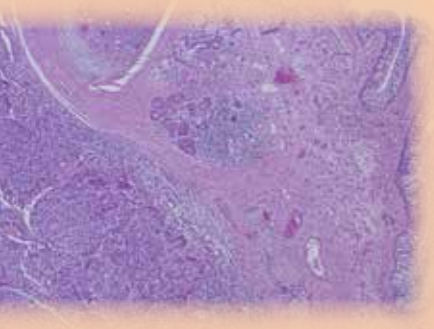
World Health Organization

WHO list of priority medical devices for cancer management

WHO Medical device technical series



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Navigation diagram

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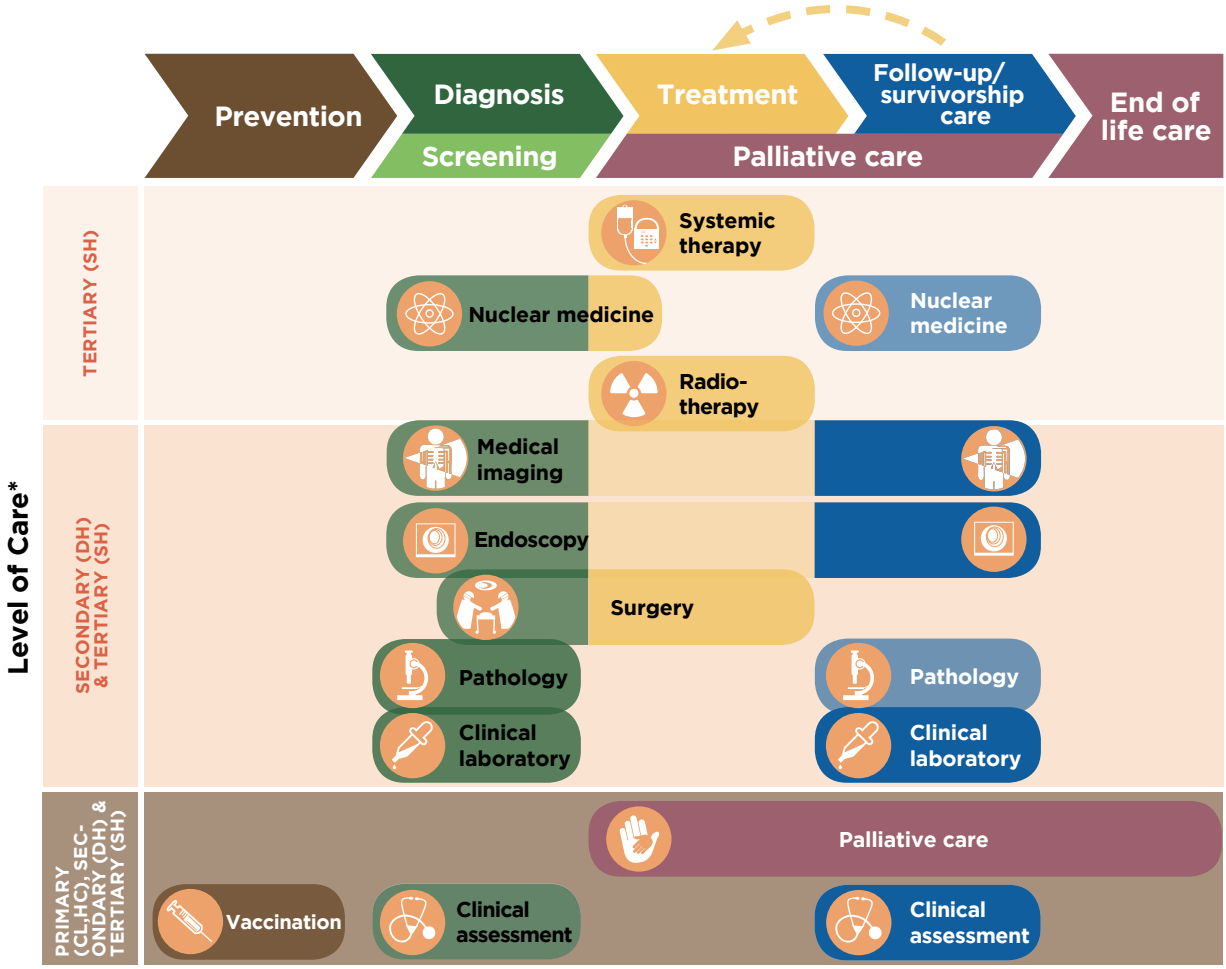


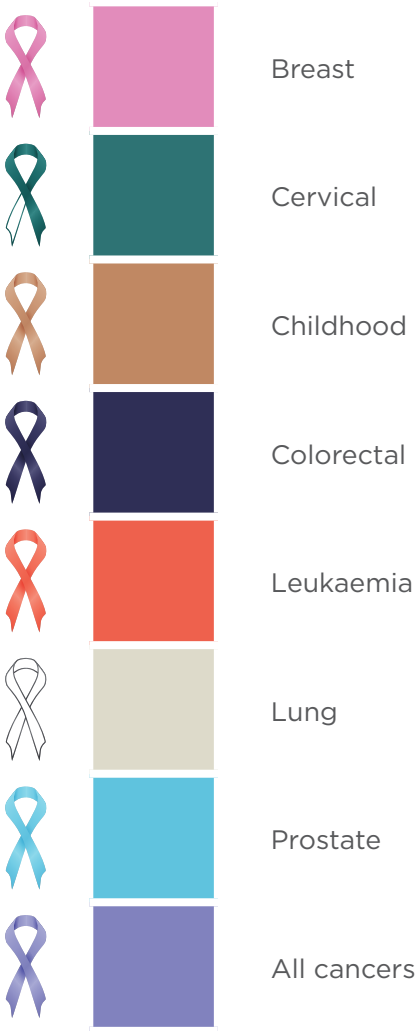
* Appropriate level of care will depend on the particular intervention, setting, and available infrastructure and human resources.

CL Community Level health post DH District Hospital HC Health Centre SH Specialized Hospital

Acronyms and abbreviations

ACR	American College of Radiology
ACS	American Cancer Society
AORTIC	African Organisation for Research and Training in Cancer
ASCO	American Society of Clinical Oncology
BHGI	Breast Health Global Initiative
BLQS	Bureau of Laboratory Quality and Standards, Thailand
BSS	Basic Safety Standards
C Difficile	Clostridium difficile infection, also named CDI
CBC	Complete blood count
CEA	Carcinoembryonic antigen
CGL	Clinical guidelines
CKC	cold knife conization
CL	Community Level health post
CT	Computed Tomography
DH	District Hospital
DIC	Disseminated intravascular coagulation
DICOM	Digital Imaging and Communications in Medicine
DITTA	Global Diagnostic Imaging, Healthcare IT, and Radiation Therapy Trade Association
DSM	Department of Standards Malaysia
DSRS	Digital specimen radiography system
ECC	Endocervical Curettage
EQA	External Quality assurance
ESMO	European Society for Medical Oncology
EVIDEM	Evidence and Value Impact on Decision Making
FIT	Faecal immunochemical testing
gFOBT	Guaiac faecal occult blood test
GIEESC	Global Initiative for Emergency and Essential Surgical Care
GMTA	Global Medical Technology Alliance
HC	Health Center
HIC	High-income country
HPV	Human papillomavirus
HTA	Health Technology Assessment
HTAi	Health Technology Assessment International
HTM	Health Technology Management
IAEA	International Atomic Energy Agency
IANZ	International Accreditation New Zealand
IAPO	International Alliance of Patients' Organizations
IARC	International Agency for Research on Cancer
ICEDOC	International Campaign for Establishment and Development of Oncology Centres
ICRP	International Commission on Radiological Protection
ICT	Information and communication technology
IFBLS	International Federation of Biomedical Laboratory Science
IFCC	International Federation of Clinical Chemistry and Laboratory Medicine
IFHE	International Federation of Hospital Engineering
IFMBE	International Federation for Medical and Biological Engineering
ILO	International Labour Office
IOMP	International Organization for Medical Physics
ISR	International Society of Radiology
ISRRT	International Society of Radiographers and Radiological Technologists
IUA	International Union of Architects
LEEP/LLETZ	Large loop excision of transformation zone
LMIC	Low-middle income country
MCDA	Multi criteria decision analysis
MDT	Medical Devices Team
mHealth	Mobile health
MRI	Magnetic Resonance Imaging
MRSA	Methicillin resistant Staphylococcus Aureus
NABL	National Accreditation Board for Testing and Calibration Laboratories, India
NATA	National Association of Testing Authorities
NCCN	National Comprehensive Cancer Network
NCD	Noncommunicable disease
NCI	National Cancer Institute
NCRP	National Council on Radiation Protection and Measurements
NEQAS	National External Quality Assurance Service
NGO	Non-Governmental Organization
NIH	National Institutes of Health
NordiQC	Nordic immunohistochemical Quality Control
OFID	OPEC Fund for International Development
PACS	Picture Archiving Communication System
PACT	Programme of Action for Cancer Therapy
PAHO	Pan American Health Organization
PEG	Percutaneous endoscopic gastrostomy
PEN	Package of Essential Noncommunicable diseases, WHO
PET	Positron Emission Tomography
PICC	Peripheral Inserted Central Catheter
PMD	Priority Medical Devices
POC	Point-of-care
PPE	Personal protective equipment
PT	prothrombin time
PTT	partial thromboplastin time
QA	Quality Assurance
QC	Quality control
RCPA-QAP	Royal College of Pathologists of Australia - Quality Assurance Program
RCR	Royal College of Radiologists
RIS	Radiological Information System
RTT	Radiation Therapist/Radiation Therapy Technologist
SANAS	South African National Accreditation System
SH	Specialized Hospital
SLACOM	Sociedad Latinoamericana y del Caribe de Oncología Médica
SPECT	Single Photon Emission Computed Tomography
TPS	Treatment Planning System
TRUS	Transrectal ultrasound
UICC	Union for International Cancer Control
UKAS	United Kingdom Accreditation system
UN	United Nations
UNICEF	United Nations Children's Fund
UNOPS	United Nations Office for Project Services
UPS	Uninterruptible Power System
WASPaLM	World Association of Societies of Pathology and Laboratory Medicine
WFUMB	World Federation for Ultrasound in Medicine and Biology
WHA	World Health Assembly
WHO	World Health Organization

Cancer colour codes



Breast

Cervical

Childhood

Colorectal

Leukaemia

Lung

Prostate

All cancers

Executive summary

Medical devices are indispensable for health care provision, as emphasized in various WHO resolutions. The rise of noncommunicable diseases (NCDs) demands that WHO identify appropriate, basic and priority medical devices, and compile a WHO model list and clearing house that can serve as a reference to Member States. The outcome of this process is the *WHO list of priority medical devices for cancer management* publication, which describes the medical devices that are required to manage cancer, based on the list of clinical interventions selected from clinical guidelines on prevention, screening, diagnosis, treatment, palliative care, monitoring and end of life care. This publication addresses medical devices that can be used for management of cancer and specifically describes medical devices for six types of cancer: breast, cervical, colorectal, leukemia, lung and prostate.

The first section of this publication defines the global increase in cancer cases, the global goals to manage NCDs and the WHO activities related to these goals.

The second section presents the methodology used for the selection of medical devices that support clinical interventions required to screen, diagnose, treat and monitor cancer stages, as well as the provision of palliative care, based on evidence-based information.

The third section lists the priority medical devices required to manage cancer in seven different units of health care services: 1. Vaccination, clinical assessment and endoscopy, 2. Medical imaging and nuclear medicine, 3. Surgery, 4. Laboratory and pathology, 5. Radiotherapy, 6. Systemic therapy and 7. Palliative and end of life care. The lists include the basic technologies required to provide general services and the specific priority medical devices to manage cancer. This section also examines other health system components such as infrastructure, human resources and quality management requirements and guidance documents by service unit. This is the core information presented by clinical service unit. It is very important to note the need for effective communication with the patient and among clinicians of diagnostic results and treatments across all components of the care pathway, of the different units and to note the interaction and sequencing of the interventions as thus of all the medical devices required to perform them.

The last section proposes the activities required in a country or setting where the present guidance and lists are to be implemented, on available clinical guidelines based on evidence and multidecision criteria by international experts but the expensive and specialized technologies for specialized hospitals may require a comprehensive health technology assessment considering local infrastructure, human resources and costing. These activities include performing a needs assessment and cross-referencing and adjusting lists according to country priorities, infrastructure, specialized human resources available and budget; a health technology assessment for the prioritization of medical devices to be included in the country's benefits package or to cost them for reimbursement if this is applicable; and the selection and incorporation of the devices into the healthcare system within a health technology management process.

Finally, this document mentions future activities in the development of the WHO list of priority medical devices for cancer management where further investments are needed.

The annexes describe the clinical interventions considered in this study, the experts information as well as the methodological tools used to develop these lists, including the three working tools to prioritize and select the interventions and technologies and finally a compilation of all the medical devices listed in this publication, by categories, for the users reference.

This book is intended for ministries of health, public health planners, health technology managers, disease management, researchers, policy makers, funding and procurement agencies, and support and advocacy groups for cancer patients.

Special acknowledgments go to all experts involved in the development of this document, who collaborated with the main goal of helping Member States, NGOs, academia and the private sector to together address the technological gap in order to improve management of cancer patients worldwide, and especially in low-resource settings.

I. Background

I.I WHO leadership priorities: increasing access to medical products

Equity in public health depends on access to essential, safe, high-quality, affordable and effective medical technologies. Improving access to medical products is central to the achievement of universal health coverage, and is one of six *WHO Leadership Priorities* (1) (Fig.1). To this end, the *WHO Global Programme of Work* includes a section dedicated to increasing access to medicines and health technologies and strengthening regulatory capacity. A target output for this work is to enable countries to develop or update, implement, monitor, and evaluate national policies on better access to health technologies; and to strengthen evidence-based selection and rational use of health technologies (2).

Fig. 1. WHO Leadership Priorities Infographic. (1)

I.II WHO resolution on health technologies

The first resolution on health technologies by the World Health Assembly was approved in May 2007 (WHA60.29). Through the passing of this resolution, delegations from Member States acknowledged the importance of health technologies for the achievement of health-related development goals, urged the expansion of expertise in the field of health technologies (in particular medical devices), and requested WHO to take specific actions to support Member States (3).

The WHA60.29 Health Technology Resolution specifically requests WHO:

1. To provide support to Member States, where necessary in establishing mechanisms to assess national needs for health technologies, and to assure their availability and safe use.
2. To provide technical guidance and support to Member States in analysing their needs and health systems prerequisites for health technologies, in particular for medical devices.
3. To work jointly with other organizations of the United Nations system, international organizations, academic institutions and professional bodies in order to provide support to Member States in the prioritization, selection and use of health technologies, in particular medical devices.
4. To establish and regularly update an evidence- and web-based health technologies database to serve as a clearing house which will provide guidance on appropriate medical devices according to levels of care, setting, environment, and intended health intervention, tailored to the specific needs of countries or regions.
5. To provide support to Member States with vulnerable health care systems to identify and put in place appropriate health technologies, in particular medical devices, that facilitate access to quality services in primary health care.

Other resolutions aim to ensure improved access, quality and use of medical products and technologies, as does the WHO Global Programme of Work. For example, WHA67.20 (4) calls for medical devices regulations and WHA67.23 (5) stresses the importance of health technology assessments to select technologies in order to provide universal health coverage.

I.III UN declaration and action plan for noncommunicable diseases

NCDs – mainly cardiovascular diseases, cancers, chronic respiratory diseases and diabetes – are the biggest cause of death worldwide. Approximately 38 million deaths occur annually from NCDs (68% of global deaths), including 16 million people who die prematurely before the age of 70 (6). Most of these premature deaths from NCDs occur in low- and middle-income countries (LMIC), where the burden of NCDs is rising disproportionately. Most premature deaths are linked to common risk factors, namely tobacco use, unhealthy diet, physical inactivity, and harmful consumption of alcohol.

To strengthen national efforts to address the burden of NCDs, the United Nations General Assembly adopted the Political Declaration on NCDs in 2011. The 66th World Health Assembly endorsed the WHO Global Action Plan for the Prevention and Control of NCDs 2013-2020 (resolution WHA66.10) (7) and the Global Monitoring Framework for NCDs that tracks its implementation. The tracking will occur through monitoring and reporting on the attainment of nine voluntary global targets to decrease premature mortality from noncommunicable diseases by 25% by 2025 (“25 by 25”). One of these nine targets specifically concerns access to medical technologies:

> **“80% availability of the affordable basic technologies and essential medicines, including generics, required for treating major NCDs in both public and private facilities.”**

I.IV The burden of cancer

Cancer is a generic term for a large group of diseases that can affect any part of the body. Other terms used are malignant tumours and neoplasms. One defining feature of cancer is the rapid creation of abnormal cells that grow beyond their usual boundaries, which can then invade adjoining parts of the body and spread to other organs. The latter process is referred to as metastasis (8). Metastases are the major cause of death from cancer (9).

With approximately 14 million new cases, 8.2 million cancer related deaths, and 32.6 million people living with cancer in 2012, cancer represents the leading cause of death worldwide (10, 11), killing more people than HIV/AIDS, malaria and tuberculosis combined (Fig. 2). The number of new cases is expected to rise from 14 million to 22 million by 2030; this is about a 70% increase in only two decades (11) and the number of global cancer deaths is projected to increase by 45% in the period from 2007 to 2030.

The five most common sites of cancer diagnosed among men in 2012 were: lung, prostate, colorectal, stomach, and liver cancer. Among women in 2012 they were: breast, colorectal, lung, cervix, and stomach cancer (9). Five leading risk factors causing approximately one third of all cancers are: high body mass index, low fruit and vegetable intake, lack of physical activity, tobacco use and alcohol use (9, 11). Tobacco use is the most important risk factor and causes almost 20% of global cancer deaths and 70% of global lung cancer deaths (9, 11). Viral infections such as Hepatitis B and C viruses (HBV/HCV) and Human papillomavirus (HPV) are responsible for up to 20% of cancer deaths in many LMICs (9).

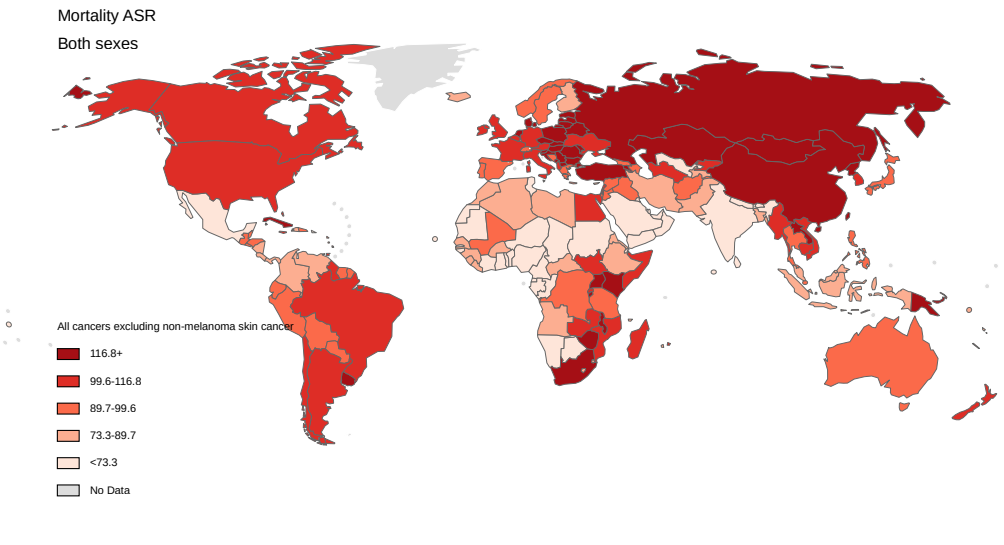


Fig. 2. Estimated cancer mortality worldwide in 2012. Both sexes, GLOBOCAN 2012. (12)

In most high-income countries (HICs), cancer is the second leading cause of death after cardiovascular disease. WHO estimates that 70% of global deaths attributable to cancer occur in LMICs, and more than 60% of global annual new cases occur in Africa, Asia and Central and South America (10).

Access to effective and affordable cancer treatments in developing countries would significantly reduce mortality (10, 11).

According to Cancer Research UK, there were 8.2 million cancer deaths worldwide, with over half of all deaths occurring in low and middle income countries. A recent analysis has estimated that in high-income countries 69-82% of dying people would benefit from access to palliative care (Murtagh et al 2014). It has been estimated that globally 20 million people with advanced disease need palliative care in the last year of life, and a further 20 million people need end of life care annually (WHO and WPCA 2014). There are great disparities in the availability of palliative care across the world (The Lien Foundation 2015). Globally the majority of patients who are diagnosed with cancer have advanced disease which is no longer amenable to curative treatment. This means that they are likely to experience distress from pain and other symptoms, and psychosocial concerns. In low-income countries many cancer patients are unable to receive even basic anti-cancer treatment. In these countries, palliative care is the first choice for economically disadvantaged people (Payne et al 2012). There appears to be an increasing recognition that palliative care should be delivered early in the disease trajectory and offers opportunities to improve not only physical symptom management but also enhances communication, psychosocial care and promotes quality of life. An influential study of early integration of palliative care into oncology treatment of patients with lung cancer, demonstrated that adding palliative care consultations to standard cancer treatment significantly improved quality of life and increased survival by a few months compared to controls in the USA (Temel et al 2010).

Country profiles highlighting the status of NCDs including cancer, as of 2014, in each WHO Member State are available at: http://www.who.int/nmh/publications/ncd-profiles-2014/en/.

I.V Availability of specific medical devices for cancer

Medical devices are indispensable for effective screening, diagnosis, treatment, palliation and rehabilitation of illness and disease. Cancer mortality can be significantly reduced if cases are detected and treated in a timely manner, yet many preventable deaths occur as a result of lack of available technologies to screen, diagnose and treat diseases (9).

Early diagnosis of cancer improves the outcome of treatment, however, many patients in low-income settings do not have access to laboratory, pathology, radiology or other diagnostic methods for early diagnosis (9). As a result, the majority of patients with malignant neoplasms in developing countries present at a late stage with incurable disease. Point-of-care (POC) diagnostic tools allow for detection and monitoring at the primary health care level, and are especially useful where patients would otherwise have to travel long distances to reach a health facility with a well-equipped laboratory. The development of simple, affordable diagnostic tools is needed to enable cancer screening in the places of highest cancer burden.

The most common cancer treatments are surgery, systemic therapy and radiotherapy, and curability is attributed as follows: surgery (49%), radiotherapy (40%), and chemotherapy (11%) (11). Nonetheless, many of the technologies required for these treatments are inaccessible to the developing world. Radiotherapy, for example, has the potential to benefit approximately 60% of cancer patients during the course of their disease, yet LMICs face the largest shortages of radiotherapy units, with approximately 30 countries in Africa and Southeast Asia having no radiotherapy services available (11). The need for technologies to palliate incurable disease and improve and prolong quality of life is also being addressed by this project (13).

An estimated 1.5 million different medical devices exist, in more than 10,000 types of generic device groups. In 2008, WHO initiated the first global effort to identify global needs for medical devices, i.e. to prioritize and select the essential and affordable medical devices of greatest importance considering the disease burden of the individual country. In 2010, a very first global survey on medical devices revealed major gaps in the availability of and access to medical devices in countries (14), as well as vast discrepancies between countries in regards to the existence of regulatory capacities, national policies, national lists and technical specifications for procurement and reimbursement of medical devices. As reported in the Global Health Observatory (14), the following maps represent the density of high cost technologies, some of which are indispensable for treating cancer (mammography, radiotherapy and computed tomography equipment) and other technologies that are available almost exclusively in middle-high and high income countries (gamma camera, magnetic resonance imaging, and positron emission tomography) (Fig. 3–8):

Note: The boundaries and names shown and the designations used on maps do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

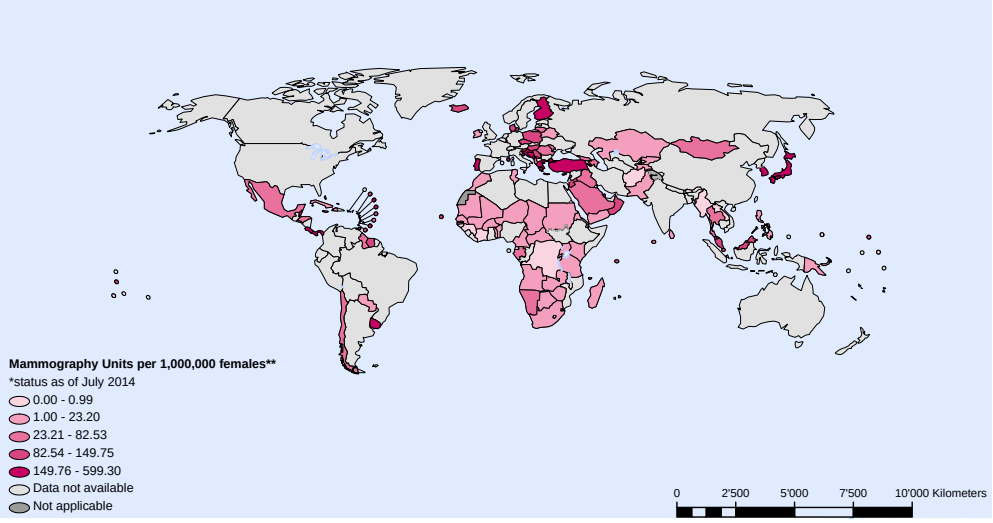


Fig. 3. Mammography units per million females aged between 50 and 69 years old. 2014. Data from Global Health Observatory (14).

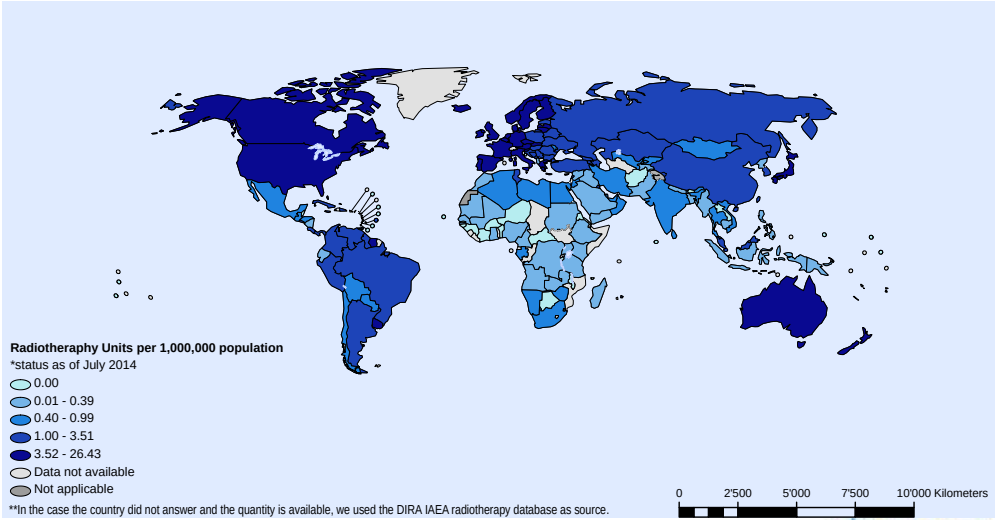


Fig. 4. Radiotherapy units per million population. 2014. Data from Global Health Observatory (14).

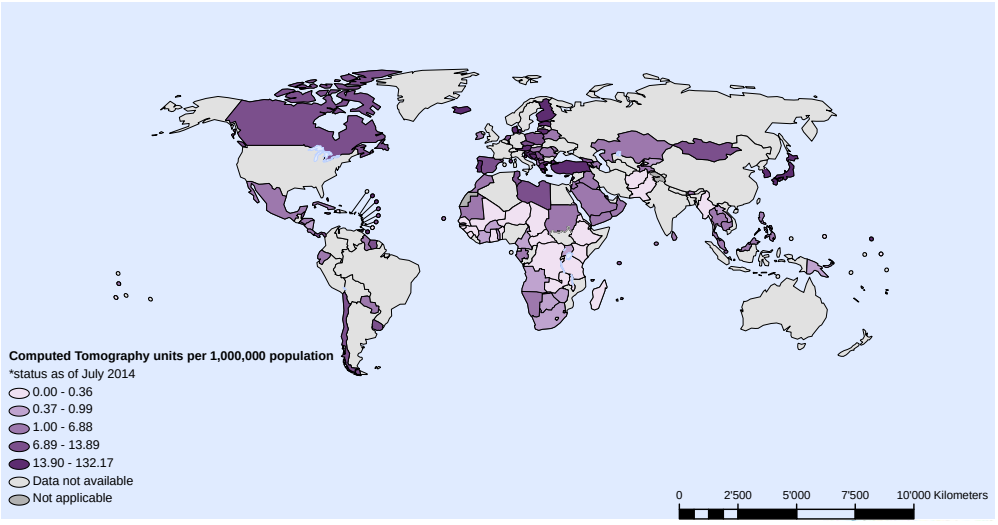


Fig. 5. Computed Tomography (CT) units per million population. 2014.Data from Global Health Observatory (14).

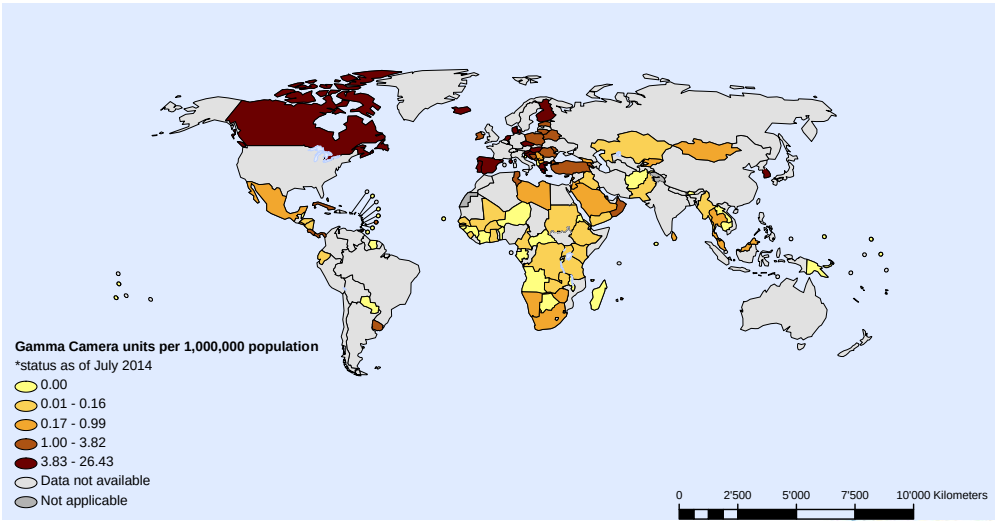


Fig. 6. Gamma Camera units per million population. 2014. Data from Global Health Observatory (14).

