs; bringing expert knowledge and experience to shape policy and strategy; giving power to the marginalized; and encouraging citizen engagement.
- Develop their expertise and capacities to establish, on behalf of the Ministry of Health or the cancer centre, institutions and services critical to the monitoring, evaluation and improvement of clinical outcomes, as well as provide trusted sources of information for the public, such as the national cancer control strategy, cancer registry, national cancer research institute, cancer society, national cancer patient network and professional organizations across the disciplines of cancer care.

Collaboration of the cancer centre with CSOs can support and enhance the impact of clinical services by sensitizing the community to cancer signs and symptoms and helping patients to get diagnosed and treated as soon as possible, optimizing the opportunity for curative therapy and improving access to pain relief and palliative care. CSO engagement in the catchment area of the centre can also support care in the home or hospice care, which can release beds in the clinic, improve patient and carer satisfaction and ease the financial strain on families. In addition, CSOs can partner with clinics to provide financial

assistance and, in some cases, access to cancer medicines that would otherwise not be available to the clinic or patient.

Patient navigation is a patient centred health care service delivery model that helps to reduce barriers — such as economic, language, cultural, communication, health care system and transportation barriers, as well as fear — to patients accessing the health care system in a culturally sensitive manner. Specifically, they have been shown to improve access to proper cancer care for underserved individuals. It has been reported in the literature that patient satisfaction was higher for navigated patients than for matched comparison patients [4.125], and a three year study showed that total costs per quarter decreased for navigated patients versus the control group [4.126]. CSOs in less developed settings are increasingly able to provide this type of expert support. For example, the Breast Health Foundation in South Africa began as a patient navigation organization in one cancer centre. The navigator network of breast cancer survivors (Bosom Buddies programme) now extends its work to include community sensitization (Buddies for Life programme), recognizing that peer to peer engagement within the community is most effective. Navigators are extending their reach beyond their first catchment area of Johannesburg to work across the country using e-health technology to ensure that women with breast cancer symptoms in remote communities are not lost in the system, are accompanied to treatment centres and are linked to cancer centre personnel for optimal follow-up. In addition, the Breast Health Foundation is now extending its services to the training of community health workers² (see Annex III for more references).

4.5.5. Patient organizations

A strategy to assess and improve the patient experience represents an organizational commitment to partnering with patients to identify and address the aspects of their experience that are most important to them. Patient organizations can facilitate this exchange and play an important role in educating health care professionals by sharing individual care experiences and providing ideas on how to improve the delivery of care. For example, the recently built cancer centre of Guy's and St Thomas' in London, United Kingdom, invited patients into the design advisory group. These volunteers continued after the building was completed to provide tours for new cancer patients and support public open days at the centre.

Patients and their families play a pivotal role in informing care and making joint treatment decisions. The principles of patient centred care and the patient experience include patient information and digital tools, as well as provider

² <https://www.mybreast.org.za/>

training. A good summary of best practices is provided in Ref. [4.127], which elaborates on the opportunities to engage patients, such as recruiting and training past or current patients and caregivers to serve official roles within the cancer centre, often referred to as patient partners or patient advisors; encouraging and requesting patient consultation and involvement in the development and evaluation of services and programmes; and integrating patient engagement into provider training. The scheme of cancer buddies, which pairs newly diagnosed patients with peer volunteers who have completed a similar cancer journey, is a good example of service support offered by CSOs that is well established in a number of countries.

4.5.5.1. The Cancerpedia framework: A resource for key issues and supporting literature

Cancerpedia is a cohesive framework for a comprehensive cancer centre or programme that provides the full spectrum of cancer care, serves as a hub for education and research, and is integrated into broader cancer control and health systems. It can serve as a checklist for health care professionals wishing to develop, scale up or evaluate a cancer centre. The framework was constructed around the needs of patients with suspected or diagnosed cancer and provides a system level perspective, as well as a granular view of the fundamental resources and structures needed for a cancer centre. The framework also covers cancer control as part of a larger health system that extends beyond the cancer centre [4.127].

In summary, the cancer centre has an important role in forging connections with CSOs, cancer societies and community based organizations to facilitate access to important services and support throughout the care trajectory. Formalized partnerships at local, national and international level can allow the cancer centre to work with external organizations to resolve unmet patient needs and advocate for patient services and support that are outside the scope of the cancer centre or are best delivered in the community.

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Chapter 5

ANCILLARY SERVICES AND CONSIDERATIONS

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5.1. INFRASTRUCTURE

5.1.1. Infrastructure considerations

Planning a cancer centre depends on the diagnostic and treatment needs of a given location, be it for outpatients, inpatients or palliative care [5.1]. The process of hospital planning therefore starts with a needs assessment, along with a systematic demographic and situational assessment, which will determine whether the plan is to achieve the following:

- Create a stand-alone comprehensive cancer care facility with necessary allocations for all components of cancer care, as outlined in Chapter 2.
- Expand an existing facility to include one or more components of cancer care.
- Introduce individual components of cancer care in a location in a phased manner.
- Create an integrated care network, according to the WHO definition: “Integrated care is a concept bringing together inputs, delivery, management and organization of services related to diagnosis, treatment, care, rehabilitation and health promotion” [5.2].
- Use integration as a means to improve services in relation to access, quality, user satisfaction and efficiency [5.3]. Once this is decided, factors such as the number of room types required, essential equipment and their space requirements, circulation pattern and support areas can be decided [5.4], bearing in mind critical design principles.

5.1.2. Elements for consideration when planning infrastructure

- Patient centric design. Hospital design and operations have traditionally been focused on meeting the needs of physicians, but increasingly patient experience is also considered important. Hospital designs have a relatively

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large impact on the well-being and recovery of patients and on reducing their average length of stay.

- Clear directional signage. Complex buildings such as hospitals may be confusing to navigate, especially during times of stress. Clear directional signs help patients or relatives to reach their destination in the most efficient way and with minimal need to ask staff for directions or consult a map.
- Streamlined patient flow in hospitals to improve patient experience. With health care facilities handling increasing numbers of patients and wishing to make patients' experience as satisfying as possible, departments used by patients can benefit from being adjacent to each other. Easy access between departments can help to improve the quality of care and patient experience.
- Adherence to health care guidelines. This includes all necessary precautions that focus on optimal infection control practices; regulatory radiation guidelines; segregation of clean, dirty and sterile equipment and consumables; selection of appropriate surfaces and furnishings; hospital layout; air quality; light and ventilation; sanitation; noise levels; medical gas planning; pneumatic chute system; telecommunications and HIS [5.3, 5.5].
- Flexible, universal 'structural grids'. Unlike other buildings, hospitals are used for 50 years or more. During this time, rooms may be changed or replaced as clinical methodologies, equipment and operating procedures change. A universal structural grid allows for departments to be moved or replanned within the same structural parameters with minimal implications (see Box 5.1) [5.4].
- Access to, and views of, natural/landscaped areas. Health care environments are not just buildings accommodating modern technology for treatment of ailments and diseases. Anxiety and stress levels in patients are reduced when patients are provided with visual connection to landscape areas and access to nature. Access to these areas acts as a positive distraction, which help in the patient's recovery process. It also provides relief for the staff, reducing stress and mental fatigue, thus enhancing their care giving capabilities.

BOX 5.1. USING A FLEXIBLE, UNIVERSAL DESIGN GRID

Use of a standard grid allows space to be organized in a way that maximizes operational efficiency across functions, as follows:

Flexibility: Standardized floor plates based on a universal grid offer the highest flexibility in terms of accommodating a variety of configurations of medical uses.

Cost effectiveness: Structures that employ a standard grid design, such as flat slab constructions, can be cost efficient and quick to build.

Future proofing: The programmes and interiors within the universal standard grid can be easily modified repeatedly to best reflect the emerging needs of every medical centre.

5.1.3. Infrastructure requirements by department

This section outlines the key functions, optimal design features and desired location for various cancer centre departments, including the emergency, outpatient, diagnostic imaging, chemotherapy, nuclear medicine, radiation oncology and surgery departments.-

5.1.3.1. Emergency department

An emergency department (ED) is the first point of contact for any critically ill patient requiring immediate medical attention. Hence, this facility is ideally located with a separate entrance to avoid delays and is equipped to attend to unscheduled patients 24 hours a day, 365 days a year, with the help of qualified doctors, emergency room nurses and paramedics. These professionals have to manage various unplanned cancer related complications, such as febrile neutropenia, respiratory distress, acute pain, uncontrolled nausea and vomiting [5.6, 5.7] (see Table 5.1 and Fig. 5.1).

TABLE 5.1. KEY FUNCTIONS OF AN EMERGENCY DEPARTMENT

No.	Function
General spaces	
1	Reception, billing and waiting
2	Examination/consultation room
Medical functions	
3	Minor operation theatre/procedure room
4	Observation bays
Clinical support functions	
5	Nurse station
6	Crash cart bay
7	Clinical support
8	Observation bays

Design principles

The following design principles apply:

- Patient care and safety are the key focus of ED design.
- The ED has a pivotal role in providing patients with effective clinical care. It is the point responsible for receiving, analysing, stabilizing and managing patients arriving at the hospital with different degrees of urgency and severity. The condition of patients requiring emergency care can vary from major trauma to stroke.
- The department’s design has to instil a sense of care, efficiency and safety. The patient’s right to privacy needs to be safeguarded.
- Separate entrances are preferred for walking and emergency vehicles. The entrance is not to be used as a general entrance into the hospital and the flow of other patients and staff should not cross paths.

Description of adjacency

The following principles apply:

- Location. The ED needs to be placed at a location where it is easily accessible to ambulances and vehicles entering the site and allows ease of egress from the department.
- Signage. A hospital with an ED needs to have a signage strategically located such that it is visible from major roads surrounding the campus.
- Access. The ED needs to have ready access to the critical care areas and diagnostic facilities necessary for stabilizing and giving due medical care to critical patients. Clinical areas that have an unobstructed access to the ED include the following:
 - ICU and high dependency unit;
 - Diagnostic imaging department;
 - Emergency operating theatres;
 - Inpatient wards and observation bays.



FIG. 5.1. Operational flow of an emergency department.

5.1.3.2. *Outpatient department*

The outpatient department (OPD) is a hub of activity that is kept open for a fixed number of hours every day for patients to schedule their primary, follow-up or after-care appointments, minor procedures such as dressing, diagnostic check-ups and rehabilitation therapy¹ [5.8–5. 10]. Table 5.2 lists the areas or dedicated spaces for various general, medical and support functions.

TABLE 5.2. KEY FUNCTIONS OF AN OUTPATIENT DEPARTMENT

No.	Function
General spaces	
1	Reception, billing and waiting
2	Insurance and assistance
3	Pharmacy
4	Social services
5	Recreation area/play area
6	Prayer rooms
7	Retail area
8	Coffee shop
Medical functions	
9	Cancer registry
10	Assessment stations
11	Phlebotomy room (with/without toilet)
12	Consultation rooms and joint clinics

¹ <https://hospaccxconsulting.com/>

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TABLE 5.2. KEY FUNCTIONS OF AN OUTPATIENT DEPARTMENT
(cont.)

No.	Function
13	OPDs with special equipment (dental, otorhinolaryngology, gynaecology)
14	Dental laboratory and orthopantomogram
15	Electrocardiogram, echocardiogram, tread mill test, pulmonary function test
16	Electroencephalogram, electromyography
17	Audiometry
18	Speech therapy
19	Occupational therapy
20	Home care
21	Treatment room
22	Procedure room
23	Physiotherapy and rehabilitation
Clinical support functions	
24	Nurse stations
25	Clinical support
26	Tumour board room
27	Patient care office
28	Staff amenities

Note: This is an expansive programme. Various cancer centres may decide their own mix of outpatient services on the basis of various factors, including burden of disease in the region as well as investment capital and available space.

Design principles

The OPD needs to be located where it is easily accessible through a designated entrance from the main road. The department has to be adjacent to support facilities, such as diagnostic imaging and laboratory facilities, so as to minimize travel time for the clinicians and staff.

The OPD design and services to be provided depend on the following:

- Type of hospital;
- Numbers and types of specialized clinics;
- Operational hours of the OPD;
- Daily foot traffic of OPD patients;
- Infrastructure and plans for future expansion.

Patient flow needs to move in one direction to avoid undue back traffic. The circulation paths of patients/visitors and staff should not cross at any given point in time. Vertical circulation has to be planned strategically by means of lifts and staircases.

The design has to make it easy for the patients to find their way. The reception, registration, admission, enquiries and other units need to be easy to locate.

Description of adjacency

OPD facilities are divided into the following categories (Fig. 5.2):

- Zone I: Public area. Patient centric services, including entrance, reception, waiting areas and registration.
- Zone II: Clinical areas. Consultation rooms, treatment rooms and procedure rooms, with proper monitoring and access control.
- Zone III: Clinical support areas. Staff centric services, such as clinical support, and staff amenities, such as staff lounges and board rooms, need to be placed in Zone III, towards the rear end of the department and away from patient and visitor circulation areas.

Circulation areas (corridors, staircases and lifts) are shown in Fig. 5.2.

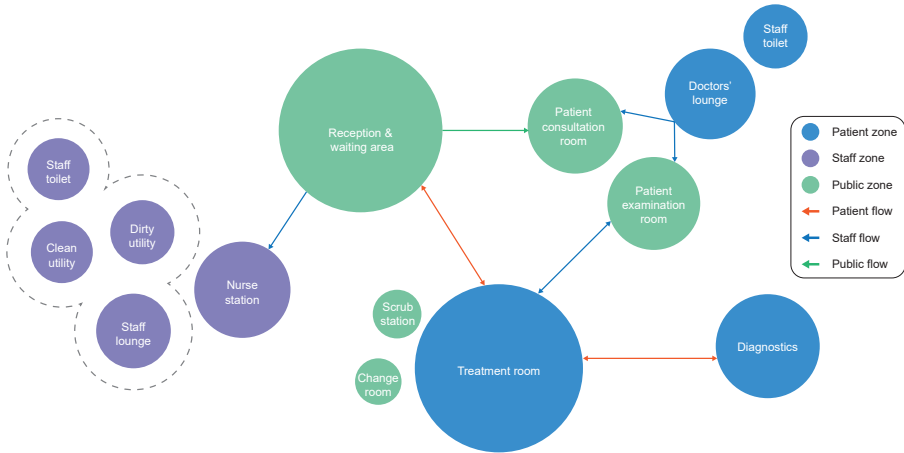


FIG. 5.2. Operational flow of an outpatient department.

5.1.3.3. Diagnostic imaging department

The infrastructure needs to be considered before taking any procurement decisions. For example, electrical power has to be suitable and reliable enough for installing different imaging systems. If the regional power plant is unstable, powerful circuit breakers need to be obtained to avoid damage to the instruments and support their continuous functioning. For repairs, transport infrastructure is necessary to enable expedient delivery of spare parts and components, which may not exist in the country. Moreover, for some technologies it is critical to define upfront with the local regulatory agencies any potential restrictions on using new contrast agents (e.g. dyes or radiotracers used during imaging; see Box 5.2 [5.11] for the IT infrastructure), if not already available in the country² [5.12].

² <https://fgiguideines.org/>

BOX 5.2. IT INFRASTRUCTURE [5.11]

The RIS, PACS and DICOM image formats, as well as the workstation areas where the imaging professionals view and interpret images, are described in Ref. [5.13]. Anticipated DICOM and PACS software and user licence renewals/updates and related costs can potentially be negotiated upfront, or at least clarified as part of the initial procurement contract. Similarly, overlooking long term hardware maintenance and software contracts can bring to a halt the functioning of the medical imaging unit. Multiple examples exist, in low resource settings, of unexpected long term post-procurement costs.

Design principles

The main radiology services need to be easily accessible to both inpatients and outpatients and need to be located near the OPD, nuclear medicine and — most importantly — the ED, to which there needs to be a fast, direct access to ensure timely diagnosis for critical patients.

The modalities provided by the diagnostic imaging department include the following:

- CT;
- MRI;
- Ultrasound;
- Mammography;
- X ray imaging;
- Fluoroscopy.

All radiology procedure rooms must be designed to do the following:

- Accommodate patients with disabilities and facilitate transfer of patients on a stretcher;
- Absorb vibrations produced by heavy equipment;
- Shield patients from harmful rays;
- Be soundproof for a better healing environment;
- Promote patient safety.

Description of adjacency

The registration and waiting areas need to be located near the main entrance. The diagnostic imaging department needs to have direct access from

the main registration area. The diagnostics and imaging modalities need to have controlled access. A centralized patient check-in facility needs to be provided to simplify patient visits and increase staff efficiency.

Patient waiting areas need to be located near busy departments such as X ray and ultrasound. Radiology procedure rooms that have a quick turnaround and high volume examinations, such as the X ray room, need to be located near the reception and waiting areas to reduce travel time and distance for both patients and visitors.

Rooms with longer procedure times, such as MRI rooms, need to be strategically located. For safety reasons, only patients requiring access to this zone have to be able to enter it.

The control room for each radiology room accommodates the controls and enables the technicians to supervise the patients during the procedure. Appropriate accessories and protection from radiation have to be ensured (Table 5.3 and Fig. 5.3).

5.1.3.4. Chemotherapy

A chemotherapy unit or ward is specifically designed as a day care unit, where patients can schedule their infusions with their care teams. Administration

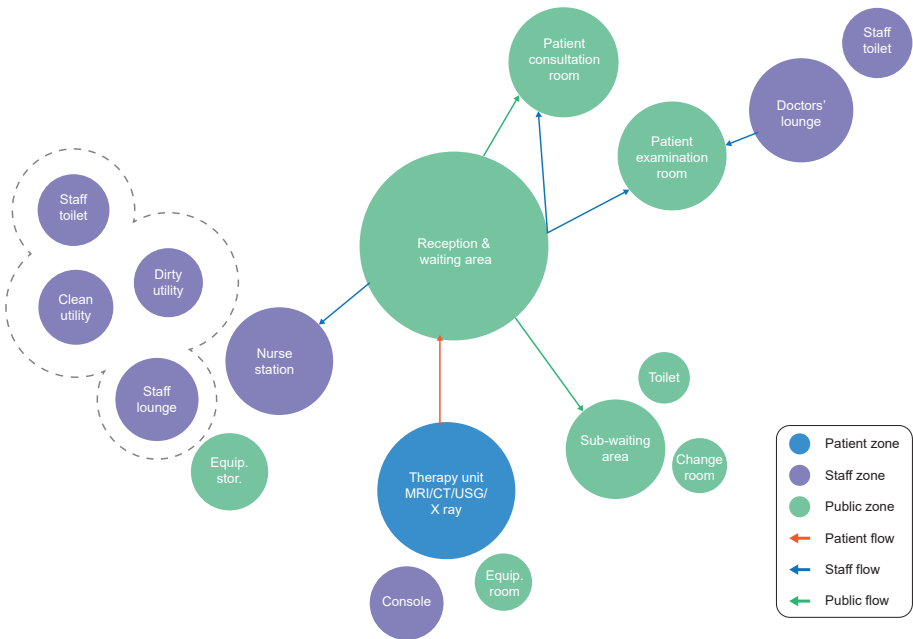


FIG. 5.3. Operational flow of a diagnostic imaging department.

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of these infusions may vary from a few minutes to a few hours. While the ratio can change on the basis of regional preferences, this unit usually has a mix of reclining/resting chairs and beds. In addition to regular inpatient wards, this unit is provided with an area to store and prepare medicines in safe conditions using a biosafety cabinet [5.14, 5.15].

TABLE 5.3. KEY INFRASTRUCTURE FUNCTIONS OF A DIAGNOSTIC IMAGING DEPARTMENT

No.	Function
General spaces	
1	Reception, billing and waiting
2	Consultation rooms
Medical functions	
3	Ultrasound — general
4	Mammography
5	X ray
6	Fluoroscopy
7	MRI
8	CT scan
Clinical support functions	
11	Patient changing (with/without toilets)
12	Equipment rooms
13	Control rooms
14	Reporting room

Design principles

A chemotherapy unit can be divided into the following functional zones (see Table 5.4):

- (a) Entry/public zone:
 - Reception and waiting areas;
 - Counselling room for discussions with attendants and treatment planning.
- (b) Treatment zone:
 - Treatment chair or bed bays;
 - Isolation rooms;
 - Patient toilets;
 - Treatment/procedure room;
 - Dedicated treatment areas for paediatric patients can be provided, considering the nature of the patients.
- (c) Clinical support zone:
 - Nurse stations;
 - Clean utility;
 - Dirty utility;
 - Medicine preparation;
 - Chemotherapy pharmacy.
- (d) Staff zone:
 - Meeting rooms;
 - Staff room;
 - Toilets, shower and locker areas.

Description of adjacency

The chemotherapy department can be part of the day care zone or an independent department (see Fig. 5.4). It needs to have direct access from the main entrance lobby and reception. Finding the way to/inside the department needs to be easy for the patient and visitors. The chemotherapy department also needs to be adjacent to clinical units such as the OPD, RT, diagnostic imaging and clinical support areas. In addition, the unit needs to have access to the inpatient areas and the operating theatre in case of emergencies. Finally, controlled access is needed to ancillary support areas such as storerooms for the delivery of items, e.g. bulk fluids, as well as the central sterile supply department laundry for linen supplies and the kitchen for delivery of food.

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TABLE 5.4. KEY FUNCTIONS OF A CHEMOTHERAPY UNIT

No.	Function
General spaces	
1	Reception and waiting
2	Daycare manager office
3	Consultation rooms
4	Food kiosk
Medical functions	
5	Chemotherapy beds
6	Chemotherapy chairs
7	Chemotherapy medicine preparation
8	Chemotherapy pharmacy
Clinical support functions	
9	Clinical support
10	Staff amenities

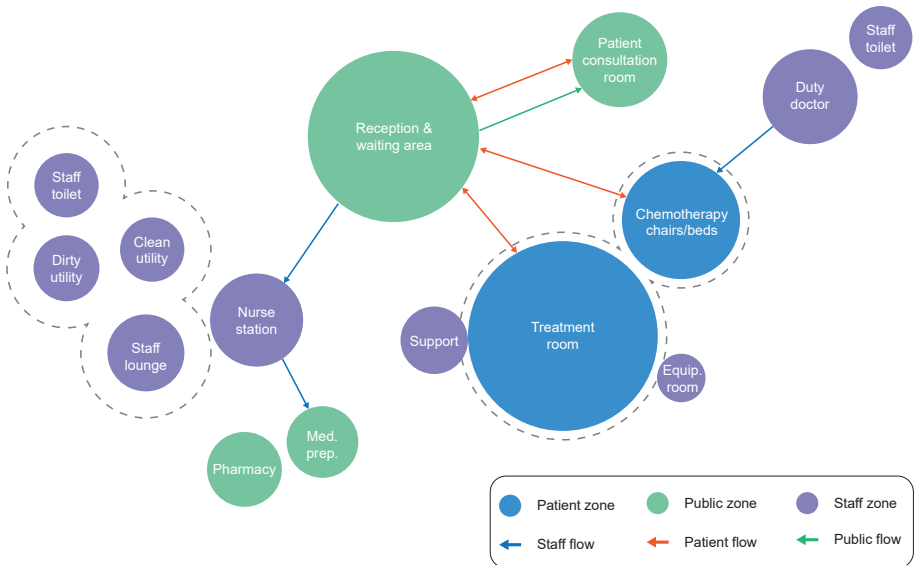


FIG. 5.4. Operational flow of a chemotherapy department.

5.1.3.5. *Radiotherapy department*

The IAEA recommends that RT facilities are designed so that any future expansion can be made without disruption of existing services [5.16]. Figure 5.5 introduces the concept of five functional areas: reception, administration and waiting areas; clinical consultation areas; external beam RT; brachytherapy; and the imaging and treatment planning area. These areas together constitute an overall footprint of approximately 1450 m² and need to be positioned in accordance with the preferred workflow of the staff and the patients. The facility needs to be conveniently sited in relation to the hospital infrastructure (see key functions in Table 5.5). Rooms containing RT treatment equipment (external beam RT and brachytherapy bunkers) are highly specialized, and a core implementation team with adequate expertise needs to be constituted to design the facility and to manage the construction. The IAEA has extensive, publicly accessible guidelines on appropriate buildings and essential equipment for an RT unit [5.17].

Equipment for radiation oncology includes external beam and brachytherapy treatment units; imaging machinery for treatment planning and simulation; computerized treatment planning systems; an oncology information system; dosimetry, QC and safety equipment; mould room equipment; and positioning and immobilization devices, including consumable equipment. Some RT processes may require additional medical equipment, such as beam measurement, QA, safety and radiation protection physics equipment; conventional and CT simulator (or access to a CT); computerized treatment planning systems for external beam RT and brachytherapy; patient immobilization devices and mould room equipment; at least one brachytherapy afterloader with an X ray C-arm for verification; and a full range of applicators appropriate to the case mix.

Design principles

Patient privacy and dignity are prime considerations in the design of RT facilities. The design principles of RT facilities are as follows:

- The travel distance from the parking lot and main entrance to the RT department waiting room needs to be as short as possible. The RT facility needs to be located close to other diagnostic facilities that may assist in the coordination of patient service.
- The reception area controls access to the patient areas and prevents unauthorized access to the department.
- The design has to be sensitive to patient needs and comfort, as these patients are physically weak owing to illness.

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TABLE 5.5. KEY FUNCTIONS OF A RADIOTHERAPY DEPARTMENT

No.	Function
General spaces	
1	Reception and waiting
2	Consultation rooms
Medical functions	
3	LINAC
4	MRI simulator
5	CT simulator
6	Brachytherapy
7	Procedure room
8	Mould room
9	Treatment planning room
10	Consulting — radiation oncologist
11	Consulting — physicist
12	Radiation safety officer's office
13	Minor operation theatre
14	Tumour board
15	Holding beds
Clinical support functions	
16	Nurse stations
17	Clean utility room/dirty utility room

TABLE 5.5. KEY FUNCTIONS OF A RADIOTHERAPY DEPARTMENT
(cont.)

No.	Function
18	Pantry
19	Equipment rooms
20	Reporting room
21	Control rooms
22	Uninterruptible power supply (UPS) — battery rooms
23	Scrub station (brachytherapy)
24	Patient change (with toilets)
25	Staff amenities

Note: This is an expansive programme. Various cancer care centres may arrive at their own mix of programmes for RT on the basis of various factors, including burden of the disease in the region, investment capital and available space.

- Adequate waiting areas need to be provided for both inpatients and outpatients. The number of attendants accompanying the patients have to be considered while planning these areas.
- Patient areas need to be consolidated to control patient access and to maintain patient privacy, security and dignity.
- Shielding and safety of the patients and staff plays a crucial role in the RT department, including walls of a specified thickness to act as a shield to prevent any leakage of the rays.
- The LINAC units need to be located back to back to optimize the wall thickness. This aids in reducing the construction costs, as well.
- Guidance for technical specifications has been provided by WHO and the IAEA [5.18].

Description of adjacency

The following principles apply for the different zones of an RT department (see Fig. 5.5):

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- (a) Entry/public zone:
 - The reception and the waiting area need to be located so that they provide a clear view of the entry and egress points for patients and staff.
 - The oncology examination rooms and counselling rooms need to be provided at the interface of the public and clinical zones. Outpatient movement needs to be restricted beyond this point in case of unscheduled appointments.
- (b) External beam RT:
 - The ideal location for the bunkers is on the ground level, given the complexities and design of the structure.
 - The RT block has to be accessible from the main lobby of the hospital or may also have a dedicated entrance.
 - The CT simulator and brachytherapy suite need to be part of the RT block. Other clinical support areas for brachytherapy, such as the minor procedure room and associated recovery bays, need to be part of the suite.
 - The radiology and nuclear medicine department need to be located close to the RT block.
- (c) Clinical zone:
 - Staff and patient changing areas need to be provided near the entrance to the department.
 - Control stations are required to provide controlled access to the department.
 - The bunkers, CT simulator and brachytherapy suite are provided in this zone.
 - Patient toilets need to be provided near the LINAC units.
 - The radiation safety officer's office, medical physicist's office, treatment planning room, mould room and clinical support need to be placed in this zone.
- (d) Staff amenities:
 - The staff lounge and toilets need to be at the rear of the department.

5.1.3.6. *Nuclear medicine department*

The nuclear medicine department has to be designed specifically and in complete adherence to the statutory requirements of the atomic energy agency of the country (Table 5.6). An institute may decide to plan for a PET/CT unit alone and can choose to defer installation of a gamma camera for a later time.

In nuclear medicine, it is possible to import technetium generators and other radiopharmaceuticals that are required, as long as the local regulatory agencies support it. For PET, a cyclotron is needed within a 500 km range to provide the most common radiotracer (fluorodeoxyglucose or FDG). Therefore, a relevant supply chain needs to be set up. The costs of such logistical arrangements can reach as much as 10% of the total cost of a single product.

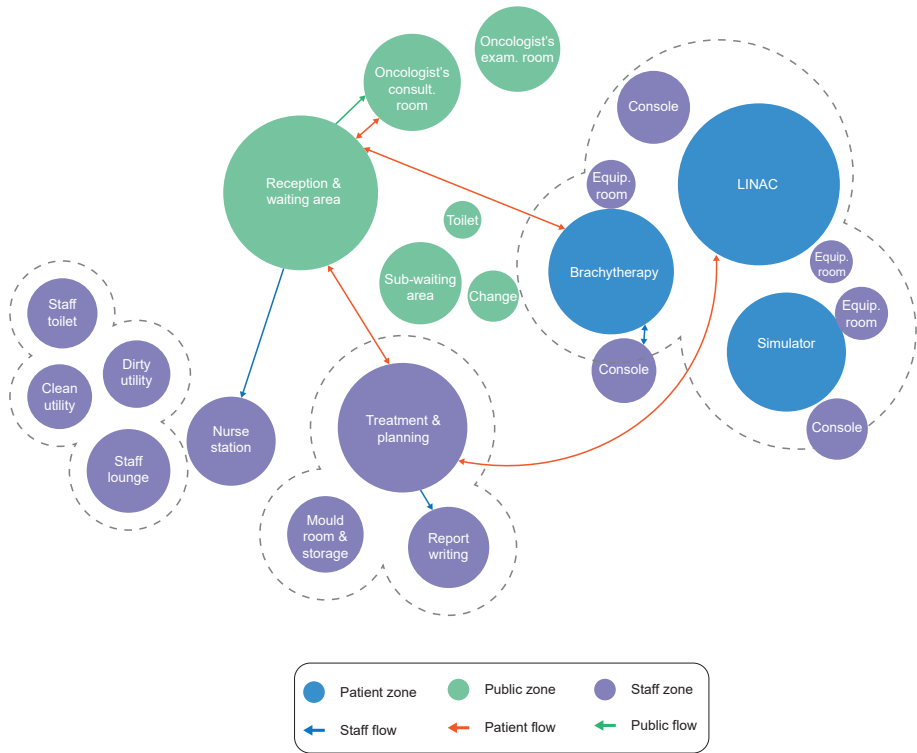


FIG. 5.5. Operational flow of a radiotherapy department.

Design principles

The following design principles apply (see Fig. 5.6):

- The nuclear medicine department has specific design considerations for shielding. The walls can be either 22.86 cm (9 inch) deep brick walls or 15.24 cm (6 inch) deep concrete walls.
- The department has to be designed to separate non-radioactive areas from radioactive areas.
- Dose administered patients awaiting procedures may require dedicated rooms and toilet facilities for various stages of the treatment process to protect other patients from getting exposed to radiation.

Description of adjacency

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TABLE 5.6. KEY FUNCTIONS OF A NUCLEAR MEDICINE DEPARTMENT

No.	Function
General spaces	
1	Reception and waiting
2	Consultation rooms
Medical functions	
3	Gamma camera
4	Hot laboratory
5	PET scan
6	Iodine therapy
Clinical support functions	
7	Nurse stations
8	Clean utility/dirty utility rooms
9	Equipment rooms
10	Reporting room
11	Control rooms
12	Chiller rooms
13	Dose administration rooms
14	Radio source storage rooms
15	Decontamination rooms
16	Radio waste storage rooms
17	Post-dose: waiting

TABLE 5.6. KEY FUNCTIONS OF A NUCLEAR MEDICINE DEPARTMENT (cont.)

No.	Function
18	Hot toilets ^a
19	Patient change (with toilets)
20	Staff amenities

^a Dedicated toilets for patients to use post injection.

Note: This is an expansive programme. Various cancer care centres may arrive at their own mix of programmes for nuclear medicine on the basis of factors such as the burden of disease in the region, investment capital and available space.

The nuclear medicine department needs to be easily accessible from the main hospital's entrance lobby or can share an entrance with the RT department. It also needs to be located close to or on the same floor as the following:

- Radiology department;
- RT;
- Central laboratory.

(a) Public zone:

- The reception and waiting areas in the public zone act as control points for access to the clinical zone.
- The counselling/interview rooms must be located in the public zone or at the interface of the public and clinical zones.

(b) Clinical zone:

- The patient changing rooms need to be near the entry to the clinical zone.
- The radioactive zone comprises the dose administration, hot lab, active stores and post-dose administration hold room.
- The imaging modalities, such as PET/CT and gamma camera, need to have easy access from the post-dose administration room.
- Clinical support areas (which comprise the technician work rooms, clean supply room, soiled hold) need to be located nearby to minimize travel distance for staff. The medical physicist's room, offices and report reading and writing rooms should not be accessible to the patients and have to be private.

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- (c) Staff amenities:
- Staff areas (lounge, toilets and offices) need to be clean and not overlap in any way with patient activities.
 - They can be located within the department or can be shared with departments of a similar nature.

5.1.3.7. Surgical suite

A surgical suite is the nucleus of a hospital in terms of patient safety and infection control. It can contain any number of operating rooms according to demand analysis and in appropriate ratio to its supporting clinical functions, such as the surgical ICU and inpatient areas, and caters to scheduled surgeries over a period of time, as well as unplanned emergencies requiring surgical management.

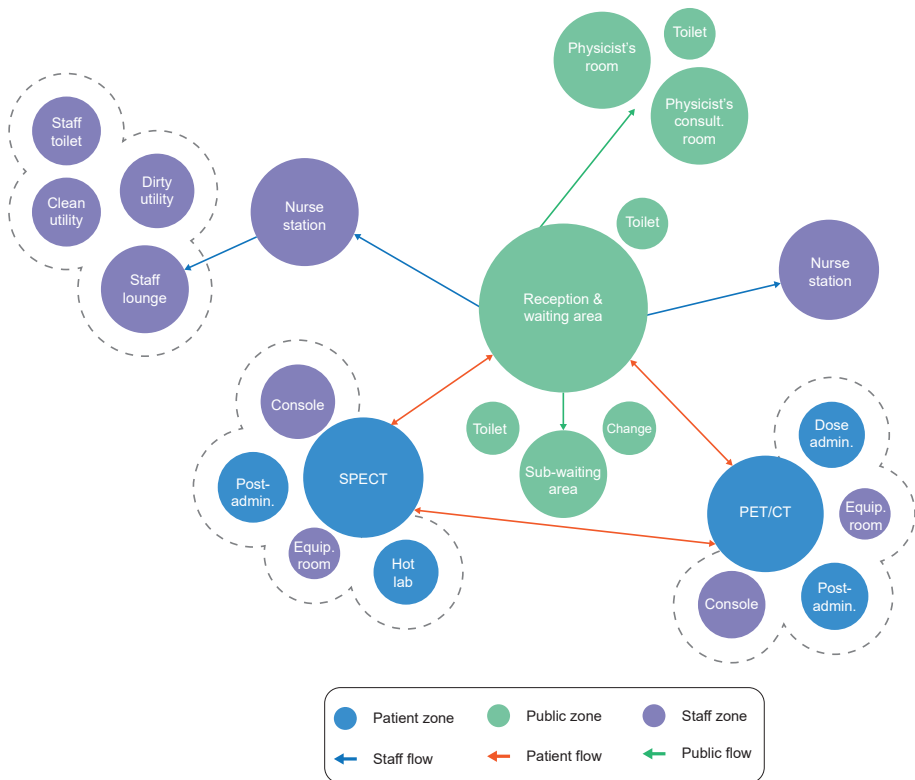


FIG. 5.6. Operational flow of a nuclear medicine department.