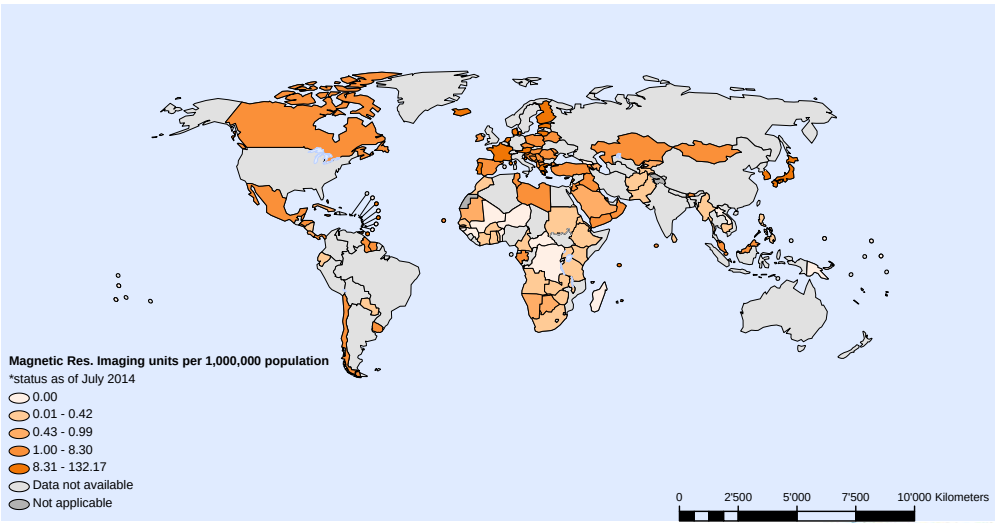


Fig. 7. Magnetic Resonance Imaging (MRI) units per million population. 2014. Data from Global Health Observatory (14).

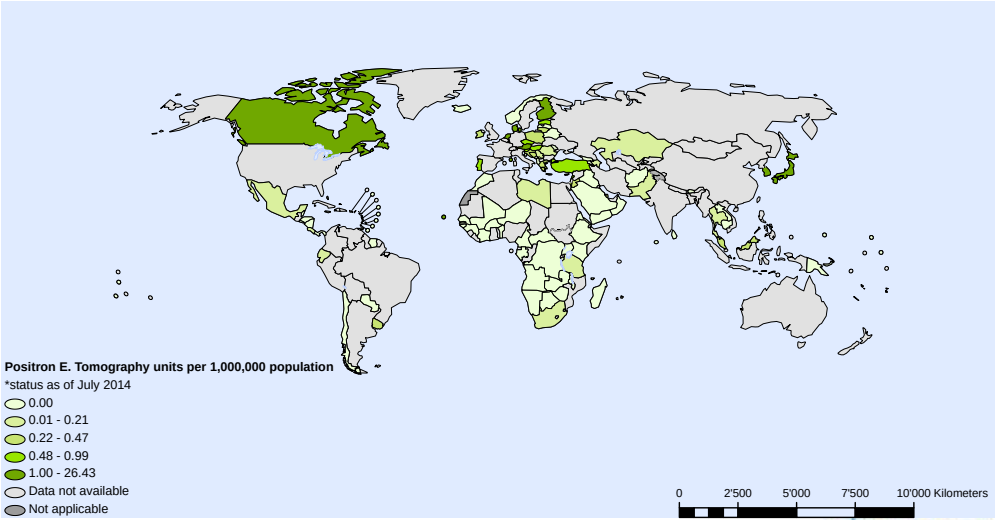


Fig. 8. Positron Emission Tomography (PET) units per million population. 2014. Data from Global Health Observatory (14).

This background, combined with the recent global response to the growing emergence of noncommunicable diseases formed the basis for the development of this project in 2014 (13).

As will be described in the present book, surgery is an essential component of the treatment of cancer. The Lancet commission on Global Surgery published in 2015, the proportion of population without access to safe affordable surgery which is presented in figure 9. (15)

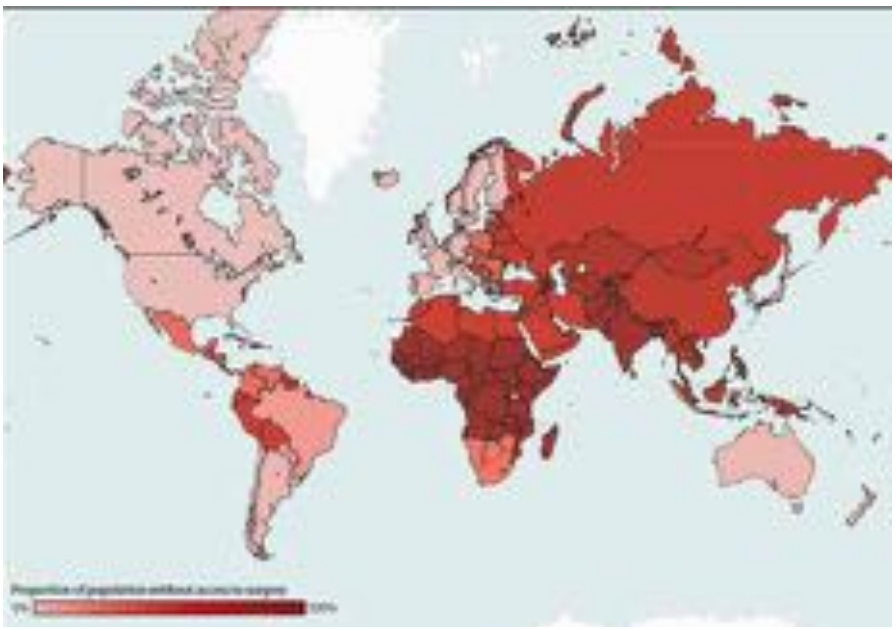


Fig. 9. proportion of population without access to safe affordable surgery. 2015. Lancet Global Health (15).

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World Health Organisation and Worldwide Palliative Care Alliance (2014) Global Atlas of Palliative Care at the End of Life. WPCA: New York."

II. Methodology

The methodology used to select the priority medical devices (PMD) for cancer was based on the methodology defined by WHO to select the I*nteragency list of priority medical devices for essential interventions for reproductive, maternal, newborn and child health* (1), which involved the revision of WHO guidelines to define the interventions and the medical devices required to perform each intervention by levels of care. However, for this specific cancer project, there were very few WHO guidelines available; thus the methodology had to be modified accordingly, with supervision and approval of the WHO Guidelines Review Committee.

The following overview presents the milestones and the adaptation of the methodology throughout the process, which led to the present publication.

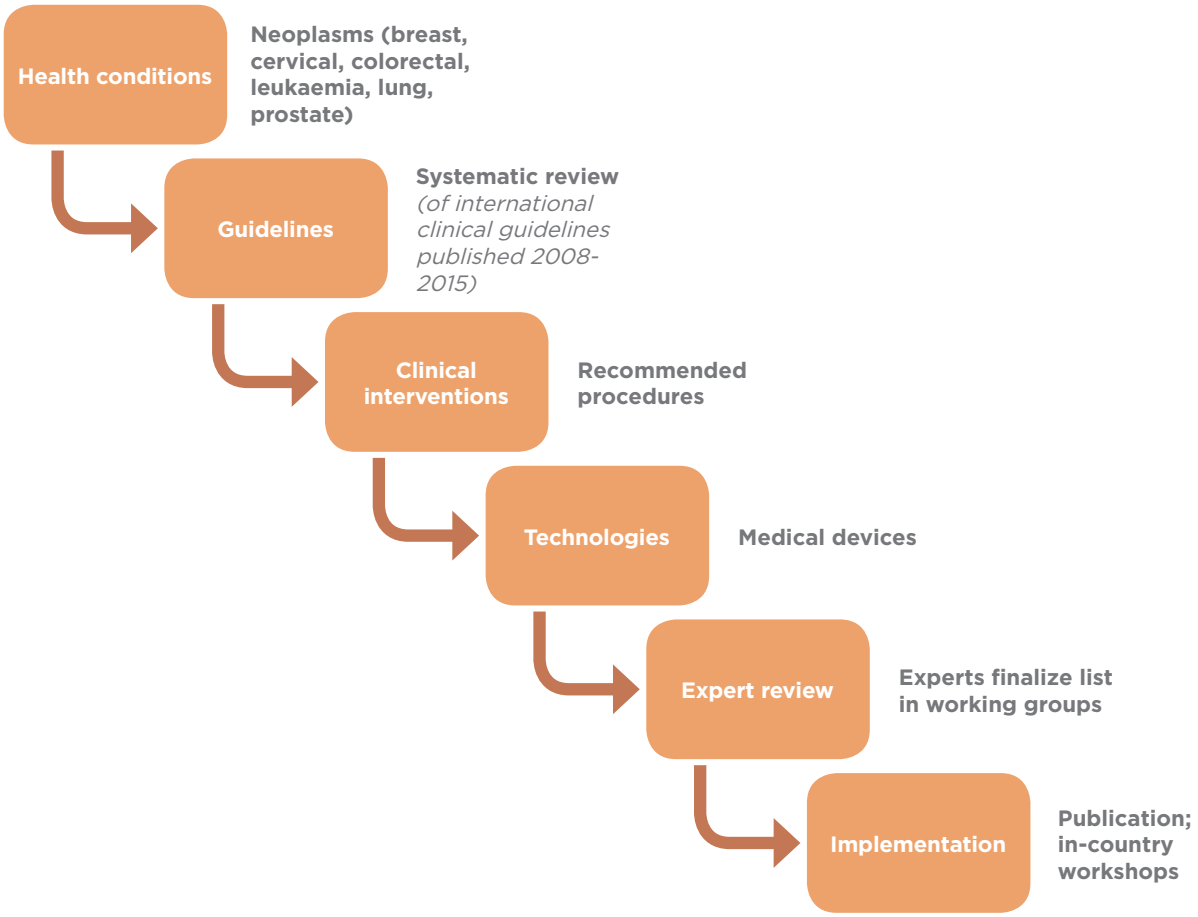

Fig. 9. Overview of project methodology

The overall project methodology, as per Fig. 9 above, included the following steps and timeline:

Step 1: Development of preliminary medical devices list for cancer management (Nov 2014–Feb 2015)

Cancer types: Breast, cervical, colorectal, leukaemia, lung, and prostate

↘

Guidelines: Systematic reviews of selected international guidelines for each cancer type

↘

Interventions: Recommended procedures identified from guidelines

↘

Technologies: Medical devices required for each intervention identified

Step 2: General consultation (April 2015)

- Initial review of preliminary list and methodology
- Define action plan and timeline
- Activities recommended from this general consultation took place May–August 2015

Step 3: Advisory committee meeting (September 2015)

- Define methodology for selection/classification of PMD list
- Define working groups and objectives for expert review of list

Step 4: Expert groups review (November 2015–February 2016)

- Five expert groups reviewed the following subjects:
  - Imaging and nuclear medicine
  - Pathology and laboratory
  - Surgery
  - Radiotherapy
  - Systemic therapy and palliative care and end of life care
- Teleconferences to finalize lists and discuss unit infrastructure, human resources, and quality management (Nov-Dec 2015)

Step 5: Consultation to review the publication (March–April 2016)

- Review of the document by all members of consultations and expert groups

Step 6: Country or regional review for implementation (June–December 2016)

- Country workshops and dissemination of publication

The detailed activities performed during each step are described below:

Step 1: Development of preliminary medical devices list for cancer management

The WHO Medical Devices Team (MDT) within the Policy Access and Use Unit of the Essential Medicines and Health Products Department followed a stepwise approach to identify medical devices relevant for delivering health care services for six cancer types.

This first step was to conduct literature searches to identify internationally available clinical guidelines for the management of six cancer types: breast, cervical, colorectal, prostate, lung and leukaemia. To extract information on the interventions along the continuum of care (prevention, screening, diagnosis, treatment, follow-up, and palliative care) for the six types of cancer, a total of 27 clinical guidelines (CGL), provided by 6 different Organizations, have been included (6 CGL for breast cancer; 1 CGL for cervical cancer; 5 CGL for colorectal cancer; 6 CGL for leukaemia; 5 CGL for lung cancer; 4 CGL for prostate cancer), as listed in Table 1 below.

Type of Cancer	Provider Organization	Publication Year	Reference
Breast Cancer	World Health Organization	2014	WHO position paper on mammography screening (2014); ISBN 9789241507936
	The Breast Health Global Initiative	2008	Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008; 113(S8): i–ix, 2215–2371
	National Institute for Clinical Excellence	2014	Early and locally advanced breast cancer. NICE clinical guideline 80. 2014.
	National Institute for Clinical Excellence	2014	Advanced breast cancer. NICE clinical guideline 81. 2014.
	National Comprehensive Cancer Network	2014	NCCN. Breast Cancer Screening and Diagnosis. Version 1.2014
	National Comprehensive Cancer Network	2014	NCCN. Breast Cancer. Version 3.2014
Cervical Cancer	World Health Organization	2014	WHO Comprehensive cervical cancer control: a guide to essential practice – 2nd ed. 2014.
Colorectal Cancer	National Institute for Clinical Excellence	2014	Colorectal cancer. NICE clinical guideline 131. 2014.
	European Registration of Cancer Care	2014	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan; 50(1):1.e1-1.e34
	National Comprehensive Cancer Network	2014	NCCN. Colorectal Cancer Screening. Version 1.2014
	National Comprehensive Cancer Network	2015	NCCN. Rectal Cancer. Version 2.2015
	National Comprehensive Cancer Network	2015	NCCN. Colon Cancer. Version 2.2015
Leukaemia	National Comprehensive Cancer Network	2014	NCCN. Acute Lymphoblastic Leukemia. Version 2.2014
	National Comprehensive Cancer Network	2015	NCCN. Acute Myeloid Leukemia. Version 1.2015
	National Comprehensive Cancer Network	2015	NCCN. Chronic Myelogenous Leukemia. Version 1.2015
	European Society for Medical Oncology	2013	Fey MF, Buske C, on behalf of the ESMO Guidelines Working Group. Acute myeloblastic leukaemias in adult patients: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013; 24(6): vi138–vi143
	European Society for Medical Oncology	2011	Eichhorst B, Dreyling M, Robak T, Montserrat E, Hallek M, on behalf of the ESMO Guidelines Working Group. Chronic lymphocytic leukemia: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2011; 22(6): vi50–vi54
	European Society for Medical Oncology	2012	Baccarani M, Pileri S, Steegmann JL, Muller M, Soverini S, Dreyling M; ESMO Guidelines Working Group. Chronic myeloid leukemia: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2012; 23(7): vii72-7
Lung Cancer	National Institute for Clinical Excellence	2011	Lung cancer. NICE clinical guideline 121. 2011.
	European Society for Medical Oncology	2013	Vansteenkiste J, De Ruysscher D, Eberhardt WE, et al.; ESMO Guidelines Working Group. Early and locally advanced non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013; 24(6):vi89-98
	European Society for Medical Oncology	2014	Reck M, Popat S, Reinmuth N, et al.; ESMO Guidelines Working Group. Metastatic non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2014; 25(3):iii27-39
	National Comprehensive Cancer Network	2015	NCCN. Lung Cancer Screening. Version 1.2015
	National Comprehensive Cancer Network	2015	NCCN. Non-Small Cell Lung Cancer. Version 3.2015
Prostate Cancer	National Institute for Clinical Excellence	2014	Prostate cancer. NICE clinical guideline 175. 2014.
	European Society for Medical Oncology	2013	Horwich A, Parker C, de Reijke T, et al.; ESMO Guidelines Working Group. Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi106-14
	National Comprehensive Cancer Network	2014	NCCN. Prostate Cancer Early Detection. Version 1.2014
	National Comprehensive Cancer Network	2015	NCCN. Prostate Cancer. Version 1.2015

Table 1. Internationally available clinical guidelines identified for the management of six cancer types

Clinical interventions were extracted from each of the clinical guidelines identified, as described and listed in Annex 1. The medical devices needed to carry out each of the interventions were identified from protocols, guidelines and procedures. A non-exclusive list of medical devices associated with each intervention was compiled in line with previous MDT methods. The medical devices were categorized according to intervention and general clinical areas, e.g. Surgery, Laboratory, Radiotherapy, etc.

Step 2: General Consultation

From the 29-30th of April 2015, the MDT hosted an expert consultation on "Priority Medical Devices for Cancer Management - Targeting Low and Middle-Income Countries" at WHO. The consultation brought together over 70 participants from 28 countries. Participants included country representatives from national Ministries of Health and cancer care professionals from teaching hospitals and research institutes in Bhutan, China, Ethiopia, Ghana, India, Japan, Mexico, Sri Lanka, Uganda, and Zambia. Representatives of WHO regional offices and headquarters were present along with experts from governmental agencies, academic institutions, NGOs, professional associations, collaborating centres and UN Agencies.

Participants commented on the preliminary medical devices list and noted additions or deletions as necessary. The key conclusions from the consultation that informed the further development of the document included: (1) Use of generic names for medical devices (devices should be clearly identifiable by the descriptions provided – avoiding provision of full technical specifications) and categorization of devices, (2) classification of the devices by general use (the devices used for general management of cancers and other diseases in each clinical area) and specific use for each cancer type (the devices specifically needed for a particular neoplasm), (3) identification of the contextual elements that should be considered when using the list and (4) clarification of the role of resource level stratification in this project.

Step 3: Advisory committee meeting

From May to July 2015, WHO developed the actions requested in the April consultation. Then WHO called for an advisory committee to define the methodology for selection, classification and presentation of the medical devices list. This advisory committee meeting brought together 24 participants including 13 advisers, two WHO regional officers, five WHO headquarters staff and four observers. The advisers provided expertise in the following specialized areas: surgical oncology, medical oncology, radiation oncology, biomedical engineering and health technology assessment.

The key conclusions from the advisory committee meeting that informed the further development of the document included: (1) Expansion of the "basic medical devices" according to the NCD Action Plan Voluntary Target 9, (2) definition of the core devices (high end or consumables) for cancer management, and (3) the importance of setting/situation and each country's need to define the implementation steps for the acquisition of the technologies, in accordance with their own settings' situation. The proposed methodology for devices selection was defined as follows:

i. Definition of the core services/ interventions.
ii. Definition of the basic devices that could achieve the basic interventions in these core services.
iii. When there is more than one multiple general approach or/and to provide data on devices considered, the working groups will use a pragmatic qualitative multi-criteria decision analysis (MCDA) approach.
iv. The committee decided against stratifying the devices and to have just one basic level for the PMD lists, thereby encouraging the countries to purchase at least the basic requirements and then continue improving as per availability of resources (human, infrastructure, financial) and based on local needs.

Moreover, it was agreed that six working groups (Imaging and Nuclear Medicine, Surgery, Pathology and Laboratory, Radiotherapy, Systemic Therapy and Palliative care) would follow the methodology with members of different disciplines for each group (oncologic surgeon, radiation oncologists, medical physicist, pathologist, laboratory specialist, biomedical engineer, etc.) from different regions of the world, from different income groups and with gender balance.

Further actions for WHO included the development of: instructions and terms of reference for the working groups, a nomination template for selection of members of the groups, working tools for device selection and MCDA, and coordination of teleconferences for each group to generate a final document.

Step 4: Expert groups review

Five expert groups instead of six were defined based on key disciplines (systemic therapy and palliative care were merged into one group). The advisory committee nominated the experts to form the expert groups. Additional consultants and internal WHO personnel were included. Eighty-three nominations were received and 60 experts were selected based on the criteria to form the five expert groups. The experts came from 29 Member States distributed across the six WHO regions, from all income countries and with 38% female participants. Experts' contact information, affiliations, and declarations of interest are available in Annex 2.

Through 25 daily conferences with the 5 groups, the experts were asked to perform the following activities based on their background, expertise, knowledge and the relevant scientific information, using three WHO working tools (experts terms of reference and working tool examples included in Annex 3) developed for this review:

1. Review the list of general basic medical devices per clinical area (using working tool 1).
2. Identify the basic services, functions/interventions and specific basic medical devices to be included in the WHO list of medical devices for cancer management, and include key implementation criteria, including human resources, interdependencies, infrastructure and quality management requirements (using working tool 2, adapted from the contextual tool of the MCDA EVIDEM framework).
3. Use the MCDA tool to complement the selection and prioritization exercise in case of contentious options or/and to provide data on devices considered, using the following value criteria specifically designed for this project, including effectiveness, safety, patient-reported outcomes, therapeutic benefit, multi-disease, multi-cancer, ease of use, ease of training, telemedicine capabilities, affordability, positive consequences on healthcare resource utilization, and quality of evidence (working tool 3, adapted from the Core Model of the MCDA EVIDEM framework).

The working tools 1, 2 and 3 completed by the experts for the priority devices are available in the supplementary material (Working tools data) posted on the WHO web site on medical devices for cancer. (http://www.who.int/medical_devices/en/). Following the expert groups' reviews, the PMD lists were divided by clinical services into seven subchapters. For each chapter, a main author was designated to identify the contextual elements that should be considered when using the list for implementation purposes (special notes). This included references to infrastructure requirements, quality management, human resource, and/or other necessary capacity. The members of each group, who had participated in the teleconferences, complemented the information.

Step 5: Consultation to review the final publication

A consultation to review the outcome lists and the complete document was performed, with all participants of the general consultation meeting, advisory committee meeting and expert groups. All reviewers' edits and comments were integrated into the document during the WHO internal review. As a result of feedback received during this consultation, the PMD lists were divided into two levels: those absolutely necessary for cancer management in district hospitals at the second level of care, and those considered standard for cancer care but due to financial and infrastructure requirements may be better suited for a specialized hospital at the third level.

Step 6: Country or regional review for implementation

The publication will also undergo country and/or regional review for implementation strategy development on the basis of performing a needs assessment unique to their setting and priorities.

Bibliography:

1) Interagency list of medical devices for essential interventions for reproductive, maternal, newborn and child health. World Health Organization, 2015. Available at: http://www.who.int/medical_devices/md_maternal_v12_web.pdf

Guidance documents:

Package of Essential Noncommunicable (PEN) Disease interventions for Primary Health Care in Low Resource Settings, 2010
www.who.int/nmh/publications/essential_ncd_interventions_lr_settings.pdf

Clinical Practice Guidelines from CENETEC, Mexico:
http://www.cenetec.salud.gob.mx/contenidos/gpc/catalogoMaestroGPC.html

Clinical Practice Guidelines from Ministry of Health and Social Protection, Colombia:
http://gpc.minsalud.gov.co/Pages/Default.aspx

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http://www.moph.gov.lb/Drugs/Documents/16UNDPcancerbook%202012web.pdf

Canadian Association of Radiologists Diagnostic Imaging Referral Guidelines for Cancer:
http://www.car.ca/uploads/standards%20guidelines/car-referralguidelines-k-en-20130726.pdf

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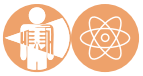
http://kehpca.org/wp-content/uploads/National-Cancer-Treatment-Guidelines2.pdf

Standard Treatment Guidelines, National Health Mission, India:
http://nrhm.gov.in/nhm/nrhm/guidelines/nrhm-guidelines/standard-treatment-guidelines.html

III. Priority medical devices by clinical areas

This chapter includes the list of priority medical devices for cancer management of primarily six cancer types (breast, cervical, colorectal, leukaemia, lung, and prostate); however, as detailed below, much of the information in these units including medical devices lists, infrastructure requirements and guidance documents are pertinent to other cancers as well as other diseases. The list is grouped into specific clinical units as presented in the following sub-chapters:

1. Vaccination, clinical assessment & endoscopy



2. Medical imaging & nuclear medicine

3. Surgery

4. Clinical laboratory & pathology

5. Radiotherapy

6. Systemic therapy

7. Palliative care & end of life care

Each subchapter includes the following sections:

1. General description of the unit: the general purpose of the clinical area within the health service delivery sequence is described and the relevant clinical interventions are listed.
2. Priority medical devices: the list of medical devices is presented in two parts:
   i. **General Medical Devices** that need to be available for basic use of the clinical unit to perform the majority of interventions, and can be used for various diseases including cancers (Radiotherapy and Systemic Therapy chapters are specific to cancer treatment).
   ii. **Specific Medical Devices** for diagnosis or treatment of a specific neoplasm or type of cancer.

It is important to note that this is a non-exclusive list and that the devices could differ according to different methods or techniques for the same intervention or procedure. The intended purpose of these lists is to present the medical devices needed for a general approach to the defined cancer interventions within each clinical area.

Throughout this publication, the priority medical devices may include any of the following subcategories:

- Laboratory and pathology equipment
- Medical equipment
- Medical furniture
- Other (glassware, utensils, etc.)
- Personal protective equipment and clothing (PPE)
- Quality assurance devices
- Radiation protection devices
- Single use devices/disposables/medical supplies
- Solutions and reagents
- Software
- Surgical instruments.

For the purpose of this publication, the medical devices were classified upon :

3. Capital investment (equipment, furniture and surgical instruments) all of the above are reused and requires maintenance through out the life cycle.
4. Operational costs (consumables, single use devices) as per the national health accounts, to facilitate tracking and quantification of expenses.

Every country can re- classify as needed and adapt the lists. it is important to note that also capital equipment can be leased or rented.

5. Human resources: a list of the specialized human resources required to use the devices listed and perform the interventions, and alternative options in case these are not available.
6. Infrastructure requirements: a general description of the layout distribution, shielding and radiation protection (if applicable), electrical systems, heating, ventilation and air conditioning systems, safety, and information and communication system requirements.
7. Quality management: description of activities within a quality policy framework to guarantee quality in the clinical area.
8. Guidance documents: guidelines and documents from UN Agencies, NGOs, publications and other relevant information to expand upon the topics already generally described in the subchapter.

Cancer patient continuum of care

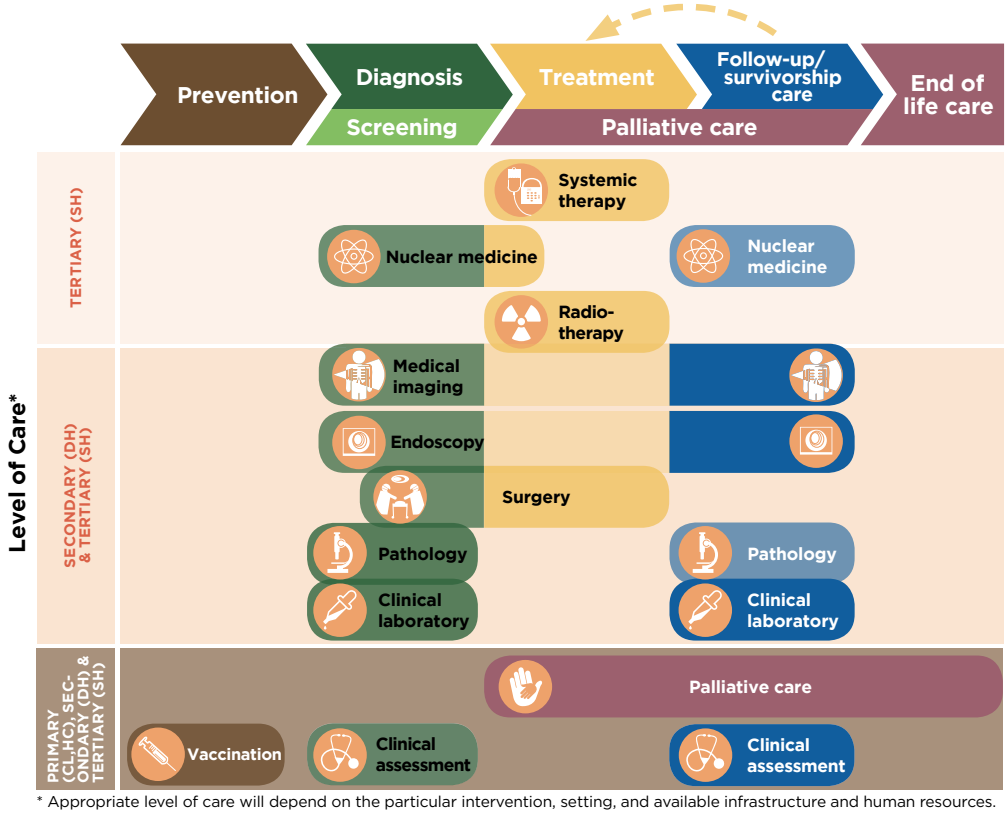
The clinical units in the subchapters correspond to the cancer patient continuum of care. Prevention and early detection should ideally take place in primary health care settings, with referral to a secondary level for diagnosis and treatment capabilities, and to the more specialized tertiary levels whenever needed. However, in many LMICs there are limited early detection and diagnostic capabilities, and the patient may arrive with an advanced stage of cancer and an increased mortality risk. These cases often require direct referral to tertiary level facilities where available, and burdensome costs for patients and healthcare systems.

It is important to note that the type of hospitals that correspond to each healthcare system level is a contextual decision that each country should make. Generally, the district hospital corresponds to a second level of care (general hospital) and specialized hospitals (regional, national/teaching with specialized oncological human resources and infrastructure) correspond to the third level.

The following health care service delivery overview diagram shows how the clinical units mentioned in this document are interrelated and interdependent (Fig. 10). After proper diagnosis and staging, it is recommended that the treatment or therapeutic decisions be made in a multidisciplinary tumour board. This will ensure that doctors and patients decide on the best available treatment, integrating all necessary disciplines.

The medical devices lists presented in each clinical unit subchapter are defined as those necessary for cancer management in district hospitals at the second level of care, or as those considered standard for cancer care but due to financial and infrastructure requirements may be better suited for a specialized hospital at the third level. Nuclear Medicine, Radiotherapy and Systemic Therapy units are considered at the third level of specialized care.

This graph is merely a representation of some generic interventions and does not intend to include all possible pathways, which will be different depending on the patient, the stage the type of cancer and the diagnostic and treatment available in their setting.Many of the clinical services can be used for multiple functions, example screening, diagnosis and monitoring patients. Other treatments as radiotherapy, chemotherapy or surgery can be used for treatment but also as palliative care, which are represented in this graphic with the multiple colors to indicate different uses of the same technology.



* Appropriate level of care will depend on the particular intervention, setting, and available infrastructure and human resources.

CL Community Level health post DH District Hospital HC Health Centre SH Specialized Hospital

Fig. 10. Health care service delivery overview

Medical devices considerations:

The tables presented in the different sections include the priority medical devices required to perform the health interventions listed. The selection and prioritization of medical devices will be determined according to the country's different levels of health care (primary, secondary and tertiary), specialized human resources and available infrastructure, and patient flow, according to the local needs. This will be presented in greater detail in Chapter IV, Implementation strategy.

All the medical devices that are listed in this document need to be regulated, assessed and managed properly. The issues that need to be considered and will be expanded upon in Chapter IV, include the following:

1. Selection: If the devices included in these lists are approved by the ministries of health of the Member States, they can be added to the priority/basic medical devices list of the country.
2. Regulatory clearance: These devices should have regulatory clearance to be marketed in the country, after analysing the safety and effectiveness of the technology, and should be approved by a national regulatory authority related to the ministry of health.
3. Assessment: The priority medical devices, especially the ones that are most costly and complex, require specific infrastructure and trained human resources, and need an assessment process to evaluate if these can be placed for public procurement or considered in the package of interventions as a reimbursable procedure/product. These assessments consider not only the safety and efficacy of the technology, but also feasibility, cost effectiveness, ethical, organizational and human resources requirements.
4. Acquisition or incorporation: In order to procure or acquire these medical devices once the need is defined, a tender process is required which will include the definition, technical specifications, request for regulatory approval, standards compliance, delivery times, and aspects such as installation, warranty, technical support costs and training to be included in the procurement package. An extended warranty is required if maintenance is a problem in the country of use. Acquisition requirements should include software licenses, upgrade policy, commissioning (acceptance) – attributes and costs.
5. Installation: Once the bidding and contract has been completed, the mechanical guidelines must be available to prepare for installation. This is particularly specific to diagnostic imaging, and is costly and complex for radiotherapy equipment. The installation has to be to the complete satisfaction of the final user. This applies to medical equipment in general and is of very high importance for equipment required in diagnostic imaging, nuclear medicine, surgery and radiotherapy.
6. Supply chain and logistics: Reliable supply chain and logistics management are needed to ensure the right quality product is available, in the right quantities, at the right time, and for a reasonable cost.
7. Maintenance: In every area, the maintenance and repair of medical equipment are significant challenges and potentially costly, and it is important to consider service documentation, software diagnostics, special tools & critical parts to be available at the hospital site and these costs upfront, as well as to verify local or regional suppliers that can provide continued technical support. In some cases, especially for high cost equipment, multiyear service agreements are a good option to consider.
8. Training: The training of the user ensures the safe and appropriate use of most health technologies and should be requested of the manufacturer/supplier of the device when drawing up the purchase agreement.
9. Follow-up: It is important to ensure appropriate follow-up to the safe use of medical equipment and reporting of any adverse event to the regulatory authorities, as well as proper final decommissioning, according to national and global guidelines.
10. Donations: Device donations from high-resource settings should only be deployed to other settings after careful deliberation on appropriateness, costs of maintenance, and relevance. When a donation is received, care should be taken that the equipment or technology is in good condition and complies with standards of safety and quality.
11. Infrastructure considerations: It is important to note that in low- and middle-income countries, infrastructure concerns like stable power supply, availability of running water, oxygen supply or air conditioning might be limited and humidity and high temperatures could affect the performance of the medical technologies.
12. Telemedicine: When connectivity is available, telemedicine can be a resource for training users, sending images or information for diagnosis or treatment alternatives, or to have a second opinion or to send to experts.

13. Mobile health: Mobile health (mHealth) solutions might also be available and should be considered.
14. Data security: Data storage and patient data confidentiality should also be addressed. Laboratory, radiology or hospital information systems and electronic health records could be available in different settings, and it is important to consider interoperability to ensure data management.

For all these steps, WHO has developed reference resources available at www.who.int/medical_devices/en. The WHO medical devices technical series (Fig. 11) provides specific guidance on each of the above steps.

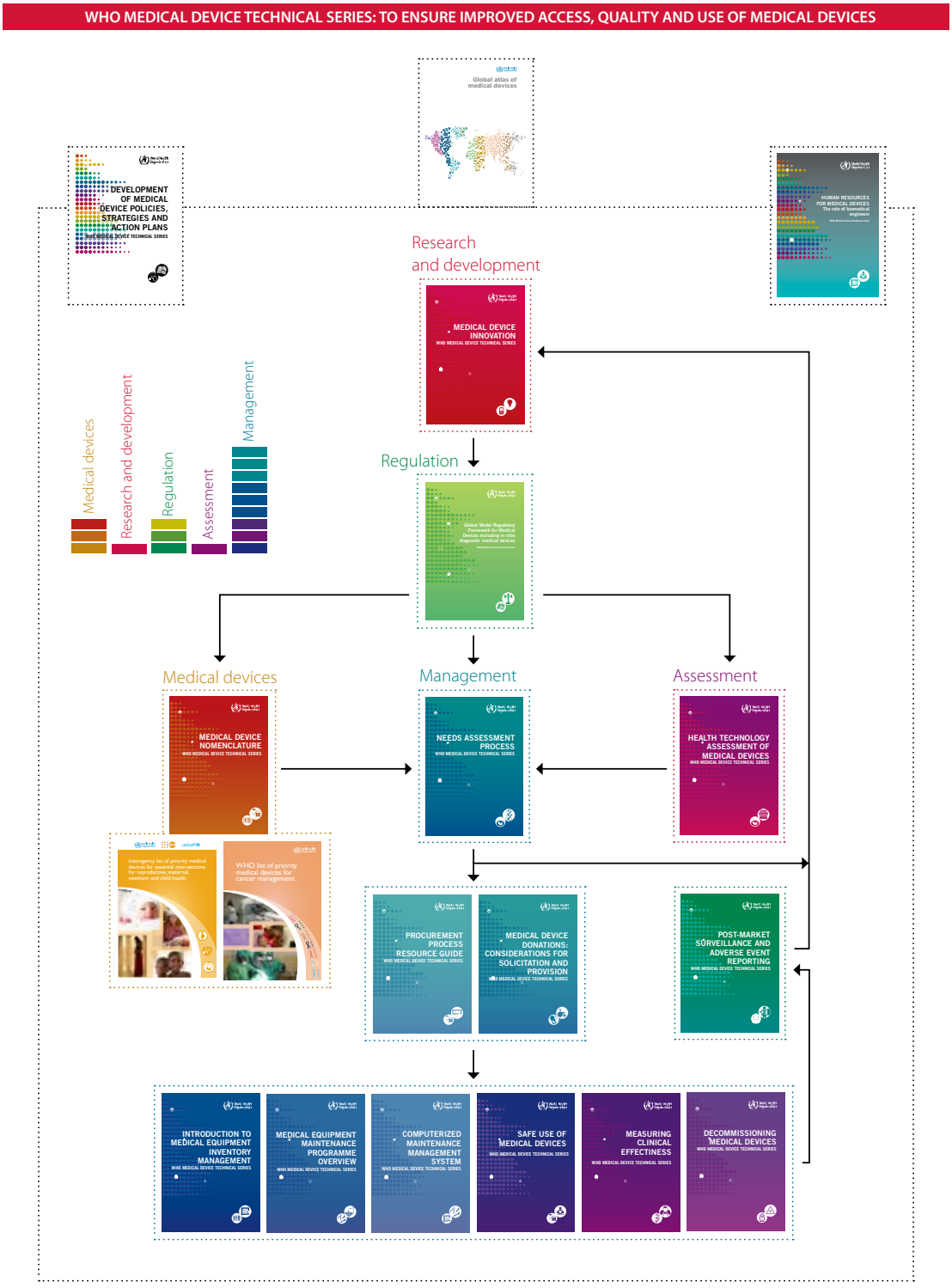
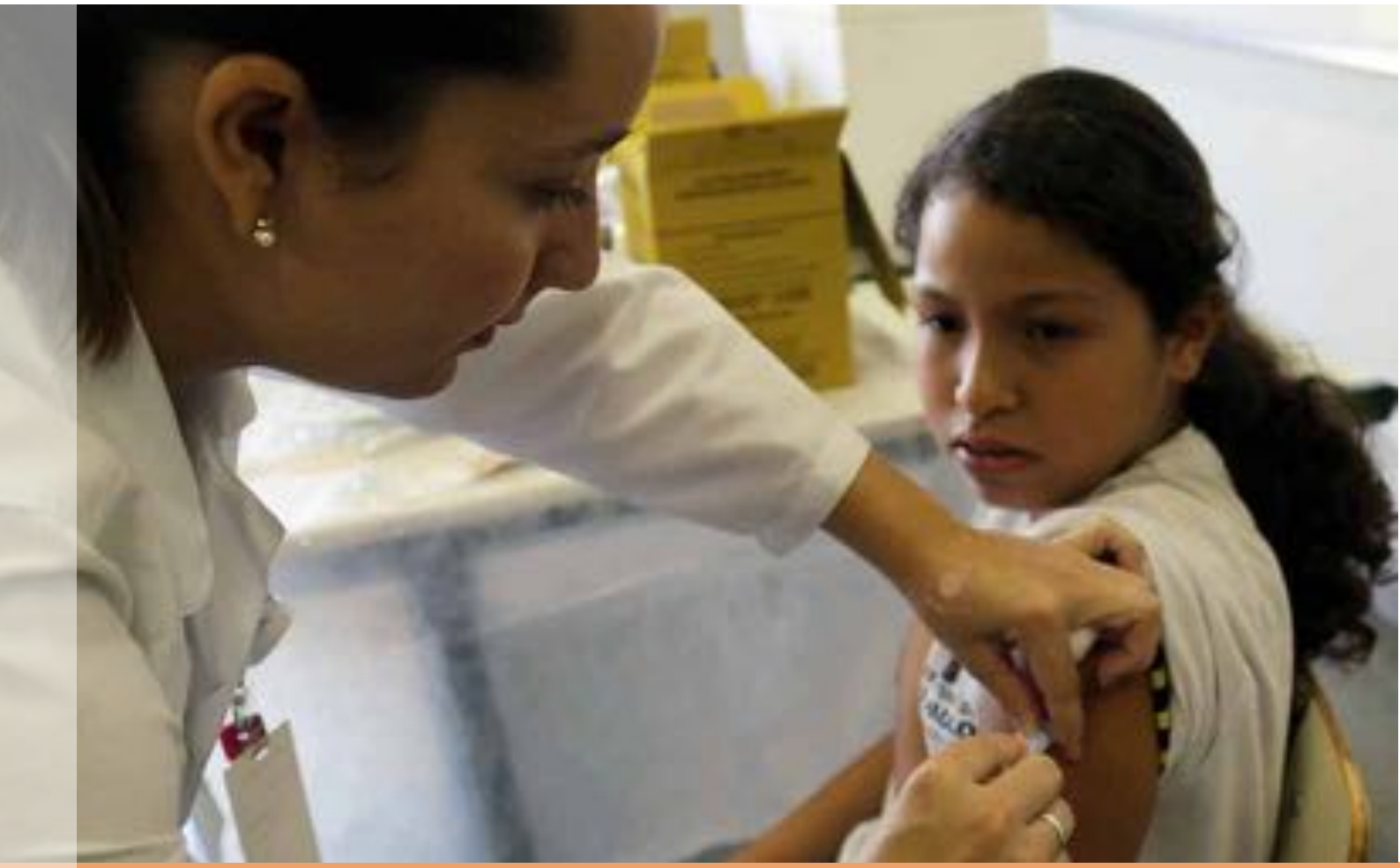


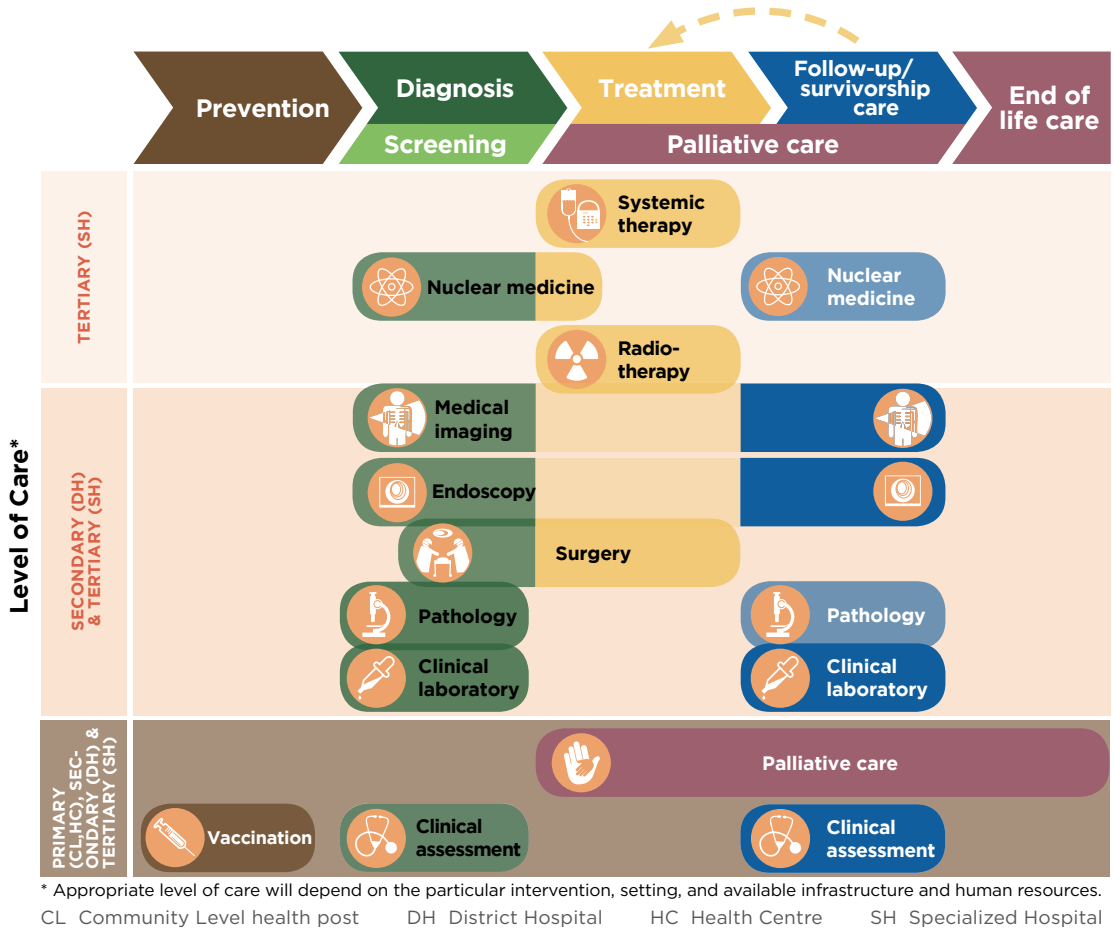
Fig. 11. WHO medical device technical series

1. Vaccination, clinical assessment & endoscopy



Health service delivery sequence overview:

This diagram expresses the flow of cancer patient to and from the vaccination, clinical assessment and endoscopy units, and the elements to consider as support for the unit (Fig 10.1).



* Appropriate level of care will depend on the particular intervention, setting, and available infrastructure and human resources.
CL Community Level health post DH District Hospital HC Health Centre SH Specialized Hospital

Fig. 10.1. Health care service delivery overview – vaccination, clinical assessment and endoscopy

1.1 General description of the unit

This unit includes three sections, two of which can be done starting at primary health care level, these are: first the preventive measure, which is the HPV vaccination for cervical cancer. and secondly the initial clinical assessments.

As indicated in the WHO cervical cancer control guidelines, it is recommended that the HPV vaccine is applied for girls from 9 to 13 years, as cervical cancer is caused by high risk types of HPV, therefore vaccination is a very important prevention intervention. The same applies to Hepatitis B for liver cancer, which has a high prevalence in many LMIC. The other public health solutions for prevention of NCDs are healthy behaviour, including physical activity, adequate nutrition, and avoiding tobacco and consumption of alcohol, among others.

Some screening and diagnosis, can be done in health clinics and district hospitals. In the case of cervical cancer WHO recommends HPV testing, cytology and visual inspections with acetic acid. Then the women with positive screening test must receive effective treatment.

As indicated in the Package of Essential Noncommunicable interventions for primary health care, " Efficient use of limited health care resources, sustainable health financing, access to basic diagnostics, essential medicines, and organized medical information and referral systems are indispensable for the delivery of equitable care for persons with and at risk of NCDs. Therefore, every chapter contains health systems requirements to support the complete approach to tackle NCDs.

The annex A of the PEN, indicates specifically three cost effective interventions for primary health care:

1. One visit VIA (screening and treatment for woman between 30 to 49, and can be earlier if needed)
2. Three visits cytology for woman between 30 to 49
3 Examination of breast by health care worker in clinical annually

The third section is on endoscopy, usually performed in secondary and tertiary level.

1.2 Priority medical devices for vaccination

The following table present the priority medical devices required to perform the following health interventions:

Cancer type	Interventions
Cervical cancer	• HPV vaccination

1.2.1 Specific medical devices for vaccination

1.2.1.1 Cervical

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
Human papillomavirus vaccination	Personal protective equipment and clothing		Gloves, examination, non-sterile, single use (various sizes)
	Single use devices/ disposables/medical supplies		Safety box, for used syringes/ needles Cotton wool, 500g, roll, non-sterile Syringes, autodisable (AD), (various capacities)

1.3 Priority medical devices for clinical assessment

The following tables present the general medical devices for clinical assessment and minor procedures, which can be used for screening, diagnosis, staging, and follow-up of many diseases including several cancers, and specific medical devices, which are used for interventions for specific cancer types.

Please note: Components of all surgical instrument sets as well as needle and catheter gauge sizes (G) are listed in the chapter annex at the end of this chapter.

The following tables present the priority medical devices required to perform the following health interventions:

Cancer type	Interventions
All cancers	• Clinical assessment and minor procedures
Breast cancer	• Clinical examination of breast
Cervical cancer	• Gynaecological examination and gynaecological procedures • Colposcopy • Cryotherapy • Endocervical curettage ECC • Large loop excision of transformation zone (LEEP/LLETZ) • Pap smear • Visual inspection with acetic acid
Colorectal cancer	• Dietary counselling • Digital rectal examination and examination of abdomen, liver and lymph nodes • Rigid sigmoidoscopy • Proctoscopy • Faecal ocult blood test
Lung cancer	• Spirometry • Bronchoscopy
Prostate cancer	• Digital rectal examination • PSA
Cervical and prostate cancers	• Cystoscopy

1.3.1 General medical devices for clinical assessment

These are general as they can be used for various diseases including all types of cancer excluding Leukaemia. Please note they are organized by clinical procedure.

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
Clinical assessment and minor procedures	Medical equipment	Aneroid sphygmomanometer	Blood pressure cuffs
		Stethoscope	
		Thermometer	
		Examination table	
		Resuscitation trolley, equipped, with medicines and defibrillator	
		Fixed examination/treatment light	
		Pulse oximeter	Spare probes, adult and paediatric
		Electrocardiography system (Assessment for cardiological disease)	• Electrodes • Leads • Gel, etc.
		Blood glucometer (Assessment for diabetes, glucose measurement)	Micro cuvettes, strips or similar Lancet, blood, safety, sterile (various sizes)
		Floor scale and stadiometer	Tape measurement
		Laryngoscope	
	Medical furniture	X-ray, viewer (negatoscope)	
		Stand, infusion, double hook, on casters	
		Tray, dressing, stainless steel, approx. 300 x 200 x 30 mm	
		Trolley, dressing, stainless steel, 2 trays	
		Cabinet, instruments, double door	
	Personal protective equipment and clothing		Gloves, examination, non-sterile, single use (various sizes)
	Single use devices/ disposables/ medical supplies		Syringes with needles
			Compress, gauze, sterile & non-sterile, single use
			Skin-cleaning wipe
			Bags for contaminated supplies
			Transparent film dressings with a gel pad
			Infusion giving set, sterile, single use
			Intravenous cannulas or catheters
	Solutions and reagents		Alcohol isopropyl 70%
			IV solution
			Iodine povacrylex and isopropyl alcohol solution or similar
			High level disinfectant, 0.5% chlorine solution for decontaminating instruments
			Distilled water
	Other		Brush, hand, scrubbing, plastic
			Bowl, polypropylene
			Basin, kidney, polypropylene
			Safety box, for used syringes/needles
		Receptacle, waste, stainless steel, pedal action	
		Arm/leg tourniquet	

1.3.2 Specific medical devices for clinical assessment and minor procedures by cancer type

1.3.2.1 Cervical

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
Gynaecological examination and gynaecological procedures[1]	Medical equipment	Bright light source	
		Gynaecological examination/ treatment table	
	Instruments	Forceps tissue-long	
		Cheron forceps	
		Long needle holders	
		Cervical punch biopsy forceps	
		Ring forceps	
		Vaginal sidewall retractors	
		Vaginal speculum, reusable	
			Compress, gauze, sterile & non-sterile, single use
			Specimen container
			Absorbent tipped applicator/large
			Tongue depressor, single use (wooden or plastic spatula)
			Examination table paper cover
	Personal protective equipment and clothing		Gloves, examination, non-sterile, single use (various sizes)
	Solutions and reagents		Formalin 10%, or tissue fixation reagents. Phosphate buffered
			Lubricating jelly (K-Y)
			Monsel's paste
			Saline solution
			Lugol iodine, bottle/Acetic acid solution 3–5%
			0.5% chlorine solution for decontaminating instruments
	Other		Container for warm water
			Bags for contaminated disposable supplies
Colposcopy	Medical equipment	Colposcope	
Cryotherapy	Medical equipment	Cryosurgery unit, with all parts and accessories listed	Probe, trigger, handle grip, yoke, inlet of gas cylinder, tightening knob, pressure gauge showing cylinder pressure, silencer outlet, gas-conveying tube probe tip
		Colposcope	
Endocervical curettage ECC	Medical equipment	Colposcope	
	Instruments	Endocervical curette	

1 *The devices listed in this procedure should be considered in addition to the equipment enlisted for the following procedures: cold knife conization (CKC), colposcopy, large loop excision of transformation zone (LEEP/LLETZ) and cryotherapy, visual inspection with acetic acid, endocervical curettage, pap smear and proctoscopy.*

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
Large loop excision of transformation zone (LEEP/ LLETZ)	Medical equipment	Electrosurgical unit, with all parts and accessories listed	Electrocautery system electrode for LEEP Return electrode Round and square loops of different sizes (rarely deeper than 10 mm) Wire electrodes of several sizes (square loop electrode, semi-circular loop electrode) Coagulating/ball electrode
		Smoke evacuator	
		Colposcope	
	Instruments	Vaginal speculum, Non conducting preferably with side retractors	
Papanicolaou Test (Pap smear)	Instruments	Vaginal speculum, reusable	Local anaesthetic, syringes
	Personal protective equipment and clothing		Gloves, examination, non-sterile, single use (various sizes)
	Single use devices/ disposables/medical supplies		Microscope slides frosted or liquid-based container (tube containing a special preservative solution)
			Tongue depressor, single use (wooden or plastic spatula)
			Cervical cytology brush or cervical cytology scraper (optional)
			Examination table paper cover
	Solutions and reagents		0.5% chlorine solution for decontaminating instruments
			Fixative spray or solution for pap smear (if slides are used)
	Other		Container for warm water
			Bags for contaminated disposable supplies
Visual inspection with acetic acid	Instruments	Vaginal speculum, reusable	
	Single use devices/ disposables/medical supplies		Examination table paper cover
			Absorbent tipped applicator/large
	Personal protective equipment and clothing		Gloves, examination, non-sterile, single use (various sizes)
	Solutions and reagents		Lugol iodine, bottle/Acetic acid solution 3–5%
			0.5% chlorine solution for decontaminating instruments
	Other		Container for warm water
			Bags for contaminated disposable supplies

1.3.2.2 Colorectal

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
Dietary counselling	Medical equipment	Floor scale with stadiometer	
Digital rectal examination and examination of abdomen, liver and lymph nodes.	Personal protective equipment and clothing		Gloves, examination, non-sterile, single use (various sizes)
	Single use devices/ disposables/medical supplies		Lubricating jelly (K-Y)
Rigid sigmoidoscopy	Medical equipment	Rigid sigmoidoscope	

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
Proctoscopy	Medical equipment	Proctoscope (see Endoscopy tower system in General devices for endoscopy table 1.4.1.)	

1.3.2.3 Lung

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
Spirometry	Medical equipment	Diagnostic spirometer	Respiratory, noseclips filter, pulmonary function filter, mouthpiece
Bronchoscopy	Medical equipment	Bronchoscope	
		Laryngeal mask	
		Endotracheal tube	

1.3.2.4 Prostate

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
Digital rectal examination	Personal protective equipment and clothing		Gloves, examination, non-sterile, single use (various sizes)
	Single use devices/ disposables/medical supplies		Lubricating jelly (K-Y)

1.3.2.5 Cervical and Prostate

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
Cystoscopy	Medical equipment	Rigid cystoscope (strongly recommended to consider an endoscopy tower)	
	Instruments	Cystoscopy biopsy forceps	
		Cystoscope sheath	
	Single use devices/ disposables/medical supplies		Lubricating jelly (K-Y)
			Biopsy needle
	Personal protective equipment and clothing		Urological irrigation kit
			Specimen container
			Cryptographic/urethrographic catheter, female
			Gloves, examination, non-sterile, single use (various sizes)
	Solutions and reagents		Transurethral-instrument lubricant
			Formalin 10%, or tissue fixation reagents

1.4 Priority medical devices for endoscopy

The following tables present the general medical devices for endoscopy, which can be used for screening, diagnosis, staging, and follow-up of many diseases including several cancers, and specific medical devices, which are used for surgical interventions for specific cancer types.

Please note: Components of all surgical instrument sets as well as needle and catheter gauge sizes (G) are listed in the chapter annex at the end of this chapter.

The following tables present the priority medical devices required to perform the following health interventions:

Cancer type	Interventions
All applicable cancers	• General endoscopy procedures
Colorectal cancer	• Colonoscopy • Endoscopic biopsy • Flexible sigmoidoscopy

1.4.1 General medical devices for endoscopy

Endoscopy procedures can be performed outside the surgical unit.

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
General endoscopic procedures	Medical equipment	Endoscopy tower system including: Insufflator Light source Irrigation/ aspiration pump Processing unit Video image display monitor	Endoscope system
		Single-patient physiologic monitoring system for ECG, Capnography, SpO2, B.P. Thermometer	Electrodes SpO2 sensors Blood pressure cuff Temperature sensor
		Resuscitation trolley, equipped with medicines and defibrillator/ with laryngoscope	
		Endoscope sterilization/ disinfection support set	
		Endoscope washer/disinfector	
		Ultrasonic washer	
		Adequate containers to clean and disinfect endoscopes and to transport them	Endoscope cleaning brush
		Endoscope leak tester, mechanical	Endoscope lens cleaner
			Rubber bulb
			Specimen container
			Endoscope lens cleaner
	Medical furniture	Cabinet, instruments, double door	
		Cabinets for accessories and clothes	
		Endoscope drying/storage cabinet	
		Footstool, two steps	
		Intravenous pole	
		Stretcher, foldable	

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
		Trolley, dressing, stainless steel, 2 trays	
		Trolley, soiled linen	
		Cabinet, medicines, double door	
		Table, instruments, Mayo type, stainless steel, on casters	
		Hospital stretcher	
	Personal protective equipment and clothing		Gloves, examination, non-sterile, single use (various sizes)
			Glasses, safety, regular size
			Surgical cap for patients and healthcare workers
			Surgical face mask
			General-purpose sterile drape
			Gown, patient
			Medical scrubs for healthcare worker or similar
			Instrument/equipment drape, non-sterile
	Single use devices/ disposables/medical supplies		Bandage, elastic, 7.5 cm x 5 m, roll
			Compress, gauze, sterile & non-sterile, single use
			First aid gauze/bandage
			Infusion giving set, sterile, single use
			Intravenous cannulas or catheters
			Lubricating jelly (K-Y)
			Monitoring electrodes
			Paper, exam table
			Prongs, nasal, oxygen, non sterile, single use (various sizes)
			Skin-cleaning wipe
			Syringes with needles (disposable)
			Tape, medical, roll (various sizes)
			Three-way-stopcock
			Tube suction, Yankauer, 270 mm/ Yankauer suction tips
			Surgical scrub sponge
			Absorbent tipped applicator
			Intubating bougies, adult and paediatric
			Oropharyngeal airway (adult size)
	Solutions and reagents		Alcohol isopropyl 70%
			Distilled water
			Endoscope cleaning kit
			Enzymatic detergent, test strip to measure the action of enzyme
			Formalin 10%, or tissue fixation reagents
			Gelatin Titanium dioxide (E171) Indigo carmine solution

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
			Glutaraldehyde 3.4% (Cidex, Maxicide, Wavicide)
			Methylene blue, bottle
			IV solutions
			Lugol iodine, bottle/Acetic acid solution 3–5%
			Peracetic acid disinfectant anticorrosion additive for endoscopes or similar
	Cleaning systems for endoscopes	Arm/leg tourniquet	Bedpan
			Sponge bowl
			Bowl/Emesis bowl
	Other		Safety box, for used syringes/needles

1.4.2 Specific medical devices for endoscopy by cancer type

1.4.2.1 Colorectal

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
Colonoscopy	Medical equipment	Rectal irrigation system	
		Video-colonoscope (see Endoscopy Tower System in General Devices for Endoscopy, Table 1.4.1.)	
Endoscopic biopsy	Medical equipment	Rectal irrigation system (see Endoscopy Tower System in General Devices for Endoscopy Table 1.4.1.)	
		Video-colonoscope (see Endoscopy Tower System in General Devices for Endoscopy Table 1.4.1.)	
	Single use devices/ disposables/medical supplies		Endoscopic hemoclip
			Polypectomy snare
			Sclerotherapy endoscopic needles
			Wire oval snare
	Surgical instruments	Biopsy forceps	
Flexible sigmoidoscopy	Medical equipment	Flexible sigmoidoscope (see Endoscopy Tower System in General Devices for Endoscopy Table1.4.1.)	