In addition to infrastructure, every speciality requires specific equipment, trained resources and additional diagnostic support, such as imaging, frozen section or pathology (see Table 5.7 for key functions).

Design principles

The surgical suite is broadly divided into five zones, categorized by level of cleanliness as follows (see Fig. 5.7):

- (a) **Public zone:** This zone consists of the reception and waiting areas for the visitors. The counselling/interview rooms need to be provided at the interface of the public and clinical zone. Visitors are restricted beyond this point.
- (b) **Protected zone:** This zone includes the pre- and post-surgery bed bays, the staff change rooms, offices of the nurse manager and operating theatre manager. The traffic is limited to staff and patients. Any patient and material transfer takes place in this zone.
- (c) **Clean zone:** Physicians and other operating theatre staff enter directly into this zone from their changing rooms. This zone includes the induction room, staff lounges and work rooms, equipment stores, closed circuit television surveillance room and emergency exits.
- (d) **Sterile zone:** This zone includes the operating rooms, clinical support areas, gas store, blood gas analyser and pathology workspace for frozen sections.

TABLE 5.7. KEY FUNCTIONS OF A SURGICAL SUITE

No.	Function
General spaces	
1	Reception and waiting
2	Interview room
3	Food kiosk
Medical functions	
4	Operating theatres (major and minor)
5	Operating theatres (brain suite)
6	Operating theatres (hybrid)
7	Pre-op and post-op holding

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- (e) Dirty zone: Soiled waste and linen are transferred from the sterile zone through this zone using a dedicated channel, such as a 'dirty' corridor.
- (f) Disposal zone: The soiled waste and linen are transferred from the sterile zone through this zone using a dedicated dirty corridor or direct transfer in trolleys or lifts.

The following points need to be considered when designing the surgical suite:

- The surgical suite has to be located so that the entry and exit of the patient is discreet and there is no overlap with the movement of the public.
- The vertical and horizontal transfer of the patients has to be made easy by providing a sufficient number of elevators.
- Provision must be made for ventilation and temperature control, keeping in mind the need for laminar flow, HEPA filter air conditioner, etc.
- A standard operating room has to be a clear, spacious, rectangular or square room with sufficient height. The area of the operating room may vary according to the technology housed inside (e.g. laparoscopy, robotics, microscope).

Description of adjacency

The following principles apply:

- The surgical suite needs to be easily and quickly accessed from the ED.
- The surgical suite needs to be easily accessible from several major departments in the hospital. The connections can be categorized as:
 - Direct:
 - ED;
 - Pre- and post-surgery beds;
 - Central sterile supply department;
 - Surgical wards;
 - Intensive care units;
 - Medical imaging.
 - Indirect:
 - Central laboratory;
 - Inpatient department.

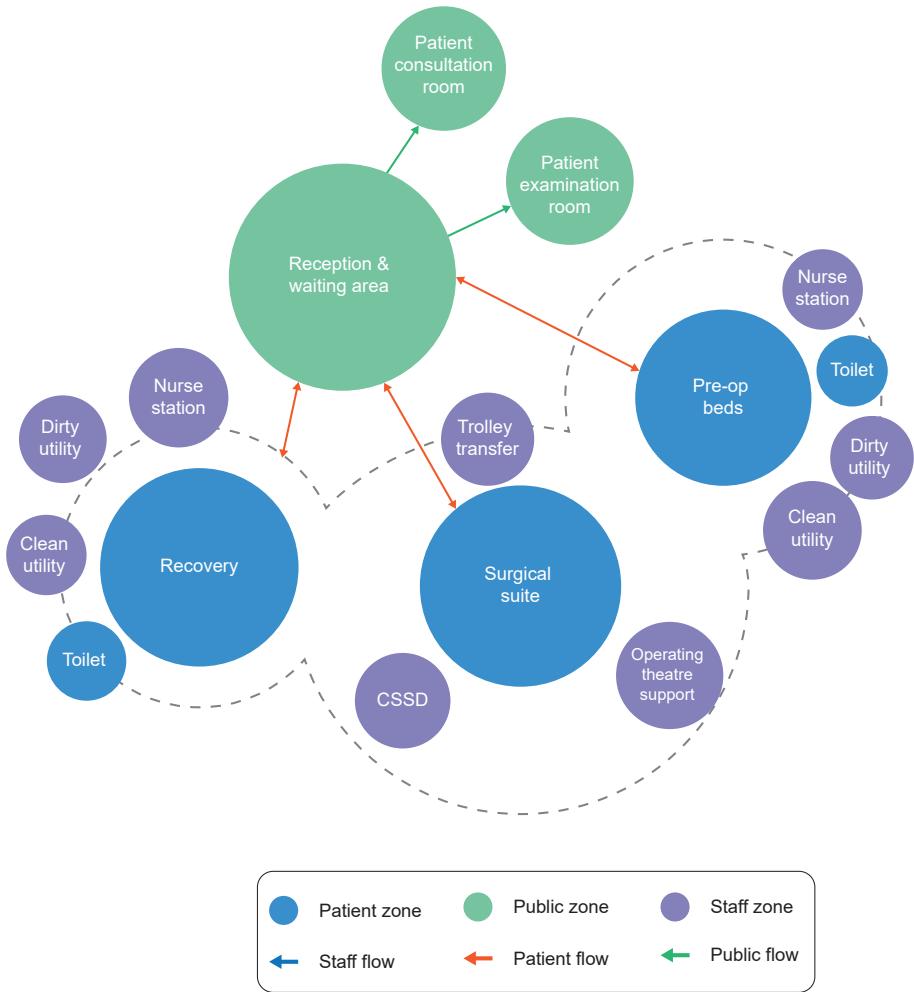


FIG. 5.7. Operational flow of a surgical suite. CSSD: central sterile supply department.

— The central sterile supply department needs to be located on the same floor as the surgical suite or be vertically connected by means of dumb waiters or elevators.

5.1.3.8. Inpatient services

A significant number of cancer patients require admission and treatment of varying durations because of the nature of treatment required — surgery, interventional procedures for diagnosis or therapy, and supportive or critical care

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TABLE 5.8. KEY FUNCTIONS OF INPATIENT ROOMS OR WARDS

No.	Function
General spaces	
1	Reception and waiting
2	Counselling room
3	Grieving room
4	Food kiosk
Medical functions	
Suite	
5	
6	Single rooms — oncology and palliative
7	Twin rooms — oncology and palliative
8	Ward — oncology and palliative
9	Hospice care
10	Chemotherapy (inpatient)
11	Radioactive iodine beds
Clinical support functions	
Nurse stations	
12	
13	Clean utility/dirty utility rooms
12	Treatment rooms

management and recovery. The design and category of inpatient rooms or wards depend on the demographic requirement, financial resources and other societal factors (Table 5.8).

Design principles

The acute care or inpatient department (see Fig. 5.8) is where patients stay during their course of recovery or while receiving inpatient care. Rooms and wards need to be designed to enhance patient comfort and to facilitate family visits, as recovery has been observed to be faster if patients are surrounded by family. It is important that all wards and rooms receive natural light and have a visual connection to the outdoors to improve the patient experience. Staff areas such as the nurses station need to be located so as to enable nurses to easily

monitor patients. The distance between the patient and clinical support areas has to be as short as possible.

Description of adjacency

The acute care unit is required to be easily accessible from the main entrance lobby of the hospital. It also has to be connected to other major departments of the hospital, such as medical imaging, central laboratories, and emergency and critical care units:

- (a) Public zone. This has to be the entry point to the unit. The public zone consists of:
 - Reception;
 - Waiting area;
 - Counselling rooms.
- (b) Patient areas. The patient areas consists of:
 - Ward areas;
 - Single and twin rooms;
 - Suites;
 - Clinical support (can be shared with two units).
- (c) Staff areas. The staff lounges and toilets are part of this zone and need to be placed at the rear of the unit.

TABLE 5.9. KEY FUNCTIONS OF THE CRITICAL CARE UNIT

No.	Function
General spaces	
1	Reception and waiting
2	Counselling room
3	Grieving room
4	Food kiosk
Medical functions	
5	Intensive care unit beds

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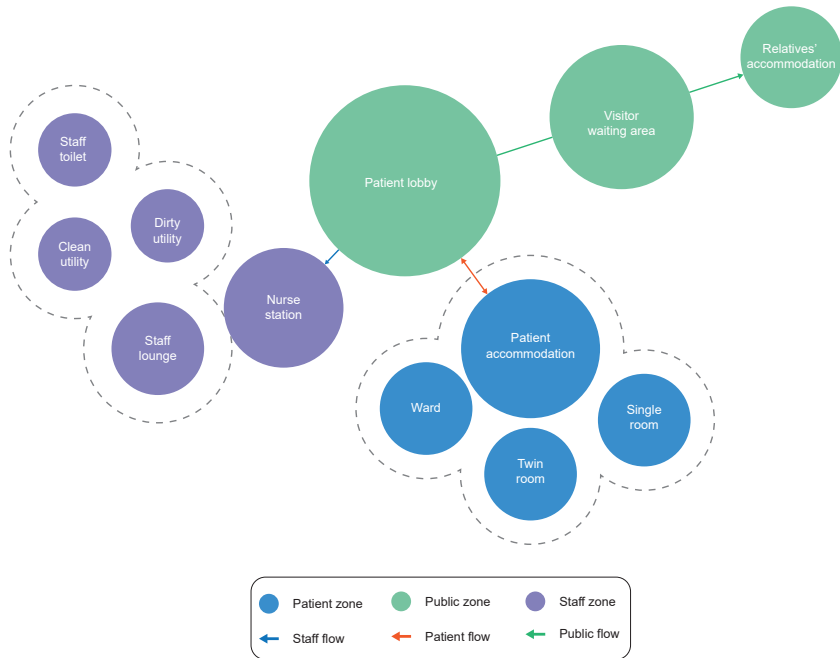


FIG. 5.8. Operational flow: inpatient services.

TABLE 5.9. KEY FUNCTIONS OF THE CRITICAL CARE UNIT (cont.)

No.	Function
6	Bone marrow transplantation bed bays
7	High dependency unit beds
8	Procedure rooms
9	Transplantation chamber
Clinical support functions	
10	Nurse stations
11	Clean utility/dirty utility room
12	Intensivist rooms

TABLE 5.9. KEY FUNCTIONS OF THE CRITICAL CARE UNIT (cont.)

No.	Function
13	Equipment stores
14	Staff facilities

5.1.3.9. Critical care unit

This specialized inpatient unit manages patients with potentially life threatening situations who need advanced forms of monitoring and intensive clinical care in a clean, controlled environment by trained critical care specialists, anaesthesiologists, pulmonologists and nurses supported by various types of equipment. Table 5.9 describes the key functions related to the critical care unit.

Design principles

The critical care unit (see Fig. 5.9) deals with patients who need specialized supervision and advanced life support. For ICUs, the following requirements apply:

- ICUs need to have an easy and short access route to the ED, surgical suite and inpatient areas. They also need to be close to medical imaging, the blood bank and pharmacy.
- Corridors have to be wide enough to enable movement of critically ill patients in beds or trolleys.
- The paths of patient and staff movement should not overlap with the movement of the public.
- The rooms or bed areas need to receive natural light to promote recovery.
- Wet points need to be avoided directly over the bed areas on the upper levels.

High dependency units: These units offer an intermediate stage for patients being transferred from an ICU to a ward and can be located near or in the ICU area, depending on the availability of space.

Description of adjacency

The critical care unit consists of four zones:

- Public zone. Consists of areas designed for family and visitors. The waiting areas and counselling/interview rooms are in this zone. Provision for overnight stay may also be provided, depending on the requirement.
- Patient care. This zone consists of bed bays/patient isolation rooms, treatment rooms and nurses' stations for monitoring the patients.
- Clinical support. This consists of utility support areas and supplies stores.
- Staff zone. This zone consists of the administrative offices, staff lounges and toilets.

The intensive care unit needs to have the following features:

- Safe, easy and fast transport of a critically sick patient has to be the priority in planning the location of the ICU. Therefore, it needs to be located in close proximity to the emergency room, operating rooms, trauma ward, etc.
- Corridors, lifts and ramps need to be spacious enough to provide easy movement of the bed/trolley of a critically sick patient.
- Close/easy proximity to diagnostic facilities, blood bank, pharmacy, etc., is also desirable.
- No thoroughfare should be provided through the ICU.

5.1.4. Equipment and other considerations in cancer centres

Medical oncology services typically include three main areas:

- Inpatient area. See discussion in Section 5.1.3.8.
- Outpatient clinic area. This must include space for outpatient consultations (e.g. for disease evaluations or laboratory monitoring), and ideally an area for isolation or acute care (for patients pending evaluation with suspected febrile neutropenia or resuscitation needs).
- Day care/chemotherapy administration area. Must have beds or couches (e.g. 30 beds/couches for a 250 bed hospital [5.19]).

Common features across these three areas include the following:

- General: Attention to hand hygiene (e.g. bedside pumps for hand hygiene products and/or sinks with soap accessible to each patient) and isolation areas to optimize infection prevention and care.

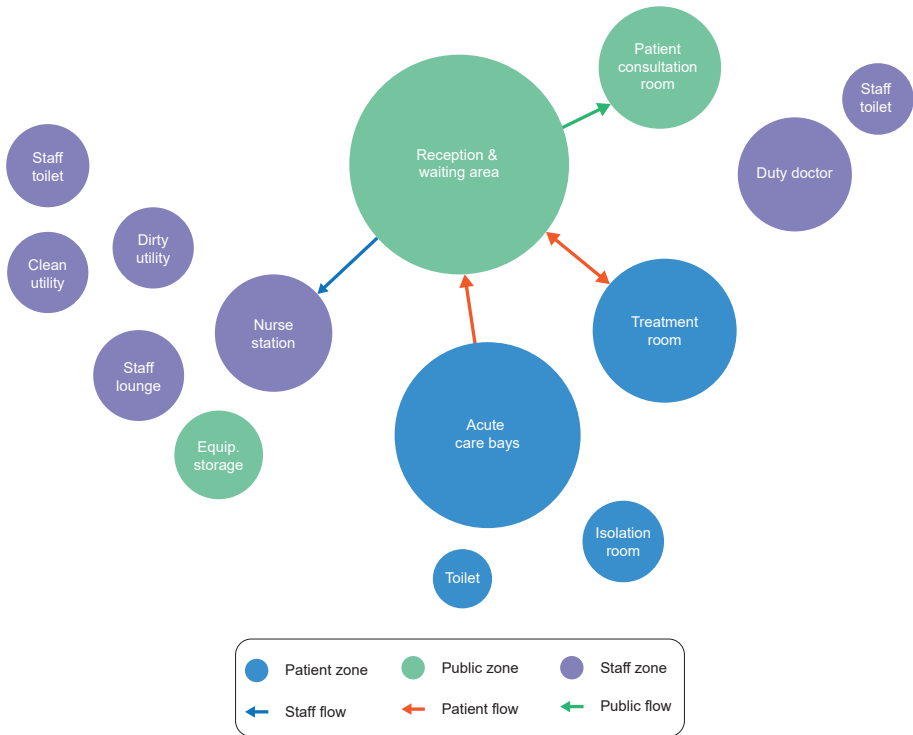


FIG. 5.9. Operational flow of the critical care unit.

— Equipment:

- Fully equipped crash cart and automated emergency devices to run emergency codes for immediate resuscitation and stabilization prior to transport to the ICU. More information is available in Ref. [5.11].
- Infusion pumps/syringe pumps to treat all patients.

The following areas may be centralized or located within the three medical oncology areas mentioned above:

- Chemotherapy and systemic therapy preparation area. This includes a vented laminar flow air hood for chemotherapy preparation and a dedicated clean area to prepare infusions (e.g. total parenteral nutrition).
- Secure storage areas for systemic and supportive therapy. These include a cold chain and secured access (e.g. locked cabinets for opioids).
- Basic point of care laboratory area. Where appropriate, this area has access to processing and/or review of CBC or tumour lysis laboratory results.

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- Area with accessible PPE. The PPE includes gowns, gloves, masks for providers and/or family members and patients.
- Counselling area. A private area for confidential discussions with families.
- Procedure area. A separate area is desirable, particularly for children, for procedures (such as venepuncture or lumbar punctures).
- Respite, play and recreation areas. Patient and family centred areas for respite (e.g. areas for families to prepare their own meals), play and recreation (e.g. adolescent specific areas), where no medical procedures or activities occur, can enhance the quality of life, particularly in centres caring for children or adolescents.

Other services that critically communicate with the medical oncology service include the following:

- Laboratory. Biochemistry, haematology, microbiology, histopathology, immunophenotyping and immunohistochemistry, and molecular testing. All results need to be available, preferably via a common information system platform. Sample core services are outlined in Ref. [5.20].
- Medical record system and IT. The system should preferably be electronic with a hospital management system, a clinical information system and a data management system. All chemotherapy protocols need to be available in the hospital management system and need to be reviewed at least annually.

At a Level 2 facility (e.g. a mid-level facility such as a district hospital), personnel, infrastructure and equipment are tailored to manage less complex conditions than at a Level 3 facility, typically with fewer speciality staff and less specialized infrastructure and equipment. For instance, specialized oncology units (e.g. for bone marrow transplant) are expected to be present, while personnel, infrastructure and equipment needed for general management of patients with febrile neutropenia are required.

At a Level 1 facility (such as a community based facility where patients can be triaged, given simple chemotherapy, which has been decided by the Level 3 or Level 2 centre, and which provides palliative care), medical officers, staff nurses and health care assistants can perform follow-up evaluation and monitoring of blood counts. A Level 1 facility can provide simple single agent chemotherapy, such as monthly administration of vincristine for patients with ALL on maintenance, as well as monitoring of patients on oral maintenance chemotherapy under the supervision of a Level 2 or Level 3 centre.

5.2. PATHOLOGY AND LABORATORY MEDICINE

The laboratory needs to have at least a 400 m² facility with equipment that the pathology team can use to study, understand, track and decode each patient's sample to provide a precise diagnosis. Figure 5.10 shows the organization and integrated structure of PALM.

The layout of PALM needs to be organized on the basis of the laboratory workflow so there is maximum efficiency. Careful consideration has to be given to establishing and maintaining a strict quality controlled environment, such as level of humidity, room temperature and uninterruptible power supply. For details, refer to Ref. [5.21] in the cancer control context.

The appropriate equipment and technologies need to be selected that correspond to the services provided [5.11]. Inventory management and supply chain availability are key features for uninterrupted and timely laboratory services.

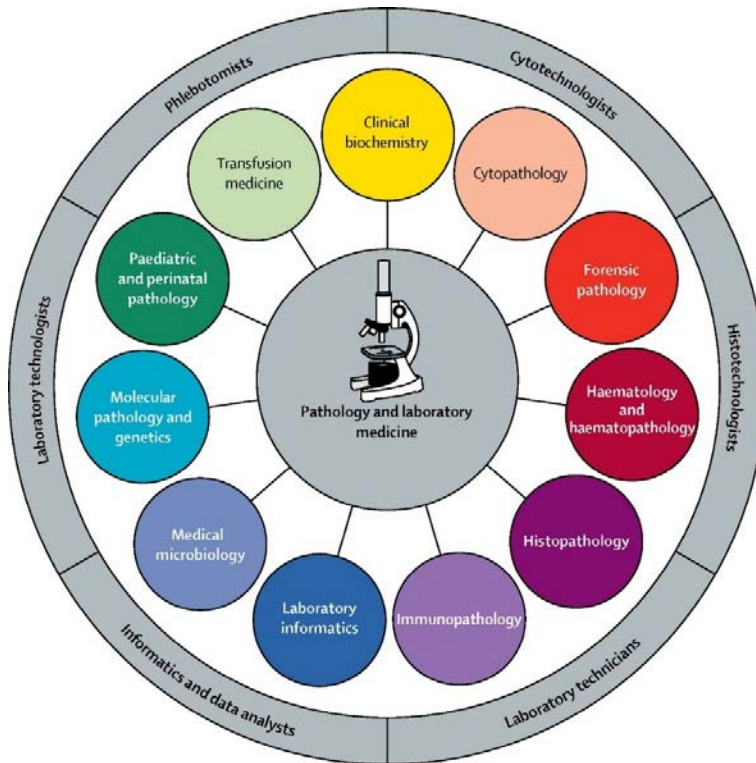


FIG. 5.10. Organization and integrated structure of PALM.

5.2.1. Overview of the clinical laboratory

The first step in establishing the infrastructure needs and functionality of a clinical laboratory is to derive the test menu, which is the list of tests that the centre requires and wants to run. Then, the availability of local laboratory personnel to run these tests needs to be determined. The laboratory test menu will have to be adjusted according to the availability of the staff. On the basis of the final realistic test menu, the availability of space and analysers, as well as funding, should be verified. Of particular importance is monitoring the ongoing expenses and financial viability of running the test.

It has to be noted that the same test may be run using different analysers/methodology, so the laboratory must determine the most financially efficient method for long term ongoing testing. Sometimes semi-automated testing might make more economic sense than fully automated tests. In addition, finding an analyser that provides local service or training might be the best choice. In all conditions, the laboratory needs to take into account that the analyser, reagents and service are a long term investment that need to be carefully considered, instead of receiving a large investment that cannot be maintained owing to financial issues.

5.2.2. Required inputs for reliable results

All organizations need to have basic level testing. Upgrading to Level 2 or Level 3 depends on the complexity and advances of the care practiced in the organization. Even in the most sophisticated centres, in highly rated institutions, Level 1 is the foundation and needs to be fully functional even if there are Level 2 or Level 3 facilities. This means that a Level 1 facility needs to be very well equipped and have trained staff at all times. Experienced staff from a Level 1 facility can be trained for Level 2 and 3 laboratories, in case of a shortage of high level trained laboratory personnel.

5.2.3. Instrumentation for laboratories by level

Level 1 laboratory. This laboratory performs basic admission and follow-up, such as a comprehensive metabolic panel and its electrolyte components; kidney function; liver function; basic metabolics; therapeutic drug levels; CBC with automated differential; PT/INR; hormones; vitamin levels; urine analysis; and some limited, automated oncological diagnostics, such as tumour markers.

Level 2 laboratory. This laboratory reports on immunophenotyping, FISH and DNA tumour markers. A Level 2 laboratory prepares samples to be analysed in a Level 3 laboratory remotely, if applicable. Remote slide scanning gives

smaller laboratories the opportunity to provide Level 3 sophisticated analysis locally at a shorter turnaround time. The Level 2 facility may also perform DNA extraction and purification and send the purified DNA for further processing at a Level 3 laboratory. This model helps centres to obtain the services of higher level centres.

Level 3 laboratory. This is the highest level facility and performs molecular diagnostics, regular and fluorescent histopathology and chromosome pathology.

Level 2 and 3 laboratories are currently required to be highly automated so that their equipment can cope with the high workload. Tests performed are closely monitored and subject to QC.

5.2.4. Basic core laboratory departments (all levels)

There are no clear lines dividing the three levels of laboratories discussed earlier. Hence, they can be described in more general terms by department. A laboratory might have some departments at Level 1, while others are at Levels 2 or 3, depending on personnel availability. Some services can even be provided remotely, through affiliation with higher level laboratories; in this case, the performing laboratories need to follow the protocols set by the referral laboratory for collection, storage, transport and sample preparation. The equipment required listed in Table 5.10 is from Ref. [5.22].

Examples of specimen handling are: blood samples need to be centrifuged; serum/plasma needs to be frozen within 30 min of collection; samples have to be transported frozen; biopsy samples need to be placed in specific lysis or fixation buffer, centrifuged and then frozen, and transported on dry ice.

Clinical chemistry unit

This unit is generally concerned with the analysis of bodily fluids for diagnostic and therapeutic purposes. Clinical chemistry is an applied form of biochemistry.

Histopathology unit

Pathologists play a crucial part in cancer diagnosis. They examine tissue samples under the microscope to determine whether cells are benign or malignant, and they often run further tests to provide an exact diagnosis. Having a complete pathology report is important. When a cancer patient has surgery to remove a tumour, the cancerous tissue is brought to the surgical pathology area to be prepared and placed on microscope slides for pathologists to examine. Other pathology specialists are in very close proximity and/or can be called upon

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locally or remotely for further input and expertise, making for a streamlined process and better care.

Tissue biopsy

A biopsy is a procedure performed to remove a piece of tissue or a sample of cells from a tumour so that it can be analysed in a laboratory. It can be a bone marrow biopsy, endoscopic biopsy, needle biopsy, aspiration biopsy, image guided biopsy, excisional biopsy or surgical biopsy.

TABLE 5.10. EQUIPMENT NEEDED TO ESTABLISH A CLINICAL LABORATORY

Device category	Instruments
Infrastructure for all levels	<ul style="list-style-type: none"> — Specimen refrigerator and freezer, reagent refrigerator and freezer — Deionized water source — Clean hoods, dirty hoods — Thermometers — Centrifuges — Water baths — Heating blocks, heating stages — pH meter — Racks, flasks, tubes, heaters, slides, slide covers — Microscopes — upright, phase contrast, stereo, inverted, etc. — Incubators, atmospheric air and 5% CO₂ incubators — Monitor and alarm systems — Backup electric generator — Computers, LIS, and electronic medical records system
Laboratory by service level	
Level 1 Biopsy collection and management of local patient treatment (up to 250 000 patients)	<ul style="list-style-type: none"> — CBC analyser with automated 3-part and 5-part differential haematology analysers — Chemistry analyser — Coagulation analyser — Automated immunoassay analyser — Urine analysis — Microscope with phase contrast — Spectrophotometer — Electrophoresis — Manual nucleic acids tools and PCR

TABLE 5.10. EQUIPMENT NEEDED TO ESTABLISH A CLINICAL LABORATORY (cont.)

Device category	Instruments
Level 2 Complete cancer diagnostics suite (up to 1 000 000 patients)	<ul style="list-style-type: none"> — Histology services — Flow cytometer — Automated immunohistochemistry system — Automated PCR purification — Fluorescent microscope — Digital pathology slide scanner — FISH slide cycler — PCR microtube DNA cycler
Level 3 Cancer referral/reference testing (more than 1 000 000 patients)	<ul style="list-style-type: none"> — DNA extraction and liquid handling — PCR and real time quantitative PCR — Genetic analyser and sequencing reactions — Image analysis system with software for chromosome pathology and haematopathology — Confocal microscope — Image analysis and tracking software — Research support devices: <ul style="list-style-type: none"> • Binding studies^a • X ray crystallography structure^a • Super resolution microscope^a • Single molecule localization biplane nanoscope^a
Equipment required by department	
Haematology laboratory unit	<ul style="list-style-type: none"> — CBC with differential counts (Level 2) — Bone marrow and cerebrospinal fluid aspirate (Level 2) — Cytochemistry (Level 2) — Bone marrow biopsy: <ul style="list-style-type: none"> • Blood cell counter with automated differential haematology analysers (Level 1) • Image analysis system with software for chromosome pathology and haematopathology (Level 3) • Flow cytometry system for immunophenotyping, providing state of the art single cell analysis technology (Level 2) • Automated immunohistochemistry system (Level 2)

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TABLE 5.10. EQUIPMENT NEEDED TO ESTABLISH A CLINICAL LABORATORY (cont.)

Device category	Instruments
Clinical chemistry unit	<ul style="list-style-type: none"> — Spectrophotometry (Level 1) — Electrophoresis equipment (Level 1) — Immunoassay (Level 1) — Common clinical chemistry tests: <ul style="list-style-type: none"> • Blood electrolytes: sodium, potassium, chloride, bicarbonate • Minerals: calcium, magnesium, phosphate • Renal (kidney) function tests: creatinine, bun albumin • Liver function tests: enzymes, SGOT SGPT, total protein (serum) • Protein electrophoresis and immunofixation • Urine protein
Histopathology unit	<ul style="list-style-type: none"> — Cytopathology (Level 2) — Chromosome pathology (Level 2) — Surgical pathology (Level 2) — Immuno-histochemistry (Level 2) — Histology (Level 2) — Tissue procurement facility (Level 2) — Fixing, staining equipment and microtome (Level 2)^a — Super-resolution microscope (Level 3)^a — Single molecule localization biplane nasoscope (Level 3)^a — Confocal microscope (Level 3)^a — Image analysis and tracking software (Level 3)
Molecular biology core facility	<ul style="list-style-type: none"> — Manual DNA extraction (Level 1) — PCR processes, PCR product cleanup and liquid handling tasks (Levels 1 and 2) — Electrophoresis equipment (Levels 1 and 2) — Genetic analyser and sequencing reactions (Level 3) — NGS analyser
Core for biomolecular structure and function	<ul style="list-style-type: none"> — Protein expression and purification (Level 3) protein characterization^a — Binding studies^a — X ray crystallography structure^a
Blood bank facility	<ul style="list-style-type: none"> — IT and registry system of donors — Area and supplies for blood donation — Temperature controlled storage and bar coding system — Equipment for blood component separation and storage

TABLE 5.10. EQUIPMENT NEEDED TO ESTABLISH A CLINICAL LABORATORY (cont.)

Device category	Instruments
-----------------	-------------

^a Devices required for research purposes.

Note: CBC: complete blood count; FISH: fluorescence in situ hybridization; LIS: laboratory information system; PCR: polymerase chain reaction; SGOT: serum glutamic oxaloacetic transaminase; SGPT: serum glutamic pyruvic transaminase.

5.3. INFORMATION TECHNOLOGY

IT and management systems have to specify the hardware requirements and software modules that can be incorporated into the functional specifications of their design and architecture. This will range from various clinical, operational and business modules of the HIS to a comprehensive approach to solutions that integrates the HIS with modules/packages such as a computerized patient record system, RIS, LIS, customer relationship module, patient portal and e-prescription, as well as applications such as enterprise resource planning and asset management frameworks. HISs and electronic medical records are currently considered an important part of every hospital and health care network, on which all the processes of care delivery are dependent.

The HIS automates clinical data storage, electronic medical records and administrative and inventory functions for the hospital to handle inpatients, outpatients, emergencies, day care and patient referral, along with specific modules to manage human and financial resources and provide an uninterrupted supply chain. This system must include the following components:

- Help desk, scheduling and patient registration.
- Admission, discharges and transfer.
- Physician orders and clinical support.
- Billing, package, contract management and accounts.
- In-built enterprise resource planning interface.
- LIS:
 - Registration, billing, contract management and accounts receivables;
 - Work list, processing and reporting;
 - QC;
 - Bar code generation, printing and reading;

- Interface with most equipment.
- RIS:
 - Registration, scheduling, billing, contract management and accounts receivables;
 - Work list, processing and reporting;
 - Interface with radiology software;
 - In-built enterprise resource planning interface.
- Material management system:
 - Item master maintenance;
 - Item indents and issues;
 - Reorder level, reorder quantity, minimum and maximum stock levels for each store;
 - Quotations and preferred vendor, purchase requests, orders creation and approval process;
 - Consignment stock receipt, consumption and regularization;
 - Expired stock and quarantine;
 - Drugs and consumable issues and return to patients;
 - Last in first out, first in first out, first expire first out methods, policy issues and methods;
 - Periodic physical stock taking and adjustments with tracking.
- Clinical data repository:
 - Integrated with the HIS;
 - Access to patient medical records.

Figure 5.11 shows the various IT components that can be used in a comprehensive cancer centre [5.22].

5.4. MEDICAL RECORDS DEPARTMENT AND CANCER REGISTRY

5.4.1. Medical records department

Medical records enable clinicians and health care personnel to access all information about a practice and patients, such as their identifying criteria, presenting complaints, clinical examination, history of illnesses, allergies, adverse reactions, habits, diagnostic results, patient consent, care plans, decisions, patient progress, medication given, record of surgery or procedures and discharge notes [5.23]. This provides a crucial record of dates, times and details of care by each staff member to ensure continuity of treatment of present and future episodes.

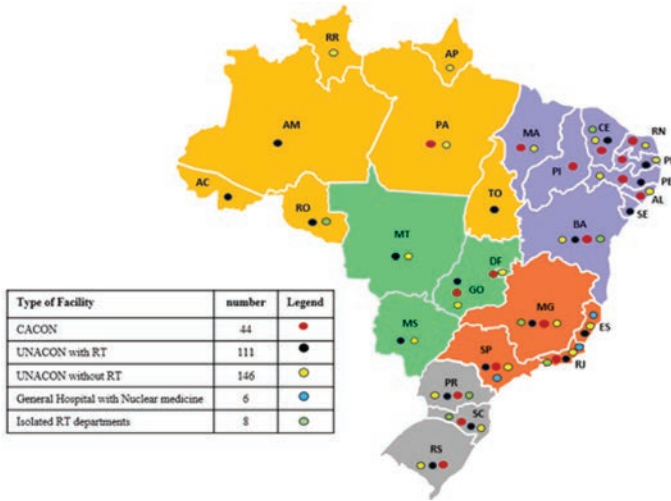


FIG. 5.11. Technology components of a comprehensive cancer centre. AI: artificial intelligence; BCMA: barcode medication administration; CDR: clinical data repository; LIS: laboratory information system; ML: machine learning; MMS: materials management system; PACS: Picture Archiving and Communications Systems; RFID: radiofrequency identification; RIS: radiology information system.

The main uses of medical records are as follows:

- To enable the use of a master patient index to identify patients and locate their medical records;
- To document the course of the patient's illness and treatment;
- To communicate between attending doctors and other health care professionals providing care to the patient;
- To inform the continuing care of the patient;
- For research of specific diseases and treatment;
- To assist in the collection of health statistics [5.24].

Medical records are increasingly relevant to the following:

- Help to create management scorecards to improve operational performance, provide health care statistics and aid medical research.
- Help judicial authorities, insurance authorities, investigating officials and enquiry officials by providing the required documents/information in time. Experts in this area believe that a successful defence against medical negligence claims rests almost entirely on the quality of medical records [5.23].