1.4.3 Guidance documents

Title	Link	Description
Package of Essential Noncommunicable (PEN) Disease interventions for Primary Health Care in Low Resource Settings	www.who.int/nmh/publications/essential_ncd_interventions_lr_settings.pdf	WHO PEN describes the minimum standard for NCDs to strengthen national capacity to integrate and scale up care of heart disease, diabetes, cancer asthma and chronic obstructive pulmonary disease in primary care in low resource settings.
Global Action Plan for the Prevention and Control of NCDs 2013-2020ASCO-ONS Standards for Safe Chemotherapy Administration	www.who.int/nmh/events/ncd_action_plan/en/	The 66th World Health Assembly endorsed the action plan for NCDs. It includes 9 voluntary global targets of which 9 is availability of affordable technologies to manage NCDs by 2015 and annex 3 on the essential interventions.
World Health Organization, Comprehensive Cervical Cancer Control. A guide to essential practice 2014	http://apps.who.int/iris/bitstream/10665/144785/1/9789241548953_eng.pdf	Provides a broad vision of a comprehensive approach and includes developments in technologies and strategies for cervical cancer prevention and control

1.5 Human resources for clinical assessment

Depending on national context including workforce availability and models, different occupations can fulfil the roles that may be required for clinical assessments. A prerequisite is having the required competencies to perform these roles and being officially recognized for it as per the scope of practice. The ISCO[2] codes are added as illustrative examples based on current practice for further reference. This should not be interpreted as guidance on occupations that should perform each role but rather indicative occupations that are currently performing these roles in different country contexts.

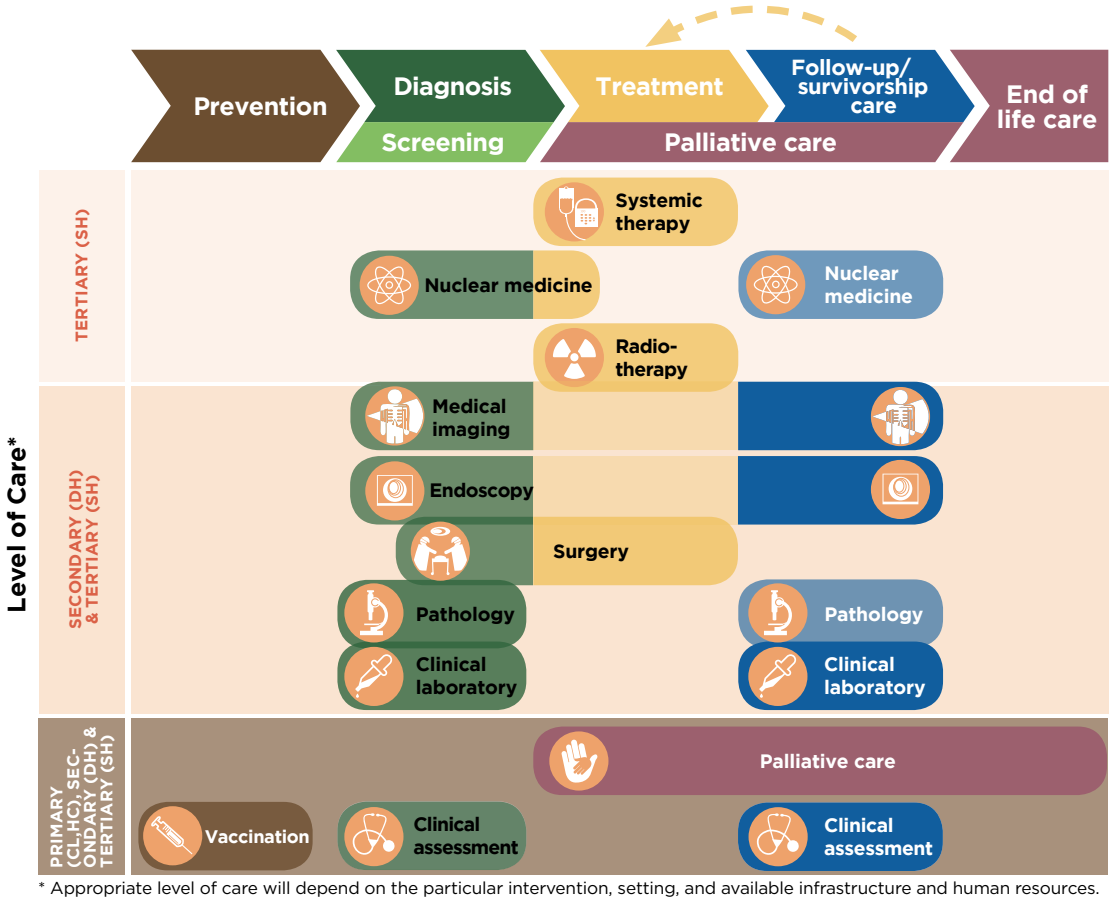
Sample role	Sample occupations (ISCO-08 codes)
General clinical assessment,	• General medical practitioner, (2211) • Nursing professional (2221) • Nursing associate professional (3221), supervised: healthcare assistant (5321) • Nurse-midwife (2221) • Haematology, clinical oncologist, Specialist medical practitioner (2212)
Blood clinical assessment	• Hematologist (2212) • Specialist medical practitioner (2212) • Biomedical Laboratory Scientist, Medical and pathology laboratory technicians (3212)
Clinical examination of breast Gynaecological examination Colposcopy	• Gynaecologist, Clinical oncologist, Specialist medical practitioner , (2212) • General medical practitioner (2211) • Nursing professional (2221) • Radiation Oncologist, Specialist medical practitioner (2212)
Prostate assessments	• Urologist, Clinical oncologist, Radiation Oncologist,Specialist medical practitioner (2212) • General medical practitioner (2211)
Lung assessments Spirometry	• Neumologist, Specialist medical practitioner (2212) • General medical practitioner (2211)r
Colonoscopy, Bronchoscopy, cystoscopy,	• Endoscopist, Urologist, Neumologist, Gastroenterologist, Specialist medical practitioner (2212) • General medical practitioner (2211)

2 *International Standard Classification of Occupations, http://www.ilo.org/public/english/bureau/stat/isco/docs/publication08.pdf*

2. Medical imaging & nuclear medicine

Health service delivery sequence overview:

This diagram expresses the flow of cancer patient to and from the medical imaging unit, and the elements to consider as support for the unit.



* Appropriate level of care will depend on the particular intervention, setting, and available infrastructure and human resources.

CL Community Level health post DH District Hospital HC Health Centre SH Specialized Hospital

Fig. 10.2. Health care service delivery overview – medical imaging and nuclear medicine

2.1 General description of the medical imaging unit

The purpose of the medical imaging unit is to perform screening, initial diagnosis, staging, treatment planning, image guided diagnosis, therapies and follow-up, using a wide variety of medical imaging equipment and techniques including: interventional radiology for treatment, conventional radiography, angiography, and nuclear medicine techniques as with positron emission tomography (PET) and gamma cameras. The latter will be described in detail in the nuclear medicine section.

Over the last decades, major technical innovations have contributed to enhancing diagnostic accuracy and have allowed for continuous improvement of imaging protocols. This has expanded the role and applications of nuclear medicine and diagnostic imaging for early detection, diagnosis and follow up of cancer patients.

The complexity of infrastructure, equipment and human resources for medical imaging services should be consistent with the capabilities of the healthcare level in which they are placed (primary, secondary or tertiary).

The expansion of the applicability of modalities that use ionizing radiation in medical imaging has resulted in a significant increase in the medical exposure of the population, especially due to the use of computed tomography (CT) scans and fluoroscopy image-guided interventional procedures. Concerning patient safety, there is a need to implement appropriate quality assurance and radiation protection programmes for patients, public and staff in all diagnostic-imaging units and interventional radiology.

Medical imaging is also indispensable for the performance of a spectrum of image-guided interventional procedures including: minimally invasive biopsies, placement of catheters for administration of chemotherapy and other medications or infusions, ablation of tumours (as with radiofrequency), among others. Specifically, image-guided procedures can be used for diagnostic purposes as well as for curative or palliative intent. The guidance can be performed using ultrasonography, computed tomography, fluoroscopy and/or angiography equipment depending on the clinical need.

The following section presents the medical devices used in imaging for the selected interventions/procedures (refer to the methodology section). A general description of infrastructure, human resources and quality management follows and guidance documents are given, in the understanding that medical devices are just one piece of the health delivery process.

2.2 Priority medical devices for medical imaging

The use of the following devices in coordination with defined evidence-based clinical procedures and protocols is very important in order to achieve the best patient outcomes. Existing imaging referral guidelines can be used to enhance appropriateness of referral. These decision support tools can inform referrers' and imaging specialists' choice of the appropriate examination *(1)*.

The minimum technical characteristics required to respond to the clinical needs are mentioned in the tables, but detailed technical specifications should be developed according to local needs.

Compliance with DICOM (Digital Imaging and Communications in Medicine) standard is required to have a functional network of medical imaging devices, along with visualization devices and printers as needed, and digital information that can be used in teleradiology applications.

It is important to mention that teleradiology with main centres and peripheral institutions could be implemented to support remote diagnosis and should be evaluated according to local needs and regulations.

The following tables present general medical devices which can be used for screening, diagnosis and treatment of many diseases including several cancers, and specific medical devices, which are used for interventions for specific cancer types. They are all working within a RIS (Radiological Information Systems) and using PACS (Picture Archiving Computerized System). Should be noted that PACS, RIS and DICOM should be considered as the ICT support for medical imaging centres locally, remotely and to support also teleradiology applications. It is important to note that besides the capital expenses of the equipment, having a DICOM license and the expected cost of maintenance/updating of the license should be considered when setting a medical imaging unit.

The following tables present the medical devices required to perform the following health interventions. It is important to note that these devices could be used for all cancers and that their appropriate use varies upon the tumour type, clinical stage, and complications. Patients undergoing therapy for virtually any malignancy would require image-guided procedures such as catheter placement. It should be noted that nuclear medicine imaging devices including gamma camera and PET are included under chapter 2.4

Cancer type	Interventions
All cancers	• Ultrasound scan • X-ray imaging • CT scan • MRI scan • Biopsy procedures (including stereotactic biopsy) • Fluoroscopic scanning for image guided procedures • Image guided procedures to place catheter for chemotherapy
Breast cancer	• Mammography • Stereotactic-guided core needle biopsy of primary tumour or metastatic lesions • Ultrasound scan • Ultrasound guided biopsy of regional lymph and sentinel nodes • Breast Tomosynthesis • Image guided procedures to place catheter for chemotherapy.
Cervical cancer	• Ultrasound scan • TVUS (transvaginal ultrasound scan) • Image guided procedures to place catheter for chemotherapy.
Colorectal cancer	• TRUS (transrectal ultrasound scan) • Image guided procedures to place catheter for chemotherapy.
Leukaemia	• Ultrasound scan • CT scan
Prostate cancer	• TRUS (transrectal ultrasound scan)-guided prostate biopsy

2.2.1 General medical devices for medical imaging

This table includes general devices that should be integral to any medical imaging facility. These are general as they can be used for various diseases including all types of cancer procedures. Please note they are organized by clinical procedure.

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
Ultrasound scan	Medical equipment	General ultrasound, preferably with capacity for colour Doppler imaging system and accessories	• Documentation system (printer or electronic) • Disposable or single use ultrasound probe drapes
		Ultrasound probe or transducer/ Convex array, middle-frequency 3-5 MHz	
		Ultrasound probe or transducer/Linear array, high-frequency 10-12 MHz	
	Quality assurance devices	Diagnostic ultrasound phantom	
	Medical furniture	Hospital stretcher, treatment table or similar	
	Single use devices/ disposables/ medical supplies		Non-sterile coupling gel

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
	Solutions and reagents		Antimicrobial solution to disinfect the transducers
X-Ray imaging	Medical equipment	General-purpose digital radiography system with 3-megapixels monitor for interpretation	
Fluoroscopic imaging process	Medical equipment	Fluoroscopy unit	
CT scan	Medical equipment	Computed Tomography (CT) System (multi-slice) including • workstation, preferably with ability to perform 3-D reconstruction, computers • 3-megapixels monitor for Interpretation • Laser/thermal printer (optional) • PACS and RIS to share images • Dual head injector	
		Appropriate dedicated coils and pediatric if needed. 3-megapixels monitor for interpretation	
	Quality assurance devices	CT phantom, CT quality control devices, including pencil style CT dose detector	
MRI scan (for specialized hospitals)	Medical equipment	Magnetic Resonance Imaging (MRI) System (1.5 T)	Software package
			Magnetic metal detector
		MRI compatible anaesthesia machine	
		MRI compatible infusion pump	
		MRI compatible patient physiologic monitoring system	
		MRI compatible resuscitation trolley equipped with medicines and defibrillator	
		MR-safe stethoscope and sphygmomanometer	
		MRI compatible general-purpose suction system	
		MR compatible biopsy / procedure equipment (optional)	
	Quality assurance devices	MRI system quality assurance device	
	Medical furniture	MRI compatible assistive footstool	
		MRI compatible cart	
		MRI compatible intravenous pole	
		MRI compatible wheelchair	
		MRI compatible stretcher	
	Solutions and reagents		MRI contrast media, injectable
	Other		MRI compatible oxygen canisters
General procedures for the area	Software		Picture Archiving Communication System (PACS)
			RIS (Radiological Information Systems)

3 Components of all surgical instrument sets as well as needle and catheter gauge sizes (G) are listed in the chapter annex at the end of the Surgery chapter

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
Biopsy, drainage or ablation procedures	Medical furniture	Patient Procedure Table / Couch	
		Table, instruments, Mayo type, stainless steel, on casters	
		Drug cupboard (local anesthesia for pain, contrast reaction)	
	Instruments	Scalpel with blades	
		Dissection forceps	
	Personal protective equipment		Surgical cap for patients and healthcare worker
			Surgical face mask
			Eye protective wear
			Operator sterile gown
			General-purpose sterile drape
	Single use devices/ disposables/ medical supplies		Cannulas, intravenous (IV) short, sterile, single use (sizes G)[1]
			Compress, gauze, sterile & non-sterile, single use
			Skin-cleansing wipe
			Skin markers
			Syringes with needles (disposable)
			Absorbent tipped applicator
			Sterile ultrasound coupling gel
			Non-implantable needle guide
			First aid gauze/bandage
			Skin-cover adhesive strip
			Microscope slides frosted
			Tongue depressor, single use
			Needles, sterile, single use: • 20–24G (for fine needle aspiration) • 11–14 G (for bone biopsy) • 16–20G (for other tissue biopsy)
			ICD set / Thoracic tube insertion set (see Surgery subchapter for instrument sets)
			Gelfoam (for plugged biopsy)
	Solutions and reagents		Formalin 10% or tissue fixation reagents
			Alcohol or iodine preparation cleansing agent
			Oxygenated water
	Other		Ruler
			Specimen container
			Label or pen for labelling specimen containers
			Basic sedation equipment
			Safety box, for used syringes/needles

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
Basic general non imaging support procedures	Medical equipment	Pulse oximeter	Spare probes, adult, paediatric and neonatal, basic
		Resuscitation trolley, equipped with medicines and defibrillator with laryngoscope	Sharps and biohazard disposal container
		Aneroid sphygmomanometer	
		Stethoscope	
		Thermometer	
		Suction system	
		Dictaphones or capacity for transcription	
	Medical furniture	Trolley, dressing, stainless steel, 2 trays	
		Wheelchair	
		Patient procedure table / couch	
		Stretcher, foldable	
	Personal protective equipment and clothing		Gloves, examination, non-sterile, single use (various sizes)
			Surgical face mask
			Examination/treatment table cover
	Solutions and reagents		Saline solution
			Alcohol or iodine preparation cleansing agent
			Chlorine solution
	Other		Basin, kidney, stainless steel/polypropylene
			Receptacle, waste, stainless steel, pedal action
			Bowl/ Emesis bowl
	Radiation protection devices		Radiation shielding goggles
			Radiation shielding apron rack
			Radiation shielding gloves
			Thyroid shielding
			Leaded gloves
			Patient radiation shielding
			Radiation shielding apron
			Gonadal shielding
			Breast shielding (optional)
			Radiation shielding headwear (optional)
			Ceiling-suspended protective screen and protective lead curtains mounted on patient table
	Radiation monitoring	Electronic dosimeters	Dosimeter, personal • film • thermoluminescence dosimeters (TLD) • optically stimulated luminescence (OSL) dosimeters

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
Contrast injection procedures (and management of contrast media reactions)	Medical equipment	Contrast medium injection system	
		Single-patient physiologic monitoring system	
		Defibrillator	
		Emergency cart with medicines and defibrillator or automated external defibrillator (AED), blood pressure/ pulse monitor, pulse oximeter	
		Suction system	
		Warming cabinet for contrast media	
	Medical furniture	Stand, infusion, double hook, on casters	
		Table, instruments, Mayo type, stainless steel, on casters	
	Personal protective equipment and clothing		Operator sterile gown
			Protective cotton gown reusable
			Gown, patient
			General-purpose sterile drape
			Surgical cap for patients and healthcare worker
	Single use devices/ disposables/ medical supplies		Catheter, Foley, sterile, single use (sizes G)[3]
			Catheter, urethral, sterile, single use (sizes G)[3]
			Compress, gauze, sterile & non-sterile, single use
			Infusion set, sterile, single use
			Skin-cleansing wipe
			Syringes with needles (disposable)
			Tape, medical, roll (various sizes)
			Catheter (18 gauge or larger)[1]
			Septo syringe
			First aid gauze/bandage
			Skin-cover adhesive strip
			Cannulas, intravenous (IV) single use (sizes G)[3] · intubation equipment
	Solutions and reagents		Contrast media, injectable
			Contrast media, oral
			Sterile saline for IV
	Other	Arm/leg tourniquet	Oxygen supply
			Safety box, for used syringes/needles

2.2.2 Specific medical devices for medical imaging by cancer type

This section describes the medical imaging devices or accessories required that complement the above list of general devices. For metastatic breast, cervical, colorectal, and prostate cancer, serial imaging staging is most commonly through CT, PET/CT, and/or potentially bone scans (gamma camera) as relevant to the case which will be described in the next section. It is important to have preparation sites for all the following procedures.

2.2.2.1 Breast

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
Mammography	Medical equipment	Mammographic X-ray system	Compression devices for additional projections e.g. cone compression (compatible with the collimators)
Stereotactic-guided core needle biopsy of primary tumor or metastatic lesions	Medical equipment	Mammographic stereotactic biopsy system (cone compression devices could be used with normal mammographic system) Optional: vacuum-assisted biopsy device and driver	
	Single use devices/ disposables/medical supplies		Biopsy needle
			Wire localization needle (e.g. Kopan's Needle 21G, 20G)
			Fiducial markers/soft tissue markers
Ultrasound guided biopsy of regional lymph and sentinel nodes[3] *(See General Medical Devices table 2.2.1 above, ultrasound procedures)*	Medical equipment	Biopsy gun	Biopsy needle (semi and automatic devices)
		Ultrasound probe or transducer/ Linear array, high-frequency transducers, small-footprint, large-bandwidth transducers with central frequency above 10 MHz are ideal	Ultrasound probe cover
	Single use devices/ disposables/medical supplies		Sterile ultrasound coupling gel
Core needle biopsy[4]	Medical equipment	Biopsy Gun	Biopsy needle
	Single use devices/ disposables/medical supplies		Specimen container
			Needles and syringes for local anaesthetic
			Skin-cleaning wipe
			Skin-cover adhesive strip
	Solutions and reagents		Formalin 10%, or tissue fixation reagents
			Alcohol or iodine preparation cleansing agent
	Other		Label or pen for labelling sample
			Ruler
Fine needle aspiration (FNA)[4]	Single use devices/ disposables/medical supplies		Specimen container
			Needles and syringes for local anaesthetic
			Syringes for the biopsy and holder (optional)

3 Can be image-guided; i.e. breast ultrasound-guided biopsy or mammogram-guided (refer to the imaging section) although core needle biopsy is more common for mammographic biopsies than fine needle aspiration (FNA).

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
			Biopsy needle (23 or 25 gauge needle)
			Microscope slides frosted
			Skin-cleaning wipe
			Skin-cover adhesive strip
	Solutions and reagents		Formalin 10%, or tissue fixation reagents
			Alcohol or iodine preparation cleansing agent
	Other		Label or pen for labelling sample
			Ruler
Procedure	**Medical devices category**	**Capital equipment *(For specialized hospitals)***	**Accessories/hardware/software/ consumables/single use devices**
MRI scan	Medical equipment	(see General Medical Devices table 2.2.1 above) with breast coil	Vascular access for chemotherapy, ports and PICCs

2.2.2.2 Cervical

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
Ultrasound scan	Single use devices/ disposables/medical supplies	(see General Medical Devices table 2.2.1 above) with vaginal ultrasound imaging system transducer	Ultrasound probe cover Sterilization solution for US transducer
Interventional radiology for palliative care	Medical equipment	General-purpose digital radiography system	

2.2.2.3 Colorectal

Only a small fraction of colorectal lesions can be sampled under TRUS, only the distal-most ones, and mention should be made that endoscopy is required for sampling of the majority of colorectal lesions. See endoscopy chapter for more information.

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
TRUS (transrectal ultrasound) *(See General Medical Devices table 2.2.1 above, ultrasound procedures)*	Medical equipment	Ultrasound system (as mentioned in the ultrasound procedure section) or ultrasound imaging system specific for TRUS, line-powered if possible, specific for this purpose including intracavitary probe for TRUS/ Rectal ultrasound imaging system transducer (see General Medical Devices table 2.2.1 above)	Sterilization solution for US transducer
		Biopsy gun	Biopsy needle
CT Colonography	Medical equipment	Computed Tomography (CT) System (multi-slice)	Foley catheter, appropriate reading software
		Air or CO2 insufflator,	
Procedure	**Medical devices category**	**Capital equipment *(For specialized hospitals)***	**Accessories/hardware/software/ consumables/single use devices**
MRI scan	Medical equipment	(see General Medical Devices table 2.2.1 above)	
		Rectal coil	

2.2.2.4 Leukaemia

Though leukaemia does not usually require much imaging, leukaemia patients very frequently require placement of a Port-a-cath or PICC for administration of chemotherapy. Both of those placements are image-guided.

Procedure	Medical devices category	Capital equipment (For specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
Ultrasound scan	Medical Equipment	General ultrasound imaging system	See 2.2.1 for general medical devices including Biopsy procedures section.
CT	Medical Equipment	Computed Tomography (CT) System (multi-slice)	See 2.2.1 for general medical devices including Biopsy procedures section.

2.2.2.5 Lung

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
Chest X-ray or other radiography	Medical Equipment	General-purpose digital radiography system	
CT	Medical Equipment	Computed Tomography (CT) System (multi-slice)	(see General Medical Devices table 2.2.1 above including Biopsy procedures section)
Ultrasound scan	Medical Equipment	(see General Medical Devices table 2.2.1 above)	
Procedure	**Medical devices category**	**Capital equipment (for specialized hospitals)**	**Accessories/hardware/software/ consumables/single use devices**
EBUS	Medical Equipment	Endobronchial ultrasound system	Capacity for transbronchial biopsy
EUS	Medical Equipment	Endoesophageal ultrasound system	Capacity for transesophageal biopsy
MRI	Medical Equipment	(see General Medical Devices table 2.2.1 above	

2.2.2.6 Prostate

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
TRUS (transrectal ultrasound)-guided prostate biopsy *(See General Medical Devices table 2.2.1 above, ultrasound procedures)*	Medical equipment	Ultrasound system (as mentioned in the ultrasound procedure section) or ultrasound imaging system specific for TRUS, line-powered if possible, specific for this purpose (see General Medical Devices table 2.2.1 above)	Sterilization solution for US transducer
		Intracavitary probe for TRUS/ Rectal ultrasound imaging system transducer	
		Biopsy gun	Prostate biopsy needle
	Instruments		Non-implantable needle guide and adaptor
	Single use devices/ disposables/medical supplies		Sterile ultrasound coupling gel Ultrasound probe cover

2.3 Other health system components for medical imaging

2.3.1 Human resources for medical imaging

A coordinated team of radiologists, and clinicians (clinical physicians) experienced in ultrasonography, radiological technologists/radiographers and sonographers, is essential in the process of producing and interpreting diagnostic images. Medical physicists have an important role in the optimization of the studies and in the development of quality assurance, dosimetry and radiation protection programmes that ensure safe and effective medical imaging. Additionally, biomedical engineers are needed for the technical management of equipment and IT specialists are needed if the establishment and maintenance of teleradiology systems. Multidisciplinary team collaboration is very important, including the participation of imaging specialists in clinical conferences such as "tumour boards" around the world.

Some of these health professionals (e.g. radiologists, nuclear medicine specialists, radiographers and medical physicists) are more familiar with medical uses of ionizing radiation, as the requirements for the above mentioned their education, training, qualification and competencies usually include diagnostic imaging also includes and radiation protection. This is not the case for other specialists (e.g. orthopaedic surgeons, cardiologists, gastroenterologists, rheumatologists and neurosurgeons, among others) who also use ionizing radiation in some situations, but for whom radiation protection is not traditionally part of their education, training, qualification and competencies. Guidance on education and training in radiation protection of health professionals is available elsewhere *(2, 3)*.

Depending on national context including workforce availability and models, different occupations can fulfil the roles that may be required for medical imaging. A prerequisite is having the required competencies to perform these roles and being officially recognized for it as per the scope of practice. The ISCO[2] codes are added as illustrative examples based on current practice for further reference. This should not be interpreted as guidance on occupations that should perform each role but rather indicative occupations that are currently performing these roles in different country contexts.

Sample role	Sample occupations (ISCO-08 codes)
• Responsible for the medical aspects of all the procedures and installations including justification and optimization of studies • Acquisition and interpretation of US and fluoroscopic studies, interpretation of conventional radiology, mammography, CT and MR studies • Performance of image-guided, minimally invasive diagnostic and therapeutic procedures (special training required) • Responsible for regular and independent audits of the programme of QA for medical exposures (in coordination with radiographer and medical physicist or related occupation)	• Radiologist , Specialist medical practitioner (2212)
• Responsible of performing the ultrasound procedures with the different probes depending on organ scanned.	• Radiologist , Specialist medical practitioner (2212) • General medical practitioner (2211) • Ultrasonographist, Medical imaging and therapeutic equipment technician (3211)
• Plan and perform the medical imaging procedure (eg. CT, MR, mammography and conventional radiology) • Responsible for overseeing team approach to protocol development with technologist and physicist • Support radiologists in performance of minimally invasive diagnostic and therapeutic image-guided procedures. • Optimization of medical imaging procedures • Implementation of radiation protection protocols (incoordination with medical physicists and radiologists). • Administrative issues of radiological services (in coordination with radiologists and administrative personnel)	• Radiographer, Medical imaging and therapeutic equipment technicians(3211)

2 *International Standard Classification of Occupations, http://www.ilo.org/public/english/bureau/stat/isco/docs/publication08.pdf*

Sample role	Sample occupations (ISCO-08 codes)
• Responsibility towards radiation protection in compliance with national and international (BSS) requirements • Responsibility to contribute to the imaging team to ensure that patients do not receive additional exposure due to inappropriate or suboptimal procedures • Optimization of studies • Establishment of comprehensive QA programmes for medical exposures including calibration and dosimetry of radiological equipment and radiation protection programmes for workers and patients • Calibration and verification of measurement instruments • Technical supervision of equipment operation and maintenance	• Medical physicist (2111)
• Scheduling, reception of patients, all other administrative tasks	• Clerical support workers (4412) • Technologists(3211), • Nurses (2221)
• Management of medical devices: planning, procurement, supervision of installation and maintenance	• Biomedical Engineer (2149) • Biomedical technician / physical and engineering science technician (3119)

2.3.2 Infrastructure

Diagnostic imaging services require several utilities and services such as: water, stable electricity, installations with proper infrastructure and adequate sanitary conditions, among others, for the protection of patients, workers and the general public.

Warning devices (e.g. signs, lights) to prevent inadvertent entry into controlled or supervised areas must be posted. Additional design features are needed for proper performance of diagnostic and interventional procedures in children. More information regarding medical radiological equipment and related software for diagnostic radiology and image guided interventional procedures are provided elsewhere, such as in the *IAEA-PAHO-WHO Safety Guide on Radiological Protection for Medical Exposure to Ionizing Radiation (4).* Appropriate steps should also be taken for safe disposal of both biological waste and disposable consumable items used in these procedures.

If available, national radiology guidelines should be followed. Codes and standards such as NFPA (National Fire Protection Association), ISO, NEC (National Electrical Code), emergency power systems, ASHRAE for Ventilation of Health Care, washing facilities and special attention to temperature and humidity for each equipment installation are needed, as required by national regulatory body both, one related to Ministry of Health and the second related to radiation energy in the country.

Facilities layout distribution considerations

The weight and dimensions of medical equipment should be considered when designing facilities, as well as the planning of how to move equipment in prior to installation. Structural considerations should inform decisions regarding equipment placement in existing facilities. Facility planning and design should incorporate convenient and dedicated placement of imaging equipment, considering the requirements of floor space (if the medical equipment is fixed), mechanical connections and the voltage required for electrical connections. Commonly, medical imaging devices are installed by the manufacturer or vendor; therefore, close coordination between all stakeholders (designers, installers, construction contractors and others) is required.

The size of all equipment areas should comply with manufacturers' recommendations and radiation protection requirements of the country or if not available, then international recommendations should be followed. Larger rooms are preferable to facilitate equipment and patient movement during the procedure. Larger rooms are also preferable for radiation protection purposes since increased distance from the radiation source confers an exponentially decreased radiation dose, as explained by the inverse square law for radiation."

Rooms and surrounding areas of MRI installations must be shielded against radiofrequency fields (Faraday cage) and must comply with safety issues related to the use of the magnetic field (ferrous metal interferes with image quality; construction must therefore minimize interference).

Moreover, MR suite entry security must be maintained since any ferromagnetic object will act as a guided projectile and will harm a patient undergoing imaging. As an example, patients have been killed by non-MR-safe oxygen canisters inadvertently brought into MR suites; those canisters subsequently acted as guided missiles. Even cleaning staff with non-MR-safe floor buffers may not enter the MR suites after-hours as those, too, rapidly pull into the bore of the magnet. An MR safety committee for the facility is advisable. All facility staff should be educated that the magnet is always on. In this spirit, prior to MR imaging, patients must undergo routine questioning as to potential ferromagnetic materials intrinsic to them: e.g. non-MR-safe implants or clips, shrapnel, and more.

Shielding and radiation protection

Appropriate structural shielding to protect workers, patients and general public from ionizing radiation must be installed to ensure adequate protection according to national and international guidelines *(4)*.

Shielding requirements including both structural and ancillary protective barriers must be considered at the design stage of planning a diagnostic imaging facility or department. A certified medical physicist or a qualified expert should specify the type, location and amount of protective barriers to be installed taking into account, amongst other things, the department layout (areas distribution) and medical equipment installed, the workload of the equipment and the occupancy factors of the surrounding areas. In rooms performing fluoroscopy- or angiography-guided interventional procedures, ceiling mounted protective screens, mobile protective barriers, table mounted leaded curtains and protective eye wears should be considered.

The patient should be visible at all times through the window or operator shielding, even when the patient is in the tilt position, and there should be some means of communication with the patient during the examination.

MRI installations must be shielded against radiofrequency fields (Faraday cage) and must comply with safety and image quality issues related to the use of magnetic fields.

In medical imaging units, the safety of patients and healthcare workers is very important to take into account; therefore, personnel dosimeters (passive and active if needed), devices for radiation protection should be included, such as lead glass eye wears (goggles), protective lead aprons, thyroid shielding for workers, breast, thyroid, eyes and gonadal shielding for patients, among others. Radiation survey meter should be available. Adequate equipment to perform quality control tests should also be included as part of the lists of required technologies, including suitable dosimetry instrumentation and calibration devices *(5)*.

Heating, ventilation and air conditioning systems

The ventilation should be adequate for the area and must comply with the manufacturers' specifications for the imaging equipment, but at the same time it should be consistent with the requirements for safety and comfort of the patient. An helium extraction pipe system must be installed in case of quenching, as well as an O2 monitor.

Information and communications technology (ICT)

RIS, PACS, DICOM and workstation areas, including the storage, privacy and security of medical records should be considered and are described further in the IAEA Human Health Series No. 28 Worldwide Implementation of Digital Imaging in Radiology *(6)*. If the use of teleradiology, PACS or RIS is considered, adequate bandwidth, image quality and information infrastructure and/or web-based platforms should be available.

It is important to mention expected DICOM and PACS license renewals/updates and incumbent costs which can potentially be negotiated or at least clarified as part of the initial contract. Omission of clear long-term hardware maintenance and software contracts has proven troublesome, with multiple examples in low resource settings where subsequent long-term costs post-procurement have been unexpected.

2.3.3 Quality management

Quality management, both generally and specifically within radiology, demands a quality culture that includes a systematic approach to the elements that govern the delivery of that service. Therefore, the concept of quality within a radiological facility covers, in its widest sense, all those factors that affect the intended outcome, such as: generation of differential diagnostic possibilities, a tissue-based diagnosis from an image-

guided biopsy, clinical restaging of cancer based upon serial imaging, assessment of response to therapy (as after radiotherapy), or palliation from an interventional radiology procedure such as radiofrequency ablation.

WHO defines quality assurance (QA) programmes in diagnostic imaging as a coordinated effort by the staff operating a facility to ensure that the images produced are of sufficiently high quality to consistently provide adequate diagnostic and/or intra-procedural information at the lowest possible cost and with the least possible exposure of the patient, personnel, and public to radiation. QA programmes related to medical exposures are mandatory and the conditions for their implementation must be ensured. Calibration, dosimetry and QA of radiological equipment must be performed by, under the oversight of, or with the documented advice of a medical physicist, along with regular independent audits of these programmes.

If teleradiology is used, the quality of the transferred images, identification and confidentiality of the patients' data, adequate transmission of clinical information, and relevant previous and/or complementary images must be audited on a regular basis.

One of the most important components of this quality framework is the comprehensive clinical audit, which involves evaluation of data, documents and resources to check performance against standards. It is essentially a process of fact-finding and interpretation and, as such, provides an efficient tool for quality improvement. Please see the *IAEA Quality Assurance Audit for Diagnostic Radiology Improvement and Learning (QUAADRIL)* publication for more information *(7).*

2.3.4 Guidance documents

Title	Link	Description
WHO-ICRQS Referral Guidelines Project IRQN "Referral Guidelines for Diagnostic Imaging"	http://www.isradiology.org/isr/quality_guidelines.php	The Project aims to promote safe use and appropriate selection of diagnostic imaging, and to ensure these procedures are justified and indicated by providing a practical guidance tool and supporting its implementation. The Project includes activities to improve clinical referral guideline awareness, access and use. The use of clinical referral guidelines supports good medical practice, patient-centered care, procedure justification, and radiation safety.
ACR (2015) American College of Radiology's Appropriateness Criteria®	http://www.acr.org/Quality-Safety/Appropriateness-Criteria	The ACR Appropriateness Criteria® (AC) are evidence-based guidelines to assist referring physicians and other providers in making the most appropriate imaging or treatment decision for a specific clinical condition. Employing these guidelines helps providers enhance quality of care and contributes to the most efficacious use of radiology.
European Qualifications Framework (EQF) Benchmarking Document: Radiographers	http://www.efrs.eu/publications/see/EFRS_EQF_level_6_benchmark?file=749	The purpose of the document is to serve as point of reference and benchmark for educational institutions, employers and professional bodies in Europe.
Radioisotope Handling Facilities (Atomic Energy Regulatory Board of India)	http://www.aerb.gov.in/AERBPortal/pages/English/t/publications/CODESGUIDES/SG-RF-RS.pdf	The objective of this Atomic Energy Regulatory Board of India safety guide is to provide guidance for implementing radiation safety requirements in facilities handling radioisotopes in order to: (a) ensure that workers and members of the public are not exposed to radiation, in excess of limits, specified by the competent authority, under the Atomic Energy (Radiation Protection) Rules, 2004, and safety directives issued by the competent authority from time to time; (b) reduce such radiation exposures to levels as low as reasonably achievable (ALARA); (c) ensure safe handling, physical security of radioactive materials and management of radioactive wastes; (d) provide means for detecting/assessing hazardous situations and initiating prompt remedial measures towards mitigating consequences; and (e) ensure accounting and recording of use of radioactive materials.

Title	Link	Description
ICRP Publication 127 on Radiological Protection in Ion Beam Radiotherapy	http://www.icrp.org/publication.asp?id=ICRP%20Publication%20127	Radiological protection and safety management should always conform with regulatory requirements. The current regulations for occupational exposures in photon radiotherapy are applicable to ion beam radiotherapy with protons or carbon ions. However, ion beam radiotherapy requires a more complex treatment system than conventional radiotherapy, and appropriate training of staff and suitable quality assurance programmes are recommended to avoid possible accidental exposure of patients, to minimise unnecessary doses to normal tissue, and to minimise radiation exposure of staff
Federal Guidance Report No. 14: Radiation Protection Guidance for Diagnostic and Interventional X-Ray Procedures	https://www.epa.gov/sites/production/files/2015-05/documents/fgr14-2014.pdf	Federal Guidance Report No. 14 provides federal facilities that use diagnostic and interventional X-ray equipment with recommendations for keeping patient doses as low as reasonably achievable without compromising the quality of patient care. This guidance is an update of Federal Guidance Report No. 9, which was issued in 1976.
ICRP Publication 129 on Radiological Protection in Cone Beam Computed Tomography (CBCT)	http://www.icrp.org/publication.asp?id=ICRP%20Publication%20129	The perception that CBCT involves lower doses was only true in initial applications. CBCT is now used widely by specialists who have little or no training in radiological protection. This publication provides recommendations on radiation dose management directed at different stakeholders, and covers principles of radiological protection, training, and quality assurance aspects. The recommendations provided in this publication may evolve in the future as CBCT equipment and applications evolve. As with previous ICRP publications, the Commission hopes that imaging professionals, medical physicists, and manufacturers will use the guidelines and recommendations provided in this publication for implementation of the Commission's principle of optimisation of protection of patients and medical workers, with the objective of keeping exposures as low as reasonably achievable, taking into account economic and societal factors, and consistent with achieving the necessary medical outcomes.
Radiation Therapy Sources, Equipment and Installations (Atomic Energy Regulatory Board of India)	http://www.aerb.gov.in/AERBPortal/pages/English/t/publications/CODESGUIDES/SC-MED-01R.pdf	The objective of this Atomic Energy Regulatory Board of India code is to stipulate the radiation safety requirements in the design, installation and operation of radiation therapy sources, equipment and installations in order to ensure: (a) that radiation workers and members of the public do not receive radiation dose in excess of the limits specified by the competent authority under the Atomic Energy (Radiation Protection) Rules, 2004, and the safety notifications/directives issued thereunder from time to time; (b) that radiation doses to workers and members of the public are optimised to levels as low as reasonably achievable; (c) availability of appropriate instruments, tools and accessories, personnel and expertise, for safe handling of equipment and sources; (d) patient protection; (e) security, safe custody, transportation and disposal of sources; (f) timely detection and prompt rectification of malfunctions of radiation safety related equipment; and (g) initiation of appropriate actions to mitigate consequences of radiation emergencies.
Safety Code For Medical Diagnostic X-Ray Equipment and Installations (Atomic Energy Regulatory Board of India)	http://www.aerb.gov.in/AERBPortal/pages/English/t/publications/CODESGUIDES/SC-MED-02-REV1.PDF	This Atomic Energy Regulatory Board of India code is intended to govern radiation safety in design, installation and operation of X-ray generating equipment for medical diagnostic purposes in order to: (a) ensure that radiation workers and members of the public are not exposed to radiation in excess of limits specified by the competent authority under the Radiation Protection Rules, 1971, and by safety directives issued from time to time; (b) reduce radiation exposures below these limits to levels as low as reasonably achievable; (c) ensure availability of appropriate equipment, personnel and expertise for safe use of the equipment and for patient protection; and (d) ensure timely detection and prompt rectification of radiation safety-related defects or malfunctioning of the equipment.
Communicating radiation risks in paediatric imaging- information to support health care discussions about benefit and risk. WHO. 2016. ISBN: 9789241510349	http://apps.who.int/iris/bitstream/10665/205033/1/9789241510349_ eng.pdf	The document is intended to serve as a tool for health care providers to communicate known or potential radiation risks associated with paediatric imaging procedures, to support risk-benefit dialogue in health care settings.

Title	Link	Description
Clinical Imaging Referral Guidelines:		
American College of Radiology (ACR) for ACR Select	http://www.acr.org/quality-safety/appropriateness-criteria/acr-select	
Canadian Association of Radiologists National Practice Guidelines	http://www.car.ca/en/standards-guidelines/standards.aspx	
European Community: referral guidelines for imaging (implementation of Council Directive 97/43/Euratom requirements concerning referral criteria for medical imaging in the European Union)	https://www.myesr.org/cms/website.php?id=/en/eu_affairs/newfile-name.htm	
IAEA Safety Reports Series No. 39 Applying Radiation Safety Standards in Diagnostic Imaging and Interventional Procedures Using X-rays (jointly co-sponsored by the WHO)	http://www-pub.iaea.org/MTCD/publications/PDF/Pub1206_web.pdf	
Radiology Information Source for Patients jointly produced by RSNA and ACR	http://www.radiology-info.org	
Royal College of Radiologists iRefer	https://www.rcr.ac.uk/clinical-radiology/being-consultant/rcr-referral-guidelines/about-irefer	
Société française de radiologie	Gbu.radiologie.fr http://www.sfrnet.org/sfr/professionnels/5-referentiels-bonnes-pratiques/guides/guide-bon-usage-examens-imagerie-medicale/index.phtml	Guide du bon usage des examens d'imagerie medicale
Western Australia Diagnostic Imaging Pathways	http://www.imag-ingpathways.health.wa.gov.au/	
WHO: Medical imaging specialists call for global referral guidelines	http://www.who.int/ionizing_radiation/medical_exposure/referral_guidelines.pdf	
Radiation Protection Initiatives and Campaigns:		
AfroSafe:	www.afrosaferad.org/	
EuroSafe	http://www.eurosa-feimaging.org/	
Image Gently	http://www.im-agegently.org/	
Image Wisely	http://www.imagewise-ly.org	
LatinSafe: the Latin American Alliance for Radiation Protection	http://www.im-agegently.org/Portals/6/Current%20News/LatinSAFE%20Launched%20English%20VF.pdf?ver=2016-05-24-110958-043tion of Patients,	

Title	Link	Description
Cancer staging by NCI and AJCC:		
	http://www.cancer.gov/about-cancer/diagnosis-staging/staging	
	https://cancerstaging.org/references-tools/Pages/What-is-Cancer-Staging.aspx	
Management of Contrast Media Reactions:		
American College of Radiology (ACR) Manual on Contrast Media Version 10.2 (2016)	http://www.acr.org/~/media/37D84428BF1D4E1B9A3A2918DA9E27A3.pdf	
Informational link on CT Colonography:		
From IAEA RPOP	https://rpop.iaea.org/rpop/rpop/content/informationfor/health-professionals/1_radiology/computedtomography/ctcolonography.htm	
Links to all the radiology-related NGOs in "official relations" with WHO		
DITTA	http://globalditta.org/	
IOMP	http://www.iomp.org/	
ISR	http://www.isradiology.org/isr/index.php	
ISRRT	http://www.isrrt.org/isrrt/default.asp	
RAD-AID	http://www.rad-aid.org/	
WFUMB	http://www.wfumb.org/	

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2) ICRP, 2009. Education and Training in Radiological Protection for Diagnostic and Interventional Procedures. ICRP Publication 113. Ann. ICRP 39(5) and EC, 2014 Radiation Protection No 175- European guidance on radiation protection education and training of medical professionals in the EU, European Commission; (http://ec.europa.eu/energy/sites/ener/files/documents/175.pdf).
3) ICRP Publication 117 on Radiological Protection in Fluoroscopically Guided Procedures outside the Imaging Department. Ann. ICRP 40(6), 2010
4) IAEA-PAHO-WHO Safety Guide on Radiological Protection for Medical Exposure to Ionizing Radiation (ISBN:92-0-111302-1).
5) BSS, 2014 - Radiation protection and safety of radiation sources: International Basic Safety Standards. - General safety requirements Part 3 Series No. GSR Part 3. Vienna.
6) IAEA Human Health Series No 28. Worldwide Implementation of Digital Imaging in Radiology, 2015.
7) Quality Assurance Audit For Diagnostic Radiology Improvement And Learning (QUAADRIL). International Atomic Energy Agency, Vienna, 2010; (http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1425_web.pdf).

2.4 General description of the nuclear medicine unit

Nuclear medicine is a field of medicine that uses small amounts of radioactive substances called radiopharmaceuticals for the diagnosis and treatment of many health conditions including certain types of cancer. Nuclear medicine procedures are usually performed in the medical imaging unit, and allow for the characterization of physiologic processes inside the body, down to the molecular level, offering the potential to identify diseases at early stages and to assess the response to therapeutic interventions. The information produced is important for doctors to determine the status and function of different organs and tissues. It helps doctors make critical decisions and tailor the treatment to the patient's needs.

Nuclear medicine studies are applicable for diagnosis, careful prognostic assessments and appropriate therapeutic decisions. They also allow the monitoring of treatment effects in a plethora of clinical conditions.

Nuclear medicine is considered an important tool for cancer management. In addition to its diagnostic applications it can be used as an integral component for the treatment of some types of cancer, such as thyroid, neuroblastoma, neuroendocrine tumours and lymphoma. It is also used for radioembolisation of liver tumours and is very effective for palliation of bone pain caused by metastases, which can occur in patients with breast, prostate and lung cancer.

Different radiopharmaceuticals may be used and their choice depends on the type of exam and the organ/structure to be evaluated. For almost all types of examinations, radiopharmaceuticals are typically injected intravenously and then taken up by the organ/structure(s) of interest. Radioactive emissions from the radiotracer are detected by the imaging device – gamma camera or PET scanner – which produces images of the target organ/structure(s).

Nuclear imaging, particularly if coupled with computed tomography (CT) or magnetic resonance imaging (MRI) can show anatomical details and reveal how the targeted body part functions. These new modalities are called hybrid imaging, including Positron Emission Tomography (PET) and, Single-photon Emission Computed Tomography (SPECT), therefore leading to SPECT/CT, PET/CT, PET/MRI.

In conclusion, nuclear medicine imaging is crucial for the diagnosis and therapeutic management of chronic diseases. Cancer diagnosis requires clinical assessment through appropriate diagnostic services such as those provided by nuclear medicine, combined with an optimal treatment.

2.5 Priority medical devices for nuclear medicine

The following tables present general medical devices, which can be used for screening, diagnosis, staging, and follow-up of many diseases including several cancers, and specific medical devices, which are used for interventions for specific cancer types.

Radiopharmaceuticals can be prepared on site or ordered from a dedicated provider either as unidoses, calibrated and ready for use, or in multidose vials, from which the appropriate activity is withdrawn for several patients. It is important to have cell labelling methodologies to distinguish between infectious and malignancies. All areas, procedures and radiation protection should follow guidance and overview from national regulatory authorities, as appropriate.

Nuclear medicine interventions using gamma camera or PET/CT scanner can be used for all selected cancer types and their appropriate use varies upon the tumour type and clinical stage. The following tables present the priority medical devices required to perform the following health interventions:

Cancer type	Interventions
 **All cancers**	• Nuclear medicine scan and radionuclide injection (including patient monitoring) • Preparing and dispensing radiopharmaceuticals
 **Breast cancer**	• Sentinel node mapping prior to surgical intervention
 **Lung, Breast, Prostate and Cervical cancer**	• Bone scan
 **Lung, Breast, Prostate, Cervical and Colorectal cancer**	• Staging, response assessment

2.5.1 General medical devices for nuclear medicine

These are general as they can be used for various diseases including all types of cancer. Please note they are organized by clinical procedure.

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
Nuclear medicine scan	Medical equipment	Gamma camera system with SPECT capability	
	Quality assurance devices	QA/QC phantoms and accessories for all existing systems in the unit	
		Dose calibrator	
Radionuclide injection (including patient monitoring)	Medical equipment	Blood glucometer	• Microcuvettes, strips or similar • Lancet, blood, safety, sterile (various sizes) • Accessories
		Infusion pump	Infusion pump administration set
		Resuscitation trolley, equipped with medicines and defibrillator. Include laryngoscope	
		Stethoscope	
		Weighing scale, range 0 –150 Kg	
		Aneroid sphygmomanometer	Blood pressure cuffs
		Single-patient physiologic monitoring system (optional)	
		Refrigerator	
	Medical furniture	Adequate furniture for patients, in the waiting area, non-absorbent surfaces	
		Trolley, dressing, stainless steel, 2 trays	
		Blood draw chairs	
		Stretcher, foldable	

3 Components of all surgical instrument sets as well as needle and catheter gauge sizes (G) are listed in the chapter annex at the end of the Surgery chapter

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
	Single use devices/ disposables/ medical supplies		Cannulas, intravenous (IV) short, sterile, single use (sizes G)[3]
			Compress, gauze, sterile & non-sterile, single use
			Infusion giving set, sterile, single use
			Needles, luer, sterile, single use (sizes G)[3]
			Needles, scalp vein, sterile, single use (sizes G)[3]
			Prongs, nasal, oxygen, non-sterile, single use (various sizes)
			Skin-cleaning wipe
			Tape, medical, roll (various sizes)
			Transparent film dressings
			Lead sharps container according to isotope energy used
			Syringes, luer, sterile, single use (various capacities)
			Instrument/equipment drape, single-use, non-sterile
			Skin-cover adhesive strip First aid gauze/ bandage
	Solutions and reagents		IV solutions
	Nuclear medicine radiation protection devices	Geiger-Müller counter radiation survey meter and measuring probe	Dosimeter, personal
		Area monitoring devices (area survey meter)	Ring dosimeter
			Mobile radiation protection shields
			Radiation shielding container, transport/ transfer
			Syringe radiation shield (Gamma, Beta and Alpha)
			Vial radiation shield
			Radiation protection blocks
			Radiation protection shields with glass
			Shielded storage bins/recipients for radioactive wastes
			Locked and adequately shielded and/or isolated area for radioactive wastes decay
			Decontamination kits
			Radiation protection gloves when managing relatively high doses, such as those for therapeutic purposes
			Radiation shielding apron
			Glasses, safety shield. All these devices need to be adapted to the radionuclides used (type of radiation, energy, activity, etc.)

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
	Radiation safety instruments	Forceps	Tongs
		Needle sheath holder	Aspiration tray
			Drip trays
	Personal protective equipment		Gloves, examination, non-sterile, single use (various sizes)
			Gown, patient
	Other	Arm/leg tourniquet	
Preparing and dispensing radiopharmaceuticals	Medical equipment	Negative Pressure Fume Hood	Require negative pressure as volatile radioisotopes (such as I-131) are manipulated
	Laboratory equipment	High performance liquid chromatography (if radiopharmaceuticals are prepared on site)	
		Thin layer chromatography scanner (if radiopharmaceuticals are prepared on site)	
		Radionuclide generator (adequately shielded); Mo99-Tc99m; Ga68 (if radiopharmaceuticals are prepared on site)	
		Positive pressure Laminar Flow cabinet for radiopharmaceutical preparation	Require positive pressure to keep pyrogens out of the working area where radiopharmaceuticals are prepared and compounded
		Refrigerator	
		Hot plate, with stirrer	
		Water bath Thermometer	
	Medical furniture	Adequate furniture for receiving, handling and preparing radiopharmaceuticals.	
	Single use devices/ disposables/ medical supplies		Needles, luer, sterile, single use (sizes G)[3]
			Syringes, luer, sterile, single use (various capacities)
			Sterile absorbing paper
	Quality assurance devices	Calibrated radioactive reference sources for quality control of activity measuring systems	

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
	Solutions and reagents radi-opharmaceuti-cal components		Non generator produced radiopharmaceuticals (I-131; Tl-201 etc.); PET tracers: multidose vials or unit doses (F18-FDG)
			Labelling kits (MDP; MAA, pyrophosphate, MIBI, MAG3, DMSA, Nanocolloids, etc.)
			Distilled water
			Saline solution
	Radiation protection devices		L-Shield
			Radiation shielding container, general-purpose (adapt thickness according to radiation energies used)
			Radioactive waste receptacle
	Personal protective equipment		Gloves, examination, non-sterile, single use (various sizes)
			Gown for staff
			Non-conductive shoe cover
			Coat, medical, woven (various sizes)
			Radiation decontamination spill kit
PET/CT	Medical equipment.	PET/CT system	See 2.5.2.3 for radiopharmaceutical components and QA devices.

2.5.2 Specific medical devices for nuclear medicine by cancer type

2.5.2.1 Breast

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
Sentinel node mapping prior to surgical intervention	Medical equipment	Gamma camera system with SPECT capability (see General Medical Devices Table 2.5.1.)	
		Gamma probes (for intraoperative use)	
	Radiopharmaceutical components		Tc99m colloid

2.5.2.2 Lung, Breast, Prostate and Cervical

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
Bone scan	Medical equipment	Gamma camera system (as per table General Medical equipment, 2.5.1 with SPECT capability)	
	Radiopharmaceutical components		Tc99m diphosphonate (MDP, HMDP, DPD ...)

2.5.2.3 Lung, Breast, Prostate, Cervical and Colorectal

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
Staging, response assessment	Medical equipment	PET/CT system	
	Quality assurance devices	QA/QC phantoms and accessories for PET/CT System	
	Radiopharmaceutical components		FDG and other radiopharmaceuticals labeled with positron emitters Radiopharmaceutical preparations using centralized radio pharmacy or from in-house radio pharmacy facility having medical cyclotron

There is strong evidence to support the use of PET/CT in diagnosis, staging, re-staging, follow-up and evaluation of therapy response and therapy planning in a variety of cancers. The use of PET/CT is considered a standard of care for several types of cancer, supported by extensive scientific literature and technology assessment reports *(1, 2)*. In addition, constant research is generating medical evidence on its usefulness in a variety of other clinical conditions. The ongoing development of new tracers is continuously revealing new clinical applications in the medical community. Nonetheless, the use of this equipment involves significant technical difficulties, financial, logistical, educational and quality management investments that should be determined be each individual country. They are mainly due to the very short half-life of the isotopes (less than 2 hours) and the very high energy (511 KeV) of the emitted radiation. Depending upon the country, isotopes may have to be produced on site, in a cyclotron.

2.6 Other health system components for nuclear medicine

2.6.1 Human resources for nuclear medicine

Nuclear medicine encompasses diagnostic and therapeutic procedures applicable to several clinical conditions, covered by many clinical specialties. Close interaction with referring clinicians is necessary in order to increase the effectiveness of patient management. This interaction should be extended to educate the medical community on the appropriate use of nuclear medicine applications and to expand research pportunities, when applicable. Nuclear medicine has an inherent interdisciplinary nature. Aside from nuclear medicine physicians and other medical personnel (e.g. nurses, radiographer/nuclear medicine technologist), it requires cooperation with other professionals such as radio pharmacists, radiochemists, medical physicists, engineers and IT specialists. Also, administrative and support services play an essential role. Responsibilities must be defined and communication methods need to be in place.

Depending on national context including workforce availability and models, different occupations can fulfil the roles that may be required for nuclear medicine. A prerequisite is having the required competencies to perform these roles and being officially recognized for it as per the scope of practice. The ISCO[2] codes are added as illustrative examples based on current practice for further reference. This should not be interpreted as guidance on occupations that should perform each role but rather indicative occupations that are currently performing these roles in different country contexts *(3,4)*.

2 *International Standard Classification of Occupations, http://www.ilo.org/public/english/bureau/stat/isco/docs/publication08.pdf*

Sample role	Sample occupations (ISCO-08 codes)
• Define the clinical appropriateness and justification for the request or referral, both for diagnostics and for therapy • Based on departmental standard operating procedures (SOPs), give instructions for the appropriate tests and protocols • When necessary, tailor the protocols to the needs and condition of the patient • Assess and carry out interventions (physiological or pharmacological), when needed • Interpret the study based also on the clinical information • Interpret the results and provide a diagnosis insofar as possible. • Adhere to SOPs to ensure the safety of both the patient and staff • Provide training (and education) for technical and medical staff • When in managerial position, ensure proper continuous improvement of the department and adhere to Quality Management rules • Responsible for overseeing team approach to protocol • development with technologist and medical physicist	Nuclear medicine physician , Radiologist, Specialist medical practitioner (2212)
• Activity measurements • Dose administration (when permitted by local regulations) • Patient preparation • Scanner preparation • Image acquisition, data processing and or display of imaging or data • Routine quality control of instrumentation under supervision from the medical physicist, or related responsible.	Radiographer, Nuclear Medicine Technologist, Medical imaging and therapeutic equipment technician (3211)
Responsible for all aspects inherent to procurement, reception, storage, preparation of radiopharmaceuticals including safety aspects, waste disposal, and management of generators and sources to be sent back to the producer	Radiopharmacist , Chemist, pharmacist (2262) Pharmaceutical technician (3213) under supervision of Pharmacist Medical imaging and therapeutic equipment technicians (3211)
Responsible for all aspects inherent to: • Radiation safety • Quality management of the physical and technical aspects of radiation medicine • Technical supervision of equipment operation and maintenance • Computer system management and support • Technical development and validation of clinical studies • Patient dosimetry and dose optimization	Medical physicist (2111) Radiation protection expert , environmental and occupational health and hygiene professionals (2263)
Management of medical devices: planning, procurement, supervision of installation and maintenance	Biomedical Engineer (2149) Biomedical technician / physical and engineering science technician (3119)
• General physical and mental care of patients • Examination of vital signs • Administration of drugs and injections on the instruction of physician • Explanation to patients of procedures and provision of support to the receptionist • Handling of radiopharmaceuticals and radioactive waste in cooperation with pharmacists and technologists • Taking appropriate radiation protection measures for patients and families, especially those comforting children and elderly people	Nursing professional (2221), nursing associate professional (3221), supervised: healthcare assistant (5321)
Scheduling, reception of patients, filing patient data, and all other administrative tasks	Clerical support workers (4412) Technologists(3211), Nurses (2221)
Cleaners need specific training since they will operate in controlled areas where radioactivity is handled, and radioactive contamination is possible. Clear instruction on management of all type of wastes should be given	Cleaning personnel (9112)

2.6.2 Infrastructure

Nuclear medicine units need to be designed in a way that allows for safe reception, compounding, storage (including waste), and administration of radiopharmaceuticals to patients. Specific waiting areas, including toilets for injected patients, rooms for imaging and non-imaging diagnostic procedures, and areas for obtaining and measuring body fluid samples are needed. In a nuclear medicine facility, rooms for radiopharmaceutical preparation (i.e. radiopharmacies or hot labs), injection of the radiopharmaceuticals and for storage and decay of radiopharmaceuticals, meet the criteria for controlled areas and should be so designated. Imaging rooms, particularly those housing radiopharmaceutical dispensing equipment (i.e. PET radiopharmaceutical

and radioactive gas and aerosol dispenser devices), as well as waiting rooms dedicated to patients who have been injected with radiopharmaceuticals (e.g. uptake rooms in a PET facility) should also be considered controlled areas. Rooms with patients undergoing radiopharmaceutical therapy should be controlled areas. Rooms housing hybrid machines that have an X-ray component (SPECT/CT and PET/CT) should be considered controlled areas. A warning light at the entry to the room should indicate the machine is on, to prevent unintended passage. Supervised areas may include examination rooms with probes, corridors and other areas where there are patients who have been administered with radiopharmaceuticals *(5)*. Access to all controlled areas needs to be restricted to authorised persons (nuclear medicine staff, patients, caregivers) in order to avoid unnecessary radiation exposure of the general public.