5.4.1.1. *Key functions of a health records department*

The key functions of a health records department are as follows:

- Maintain all patient records, including outpatient, inpatient, death and medico-legal information.
- Ensure receipt of completed inpatient records prior to filing.
- Ensure International Classification of Diseases (ICD) and International Classification of Procedures in Medicine coding, indexing and filing to facilitate identification by patient, condition, date, etc.
- Digitize manual records, if required.
- Perform maintenance and regulatory updating of the birth and death register as per government guidelines.
- Maintain a record of any corrections, with necessary documentation.
- Issue copies of patient records as per hospital policy to the patient, attendant or regulatory body.
- Train hospital personnel on the SOPs of planning, organizing, maintaining and completing patient records (see Box 5.3 on SOPs).
- Track, retrieve and issue patient records for the purpose of research or academic activity.
- Prepare and circulate the hospital census on a daily basis.
- Conduct a deficiency check of records.
- Coordinate verification or any documentary assistance that may be required by an insurance body for claims.
- Prepare and issue information to the medical head or the clinician and attend court hearings or complaint forums with the necessary documents.
- Prepare periodic reports as mandated by the hospital management, health ministry or government agencies (Box 5.4) [5.24]. These may include daily, monthly or quarterly reports on morbidity and mortality, communicable diseases, NCDs, vaccine preventable diseases report, HIV cases, specific surgeries, snake bites, transplants, termination of pregnancy, prenatal screening and maternal deaths.

BOX 5.3. MEDICAL RECORDS DEPARTMENT STANDARD OPERATING PROCEDURES

- Confidentiality of records and information.
- Process of indexing and filing using a standardized checklist.
- Safety, security, upkeep and retention of patient records.
- Data collation, analysis and dissemination of information — internal and external.
- Policy on retention and destruction of files.
- Retrieval and issue of files or copies.
- Inpatient files detailing requirements from all departments.
- Authority matrix to make corrections in records.
- Periodicity of receiving and sharing necessary — statistics and reports.
- Managing death and medico-legal case files.
- Missing records.
- Representation at legal hearings.
- Birth and death records.
- Handling of contaminated or damaged patient records.

BOX 5.4. TYPES OF REPORT PREPARED BY THE MEDICAL RECORDS DEPARTMENT

- Hospital statistics.
- Detailed diagnostics related statistics.
- Occupancy status based on bed category.
- New and repeat OPD cases — by doctor or by unit.
- Inpatient admission and discharges — by doctor or by unit.
- Surgeries, by doctor or by unit.
- Demographic data of inpatients.
- Interventional radiology laboratory, catheter laboratory and endoscopy procedures.
- Expired patient list.

5.4.1.2. Access to records and data protection

All patient records are governed by data protection acts and have to be kept secure and confidential [5.25]. It is also a condition of registration with medical

councils to respect patient confidentiality. Every facility needs to comply with a legally permitted and documented access to records process.

5.4.1.3. Governance

Every hospital must institute a medical records committee that periodically reviews the reports. This committee needs to include the medical head, nurse in charge, head of quality, head of emergency, clinical pharmacologist/pharmacist and senior clinicians from various departments. The meeting needs to cover audit findings, gross death rate, net death rate, average length of stay, quality indicators, proposal for disposal of any record, review of a defined number of files from medical, surgical, radiation, medico-legal and death cases. The committee is also expected to review reports on data to external agencies, missing files, if any, nil reports, completion of medico-legal cases and death files, ICD coding and percentage of incomplete files.

5.4.2. Cancer registries

5.4.2.1. Hospital based cancer registry

Hospital based cancer registries (HBCRs) are concerned with the recording of information on cancer patients seen in a particular hospital. The purpose of such registries is to contribute to patient care by providing readily accessible information on cancer patients, the treatment that they received and cancer outcomes. The data are used mainly for administrative purposes and for reviewing clinical performance. These data may also be used for epidemiological purposes [5.26].

5.4.2.2. Population based cancer registry

This registry collects data on all new cases of cancer occurring in a well defined population. Usually, the population is resident in a particular geographical region. As a result, in contrast to hospital based registries, the main objective of this type of cancer registry is to produce statistics on the occurrence of cancer in a defined population and to provide a framework for assessing and controlling the impact of cancer in the community. Thus, the primary emphasis is on epidemiology and public health (see Table 5.11 for a comparison between hospital based and population based cancer registries).

5.4.2.3. *Pathology based cancer registry*

This collects information from one or more laboratories on histologically diagnosed cancers. It supports the need for laboratory based services and serves as a quick snapshot of the cancer profile at any given time in the area concerned.

TABLE 5.11. COMPARISON OF HOSPITAL BASED CANCER REGISTRIES AND POPULATION BASED CANCER REGISTRIES [5.27]

Characteristic	Hospital based cancer registry	Population based cancer registry
Primary concern	Cancer patients in a hospital	Cancer in the community
Assessment of the dimensions of the cancer problem	Number of diagnoses per year, relative frequencies of cancer by site in the hospital	Cancer incidence, mortality and prevalence, trends in cancer incidence
Contribution		
Patient care	Active follow-up and description of the length and quality of survival in relation to stage, site and treatment	Indirect follow-up, evaluation of the overall survival by site
Research — treatment	Participation in clinical research to evaluate therapy	Provide background for clinical research
Prevention	Assistance in case control studies, identification of groups with high and low frequencies	Assistance in case control and prospective studies, identification of low and high incidence groups
Health services	Assessment of the quality of care and cancer services in a hospital	Assessment of the effectiveness of preventive measures and community care

BOX 5.5. IMPLEMENTING A CANCER CONTROL CENTRE REGISTRY IN A LOW OR MIDDLE INCOME COUNTRY

Step 1: Form a cancer registry committee comprising different stakeholders of governmental or private health care institutes and social workers from the district. This committee will have joint meetings quarterly and will be updated about the progress of the HBCR. They will also be involved in spreading awareness about the cancer registry.

Step 2: Set up an office in the hospital with the required infrastructure, furniture and equipment.

Step 3: Decide how the data are collected, for example, using medical record software or in registries.

Step 4: Decide on the minimum human resources required:

- Principal investigator: to nominate staff from the hospital/medical college (pathology, preventive or social medicine).
- Cancer registrar: to collect data from different sources and find new sources.
- Data entry operator: to check the completeness and quality of the data and regularly update the software provided to the registry.
- Social worker: to provide active follow-up of the patients post-treatment.

Step 5: Train cancer registry staff. A structured training programme that runs for 7–14 days is needed to understand cancer terminology and its data capture points. Also, specific training on ICD coding and tumour, node and metastasis (TNM) staging is essential.

Step 6: Create a proforma and other data collecting tools, as required. A register is needed for each source to collect the required data. Usually, pathology centres and clinics do not keep this information, so a register is needed to maintain the data of only malignant cases. For this purpose, a letter from the government is helpful.

Step 7: List sources of data collection and set the geographical area. This is the most crucial part of the registry. The sources of data collection are the institutes where the cancer patients are diagnosed and treated; this includes the death certificate department.

Step 8: Obtain a letter from the administration granting permission to collect the data from different sources.

Step 9: Collaborate with the IARC and the International Association of Cancer Registries.

5.4.2.4. *Data collection methods*

Data are collected from the following sources: laboratory, departments (oncology and non-oncology), HIS and death certificates.

The type of data collected include variables characterizing the patient, tumour and source of the data. The contents of the standard hospital based registry form are given in Annex IV and include the following:

- Patient identification and demographic information;
- Details of diagnosis;
- Clinical stage of diagnosis;
- Type of treatment [5.28].

Data collection can be conducted by the following methods:

- Active reporting (collection at source) involves registry personnel visiting the sources of data and transferring the required information onto special forms or obtaining copies of the necessary documents;
- Passive (or self-) reporting relies on other health care workers to complete notification forms and forward them to the registry or to send copies of discharge abstracts from which the necessary data can be obtained [5.29].

Staging is an important part of the proforma, and the staging system is denoted as ‘details of clinical stage and treatment’. There are four options in the proforma:

- (a) TNM staging system;
- (b) FIGO (Federation Internationale de Gynecologie et d’Obstetrique) staging system;
- (c) Ann Arbor staging system;
- (d) Not applicable.

Other options can be specified or listed as unknown.

If a patient is staged according to TNM, then T (tumour), N (node) and M (metastasis) are the stages that need to be mentioned individually in the

proforma. Generally, the staging data are provided by clinicians and extracted from the report. If not mentioned in the report, they can be derived by following guidelines from the detailed patient report.

The purposes of follow-up are as follows:

- Lifetime medical surveillance of the cancer patient;
- Acquisition of data needed for analysis of the length and quality of survival.

In the HBCR core form, questions 36 and 37 request the date of last contact and date of death (recommended criteria). The form is not complete if the follow-up is not conducted properly. In addition, it is not always possible to track patients after they leave the hospital. Several strategies are being adopted to ensure that complete data on patients can be obtained. Some of these measures are mentioned below:

- Providing concession for travel by bus, train and air to patients and any one of their accompanying persons while attending hospital for treatment/follow-up;
- Maintaining an address form consisting of at least five addresses of the patient and relatives, friends, workplace and referring physician, as consented by the patient;
- Dedicated staff making email or telephone enquiries and/or sending reply paid cards to all patients who do not report for follow-up on the due date;
- Making home visits and telephone enquiries for all patients at regular intervals.

The process of follow-up is described in Annex V, and the sequence of active follow-up methods is provided in Annex VI.

5.4.2.5. *Quality of registry information*

The quality of information or data in the registry is validated through comparability, validity, timeliness and completeness tests [5.30, 5.31].

Comparability is assessed using ICD coding (WHO), which provides standards for coding the topography, morphology, behaviour and grade of the tumour. In addition, ICD-O-3 provides coding for recording the basis of diagnosis and multiple primary cancers.

Validity is checked using the following criteria: morphological verification (MV%), death certificate only (DCO%), missing information (%) and internal consistency analysis. These criteria also include the proportion (or percentage)

of cases with missing data; the percentage of cases with morphologically verified diagnosis; and the percentage of cases for which the only information came from a death certificate.

Timeliness is defined by the time required for the registry to collect, process and report sufficiently complete and accurate data.

Completeness is assessed by the following methods:

- Qualitative (or semi-quantitative) methods, which give an indication of the degree of completeness relative to other registries or over time;
- Quantitative methods, which provide a numerical evaluation of the extent to which all eligible cases have been registered.

5.4.2.6. *Governance*

Each hospital needs to set up an internal multidisciplinary advisory committee with the members having clearly defined roles and responsibilities. The committee should consist of the director of the hospital, principal investigator, clinicians, public health experts, scientists, members of the hospital ethics committee and independent cancer researchers. If patient representatives, hospice caregivers and NGOs operate in the geographical area, then their representation would add value.

5.4.2.7. *Data protection*

Safeguarding the data in the cancer registry implies not only that they are sufficiently secured against unauthorized access, but also that they are not used for purposes other than those for which they were collected. The aims of confidentiality measures in cancer registration are therefore to ensure: (a) the preservation of anonymity for individuals reported to the registry and, if necessary, also for those making such notifications; (b) that cancer registry data are of the best quality possible; and (c) that the best possible usage of cancer registry data is made for the benefit of the cancer patient, for cancer control and for medical research [5.32].

The following measures are taken to protect data:

- Limited and well defined access to the registry;
- Limited and well defined access to computers with passwords giving access to information.

All cancer registry hospitals/institutions need to obtain approval of their respective institutional ethics committees before data collection begins, and it is their responsibility to update them periodically per institutional requirements.

5.4.2.8. *Publications and reports*

Upon collection and receipt of complete data from the registries, the principal investigator has to run the entire analysis plan, including data cleaning and seeking clarifications from registries, as per standard procedures. A consolidated report needs to be prepared, which can be shared and discussed with the key stakeholders. Peer reviewed manuscripts need to be prepared involving the registry investigators, clinicians and research investigators. Prior permission of the advisory and ethics committees is essential to have access to data for research purposes. The hospital has to publish factsheets, news articles, peer reviewed publications and reports. Such information will be vital for policy makers in allocating funds and resources for cancer control.

5.5. QUALITY CONTROL AND SAFETY

QMSs are defined in ISO 9000:2015 and are applicable to “all organizations, regardless of size, complexity or business model”. As such, all functional units in cancer control centres are suborganizations that provide a service, and quality is paramount in terms of the delivery of patient care and services rendered within the available resources. Maintaining quality not only ensures that activities are conducted according to a given standard but also safeguards the reputation of an organization. A QMS is necessarily dynamic in that it develops over time and needs to undergo a continuous process of QI, usually through audits, reviews, customer relations and non-conformities.

Hospital governance has to include periodical reviews of the hospital’s quality plan; QI projects; clinical audits; plans for hospital accreditation including JCI (Joint Commission International) indicators; monitoring of various hospital safety, patient safety and clinical audit committee meetings; continuous QI analysis; and various quality and patient safety initiatives undertaken or planned, accompanied by an audit plan, their findings, and the status of actions taken. It may be helpful to constitute an umbrella body dedicated to quality and patient safety.

Historically, testing and calibration laboratories undergo accreditation on the basis of ISO/IEC 17025, which was updated in 2017 to include risk. ISO/IEC 17025:2017 specifies the general requirements for the competence,

impartiality and consistent operation of laboratories. It is applicable to all organizations performing laboratory activities.

The United Nations Industrial Development Organization (UNIDO) developed a handbook on conformance to ISO standards to enhance global acceptance of testing laboratory measurements and products. Similarly, hospital accreditation is a peer assessment process used by health care organizations to assess their performance in relation to established standards and to implement ways to continuously improve. There are parallel issues of evidence based medicine, QA and medical ethics, and the reduction of medical errors is a key aim of the accreditation process. Hospital accreditation is therefore one component in the maintenance of patient safety. Recently, more attention has been given to QI in health care, owing to increasing media coverage of medical errors, and recommendations were made to address quality in cancer care.

Tata Trusts has developed an administrative framework for promoting QA throughout the cancer centre structure. The framework includes the constitution of several committees that convene regularly to discuss, review and report on matters pertaining to quality, such as laboratory safety, radiation safety, infection control, mortality and morbidity, research ethics, blood transfusion and medical records. The frequency of meetings, as well as the membership, quorum and supporting documents of each committee are discussed. QA components relevant to each clinical service and central service are discussed in Chapter 3.

5.6. ADMINISTRATION AND FINANCIAL SUSTAINABILITY

This section outlines various roles and responsibilities that need to be assigned while setting up and managing a cancer centre. It uses an indicative, four tier model depicting a network headquarters, which is essentially the governing body for a group of hospitals or a national/state level programme, and a tertiary cancer care facility (Level 3) that can be considered a centre of excellence and that may act as a reference point for national cancer care control. This is followed by an intermediate level, but comprehensive, cancer care facility (Level 2) and a basic cancer care facility (Level 1), whose main focus is prevention, health education, initial diagnosis, referral to a higher level centre, provision of basic follow-up care and palliative services.

This structure can be further connected to a state or national level programme that aligns with its goals and has a speciality focus. This includes statistical analysis of incidence and prevalence to define the need for establishing, upgrading or expanding cancer services in coordination, or otherwise, with other upcoming facilities.

The intent is to showcase the various functions necessary to manage and develop a cancer facility without focusing on details of nomenclature, level or designation. A deliberate focus has been maintained on the clinical organization.

5.6.1. Network organizational structure

When there is a network of hospitals being set up in the country that can be clustered by region (multiple or single), an indicative organizational structure, as shown in Fig. 5.12, can be used and adapted as follows:

- Indicative departments at every level (Fig. 5.13). All department leads (e.g. the clinical services lead) at Level 1, Level 2 and Level 3 report to their respective facility head (administrative reporting) and functionally to their department head at the regional level.
- A regional team created for managing unit hospitals and reporting to the centre. Department leads at the regional headquarters report to the chief operating officer/chief executive officer (administrative reporting) and to their department head at the central/country level (functional reporting).
- All strategic decisions have to be made at the central/country level, in discussion with the regional headquarters. Implementation and execution occurs at the unit level of Level 1, Level 2 and Level 3 facilities (e.g. the choice of vendor for the equipment is finalized, and contracting occurs at the country headquarters, with support from the regional headquarters; the equipment is delivered, installed, configured and maintained at the unit level). The roles and responsibilities of the central and regional teams are highlighted in Annexes 1 and 2.
- Services that can be considered for outsourcing are highlighted in orange in Figs 5.14–5.16. Outsourcing ensures standardization across facilities (if the same vendor is chosen) and reduces the need for in-house recruitment and management for certain non-critical or non-clinical but important functions.
- If clustering by region is not required, then all units can report directly to the central/country headquarters, and the regional team can be omitted.

5.7. RADIATION PROTECTION AND SAFETY

The safe use of ionizing radiation in cancer centres requires that appropriate safety standards for radiation protection and the safety of patients, workers, and the public be adhered to. There are different responsibilities at different levels pertaining to radiation protection. While the government has an overall responsibility to ensure the establishment of an effective legal and regulatory

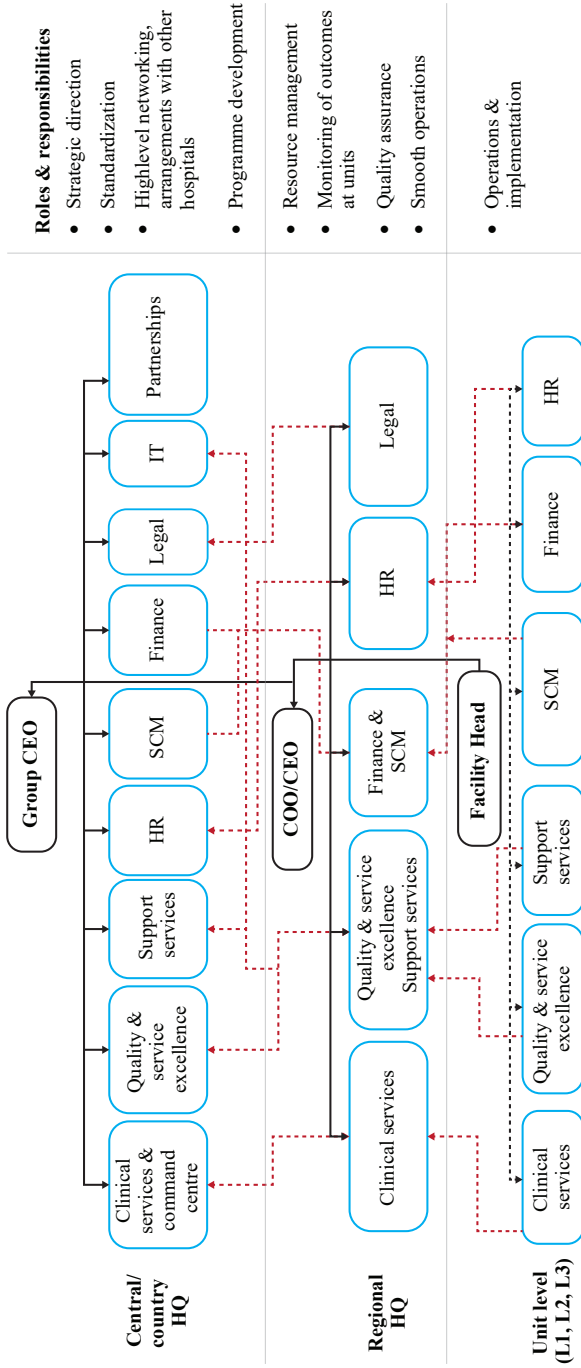


FIG. 5.12. Organizational structure for a network of comprehensive cancer centres. HR: human resources; IT: information technology; SCM: supply chain management.

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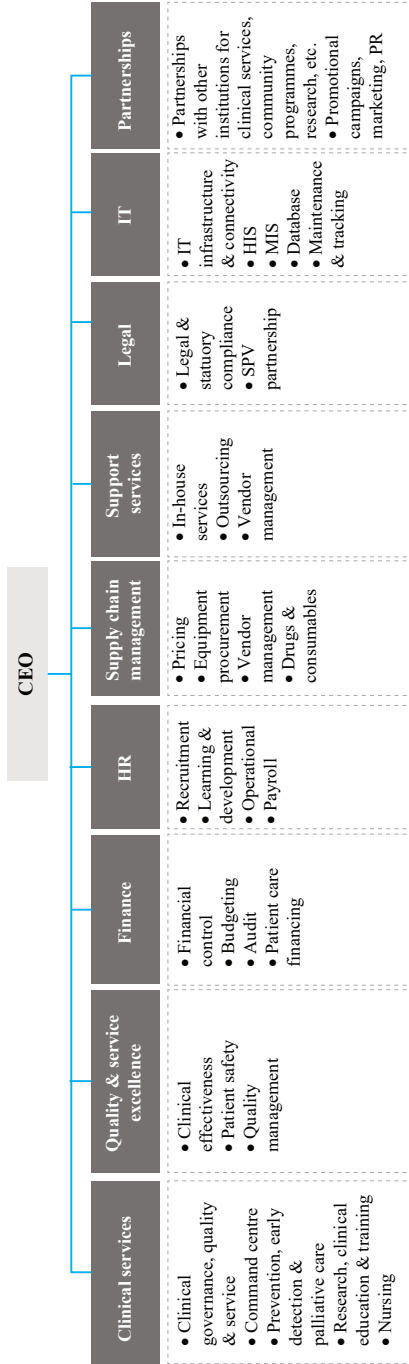


FIG. 5.13. Departmental responsibilities. HIS: hospital information system; HR: human resources; IT: information technology; MIS: medical information system PR: public relations; SPI: special purpose vehicle.

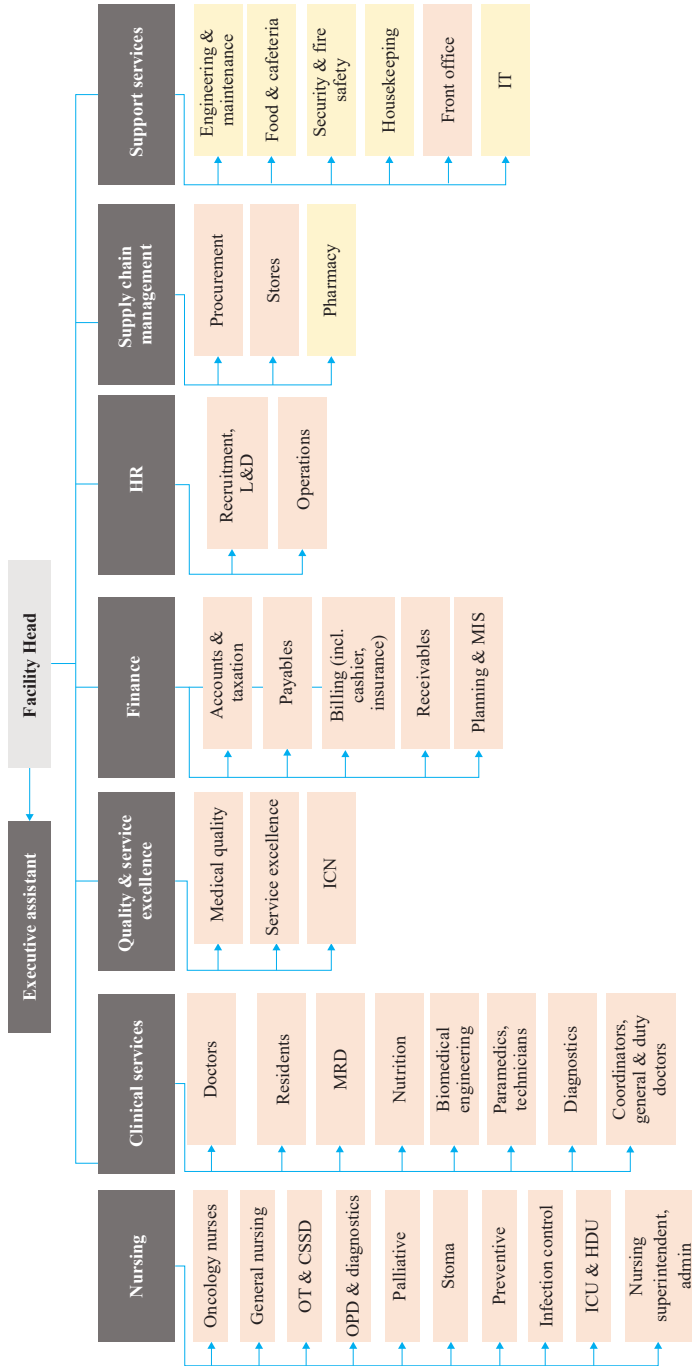


FIG. 5.14. Organizational structure for a Level 3 facility. CSSD: central sterile supply department; HDU: high dependency unit; HR: human resources; ICN: International College of Nurses; ICU: intensive care unit; IT: information technology; L&D: learning and development; MIS: medical information system; MRD: medical records department; OPD: outpatient department; OT: operating theatre.

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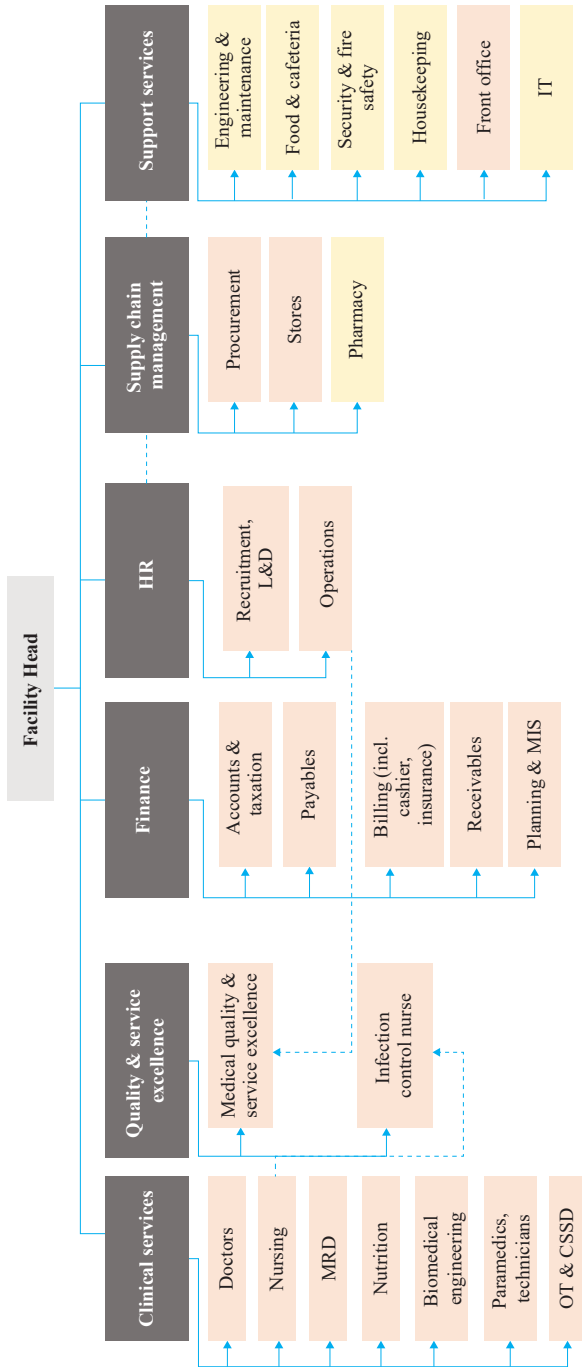


FIG. 5.15. Organizational structure for a Level 2 facility. CSSD: central sterile supply department; HR: human resources; IT: information technology; L&D: learning and development; MIS: medical information system; MRD: medical records department; OT: operating theatre.

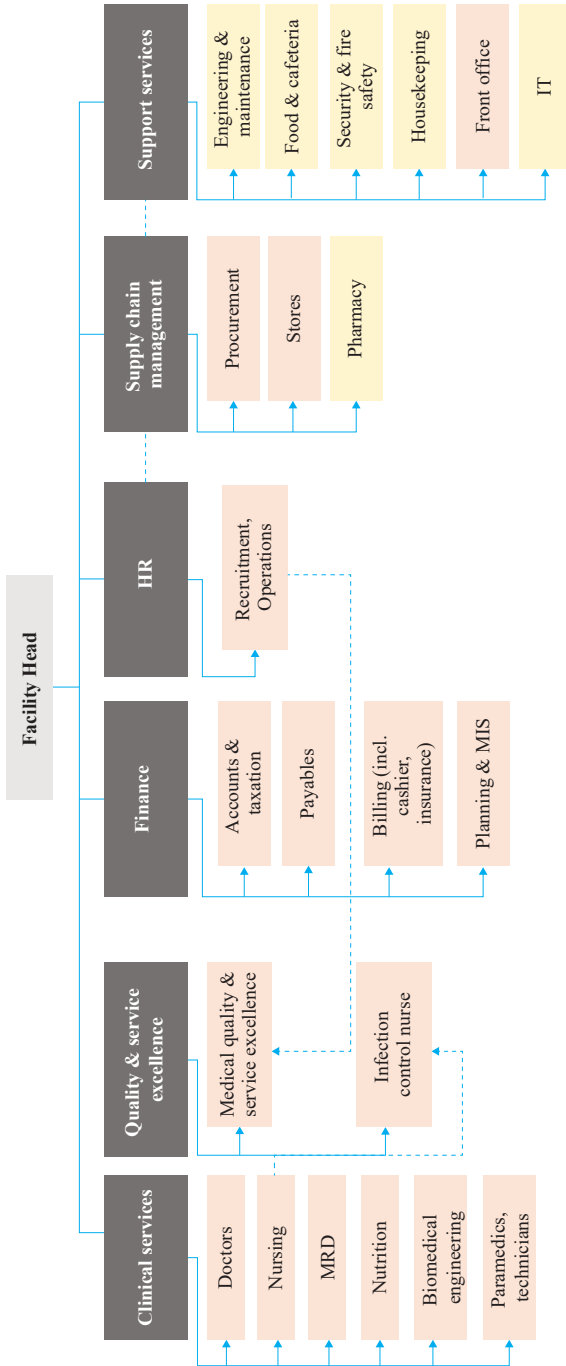


FIG. 5.16. Organizational structure for a Level 1 facility.

framework, and the health authority, regulatory body and professional bodies have other overarching roles [5.33], the prime responsibility for radiation protection and safety rests with the person or organization responsible for the medical radiation facility, referred to as the registrant or licensee. The adequate safety infrastructure, education and training of staff, appropriate level of staffing, and effective quality assurance systems are all elements of vital importance for radiation protection and safety.

According to the most recent figures from the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the total annual number of RT treatment courses in the world is estimated to be 6.2 million [5.34], comprising about 5.8 million treatment courses by external beam RT and 0.4 million by brachytherapy, which is an increase of 22% from the previous UNSCEAR 2008 Report [5.35]. These numbers give an indication of both the extent and growth of this treatment modality, suggesting that there needs to be a systematic approach to radiation protection and safety in this area [5.36].

While the International Commission on Radiological Protection (ICRP) issues recommendations for the system of radiological protection [5.37], the IAEA is authorized to establish or adopt standards of safety for the protection of health and minimization of danger to life and property, according to its statutes [5.38], as reported in the IAEA Safety Standards Series publications.

To ensure the safe operation of cancer centres and other facilities using radiation sources in a country, there needs to be appropriate governmental, legal and regulatory frameworks for safety [5.39]. The government has a responsibility to establish laws and adopt policies on safety and to establish responsibilities and functions of governmental bodies on this issue, such as an independent radiation regulatory body with the necessary legal authority, competence and resources to oversee radiation safety for patients, the public and radiation workers. The IAEA has published guidance on overcoming this challenge, including on national policy, regulatory framework and technical infrastructure [5.40].

IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [5.33], establishes requirements for safety for all uses of radiation. Optimization of radiation protection and safety involves many aspects, as outlined in GSR Part 3, such as design considerations, operational considerations, calibration, dosimetry of patients and QA.

GSR Part 3 [5.33] is supported specifically on the safety in medical radiation uses by IAEA Safety Standards Series No. SSG-46, Radiation Protection and Safety in Medical Uses of Ionizing Radiation [5.41]. SSG-46 gives general recommendations for radiation protection and safety in all medical uses of radiation and specific recommendations for different medical uses, including RT.

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Chapter 6

EDUCATION, TRAINING PROGRAMMES AND RESEARCH

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O. BELYAKOV

6.1. EDUCATION PROGRAMMES

It is important for all radiation medicine professionals in a cancer centre to have a background encompassing a proper academic education, as well as structured and supervised clinical training during which the professional competencies needed to work in a clinical environment are acquired (typically according to a defined curriculum and related portfolios [6.1–6.9] to work according to best practices. A cancer centre may work in collaboration with an academic institution or a clinical training programme and — in some instances — may host a clinical training programme, offering some of the competencies (in collaboration with other centres) or all of the competencies relevant to the professional profile [6.6]. Certification is also typically a part of the pathway towards becoming a recognized health care professional [6.7]. Connected to this is CPD, which is essential to keeping the competencies of health care professionals up to date. CPD is usually a requirement for the renewal of certification. It is expected that all activities in the cancer centre will be performed by professionals who have been proven to be competent with respect to the professional standards relevant to their professional profile.

6.1.1. Education pathways of radiation medicine professionals

National or international guidelines typically form the basis for the definition of the path to be followed to become a professional competent to work independently in one or more specialities. Competency (intended as a combination of knowledge, skills and attitudes) of the radiation medicine workforce is crucial to ensure quality of care. Some countries have set clear requirements for professionals to be allowed to work in health care; this is often the case for medical specialists. However, national requirements for other radiation medicine professionals are not as prevalent — for example, in the case of clinical medical physicists, owing to a lack of recognition of this profession in many countries.

When setting up a cancer centre, it is therefore important to devise a plan that takes into consideration a sequence of steps, such as the following:

- Identifying the professionals needed, depending on the type of radiation medicine services that will be offered in the centre.
- Referring to international or national standards and guidelines to define the responsibilities of each group of professionals.
- Identifying the appropriate competencies to be acquired and relevant educational and training paths.
- Devising a strategy for the recognition of health professionals when needed (e.g. medical physicists).
- Establishing a roadmap and timeline to be considered in the planning phase.

Suggested training for specific professionals can be found in Chapter 3.

6.2. STRUCTURED AND SUPERVISED CLINICAL TRAINING

As part of its activities, a cancer centre might offer structured and supervised clinical training in one or more competencies for radiation medicine professionals; this may occur through coordination with other cancer centres to establish a joint clinical training programme, or through running the whole training programme. Evaluating the feasibility of embarking on such an endeavour will depend on the following:

- Sustainability of such programmes, including the related methodology to be established to ensure that quality can be ensured [6.6];
- Possibility of establishing an appropriate governing structure, preferably at a national level, in the pursuit of harmonization of clinical training (e.g. for medical physicists [6.1–6.3]) in the country, and definition or adoption of a harmonized portfolio, in line with best practices, to ensure that the resident achieves established competencies;
- Feasibility of establishing written agreements, for example with relevant academic institutions, to structure the intake of the appropriate level residents;
- Number and availability of qualified health care professionals of the relevant speciality to supervise — or participate in supervising — training activities [6.4];
- Possibility of establishing monitoring and reporting processes to ensure the quality of clinical training [6.6];

- Viability of undergoing periodic external reviews of the clinical training programme [6.6]. A system of accreditation could be considered to ensure harmonization and compliance with agreed upon best practices.