In units that administer radiopharmaceuticals for therapeutic purposes, a dedicated ward for confinement may be necessary, depending on the type of treatment, administered activity, patient needs and conditions and local rules and regulations, whilst also taking into account recommendations from IAEA Basic Safety Standards *(5)*.

The establishment of nuclear medicine units able to provide diagnostic and therapeutic services, should take into consideration the permits or sanitary authorization by local regulatory authorities, as well as instalment costs and sustainability aspects.

Layout distribution

The siting and layout of a nuclear medicine department should take into account workload and patient flow, both within the nuclear medicine facility and, in cases where the nuclear medicine facility is part of a larger hospital or medical centre, with other departments of the wider facility. The nuclear medicine facility should be readily accessible, especially for outpatients, who constitute the majority of patients. Enough space should be allocated to facilitate the operation according to the workload. It should be built in a way to minimize radiation exposure to staff and members of the public and contamination of the environment (e.g. distance, wall thickness/composition, appropriate ventilation outlets, fluid drainage, waste management and storage). Areas where radioactive material is stored, handled or administered to patients as well as all rooms where patients stay after administration of radiopharmaceuticals (e.g. waiting rooms, changing areas, toilets, uptake, investigation, stress rooms, imaging suites etc.) need to be classified. Access to controlled areas should be regulated and is normally limited to patients and involved personnel. Security systems should be installed to prevent the loss or theft of radioactive sources, or contaminated lead. The nuclear medicine department should have source security systems and procedures to ensure continuity in the control and accountability of each radioactive source at all times and to prevent theft, loss, unauthorized withdrawal of radioactive materials or entrance of unauthorized personnel to the controlled areas. Please refer to IAEA Basic Safety Standards for further information *(5)*.

Electrical systems

To ensure continuity of services, stable power supply and back-up systems should be installed.

Heating, ventilation and air conditioning systems

Air conditioning may be necessary to ensure correct functioning of imaging and other electronic equipment (e.g. gamma cameras, PET/CT scanners, IT). Special care is to be given to the ventilation, with airflow going from the least to the highest contamination risk areas. In fume hoods, negative pressure should be installed to allow contaminated air with volatile radioisotopes to be evacuated, whereas in other areas in which radiopharmaceuticals are prepared for administration to patients, laminar flow hoods are required with positive pressures to keep pyrogens out of the working area.

Air conditioning, with proper humidity and temperature control should be planned, in order to avoid possible damage to imaging systems, especially to radiation detectors and related components.

Radiation protection and shielding

Structural shielding should be designed to meet the requirements for optimization of protection, taking into consideration the classification of the areas within the facility, the type of work to be done and the radionuclides (and their activity) intended to be used. When SPECT/CT or PET/CT scanners are installed, appropriate room shielding should be provided for the X-ray radiation emitted from the CT component.

However, shielding might be required even for an imaging room with a normal gamma camera to avoid interferences with other sources in the vicinity (injected patients, other camera). Shielding requirements must be assessed on a case-by-case basis.

Special systems

If telenuclear medicine is considered, the adequate bandwidth, information infrastructure or web based platforms should be available, and appropriate devices (video surveillance) should be installed for patient surveillance in diagnostic rooms during procedures and in confinement rooms for therapy.

Other considerations

Wherever radioactive contamination might occur, floors and walls should be covered with non-porous, washable material, curved to the walls, with all joints sealed and glued to the floor. The weight of equipment to be installed should be considered during planning.

2.6.3 Quality management

Quality management in nuclear medicine aims at continuous improvement of services offered to patients and referring physicians as well as insurances and providers of material and equipment. It is based on regular and systematic reviewing of all involved processes, internal and external audits with the intent of improving quality of services offered while maintaining highest ethical (appropriateness of procedures, patient information and consent, communication, etc.) and safety standards (clinical, radiation, technical, chemical, pharmacological, etc.) for patients, personnel, relatives, caregivers, members of the public and the environment.

To maximize the efficiency of the technology and ensure the accuracy of nuclear medicine devices, planning must take place prior to purchase of equipment in the areas of maintenance and quality assurance *(6-7)*. Options for maintenance including vendor service contracts and training in-house or regional health system staff, must be evaluated. Requirements for service and calibration, along with required service documentation, ancillary equipment, Quality Control tools, spare parts and diagnostics must be included in tenders (request for proposals). If the vendor does not meet service requirements in the tender, the service attributes desired must be negotiated prior to purchase, due to the difficulty and expense of post-purchase servicing.

Regular quality audits and assessments are vital for modern nuclear medicine services. More importantly, the entire quality management and audit process has to be systematic, patient orientated and outcome based. The management of services should also take into account the diversity of nuclear medicine services around the world and should invite multidisciplinary contributions. The latter include clinical, technical, radiopharmaceutical, medical physics and radiation safety procedures.

Please see the IAEA Quality Management Audits in Nuclear Medicine Practices (QUANUM 2.0) for more information, including QA/QC of equipment, an integral part of nuclear medicine quality management *(8)*.

2.6.4 Guidance documents

Title	Link	Description
Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards 2014	www-pub.iaea.org/MTCD/publications/PDF/Pub1578_web-57265295.pdf	This publication is the new edition of the International Basic Safety Standards. The edition is co-sponsored by seven other international organizations — European Commission (EC/Euratom), FAO, ILO, OECD/NEA, PAHO, UNEP and WHO. It replaces the interim edition that was published in November 2011 and the previous edition of the International Basic Safety Standards, which was published in 1996. It has been extensively revised and updated to take account of the latest findings of the United Nations Scientific Committee on the Effects of Atomic Radiation, and the latest recommendations of the International Commission on Radiological Protection. The publication details the requirements for the protection of people and the environment from harmful effects of ionizing radiation and for the safety of radiation sources. All circumstances of radiation exposure are considered.

Title	Link	Description
Planning a Clinical PET Centre	www-pub.iaea.org/MTCD/Publications/PDF/Pub1457_web.pdf	This publication presents a comprehensive overview of the steps involved in the establishment of a clinical PET facility, from strategy formulation to cyclotron implementation, radiopharmaceutical production and clinical applications. Also covered are staff requirements and radiation protection issues. It is intended for healthcare administrators, project and site planners, as well as professionals involved in providing PET services.
Quality Management Audits in Nuclear Medicine Practices	www-pub.iaea.org/MTCD/Publications/PDF/Pub1683Web-68161172.pdf	Quality management systems are essential and should be maintained with the intent to continuously improve effectiveness and efficiency, enabling nuclear medicine to achieve the expectations of its quality policy, satisfy its customers and improve professionalism. The quality management (QM) audit methodology in nuclear medicine practice, introduced in this publication, is designed to be applied to a variety of economic circumstances. A key outcome is a culture of reviewing all processes of the clinical service for continuous improvement in nuclear medicine practice. Regular quality audits and assessments are vital for modern nuclear medicine services. More importantly, the entire QM and audit process has to be systematic, patient oriented and outcome based. The management of services should also take into account the diversity of nuclear medicine services around the world and multidisciplinary contributions. The latter include clinical, technical, radiopharmaceutical, medical physics and radiation safety procedures.
Standard Operating Procedures for PET/CT: A Practical Approach for Use in Adult Oncology	www-pub.iaea.org/MTCD/Publications/PDF/Pub1616_web.pdf	Proper cancer management requires highly accurate imaging for characterizing, staging, restaging, assessing response to therapy, prognosticating and detecting recurrence of disease. The ability to provide, in a single imaging session, detailed anatomical and metabolic/functional information has established positron emission tomography/computed tomography (PET/CT) as an indispensable imaging procedure in the management of many types of cancer. The reliability of the images acquired on a PET/CT scanner depends on the quality of the imaging technique. This publication addresses this important aspect of PET/CT imaging, namely, how to perform an 18F-fluorodeoxyglucose (FDG) PET/CT scan in an adult patient with cancer. It provides a comprehensive overview that can be used both by new PET/CT centres in the process of starting up and by established imaging centres for updating older protocols.
Nuclear Medicine Resources Manual	www-pub.iaea.org/mtcd/publications/pdf/pub1198_web.pdf	This manual provides comprehensive guidance, at the international level, on many aspects of nuclear medicine practice, including education, training, facilities and equipment, quality systems, and radiopharmacy and clinical practice. It will be of use to those working in both new and more developed nuclear medicine centres.
Atlas of Bone Scintigraphy in the Developing Paediatric Skeleton: The Normal Skeleton Variants and Pitfalls	www-pub.iaea.org/MTCD/Publications/PDF/Pub1491_web.pdf	Bone scintigraphy is a widely accepted method for the evaluation of paediatric bone metabolism. Its strengths are high sensitivity and the capability to investigate the entire skeleton in a single examination. The interpretation of bone scanning in children is challenging and requires knowledge of the appearance of the maturing skeleton. The atlas provides an overview of issues related to bone physiology and variants, and points out pitfalls that might be encountered in daily routine work. Specific suggestions and hints assist in establishing adequate imaging protocols to deliver optimal image quality adjusted to the needs of each age group. The atlas will serve as a valuable reference for nuclear medicine physicians, radiologists and orthopaedic surgeons, and for those involved in teaching and performing paediatric bone scan imaging.
Appropriate Use of FDG-PET for the Management of Cancer Patients	www-pub.iaea.org/MTCD/Publications/PDF/Pub1438_web.pdf	This book provides guidance on the value and appropriateness of the use of positron emission tomography (PET), either alone or in combination with computed tomography (CT) scanners using 2-fluoro-2-deoxy-D-glucose (FDG) labelled with fluorine-18, in the management of patients affected by cancer. The concept of appropriateness provides a tool for determining which diagnostic investigations and therapies should be implemented, with the overall aim of optimizing health resource allocation, recognizing not only the cost of the intervention but also the consequences of failure to implement innovations of proven effectiveness. The book includes clinical scenarios for FDG-PET/CT indications; in all, 21 different types of cancer are considered, with seven different possible indications each.

Title	Link	Description
Practical Guidance on Peptide Receptor Radionuclide Therapy (PRRNT) for Neuroendocrine Tumours	www-pub.iaea.org/MTCD/Publications/PDF/P1560_web.pdf	This publication provides comprehensive, multidisciplinary guidance on the use of peptide receptor radionuclide therapy (PRRNT) in the treatment of patients with neuroendocrine tumours (NETs) and gastroenteropancreatic cancers, taking into account the recent international classifications of NETs. It provides comprehensive protocols for employing 90Y or 177Lu tagged somatostatin receptor targeting peptides as well as clinically assessed protocols for renal protection. It provides comprehensive, evidence based clinical guidelines, with input from experienced and renowned medical professionals in the field. The various sections of the book cover clinical presentation, patient eligibility criteria and means of assessing the effectiveness of therapy using molecular and morphological medical imaging techniques.
Guided Intraoperative Scintigraphic Tumour Targeting (GOSTT) Implementing Advanced Hybrid Molecular Imaging and Non-imaging Probes for Advanced Cancer Management	www-pub.iaea.org/MTCD/Publications/PDF/Pub1648 web-19833477.pdf	The objective of this publication is to provide an updated source for professionals using guided intra- or perioperative scintigraphic tumour targeting (GOSTT). It supports and facilitates both the clinical decision making process and the implementation of minimally invasive surgical procedures; the ultimate aim of both approaches is to improve the standard of health care received by patients with cancer. This publication provides an update on innovations in the use of radiopharmaceuticals for SLNM and SLNB, in combination with vital dyes, when appropriate, to facilitate the detection of sentinel lymph nodes. In addition, it provides an update on advances in the implementation of hybrid imaging technologies for the surgical management of patients with cancer in conjunction with intraoperative regional lymph node mapping. Experience with small-field scintigraphic imaging devices in the operating theatre is also presented.
Clinical PET/CT Atlas: A Casebook of Imaging in Oncology	www-pub.iaea.org/MTCD/Publications/PDF/Pub1680Web.pdf	Integrated positron emission tomography and computed tomography (PET/CT) has evolved since its introduction into the commercial market in 2001 into a major imaging procedure, particularly in oncological imaging. In clinical routine service, PET/CT has shown a significant impact on diagnosis, treatment planning, staging, therapy and the monitoring of treatment response, and has played an important role in the care of cancer patients. The high sensitivity from the PET component and the specificity of the CT component give this hybrid imaging modality the unique characteristics that make PET/CT one of the fastest growing imaging modalities, even 14 years after its clinical introduction. This PET/CT atlas combines nearly one hundred comprehensive cases covering all major indications of FDG–PET/CT as well as some cases of clinically relevant special tracers. The cases provide an overview of what the specific disease can look like in PET/CT, the typical pattern of the disease's spread, as well as common pitfalls and teaching points. This PET/CT atlas will be of help to all professionals working with and interested in PET/CT imaging. It contains a variety of oncological imaging and provides clinically relevant teaching files on the effectiveness and diagnostic quality of FDG–PET/CT imaging in routine applications.
PET/CT Atlas On Quality Control And Image Artefacts	www-pub.iaea.org/MTCD/Publications/PDF/Pub1642web-16821314.pdf	This atlas on quality control (QC) and PET/CT artefacts provides guidance on typical image distortions in clinical PET/CT usage scenarios. A number of cases are presented to provide nuclear medicine and radiology professionals with an assortment of examples of possible image distortions and errors in order to support the correct interpretation of images. This atlas is intended to be used as a guide on how to take proper QC measures, on performing situation and problem analysis, and on problem prevention, and will be especially useful to medical physicists, physicians, technologists and service engineers in the clinical field.
Human Health Campus Website	https://humanhealth.iaea.org/hhw/	The Human Health Campus is an educational and resources website for health professionals in Radiation Medicine and Nutrition. This website is a valuable tool used by the IAEA Division of Human Health to achieve its mission to enhance the capabilities in Member States to address needs related to the prevention, diagnosis and treatment of health problems through the application of nuclear techniques.
Quality Assurance For SPECT Systems	www-pub.iaea.org/MTCD/publications/PDF/Pub1394_web.pdf	The current publication is intended to be a resource for medical physicists, technologists and other healthcare professionals who are responsible for ensuring optimal performance of imaging instruments, particularly SPECT systems, in their respective institutions. It is intended for managers, clinicians and other decision makers who are responsible for implementing quality assurance/quality control programmes in nuclear medicine centres. It is hoped that it will play an important role in helping maintain image quality and lead to better utilization of nuclear medicine imaging instruments worldwide.
Quality Assurance For PET and PET/CT Systems	www-pub.iaea.org/MTCD/publications/PDF/Pub1393_web.pdf	This publication provides guidelines for the implementation of QA and QC programmes concerning the combined medical diagnostic modality of PET and CT technologies. The use of these independent, but complementary, imaging techniques is frequent and growing within the fields of diagnostic imaging, oncology, cardiology and neurology, where they allow physicians to locate and diagnose malignant diseases accurately. Specific topics of discussion include the frameworks for reference values, tolerances and action levels, minimal required configurations with corresponding performance characteristics, and the management of ancillary equipment.

Title	Link	Description
VA Design Guide for Nuclear Medicine	http://www.wbdg.org/FFC/VA/VADEGUID/nucmed.pdf	The Nuclear Medicine Design Guide was developed as a tool to assist Contracting Officers, Medical Center Staff, and Architects and Planners with the design and construction of Nuclear Medicine facilities
A Guide to Clinical PET in Oncology: Improving Clinical Management of Cancer Patients	www-pub.iaea.org/MTCD/publications/PDF/te_1605_web.pdf	Clinical PET, in particular with fluorine-18-fluorodeoxyglucose (18F-FDG), has already proven itself to have considerable value in oncology. The indications include malignant lymphoma and melanoma, head and neck cancers, oesophageal cancer, breast cancer, lung cancer and colorectal cancer, and it is still being expanded. The roles of clinical PET could be for 1) preoperative staging of cancers, 2) differentiation between residual tumour and scarring, 3) demonstration of suspected recurrences, 4) monitoring response to therapy, 5) prognosis and 6) radiotherapy treatment planning.
Clinical Applications of SPECT/CT: New Hybrid Nuclear Medicine Imaging System	www-pub.iaea.org/MTCD/publications/PDF/TE_1597_Web.pdf	This report presents an overview of clinical applications of SPECT/CT and a relevant source of information for nuclear medicine physicians, radiologists and clinical practitioners. This information may also be useful for decision making when allocating resources dedicated to the health care system, a critical issue that is especially important for the development of nuclear medicine in developing countries. In this regard, the IAEA may be heavily involved in the promotion of programmes aimed at the IAEA's coordinated research projects and Technical Cooperation projects.
Criteria for Palliation of Bone Metastases – Clinical Applications	www-pub.iaea.org/MTCD/publications/PDF/te_1549_web.pdf	Bone metastases are a frequent complication of cancer. It is estimated that they arise in 14–70% of all tumour patients, while it was reported that they occur in 70–85% patients in autopsy material. Although they may arise from any primary malignant tumour, certain tumours such as breast, prostate, lung, thyroid, kidney and myeloma have a predilection for a spread to bone. Bone metastases frequently cause pain, but there are also clinical situations with bone metastases causing no pain at all. The overall importance of the problem of bone metastases is well recognized by the fact that each year hundreds of thousands of cancer patients develop bone metastases. For example, more than 100 000 new patients develop this condition in the United States of America, although the prevalence is estimated to be double the number of new cases. While it is virtually unknown how many cancer patients in developing countries develop bone metastases, it is not unrealistic to expect that these figures largely surpass those coming from the developed countries.
Nuclear Medicine in Thyroid Cancer Management: A Practical Approach	www-pub.iaea.org/MTCD/publications/PDF/te_1608_web.pdf	Thyroid cancers are now being diagnosed at an earlier stage and treatments, together with follow-up strategies, are more effective. However this is not consistent throughout the world. The practice does differ considerably from country to country and region to region. Functional imaging using nuclear medicine procedures has become an indispensable tool for the diagnosis, treatment planning and management of patients. In terms of treatment, the use of radioiodine (131I) has been central to thyroid cancer and has been successfully used for over six decades. This publication is a culmination of efforts by more than twenty international experts in the field to produce a global perspective on the subject. Views expressed are those of individual experts involved and are intended to assist national or regional authorities in decisions regarding the frameworks for effective treatment of thyroid cancer.

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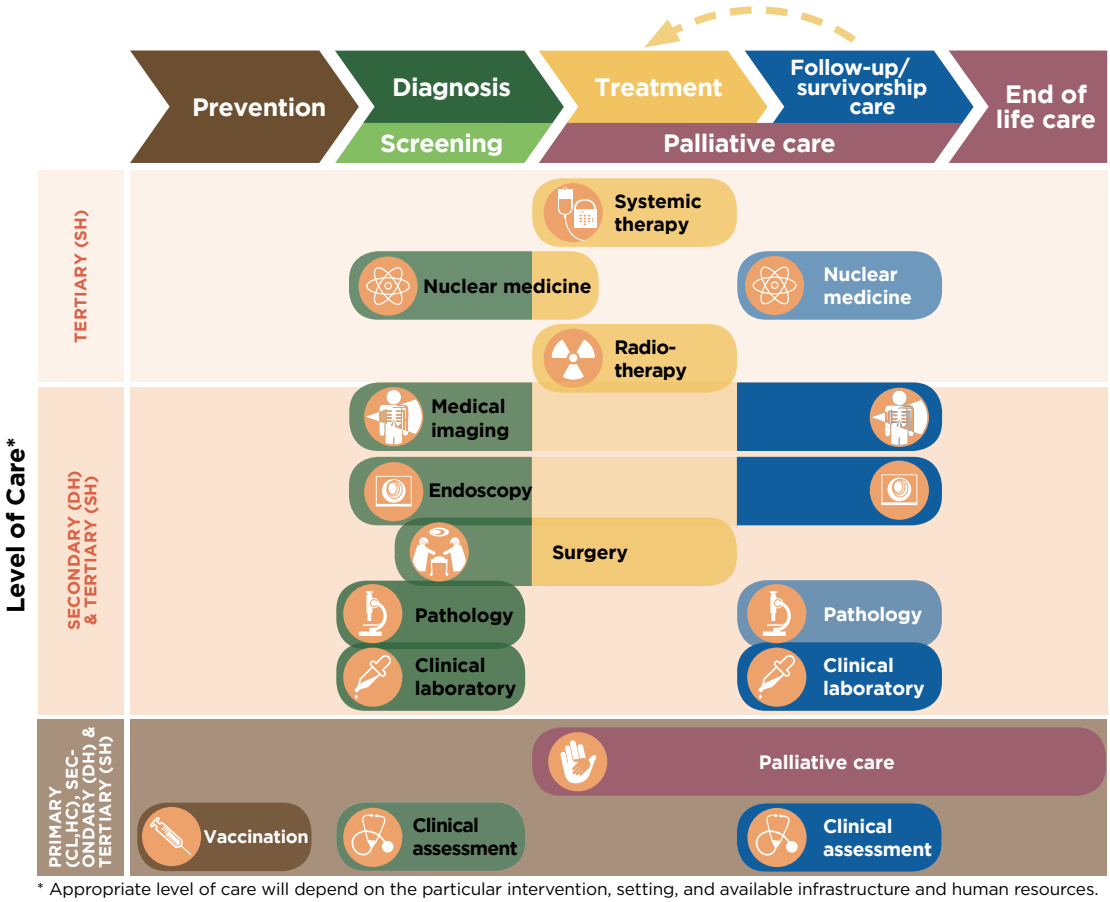
3. Surgery

Health service delivery sequence overview:

This diagram expresses the flow of cancer patient to and from the clinical assessment and surgery unit, and the elements to consider as support for the unit (Fig 10.3).



* Appropriate level of care will depend on the particular intervention, setting, and available infrastructure and human resources.
CL Community Level health post DH District Hospital HC Health Centre SH Specialized Hospital

Fig. 10.3. Health care service delivery overview – surgery

3.1 General description of the unit

The objective of a surgical unit is to provide general and specialized surgical care for patients. An important goal of surgical care is for an interventional curative treatment. Other reasons include diagnosis, palliation of symptoms, cancer prevention and reconstructive care.

It should be noted that in 2015, the Lancet Commission on Global Surgery stated that 5 billion people do not have access to safe surgery and this was recognized by all Member States in the World Health Assembly resolution 68. to Strengthen Emergency and Essential Surgical Care. (see guidance documents section 3.3.4).

Services provided by a surgical unit must be safe, high-quality, founded on guidelines or established standards such as the WHO Safe Surgery Saves Lives programme *(1)*, and coordinated with other modalities of cancer management. Multidisciplinary decision-making and treatment should be promoted. Moreover, there should be a quality management framework that addresses equity and accessibility, workload and demand, core processes and outcomes.

The surgery unit provides core services in cancer management and has a critical link with diagnostic services – particularly pathology, radiology and endoscopy. Over 80% of cancer patients will need surgery at some time *(2)*. Similar to other cancer services, surgery must be viewed as a part of the larger health system, recognizing that a surgery unit consists of broad human resource expertise, is linked to other critical health services and contributes to wide-ranging service delivery across health disciplines.

The flow of patients and information from diagnostic support services (as can be seen in Fig. 10.3 on the health services delivery process) must be timely and equitable. Primary care services may be a component of the surgery unit. Primary care services should be capable of recognising cancer signs and symptoms, performing appropriate simple biopsies, or referring for diagnostic procedures such as endoscopy.

The surgery unit extends beyond the operating room and is also linked to pre- and post-operative services involving anaesthesia, pain management and nursing services. Post-operative nursing care, for example, must be effective in identifying post-operative abnormalities and recognising changes or deterioration in patient status, escalating levels of care appropriately.

Surgical units treating cancer differ in their ability to carry out procedures depending on the available infrastructure and expertise. At its most basic, a surgical unit needs appropriately trained surgical healthcare professionals, sufficient physical infrastructure to ensure safe surgery, surgical supplies, and procedures that ensure safety and quality for both patients and staff.

3.2 Priority medical devices for surgery

It is very important to consider the four components of the customary supply chain process: product selection, procurement, distribution and se. This process requires input from all stakeholders in surgical care – from programme managers to clinical staff. Reliable supply chain and logistics management are needed to ensure the right quality product is available, in the right quantities, at the right time, and for a reasonable cost. This includes devices listed in this document, sutures, solutions, consumables and the related essential medicines in perioperative care (such as analgesics, anaesthetics and antibiotics).

The following tables present the general medical devices for surgery, which can be used for diagnosis, staging, treatment, follow-up and/or palliative care of many diseases including several cancers, and specific medical devices, which are used for surgical interventions for specific cancer types.

Please note: Components of all surgical instrument sets as well as needle and catheter gauge sizes (G) are listed in the chapter annex at the end of this chapter.