6.2.1. Training of surgical oncologists

Training and certification requirements vary across the world. In general, however, most cancer surgeons have completed a minimum of ten years of medical education. In LMICs with a dearth of specialist oncologists, medical councils could consider shortening the duration of training (i.e. ‘fast tracking’). In addition, general surgeons and gynaecologists who do not have formal training in oncology can undergo short term training to carry out diagnostic, basic and intermediate level surgical procedures in Level 1 and Level 2 centres.

There is a direct relationship between national income level and the presence of locally available fellowships for specialized cancer training [6.10]. Many LMICs rely on international collaboration for such specialized training. Finally, in many LMICs, cancer patients are more likely to have access to surgical care than to medical or radiation oncologists. In these situations, surgical oncologists become the primary caregivers for cancer patients. It is therefore important that the training of a surgical oncologist working in most LMIC settings include post-operative care, delivery of chemotherapy, basics of RT and symptom management, including management of pain and end of life care.

6.2.2. Training of radiation oncology specialists

The overall objective of radiation oncology training for trainee oncologists, nurses, RTTs and medical physicists is to enable them to reach a level where they are recognized as specialists capable of practicing radiation oncology competently and independently. Table 6.1 provides references to publications that can help in defining the path and timeline for capacity building of radiation medicine professionals.

When planning for the establishment or the scaling up of cancer centres, it is crucial to accurately plan for capacity building. Existing guidelines provide a tool to help in the development of more accurate action plans.

6.2.2.1. Radiation oncologist

The overall objective of radiation oncologist training is to be able to practice radiation oncology safely and ethically; manage complications associated with radiation; have a good knowledge of aetiology, pathology and natural history of cancers most commonly seen in their country; be familiar with

TABLE 6.1. CAPACITY BUILDING RESOURCES FOR RADIATION SPECIALIST TRAINING

Field	Topic	Reference
Medical physics	Roles and responsibilities of clinical quality management programmes	[6.4]
	Post-graduate academic programmes in medical physics	[6.11]
	Clinical training for medical physicists specializing in RT	[6.3]
	Clinical training for medical physicists specializing in diagnostic radiology	[6.1]
	Clinical training for medical physicists specializing in nuclear medicine	[6.2]
	Audit methodology for medical physics clinical training programmes	[6.6]
	Guidelines for the certification of clinically qualified medical physicists	[6.7]
	Postgraduate medical physics syllabus for academic programmes: AFRA region	[6.8]
	Clinical training for medical physicists specializing in RT: AFRA region	[6.8]
	ARCAL guidelines for academic education and clinical training for medical physicists: Latin America	[6.9]
Guidelines on professional ethics for medical physicists	[6.12]	
Radiation oncology	IAEA syllabus for the education and training of radiation oncologists	[6.13]
Nuclear medicine physician	Training curriculum for nuclear medicine physicians	[6.14]

Note: AFRA: African Regional Cooperative Agreement for Research, Development and Training Related to Nuclear Science and Technology; ARCAL: Regional Cooperation Agreement for the Promotion of Nuclear Science and Technology in Latin America and the Caribbean; RT: radiotherapy.

the diagnostic tools needed and available; have basic familiarity with medical and surgical oncology and have the capacity to interpret current advances and research in cancer and sufficient interest to move the field forward. The IAEA provides extensive guidance on the education and training of radiation

oncologists (including requirements for training institutes, training programmes, curricula and support that the IAEA provides, as well as systematic evaluations for candidates) in Ref. [6.13].

In brief, the IAEA recommends a minimum of a three year, full time training period for radiation oncology following graduation from medical school. During these years, candidates are residents in clinical radiation oncology departments and participate in seminars, conferences, teaching assignments, interdepartmental clinics and both external beam and brachytherapy procedures. They are supervised by practicing radiation oncologists.

Three levels of skills are recognized in radiation oncology:

- Level 1: planning using X ray and bony anatomy, and manually calculated dose distributions;
- Level 2: 2-D and 3-D planning using CT simulation are considered mandatory;
- Level 3: complex treatment planning using IMRT, SRS, IGRT, etc. is considered desirable, but not mandatory.

6.2.2.2. *Oncology nurse*

The overall objective of oncology nurse training is to train nurses to discuss with patients the purpose of radiation, assess patients undergoing RT for any radiation related side effects, assess the psychosocial impact of cancer diagnosis and treatment on the patient and family, develop care plans for patients receiving external RT or brachytherapy, and educate patients and families on radiation process and possible adverse effects. The IAEA recommends that oncology nurses undergo 12–16 weeks of radiation oncology nursing training after a baccalaureate degree in nursing [6.15].

6.2.2.3. *Radiotherapy technician*

The overall objective of RTT training is to train staff to be proficient in comprehending and interpreting radiation treatment prescription, treatment preparation, treatment delivery and patient set-up, treatment verification, integration of IT in health care, professionalism and radiation protection. The IAEA provides extensive guidance on the education of radiation therapists in Ref. [6.16].

In brief, the IAEA recommends a two year programme after at least secondary school education for the training of RTTs. The first year needs to be focused on topics ranging from basic sciences to medical radiation physics and professionalism. The second year involves work in the clinic and clinical

rotations. When possible, a four year degree programme could be provided to offer the opportunity to participate in advanced treatment planning, QA and dosimetry.

6.2.2.4. *Nuclear medicine physician*

At present, there are many possible training avenues for physicians seeking to practice nuclear medicine. At one end of this spectrum are radiologists trained in nuclear medicine as part of their general radiology education. At the other end are specialists who have completed multiyear dedicated training programmes in nuclear medicine.

Reference [6.14] describes the competencies that a nuclear medicine practitioner needs, drawing on the syllabus of the European Union of Medical Specialists for post-graduate specialization in nuclear medicine, the American Board of Nuclear Medicine, the Royal Australasian College of Physicians, the Joint Royal Colleges of Physicians and the Asian Board of Nuclear Medicine, among others.

6.2.2.5. *Nuclear medicine technologist*

The IAEA recommends its distance assisted training on-line (DATOL) course for nuclear medicine professionals — a comprehensive, on-line set of training materials in different languages, which provides easy to understand descriptions of nuclear medicine procedures and the science underlying them. The emphasis is on the practical application of nuclear medicine procedures in a clinical setting. The syllabus includes introduction to basic science and clinical nuclear medicine practice for basic nuclear medicine studies and multimodality imaging (SPECT/CT and PET/CT). The materials are either open access or part of instructor led courses, which include formal assessment and certification [6.17].

6.2.2.6. *Radiologist*

Well trained physicians in the different fields of radiology are critical in cancer care centres. Since training takes years, it is essential to start planning as early as possible to have enough trained radiologists.

Qualified radiologists need to have three–five years of training: for general radiology a period of three years is the minimum for providing a board certified radiologist skilled in plain X rays, breast imaging, ultrasound, CT and MRI. For more specific and deeper specialization, a one–two year additional training (fellowship) is suggested for breast imaging, muscle and skeletal imaging, interventional radiology, chest imaging, abdominal imaging and neuroradiology.

Each country has different rules for licensing radiologists to work as board certified specialists, and curricula for training radiologists are available in different teaching institutions in different countries. For continuing education, radiology societies around the world provide materials and on-line content to support self-assessment and education. The Radiological Society of North America, for example, offers many on-line courses in distinct areas of radiology for supporting education¹. The ESR supports e-learning courses through the European School of Radiology. The ESR's Education on Demand programme provides different levels of on-line training for radiologists: Level 1 (up to three years of training), Level 2 (four–five years of training in general radiology), Level 3 (subspeciality training) and also courses for radiographers.

6.2.2.7. *Medical physicist*

Structured and supervised clinical training in radiation oncology medical physics aims at equipping residents with the competencies needed to work independently and contribute to the quality, safety and effectiveness of RT. Medical physicists, for instance, play a central role in the definition of the installation design, technical specifications of RT and dosimetric equipment, acceptance testing and commissioning. The roles and responsibilities of clinically qualified medical physicists are defined in IAEA guidelines [6.3, 6.4]. However, despite these guidelines [6.4], which are also endorsed by the American Association of Physicists in Medicine and the International Organization for Medical Physics, clinical training is often overlooked for medical physics or lacks national/regional harmonization and structure, owing to the widespread lack of recognition of medical physics as a health profession. To address this challenge, efforts have been made to define regionally agreed upon clinical training curricula to facilitate collaboration in capacity building and address the scarcity of medical physics professionals [6.18]. For instance, harmonized clinical training curricula have been developed for the African [6.8] and Latin American [6.9] regions.

Considering that clinical quality management programmes involve health professionals, it is particularly important that the clinical training programmes include adequate training in professional ethics [6.12].

6.2.2.8. *Radiobiology*

Knowledge of radiobiology is essential for radiation oncologists, medical physicists, radiologists and nuclear medicine specialists because it provides

¹ <https://education.rsna.org>

a basic understanding of the action of ionizing radiation on biological objects, including tumour control, normal tissue reactions, stochastic and delayed effects [6.19]. It is important to consider the radiobiology education of personnel while planning a radiation oncology centre because it provides a scientific basis for radiation medicine and helps to understand particularities and peculiarities of different treatment regimens, as well as the curative and adverse effects of RT. Clinical research and development have to be based on the scientific background provided by biology, physics and medicine, as well as mathematical modelling of radiation effects.

Radiation biology is an interdisciplinary field of science that studies the biological rationale for the utilization of RT. IAEA activities in this area include participation in regional and international training courses on radiobiology and development of educational materials to teach radiobiology and RT trainees. The IAEA conducts radiobiology studies in coordinated research projects. There are several tracks of research in radiobiology related to radiation oncology: tissue engineering and stem cell therapy for radiation induced lesions in case of adverse effects of RT; applications of biological dosimetry methods in radiation oncology, nuclear medicine, diagnostic and interventional radiology; and studies of radiobiological foundations of ion beam therapy. In 2010, the IAEA published Ref. [6.20] and is preparing a new CPL4NET² teaching course on radiobiology for radiation oncologists.

This new radiobiology course is part of the Applied Sciences of Oncology distance learning programme [6.21]. It explains the radiobiological principles that govern the outcomes of clinical RT. The main objective of this course is to impart to participants an understanding of the clinical relevance of radiobiology. Upon successful completion, individuals will have the ability to: analyse the acute and late effects of ionizing radiation in various organs and tissue types; examine the late effects of RT; explore the impact of time and fraction size on tumour and normal tissue; examine radiobiological aspects of brachytherapy; assess the biological effects of RT at the cellular and molecular levels; and evaluate the interactions between RT and chemotherapy at the molecular level.

6.3. CONTINUING PROFESSIONAL DEVELOPMENT

Radiation medicine is closely linked to technology and therefore a continuous evolution of competencies is implicit in this field. The purpose of CPD activities is to keep health care professionals up to date and able to adapt

² <https://www.iaea.org/resources/databases/cyber-learning-platform-for-network-education-and-training-clp4net>



FIG. 6.1. Path to continuing professional development for radiation medicine professionals.

to the fast paced advances in science, medicine and technology. As such, CPD requires the following:

- A structured system to perform CPD;
- An evaluation mechanism (e.g. a credit based system);
- Competent and qualified professionals involved in delivering the relevant educational and training activities (including e-learning);
- A QC system that includes assessment of the quality of educational activities, as well as assessment of the acquired knowledge, skills and attitudes.

Figure 6.1 summarizes the steps to identify areas of improvement through CPD activities.

Depending on the local regulations in force, CPD activities might be mandatory, and specific requirements in terms of their type and number over a specific period could be a condition to, for example, renew professional certification.

Different types of activity can be included in CPD. Typically, these activities differ from the job description of the professional (as no CPD points are provided for activities that are already part of the professional's job) and could include training external to the centre, as well as internal. In the health care environment, a typical periodic CPD activity includes courses in ethics [6.12] in the clinical environment, which are often a requirement for recertification. For radiation medicine professionals, CPD on radiation protection may also be included.

6.4. RESEARCH

6.4.1. Rationale for research

Research is a critical factor in the design of a comprehensive cancer centre and is key to integrated medical training (Box 6.1). The complexity and organization of the research programme will vary according to the characteristics

of the centre and require careful and thoughtful planning for sustainable operations. Four elements are required: a qualified research team; financial management and funding; a research governance framework (e.g. IRB); and a quality and safety approach.

BOX 6.1. RESEARCH AS PART OF A COMPREHENSIVE CANCER CENTRE

In the context of a comprehensive cancer centre, research is defined as a structured and systematic way of producing new knowledge that provides the foundation for better patient care and community benefit. Research in health covers a wide scope, from basic discovery research to changes in policy making, in a continuum. Clinical research is critical to address identified questions, create new evidence to guide standard of care, and advance the profession or field of cancer care.

Clinical research is often the biggest research component in cancer centres. For the scope of this guide, the focus is on clinical research, which can be defined as any health related research that involves human subjects, their tissues or data. The highest level of clinical research to develop evidence to guide care is clinical trials. WHO defines a clinical trial 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. In this context, interventions include, but are not restricted to, drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process of care changes and preventive care [6.22, 6.23].

Clinical research is usually conducted in four phases, which build on each other. The four phases are: phase I studies, where the safety of a new intervention is tested; phase II, where interventions proven to be safe in phase I are tested for efficacy to test the benefit or response; phase III trials, which compare the safety and effectiveness of an experimental intervention against a reference treatment; and phase IV studies, which test approved interventions on a larger scale over a longer period of time to get full knowledge of the performance of these interventions [6.23].

Community based research focuses on social, structural and physical environmental inequities through the active involvement of community members, organizational representatives and researchers in all aspects of the research process [6.24]. In this case, the centre of gravity is displaced towards the community centres, while the cancer centre itself provides research coordination

and support, sometimes in collaboration with other partners, such as local universities. This approach to health research recognizes the importance of social, political and economic factors to health systems, and contributes to the understanding of the entire spectrum of determinants of health. Community based research may also drive the translation of research findings into practice and policy making.

6.4.2. Governance

Research governance is a comprehensive and integrated system for the administration and supervision of a research programme. It is highly regulated to protect vulnerable individuals and research ethics and to preserve accountability in the funding institutions. The term ‘vulnerable individuals’ refers to minority ethnic groups, institutionalized individuals, socially excluded people and participants from developing countries [6.25].

This concept goes beyond administrative and operational issues to include a broad set of regulations, principles and standards of good practice used to achieve and continuously improve research quality [6.26, 6.27]. A research governance framework is a set of resources that the centre, or a higher regulatory authority, uses to ensure adequate governance of the entire research programme.

Research governance is needed to safeguard participants and investigators in the research conducted. This is achieved by providing a clear framework within which to work; preserve and enhance scientific quality and reduce fraud and misconduct; mitigate possible risks associated with proposed interventions; monitor and evaluate performance; promote good practices; ensure accountability of the funding institutions; resolve ethical issues associated with the research question or method; and protect vulnerable groups [6.23, 6.26, 6.27].

For example, in the United Kingdom the NHS has developed a complete set of materials and a comprehensive approach to research governance to help in implementing a research governance framework [6.28]. According to the NHS, a research governance framework has five elements: science, including a clear definition of the research goals and design, approval and data management; information for the patient and for the public and consideration of intellectual property; financial transparency and accountability; risk assessment, health and patient safety assurance for the patient, the researcher and other participants associated with the research; and ethics, concerning the dignity, rights and well-being of all those who participate in the research.

The basis for the development of a research governance policy is given by the International Council on Harmonization Good Clinical Practice (ICH-GCP) guidelines, an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects [6.29]. The guidelines were developed with consideration of the current good clinical practices of the European Union, Japan and the USA, as well as those of Australia, Canada, the Nordic countries and WHO. The foundation for the ICH-GCP guidelines is the Declaration of Helsinki, a set of ethical principles regarding human experimentation developed and adopted by the World Medical Association at the 18th World Medical Assembly in Helsinki in 1964 and amended in 1975, 1983, 1989 and 1996 [6.23].

Central to the research governance framework is the ethics committee (see Table 6.2). The Declaration of Helsinki states that research protocols need to be submitted for review to an ethics committee, which has to be independent of the investigator, the sponsor or any other kind of undue influence. The IHC defines an IRB as a group designated to protect the rights, safety and well-being of humans involved in clinical research by reviewing and approving all aspects of the research protocol. The IRB has the authority to approve, disapprove, monitor or require modifications in all research activities under its jurisdiction. IRBs can also be called independent ethics committees [6.23]. The ethics review committee has to include, but is not limited to, the following members: a chairperson independent of the institution, a basic scientist, a pharmacologist, clinicians, a legal expert, a social scientist, a philosopher, an educationist and representatives of the public.

A clinical review council may be developed to review the scientific merit of the clinical research prior to submitting the protocol to the IRB. It consists of subject experts, statisticians and research staff.

6.4.3. Quality assurance and safety

Any research programme requires an integrated and comprehensive system to ensure quality and safety. Quality and safety are related concepts, with safety a consequence of a strong approach to quality management. A QMS includes all activities of the overall management of the programme that determine the quality policy, objectives and responsibilities and their implementation.

Quality management is a cross-cutting activity in a cancer centre that has to be managed in an integrated and comprehensive way through a QMS that includes the research component. Depending on the complexity of the cancer centre and the research programme, it may be worth creating, implementing and maintaining a subsystem for the research programme that is connected to the main QMS.

TABLE 6.2. RESEARCH ETHICS COMMITTEE: REPRESENTATION, ROLE AND RESPONSIBILITIES

Name	Requirement	Minimum frequency of meeting	Essential members (unit may add more members as appropriate)	Essential agenda items	Documents to be tabled
Research ethics committee	Mandatory (conducting human research)	Every two months	Chairperson, member secretary, one basic scientist (preferably pharmacologist), one–two clinicians, one legal expert, one social scientist, one philosopher, one educationist, one lay person	Information to chairperson of appointment of new member, submission of new projects, submission of ongoing projects, review of any previous meeting action items	Protocol, informed consent form, verification certificates, questionnaire, investigator brochure, insurance policy and investigator undertaking, clinical trial agreement, signed curriculum vitae of research members, subject recruitment process, case report form, patient instruction card, regulatory approval, good clinical practice training certificates, clinical trials registry registration documentation, percentage of research activities approved, any patient withdrawals from study, any deviations from protocols, any sentinel events

Depending on the criteria used for setting up the QMS, its main components are the policy statement (Level 1), the documentation (Level 2, procedures; Level 3, SOPs and work instructions; and Level 4, records), the control and monitoring system, the quality audit system and the quality committee. A data safety board is needed to monitor and discuss safety aspects of the research.

6.4.4. Human resources

The most critical component to ensure high quality clinical research is the research staff. In setting a sustainable human resources model for research in a cancer centre, it is important to create a qualified research team and a team based approach to research. Staffing a research programme requires an understanding of the research that will be performed. The human resources needed fall into three different staff categories: research, support and administrative.

6.4.4.1. Research staff

The research staff (led by the principal investigators, or coordinating study investigators) are responsible for the scientific component of the research programme, the study design, feasibility, conduct of the trial, data quality and interpretation of the result. The principal investigators are also responsible for the overall integrity of the research conducted. Depending on the research that the cancer centre will be involved in, the profile of the research staff will change. Basic research will involve professionals in basic scientific disciplines, whereas potential clinical research investigators will be clinical staff of various medical or surgical specialities with a background or interest in research.

6.4.4.2. Clinical research nurse

As cancer care evolves in LMICs, clinical trials can expand to address the needs of the population. For example, countries in sub-Saharan Africa require skilled health care professionals, including nurses specializing in oncology, to care for cancer patients [6.30, 6.31]. However, a recent study suggests that sub-Saharan Africa faces barriers to conducting research, in addition to needing support for conducting cancer research that is associated with clinical care [6.32]. There is a need to better understand the designing, testing and staffing of cancer focused clinical studies in LMICs. One role being introduced into clinical research is the clinical research nurse (CRN). Training CRNs in the specific skills needed to conduct clinical trials in sub-Saharan Africa is essential for effective clinical research, timely treatments and management of symptoms.

The CRN plays a vital tripartite role in the research enterprise, serving simultaneously as an expert nursing caregiver, a member of the scientific team conducting the study and as an advocate for research participants [6.33]. The CRN's responsibilities are as follows:

- Advocacy for the patient enrolled in the clinical trial;
- Ensuring initial and ongoing informed consent;
- Fidelity to the research protocol;
- Observation to identify the early signs of adverse events;
- Advanced technical proficiency and fastidious recordkeeping;
- Precise timing of sample collection and sample preparation;
- Conformity with complex regulations.

These and other responsibilities need to be met so that the research data collected support applications for cancer treatments, such as new drugs, biological products and devices. The role of the CRN in sub-Saharan Africa is particularly important, considering the dramatic increase in the number of research participants, as well as the rigorous standards for informed consent, the sophisticated science under study and the need for compliance with regulations governing clinical research. The International Association of Clinical Research Nurses (IACRN) developed the Scope and Standards for Clinical Research Nursing adopted by the American Nursing Association in 2016 [6.34].

6.4.4.3. *Support staff*

Staff research associates or research staff assistants perform tasks or procedures to support supervised research. They play a very important role in ensuring the continuity of the research programme. Study/research coordinators, sometimes in association with the study nurse, connect the research protocol with the needs of the patients who participate in the study. Depending on the research profile at the cancer centre, the profile of the support staff varies and includes laboratory technicians, data management specialists, pathology laboratory technicians, cancer registry data collection specialists and statisticians, pharmacy nurses, technicians and pharmacists.

6.4.4.4. *Administrative staff*

Administrative staff support the research activities by providing administrative support to the research programme. This includes data management in terms of financial resources, document management, coordination and communication support.

Training human resources is essential for a successful and sustainable cancer research programme. The Association of Clinical Research Professionals, in collaboration with the Joint Task Force for Clinical Trial Competency, has developed a framework of eight core competency domains designed to standardize the professional development of the workforce involved in clinical research [6.35].

6.4.5. Infrastructure and equipment

The infrastructure and equipment needed to set up a research programme in a cancer centre depend on the type of research planned. Here, ‘equipment’ refers to a set of articles, physical resources or apparatus that equip a research infrastructure.³ The following infrastructure and equipment are essential to conduct clinical research:

- Core treatment facilities. Depending on the type of research, core treatment facilities include: specialized calibrated equipment; surgical areas, including intensive care unit; blood, biomarker and other sample collection and processing; and monitoring and specialized nursing area.
- Access to central services, such as a specialized laboratory, pathology, imaging and pharmacy areas, together with the skilled personnel.
- Document management infrastructure and equipment.
- Administrative areas.

Source documentation management infrastructure and equipment are necessary for compliance with good clinical practice. Reference [6.36] states that: “All clinical trial information should be recorded, handled, and stored in a way that allows accurate reporting, interpretation, and verification.” This principle applies to all records, irrespective of the type of media used.

Filing and archiving the trial documentation are mandatory for two main reasons: (1) adequate reporting, interpretation and verification (including the traceability of all events) and (2) ensuring the protection of the participating individuals.

In community based research, the focus shifts to community centres, while the cancer centre provides research coordination and support, sometimes in collaboration with partners such as local universities. In this case, the infrastructure required is simpler, with limited core needs and access to central services and

³ The literature on infrastructure and equipment for research is limited and does not present an integrated view across the spectrum of research.

TABLE 6.3. RESEARCH LEVELS AND SPECIFIC REQUIREMENTS

Level of cancer centre	Research level		
	Implementation	Clinical trials	Pre-clinical
Level 1	Database, registry study	Basic clinical research	None
Level 2	Database, registry study	Randomized clinical trials	None
Level 3	Database, registry study	Randomized clinical trials	High level pre-clinical research

greater need for access to other support and administrative infrastructure and equipment (Table 6.3 shows the research levels and specific requirements).

Common to all types of research is the basic support infrastructure. This includes meeting and working areas; libraries (including licences for e-libraries) and archives; computers and Internet access (including videoconferencing) and data storage (either physical or cloud space); interview equipment (especially for community based research); office space and equipment; and publishing and printing equipment.

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Chapter 7

SERVICE DELIVERY MATRIX, DISEASE SPECIFIC PROGRAMMES

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7.1. MULTIDISCIPLINARY CANCER CARE MATRIX

The matrix for service delivery has to provide the infrastructure to ensure patient centred, consistent, safe, high quality and evidence based care for people with cancer. This matrix is not simply a cancer centre, but rather a network of MDTs involved in every step of cancer care. One example of a general framework for such a matrix is shown in Fig. 7.1, which was based on W. Edwards Deming's 'system of profound knowledge' [7.1].

Key elements of the cancer care matrix are systems to deliver care that is both patient centred and multidisciplinary, which requires a well organized system of communication and coordination; systems to ensure the safety and quality of care; and clinical and translational research capability. Each of these elements is discussed below.

7.1.1. Patient centred care

Patient centred cancer care is a crucial component of high quality health care. The cancer service matrix needs to be respectful of, and responsive to, the preferences, needs and values of patients and their caregivers.

7.1.2. Multidisciplinary care

Multidisciplinary care requires a well integrated team of medical and allied health professionals who consider all relevant treatment options and collaboratively develop individualized treatment and care plans for each patient. The recommended treatment plans or interventions need to be communicated



FIG. 7.1. Component functions of a patient centred, multidisciplinary cancer care matrix.

and discussed among members of the care team, in addition to the patients and caregivers.

7.1.3. Communication and coordination

A successful multidisciplinary cancer service delivery matrix requires a well organized network to facilitate free communications among team members. A leading physician needs to be identified to take the responsibility of communication and coordination to the referral physician, other team members, patients and their caregivers.

7.1.4. Cost effectiveness and adaptation

While it is important to maintain quality and ensure that all decisions are evidence based, decisions have to reflect cost effectiveness and the availability of the recommendation within the jurisdiction. They need to be based on the concept of universal health coverage, with equity in access and financial risk protection. It is important to adapt decisions to the individual and the country's health care financing system.

7.1.5. Safety and quality

Programmes for education and training in safety and quality for community and specialized clinicians, hospitals and clinics with the cancer care delivery core capacity (i.e. equipment and staffing) are essential to ensure safe and high quality cancer care. Cancer treatment pathways need to be developed for each specific disease according to well established practice guidelines. The process has to involve standardized nomenclature, with automation, if possible (e.g. auto-planning for RT), and have to be simple, consistent and repeatable. Information on patient experiences and outcomes needs to be collected and evaluated periodically to assess the performance of the matrix, particularly for identifying bottlenecks and opportunities for improvement.

7.1.6. Education, prevention and screening

For each specific cancer service delivery matrix, it is important to build in programmes for cancer prevention and screening. Both will benefit from an effective educational programme to raise awareness of the risk factors of cancer, cancer symptoms and options for cancer treatment.

7.1.7. Clinical and translational research

Clinical and translational research have critical roles in advancing cancer care and improving outcomes. Clinical trials are the accepted scientific approach for addressing clinical questions and establishing standardization, efficacy and safety for a range of treatment interventions. Translational research can reveal new therapies or new methods to address clinical issues. The importance of clinical trials and translational research cannot be emphasized enough and they need to be essential components when creating any service delivery matrix for patients with cancer.

7.2. BREAST CANCER

Breast cancer is the most common type of cancer diagnosed in women, affecting one in eight women worldwide and accounting for an estimated 12% of cancer incidence in 2022. As such, breast cancer represents a significant universal health challenge, with profound social and medical effects [7.2]. A core breast cancer facility has to provide services from early screening and prevention, to diagnosis, treatment modalities, and ultimately survivorship and end of life care.

Accessing the service can be facilitated through the service units, which can perform education, early detection and clinical breast examinations, in addition to the use of mobile teams equipped with mammography and breast ultrasound units. Diagnosis is typically through pathological evaluation of breast biopsy specimens obtained via core needle biopsy or excisional biopsy. Classification of the tumour for proper treatment selection requires immunohistochemistry to determine receptor subtype (ER/PR/Her2), while FISH examines the number of copies of the HER2 gene in the cancer cells [7.3]. More sophisticated biomarkers study is desirable for more individualized care, but it is not readily available.

After diagnosis, imaging with diagnostic mammograms and/or breast ultrasound for estimation of the tumour location, size and relation to the surrounding structures, as well as imaging to exclude disease spread via chest X ray, CT, MRI or nuclear scanning, is typically pursued [7.4]. Sentinel node biopsy or axillary lymph node dissection provide assessment of disease spread in the axillary lymph nodes [7.5].

After laboratory work-up confirming normal blood counts and chemistry, treatment is preferably performed in a multidisciplinary setting with staff expertise in breast surgery, medical oncology, radiation oncology, radiology, nuclear medicine and nursing, once the biology of the disease and its extent are established. Treatment of breast cancer is complex and generally involves a

combination of local/regional treatments with surgery (lumpectomy, mastectomy and reconstruction), axillary nodal evaluation (dissection, sentinel lymph node evaluation) and RT. Systemic anticancer treatments with traditional chemotherapy, hormone therapy and/or targeted therapies are typically delivered as the main therapy in cases presenting with distant disease or in combination with local therapies, either before or after surgery in localized disease [7.6]. Supportive measures to manage expected side effects from low blood counts, electrolyte imbalance and allergic reaction are paramount with aggressive regimens.

For example, for women with clinically localized breast disease with nodal spread, the tests to consider are as follows:

- CBC with comprehensive metabolic panel;
- Chest radiograph or chest–abdomen–pelvis diagnostic CT with contrast;
- Bone scan or sodium fluoride PET/CT.

Management will include the following:

- Lumpectomy or mastectomy/breast reconstruction with axillary assessment;
- Systemic therapy either before or after surgery;
- RT.

After completion of treatment, regular follow-up visits are recommended every three to four months in the first two years, every six to eight months from years three to five and annually thereafter. Every visit needs to include a thorough history and physical examination with the aim of early detection of tumour recurrence and managing late side effects of treatment. The long term follow-up is typically addressed by a survivorship programme to manage the late physical, psychological and social consequences of breast cancer treatment.

Advanced cases and/or those progressing on therapy, where an aggressive treatment strategy is not indicated, might benefit from end of life care to manage symptoms outside a hospital setting, such as pain management, anxiety, breathing or digestive symptoms (see Table 7.1; see Annex IV for more references).

7.3. LUNG CANCER

Lung cancer is the most commonly diagnosed cancer and the leading cause of cancer mortality in the world [7.2]. According to WHO estimates, it was responsible for 1.8 million deaths, with approximately 85% caused by smoking in 2020 [7.7]. Lung cancer incidence and mortality are among the highest in LMICs, where cigarette smoking is common and access to cancer care is limited.

TABLE 7.1. BREAST CANCER TREATMENT REQUIREMENTS

Access	
L1, L2, L3 ^a	Establish a network with communication channels between the primary care physician and breast cancer specialists to ensure timely referral and coordination with the MDT
L2, L3	<ul style="list-style-type: none"> — System navigators who are well connected with referral physicians and specialized cancer services — Mobile mammography units for screening and education — Outreach programmes to promote screening and other preventive measures
L1	<ul style="list-style-type: none"> — Timely evaluation of patients by cancer specialists — Multidisciplinary clinic for evaluation and decision making shortened to just one day
Prevention and early detection	
L1, L2, L3	<ul style="list-style-type: none"> — Selective oestrogen receptor modulators have been found to reduce breast cancer occurrence in women at high risk — Genetic counselling for women with strong family history with a positive breast cancer gene mutation to undergo prophylactic mastectomy/oophorectomy
L2, L3	— Breast MRI for younger women with strong family history prior to radiation, or those whose mammograms provide equivocal results due to dense breast tissue
L1	<ul style="list-style-type: none"> — Breast diagnostic mammograms — Clinical examinations for early detection and education
Diagnosis	
L1, L2, L3	<ul style="list-style-type: none"> — Radiography: Bone scan; dual energy X ray bone densitometer; echocardiography; multigated acquisition scan; sentinel node biopsy lymphoscintigraphy — Pathology: Full immunohistochemistry panel with Her-2-neu immunohistochemistry and FISH analysis; molecular analysis using commercially available multigene score assay; NGS to guide treatment decisions; genetic analysis for carrier mutation for family and genetic counselling

TABLE 7.1. BREAST CANCER TREATMENT REQUIREMENTS (cont.)

L1	<ul style="list-style-type: none"> — Radiography: Breast ultrasound; chest X ray; CT scan — Pathology: Fine needle aspiration cytology; oestrogen and progesterone receptor immunohistochemistry — Laboratory: CBC; liver function; kidney function
Treatments	
L1, L2, L3	<ul style="list-style-type: none"> — In the same location, the MDT has to include: <ul style="list-style-type: none"> • Breast surgeons/plastic surgeons • Radiation oncologists • Medical oncologists • Diagnostic imaging specialists/nuclear medicine physicians • Pathologists • Psychiatrists • Members of a specialist palliative care team • Pharmacists • Dietician • MDT coordinator • Clinical research coordinator • Social worker — Breast surgery: <ul style="list-style-type: none"> • Surgical intensive care unit • Hospital bed capacity • Qualified specialized nursing support to manage complex surgery • Appropriate specialized breast and oncoplastic surgeons • 24 hour medical staff availability • 24 hour operating room access • Intra-operation pathology (frozen sections) • In-house access to interventional radiology • Access to a blood bank
L1, L2, L3	<ul style="list-style-type: none"> — Radiation oncology: <ul style="list-style-type: none"> • RT facility co-located with chemotherapy infusion facilities • Medical physics support • Dosimetry support • Quality and safety programme • Trained therapists, nurse • SBRT capability • Particle therapy

TABLE 7.1. BREAST CANCER TREATMENT REQUIREMENTS (cont.)

—	<p>Systemic treatments:</p> <ul style="list-style-type: none"> • Medical oncology clinic space, which is integrated with the multidisciplinary clinic • Outpatient infusion centre, ideally co-located with RT facilities • Medical oncologist with proper training and credentialling, ideally specialized in breast cancer • Nursing staff with training and experience in chemotherapy administration, including premedication, recognition and emergent management of acute side effects, relevant clinical protocols • Clinical laboratory for haematological and biochemistry testing • Clinical pharmacy and well trained clinical pharmacist with experience in preparation, dose calculation, interaction of chemotherapy agents • Urgent care centre, where patients with minor side effects of chemotherapy can be treated without hospitalization • Emergency room capacity • Inpatient capacity
—	<p>Palliative care:</p> <ul style="list-style-type: none"> • MDT of physicians, pulmonologists and nurses for lung cancer • Care coordinator to ensure continuity of palliative care • Pain management specialist • Access to social workers and chaplains • Access to psychosocial support assistance with treatment decision making for patients with serious illnesses, their families and their other health care providers • Home visiting nurse • Hospice
L1	<p>— Surgical services: Operating room with equipment sterilization unit</p> <p>— RT: LINAC with beam shaping abilities and portal film verification</p> <p>— Systemic therapy: Hormonal therapy dispensary and systemic therapy infusion centre with its auxiliary laboratory and pharmacy</p>

Survivorship

L1, L2, L3	<p>— Long term follow-up/survivorship clinic staffed by a community physician, advanced nurse practitioner or appropriately trained nurse</p> <p>— Plastic surgery, lymphedema clinic and other functional rehabilitation programme</p> <p>— Psychological counselling</p> <p>— Survivorship education programme to teach patient self-care and active involvement in the maintenance of survivorship</p>
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TABLE 7.1. BREAST CANCER TREATMENT REQUIREMENTS (cont.)

	<ul style="list-style-type: none"> — Breast cancer survivor support group — Community support group — Coordination of care between all providers to ensure that contact with breast cancer survivors is not lost during transitions
End of life	
L1, L2, L3	<ul style="list-style-type: none"> — Training and education for providers in terms of end of life discussion with patients and their families — Discussion about DNR decisions — Advanced directive planning — Best supportive care options — Counselling — Consideration of an appropriate place of care and preferred place of death

^a L1: Level 1 represents the most basic requirements. L2: Level 2 is the next highest set of requirements. L3: Level 3 is the highest level of requirements.

Note: CBC: complete blood count; CBCT: cone beam CT; CRT: conformal RT; CT: computed tomography; DNR: do not resuscitate; FISH: fluorescence in situ hybridization; IMRT: intensity modulated RT; MDT: multidisciplinary team; MRI: magnetic resonance imaging; NGS: next generation sequencing; PET: positron emission tomography; RT: radiotherapy; SBRT: stereotactic body RT; VMAT: volumetric modulated arc therapy.

The management of lung cancer is complex and requires specialist expertise that is not always locally available. Thus, developing specialized care centres for lung cancer patients is critical to ensure timely, effective and affordable care to improve the outcome for lung cancer patients.

Access to specialized lung cancer service starts with the primary care provider. Educational programmes to increase the awareness, risk factors and symptoms of lung cancer in the community has to be developed. Referral to the service needs to involve the use of primary care based assessment of the risk of lung cancer using established guidelines. A triage system needs to be established in secondary care centres to ensure that patients are seen in the lung cancer clinic in a timely fashion. The service matrix has to provide access to the most advanced care, directed by appropriate cancer specialists, access to locally or centrally provided expert diagnostic, staging and fitness assessment, and an MDT.

Cigarette smoking is the primary risk factor responsible for lung cancer deaths in men and women [7.8]. Therefore, preventing use of tobacco and cessation of smoking remain the principal approaches for lung cancer prevention

and control. These efforts require a multidisciplinary prevention programme in all lung cancer services. The programme's aim has to be to prevent initiation of cigarette smoking in adolescents and in facilitating efforts to stop adults from smoking. The centre needs to raise the public awareness of the harm of smoking and provide tools to help smoking cessation. Early detection using low dose CT screening is an option in a dedicated lung cancer service matrix with QC, experience in CT screening, and multidisciplinary management of suspicious findings. The target population includes asymptomatic adults aged 55–80 years who have a 30 pack-year smoking history and currently smoke or have quit within the past 15 years [7.9].

The diagnosis of lung cancer is usually first indicated by CT imaging and should be confirmed by tissue diagnosis. Tumour molecular genetic mutation analysis to identify targetable gene mutations and analysis of PD-1/PD-L1 expression to guide checkpoint inhibitor immunotherapy may be appropriate in select settings. CT scans and/or PET/CT (in resource appropriate settings) evaluate the spread of the disease and provide critical information in the overall treatment plan.

The treatment of lung cancer requires a multidisciplinary care team, which can include a pulmonologist, thoracic surgeons, thoracic radiation oncologists, medical oncologist, nursing and care coordinators. A multidisciplinary tumour board acting as a platform for all disciplines is needed to provide input on the diagnosis and management of each case to ensure that treatment guidelines are followed. Patients' co-morbidities, tolerability for surgery, tumour resectability and status of molecular testing need to be carefully reviewed. The final treatment recommendation needs to take into consideration the patient's concerns, preferences and social circumstances, as well as the intention of treatment. Whenever possible, relevant clinical research protocols need to be presented and discussed on the tumour board, and patients who are eligible for a clinical trial need to be offered a protocol for their consideration. It is also important to initiate advanced directives and care planning with patients at this stage if it is appropriate.

Lung cancer survivors may have continued symptoms as the result of the disease and its therapy, and psychosocial issues in coping with work or daily life (see Table 7.2). Lung cancer treatments may cause injury in the lung, oesophagus and the heart, which can impact the function of these organs. All lung cancer survivors have to be encouraged to participate in rehabilitation programmes to improve cardiopulmonary functions. Gastroenterology evaluation for persistent oesophageal symptoms may be needed. All lung cancer patients have to undergo surveillance for disease status in the community by the referring physician following established guidelines (e.g. NCCN, ESMO), with clear

communication and timely update and coordination among the original MDT (see references in Annex IV).

TABLE 7.2. LUNG CANCER TREATMENT REQUIREMENTS

Access	
L1, L2, L3 ^a	Establish network with communication channels between primary care physician and lung cancer specialist (centre) to ensure timely referral and coordination of multidisciplinary care.
L1, L2, L3	Appoint a system navigator who is well connected with the referral physicians and specialized cancer service. A road map can be developed to assist patient progress through the matrix.
L2, L3	Reduce travel time. The geographical location of the lung cancer service has to facilitate transportation of patients to the centre. <ul style="list-style-type: none"> — Smoking is known to be directly related to the development of all subtypes of lung cancer, especially small cell lung cancer. Establishing lung cancer care centres in regions where the prevalence of smoking is high is ideal. — Certain mining areas may also have a high incidence of lung cancer.
L1	Timely and easy requisition of clinic appointment with the lung cancer specialist: <ul style="list-style-type: none"> — In a tertiary referral centre, the specialist has to see patients within one week of referral. — Triage clinic in the cancer centre when a patient comes without an appointment. In many LMICs, walk-ins are probably the most common way to access the specialized lung cancer centre.
Prevention and screening	
L1, L2, L3	Prevention for current smokers: Smoking cessation counselling and service need to be offered to all current smokers during every step of the care delivery process and it is the responsibility of every member of the care team. Structured professional interventions, group counselling, nicotine replacement therapy and web applications are some effective approaches to help people to quit smoking. ^b
L1, L2, L3	Smoking prevention: Education programmes have to be included as an essential component in the health care system to raise public awareness of the harm of cigarette smoking. The education has to focus on adolescents in middle and high school to prevent the start of cigarette smoking. Many organizations offer these types of education programme. ^c

TABLE 7.2. LUNG CANCER TREATMENT REQUIREMENTS (cont.)

L3	Screening: Low dose CT screening may reduce lung cancer mortality and may be integrated into the service delivery matrix. However, screening for lung cancer is not considered essential core capacity. Chest X rays are not recommended for screening.
Diagnosis	
L1, L2, L3	Pathological diagnosis: — Bronchoscopy, including endobronchial ultrasound — CT guided biopsy — Excisional biopsy or needle biopsy of metastasis — Cytology of pleural effusion, pericardial effusion
L2, L3	— Thoracoscopy — Thoracotomy — Mediastinoscopy
L3	— Liquid biopsy for circulating free DNA is a developing method to obtain tumour marker analysis — Tumour molecular genetic mutation analysis for EGFR, ALK, Braf and PD-L1 need to be obtained whenever possible to guide treatment decision
L1, L2, L3	Radiographic diagnosis: — Chest X ray — CT scan — Bone scan — Special high resolution, low dose CT
L2, L3	— MRI — PET/CT
L3	— Lung and cardiac SPECT
L1, L2, L3	Function evaluation: — Pulmonary functional test — A six minute walk test is an extremely accurate and affordable examination to determine if a patient is a candidate for surgery
L2, L3	— Cardiopulmonary function evaluation if patient is considered as surgical candidate
L1, L2, L3	Laboratory evaluations: — Haematological examinations (CBC, diff, absolute blood counts, etc.) — Liver functional test — Kidney functional test
Treatments	

TABLE 7.2. LUNG CANCER TREATMENT REQUIREMENTS (cont.)

	The multidisciplinary lung cancer care team (a network of MDT members who are not necessarily working at the same location):
L1, L2, L3	<ul style="list-style-type: none"> — Thoracic surgeons — Radiation oncologists — Medical oncologists — Diagnostic imaging specialists — Pathologists
L2, L3	<ul style="list-style-type: none"> — Respiratory physicians — Lung cancer nurse specialists — Members of the specialist palliative care team — Pharmacists — Dietician
L3	<ul style="list-style-type: none"> — MDT coordinator — Clinical research coordinator — Social worker
	Thoracic surgery:
L2, L3	<ul style="list-style-type: none"> — Surgical intensive care unit — Hospital bed capacity — Qualified specialized nursing support to manage complex surgery — Appropriate specialized (thoracic, orthopaedic, neurological) surgeons — 24 hour medical staff availability — 24 hour operating room access — Intra-operation pathology (frozen sections) — In-house access to interventional radiology — Access to blood bank
	Radiation oncology:
L1, L2, L3	<ul style="list-style-type: none"> — The RT facility needs to be ideally co-located with chemotherapy infusion facilities — CT simulation — Treatment machine with volumetric imaging guidance on board image (CBCT) — 3-D CRT, IMRT, VMAT — Medical physics support — Dosimetry support
L2, L3	<ul style="list-style-type: none"> — Quality and safety programme — Trained therapists, nurse — Access to nutrition and respiratory health and advice — Access to social worker
L3	<ul style="list-style-type: none"> — 4-D CT scanning for simulation and planning — Motion management capacity in simulation and treatment machine — SBRT capability — Particle therapy — MRI simulation

TABLE 7.2. LUNG CANCER TREATMENT REQUIREMENTS (cont.)

L1, L2, L3	<p>Systemic treatments:</p> <ul style="list-style-type: none"> — Medical oncology clinic space that is integrated with the multidisciplinary clinic — Outpatient infusion centre, co-located with RT therapy facilities — Medical oncologist with proper training and credentialling, ideally specialized in lung cancer — Nursing staff with adequate training and experience in chemotherapy administration, including premedication, recognition and emergent management of acute side effects, and relevant clinical protocols
L2, L3	<ul style="list-style-type: none"> — Clinical laboratory for haematological and biochemistry testing — Clinical pharmacy and well trained clinical pharmacist with experience in preparation, dose calculation and interaction of chemotherapy agents. The clinical pharmacists have to be familiar with clinical protocols for chemotherapy and are responsible to develop a chemotherapy plan to be carried out in the local oncology clinic for repeat treatment cycles. If some portion of the chemotherapy treatment is administered in a local clinic, communication of the treatment plan is essential — Urgent care centre, where patients with minor side effects of chemotherapy can be treated without hospitalization — Emergent room capacity — Inpatient capacity
L1, L2, L3	<p>Palliative care:</p> <ul style="list-style-type: none"> — MDT of physicians, pulmonologists and nurses for lung cancer — Care coordinator to ensure continuity of palliative care — Pain management specialist — Access to social workers — Access to chaplains — Access to psychosocial support assistance with treatment decision making for patients with serious illnesses, their families and their other health care providers — Home visiting nurse — Hospice
Surveillance/recurrence	
L1, L2, L3	<p>The core capacities include:</p> <ul style="list-style-type: none"> — Established pathway to standardize surveillance — Access to the original lung cancer MDT if any intervention is indicated — Multidisciplinary management of disease relapse, including early referral to palliative care — Access to a range of health professions may be required including physiotherapy, occupational therapy, nursing social work, dietetics, clinical psychology and palliative care

TABLE 7.2. LUNG CANCER TREATMENT REQUIREMENTS (cont.)

Survivorship	
L1, L2, L3	<p>The core capacities for a cancer survivorship programme include:</p> <ul style="list-style-type: none"> — Long term follow-up/survivorship clinic, which can be staffed by a community physician, advanced nurse practitioner or appropriately trained nurse — Pulmonary and other functional rehabilitation programme — very important for lung cancer patients who underwent surgery and/or radiation — Psychological counselling — Survivorship education programme to teach patient self-care and active involvement in the maintenance of survivorship — Lung cancer survivor support group — Community support group — Coordination of care between all providers to ensure that lung cancer survivors are not lost in transition
End of life	
L1, L2, L3	<p>The core capacity needs to include:</p> <ul style="list-style-type: none"> — Training and education for providers in terms of end of life discussion with patients and family — Discussion about DNR decisions — Advanced directive planning — Best supportive care options — Counselling — Consideration of an appropriate place of care and preferred place of death

^a L1: Level 1 represents the most basic requirements. L2: Level 2 is the next highest set of requirements. L3: Level 3 is the highest level of requirements.

^b See <https://smokefree.gov>; <https://www.lung.org/stop-smoking/i-want-to-quit/>

^c See <https://www.cancer.gov/about-cancer/causes-prevention/risk/tobacco/cessation-fact-sheet>

Note: CBC: complete blood count; CBCT: cone beam CT; CRT: conformal RT; CT: computed tomography; DNR: do not resuscitate; IMRT: intensity modulated RT; LMICs: low and middle income countries; MDT: multidisciplinary team; MRI: magnetic resonance imaging; PET: positron emission tomography; RT: radiotherapy; SBRT: stereotactic body RT; SPECT: single photon emission CT; VMAT: volumetric modulated arc therapy.

7.4. CERVICAL CANCER

Effective cervical cancer prevention and control requires a coordinated approach involving primary, secondary and tertiary levels of health care. Cervical cancer prevention, screening, diagnosis, treatment, symptom management, survivorship, surveillance and end of life care all need to be covered routinely through universal health coverage. Effective cervical cancer control also requires robust health data systems, which can support the development of population based vaccine, screening, cancer and death registries, as well as allow accurate tracking of an individual female patient through the health care system to evaluate timeliness and quality of care and make patient navigation possible. Community education on HPV and cervical cancer is also a critical component.

All cervical cancers are caused by chronic HPV infection. Prophylactic HPV vaccines have demonstrated near 100% efficacy in preventing chronic, type specific HPV infection and precancer. At present, WHO recommends that adolescent girls aged 9–14 receive two doses, given at least six months apart, of any of the three vaccines currently available [7.10]. WHO currently recommends three approaches to screening: cytological smears of cervical epithelial cells ('Pap' smear), HPV diagnostics and visual inspection with acetic acid by a health care provider. The HPV diagnostic test may also be obtained from the cervix from a vaginal swab obtained by the woman after appropriate education ('self-sampling'). The most effective screening programmes are those that are population based, in which all women at risk for cervical cancer are offered screening.

Women found to have an abnormal screening test need further evaluation to determine appropriate management. The success rates for ablative or excisional treatment of cervical precancer (CIN 2-3) are 90% or higher. Early invasive cervical cancer can be treated with surgery. Locally advanced cervical cancer is generally treated with combined external pelvic RT, intracavitary brachytherapy and concomitant chemotherapy.

Early intervention for the management of symptoms related to cancer and cancer treatment, as well as survivorship programmes, can help women to return to normal family and work life as completely as possible after cancer treatment. Palliative and end of life care need to be offered to all women with incurable cervical cancer, including distant metastases (stage IVB) and recurrent disease that cannot be treated with RT or surgery [7.11]. Palliative/end of life care needs to be delivered as close to the patient's home as possible, with support at the primary and secondary care levels (Table 7.3).

TABLE 7.3. CERVICAL CANCER TREATMENT REQUIREMENTS

Access	
L1, L2, L3 ^a	<ul style="list-style-type: none"> — Establish network with communication channels between primary care physician and cervical cancer specialist (centre) to ensure timely referral and coordination of multidisciplinary care. — System navigators who are well connected with the referral physicians and specialized cancer service. A road map can be developed to assist patients to navigate through the process from prevention and early detection to treatment and survivorship.
L2, L3	<ul style="list-style-type: none"> — The geographical location of the cervical cancer service has to facilitate transportation of patients to the centre. — Timely and easy requisition of clinic appointment with the cervical cancer specialist: <ul style="list-style-type: none"> • In a tertiary referral centre, the specialist has to see patients within two weeks of referral; • Triage clinic within the cancer centre if a patient comes without an appointment.
Prevention and screening	
L1, L2, L3	<p>Prevention: Establish a national HPV vaccination programme, integrated within the national immunization programme. An education programme has to cover HIV, HPV and cancer, other sexually transmitted infections, sexual health and cancer screening. The education programme needs to span adolescence, young adults and older adults.</p>
L1, L2, L3	<p>Screening: Establish a routine cervical cancer screening programme. The standard screening procedure needs to be mandated and serve as a quality metric for primary care clinics and clinics serving women, such as those for HIV+ individuals, as well as maternal, newborn and child health, and specialized cervical cancer centres.</p>
Diagnosis	
L1, L2, L3	<p>Pathological diagnosis:</p> <ul style="list-style-type: none"> — Pap smear or HPV diagnostic test — Excisional biopsy — Excisional biopsy or needle biopsy of metastasis — Cytology

TABLE 7.3. CERVICAL CANCER TREATMENT REQUIREMENTS (cont.)

L1, L2, L3	Radiographic diagnosis: — Chest X ray
L2, L3	— CT scan, bone scan, MRI
L3	— PET/CT
L1, L2, L3	Laboratory evaluations: — Haematological examinations (CBC, differential, absolute blood counts, etc.)
L2, L3	— Liver functional test, kidney function test, HPV test
L3	— Anatomical pathology, including haematoxylin/eosin staining
	— Immunohistochemistry, HPV genotyping
Treatments	
L1, L2, L3	Multidisciplinary cervical cancer care team (a network of MDT members who are not necessarily working at the same location): — L1: Community health worker, nurse practitioner, nurse midwife, primary care physician — L2: Gynaecologist, diagnostic imaging specialist, pathologist — L3: • Gynaecological oncologists • Gynaecological radiation oncologists • Medical oncologists • Diagnostic imaging specialists • Pathologists • Cervical cancer nurse specialists • Members of the specialist palliative care team • Pharmacists • Dietician • MDT coordinator • Clinical research coordinator — Social worker
L2, L3	Gynaecological surgery and gynaecological cancer surgery: — Well women clinic — Surgical intensive care unit — Hospital bed capacity — Qualified specialized nursing support to manage complex surgery — 24 hour medical staff availability — 24 hour operating room access — Intra-operation pathology (frozen sections) — Access to blood bank

TABLE 7.3. CERVICAL CANCER TREATMENT REQUIREMENTS (cont.)

L3	<p>Gynaecological radiation oncology:</p> <ul style="list-style-type: none"> — RT facility needs to be co-located with chemotherapy infusion facilities — CT simulation, MRI simulation — Treatment machine with volumetric imaging guidance on board image (CBCT) — 3-D CRT, IMRT, VMAT — Brachytherapy facility — Medical physics support — Dosimetry support — Quality and safety programme — Trained therapists, nurse — Access to social worker — Particle therapy — MRI LINAC
L2, L3	<p>Systemic treatments:</p> <ul style="list-style-type: none"> — Medical oncology clinic space integrated with the multidisciplinary clinic. — Outpatient infusion centre, co-located with RT facilities. — Medical oncologist with proper training and credentialling, specialized in cervical cancer. — Nursing staff with adequate training and experience in chemotherapy administration, including premedication, recognition and emergent management of acute side effects, and relevant clinical protocols. — Clinical laboratory for haematological and biochemistry testing. — Clinical pharmacy and well trained clinical pharmacist with experience in preparation, dose calculation, and interaction of chemotherapy agents. The clinical pharmacists have to be familiar with clinical protocols for chemotherapy and are responsible for developing a chemotherapy treatment plan for local oncology clinics for repeat cycles of treatment. If some portion of the chemotherapy treatment is administered in a local clinic, communication of the treatment plan is essential. — Urgent care centre, where patients with minor side effects of chemotherapy can be treated without hospitalization. — Emergency room capacity. — Inpatient capacity.

TABLE 7.3. CERVICAL CANCER TREATMENT REQUIREMENTS (cont.)

L1, L2, L3	<p>Palliative care:</p> <ul style="list-style-type: none"> — An MDT of palliative care specialist, gynaecological oncologist and nurses for cervical cancer — Care coordinator to ensure continuity of palliative care — Fistula, bleeding and other cervical cancer specific management specialists — Social workers — Chaplains — Psychosocial support assistance with treatment decision making for patients with serious illnesses, their families and their other health care providers — Home visiting nurse — Hospice
Surveillance/recurrence	
L1, L2, L3	<p>The core capacities include:</p> <ul style="list-style-type: none"> — Established pathway to standardize surveillance — Gynaecological clinic for pelvic examinations — Access to the original cervical cancer MDT if any intervention is indicated — Multidisciplinary management of disease relapse, including early referral to palliation care — Access to a range of health professions, including physiotherapy, occupational therapy, nursing social work, dietetics, clinical psychology and palliative care
Survivorship	
L1, L2, L3	<p>The core capacities for a cancer survivorship programme include:</p> <ul style="list-style-type: none"> — Long term follow-up/survivorship clinic, which can be staffed by a community physician, advanced nurse practitioner or appropriately trained nurse — Psychological counselling, including intimacy — Survivorship education programme to teach patient self-care and active involvement in the maintenance of survivorship — Community support group — Coordination of care between all providers to ensure that contact with cervical cancer survivors is not lost during transitions
End of life	

TABLE 7.3. CERVICAL CANCER TREATMENT REQUIREMENTS (cont.)

L1, L2, L3	<p>The core capacities for end of life need to include:</p> <ul style="list-style-type: none"> — Training and education for providers for end of life discussion with their patients and family — Discussion about DNR decisions — Advanced directive planning — Best supportive care options — Counselling — Consideration of an appropriate place of care and preferred place of death
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^a L1: Level 1 represents the most basic requirements. L2: Level 2 is the next highest level of requirements. L3: Level 3 is the highest level of requirements.

Note: CBC: complete blood count; CBCT: cone beam CT; CRT: conformal RT; CT: computed tomography; DNR: do not resuscitate; HPV: human papillomavirus; IMRT: intensity modulated RT; MDT: multidisciplinary team; MRI: magnetic resonance imaging; PET: positron emission tomography; RT: radiotherapy; VMAT: volumetric modulated arc therapy.

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Chapter 8

FINANCING CANCER CENTRES IN LOW AND MIDDLE INCOME COUNTRIES

V. SAPKOTA, L. VUKADINOVIC, C. KREMER, L. STEVENS

8.1. RATIONALE FOR CANCER CENTRE FINANCING

Cancer control remains severely underfunded in LMICs. This is in sharp contrast to the significant cancer burden faced by these countries, especially since this burden is predicted to increase. Seeking adequate funding is imperative. Over the past decades, several organizations, including the WHO and the IAEA, have championed the case for combating the global cancer burden. This has led to increased importance being placed on cancer in the global health agenda. However, funding prioritization has not aligned accordingly, and challenges remain for financing cancer control in LMICs.

For cancer control, external funding is often provided for the construction of cancer centres, procurement of equipment, capacity building of human resources and establishment of safety and security infrastructure. It has traditionally been delivered in the form of grants, loans or in-kind support from donor countries, international financial institutions and the private sectors. This is often coupled with domestic resource mobilization efforts.

Comprehensive data are not yet available to demonstrate whether the traditional approaches to funding have achieved an effective and sustainable outcome on meeting a country's needs. However, innovative financing for cancer care and strong commitment from national governments in prioritizing cancer care in national policy show promising signs for addressing the funding needs in the future.

8.2. GROWING CANCER BURDEN AND DISPROPORTIONATE FUNDING

The need for funding cancer centres is paramount. While many countries lack essential and life-saving treatment capacity, cancer incidence and mortality are projected to grow, again disproportionately in lower income countries [8.1, 8.2].

Nevertheless, cancer control has lacked priority in funding in many developing countries. Out of the development assistance provided in health to countries from 2000 to 2018, NCDs accounted for a meagre 2% of the total funding, cancer being only one of the NCDs [8.3] (see Fig. 8.1).

The total development assistance for health has seen an overall increasing trend since 1990, ranging from less than US \$8 billion in 1990 to over US \$38 billion in 2017 and 2018 [8.5]. However, NCDs, including cancer (shown in black in the figure), accounted for only 2% of the total share over the 2000–2018 period.

Nevertheless, international organizations and CSOs have played an important role in raising cancer care in national and international health agendas. Most countries have integrated cancer control or a broader NCD plan in their national policy [8.6]. In this sense, there is an opportunity for advocates and implementing organizations to tap into traditional and innovative financing mechanisms to help to provide better and sustainable cancer care for all patients.

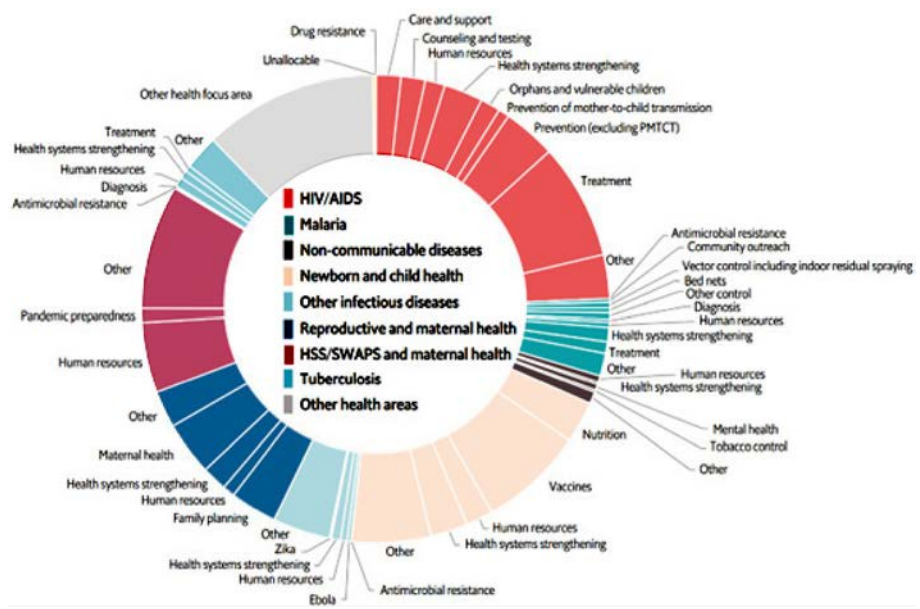


FIG. 8.1. Development assistance for health by programme (adapted with permission from Ref. [8.4]).

8.3. ACTORS IN FINANCING CANCER CENTRES: GOVERNMENTS AND EXTERNAL AGENCIES

A multitude of actors have played a crucial role in integrating cancer into the global health agenda and mobilizing resources for advancing cancer control in developing countries. That includes, but is not limited to, international organizations, governments, international financial institutions, NGOs, the private sector and CSOs. Further integrating efforts from different partners for a common cause will be key in sustaining the gains made in reducing the global cancer burden.

WHO has led the path in adopting important policy documents, hailed as ‘landmark’ declarations by experts and advocates, that have been crucial in providing the impetus to the actors in the fight against cancer [8.7]. Some of them include the WHO Cancer Resolution [8.7], adopted at the 70th World Health Assembly, which built upon the 2005 WHO Cancer Resolution [8.8], the Global Strategy to Accelerate Elimination of Cervical Cancer [8.9] and the Global Initiative for Childhood Cancer [8.10].

International agencies, including the IAEA’s PACT, coordinate with donor and recipient governments to support infrastructure, procurement and human resource development across the cancer care continuum in developing countries. This mechanism relies largely on traditional funding from donor countries, which have provided a stable funding stream to international organizations, with some support coming from corporate funding, non-profit donors and international financial institutions [8.11].

International development banks and financial institutions have also played a role in providing funding to countries in building cancer care infrastructure, procurement and training human resources. Financial institutions, such as the World Bank, the Inter-American Development Bank, the Islamic Development Bank and the Abu Dhabi Fund for Development, have provided or expressed interest in providing funding to cancer control projects at national and regional levels. In addition, the private sector, most notably medical technology corporations and the pharmaceutical industry, have provided funding support for cancer care infrastructure or training as part of their corporate social responsibility goals [8.12].

CSOs can play an important role in fundraising at the local level for cancer care initiatives. This has been more successful in HICs, targeting specific cancers such as breast cancer [8.13]. Innovative advocacy and fundraising strategies such as event based fundraising (walks, races, galas), cause related marketing (collaboration with a corporation for mutual benefits) and direct solicitations with individual and corporate donors, have been successfully adopted by breast cancer organizations in HICs [8.12]. In comparison, CSOs in lower income

countries have had limited impact so far. However, successes in HICs provide opportunities to explore similar approaches in lower income countries, with necessary adaptations.

Lastly, but most importantly, national governments play an important role in ensuring continuous operation of the national health system through revenues generated from taxes. The majority of health facilities in developing countries are public, relying predominantly on government revenues. In addition, many LMICs have also implemented some form of public insurance coverage for medical costs, which relies at least partly on revenues collected by the government [8.14]. Expansion of cancer centres and strengthening of cancer control policies are needed with increased domestic resource mobilization for the long term sustainability of cancer control projects implemented in the country (e.g. facility and equipment maintenance, human resource costs).

8.4. FINANCIAL CHALLENGES

A cancer diagnosis can be intimidating news to anyone, even in settings where resources are available. Given the threat that a diagnosis poses and the economic strain that it can impose on individuals, this is not surprising. It is further compounded by the fact that cancer care often involves multiple stages of high cost treatment and palliative care.

For a comprehensive cancer control intervention in low resource settings, there is also need for strategic consideration of the earlier stages of the care continuum, such as prevention, early diagnosis and screening. Often, they are coupled with public health education and awareness schemes. This needs to be linked to access to affordable, quality treatment services.

This has led to a mindset among policy makers and budget holders that ‘cancer is expensive’, which in turn affects much the needed attention and prioritization for investing in cancer care in these settings [8.3].

In countries with insufficient infrastructure and human resources for cancer care, establishing a cancer centre can take years. To properly evaluate the impact of global initiatives, such as the recently launched ‘Rays of Hope’ initiative by the IAEA [8.15, 8.16], which seeks to provide essential technology and human resources in countries with no or limited radiation medicine capacity, it is important to consider that these are long term projects requiring sustained attention and funding.

Another aspect to consider is domestic health spending in lower income countries. Only about 20% of global health spending occurred in LMICs in 2019, compared with the remaining 80% occurring in HICs. In low income countries, out of pocket spending was the main source of health expenditure (44%),

followed by external aid (29%). In contrast, 70% of health spending in HICs came from government budgets [8.17]. This demonstrates a lack of domestic resource mobilization in health in lower income countries, which is crucial for the sustainability of health interventions, especially in cancer control.

Lack of sustainability compromises efforts to meet targets and generate impactful outcomes. In combination, these aspects can create a vicious cycle of low funding and lack of prioritization (see Fig. 8.2). Given the amount of time, effort and investment required for raising adequate resources for comprehensive cancer control, failure to demonstrate effectiveness could dissuade governments and funding agencies from prioritizing funding in cancer control. This could lead to prioritization in other areas of health care that can generate short term health impacts and deprive the field of cancer care from much needed funding.

Lack of prioritization at national and international levels can lead to low resource allocation and funding for cancer care. To overcome this challenge, funding from external agencies, as well as robust domestic resource mobilization, need to go hand in hand in developing countries. Recent studies have demonstrated a clear case for investment in cancer control [8.18]. Data collection methodologies to evaluate the long term impact of cancer control interventions need to be designed early to assess the actual return on investment and other key performance indicators.

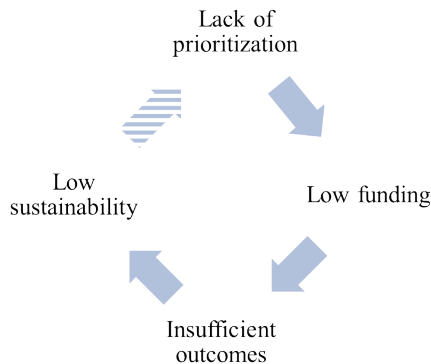


FIG. 8.2. Challenges in funding cancer care [8.4].

8.5. WAY FORWARD

8.5.1. Diversification and integration

Unforeseen regional and global upheavals, such as pandemics, financial crises and military conflicts, can cause huge disruptions in funding for cancer control, often diverting attention and potentially impacting millions of lives. In this regard, it is important for implementing agencies to expand beyond traditional funding streams and development assistance for health, and proactively seek to diversify partnerships. Diversification in funding mechanisms, including innovative financing (see Section 8.5.3), can help in minimizing interruption of services and create more resilient health systems during times of economic disruptions and crises.

Along with diversification, integration with implementing partners on the ground can promote cost-effectiveness and efficient utilization of resources. For example, HPV vaccination, which has been shown to be effective in preventing cervical cancer in women, can be integrated with other vaccination campaigns already being implemented by the government with partner organizations. Similarly, a review of sexual and reproductive health programmes in sub-Saharan Africa that integrated cervical cancer screening and prevention services in family planning or HIV/AIDS services showed increased use and coverage of both services across the general population [8.19].

8.5.2. Government led policy implementation and financing

Recent reviews of cervical cancer financing in some countries, conducted by ThinkWell, provide a greater insight into the role and importance of government led policy implementation and financing for cancer control.

Cervical cancer presents an interesting case for examining funding mechanisms for one of the most preventable and treatable cancers in women. Owing to its largely preventable nature, cervical cancer funding has been primarily devoted to providing vaccines and secondary prevention services to women and girls, aimed at eventual eradication. A summary of the country profile for the Philippines from the ThinkWell report is presented in Box 8.1.

As LMICs continue to receive external assistance in building cancer control capacity and policies, domestic efforts in strengthening national programmes and transitioning to sustainable financing need to be key priorities for ensuring a sustainable impact in the long run.

BOX 8.1. CASE STUDY: GOVERNMENT LED POLICY IMPLEMENTATION AND CANCER CONTROL FINANCING IN THE PHILIPPINES [8.20]

The Philippines is one of the countries participating in the Scale Up Cervical Cancer Elimination with Secondary Prevention Strategy (SUCCESS) programme, funded by UNITAID. In many ways, the Philippines offers a strong national policy environment for action on cancer care among the four countries that are part of the SUCCESS programme [8.21–8.23].

Most of the current Philippine policy response dedicated to cancer has been quite recent. The National Integrated Cancer Control Act (NICCA) was enacted in 2019, followed by the National Integrated Cancer Control Strategic Plan 2021–2030. The Government set aside more than US \$10 million from its national budget for the implementation of NICCA in 2021. According to NICCA’s mandate, the Government also established the Philippine Cancer Center, the National Cancer Assistance Fund and the National Integrated Cancer Council, with the latter including representation from CSOs.

The Philippines also has a National Health Insurance Program (NHIP) managed by the Philippine Health Insurance Corporation (PhilHealth). The NHIP covers 98% of the population, although the programme pays only for a portion of medical costs. It includes a package called Z-benefits covering cancer care. Data from 2019 show considerable public expenditure in cancer treatment and medicines.

Government funds for health come primarily from revenues generated from general taxes, as well as taxes on casino and lottery earnings, plus taxes on consumption of alcohol, sugary beverages and tobacco products. In addition, PhilHealth also pools premium contributions from individuals and employers for insurance coverage of all Filipinos. Government spending in terms of national health expenditure therefore increased to 45%, and out of pocket spending declined to 45% in 2020. The trend of increased public spending and decreased out of pocket spending remained consistent over 2018–2020. External donor support amounts to only 0.41% of the total health expenditure in the Philippines.