The following tables present the priority medical devices required to perform the following health interventions:

Cancer type	Interventions
All applicable cancers	• General surgical procedures • Laparoscopic procedures
Breast cancer	• Excisional biopsy • Breast conservation surgery/lumpectomy/partial resection • Modified radical mastectomy (includes nodes)/Total mastectomy • Core biopsy and sentinel nodes (see section 2.5)
Cervical cancer	• Cervical biopsy • Cervix (cold knife) conization (CKC) • Simple hysterectomy • Radical hysterectomy‡
Colorectal cancer	• Open excision/resection/Hemicolectomy/Polypectomy • Colonoscopy (see section 1.3)
Lung cancer	• Thoracentesis • Aspiration with drainage catheter • Pleurodesis • Pneumonectomy‡/Lobectomy‡/Wedge resection of lung‡
Prostate cancer	• Orchiectomy • Radical Prostatectomy

‡Requires highly trained/specialized surgeon

3.2.1 General medical devices for surgery

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/consumables/single use devices
General surgical procedures	Medical equipment	Anaesthesia unit, mobile, basic	Children and adult patient circuit Children and adult mask Oxygen and nitrous oxide supply Breathing bag Absorber and soda lime Anaesthetics
		General-purpose suction system, vacuum	Tube suction, Yankauer, 270 mm, Yankauer suction tips Tube, suction, L50 cm, catheter tip, sterile, single use (sizes G)[3] Suction system canister/bottle holder Suction trap to collect fluid specimens
		Electrosurgical unit, with accessories	Electrosurgical pencil/Monopolar pen Electrosurgical return electrode Negative/ground plate disposable or reusable Vessel sealing system generator (unit for haemostasis by thermocoagulation) (optional)
		Infusion pump	Infusion given set
		Mobile diagnostic X-ray digital system (C-arm)	
		Operating light, light source (lamp & flashlight)	Spare lamps
		Pulse oximeter	Spare probes, adult and paediatric, basic
		Stethoscope	
		Thermometer	

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
		Universal operating table	Table accessories for urology, gynecology, as needed
		Aneroid sphygmomanometer	Blood pressure cuffs (adult and paediatric sizes)
		Single-patient physiologic monitoring system (Include ECG, Capnography, SpO2, B.P. Thermometer)	With accessories for adult and paediatric patients
		Resuscitation trolley, equipped with medicines and defibrillator	Laryngoscope, adult/child, set (consider if not included in resuscitation trolley)
	Medical furniture	Hospital stretcher	Patients rollout device
		Transport stretcher	
		Anaesthetist's trolley	
		Instrument storage cabinet	
		Instrument table	
		Stand, infusion, double hook, on casters	
		Kick bucket	
		Operating room stool	
		Surgical scrub station	
		Trolley, dressing, stainless steel, 2 trays	
		Trolley, emergency, with drawers	
		Trolley, soiled linen	
		X-ray, viewer (negatoscope), 1 to 3 bodies	
		Stand, single bowl, on casters	
		Mayo stand	
		Blanket warmer	
		Cabinet, medicines, double door	
		Wheelchair, adult	
	Instruments	Chest tube insertion kit	
		Cricothyroidotomy set	
		Forcep, artery	
		Dissecting forceps	
		Laryngoscope handle with Macintosh blades	
		McGill forceps adult and paediatric	
		Needle holders	
		Scalpel with blades	
		Scissors (various sizes)	
		Retractors (various sizes and types)	
	Personal protective equipment and clothing		Clogs, plastic (various sizes)
			Drawsheet, plastic, approx. 90x180 cm
			Glasses, safety, regular size
			Gloves, examination, non-sterile, single use (various sizes)

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
			Gloves, surgical sterile, (various sizes)
			Non-conductive shoe cover
			Surgical cap for patients and healthcare workers
			Gown, protective for health care workers
			Aprons, impermeable
			Surgical face mask
			General-purpose sterile drape
			Gown, patient
			Medical scrubs for healthcare workers or similar
	Single use devices/ disposables/medical supplies		Anaesthesia breathing circuit
			Compress, gauze, sterile & non-sterile, single use
			Elastic bandage
			Endotracheal tubes adult and paediatric
			Infusion giving set, sterile, single use
			IV infusor bags/sets
			Mask and tubing for oxygen
			Monitoring electrodes
			Nasogastric tubes
			Operating room laundry bag
			Organ bag
			Bags (various colors)
			Skin-cleaning wipe
			Sutures
			Syringes with needles (disposable)
			Tape, medical, roll (various sizes)
			Three-way-stopcock
			Ureteral catheter connector and other connectors as required
			Urinary catheter (Foley)
			Urine drain bag
			Surgical scrub sponge
			Intravenous cannulas or catheters
			Laryngeal mask airways sizes 2, 3, 4, three sets per O.R, Oropharyngeal airway (adult size and paediatric)
			Intubating bougies, adult and paediatric
			Operating table cover
			Bedmat, absorbable
	Solutions and reagents		IV solutions
			Formalin 10%, Phospate buffered or tissue fixation reagents

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
			Iodine povacrylex and isopropyl alcohol solution, chlorhexidine, or similar
	Other	Arm/leg tourniquet	
		Bedpan	
			Waste disposal container
			Sponge bowl
			Skin marker pen
		Bowl/ Emesis bowl	
		Resuscitator bag valve and mask (adult and paediatric)	
			Safety box, for used syringes/needles
Laparoscopic procedures	Medical equipment	Laparoscopic tower system, including: Video recorder, video monitor, laparoscopic light source, laparoscopic processing unit, CCD (Charge-coupled device), high-flow laparoscopic insufflator with C02 gas source and pressure regulation unit (Laparoscope can be 5 mm, 10 mm, 30 degree angled or straight)	
		High-frequency generator, both mono and bipolar for laparoscopic procedures	Monopolar and Bipolar coagulation forceps/dissector
	Instruments	Laparoscopic multi-instrument access port (optional for single-incision laparoscopic surgery)	
		Laparoscopic irrigation/aspiration cannula	
		Laparoscopic needle holder	
		Trocars with safety sheath (multiple sizes)	
		Specific instruments for the laparoscopic intervention: (for dissection or haemostasis, e.g. Laparoscopic dissection spatula, Internally-anchored endotherapy retractor, Laparoscopic grasping forceps, Laparoscopic swab forceps, Laparoscopic biopsy forceps, Endoclip-applicator, Laparotomy ring)	
		Staples, Implantable (optional)	
		Laparoscope holder (optional)	
		Suction and irrigation device	
		Laparoscopic electrosurgical blunt dissector	
		Laparoscopic grasper	
	Single use devices	Veress needle (optional, for transperitoneal access only)‡	

‡ Requires highly trained/specialized surgeon

3.2.2 Specific medical devices for surgery by cancer type

3.2.2.1 Breast

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
Excisional biopsy	Instruments	Excisional breast biopsy set	
Breast-conservation surgery-lumpectomy/ partial resection	Instruments	Mastectomy set[3]	
	Single use devices/ disposables/medical supplies		Surgical clip
Core needle biopsy[4]	Medical equipment	Biopsy Gun	Biopsy needle
	Single use devices/ disposables/medical supplies		Specimen container
			Needles and syringes for local anaesthetic
			Skin-cleaning wipe
			Skin-cover adhesive strip
	Solutions and reagents		Formalin 10%, or tissue fixation reagents
			Alcohol or iodine preparation cleansing agent
	Other		Label or pen for labelling sample
			Ruler
Procedure	**Medical devices category**	**Capital equipment (for specialized hospitals)**	**Accessories/hardware/software/ consumables/single use devices**
Modified radical mastectomy (includes nodes)/Total mastectomy	Instruments	Mastectomy set[3]	
	Single use devices/ disposables/medical supplies		Closed-wound drainage reservoir system with closed wound drain connector

3.2.2.2 Cervical

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
Cervical biopsy	Instruments	Gynaecologic biopsy set[3]	
Cervical Conization	Medical equipment	Electrosurgical unit, with accessories, smoke evacuator	Loop electrodes, ball electrodes, ferric subsulfate solution (Monsel's solution)
	Instruments	Cervix conization set[3] Vaginal speculum, Non-conducting preferably with side retractors	
Simple Hysterectomy	Instruments	Vaginal hysterectomy set[3] and Abdominal Hysterectomy set[3]	
	Single use devices/ disposables/medical supplies		Cervical aspiration catheter
			Closed-wound drainage reservoir system with closed wound drain connector
Procedure	**Medical devices category**	**Capital equipment (for specialized hospitals)**	**Accessories/hardware/software/ consumables/single use devices**
Radical hysterectomy‡	Instruments	Vaginal Hysterectomy set[3] and Abdominal Hysterectomy set[3]	
	Single use devices/ disposables/medical supplies		Cervical aspiration catheter
			Closed-wound drainage reservoir system with closed wound drain connector

‡ Requires highly trained/specialized surgeon

3. Components of all surgical instrument sets as well as needle and catheter gauge sizes (G) are listed in the chapter annex at the end of the Surgery chapter

3.2.2.3 Colorectal

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
Open excision/ resection/ Hemicolecto-my/ Polypectomy	Instruments	Basic Colon Surgery set[3]	
		Laparotomy set[3]	

3.2.2.4 Lung

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
Lung procedures	Medical equipment	Single-patient physiologic monitoring system for ECG, Capnography, SpO2, B.P.	Cables and sensor
Thoracentesis	Instruments	Thoracentesis set	Underwater seal drainage
	Single use devices/ disposables/medical supplies		Sterile sample container
			Needles and syringes for local anaesthetic
			Flexible silicon catheter with needle
Aspiration with drainage catheter	Instruments	Chest tube set (clamps included)	
	Single use devices/ disposables/medical supplies		Chest tube
			Sterile sample container
			Needles and syringes for local anaesthetic
			Drainage bag including gravitational IV tube or connect to suction system.
Pleurodesis	Instruments	Chest tube set[3] (clamps included)	
	Single use devices/ disposables/medical supplies		Chest tube
			Sterile sample container
			Needles and syringes for local anaesthetic
			Drainage bag including gravitational IV tube or connect to suction system.
	Solutions and reagents		Sclerodesis agent (e.g. talc)
Procedure	**Medical devices category**	**Capital equipment (for specialized hospitals)**	**Accessories/hardware/software/ consumables/single use devices**
Open Lobec-tomy/Pneu-monectomy/ Wedge resec-tion of lung (Thoracotomy)‡	Medical equipment	Endoscopy tower system (Insufflator, Light source, Irrigation/ aspiration pump, Processing unit, Video image display monitor, Bronchoscope	
	Instruments	Thoracotomy set[3]	
		Lobectomy and segmental lung set[3]	
	Single use devices		Surgery table, padded accessories for patient positioning or similar
			Safety straps
			Chest tubes drainage
			Hemoclips/clip cartridge or similar for cardiothoracic surgery
			Staplers (linear and thoracotomy) with staples reloads
			Epidural catheter
			Pneumonectomy pleurevacs only for Pneumonectomy

‡ Requires highly trained/specialized surgeon

3.2.2.5 Prostate

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
Orchiectomy	Instruments	Basic Surgery set[1]/ Minor tray	
Radical Prostatectomy	Instruments	Prostatectomy set[1]	

3.2.3 Surgical instrument sets, catheter and needle sizes

Basic Surgery set / Minor tray
4 x Clamp, towel, Backhaus, 130 mm
2 x Forceps, tissue seizing, Allis, 150 mm
6 x Forceps, artery, Halsted-Mosquito, 125 mm, curved
1 x Forceps, artery, Kocher, 140 mm, straight
1 x Forceps, dressing, standard, 155 mm, straight
1 x Forceps, tissue holding, Collin, 160 mm
1 x Forceps, tissue, standard, 145 mm, straight
1 x Forceps, dressing & polypus, Cheron, 250 mm
1 x Needle holder, Mayo-Hegar, 180 mm, straight
1 x Probe, double-ended, 145 mm
1 x Retractor, Farabeuf, double-ended, 120 mm, pair
2 x Scalpel handles: number 3 and 4, one each
1 x Scissors, Metzenbaum, 140 mm, curved, blunt/ blunt
1 x Scissors, Mayo, 140 mm, curved, blunt/blunt
1 x Bowl, stainless steel, 180 ml
2 x Dishes, kidney type
1 x Forceps Rampleys, sponge holding

Dressing set
1 x Forceps, artery, Kocher, 140 mm, str
1 x Forceps, dressing, standard, 155 mm, str
1 x Scissors, Deaver, 140 mm, str, s/b
2 x Dishes, kidney type

Laparotomy set
4 x Forceps, Ring c and r
2 x Babcock clamps
1 x Needle holder, Mayo-Hegar, straight, small, medium and large
1 x Forceps, dressing, standard, 155 mm, straight
1 x Forceps, dressing, standard, 250 mm, straight
1 x Dissecting Forceps, teeth, fenestrated, long and short
1 x Dissecting Forceps, large non teeth
1 x Retractor, Farabeuf, double-ended, 180 mm, pair
1 x Retractor, abdominal, Balfour, 3 blades
1 x Forceps, artery, Kelly, 140 mm, curved (long and short)
2 x Forceps, tissue seizing, Allis, 150 mm (short and long)
6 x Forceps, artery, Halsted-Mosquito, 125 mm, curved
1 x Tube suction, Yankauer, 270 mm
2 x Bowl, stainless steel, 600 ml
2 x Dishes, kidney type
1 x Forceps Rampley's, sponge holding
Coucher Forceps
Richardson retractor
Allis clamps, extra large
Diverse scissors
Snaider clamps long
Cistic clamp long
2 x Spatula, abdominal, malleable, 270 mm
1 x Retractor, abdominal, Collin, 3 blades
Deavers Abdominal Retractors
Doyen Abdominal Retractor
4 x Clamp, towel, Backhaus, 130 mm
1 x Scalpel handle, no.4

Suture set
1 x Scissors, Deaver, 140 mm, curved, sharp/blunt
1 x Needle holder, Mayo-Hegar, 180 mm, straight
1 x Forceps, artery, Kocher, 140 mm, straight
1 x Scalpel handle, no. 4
1 x Forceps, tissue, standard, 145 mm, straight
1 x Probe, double-ended, 145 mm
2 x Dishes, kidney type
1 x Forceps, dissecting w tooth
1 x Forceps, dissecting , non tooth

Examination/suturing, vaginal/cervical set
1 x Scissors, Mayo, 170 mm, curved, blunt/blunt
1 x Needle holder, Mayo-Hegar, 180 mm, straight
2 x Retractor, vaginal, Doyen, 45x85 mm
1 x Speculum, vaginal, Graves, 75x20 mm
1 x Speculum, vaginal, Graves, 95x35 mm
1 x Speculum, vaginal, Graves, 115x35 mm
2 x Forceps, dressing & polypus, Cheron, 250 mm
2 x Dishes, kidney type
1 x Forceps Vulselum
2 x Forceps Rampley's

Catheter placement set
2 x Forceps, Halsted Mosquito, 120 to 130 mm, curved, no teeth
1 x Needle holder, Mayo-Hegar, 150 to 160 mm, straight
2 x Basin, kidney, approx. 1000 ml
2 x Bowl, stainless steel, 180 ml
1 x Forceps Foerster or Foerster-Ballenger, 240 to 250 mm, straight, blunt
1 x Scissors, straight
2 x Forceps, Rampley's

Basic Rectal Surgery set
1 x Anuscope, Bensaude or Hirschmann or Newman, small
1 x Anuscope, Bensaude or Hirschmann or Newman, medium
1 x Scalpel large handle, no.7,
2 x Scalpel handle, no.3,
1 x Anuscope Fansler, 340 to 570 mm
1 x Anuscope Pratt, screw graduation, 150 mm
6 x Forceps, Backhaus, 150 to 155 mm
6 x Forceps, Crille or Crille-Rankin, 155 to 160 mm, curved
1 x Forceps, Standard, 130 to 140 mm, straight, 1 x 2 teeth
1 x Forceps, Standard, 130 to 140 mm, straight, 1 x 2 teeth
1 x Forceps, Foerster or Foerster-Ballanger, 240 to 250 mm, curved, grasping
6 x Forceps, artery, Halsted-Mosquito, 120 to 130 mm, curved
1 x Forceps, artery, Pean/Rochester, 220 mm, straight, grasping
1 x Forceps, Yeoman grasping, rectal biopsy, curved, 330 mm
1 x Forceps, Yeoman grasping, rectal biopsy, 280 mm
1 x Needle holder, Mayo-Hegar, 200 to 210 mm, straight
1 x Scissors, Mayo, 170 mm, straight
1 x Scissors, Metzenbaum, 180 mm, curve
1 x Bowl, stainless steel, 100 ml
1 x Dissecting Forceps, Russ Model, 200 mm, teeth, fenestrated
1 x Tube, corrugated, 140 mm to 145 mm
1 x Rectal specula, Pratt or Crypt
1 x Exploration blunt
1 x Rectal specula, Stewart, handheld 150 mm, 29 mm
2 x Dishes, kidney type
1 x Forceps Rampley's

Cervix Conization set
1 x Table, instruments, Mayo type, stainless steel,
6 x Forceps, Allis, 155 to 160 mm
1 x Forceps, Bozemann, S Shaped, Uterine Scissors, 240 to 260 mm,
2 x Tower Clamp, curved, blunt
1 x Forceps, Standard, 250 to 260 mm, straight, grasping
1 x Forceps, Standard, 130 to 140 mm, straight 1 x 2 teeth
1 x Forceps, Standard, 200 to 205 mm, straight, 1 x 2 teeth
6 x Forceps, Crille or Crille-Rankin, 155 to 160 mm, curved
2 x Needle holder, Mayo-Hegar, 180 mm, straight
2 x Retractor, Farabeuf, 150 to 155 mm
1 x Scissors, Mayo-Stille, 170 mm, curved
1 x Scissors, Mayo, 170 mm, straight
1 x Scissors, Metzenbaum, 150 to 160 mm, straight
2 x Dishes, kidney type
2 x Forceps Rampley's
2 x Bowls stainless steel

Vaginal Hysterectomy set
1 x Tube suction, Yankauer, 300 mm
1 x Table, instruments, Mayo type, stainless steel,
10 x Forceps, Crille, 140 mm, curved, grasping
10 x Forceps, Allis, 180 to 190 mm, 5 or 6 teeth
1 x Forceps, Bozemann, S Shaped, Uterine Scissors, 240 to 260 mm, grasping

1 x Forceps, Standard, 100 to 110 mm, straight, 1 x 2 teeth
1 x Forceps, Standard, 240 to 250 mm, straight, grasping
2 x Forceps Foerster or Foerster-Ballenger, 240 to 250 mm, curved, grasping
6 x Forceps, Heaney, 205 to 210 mm, 2 teeth
6 x Forceps, artery, Pean/Rochester, 180 to 185 mm, curved, grasping
1 x Needle holder, Heaney, 200 to 210 mm, curved
1 x Needle holder, Hegar or Mayo-Hegar, 160 mm, straight
1 x Needle holder, Hegar or Mayo-Hegar, 200 to 210 mm, straight
1 x Retractor, vaginal, Doyen, 45x85 mm, length 240 mm
1 x Retractor, vaginal, Doyen, 45x85 mm, length 240 mm
1 x Scissors, Mayo, 170 mm, curved, blunt/blunt
1 x Scissors, Metzenbaum, 200 to 205 mm, curved
1 x Scissors, Metzenbaum, 150 to 160 mm, straight
1 x Bowl, stainless steel, 30 ml
1 x Dissecting forceps, Standard, 130 to 140 mm, grasping
1 x Scissors, Mayo, 170 mm, straight, blunt/blunt
2 x Basin, kidney, approx. 500 ml
2 x Scalpel handle, no. 4
6 x Forceps, Backhaus, 150 mm to 155 mm
2 x Forceps, Pozzi, 240 mm
2 x Forceps Rampley's
1 x Forceps Vulselum

Abdominal Hysterectomy set
2 x Scalpel handle, no. 4
1 x Tube suction, Yankauer, 300 mm
1 x Tube suction, Yankauer, 22.8 mm, screw off button
1 x Table, instruments, Mayo type, stainless steel,
1 x Forceps, Aldlerkreutz, 200 mm, straight,
8 x Forceps, Allis, 250 to 260 mm, 5 or 6 teeth
6 x Forceps, Backhaus, 150 to 155 mm
1 x Forceps, Bozemann, S Shaped, grasping
10 x Forceps, Crille or Crille-Rankin, 155 to 160 mm, curved
1 x Forceps, Dartigues or Hiterolabo, 255 to 270 mm, curved
1 x Dissecting Forceps, Standard, 130 to 140 mm, teethless, graves
1 x Forceps, Standard, 250 to 260 mm, straight, grasping

1 x Forceps, Standard, 130 to 140 mm, straight, 1 x 2 teeth
2 x Forceps, Standard, 250 to 260 mm, straight, grasping
2 x Forceps Foerster or Foerster-Ballenger, 240 to 250 mm, curved, grasping
2 x Forceps Foerster or Foerster-Ballenger, 240 to 250 mm, straight, grasping
6 x Forceps, Heaney, 220 mm, 2 teeth, curved, grasping
6 x Forceps, artery, Pean/Rochester, 220 to 225 mm, curved, grasping
2 x Forceps, artery, Rochester Ochsner or Kocher-Ochsner, 240 to 225 mm, curved, teeth
1 x Needle holder, Mayo-Hegar, 180 mm, straight
1 x Needle holder, Hegar or Mayo-Hegar, 240 mm, straight
1 x Deaver Bladder, valve 25 x 300 mm
1 x Deaver Bladder, valve 75 x 300 to 310 mm
1 x Farabeuf Bladder, 2 x 150 to 155 mm
1 x O´Sullivan O´Connor, 3 sleves
1 x Scissors, Mayo, 170 mm, curved, blunt/blunt
1 x Scissors, Mayo, 170 mm, straight, blunt/blunt
1 x Scissors, Mayo, 170 mm, straight, blunt/blunt
1 x Scissors, Mayo, 230 mm, straight, blunt/blunt
1 x Scissors, Mayo-Harrington, 225 to 230 mm, curved, blunt/blunt
1 x Scissors, Metzenbaum, 180 mm, curved
1 x Scissors, Metzenbaum, 230 mm, curved, blunt
2 x Basin, kidney, approx. 1000 ml
1 x Bowl, stainless steel, 250 ml

Prostatectomy set
2 x Tube suction, Yankauer, 22.8 mm, screw off button
1 x Table, instruments, Mayo type, stainless steel,
2 x Scalpel handle, one no.3 and one no.4
10 x Forceps, Allis, 180 to 190 mm, 5 or 6 teeth
10 x Forceps, Crille, 140 mm, curved, grasping
2 x Forceps, Bakey, dissection, straight, branches 2 mm, 190 to 200 mm length
1 x Forceps, Standard, 130 to 140 mm, straight, 1 x 2 teeth
2 x Standard, 250 to 260 mm, straight, grasping
2 x Forceps Foerster or Foerster-Ballenger, 180 mm to 200 mm, curved, grasping
2x Forceps, Mixter, 230 mm, grasping
4 x Forceps, artery, Pean/Rochester, 200 to 205 mm, curved, grasping
2 x Forceps, Potts Smith, 230 mm, grasping

2 x Forceps, Satinsky, 255 to 265 mm, double angulation
1 x Needle holder, Mayo-Hegar, 180 mm, straight
1 x Needle holder, Hegar or Mayo-Hegar, 180 to 185 mm, straight
1 x Needle holder, Hegar or Mayo-Hegar, 300 mm, straight
1 x Balfour Bladder, central valve of 65 to 80 mm x 80 to 85 mm, lateral valves, fenestrated, maximum 250 to 255 mm
1 x Deaver Bladder, valve 19 x 180 mm
1 x Deaver Bladder, valve 25 x 300 mm
1 x Desmarres Bladder, valve 13 x 14 mm, 130 to 140 mm length
1 x Richardson Bladder, valve 38 x 44 x 30–38 mm, length 240 to 245 mm
1 x Basin, kidney, approx. 1000 ml
1 x Basin, kidney, approx. 500 ml
1 x Farabeuf Bladder, 2, 150 to 155 mm length
2 x Scissors, Bakey, angulated 60°, 230 to 240 mm length
2 x Scissors, Mayo, 150 to 155 mm, straight, blunt/ blunt
4 x Standard, 250 to 260 mm, straight, grasping
4 x Forceps Foerster or Foerster-Ballenger, 180 to 200 mm, curved, grasping
4 x Forceps, Mixter, 230 mm, grasping
4 x Forceps, artery, Pean/Rochester, 200 to 205 mm, curved, grasping
4 x Forceps, Potts Smith, 180 to 240 mm length
Diverse retractors
Babcock forceps
Curved needle holder
Bull dog clamps
Hoitgrewe malleable blade
McDougal clamp
Right angle clamp
2 x Forceps Rampleys

Tracheostomy set
5 x Forceps, Field
2 x Forceps, Mosco, curved
2 x Forceps, artery, Kelly, short
1 x Forceps, Allis, large
2 x Farabeu Bladder
2 x hook
2 x Dissecting forceps, small
1 x Needle holder
1 x Scalpel handle, no.7
1 x Dishes, kidney type
2 x Forceps Rampley
2 x Bowl, stainless steel

Gynecological and Kidney set
1 x Forceps, uterine
1 x Speculum, vaginal,
1 x Basin, kidney, approx. 500 ml

Urology set
Sterilization container for the set of instruments, with cover, perforation and filter
1 x Urethral sounds metal Otis-Clutton curved with olive ends (Sizes 4, 6, 8, 10, 12 FG)
1 x Bougies neoplex filiform (smaller sizes olive tipped)
1 x Sounds metal large Powell's straight blunt plain end
1 x Cystoscope fibre-lit 30 deg telescope with sheath and obturator, operated by standard Heine battery handle
Tiemann brown rubber catheters Ch. 12-24
1 x Foley-Tiemann urinary catheters Ch. 12-24
1 x Introducer for catheterisation 460 mm
1 x kidney dishes assorted 6", 8", 10"
3 x Gallipots stainless steel 70 mm diameter
2 Lotion bowls stainless steel 105 mm diameter x 40 mm

Lumbar Puncture set, Adult
1 x Instrument tray
1 x Kidney dish, 20 cm
1 x Galipot, 3 oz
1 x Sponge holder, 17 cm
1 x Lumbar puncture needles with stilettoes, different sizes for adult
1 x Spinal manometer
1 x 3-way Stopcock, Luer Lock
1 x Adapter
1 x Syringe Luer Lock
1 x Bijou sterile bottle
1 x Hypodermic needles, lock, 22 G
1 x Spinal needle (trocar & cannula), 22G
1 x Spinal needle (trocar & cannula), 20G
1 x Spinal needle (trocar & cannula), 23G
1 x Spinal needle (trocar & cannula), 18G

Lumbar Puncture set, Paediatrics
1 x Instrument tray
1 x Kidney dish, 20 cm
1 x Galipot, 3 oz
1 x Sponge Holder, 17 cm
1 x Lumbar puncture needles with stilettoes, different sizes for child
1 x Spinal manometer
3-way Stopcock, Luer Lock
1 x Adapter
1 x Syringe Luer Lock
1 x Bijou sterile bottle
1 x Hypodermic needles, Lock, 25 G
1 x Spinal needle (trocar & cannula), 25 G

Pleural Biopsy set
1 x Sterilization container for the set of instruments, with cover, perforation and filter
2 x Kidney dish, 20 cm
2 x Galipot, 6 oz
4 x Sponge holder, 17 cm
2 x Dissecting forceps, plain, 15 cm
2 x Scalpel handle, no. 3
8 x Towel clips, Backhaus, 8 cm
2 x Set Abram's pleural biopsy needles (8 G x 3 ")
5 x Two way adaptor
2 x Syringe, with metal tip, Luer lock
10 x Hypodermic needle, Luer lock, 23 G
10 x Hypodermic needle, Luer lock, 21 G
2 x Galipot, 3 oz

Mastectomy set
2 x Needle holder, Mayo-Hegar, 180 mm, straight
1 x Retractor, Farabeuf, double-ended, 120 mm, pair
1 x Tube suction, Yankauer, 270 mm
10 x Forceps, artery, Kelly, 140 mm, curved
5 x Forceps, tissue seizing, Allis, 150 mm
4 x Richardson Bladder, valve 38x44x30–38 mm, length 240 to 245 mm
10 x Forceps, artery, Halsted-Mosquito, 125 mm, curved
2 x Forceps, dressing, ring
2 x Forceps grasper short, 5 mm
1 x Volkman retractor
1 x Scalpel No 4 and 7 with blade
1 x Gerald Dressing Forceps, 18 cm, straight
2 x Dishes, kidney type

Chest Aspirations set
1 x Instrument tray, 24 x 5 cm
1 x Kidney dish, 20 cm
1 x Galipot, 6 oz
1 x Sponge holder, 17 cm
1 x Marting Aspiration Needles, 17 G
1 x Trocar and Cannulae, size 11 G and 14 G
1 x Two way Adaptor
1 x Doz. Hypodermic Needles, Luer Lock, 21 G x 1
1 x Doz. Hypodermic Needles, Luer Lock, 23 G x 1
1 x Galipot, 3 oz

Gynecologic biopsy set
1 x Forceps, uterine, ovum, Bierer, large
1 x Forceps, uterine, ovum, Bierer, small
1 x Forceps, uterine, ovum, Sopher, small
1 x Posi-Locking Instrument Holder
1 x Speculum, vaginal, Graves, wide mouth
1 x Fixed-diameter cervical dilator, reusable
1 x Disposable self-retaining retraction system ring
2 x Dishes, kidney type

Excisional breast biopsy set
1 x Retractor, Farabeuf, double-ended, 120 mm, pair
2 x Needle holder, Mayo-Hegar, 180 mm, straight
2 x Forceps, tissue seizing, Allis, 150 mm
1 x Forceps, artery, Kelly, 140 mm, curved (long and short)
2 x Forceps, Halsted Mosquito, 120 to 130 mm, curved, no teeth
2 x Forceps, Ring c and r
1 x Forceps, dressing, standard, 155 mm, straight
1 x Forceps, tissue holding, Collin, 160 mm
2 x Forceps, tissue, standard, 145 mm, straight
2 x Dissecting Forceps, teeth and non teeth, fenestrated, long and short
2 x Dishes, kidney type

Lobectomy and segmental lung set
Chest retractor of surgeon election (Volkman retractors, Harrington, Richardson, Malleable ribbon, Kelly vaginal)
Long medium and large clip appliers
Bronchus clamps
Duval lung clamps
Allison lung retractor (whisk)
Scapular retractor
Doyen periosteal elevator (doyen raspatory right and left)
Elevators (Cameron, alexander, periosteal or others)
Box cutter, Bethune (stille-giertz) rib shears, Guillotine
Bailey rib approximator
Yankauer or Baron suction tube
Finochietto rib spreader or Burford (short or long blades)
Soft tissue retractor (eg. Sauerbruch)
DeBakey Clamps long and short
Volkman retractors
Rib Elevator
Freer Elevator, with blunt sharp blade
Martin Tissue Forceps 7 1/2
Potts-Smith Tissue Forceps
Forceps (eg, Kelly, Pean, Coller, Mixter)
Towel Clamp
Needle Holder
Bone Rongeur
Mixter Thoracic Forceps
Nelson Metzenbaum dissecting Lobectomy Scissors
Sarot Intra-Thoracic Artery Forceps and Bronchus clamp (optional)
2 x Dishes, kidney type

Thoracotomy set
1 x Forceps, artery, Halstead
2 x Forceps, Sponge, Rampley
2 x Forceps, tissue, Allis
5 x Forceps, towel, Mayo
2 x Instrument Pin
2 x Knife handle, Surgical, No. 3
2 x Knife handle, Surgical, No. 4
1 x Needle Holder,
2 x Retractor, Double, blunt hook
1 x Scissors, Mcindoe
1 x Scissors, suture
2 x trocar & canula for chest puncture
2 x Dishes, kidney type

Sterile, single-use hypodermic needles: equivalence gauge/mm and colour coding for identification (EN-ISO 6009)		
29 G	0.3mm	-
27 G	0.4mm	Grey
26 G	0.45mm	Brown
25 G	0.5mm	Orange
23 G	0.6mm	Blue
22 G	0.7mm	Black
21G	0.8mm	Dark green
20 G	0.9mm	Yellow
19 G	1.0mm	Cream
18 G	1.2mm	Pink
17 G	1.5mm	Red-violet
16 G	1.6mm	White
15 G	1.8mm	Grey-blue
14 G	2.1mm	Light green
13 G	2.4mm	-

Sterile, single-use intravascular catheters: equivalence gauge/mm and colour coding for identification (EN-ISO 10555)		
26 G	0.6mm	Violet
24 G	0.7mm	Yellow
22 G	0.8, 0.9mm	Blue
20 G	1.0, 1.1mm	Pink
18 G	1.2, 1.3mm	Green
17 G	1.4, 1.5mm	White
16 G	1.6, 1.7, 1.8mm	Grey
14 G	1.9, 2.0, 2.1, 2.2mm	Orange

3.3 Other health system components

3.3.1 Human resources for surgery

A range of health professionals and other human resources are needed to provide safe and high quality surgical services for cancer. The guiding principle in surgical human resources should be that all professionals and technicians are appropriately trained to deliver quality care and are recognized by appropriately mandated national and supra-national accreditation where appropriate. The accreditation of the healthcare professional who performs the operative procedure depends on the procedure performed and requirements of national legislation and professional regulation. For example, basic procedures (e.g. Large loop excision of transformation zone (LEEP/LLETZ)) may be performed by primary care providers, more complex procedures done by accredited surgeons (e.g. mastectomy) working under a recognized regulatory system, and the most advanced operations provided by surgical oncologists, gynaecologic oncologists, or other specialist (e.g. proctectomy with total mesorectal excision). Regardless of the professional accreditation, the focus must be on the appropriateness of the procedure, quality and safety.

Additional human resource interdependencies include pathology and radiology. Multidisciplinary care contributes to surgical judgment and delivering quality surgery. Hospital managers and/or administrative personnel must work alongside surgical staff to ensure availability of essential equipment and reliable supply chains.

Depending on national context including workforce availability and models, different occupations can fulfil the roles that may be required for Surgery. A prerequisite is having the required competencies to perform these roles and being officially recognized for it as per the scope of practice. The ISCO[2] codes are added as illustrative examples based on current practice for further reference. This should not be interpreted as guidance on occupations that should perform each role but rather indicative occupations that are currently performing these roles in different country contexts.