Overall, the Philippines has begun implementing strong health policies for more affordable and accessible health care at the national level. However, challenges remain in distribution at the local levels owing to fragmented implementation and resource allocation. Given the decentralized nature of health governance in the Philippines, where local government units have full fiscal autonomy in health

programming, stronger advocacy and partnership efforts need to grow from the local level to prioritize health and cancer care for all Filipinos.

There is still work to be done to reduce the significant cancer burden in the Philippines, but with sustained economic growth and increased public spending on health, substantial progress could be made in the years to come.

8.5.3. Innovative financing

Comprehensive cancer care infrastructure requires substantial financing. That includes equipment and infrastructure, such as bunkers for RT. Capacity building of human resources for cancer care adds to the financial needs. Given the limited availability of donor funds and insufficient health budget in lower income countries, covering all these costs through traditional funding mechanisms and domestic budgets alone is hard to achieve.

With the annual financing gap needed to achieve the health targets of the UN Sustainable Development Goals surpassing US \$370 billion in 2017, innovative new financing mechanisms for health in global and domestic resource mobilization efforts have become crucial [8.24]. Although specific financing mechanisms for NCDs or cancer control have not been developed, there are examples of innovative financing approaches used in international health and the broader development scenario.

One approach of innovative financing that has been deployed in the international development sector includes development impact bonds. These are a results based financing mechanisms where private investors provide upfront capital to fund development projects carried out by implementing partners. An outcome payer, usually the government or an international development agency, guarantees repayment based on the achievement of measured outcomes. Development impact bonds offer the advantage of leveraging the private sector and offering incentives to promote efficiency to achieve results. Recent results of a development impact bond in Kenya and Uganda for poverty alleviation demonstrated powerful positive impact, despite the COVID-19 pandemic, indicating potential resilience of such approaches [8.25].

In the health sector, various innovative approaches of financing have been developed and implemented for fighting HIV/AIDS, malaria, tuberculosis and other infectious diseases. The Global Fund to Fight AIDS, Tuberculosis and Malaria, for instance, uses debt swaps (i.e. cancelling debt repayment in return for investments in health programmes), blended finance (combining grants, loans

and other sources of financing from various institutions), consumer donations and results based financing to invest in local health programmes around the world. In another example, Gavi, the Vaccine Alliance, uses a coordinated procurement model, referred to as pooled procurement, to forecast demand and procure vaccines for the participating LMICs [8.3].

One of the current strategies for cancer control has been to leverage existing mechanisms in women's and reproductive health, linking to prevention of some of the most treatable and preventable types of cancer. For example, the pooled procurement model used by Gavi has also been leveraged by UNITAID-CHAI to procure HPV tests and thermal ablation devices, which are used to screen and treat women for cervical cancer, at reduced prices [8.3].

As innovative financing continues to be adopted more in the health and development sectors, there is an opportunity for actors in cancer control to leverage and build on similar mechanisms for broader cancer control projects. Women's cancers and paediatric cancers, for instance, that have low mortality rates in HICs, provide excellent entry points to leverage existing mechanisms for financing women's and children's health in developing countries.

8.6. CONCLUSION

Although strides have been made, low prioritization of cancer control at national and international levels has resulted in a dearth of funding to adequately address the growing cancer burden. Despite funding from governments and international agencies, the amount of time, effort and investment required for cancer control presents significant challenges in LMICs. However, government led prioritization of cancer policies and financing at the domestic level, by leveraging innovative financing from the private sector and other funding sources, provide strong opportunities to fill the funding gap to meet the NCD target of the UN Sustainable Development Goals by 2030.

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Chapter 9

COUNTRY EXAMPLES

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S.M. HAHN, A. ROSA

9.1. INDIA

9.1.1. Case study: A distributed cancer care model to improve patient access to cancer care by Tata Trusts and the Government of Assam

In India, home to one fifth of the world's population, cancer contributed 5.0% (95% uncertainty interval 4.6–5.5) of the total disability adjusted life years and 8.3% of all deaths in 2016, an increase of 90.9% and 112.8%, respectively, from 1990 [9.1]. This is an estimated rise from 548 000 in 1990 to 1 069 000 in 2016.¹ The crude cancer incidence rate in India increased by 28.2% (95% uncertainty interval 19.9–35.5), from 63.4 per 100 000 people in 1990 to 81.2 per 100 000 people in 2016, but there was no change in the age standardized incidence rate.

These figures are just reported cases. Experts in India believe that current projections are likely to be an underestimate owing to various factors, including infection related mortality, ageing population, malnutrition, existing barriers to access of care and severe under-reporting. The actual numbers could be 1.5–2 times those reported.

In India, all facets of cancer control are compromised because of the high patient load at the limited affordable facilities providing quality care. Despite the efforts of the national cancer care programme, initiated in 1975, to increase capacity for detection and treatment, as well as a comprehensive law for tobacco control enacted in 2003, the density and distribution of cancer centres does not mirror the incidence and prevalence of cancers [9.2]. In several states, such as in the north-eastern region, patients are particularly seriously affected owing to the acute lack of a well developed cancer control infrastructure; inadequate supply of human resources trained in oncology; late presentation and delayed diagnosis, requiring complex treatment; high incidence of preventable cancers due to tobacco consumption; limited connectivity; and expensive private care.

¹ <https://cancerpedia.ca/>

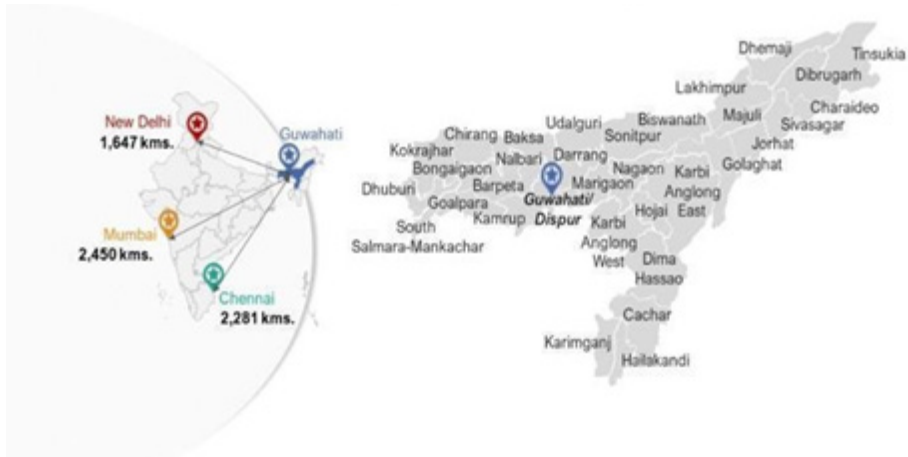


FIG. 9.1. Districts of Assam, India, and distance from major cities.

Most patients have to travel long distances (Fig. 9.1) across the country for treatment owing to the complexities of the stage at which they are diagnosed. This adds to the cost of care for the majority of the patients. A recent study by the All India Institute of Medical Sciences, New Delhi, showed that at least 72% of the cost borne by patients is towards travel, food and accommodation [9.3].

9.1.2. Tata Memorial Centre

Since its foundation in 1932, Tata Memorial Centre (TMC) has established a hub and spoke model to make the best use of resources in a resource constrained setting. TMC's hub (Tata Memorial Hospital) is a highly specialized centre with state of the art technology, education and research facilities, and serves a population of about 40–50 million. Its spokes (community hospitals and primary care clinics) act as the first interface for every individual with suspected or diagnosed cancer. Several spokes together feed into a single hub. The spoke is less capital intensive and has the ability to provide preliminary assessment and diagnosis and deliver care to the local population for common cancers when a treatment plan is formalized by the hub.

Tata Memorial Hospital has also adopted the Disease Management Group concept, which involves a multidisciplinary care team delivering cancer care through specialists in various anatomical cancers. These specialists ensure a uniform standard of care using a multi-pronged approach in terms of human resources development and training, material resources procurement and maintenance, standard shared operating protocols and regular audits to

maintain quality. TMC also uses a cross-subsidization model to address this need, where the patients who can afford to pay for treatment are charged slightly more to subsidize treatment for the underprivileged. Currently, the ratio of paying to subsidized patients at TMC is around 40:60.

9.1.3. Tata Trusts model of care

The Tata Trusts model of cancer care is based on seven elements aimed at setting up a dynamic, interdependent, cross-flowing, technology driven and tiered model of care. These elements are discussed below².

9.1.3.1. Access through disaggregation

The model includes three levels of care with specific components. The third level (L3; Fig. 9.2) involves a day care centre, situated adjacent to the district/civil hospital, that offers diagnostic services (radiology and pathology), along with protocol driven day care management of chemotherapy and RT. Such centres will ease the burden of routine care currently managed by the few apex centres. The second level (L2) is a comprehensive 130 bed cancer centre located at a Government Medical College; it will offer comprehensive cancer services, with the exception of highly technical components such as bone marrow transplant, neurosurgery and complex surgical resections or reconstructive work, as well as advanced diagnostics (molecular biology, genomics and proteomics). The apex level (L1), a 300 bed hospital where all the supply is currently concentrated, will focus on complex care, education and research.

9.1.3.2. Technology driven integration

Radiology, pathology and nuclear medicine reporting and treatment planning can be conducted virtually and remotely from a location where oncology specialists are available using PACS. This will help to overcome the lack of specialized human resources at delivery centres [9.5]. The command centre will manage the following:

- Patient navigation and information dissemination through a multilingual call centre for patient queries, reminders and counselling.
- Collaboration between clinicians through virtual tumour boards, treatment planning, reporting, and asset management and utilization.

² This section is based on Ref. [9.4].

- Standardization and downstreaming of pathways using a ‘maker and checker’ mechanism for diagnostics, chemotherapy and RT. This will support the upskilling of posted resources.
- Tracking the use of assets and movement of personnel in terms of bed utilization, emergency care, billing, QA, shift management and leave support.

The relationship between the service centres and the command centre are illustrated in Fig. 9.3. Technology will be the backbone of this service network.

9.1.3.3. *Standardization of care delivery*

This element includes standardized clinical protocols that follow guidelines issued by the national cancer grid and standard operational procedures, along with equivalent patient experience aspects across all centres [9.5]. Consistent infrastructure and uniform facilities across all centres available close to patients’ homes will eventually mean that patients will not seek to attend only large, city based hospitals for their clinical reputation. A representative high level clinical pathway, using oral cancer as an example, is shown in Fig. 9.4.



FIG. 9.2. A tiered service delivery model aimed at ensuring availability of cancer care at every level (reproduced from Ref. [9.4]). DH: district hospital; GMC: Government Medical College; MSH: multi-speciality hospital.

COUNTRY EXAMPLES

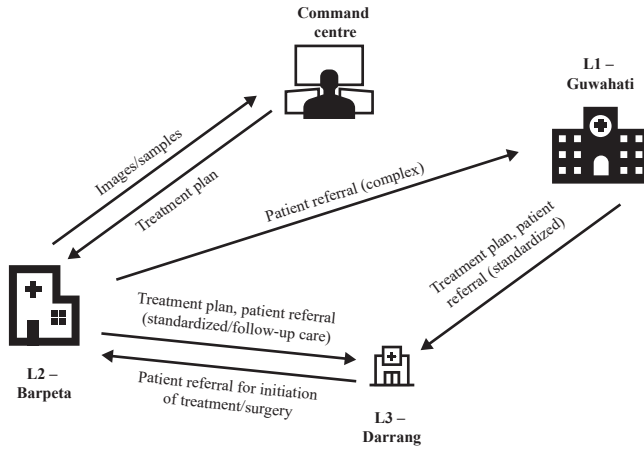


FIG. 9.3. Relationship between the service centres and the command centre (reproduced from Ref. [9.4]).

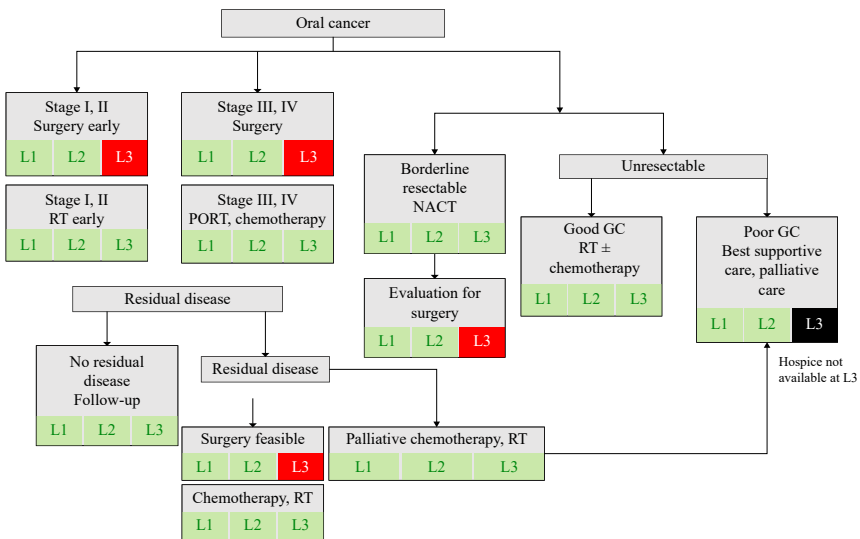


FIG. 9.4. Representative high level clinical pathway for oral cancer. Chemotherapy and radiotherapy are initiated at the centre where surgery is performed and are continued at the centre closest to the patient, under the supervision of the primary physician through the command centre. GC: general condition; NACT: neoadjuvant chemotherapy; PORT: postoperative radiotherapy; RT: radiotherapy.

9.1.3.4. *Patient care financing*

Financial barriers are often quoted as the reason for patients choosing not to access treatment or for dropping out mid-treatment. Each centre is equipped to educate and assist patients take advantage of appropriate insurance schemes, such as ‘Ayushman Bharat’ (Central Government scheme) or ‘Atal Amrit Abhiyan’ (insurance scheme floated by the Government of Assam).^{3,4} Other instruments that may be considered to address this problem are patent loans and subscriptions to the provider centres.

9.1.3.5. *Personnel and training*

The staff in these facilities will pilot a unique model, which is well established in developed countries but is new to India. A team of specialists and nurses being trained through bespoke fellowship courses in oncology of three and six months duration, respectively. The intent is to relieve oncologists of tasks that can be provided by specialist medical personnel with adequate training, thereby addressing the requirement of capable human resources in a limited supply scenario. Such models have already been tried elsewhere across the world [9.6–9.11].

9.1.3.6. *Early detection*

The proposed model adopts a ‘catchment’ approach that goes beyond infrastructure creation using the following initiatives:

- Conducting screening camps. Population based screening for common cancers based on the guidelines of the Government of India for the early detection of cancer and management of the referral system.
- Community awareness about risk factors of cancer and prevention measures. Training of frontline health workers and of women’s self-help groups.
- Tobacco control. Outreach programme for students and teachers from colleges, schools (8–10 class), nursing college students and teachers. Organizing a ‘Cigarette and Other Tobacco Products Act’ sensitization workshop for law enforcement and education officers and working with the Education Department for enforcement of policies for tobacco free educational institutions.

³ <https://www.india.gov.in/spotlight/ayushman-bharat-national-health-protection-mission>

⁴ <https://www.pib.gov.in/PressReleaseIframePage.aspx?PRID=1518544>

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- Training of private practitioners for timely referrals and training of allopathic practitioners (general practitioners, dentists, gynaecologists, etc.).
- Cancer registry. Enabling recording and reporting of cancer cases in every state, implementation of a hospital based cancer registry for hospitals, implementation of a population based cancer registry.
- Palliative care. Providing home based palliative care services to the community in the catchment area. Holding sensitization workshops with relevant government departments to ensure availability of opioids in institutions.
- Patient affordability. Facilitating awareness in the catchment population of government insurance schemes.

9.1.3.7. Research programmes

In addition to clinical and training initiatives, an ambitious research programme in public health, cancer therapeutics and low cost technology has attracted significant grant funding from around the world. Researchers in India from an interdisciplinary background collaborate with international organizations such as King’s College London, UK, the National Cancer Institute and Harvard University, USA, as well as industry partners in biotechnology and therapeutics (Fig. 9.5).

The locations identified for the implementation of this network are shown in Fig. 9.6. The L1 centre at the State Cancer Institute in Guwahati will be

Oral cancer	Risk stratification in oral cancer, in collaboration with Tata Memorial Centre, Mumbai, and National Cancer Institute, USA
Tobacco cessation	A randomized trial using the social contextual model for tobacco cessation, in collaboration with Healis, Mumbai, and Harvard University, USA
Hep B/C epidemiology study	Prevalence of Hep B/C in Assam, in collaboration with Tata Medical Centre, Kolkata, and Assam Medical College
Cervical cancer	Cervical cancer screening: low cost technology to screen and treat, in collaboration with King’s College, London; IIT, Mumbai; RTE, QuantumDx and IARC, Lyon
Future therapeutics study	Intratumorally administered tigilanol tiglate in patients with head and neck squamous cell carcinoma

FIG. 9.5. Research projects in Assam, India in the areas of public health, cancer therapeutics and low cost technology.



FIG. 9.6. Locations of centres of the cancer care network in Assam, India.

strengthened. An L1 centre will be established at the Assam Medical College in Dibrugarh. L2 centres will be established at Government Medical Colleges (existing and proposed) in Barpeta, Dhubri, Jorhat, Karbi Anglong, Karimganj, Kokrajhar, Jorhat, Lakhimpur, Nagaon, Silchar, Tezpur and Tinsukia. L3 centres will be established at District Hospitals in Darrang, Dima Hasao, Goalpara, Golaghat and Sivasagar. Accommodation will be provided for staff at all facilities and for patients near L2 facilities. Parking areas will also be provided. This network will reduce travel times to access cancer services to less than 2.5 h for every person in Assam. The centres are mapped in Fig. 9.6.

9.1.4. Key outputs and intended outcomes

The following key outputs and outcomes are expected from the implementation of the Tata Trusts model of care:

- The model will promote the development of facilities that reduce travel time by up to 80% for patients to access affordable quality care. For instance, for the district of Dhemaji, travel time to the closest facility will decrease from 11 h to 2.5 h; in reality, it will decrease from 60 h to 2.5 h, as most patients are referred directly to Mumbai by their family doctor when cancer is suspected.
- According to estimates, the actual number of newly diagnosed cancer patients per year is approximately 60 000, of which only 20 000 are currently

reported. The network is expected to meet this latent demand for reporting new cancer diagnoses within the state and in a timely manner.

- The model will encourage patients to access care in a timely manner, thereby obtaining diagnosis of the disease at an earlier stage and improving prognosis. Currently, 70% of cases are detected at late stages, with a poor prognosis. Within ten years this is expected to decrease to only 30% of cases being detected at a late stage.
- Assam has a functional insurance scheme for cancer patients. This scheme will provide cost free care to all individuals with an annual family income of less than 500 000 Indian rupees, thereby covering approximately 92% of Assam's population.
- The costs for just accessing cancer care are significant because of initial misdiagnosis and ensuing treatment for other diseases; the need to travel to distant places for accessing care; and accommodation in expensive cities while obtaining care. Implementation of the proposed project is expected to reduce those costs to 10% of the previous amounts. Moreover, out of pocket expenditures will also be reduced owing to a reduction in the cost of providing care and insurance coverage.
- The proposed project will create a cohort of health care professionals to serve the states. The bespoke fellowship and certificate programmes being designed will lead to the availability of specialists, nurses and paramedics who can take on a larger role, fulfilling many tasks expected from oncologists. This will reduce the requirement of superspecialists to about 40% of current requirements.

9.2. GHANA

9.2.1. Case study: Cancer burden in Africa

Ghana is classified by the World Bank as an LMIC. It has a population of 30.8 million and has an agrarian economy, with about 60% of the population employed in the agricultural sector. Ghana's population pyramid has a wide base, a population growth rate of 2.18% and a life expectancy at birth of 66.6 years.⁵ Cancer causes about 5% of all deaths in the country [9.12] and is the second most common cause of death from a non-communicable disease after cardiovascular disease.

The burden of cancer is projected to increase exponentially, particularly in developing countries, driven largely by an increase in life expectancy at birth due

⁵ <https://statsghana.gov.gh/>

to better control of infectious diseases, improved health care systems, adoption of a western lifestyle, obesity, diet, lack of exercise, harmful alcohol intake and smoking. This demographic transition, with its accompanying ramifications, is not unique to Ghana, but is shared with many developing countries.

The increasing burden of cancer demands actions to lessen its impact on countries and societies. This section describes the current installed capacity and processes for the management of cancer in Ghana, providing suggestions and sharing actions that, in hindsight, could result in different outcomes in other developing countries. This will help to formulate guidance on what not to do in the future, as well as actions that are worth repeating, as developing countries make strenuous efforts to improve their capacity to provide satisfactory care through the establishment of comprehensive cancer centres in low resource settings.

Many countries in Africa do not possess the full set of facilities required for comprehensive cancer centres. In most situations, RT services are absent, although they are essential for the care of cancer patients. Other components of care — including laboratory services, imaging, surgical and systemic therapy services — may also be rudimentary and could be improved.

Cancer planning has to be viewed in the broad context of NCDs, as stated in Agenda 3.4 of the United Nations Sustainable Development Goals, which seeks to reduce premature deaths from NCDs, including cancer, by a third by 2030.

The establishment of comprehensive cancer centres needs to begin with a thorough understanding of health systems in a country and of how comprehensive centres will fit into the broad objective of providing care for a country's citizens. Even in developing countries, it is not common to find such centres in all jurisdictions, because either they are too expensive to set up or they may not constitute the most efficient use of resources. Therefore, in establishing or improving comprehensive cancer centres, the referral patterns and health system funding must be scrutinized to provide an objective means of integration into the health system to maximize outcomes within the context of limited resources and to determine where to site them for effectiveness. Thus, the location of such centres must be based on population density (Fig. 9.7).

Reference [9.14] summarizes the structure of the health system in Ghana. Comprehensive cancer management is largely limited to two teaching hospitals located in Accra in the Greater Accra Region and Kumasi in the Ashanti region. These are the most populous regions in the country, with populations of 5.45 million and 5.44 million, respectively (see footnote 5). Access to these teaching hospitals and to the RT services that they offer is only available through a well developed referral system. However, surgery, chemotherapy and related disciplines and services are available in some regional hospitals.

The mandate of teaching hospitals is to provide high level complex care, teaching, training and research and to play a leading role in setting high quality

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clinical standards, guiding policy development and establishing treatment protocols. Teaching hospitals that possess the full set of resources needed for a comprehensive cancer centre provide support to regional hospitals and other teaching hospitals that may not have these resources, in the form of expertise and equipment for RT, chemotherapy and, occasionally, surgery. This support includes participation and oversight of multidisciplinary tumour board meetings that outline management plans for individual patients, either in face to face meetings or remotely. The meetings use the National Guidelines for the Treatment of Cancer to arrive at decisions on the management of patients. In addition to detailing pathways to treatment, this document provides guidance on medical procedures that can be performed by different jurisdictions and should therefore guide referrals. Table 9.1 is an extract from the Treatment Guidelines on how breast cancer can be managed at different levels of care.



FIG. 9.7. Location of cancer centres in Ghana (reproduced with permission from Ref. [9.13]).

TABLE 9.1. LEVELS OF HEALTH CARE (BREAST CANCER) IN GHANA

Procedure	National specialized	Regional	District	Subdistrict	Community
Clinical breast examination	✓	✓	✓	✓	✓
Mammography	✓	✓	✓		
Ultrasound	✓	✓	✓	✓	✓
Wide local excision	✓	✓	✓		
Axillary lymph node dissection	✓	✓	✓		
Sentinel lymph node dissection	✓	✓			
Mastectomy	✓	✓	✓		
Chemotherapy	✓	✓ ^a			
Radiotherapy	✓				
Hormonal therapy	✓	✓	✓	✓	✓
Targeted therapy	✓	✓ ^a			

✓: Provided that there is a trained surgeon or health staff member.

✓^a: Under supervision of a trained person (telemedicine mentoring is encouraged).

9.2.2. Cancer control programme

Comprehensive cancer centres should not be viewed as stand-alone services in cancer care. They need to be seen as part of a well structured cancer control programme consisting of all components of the cancer control continuum; namely, prevention, screening, diagnosis, treatment, palliation and survivorship. At present, these centres address only the treatment component of the cancer control continuum in Ghana, with other aspects dealt with by different agencies. To ensure countrywide coverage of prevention and screening activities

in relation to cancer, implementation needs to be decentralized to district health management teams.

Ghana has a cancer control policy and strategy in line with WHO recommendations. It is currently under review to cover a five year period beginning in 2023. Cancer control activities are incorporated into the non-communicable disease programme of the Ministry of Health. Prevention activities are targeted against modifiable risk factors through public education on alcohol and tobacco use, diet, fruit and vegetable intake, and physical activity. Although Ghana has implemented several aspects of the Framework Convention on Tobacco Control, other aspects of health promotion are not implemented in a systematic fashion and remain largely ad hoc, often gaining traction when marking and celebrating world disease days.

The expanded programme on immunization includes hepatitis B vaccinations for children and adults at risk. The incidence of liver cancer, which ranks third among the most common causes of cancer death, is therefore expected to decrease over time. HPV vaccinations of eligible boys and girls is yet to be added to the immunization panel; it is, however, available in private facilities on demand for a fee.

Screening for cervical cancer is available on demand in some centres. However, there is no national programme for cervical cancer screening, even though there are plans to establish one. In the same vein, there is no national breast screening programme. Screening for breast cancer is largely opportunistic, and walk-in breast screening services are available in some teaching hospitals. Most regional hospitals have a mammography machine, but the concentration is highest in Accra and Kumasi. Failure to attend to this component of the health service and the cancer control continuum will mean that the incidence of preventable cases of cancer and those amenable to early detection will remain high, such that even the best comprehensive cancer care model will struggle to cope.

9.2.3. Clinical care

A comprehensive cancer centre is complete only when all three treatment modalities — namely, surgery, RT and chemotherapy — are present. In addition, relevant imaging, laboratory and pathology reporting services need to be available. For most LMICs, such as Ghana, the availability of RT is limited, owing to its large initial capital requirements and technical nature.

In Ghana, cancer treatment centres do not stand alone as hospitals in the public sector. Rather, oncology centres that offer radiation and systemic therapy operate within hospitals that already exist. These hospitals, therefore, offer other clinical services, including obstetrics and gynaecology, internal medicine, general surgery, paediatrics, imaging and laboratory services. These

departments offer services other than cancer care and extend their services to cancer care depending on the specific diagnosis of the patient, and they typically have facilities for inpatient admission. In contrast, centres that are purpose built to manage only cancer do not receive patients with other diagnoses. For most developing countries, where resources are constrained, the former model is more suitable than the latter; it is easier to deploy and manage, making use of already existing resources such as pathology, imaging, laboratory services and operating theatres. Multidisciplinary tumour board meetings are also easier to organize.

9.2.3.1. Surgery

Surgery for common cancers such as breast, prostate and cervical cancer, is available in a few regional hospitals, but is mostly available in teaching hospitals, where mastectomy, breast conserving surgery, radical prostatectomy, Wertheim's hysterectomy and head and neck surgery are performed on a routine basis. There is therefore a structured referral system from the periphery to district hospitals, and then to regional and teaching hospitals.

Nevertheless, there may be cracks in the referral system, with a proportion of patients 'falling through' these cracks for a number of reasons, ranging from financial difficulties to health seeking behaviours influenced by the adoption of complementary and alternative medicine. The Ghana College of Physicians and Surgeons is responsible for training specialists and generates graduates each year. Over time, surgeons with the capacity to perform cancer surgery have increased in number and move from the teaching hospitals to the regional and district hospitals. Surgeons travel abroad on fellowships to learn special techniques related to cancer on as-needed and 'train the trainers' bases.

9.2.3.2. Oncology

Other than haematological and childhood cancers, which are managed by haematologists and paediatricians, chemotherapy was largely limited to breast cancer treatment until the establishment of RT services in Accra in 1997 and in Kumasi in 2004. This led to the expansion of systemic therapy services for all other cancers. Chemotherapy is delivered by clinical oncologists who have expertise in both radiation and medical oncology. The teaching hospitals (Accra, Kumasi, Ho, Cape Coast and Tamale) have the capacity for procurement, administration and management of the side effects of chemotherapy. As this capacity is inadequate for the country, there is a national plan to establish centres in five other sites that are evenly distributed across the country to increase geographical access to oncology services.

9.2.3.3. *Laboratory, pathology, imaging and multidisciplinary tumour boards*

The existing public cancer centres are not stand-alone centres, but they were built in locations where there were already hospitals with the necessary pathology, laboratory and imaging services — all of which are essential to the successful operation of a cancer centre.

Multidisciplinary tumour boards remain an essential component of cancer care and influence treatment outcomes. It is therefore essential that the requisite surgical and medical experts confer with radiologists, pathologists and ancillary services for decision management. There are tumour boards for common malignancies in the teaching hospitals. Specialized pathology services and laboratory tests that cannot be performed by the hospital's pathology service but are essential to decision making are sent to privately owned laboratory services in the country. These laboratories often have links with foreign facilities and are able to respond, albeit at increased cost and delayed delivery.

There is one private cancer centre in Accra that offers radiotherapy and systemic treatment. However, it relies on surgical services from elsewhere. In addition, it has in-house imaging and engages radiologists on a part-time basis to interpret imaging results. Laboratory services are off-site, with a reliable courier system to transport samples to laboratory services elsewhere for testing.

9.2.4. Establishment of RT services in Ghana

This section describes Ghana's experience in establishing an RT service, along with the lessons learned, both constructive and adverse. An RT service is often absent in most developing countries when establishing comprehensive cancer care. This is largely attributable to the capital intensive nature of the project and the challenging technical demands. There are two functional public RT centres: one in Accra and one in Kumasi. They were sited in those locations because of the thriving medical schools with teaching hospitals located there.

To operate RT services, the Government of Ghana established the National Radiotherapy Committee. Its membership was drawn from the Ghana Atomic Energy Commission, which held the chairmanship, and from the Ministry of Health, the Ministry of Science and Technology, architectural firms, the two teaching hospitals and faculty from the associated universities, namely the University of Ghana and the University of Science and Technology.

At the time, the IAEA considered this project, which was approved in 1994, as a model to demonstrate how strong government commitment, public support and the IAEA's assistance could be mobilized to make the benefits of nuclear technology in medicine directly available to the general population of Member States.

The IAEA's contribution was in the form of Technical Cooperation funds, which were used to finance expert services, equipment and training fellowships, and through extrabudgetary contributions from China and the USA to finance expert services, coordination meetings, equipment, training courses and workshops. The centre in Accra was commissioned in 1997, while the one in Kumasi became operational in 2004.

9.2.4.1. Equipment

The USA supplied brachytherapy manual afterloaders; two for Accra (Korle Bu Teaching Hospital) and one for Kumasi (Komfo Anokye Teaching Hospital), which are government owned. A simulator and a cobalt-60 teletherapy machine provided to Accra were gifts from China. They were manufactured by the China Nuclear Energy Industry Corporation. A cobalt-60 teletherapy machine from Cis-Us, USA, was given to Kumasi. A treatment planning system from SSGI, USA, and dosimetry equipment from PTW New York Corporation, USA, were supplied to Accra.

Expert missions sponsored by the IAEA were carried out for site verification, installation design, commissioning and acceptance testing of the planning system and teletherapy unit.

9.2.4.2. Human resources

The IAEA sponsored the training of five radiation/clinical oncologists, four medical physicists, five RT technologists and three nurses. The duration of the training ranged from six months to four years, depending on the discipline. An engineer received two months of training in China on the maintenance of the equipment.

Two radiation oncologists were sponsored to start service delivery, pending arrival of Ghanaian oncologists in training. The first one was an IAEA expert who spent a total of ten months in charge of coordinating the establishment of the new RT service, its integration into the hospital, the organization of the clinical service, training and research, and the provision of clinical services to patients while the Ghanaian staff were undergoing training. When the tenure of this oncologist expired, he was replaced, until the eventual return of the Ghanaian oncologists from training.

The programme suffered employee attrition, as one medical physicist, two oncologists and three RT technologists left the programme during training or soon afterwards.

9.2.5. Upgrading of radiotherapy services

A field evaluation undertaken by the IAEA in December 1998 brought into sharp focus the inherent deficiencies in the set-up of RT services in Ghana; this was highlighted in a report issued at the end of the evaluation. Among other recommendations, there was a need for the IAEA to verify the quality of equipment supplied through extrabudgetary contributions prior to actual delivery of the equipment and to consider the possibility of replacing the cobalt unit with another one of better proven performance and reliability.

By 2002, the inadequacies of the installed capacity had become very obvious; this was reported to the Project Management Officer for Ghana at the IAEA in one of the periodic reports. The response was that the IAEA could assist Ghana to procure a reliable project, the only proviso being that a letter had to be secured from Ghana's responsible authorities indicating preparedness of the country to pay back any loan procured with assistance from the IAEA.

A letter to this effect was secured in 2005, leading to the invitation of five individuals representing the Ministry of Health and the two teaching hospitals to the IAEA headquarters in Vienna to prepare a document that would eventually be used to procure a loan from the donor market. The document remained inactive until 2008, when the same team was again invited to the IAEA to revise the initial programme and estimates, which were expected to vary with the passage of time.

The completed proposal was submitted to the Ministry of Finance for onward transmission to potential donors. The request was to upgrade the existing treatment centres and to establish a new one in Tamale, which is located in the northern part of the country. While the request for assistance to set up a new treatment centre in Tamale was declined, the Arab Bank for Economic Development in Africa and the Organization of the Petroleum Exporting Countries (OPEC) Fund for International Development agreed to co-sponsor the expansion of RT services in the two existing centres.

Cabinet and parliamentary approval for the US \$13.6 million loan came in October and December of 2009, respectively, followed by legal consultation in March of the following year with a declaration of effectiveness of the loan in March 2010. The Ministry of Health then appointed a project management unit and a steering committee to oversee the project. This was followed by a request for proposals, which led to the selection of companies to carry out construction work and to supply the requested equipment. The Government of Ghana provided 8.66% as counterpart funding, with the remaining amount as a loan.

In February 2012, the Arab Bank for Economic Development in Africa and the OPEC Fund for International Development indicated that the total cost of the equipment exceeded the allocation, with the need therefore to prioritize which equipment was to be purchased to operate within the allocation. The SPECT

camera, CT simulator and dosimetry equipment were removed from the list for Korle Bu, and the following were supplied: a LINAC, a cobalt unit, a treatment planning system, a high dose rate brachytherapy unit and a simulator. All the equipment is currently in operation. In addition, Korle Bu has since acquired a CT simulator, and C-arm fluoroscopy machine dedicated to brachytherapy and a CT SPECT machine. Kumasi received a LINAC, a simulator, a SPECT machine, a treatment planning system and a high dose rate brachytherapy machine.

The implementation of the project was delayed as a result of the aforementioned issues, in addition to delays in the construction of bunkers, in the purchase of equipment for dosimetry and in the purchase of a chiller (this was not included as a cost item in the original document developed in conjunction with the IAEA).

In Accra, there was retrofitting of the bunker housing a decommissioned cobalt unit to accommodate the LINAC. In addition, the decision was made to opt for newer technology in IMRT and VMAT over a dual energy LINAC with electrons, which were supplied to Kumasi.

9.2.5.1. Private sector participation

The private Sweden Ghana Medical Centre became operational in 2012 with installed capacity as follows: LINAC (Elekta) with dual energy and electrons, CT scanner and MRI on-site and Oncentra Planning System; there was no brachytherapy service at the onset. Brachytherapy became available in 2018. Patients requiring brachytherapy for cervical cancer were treated in the government owned set-up until recently. For the first few years of its existence, the centre operated with oncologists, medical physicists and RT technologists from abroad, but now the majority of staff are Ghanaian trained.

The centre also offers chemotherapy for solid tumours and has the required core staff for that purpose, including clinical oncologists and nurses. However, it lacks surgical services and relies on surgeries performed elsewhere.

9.2.6. Cancer registration and radiotherapy utilization

Efficient planning of cancer services needs to be based on data on cancer incidence, types and distribution. Ghana is in the process of developing population based cancer registries. One such registry exists in Kumasi and another in Accra, and they are closely related to the corresponding cancer centres. The country has relied on figures produced by WHO, although these are largely based on extrapolations and estimates. The quality of data in the report issued by the IARC on Ghana for 2012 was classified as 'F', meaning reliance

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TABLE 9.2. INSTALLED RADIOTHERAPY CAPACITY IN GHANA

	Before 2012			After 2012		
	KBTH	KATH	SGMC	KBTH	KATH	SGMC
External beam teletherapy unit	1	1		2	2	1
LINAC				1	1	1
Cobalt-60	1	1		1	1	
Operational units	1	1		2	1	1
Brachytherapy unit	1	1		1	1	1
Low dose rate unit	1	1			1	
High dose rate unit				1		1
Operational units	1	1		1	1	1

Note: KBTH: KATH: Komfo Anokye Teaching Hospital; Korle Bu Teaching Hospital; SGMC: Sweden Ghana Medical Center.

on frequency data, instead of the recommended ‘high quality national or regional data’ with coverage of over 50% [9.15].

In the meantime, progress has been made at establishing population based cancer registries. Data from the Accra Cancer Registry for 2017 gave an incidence rate of 117.6 per 100 000 population, with the ten most common cancers listed as follows in decreasing order of incidence: breast; prostate; cervical; colorectal; liver; stomach; uterus; bladder; lymphoma; connective and soft tissue; and oesophageal cancer [9.16].

Ghana participated in a study under the auspices of the IAEA to determine RT utilization in LMICs. Using a well established methodology, the optimum and actual RT utilization were determined to be 51% and 9%, respectively [9.15]. The reasons for the wide gap in expected and actual utilization have not been formally studied but can be attributed to a number of factors, such as the number and distribution of RT machines across the country, as shown in Table 9.2.

Ghana requires 22 megavoltage machines working 12 h days to enable its 30 million inhabitants to have complete access to RT services according to international standards [9.17]. The current installed capacity of only three

machines and their locations mean that patients have to travel long distances to access these centres and have to stay for long periods away from their families while coping with an inadequate transportation and housing system. Out of pocket payments may be another reason for the observed low RT utilization figures: although RT services are highly subsidized, they remain unaffordable for some patients. Assistance from extended family, social services, religious bodies and private health insurance, as explained previously, has proved helpful but is insufficient to cover health care expenses for a significant number of patients.

The absence of well organized screening programmes for common cancers (which results in many patients remaining undiagnosed or presenting with late stage disease), the use of complementary and alternative medicines, the paradigm to disease causation and therefore health seeking behaviour, and the suboptimal referral systems may all account for the low level of patronage of RT services, leading to a wide gap between the expected utilization rate (51%) and the observed rate (9%) among cancer patients. The low level of unregistered deaths also means that the cause of death cannot be established with certainty in some cases, thus reducing the accuracy of the incidence and type of cancers reported [9.18].

9.2.7. Transition from two dimensional to three dimensional treatment

In 2007, the planning system that was supplied to Komfo Anokye Teaching Hospital at inception ceased operation. The IAEA provided assistance through a cost sharing mechanism to purchase an upgraded version of the Prowess Panther Planning System, which has 3-D planning capability. The challenge then was image acquisition, since there was no CT on-site at the time. The CT scanner of the hospital was too busy to perform this additional function.

Addressing this challenge required a creative solution, using a flat board insert, a laser system and the calibration of two externally located CT scanners. Patients were accompanied by trained radiographers to the locations of the scanners to perform CT scans according to our specification. The images were then transferred to CDs and brought to the centre's planning system. This allowed 3-D planning and treatment on the cobalt-60 unit until recently, when the facility acquired a dedicated CT scanner and a LINAC. Training on dosimetry and contouring has been provided through medium and short training courses since the system was acquired. The above solution was successful in enabling a seamless transition to the use of the newly acquired on-site CT scanner and planning system. Radiation oncologists and physicists have also benefitted from one-year post-qualification fellowships abroad to subspecialize in various tumour sites. These fellowships entail acquisition of skills essential to the application of modern techniques.

9.2.8. Cobalt unit versus LINAC

The cobalt teletherapy machine has relatively simpler electrical and mechanical parts and is less sophisticated than a LINAC. QA protocols are therefore simple, as unstable isotopes decay spontaneously. Cobalt units are less expensive than LINACs; they were used for over a decade with very little machine downtime and are therefore appropriate for low income countries. Cobalt machines have also been used to cure several patients.

Radioactive source change protocols, including transportation and storage of spent sources, can however be challenging and expensive. Dosimetry for the treatment of deep seated tumour sites and in patients with wide separation may also be compromised, as is dosimetry for very superficial sites.

The current installed capacity in Ghana consists of both cobalt units and LINACs. The advantages of the LINAC over the cobalt unit are clear, particularly in increasing therapeutic ratio. However, because of the scarcity of this equipment in West Africa, most vendors consider that it is not economical to situate equipment management sites there. This means that response to equipment malfunction and timely availability of machine parts are compromised. In addition, equipment maintenance contracts are often very expensive, making treatment very costly for patients in the absence of a funding system. This compromises the sustainability of many RT centres and, by extension, comprehensive cancer centres.

9.2.9. Administration

Although the centre is located within the hospital in Accra, it was granted some degree of autonomy from the onset with regard to management. It is fairly independent of the hospital administration, it is audited separately and it has direct access to the Ministry of Health, thus reducing the bureaucracy involved in going through the hospital administration for approvals. The result is that the Accra centre is managed efficiently.

9.2.10. Training

To ensure a sustained supply of staff required for non-surgical treatment of cancer and to solve the perennial problem of employee attrition and over-reliance on development partners for training assistance, Ghana started training radiation/clinical oncologists in 2004 under the supervision of the Ghana College of Physicians and Surgeons, which is accredited to provide training. To maintain and improve standards of practice, foreign external examiners are often invited for examinations. Trainees and graduates have benefited greatly from short training courses, targeted at specific needs, including IAEA programmes.

Training of medical physicists is conducted by the School of Nuclear and Allied Sciences of the University of Ghana through a two year master's programme. To gain admission to the programme, applicants need to obtain a bachelor's degree in physics. The RT programme runs for four years after completing secondary education, resulting in a Bachelor of Science degree from the University of Ghana.

The training of other professionals involved in cancer care, including surgeons, laboratory medicine physicians, pathologists and others, is conducted under the auspices of the Ghana College of Physicians and Surgeons. In addition, there is a framework for CPD through courses organized by the college, as well as sponsorship for international programmes and courses when new techniques are introduced.

At present, Ghana is well positioned to give back to the cancer health care community the benefit that it has derived from the international community. It now offers both long term and short term training in cancer care for many African countries in Clinical Oncology, Medical Physics and Radiation Therapy Technology.

9.2.11. Social sector summary budget brief funding

Ghana subscribes to universal health coverage, which emphasizes access to quality health care where and when people need it without causing financial hardship. However, 27% of the funding for health care is from internally generated funds, which is essentially out of pocket payments. The expenditure on health as a proportion of government spending is 7.6%; this is below the recommended 15% for the subregion [9.19].

Cancer care is not different, capital items including equipment and labour are funded by the Government, but service delivery is mostly funded by out of pocket payments. The National Health Insurance Scheme in Ghana covers aspects of the treatment for breast and cervical cancer only, which means that a large proportion of cancer patients rely on out of pocket payments.

9.2.12. Lessons and conclusion

The incidence of cancer is rising in developing countries, including Ghana. Therefore, cancer care cannot be limited to treatment alone, as in most low income countries, but it needs to include prevention and early detection strategies. RT and chemotherapy play indispensable roles in the management of cancer. Forward planning based on competent data is required to ensure geographical access. Other considerations are siting, to enable full utilization of services, as well as the demography, disease burden and types of cancer in the country.

In Ghana, systemic therapy for cancer has developed in tandem with RT and needs to be considered together during the planning process. Training of staff needs to start well in advance of the commissioning of equipment. External assistance may be necessary in some countries to start an RT service and to upgrade it. However, there needs to be strict monitoring of plans and timely implementation. New and modern, rather than refurbished, equipment needs to be purchased, as this ensures a longer life span, relevance and reduced machine downtime. Maintenance agreements for a minimum of five years should be purchased and incorporated into the vetting of bids, instead of considering the price of only the equipment in the commercial assessment.

A training and recruitment plan to ensure a steady supply of competent staff in all the facets of comprehensive cancer care is crucial. This should include incorporation of staff into the university system, leading to institutionalization of research. Multidisciplinary oncology teams have to be employed and be coordinated in the care of cancer patients. There has to be a structured process for assistance of less staffed centres by better equipped ones.

Sustainability plans need to be put in place to ensure uninterrupted service and satisfactory delivery. Particular attention has to be paid to the quality of equipment supplied on the basis of a detailed budget that includes all components required for successful delivery.

Where RT services are non-existent, the structure for their integration into the health service needs to be clearly defined. Direct access to budget holders is essential for survival of the service.

9.3. UNITED KINGDOM

9.3.1. Cancer incidence in the United Kingdom

The incidence of cancer in the United Kingdom, as elsewhere in the world, is rising, and over 400 000 new cases are diagnosed each year in a population of 68 million people. The NHS in England and Wales, Scotland and Northern Ireland aims to provide free health care at the point of delivery from cradle to grave. Health services are organized in several tiers, from local community services to district hospitals and larger tertiary referral centres. Primary care involves local general practitioners working with populations of 10 000–25 000; district general hospitals serving populations of 200 000–500 000; and specialist centres, which work with populations greater than one million. Health care needs are intended to be met on an equitable basis, irrespective of the location in the

country. Cancer services have always been part of the NHS⁶ since its inception in 1948. Hospital departments with RT have grown in all major towns, but there has been little national coordination and services vary widely across the country.

9.3.2. Cancer service organizations in the United Kingdom

In April 1995, the Department of Health in England and Wales published a policy framework for commissioning cancer services (Calman–Hine report). This report described a model of providing cancer services. The new structure was to be based on a network of expertise in cancer care.

Three levels of cancer care were proposed [9.20]:

- Level 1: Primary care was seen as the focus of care. Models of referral and follow-up were designed to ensure the best outcomes. Primary care practitioners were provided with referral guidelines for cases where cancer is suspected and were intimately involved in the overall care of people with cancer.
- Level 2: Designated cancer units were created in many district general hospitals. These were of sufficient size to support clinical teams with expertise and facilities to manage the more common types of cancer and to deliver systemic therapies.
- Level 3: Designated cancer centres were developed, usually in tertiary referral centres, to provide expertise in the management of all cancers, including common cancers within their immediate geographical area and less common cancers by referral from cancer units. These provide specialist diagnostic and therapeutic techniques, including RT.

The integration of these three levels of care with each other provides a comprehensive cancer service using local expertise and agreed protocols. The network is one of proficiency, not buildings.

The model suggested in the Calman–Hine report was implemented in the United Kingdom, and the MDT model has become the norm for all cancer types in all centres across the country [9.20].

9.3.3. Cancer prevention and screening

Smoking cessation programmes, as well as programmes to promote healthy eating and exercise, have been set up throughout the United Kingdom. These are generally organized within the primary care setting, but the concept that

⁶ <https://www.nhs.uk/>

every contact counts is one that ensures that any health professional will discuss healthy lifestyles with patients at every opportunity.

Since 1988, national screening programmes have been running for breast and cervical cancer. Three-yearly mammographic screenings were set up for all women aged 50–65 and the programme has now been extended to ages up to 70 years. All women aged 25–64 are invited for screening for cervical cancer. Bowel cancer screening for all people aged 60–74 has been taking place since 2006. These screening programmes have been reviewed recently by M. Richards and various modifications to their organization have been proposed [9.21].

9.3.4. Radiotherapy provisions in the United Kingdom

RT is currently delivered through 58 RT centres in the United Kingdom, with 2–11 treatment machines at each site. All centres have access to CT planning, PET/CT and MRI, as well as standard imaging modalities.

Additional RT machines are sited in satellite facilities at a distance from the main centres, but all work is according to protocols and share staff from the centres. Setting up a new RT service or cancer centre is a complex process, not only in designing the bunkers for RT but also in ensuring that the facilities and staff are adequate for safe care. The aim is that for most people in the United Kingdom are within 30–45 min from an RT facility, since there is strong evidence that the access rates are inversely proportional to the distance travelled. Lessons learned from setting up new RT services include the need to integrate them with surgical and other cancer services and that usually more than one RT machine is needed in a satellite facility.

9.3.5. Protons and specialized radiotherapy

In the United Kingdom, access to proton therapy for NHS patients is determined by a national commissioning board, which has well defined protocols for treatment. Until 2018, when proton therapy became available in the United Kingdom, patients were being referred to facilities in the USA or other European countries for treatment.

Stereotactic ablative RT (SABR) has been rolled out in a systematic way across the United Kingdom in a process of commissioning through evaluation. All patients receiving SABR have been recorded and their outcomes have been audited to provide evidence to define the clinical rationale for SABR.

9.3.6. Cancer alliances in the United Kingdom

In 2000, the NHS planned an ambitious programme of investment and reform to develop cancer networks and improve cancer services, including prevention, screening, diagnosis, treatment, supportive care and specialist palliative care. Around 30 cancer networks were set up in England and were tasked with implementing the recommendations in the report. There was investment in the provision of physical facilities, increasing the workforce and developing information systems and treatments. Emphasis was also placed on research, with the goal that 10% of all cancer patients in the country would be enrolled in clinical trials. Over the next 15 years, cancer networks across the country developed local protocols and treatment pathways for specific cancer sites and raised the level of trial involvement until more patients were enrolled in clinical trials than in either the USA or mainland Europe.

RT access in the United Kingdom was at around 37% in 2007, compared with the ideal rate of 50%, which was being achieved in Sweden. Therefore, the National Radiotherapy Advisory Group was set up to improve awareness of RT as a treatment and to increase the number of treatment machines and develop RT techniques. National funding was obtained to train all oncologists in IMRT; the training was carried out through the Royal College of Radiologists, which oversees training and standards in RT in the country.

Trials for breast cancer RT incorporated RT QA procedures. In this way, the standard of routine RT was improved across the country. The major challenges to the provision of cancer services and, in particular, RT in the United Kingdom, are related to staffing. In 2007, the National Radiotherapy Advisory Group proposed various workforce models to ensure sustainable cancer care, and improvements were made; however, in 2019 the level of staffing in all areas remained a significant problem.

Peer review of all cancer services was also set up so that the pathways and treatments in every network were examined by external teams. The close interaction between diagnostic teams in pathology and radiology and therapeutic teams in surgical, medical, clinical and radiation oncology are key drivers to success. The benefits of peer review were accrued not only by those reviewed, but also by the reviewers, who investigated other services and learned from them. Currently, cancer alliances in England and Wales, and similar systems in Scotland and Northern Ireland, are continuing to develop the cancer services across the country.

9.3.7. Service guidelines in the United Kingdom

National service guidance exists for every cancer type. These were developed by the Improving Outcomes guidance until 1999, when the National Institute for Health and Care Excellence took over. These guidelines are updated regularly and include details on RT. Today, the guideline development programme is run by the National Guideline Alliance for National Institute for Health and Care Excellence and their output is available to the general public on the National Institute for Health and Care Excellence website [9.22].

A mandated national RT data set has been set up so that all RT departments monitor their activity and efficiency against others in the United Kingdom. Following the publication of various documents by the Royal College of Radiologists, including guidelines towards safer RT, national reporting of errors and near misses in RT has been used as a learning device for all [9.23]. In addition to clinical audits in cancer centres, these facilities take part in national audits of RT and other treatments, providing comparative information on the state of RT in the United Kingdom. Similar systems apply for systemic therapy, following the NCEPOD (National Confidential Enquiry into Patient Outcome and Death) report in 2007.

9.3.8. Challenges for radiotherapy services in the United Kingdom

9.3.8.1. Workforce

The cancer workforce in the NHS is under strain, with vacancies in almost all professional groups. Therefore, remodelling of services to maximize efficiency and training programmes are needed. Radiation technologists are being trained in planning techniques to alleviate the clinical workload and to generate capacity for clinical oncologists (the doctors responsible for RT and systemic therapies) to use their skills most effectively. Similarly, physics technicians can free up time for clinical physicists.

Training in clinical oncology is organized nationally by the Royal College of Radiologists, with a five year training programme resulting in a fellowship of the Royal College of Radiologists and certification by the General Medical Council. In physics and therapeutic radiography, national training programmes with accreditation and competency assessments are being conducted. These programmes are world renowned, and the standards have been widely adopted in many countries.

9.3.8.2. *Equipment*

Replacement programmes for expensive machinery are being implemented in the NHS with the aim of ensuring equity of RT provision around the country. These programmes always need more resources and, in a tax based health system, RT has to compete with other national priorities. Therefore, not all centres have the latest equipment. However, the standards for all equipment are closely monitored to ensure safe RT anywhere in the country. Regulations for radiation exposure in the United Kingdom under Ionizing Radiation (Medical Exposure) Regulations are tightly controlled, and radiation incidents are reported both in a voluntary and a mandated way to ensure learning from all events [9.24].

9.3.9. Summary

Cancer services are highly organized in the United Kingdom and set up according to strict guidelines to ensure equity of provision across the entire population. As cancer incidence is expected to continue to rise, it will be important to monitor and adopt advances in diagnosis and treatment at the earliest opportunity.

9.4. UNITED STATES OF AMERICA

9.4.1. Cancer control initiatives in the United States of America

Cancer control programmes are the combined efforts of many stakeholders, which collectively form a cancer care system. These stakeholders span the spectrum of health care, including government, industry, hospitals, physicians, researchers and patients. Although some initiatives have been undertaken to coordinate the efforts of these diverse entities, historically they have acted autonomously, without a unifying national strategy. As stated in a 2019 report from the US National Academy of Sciences:

“[T]he current processes and systems of cancer control are at best reactive to circumstances. A proactive and progressive planning system for cancer control policies and operations would necessitate a learning mindset, from individuals to institutions, focused on periodically determining what activities need to be initiated, expanded, or terminated, as well as critically analyzing the trade-offs and tracking the consequences of related decisions” [9.25].

This report also proposes “a complex adaptive system whose elements are interactive and influential at multiple levels of society, starting with the individual” [9.25]. It is recognized that the cancer control system is undergoing transformation and will continue to evolve to provide equitable, high quality cancer care for the population of the USA. The following sections review the cancer care system from three perspectives: finance, research and patient care.

9.4.2. Finance

The USA spends approximately twice as much on health care as other HICs [9.26]. In 2017 alone, the national health expenditure totalled US \$3.5 trillion, or approximately US \$10 000 per person, and 18% of the gross domestic product [9.27]. These medical care costs are projected to increase by 5.5% per year and total US \$6 trillion by 2027 [9.27]. Up to 75% of these health care costs can be attributed to the management of chronic diseases, including cancer, and are expected to increase with the growing proportion of individuals over the age of 65 [9.28]. Cancer related care was estimated to total US \$124.57 billion in 2010 and is projected to increase to US \$157 billion in 2020 [9.29]. Much of this increase in cancer care expenditure in the USA compared with other HICs is driven by rising costs in labour, pharmaceuticals and administration [9.26].

Figure 9.8 illustrates the organization of the country’s cancer care system. Unlike many other HICs, the USA does not have a universal health care system. Instead, insurance coverage is provided through one or several federal, state and private programmes. Medicare is a federal health insurance programme funded by a payroll tax for individuals older than 65 or younger individuals with certain disabilities. Medicaid is a state and federal health insurance programme that covers low income individuals and can be applied in addition to Medicare if the person is eligible for both. The Children’s Health Insurance Program is a state and federally funded paediatric insurance programme covering children in low income families who do not qualify for Medicaid. Private insurance is often obtained through an individual’s employer and funded through tax-exempt premiums. Private insurance can also be purchased directly through the Patient Protection and Affordable Care Act (PPACA) marketplace, which subsidizes costs for low income US citizens.

The PPACA was the most significant restructuring of the US health care system since Medicare and Medicaid were established in 1965. In 2010, the PPACA was enacted with the intent of providing affordable, high quality insurance for US citizens. The PPACA established health insurance marketplaces for private insurance programmes that included subsidies for low income individuals. By 2018, 91.5% of the US population had health insurance coverage,

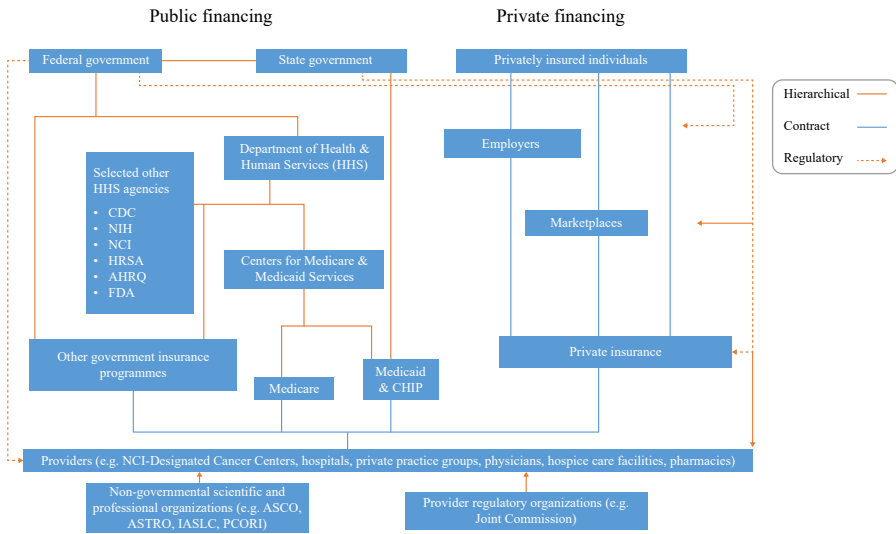


FIG. 9.8. Financial organization of the cancer care system in the USA. As indicated in the figure, there is no distinct cancer care system, and cancer care is integrated within the health care system (figure adapted with permission from Ref. [9.30]). AHRQ: Agency for Healthcare Research and Quality; ASCO: American Society of Clinical Oncology; ASTRO: American Society for Radiation Oncology; CDC: Centers for Disease Control and Prevention; CHIP: Children's Health Insurance Program; FDA: Food and Drug Administration; HRSA: Health Resources and Services Administration; IASLC: International Association for the Study of Lung Cancer; NCI: National Cancer Institute; NIH: National Institutes of Health; PCORI: Patient-Centered Outcomes Research Institute.

with 67.3% from private sources and 34.4% from public funding [9.31]. The PPACA has broadly increased the insurance coverage of individuals with chronic diseases, including cancer. Among individuals with newly diagnosed cancer, the proportion of uninsured patients decreased by one third, from 5.73% before PPACA to 3.81% afterwards [9.32]. Moreover, the PPACA prohibits insurers from denying coverage based on pre-existing conditions. As a result, cancer survivors who in the past would be denied insurance for their cancer history are now eligible for continued coverage [9.33]. However, the future of this programme depends on the acting administrator.

9.4.3. Cancer research

Cancer research in the USA is a broad effort encompassing the spectrum of basic, biomedical, clinical, translational, epidemiological and health services research. In contrast to other countries, where research is consolidated at

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governmental laboratories, medical research in the USA is conducted primarily at universities and directed by independent staff or multi-institutional collaborative study groups [9.34]. Funding for these efforts comes from numerous sources, including government, industry, philanthropic organizations and individual donors. Given the diversity of stakeholder interests, the goals of cancer research can vary tremendously, from the development of novel, high profit pharmaceuticals to enhancing patient–provider communication (Fig. 9.9).

Approximately 1.7 million new cancer cases and 600 000 cancer related deaths were anticipated for 2019 [9.35, 9.36]. The incidence of cancer has remained relatively stable in women and decreased slightly in men, and cancer mortality has decreased by 27% between 1991 and 2016 [9.35]. As a result of this stable incidence and decreased mortality, the number of cancer survivors, defined as persons with a history of a cancer diagnosis, is projected to increase from 16.9 million in 2019 to 22.1 million by 2030 [9.35]. Along the course of their cancer care, these patients will interface with many facets of patient care facilities and their respective providers.

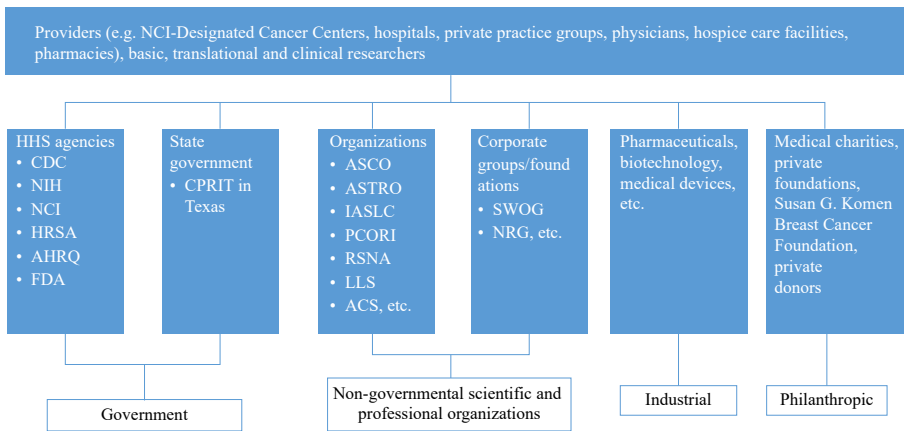


FIG. 9.9. Organization of cancer research funding in the USA. ACS: American Cancer Society; AHRQ: Agency for Healthcare Research and Quality; ASCO: American Society of Clinical Oncology; ASTRO: American Society for Radiation Oncology; CDC: Centers for Disease Control and Prevention; CPRIT: Cancer Prevention and Research Institute of Texas; FDA: Food and Drug Administration; HHS: Department of Health and Human Services; HRSA: Health Resources and Services Administration; IASLC: International Association for the Study of Lung Cancer; LLS: Leukemia and Lymphoma Society; NCI: National Cancer Institute; NIH: National Institutes of Health; NRG: NRG Oncology; PCORI: Patient-Centered Outcomes Research Institute; RSNA: Radiological Society of North America; SWOG: SWOG Cancer Research Network.

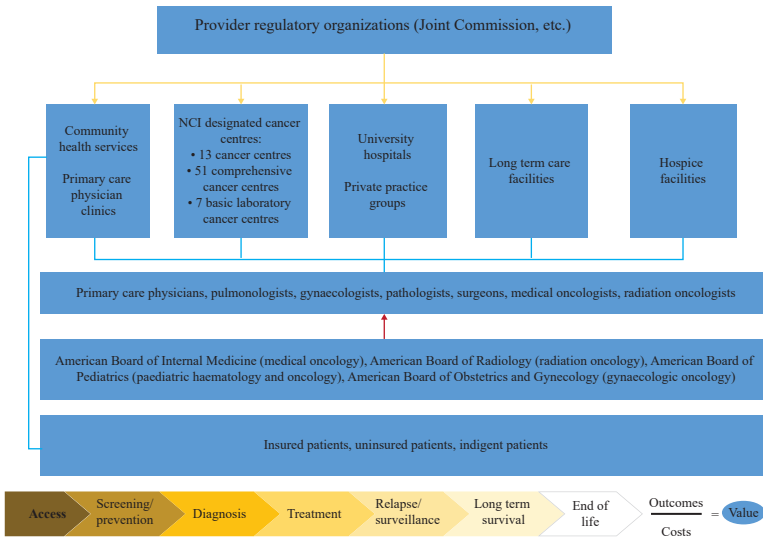


FIG. 9.10. Organization of cancer care providers in the USA.

The current organization of cancer patient care providers is illustrated in Fig. 9.10.

9.4.4. Summary

A 2013 report by the National Academies of Sciences, Engineering, and Medicine stated that cancer care in the USA was ‘in crisis’.⁷ The causes and effects of cancer are complex, and addressing this complexity requires efforts across the continuum of cancer care, starting from basic risk awareness through the processes of cancer prevention, detection, diagnosis and treatment, as well as palliative care, survivorship care and hospice care, and all of the supporting services linked to these efforts. The current cancer control system of the USA is very complex and has evolved over time without a unifying national plan. Numerous federal agencies have diverse roles in cancer control, with little cross-agency coordination or synergy. Each state and territory develops its own cancer control plan, with no integrated strategy or centralized guidance. Perhaps not surprisingly, the current cancer control system is underperforming because of poorly integrated resources, uncoordinated activities and conflicting interests and incentives. As a result, the current cancer control system is reactive at best and is in the process of transformation.

⁷ This section is based on Ref. [9.25].

Extensive research has been carried out to characterize the current cancer care system, identify areas with opportunities for improvement and establish centralized guidance for cancer system transformation. The 2019 report of the National Academies of Sciences, Engineering, and Medicine proposed the concept of a ‘complex adaptive system’: a system consisting of individual entities that act and interact with one another to advance their own interests, “modifying their behaviour in response to what is happening in the rest of the system. The behaviour of a complex adaptive system cannot be understood simply by examining its individual parts in isolation. Instead, the overall behaviour is a product of the way that the individual components influence one another. The hallmark of complex adaptive systems is that behaviours emerge that could not have been predicted by understanding the behaviours of the individual components” [9.25]. Metrics to quantify the value of system performance have been developed to ensure that the transformation is meaningful to cancer patients, payers, providers and the public. Obviously, such a system will need continuous monitoring, feedback, adjustment, modification and transformation to adapt to the need for cancer control in the country.

9.5. BRAZIL

9.5.1. Cancer care organization and cancer centres in Brazil

Brazil is the fifth largest country in the world with an area of 8.5 million square kilometres and widespread regional and social inequalities. It is composed of 26 states and the Federal District and has a population of 209 million people, which is not evenly distributed. There is a strong economic concentration in the south and southeast regions, as well as in the state capitals, where better health care is usually available. The expected cancer incidence in 2018 was 634 000 cases, including non-melanoma skin cancer.

9.5.1.1. Health system

The Brazilian health system is composed of multiple public and private institutions, with funding coming from both sectors individually and in mixed ways. In 2019, 87% of the population relied only on public health care [9.37].

In 1988, the National Constitution Assembly created a public health care system (the Unified Healthcare System or Sistema Unico de Saude (SUS)), which is based on the doctrine of health as a civil right and the state’s obligation [9.38]. SUS aims to offer free comprehensive health care organized in three levels of administration: county, state and federal. Full implementation of SUS has been

TABLE 9.3. MOST COMMON CANCERS IN BRAZIL

Men		Women	
Type	Incidence	Type	Incidence
Prostate	29.2%	Breast	29.7%
Colon and rectum	9.1%	Colon and rectum	9.2%
Lung	7.9%	Uterine cervix	7.4%
Stomach	5.9%	Lung	5.6%
Oral cavity	5.0%	Thyroid	5.4%

hindered by chronic underfunding and the concentration of health assistance in more developed regions [9.39].

For cancer treatments, such as RT and chemotherapy, procedures are paid for through a system of Authorizations for High Complexity Procedures (APACs). The APAC values are linked to bundled payments that do not usually cover the cost of the procedures, especially for new drugs and technologies. The most common cancers in Brazil are listed in Table 9.3 [9.40].

In 1998, the National Cancer Institute (INCA), supported by the Ministry of Health, designed a strategy to expand national public oncological care with the goal of offering complete and integrated assistance. The initiative involved education, research, prevention, assistance and information. Suitable infrastructure was organized, including the creation of Centres and Units for High Complexity Oncological Assistance (CACONs and UNACONs) to provide a comprehensive approach to malignant tumours, from diagnosis and staging to treatment, including surgery, RT, chemotherapy and support services, rehabilitation and palliative care. In 2006, this plan was revised and the National Policy for Oncologic Care was implemented, using as a foundation a regional oncological care network, to tailor the cancer prevention and treatment needs of each state and region of the country. In addition to the entire public infrastructure being directed to cancer care and prevention, the Government also has the help of private and public university hospitals and of a network of philanthropic institutions registered in SUS (Fig. 9.11).

There are 5570 counties in Brazil, and in 2018 there were 360 facilities providing public cancer care in only 182 of those counties (3.26%), with 148 located in state capitals. A little more than half of these facilities, 189, are held

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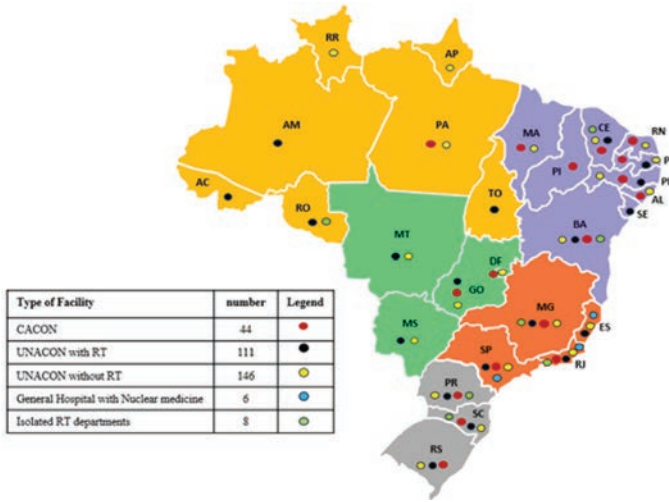


FIG. 9.11. Distribution of oncology centres in Brazil by level of infrastructure. CACON: Centre for High Complexity Oncological Assistance; RT: radiotherapy; UNACON: Unit for High Complexity Oncological Assistance (figure adapted with permission from <http://atlas.oncoguia.org.br>).

by philanthropic organizations; public administration accounts for 35%; and 12% are provided by private initiatives.⁸ Therefore, organizing logistics for cancer care in Brazil, especially in the more remote regions, is an enormous challenge.

9.5.2. Radiotherapy

Despite the Government's efforts, RT availability and access remain limited. To address this, two RT expansion projects were launched. In 2002, Projeto EXPANDE, guided by INCA, was designed to expand infrastructure and RT resources in CACONs and UNACONs. Projeto EXPANDE has implemented only 20 complete and 4 incomplete projects as of 2018 [9.41]. Local budget and management limitations of the recipient hospitals along with bureaucracy compromised the project. The other initiative of the Ministry of Health is the ongoing PERSUS (Projeto de Expansão de Radioterapia no SUS), which was launched in 2012 and was planned to install 80 RT units (80 LINACs and 10 high dose rate brachytherapy units) to expand public access to treatment; as of September 2019, 20 units are operational.

There are still considerable limitations to RT access, with infrastructure concentrated in the southeast and south regions and in the state capitals. The 2018

⁸ <https://www.gov.br/cgu/pt-br>

Ministry of Health census accounts for 363 LINACs and 20 cobalt machines, distributed in 242 departments. Of these, 252 LINACs and 20 cobalt machines are available to SUS in 162 departments. There are two states with no treatment machines available. Further machine obsolescence is expected according to 2022 projections, which predict that 44.6% of machines in general and 50.5% in SUS will become obsolete. The country also has a shortage of brachytherapy machines, which is especially important because of the high incidence of cervical cancer. There are 115 high dose rate brachytherapy units available, 88 of those in SUS.

The techniques available in RT departments, as reported in the 2018 census, are as follows: 2-D RT (69.8% of RT departments); 3-D RT (96.7%); IMRT (53.7%); VMAT (28.5%); radiosurgery (40.1%); and SBRT (24%). Availability of IGRT with CBCT was 19.8% in the departments, 6.2% for ExactTrack and 1.6% for Transponders.

9.5.3. Human resources in radiation medicine

Another problem is staffing. There are 734 RT specialists registered at the National Federal Council, with an average of 19.4 years from graduation and 44.7 years of age. They are concentrated in the southeast region (57.2%), where most of the machines are located.⁹ The National Atomic Agency (Comissão Nacional de Energia Nuclear) has registered only 304 certified radioprotection supervisors, and the problem is exacerbated by a lack of certified physicists, with an estimated 450 medical physics specialists working in Brazil.

9.5.4. Training programmes

There are 32 certified RT residency programmes under the supervision of the Ministry of Education. The RT expansion programme made available 80 new LINACs, for which the Federal Government created incentives for new residencies to increase medical human resources. The increase in the number of residency positions was not proportional to Board Examination approval and there is an ongoing re-evaluation of the skills and competencies to be developed during training. The current programme was also extended from three to four years. For medical physics, there is a two year training programme certified by the Ministry of Education, with 26 positions every year.

There is only one school for dosimetrists, and most specialists are trained in-house, with no formal specialized education required. Therapists have many schools across the country, but most of them offer theoretical training. The practical skills are usually acquired in-house after recruitment.

⁹ <https://portal.cfm.org.br/>

9.5.5. Future directions

There is an ongoing plan to re-evaluate the national demands in oncology and to develop a plan to fulfil the needs in cancer care. The Brazilian Society of Radiotherapy has also launched a project, called RT2030, to assess the RT situation in 2020 and to project the needs for 2030, considering epidemiological and demographic transitions. A reputable business school was appointed to engage specialists to find solutions towards covering 100% of Brazil's needs in infrastructure, human resources, regulation, technology, management, finance and information by 2030. Currently, the Government, medical and industrial societies, maintenance companies, the National Atomic Agency, INCA and NGOs, among others, are working together to find balanced solutions for these challenges.

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Further Reading

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Annex I

DEFINITION OF A NURSE

The International Council of Nurses defines a nurse as follows¹:

“The nurse is a person who has completed a program of basic, generalized nursing education and is authorized by the appropriate regulatory authority to practice nursing in his/her country. Basic nursing education is a formally recognised programme of study providing a broad and sound foundation in the behavioural, life, and nursing sciences for the general practice of nursing, for a leadership role, and for post-basic education for specialty or advanced nursing practice. The nurse is prepared and authorized:

- (1) To engage in the general scope of nursing practice, including the promotion of health, prevention of illness, and care of physically ill, mentally ill, and disabled people of all ages and in all health care and other community settings
- (2) To carry out health care teaching
- (3) To participate fully as a member of the health care team
- (4) To supervise and train nursing and health care auxiliaries
- (5) To be involved in research”.

¹ See <https://www.icn.ch/nursing-policy/nursing-definitions>

Annex II

ONCOLOGY NURSING PROFESSIONAL ORGANIZATIONS

There are many national and international professional organizations for oncology nurses. These include the following:

- International Society for Nurses in Cancer Care;
- Oncology Nursing Society;
- Canadian Association of Nurses in Oncology;
- Cancer Nurses Society of Australia;
- European Oncology Nursing Society;
- Asian Oncology Nursing Society;
- Colombian Association of Oncology Nursing.

Professional societies develop standards of oncology nursing practice, including safe handling of antineoplastic agents, guidelines, standards, guidelines and position statements, and advocate for people with cancer, the profession and cancer care at the policy level.

Cancer care is provided in different settings and populations requiring speciality roles for clinicians. In reviewing levels of cancer care services, three levels are identified regarding the setting, services provided and oncology nursing roles (see Table 4.2). Oncology specialized nurses are needed on the basis of population needs, services provided, availability of resources, local regulations and institutional policies.

Staffing is informed by models used to adjust staffing to patient acuity, such as the Magnuson Model and acuity based staffing. Tools to measure patient needs, team communication and transparency about roles are essential to ensuring suitable staffing for the complexity of care and safety of patients and staff. Oncology specialized nurses provide advanced care for people with cancer and may be integrated into cancer centres on the basis of the services provided, resources available and expertise required to meet the needs of a population, community or country.

Annex III

NURSING SUPPORT FOR MOST COMMON SYMPTOMS AFTER SURGERY, CHEMOTHERAPY, IMMUNOTHERAPY AND RADIOTHERAPY

Tables III–1 to III–4 provide information on the most common side effects of cancer treatments and the required nursing support.

TABLE III–1. NURSING SUPPORT FOR PATIENTS EXPERIENCING SIDE EFFECTS FROM CANCER TREATMENTS — SURGERY^a

Common/frequent symptoms	Assessment	Interventions
Shortness of breath	Assess for level of consciousness, hypoxia, desaturation	<ul style="list-style-type: none"> — Routine vital signs: respiratory rate, heart rate, blood pressure, temperature, SpO₂ — Deep breathing and coughing — Daily exercise — Monitor vital signs, including O₂ saturation — Oxygen therapy prn
Pain ^b	<ul style="list-style-type: none"> — Use a validated tool for screening (e.g. pain thermometer, ESAS, Brief Pain Inventory – Short Form) and more in-depth assessment for pain (e.g. OPQRSTUV) in addition to physical assessment, patient history, risk or history of addictions, psychosocial and spiritual assessment — Assess type of pain (nociceptive, neuropathic, bone metastases, etc.) 	<ul style="list-style-type: none"> — Accessible analgesics (anti-inflammatory, opioids, co-analgesics, etc.) for mild, moderate or severe pain; consider multi-modality approach of opioid sparing to reduce nausea, vomiting, sedation — Consider adjustments needed for opiate naïve patients — Develop analgesic regimen or schedule with breakthrough medication — Consider adjuvant physical or complimentary therapies — Patient and family education regarding plan, self-management and resources

TABLE III–1. NURSING SUPPORT FOR PATIENTS EXPERIENCING SIDE EFFECTS FROM CANCER TREATMENTS — SURGERY^a (cont.)

Common/frequent symptoms	Assessment	Interventions
Infection	<ul style="list-style-type: none"> — Temperature — Signs and symptoms of infection 	<ul style="list-style-type: none"> — Treat with antibiotics prn — Patient and family education on infection prevention, handwashing and safety
Post-operative bleeding	Monitor for haemorrhage (internal or external)	Transfuse red cells, plasma or platelets prn
Nausea/vomiting ^c	<ul style="list-style-type: none"> — Use a validated tool to assess symptom distress (ESAS, NCCN) and more in-depth assessment (e.g. OPQRSTUV) 	<ul style="list-style-type: none"> — Administer antiemetics — Initiate clear fluids after vomiting has stopped — When clear fluids are tolerated, add starchy foods; when tolerated increase to protein rich foods; refer to dietitian if available
Wound and skin care	Monitor surgical site wound for erythema, risk of dehiscence, vascular supply	<ul style="list-style-type: none"> — Prevent skin breakdown – q2h turning and positioning of non-ambulatory patients — Sterile wound care and dressings changes prn
Hydration, dehydration, intake and output, electrolyte balance	<ul style="list-style-type: none"> — Intravenous or oral intake — Urine output — Blood work prn, electrolytes — Postural blood pressure 	<ul style="list-style-type: none"> — Monitor fluid balance — Oral or intravenous hydration prn — Electrolyte supplementation prn
Gastrointestinal function	Bowel sounds, abdominal tenderness, distention	<ul style="list-style-type: none"> — Monitor frequency of bowel movements — Medications to prevent constipation

TABLE III–1. NURSING SUPPORT FOR PATIENTS EXPERIENCING SIDE EFFECTS FROM CANCER TREATMENTS — SURGERY^a (cont.)

Common/frequent symptoms	Assessment	Interventions
<p>^a General resources: https://www.rch.org.au/rchcpg/hospital_clinical_guideline_index/Routine_post_anaesthetic_observation/#Assessment</p> <p>^b See https://www.ons.org/pep/acute-pain</p> <p>^c See the following links:</p> <ul style="list-style-type: none"> — https://reader.elsevier.com/reader/sd/pii/S2256208714001230?token=D514C158DA413009BDE617C179B6FCF965F1CC53CF03D47A94CB8400A39F5DFE3D5C9A1C509751231DBB6854F16F3DF1 — https://www.cancercareontario.ca/en/symptom-management/3131 <p>Note: ESAS: Edmonton Symptom Assessment System; NCCN: National Comprehensive Cancer Network; prn: pro re nata (i.e. as needed).</p>		

TABLE III–2. NURSING SUPPORT FOR PATIENTS EXPERIENCING SIDE EFFECTS FROM CANCER TREATMENTS — CHEMOTHERAPY^a

Common/frequent symptoms	Assessment	Interventions
Neutropenia, pancytopenia	— Patient education for infection prevention, along with signs and symptoms of infection and contact information and/or emergency attention	— Routine or scheduled monitoring of blood counts
Fever (considered a medical/oncological emergency)	<ul style="list-style-type: none"> — Prophylactic use of colony stimulating factors if warranted (by protocol, disease, etc.) — Temperature (>38.5°C), blood pressure (hypotension), respiratory rate (tachypnoea) — Work-up for source of infection, including cultures (blood and urine), chest X ray, viral swabs if indicated 	<ul style="list-style-type: none"> — Prompt administration of fluids and intravenous antibiotics — Prompt/emergency management of cardiovascular deterioration — Intensive care unit admission as needed

TABLE III–2. NURSING SUPPORT FOR PATIENTS EXPERIENCING SIDE EFFECTS FROM CANCER TREATMENTS — CHEMOTHERAPY^a
(cont.)

Common/ frequent symptoms	Assessment	Interventions
Mucositis, oral/throat sores and pain	<ul style="list-style-type: none"> — Conduct routine oral exam with good light source — Assess pattern of mucositis and impact on other symptoms, nutritional intake, activities of daily living 	<ul style="list-style-type: none"> — Implement routine oral care with patient (brushing, flossing prn, oral rinses, lubricants, analgesics, dental follow-up, etc.) — Implement normal saline or bicarbonate oral rinses (1 teaspoon of salt or baking soda in 500 ml/ two cups of water) — Administer analgesics — Ensure fluid intake to meet patient requirements — Avoid physical irritants — Modify diet to bland, soft, liquid, high calorie diet — Sitz bath for mucositis affecting the rectal tissues
Nausea/ vomiting (n/v)	<ul style="list-style-type: none"> — History and pattern of n/v and contributing risk factors (patient, treatment, environmental and other risk factors (e.g. medication history, family conflict)) — OPQRSTUV with subsequent cycles of chemo — Impact of n/v: nutritional intake, weight loss, appetite, etc. 	<ul style="list-style-type: none"> — Combination of strategies or interventions (e.g. drug therapies, information provision, behavioural, psychological) — Intervene with other symptoms (e.g. pain) which may exacerbate n/v — Refer to registered dietitian or provide dietary recommendations
Diarrhoea	<ul style="list-style-type: none"> — Frequency, consistency — Risk of or actual skin breakdown — Hydration and nutrition intake — Dietary advice and foods to avoid 	<ul style="list-style-type: none"> — Antidiarrhoeal medications based on cause — Provide intravenous hydration prn — Maintain hydration orally as soon as possible — Eat small, frequent meals

TABLE III–2. NURSING SUPPORT FOR PATIENTS EXPERIENCING SIDE EFFECTS FROM CANCER TREATMENTS — CHEMOTHERAPY^a
(cont.)

Common/ frequent symptoms	Assessment	Interventions
Constipation	<ul style="list-style-type: none"> — Cause (analgesics, specific chemotherapy drugs, patient history of existing concern, insufficient food/fluid intake) — Assess for bowel obstruction (bowel sounds, palpation, etc.) 	<ul style="list-style-type: none"> — Prevention is critical — ensure flexible bowel routine established — Collaborate with team to ensure patient does not have a bowel obstruction — Treat with fluids, laxatives, stool softeners, stimulants, enemas, etc., depending on opioid induced or non-opioid induced
Fatigue	<ul style="list-style-type: none"> — Focused assessment on fatigue: OPQRSTUV — Other causes: anaemia, infection, fever, nutritional deficiencies, fluid and electrolyte imbalance, medications (e.g. opioids), co-morbidities (e.g. cardiac), other symptoms (e.g. pain) — Laboratory tests: electrolytes, haemoglobin, etc. — Physical examination: muscle wasting, shortness of breath on examination, etc. 	<ul style="list-style-type: none"> — Physical activity with moderate intensity — Energy balance — Coping skills support for chronic fatigue — Referral to physiotherapy or rehabilitation programme — Stress reduction activities — Attention restoring activities (music, gardening, etc.) — Pharmacological interventions are not supported unless to manage a causative factor (e.g. anaemia)

TABLE III–2. NURSING SUPPORT FOR PATIENTS EXPERIENCING SIDE EFFECTS FROM CANCER TREATMENTS — CHEMOTHERAPY^a
(cont.)

Common/frequent symptoms	Assessment	Interventions
‘Chemo brain’, cognitive changes	<ul style="list-style-type: none"> — Causes and associated symptoms (anaemia, infection, hormone changes, fatigue, pain, lack of sleep, etc.) — Impact on patient and family: concentration, memory, multi-tasking, ability to work or return to school, time to do tasks, recall — Track meals, sleep and activities to determine patterns 	<ul style="list-style-type: none"> — Encourage patient to take notes, use calendars, timers and other strategies as reminders or memory aides and organizers — Use phone and electronic reminders or navigation systems — Create and maintain routines — Organize and declutter space — Use a pill organizer — Sharpen mental ability: use repetition, filter out unnecessary information, group similar tasks or information, maintain a diary, practice focusing attention and concentration — Physical exercise — Healthy diet and sustained hydration — Adequate sleep
Weight loss	Per cent weight loss over period of time	Referral to a dietitian, if available

^a General resources:

- <https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/38571>
 - <https://www.ons.org/explore-resources?display=source&source=1506&ref=RO>
- Screening/grading tools and references (used to guide deeper assessment):
- NCCN Distress Thermometer and Problem List, https://www.nccn.org/patients/resources/life_with_cancer/pdf/nccn_distress_thermometer.pdf
 - CUTILLO, A., et al., NCCN Distress Thermometer: Cut off points and clinical utility, *Oncol. Nurs. Forum* **44** 3 (2017) 329–336.
 - Edmonton Symptom Assessment System (ESAS) distress tool, http://www.npcrc.org/files/news/edmonton_symptom_assessment_scale.pdf
 - MD Anderson Symptom Inventory (MDASI), <https://www.mdanderson.org/research/departments-labs-institutes/departments-divisions/symptom-research/symptom-assessment-tools/md-anderson-symptom-inventory.html>

TABLE III–3. NURSING SUPPORT FOR PATIENTS EXPERIENCING SIDE EFFECTS FROM CANCER TREATMENTS — IMMUNOTHERAPY^a

Immune related adverse events	Assessment	Interventions
Infusion reactions		Not treated in the same way as chemotherapy side effects
Dermatological: rash, blisters (<10% of the body), pruritus	<ul style="list-style-type: none"> — Maculopapular rash on limbs or trunk — Pruritus — Impact on sleep — Depigmentation of the skin — Alopecia — More severe reactions may include vitiligo, bullous pemphigoid, psoriatic rashes and severe reactions (e.g. Stevens–Johnson syndrome) 	<ul style="list-style-type: none"> — Topical or systemic corticosteroids — Antipruritic medications — Cold compresses — Oatmeal baths — Systemic antihistamines — GABA agonists in more severe cases — Dose adjustment of immunotherapy — Hospital admission for severe cases: supportive care, intravenous fluids, electrolytes, intravenous steroids
Colitis	<ul style="list-style-type: none"> — Onset and pattern of symptoms — Baseline bowel routine — Frequency of watery bowel movements, urgency, gas, bloating — Presence of blood or mucus in the stool — Abdominal cramping — Any medications taken to manage symptoms — Rule out infection 	<ul style="list-style-type: none"> — CT scan may be required — Rule out infection (C-difficile, bacteria, viral) — Management dependent on cause and frequency of bowel movements — Antidiarrheal medication — Oral or intravenous fluids with electrolyte replacement — Dietary modification — Oral steroids: taper over 6–8 weeks — Intravenous steroids for severe cramping, fever or blood in the stool; may require hospital admission — May require endoscopy — Stop treatment prn

TABLE III–3. NURSING SUPPORT FOR PATIENTS EXPERIENCING SIDE EFFECTS FROM CANCER TREATMENTS — IMMUNOTHERAPY^a (cont.)

Immune related adverse events	Assessment	Interventions
Pneumonitis	<ul style="list-style-type: none"> — Symptoms similar to upper respiratory infection, pneumonia or chronic obstructive pulmonary disease — Rule out infection — Chest CT will be required 	<ul style="list-style-type: none"> — Steroids — Antibiotics — Severity may require intensive care unit admission
Thyroiditis; hypo or hyperthyroidism	<ul style="list-style-type: none"> — Thyroid function prior to each dose of immunotherapy (TSH, T4) — Fatigue 	<ul style="list-style-type: none"> — Steroids (prednisone) for acute thyroiditis — Beta blockers used to manage symptoms of hyperthyroidism — Hypothyroidism: thyroid hormone replacement
Chronic fatigue	See Table 4.2	See Table 4.2

^a General resources:

- <https://www.cancercareontario.ca/en/guidelines-advice/modality/immunotherapy/immune-therapy-toolkit>
- <https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/52976>

Note: Immunotherapy may include active or passive therapies. Active therapies include chimeric antigen receptor (CAR) therapy and cancer vaccines, which stimulate the immune system to recognize and kill cancer cells and are administered only once. The immune system then recognizes future exposure. Passive therapies include immune checkpoint inhibitors and monoclonal antibodies, which require frequent administration to optimize the immune system in its own surveillance of cancer cells. This table focuses on the passive therapies and the most common toxicities, although any body system can be affected.

TABLE III-4. NURSING SUPPORT FOR PATIENTS EXPERIENCING SIDE EFFECTS FROM CANCER TREATMENTS — RADIATION THERAPY^a

Common/ frequent symptoms	Assessment	Interventions
Skin reactions	<ul style="list-style-type: none"> — Grade or degree of skin reaction (RTOG, RISRAS grading tools) — Impact on pain and other symptoms 	<ul style="list-style-type: none"> — Maintain hygiene, gentle washing of intact skin; use mild soap, baby shampoo, sitz bath in perianal areas; pat dry with soft towel — Avoid cosmetic or fragranced products — Patient may use deodorant or antiperspirant — No restrictions on timing of lotions or creams before daily treatments — Use loose clothing, cotton or soft fabrics — Avoid cornstarch and baby powders — Use electric razor for shaving — Moisturize skin (only on intact skin) — Use saline soaks or sitz baths to cool and soothe the skin — Use barrier creams and/or films to reduce moisture loss, reduce friction — Apply topical corticosteroids for pruritus — Use antimicrobial dressings prn — Apply specialized ointments and/or dressings prn — Monitor for signs and symptoms of infection — Use post-treatment sun protection in treated areas
Fatigue	See Table 4.2	See Table 4.2

TABLE III–4. NURSING SUPPORT FOR PATIENTS EXPERIENCING SIDE EFFECTS FROM CANCER TREATMENTS — RADIATION THERAPY^a (cont.)

Common/ frequent symptoms	Assessment	Interventions
Nausea/ vomiting (abdominal radiation)	See Table 4.2	See Table 4.2
Dysphagia/ difficulty swallowing (head and neck, upper oesophagus)	<ul style="list-style-type: none"> — Nutritional intake — Hydration status — Assessment by Speech Language Pathologist if available — Risk of aspiration and need to be NPO 	<ul style="list-style-type: none"> — Encourage swallowing exercises TID for 6–12 months — Promote oral intake to use muscles of swallowing with dietary adjustments from regular solids to soft to moist bite sized solids to minced and moist foods to pureed and moist solids to liquids — Limit distractions during eating; single small sips of liquid and bites of food; eat slowly — Hard swallows, twice with each mouthful; use liquid to clear any food sticking in the throat — Assessment by or referral to a speech language pathologist, as available

TABLE III–4. NURSING SUPPORT FOR PATIENTS EXPERIENCING SIDE EFFECTS FROM CANCER TREATMENTS — RADIATION THERAPY^a (cont.)

Common/ frequent symptoms	Assessment	Interventions
Site specific side effects	<p>— Assess for specific side effects of treatment:</p> <ul style="list-style-type: none"> • Brain: skin, hair loss, n/v, cognitive problems • Head and neck cancer: skin, mucositis, xerostomia (dry mouth), loss of appetite, odynophagia (pain with swallowing), trismus (jaw pain/stiffness), dental problems, n/v, osteoradionecrosis • Chest: skin, hair loss, odynophagia, dysphagia, n/v, radiation pneumonitis • Abdomen: skin, n/v, indigestion, bloating, gas, diarrhoea, radiation enteritis • Pelvis: skin, diarrhoea, n/v, rectal inflammation, pain with bowel movements, bowel incontinence, radiation enteritis, sexual health problems 	
Late effects of treatment	<p>Fertility, cardiac (chest radiotherapy), radiation pneumonitis, skin changes (telangectasia, hyper or hypopigmentation), secondary cancers</p>	

TABLE III–4. NURSING SUPPORT FOR PATIENTS EXPERIENCING SIDE EFFECTS FROM CANCER TREATMENTS — RADIATION THERAPY^a (cont.)

Common/ frequent symptoms	Assessment	Interventions
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- ^a General resources:
- <https://www.cancercareontario.ca/en/symptom-management>
 - <https://www.ons.org/explore-resources?display=source&source=1506&ref=RO>
- Screening/grading tools and references (used to guide deeper assessment):
- Distress thermometer and problem list,
https://www.nccn.org/docs/default-source/patient-resources/nccn_distress_thermometer.pdf?sfvrsn=ef1df1a2_9
 - Edmonton Symptom Assessment System (ESAS)/distress tool,
http://www.nprc.org/files/news/edmonton_symptom_assessment_scale.pdf
 - M.D. Anderson Symptom Inventory (MDASI),
<https://www.mdanderson.org/research/departments-labs-institutes/departments-divisions/symptom-research/symptom-assessment-tools/md-anderson-symptom-inventory.html>

Note: NPO: nil per os (i.e. nothing by mouth); n/v: nausea/vomiting; TID: ter in die (i.e. three times a day).

Annex IV

STANDARD HOSPITAL BASED REGISTRY FORM

1. AADHAR number

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2. HBCR registration number

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

3. Hospital case file number

4. Name of the patient

A. Age (at the time of first contact with HBCR)

B. Age (at the time of diagnosis of cancer)

5. Gender **Male** **Female** **Other**

6. Address of the patient

District _____

State _____ POST CODE _____

Contact number of the patient _____

7. Other details

Name	Relation	Contact No.

8. Education of the patient

(1) Not applicable (for children below 5 years); (2) Illiterate; (3) Primary; (4) Middle; (5) Secondary; (6) Technical — after metric; (7) College and above; (8) Others — specify; (9) Unknown

9. Religion

(1) Hindu; (2) Muslim; (3) Christian; (4) Sikh; (5) Jain; (6) Buddhist; (7) Parsi; (8) Indigenous faith/other (specify); (9) Unknown

10. Occupation

(1) Professional; (2) Semiprofessional; (3) Clerical, shop owner; (4) Farmer;
(5) Skilled worker; (6) Semiskilled worker; (7) Unskilled worker; (8) Unemployed;
(9) Student; (10) Housewife; (11) Government employee; (12) Private employee;
(13) Other (Specify); (14) Not applicable to children

11. Patient referred from other hospital

YES/NO

12. If YES in Q12, then referred from which hospital

13. Date of diagnosis

--	--	--	--	--	--	--	--	--	--

14. Basis of diagnosis

(1) Death certificate; (2) Clinical; (3) Radiology (X ray, USG, MRI, CT & endoscopy);
(4) Specific tumour markers; (5) Histology; (6) Cytology; (7) Bone marrow; (8) Other;
(9) Unknown/no information

15. Clinical extent of disease

(1) In situ; (2) Localized; (3) Direct extension; (4) Regional lymph node involvement;
(5) Direct extension with regional node involvement; (6) Distant metastasis;
(7) Not palpable; (8) Very advanced; (9) Unknown/no information

16. Primary site of the tumour — Topography _____

ICD-O-3 Coding

C

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17. Primary histology — Morphology _____

ICD-O-3 Coding

--	--	--	--	--	--	--

 M

18. Secondary site _____

ICD-O-3 Coding

C

--	--	--	--

19. Histology — Secondary _____

ICD-O-3 Coding

M

--	--	--	--	--	--

20. Site of the tumour (ICD-10)

--	--	--	--	--	--	--	--

21. Staging system followed

(1) TNM; (2) FIGO; (3) Ann Arbour; (4) Not applicable; (5) Others (specify); (9) Unknown

TNM

T

N

M

22. Intent of treatment

a. Curative

b. Palliative

23. Date of start of treatment (dd/mm/yy)

--	--	--	--	--	--	--	--

24. Treatment status

24.1.

(1) Complete; (2) Continued; (3) Left the treatment; (4) No treatment availed; (5) Observe; (6) Referred for treatment outside hospital; (7) Best supportive care; (8) Unknown

24.2. Types of treatment given

(1) Surgery (S); (2) Radiotherapy (R); (3) Chemotherapy (C); (4) S + R; (5) S + C; (6) R + C; (7) S + R + C; (8) Hormonal therapy (H); (9) S + H; (10) R + H; (11) C + H; (12) S+ R +H; (13) S+ C + H; (14) R + C + H; (15) S + R + C + H; (88) Other (specify); (99) Unknown

25. Date of last follow-up

--	--	--	--	--	--	--	--

26. Patient status

A. Alive — If alive, date of follow-up

--	--	--	--	--	--	--	--	--	--

B. Dead — If dead, date of death

--	--	--	--	--	--	--	--	--	--

Cause of death _____

27. Mode of cost payment for treatment

(1) Government scheme; (2) Government employees to file for reimbursement; (3) Other health scheme; (4) By own/no scheme

28. Name of the person completing form _____

Annex V

PROCESS OF FOLLOW-UP (MEDICAL RECORDS DEPARTMENT AND CANCER REGISTRY)

Medical records provide healthcare personnel with access to all relevant information of patients, thus helping to ensure treatment continuity. Figure V–1 illustrates a process for properly following up on patients to ensure that records reflect complete data.

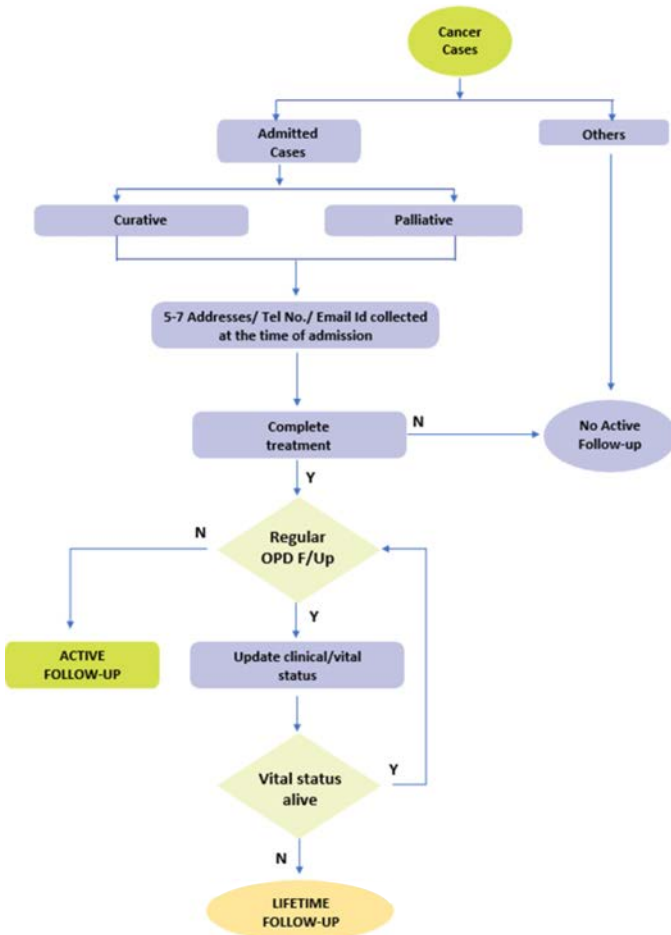


FIG. V-1. Active follow-up of patients.

Annex VI

SEQUENCE OF ACTIVE FOLLOW-UP METHODS (MEDICAL RECORDS DEPARTMENT AND CANCER REGISTRY)

Figure VI-1 outlines the sequence of steps used by active follow-up methods.

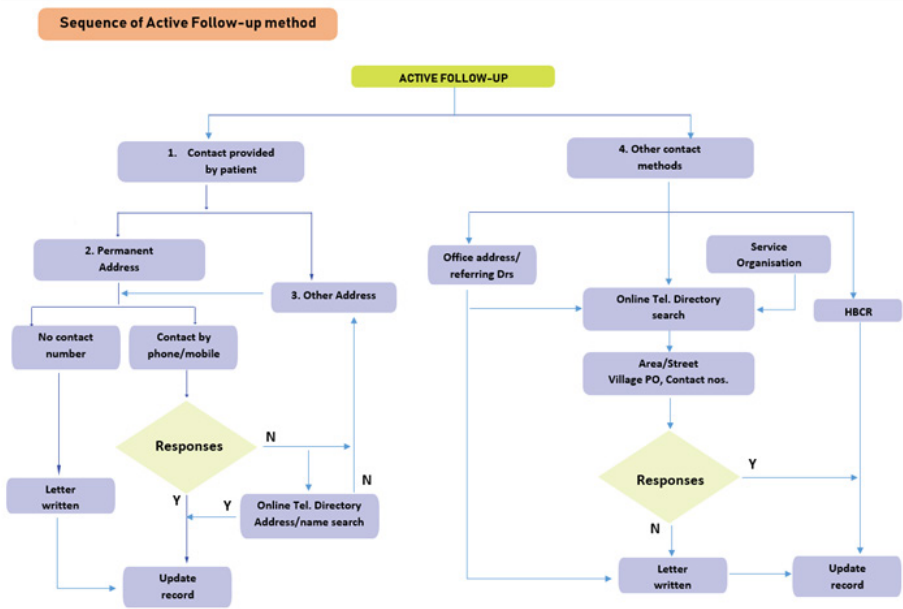


FIG. VI-1. Sequence of steps in active follow-up methods.

ABBREVIATIONS

ALL	acute lymphoblastic leukaemia
APN	advanced practice nurse
ASCO	American Society of Clinical Oncology
CBC	complete blood count
CHC	community health centre
CPD	continuing professional development
CRN	clinical research nurse
CRT	conformal radiotherapy
CSO	civil society organization
CT	computed tomography
DICOM	Digital Imaging and Communications
DNP	Doctor of Nursing Practice
DNR	do not resuscitate
ED	emergency department
ePMA	electronic prescribing and medicines administration
ESMO	European Society for Medical Oncology
ESR	European Society of Radiology
FISH	fluorescence in situ hybridization
GLOBOCAN	Global Cancer Observatory
HBCR	hospital based cancer registry
HIC	high income country
HIS	hospital information system
HPV	human papillomavirus
IACRN	International Association of Clinical Research Nurses
IARC	International Association for Research on Cancer
ICD	International Classification of Diseases
ICH-GCP	International Council on Harmonization – Good Clinical Practice
ICN	International Council of Nurses
ICU	intensive care unit
IGRT	image guided radiation therapy
IMP	investigational medicinal product
IMRT	intensity modulated radiation therapy
INCA	National Cancer Institute (Brazil)
INR	international normalized ratio
IRB	institutional review board
ISO	International Organization for Standardization
IT	information technology

LEEP/LLETZ	large loop excision of transformation zone
LINAC	linear accelerator
LIS	laboratory information system
LMIC	low and middle income country
MDCT	multidetector computed tomography
MDT	multidisciplinary team
MNT	medical nutrition therapy
MRI	magnetic resonance imaging
NCCN	National Comprehensive Cancer Network (United States of America)
NCCP	national cancer control programme
NCD	non-communicable disease
NGO	non-governmental organization
NGS	next generation sequencing
NHIP	National Health Insurance Program (Philippines)
NHS	National Health Service (United Kingdom)
NICCA	National Integrated Cancer Control Act (Philippines)
OOH	out of hospital
OPD	outpatient department
OPEC	Organization of the Petroleum Exporting Countries
PACS	Picture Archiving and Communications System
PACT	Programme of Action for Cancer Therapy
PAHO	Pan American Health Organization
PALM	pathology and laboratory medicine
PCR	polymerase chain reaction
PET	positron emission tomography
PPACA	Patient Protection and Affordable Care Act
PPE	personal protective equipment
QA	quality assurance
QC	quality control
QI	quality improvement
QMS	quality management system
QUATRO	Quality Assurance Team for Radiation Oncology
RIS	Radiology Information System
RT	radiation therapy
RTT	radiation therapy technician
SABR	stereotactic ablative radiotherapy
SACT	systemic anticancer therapy
SBRT	stereotactic body radiation therapy
SHS	serious health related suffering
SOP	standard operating procedure

SPECT	single photon emission computed tomography
SRS	stereotactic radiosurgery
SUCCESS	Scale Up Cervical Cancer Elimination with Secondary Prevention Strategy
TMC	Tata Memorial Centre
TNM	tumour, node and metastasis
UNIDO	United Nations Industrial Development Organization
VMAT	volumetric modulated arc therapy
WHO	World Health Organization

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Cancer centres are a major resource in ensuring a comprehensive approach to cancer treatment and its planning. This publication proposes a framework to develop a cancer centre and/or to strengthen the provision of services in an existing cancer centre. The framework provides the features of multidisciplinary cancer care and details the infrastructure, human resources and equipment for different services. This framework is expected to be used as a guide to developing cancer centres, taking into consideration the local context and resources.

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