Sample role	Sample occupations (ISCO-08 codes)
Perform surgical procedure.	Specialist medical practitioner (2212) Surgeon , oncological surgeon, (2212) • Note: select surgical procedures such as radical prostatectomy require may require specialist surgeons such as a urologist or urologic oncologist (2212)
Perform minimal invasive surgery using endoscopic instruments. Note: this requires especial training and be performed in advanced level hospitals. Simple cystoscopy can be done by a trained general surgeon. Endoscopic rectal ultrasound and biopsy requires considerable expertise.	Specialist medical practitioner (2212) Physician /surgeon with endoscopic training (2212)
Provide anaesthesia. May also provide palliative care services and pain relief.	Specialist medical practitioner (2212) Anaesthetist/ Anaesthesiologist (2212)

2 *International Standard Classification of Occupations, http://www.ilo.org/public/english/bureau/stat/isco/docs/publication08.pdf*

Sample role	Sample occupations (ISCO-08 codes)
Assist the surgical, anaesthetic, or endoscopic procedures, outside the sterile field. Should also assist with the safety checklist and the registration of the supplies opened for the procedure.	Circulating nurse, Nurse professional (2221)
Directly participate in the surgical field, handling the sterile instruments or equipment.	Surgical nurse, Nursing professional (2221) Surgical technician, paramedical practitioner (2240)
Perform screening and early diagnosis like PAP smear and VIA	General medical practitioner (2211) Nursing professional (2221) or midwifery professional (2222)
Deliver pre- and post-operative care, including pre-operative assessment and confirmation of operative site, postoperative monitoring and care.	Nursing professional (2221), nursing associate professional (3221), supervised: healthcare assistant (5321)
Control contaminations and infection prevention control, sterilization procedures.	Infection prevention control specialist, nursing professional (2221), environmental and occupation health inspectors and associates (3257)
Control the sterilization process , fill correctly autoclaves, check control items	Sterilization specialist, nursing associate professional (3221), personal care workers in health services (5329),
Management of medical devices: planning, procurement, Supervision or performance of: installation, users training, maintenance and decommissioning.	Biomedical Engineer (2149) Biomedical technician / physical and engineering science technician (3119)
Scheduling, reception of patients, filing patient data, and all other administrative tasks	Clerical support workers (4412) Technologists(3211), nurses (2221)
Cleaners need specific training for cleaning operating room (facilitate OR turnover time) and perioperative wards since they will operate in controlled areas. Clear instruction on management of all type of wastes should be given	Cleaning personnel (9112)

3.3.2 Infrastructure

A surgical unit requires basic infrastructure for reliable service delivery that includes the devices listed above, functioning operating rooms with electricity, a building structure with reliable ventilation, oxygen supply, and mechanisms for maintaining a sterile environment *(3)*.

Layout distribution

The functional programme of the surgical unit should include:

- A room for surgical procedures preferably with central gas supply line, laminar air flow, air temperature control
- Equipment storage rooms (include storage space for stretchers, supplies and equipment)
- Pre- and postoperative anaesthesia patient care areas (under the direct visual control of the nursing staff and if needed could be in the same area)
- Nurse station with charting facilities
- Hand-washing stations
- Scrub facilities
- Toilets and rooms for changing clothes
- Space for provisions for storage and distribution of drugs and routine medication
- Clean workroom or clean supply room
- Soiled workroom
- Outpatient examination and treatment area (for patient examination, interviews, preparation, testing and obtaining vital signs of patients
- Inpatient surgical ward/care areas
- Anaesthesia workroom
- Storage for blood, organs and pathological specimens

- Area for preparation and examination of frozen sections (if the laboratory isn't near the surgical unit)
- Sterilization facilities.

The size, location, and configuration of the surgical suite and support areas should reflect the projected volume of patients *(4)*.

Surgical infrastructure also relies on a strong referral mechanism that promotes links between and integration of services. This includes communication between primary and specialty care, cancer surgery and multidisciplinary services including pathology and radiotherapy, and links among facilities providing cancer care.

An adequate preoperative assessment is directly related to better surgical outcomes. Access to reliable basic imaging, laboratory, pathology and clinical evaluation is important in order to plan the surgical procedure, and to prevent surgical and anaesthetic complications.

Moreover, access to safe, quality, and efficacious blood products is an objective of the WHO programme on Blood Transfusion Safety and relevant to the delivery of cancer surgery service. Perioperative transfusion may be needed due to a patient's underlying condition, co-morbid diseases, or the complexity of surgical care. The availability of facilities that provide safe blood enables cancer surgical care.

Electrical systems

Operating rooms should have appropriate electrical systems, such as emergency outlets supplied by backup generators in case of grid failure, and isolated power systems.

Heating, ventilation and air conditioning systems

The ventilation system should be designed to protect the suite from the environment but above of all to protect the patient from the environment. Ideally, the temperature of the operating room should be maintained between 22°C and 26°C. There should be a reference supply airflow. There should be positive pressure in relationship to other areas.

Communication systems

Each room should have a system for emergency communication with the surgical suite control station.

Special systems

Aspects to be considered include oxygen availability (oxygen concentrator, oxygen/gas pipeline, cylinder) in surgery and endoscopy, and vacuum availability (suction pump, vacuum central pump). If applicable, sufficient outlets for oxygen, vacuum and medical air systems should be considered.

Regarding architectural details, the operating room perimeter: walls, ceilings, and floors, including penetrations, should be sealed and washable.

3.3.3 Quality management

Six domains of quality should be monitored, as articulated in WHO Quality of Care: A Process for Making Strategic Choices in Health Systems (2006): quality of care should be effective, efficient, accessible, acceptable/patient-centred, equitable, and safe. Each of these domains should be evaluated in quality assurance programmes implemented with key stakeholders in interdependent fields. Surgical care is based on a team model that requires commitment from all partners to improve quality and outcomes.

Broad strategies used to improve quality include establishing quality management guidelines, establishing surgical standards, utilizing forums like Morbidity & Mortality conferences (M&M), collecting and monitoring indicators of quality, and performing comprehensive audits of surgical procedures done at the regional or national level. While outcome data generally reflect the overall effectiveness and quality of care (such as percentage of cancer patients who survive at one year), additional factors should be assessed that can impact outcomes, such as delays in care or resource limitations.

Quality care must be accessible and delivered in a timely manner. Sample quality indicators proposed in WHO Cancer Control Modules: Diagnosis & Treatment (2008) include the number of patients receiving timely treatment and trained human resources *(5)*. Treatment guidelines can also improve quality of care and can be measured through indicators such as percentage of patients treated according to guidelines, as suggested in WHO National Cancer Control Programmes (2002) *(6)*.

Quality and safety are fundamental to effective cancer surgery. Surgical and anaesthesia services have a long history of promoting safety and include the WHO Safe Surgery programme. The Safe Surgery Saves Lives programme aims to improve the quality of surgical care by defining a core set of safety standards to be applied in all facilities. Safe surgery requires the participation of all members of the surgical team, including nurses, anaesthesia providers, and surgeons, who together promote a culture of safety. High quality, appropriate and safe anaesthesia and nursing are critical to effective operative care.

Monitoring and evaluation programmes must be fed back to the surgical team for ongoing quality improvement. For example, a surgical team receiving feedback on a disproportionately high incidence of surgical site infections can evaluate potential etiologies such as poor sterilization, incorrectly timed or administered antimicrobials, improperly prepared skin with antiseptics, or other factors. Continuous quality improvement linked to service delivery, safety, and integrated care is critical to successful cancer surgery.

3.3.4 Guidance documents

Title	Link	Description
World Health Assembly resolution on Strengthening Emergency and Essential Surgical Care and Anaesthesia, 2015	http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_R15-en.pdf	Recognising the crucial importance of surgical services, and the huge gaps in global access, the resolution underlines the importance of building political commitment to expand access, and of strengthening the surgical workforce through training and knowledge exchange.
Surgical Services for Cancer Care	http://dcp-3.org/sites/default/files/chapters/DCP3%20Cancer_Ch%2013.pdf	DCP3 Chapter from Cancer Volume, Part II: Interventions
WHO Safe Surgery Saves Lives	http://apps.who.int/iris/bitstream/10665/44185/1/9789241598552_eng.pdf	Guidelines for implementation of the Surgical Safety Checklist.
Integrated Management for Emergency and Essential Surgical Care (IMEESC) toolkit	http://www.who.int/surgery/publications/imeesc/en/	The WHO Integrated Management for Emergency & Essential Surgical Care e-learning toolkit (CD) was developed by the Clinical Procedures Unit in collaboration with the Global Initiative for Emergency & Essential Surgical Care members. This tool targets policy-makers, managers and health-care providers (surgeons, anaesthetists, non-specialist doctors, health officers, nurses, and technicians). This tool contains WHO recommendations for minimum standards to improve quality and safety of emergency, surgery, trauma, obstetrics and anaesthesia at first-referral level health-care facilities.
The Lancet Commission on Global Surgery	http://www.thelancet.com/commissions/global-surgery	The global burden of disease amenable to surgical intervention, such as trauma, cancer, and complications from childbirth, is substantial and growing. Despite this, there are currently gross disparities in access to safe surgical care worldwide. Surgery is an integral, indivisible component of a properly functioning health system, and all people should have access to safe, high-quality surgical and anaesthesia care with financial protection when needed. The purpose of The Lancet Commission on Global Surgery is to make this vision a reality by embedding surgery within the global health agenda, catalysing political change, and defining scalable solutions for provision of quality surgical and anaesthesia care for all.

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1) WHO guidelines for safe surgery.
Available at: http://www.who.int/patientsafety/safesurgery/en/

2) Sullivan, Richard, et al. "Global cancer surgery: delivering safe, affordable, and timely cancer surgery." The Lancet Oncology 16.11 (2015): 1193-1224.
Available at: http://www.thelancet.com/commissions/global-cancer-surgery

3) WHO Surgical Care at the District Hospital.
Available at: http://www.who.int/surgery/publications/en/SCDH.pdf

4) Guidelines for design and construction of Health Care Facilities. The Facility Guidelines Institute.
Available at: http://www.ashe.org/advocacy/orgs/fgi.shtml

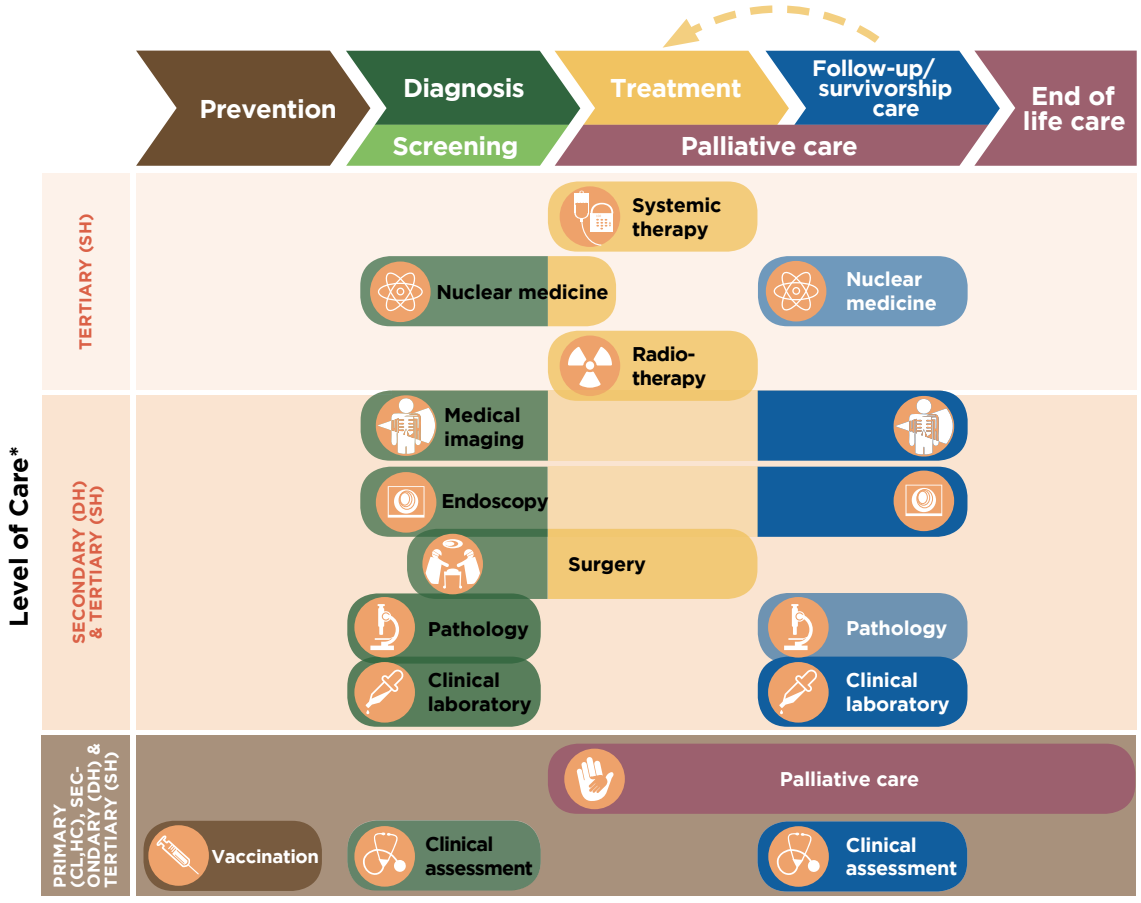
5) WHO Cancer Control Modules: Diagnosis & Treatment (2008).
Available at: http://www.who.int/cancer/publications/cancer_control_diagnosis/en/

6) WHO National Cancer Control Programmes (2002).
Available at: http://www.who.int/cancer/publications/nccp2002/en/

4. Clinical laboratory & pathology

Health service delivery sequence overview:

This diagram expresses the flow of cancer patients to and from the clinical laboratory and pathology unit, and the elements to consider as support for the unit.



* Appropriate level of care will depend on the particular intervention, setting, and available infrastructure and human resources.
CL Community Level health post DH District Hospital HC Health Centre SH Specialized Hospital

Fig. 10.4 Health care service delivery overview – clinical laboratory and pathology

4.1 General description of the unit

The purpose of the pathology and laboratory medicine unit is to perform accurate testing in a timely fashion on patient samples and to analyse and interpret the results, thereby guiding the diagnosis, treatment and management of the patient. The intention is to provide these results based on examination of the patient's cells, tissues, blood and other body fluids, while ensuring the safety of personnel, public and patients. Timeliness, accuracy of results, quality management and universal safety are critical elements in medicine and in the safe functioning of the pathology and laboratory medicine unit.

The Pathology laboratory handles tissues, body fluids and other specimen types. Specimens submitted for pathologic examination may be solid tissues from surgical excisions or biopsies (histopathology) or cells in smears, scrapings or fluid specimens (cytopathology). The significance of the pathology laboratory (in its broadest terms) is that in many cases, patient management is based on a definitive histologic or cytologic diagnosis, especially in the case of neoplasms. Future management of a patient depends on an assessment of various pathologic parameters including the histopathologic type of tumour, its grade, its extent and its stage and additional ancillary studies which insure correct treatment or inform prognosis. A complete and detailed examination of the excised tissues is therefore critical, especially in this age of personalized medicine. To ensure that all specimens are appropriately handled, guidelines and standard operating procedures must be in place for the handling of all specimens. This will prevent misdiagnosis, save time, anxiety and possible harm.

Tissues must be handled appropriately, immediately after collection by the clinician, so that the quality of the tissues available does not deteriorate and optimum preservation is maintained for accurate diagnoses and possible biomarker testing.

Effective timely communication, however, is not just crucial in reporting of pathology results, but also is vital for exchange of information about the patient and their management at all points during the pathway of care.

In addition, the clinical laboratories (laboratory medicine) provide testing in haematology, chemistry, immunology, and microbiology that are also essential for diagnosis and management of many diseases including cancers.

4.2 Priority medical devices for clinical laboratory

The following tables present general medical devices for clinical laboratory medicine, which can be used for screening, diagnosis, staging, and follow-up of many diseases including several cancers, and specific medical devices, which are used for interventions for specific cancer types.

The following tables present the priority medical devices required to perform the following health interventions:

Cancer type	Interventions
All cancers	• Pre-analytical procedure: phlebotomy, sample reception and distribution • General analytical procedures • Blood chemistry tests (liver and renal function tests, alkaline phosphatase and calcium) • Tumour lysis syndrome panel: lactate dehydrogenase (LDH), uric acid, potassium (K), Calcium (Ca), Phosphate • Complete blood count (CBC) - total white blood count with differential, platelet count, and haemoglobin level and red blood cell indices • Disseminated intravascular coagulation (DIC) panel: D-dimer, fibrinogen, prothrombin time (PT), partial thromboplastin time (PTT) • Urine free light chains • Serum free light chains • Serum protein electrophoresis • Immunoassay test
Breast cancer	• Biomarker analysis
Cervical cancer	• Baseline CD4 count test (for HIV(+) patients) • HPV Test

Cancer type	Interventions
Colorectal cancer	• Carcinoembryonic antigen (CEA) test • Faecal immunochemical testing (FIT) • Guaiac faecal occult blood test (gFOBT)
Leukaemia	• Bone marrow aspiration • Bone marrow biopsy • Cerebrospinal fluid aspirate and lumbar puncture • Comprehensive flow cytometric immunophenotyping • Optional: Cytogenetics, Cytochemistry eg myeloperoxidase, specific and non-specific esterase, sudan B and In situ hybridisation (FISH, SISH)
Prostate cancer	• PCA3 test • Prostate specific antigen PSA

4.2.1 General medical devices for clinical laboratory

Choosing equipment for laboratory services depends mainly upon volume and resources. The type of equipment needed should be considered (automated, semi-automated) according to facility capacity, and options for purchasing, leasing or renting the devices along with the relevant consumables, accessories and software.

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
Pre-analytical procedure- Phlebotomy, sample reception and distribution	Laboratory and pathology equipment	Table top centrifuge	
	Medical furniture	Adequate furniture for the laboratory devices	
		Blood draw chairs	
		Sample distribution trolley	
	Personal protective equipment		Coat, medical, woven, white (various sizes)
			Gloves, examination, non-sterile, single use (various sizes)
	Disposables/medical supplies		Bandage, adhesive, 3.0 cm, box/100
			Compress, gauze, antiseptic, 6x3 cm, sterile
			Compress, gauze, sterile & non-sterile, single use
			Needles, luer, sterile, single use (sizes G)[3]
			Paper towels
			Swab-pad, alcohol
			Syringes
			Tape, medical, roll (various sizes)
			Needle, vacuum tube, 20 G/ 22 G, sterile
			Needle holder, vacuum tubes, sterile
			Sheet, absorbent, bench, 50x40 cm
			Tube, vacuum, Ethylene Diamine Tetra-acetic Acid (EDTA), sterile (various capacities)
			Tube, vacuum, plain/dry, sterile (various capacities)
			Tube, vacuum, serum, sterile
			Lancet, blood, safety, sterile (various sizes)

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
	Solutions and reagents		Distilled water
			Ethanol
	Other		Rack, test tubes
			Tourniquet, with buckle
			Sample distribution container
			Thermic containers
			Safety box, for used syringes/needles
General analytical procedures	Laboratory and pathology equipment	Refrigerator, laboratory	
		Refrigerator/freezer, laboratory	
		Freezer, laboratory	
		Microscope, binocular	
		Camera for microscope (for telemedicine and documentation)	
		Timer, digital	
		Timer, 60 min, mechanical	
		Thermometer, glass, min/max -20°C/100°C	
		Thermometer, min/max -30°C/60°C	
		Magnifying glass	
		Centrifuge	Accessories for serology
		Centrifuge, micro - haematocrit	
		Distillation unit, 2 L/h, with tank	
		Hot plate, with stirrer	
		Incubator, 30 L, up to 80° C	
		pH meter	
		Rotator, agglutination test	
		Scale, digital, 1500 g/0.1 g	
		Scale, precision, digital, 500 g/0.01 g	
		Basic laboratory mixer/ Laboratory shaker vortex	
		Shaker, orbital	
		Spectrophotometer, ultraviolet/ visible	
		Sterilizer steam autoclave, 24 L	
		Water bath, 7 L	
		Hygrometer	Microplate, ELISA, 96 U-well
	Instruments	Forceps, dressing, 155 mm, straight	
		Spatula, stainless steel (various sizes)	
		Clamp, test tubes	
	Medical furniture	Adequate furniture for the laboratory devices	Cabinet for microscope
	Personal protective equipment		Coat, medical, woven, white (various sizes)
			Gloves, examination, latex, non-sterile, single use (various sizes)

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/consumables/single use devices
			Gloves, nitrile, powder-free, non-sterile, single use
			Mask, surgical, non-woven
			Glasses, safety, regular size
	Disposables/medical supplies		Bag, re-sealable, plastic
			Compress, gauze, 10x10 cm, non-sterile
			Cover glass, slides
			Envelope, packing, 27x36 cm
			Lancet, 2 mm, safety, sterile
			Paper towels
			Paper, dry blood spot
			Paper, lens
			Rack, drying DBS cards, 10 positions
			Slide, microscope
			Slide, microscope, frosted
			Swab, cotton-tip, tube, sterile
			Vortex, test tube
			Wooden or plastic applicator sticks
			Bag, biohazard, 20 L
			Blood collection tube, neonatal cord blood, sterile
			Container, sample, 50 ml
			Cotton wool, 500 g, roll, non-sterile
			Dressing strip, adhesive, diameter 3.0 cm, sterile
			Film, sealing, flexible, 10 cm x 38 m, roll
			Inoculation loop, plastic, sterile
			Kato-Katz, kit, stool sample preparation
			Monitor card, humidity, passive/cumulative
			Paper, filter #1
			Paper, pH indicator 2.0 to 9.0
			Paper, weighing
			Pipette, repeat, tip 2.5/5.0 ml, 10/25 ml
			Pipette, tip, barrier, 200 ul / 1000 ul, sterile
			Pipette, tip, blue, 100–1000 ul
			Pipette, tip, white, 2–20 ul
			Pipette, tip, yellow, 10–100 ul / 20–200 ul
			Pipette, transfer, 3 ml, non-sterile
			Pipette, transfer, 3 ml, sterile
			Reservoir, reagent, 60 ml
			Sealant, compound
			Tape

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
			Tube, push cap, 0.2 ml, PCR, sterile
			Tube, push cap, 5.0 ml, non-sterile
			Tube, screw cap, 0.2 ml / 0.5 ml / 2.0 ml / 5.0 ml, non-sterile
			Tube, screw cap, 0.2 ml / 0.5 ml / 2.0 ml / 5.0 ml, sterile
			Tube, screw cap, conic, 15/50 ml, non-sterile
			Tube, vacuum, EDTA, 2 ml / 4 ml / 6 ml, sterile
			Tube, vacuum, plain/dry, 4 ml / 6 ml, sterile
			Tube, vacuum, serum, 4 ml / 6 ml, sterile
			Parafilm paper
			Reservoir, reagent, 60 ml
	Solutions and reagents		Acetic acid, 36%, bottle
			Acetone, bottle
			Bromine solution
			Buffer, tablets, pH 7.2, box
			Cytology stain kit
			Diethyl ether, bottle
			Distilled water
			Ethanol, denatured, 70%, bottle
			Ethanol, denatured, 95%, bottle
			Formaldehyde, 10%, 10 ml, ampoule
			Gentian violet, solution, bottle
			Glycerol, bottle
			Hydrochloric acid, 40%, bottle
			Indian ink, black, bottle
			Isopropyl alcohol
			KI starch solution
			Lugol iodine, bottle
			Methanol, bottle
			Methylene blue, bottle
			Nitric acid
			Oil, immersion, bottle
			Oxidase test
			Petroleum gel, paraffin, bottle
			Potassium iodide
			Silica gel (desiccant for DBS), pouch
			Sodium bicarbonate
			Sodium chloride, powder, bottle
			Sodium hypochlorite, tablets
			Sodium persulfate
			Stain, Field A, solution
			Stain, Field B, solution

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
			Stain, Giemsa, solution
			Stain, Gram, set
			Stain, May-Grunwald Giemsa, set
			Stain, Ziehl–Neelsen, solution, bottle
			Sugar fermentation tests
			Sulphuric acid, 95%
			Test, Nickerson or sabouraud medium, kit
			Test, potassium hydroxide KOH, preparation
			Trichloroacetic acid, crystals, bottle
			Pipettes cleaning solution
			Substrate, adamantyl phosphate oxetane
			Wash solution
			Xylene, bottle
	Other		Safety box, for used syringes/needles
			Beaker, glass, 100 ml / 250 ml
			Bottle, amber, dropper, 30 ml
			Bottle, amber, screw cap, 100 ml / 250 ml / 1000 ml
			Bottle, plastic, 1 L
			Box, refill, pipette tips, empty
			Box, specimen transport, 2 L/4 L
			Box, storage, 100 slides
			Box, storage 0.5/2/5 ml tubes, 100 positions
			Brush, bottles and flasks (various sizes)
			Brush, test tubes (various sizes)
			Containers for hazardous waste (solutions and others)
			Cylinder, measuring, glass, 10 ml /100 ml / 500 ml/ 100 ml
			Funnel, glass
			Funnel, plastic
			Jar, Coplin, staining
			Label, biohazard, adhesive, 3x4 cm
			Label, self-adhesive, freezer
			Label, self-adhesive, 5x10 cm
			Marker pen, cryoware
			Marker pen, glassware
			Marker, diamond
			Petri dish, glass, with lid
			Pipette, digital, 10–100 ul
			Pipette, digital, 100–1000 ul
			Pipette, digital, 2–20 u

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
			Pipette, digital, 20–200 ul
			Pipette, digital, 8 channel, 20-200 ul
			Pipette, digital, 8 channel, 5–50 ul
			Pipette, filler, wheel-run, set/2
			Pipette, repeating, 5 volume
			Pipette, stand, 4 positions
			Pipettes, blood graduated, 0.05 ml
			Rack, drying glass & plastic ware
			Rack, drying slides, 12 positions
			Rack, staining slides, horizontal, 12 positions
			Rack, test tubes, 24 positions
			Rack, tubes, 0.5/2.0/5.0 ml, 24 positions
			Rod, glass
			Wash bottle, 250 ml
			Serological pipette
			Pasteur Pipette
	Single use devices		Punch, Dry Blood Spot (DBS), 3.0 mm
Blood chemistry tests (liver and renal function tests, alkaline phosphatase and calcium) Tumour lysis syndrome panel: lactate dehydrogenase (LDH), uric acid, potassium (K), Calcium (Ca), Phosphates	Laboratory and pathology equipment	Clinical chemistry Analyser	Reagents, calibrators and controls for clinical chemistry analyzer
		Ultrasonic washer	
		Table top centrifuge	
Complete blood count and - Complete blood count with differential and platelets (including full blood count and haemoglobin levels)	Laboratory and pathology equipment	Analyser Laboratory Haematology, Manual or Automated	Reagents calibrators and controls haematology analyser If not automated: Buffer solution, Wright stain, wash solution, dropper, Pasteur pipette, Wintor tube, ESR (Erythrocyte Sedimentation Rate) Analyser, Integrated slide marker/ stainer system, Rack, ESR, 5 positions, Counter, cell, manual differential, Counter, hand tally, mechanical, Counting chamber, Neubauer, Haemoglobin colour scale (starter kit), Hemoglobinometer, with accessories
Disseminated intravascular coagulation (DIC) panel: D-dimers, fibrinogen, prothrombin time (PT), partial thromboplastin time (PTT)	Laboratory and Pathology Equipment	Coagulation analyser, Manual or Automated	Reagents calibrators and controls

4.2.2 Specific medical devices for clinical laboratory by cancer type

4.2.2.1 Breast

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
Biomarker analysis	Laboratory and pathology equipment	Immunoassay unit	Reagents for immunohistochemistry lab (ie. HER2, estrogen receptor, progesterone receptor) solutions and controls, secondary antibodies
		Automated IHC staining system	Direct visualization of antibody staining for estrogen and progesterone receptor (for anti-estrogen therapy) and for Her2 antigen (for anti-Her2 therapy).

4.2.2.2 Cervical

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
Baseline CD4 count test (for HIV+ patients)	Laboratory and pathology equipment	Flow cytometer	
HPV Test	Laboratory and pathology equipment		HPV DNA Test

4.2.2.3 Colorectal

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/consumables/ single use devices
Carcinoembry-onic antigen (CEA) test	Laboratory and pathology equipment	Immunoassay unit	Depending on the technique, may include reagent sample diluent and reagents (ie.CEA test)
Faecal immuno-chemical testing (FIT)	Laboratory and pathology equipment	iFOB immunochemical analyzer, automated	
Guaiac faecal occult blood test (gFOBT)	Laboratory and pathology equipment		Faecal occult blood test (FOBT) rapid test kit (slides and applicator sticks)

4.2.2.4 Leukaemia

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
Bone marrow aspiration	Instruments	Bone marrow aspiration set	
		Scalpel with blades	
	Single use devices/ disposables/medical supplies		Aspiration tray
			Bone marrow aspiration needles 15 or 16 several lengths
			Tube containing EDTA anticoagulant
			Microscope slides frosted
			Spinal needle
	Solutions and reagents		Preservative solutions
Bone marrow biopsy	Instruments	Blunt obturator	
	Single use devices/ disposables/medical supplies		Iliac crest aspiration needles
			Microscope slides frosted
			Jamshidi needle (sizes: Adult 4 inch, 11 gauge; Paediatric 3 inch, 13 gauge) or Bone marrow biopsy needles with specially sharpened cutting edges and core securing devices
	Solutions and reagents		Formalin 10%, or tissue fixation reagents like B5, Boiuns, etc
			Antiseptic skin cleansing agent
Cerebrospinal fluid aspirate and lumbar puncture	Medical equipment	Cerebrospinal fluid manometer	
	Instruments	Lumbar Puncture set, Adult or Child	
	Single use devices/ disposables/medical supplies		Grey bottle, sterile universal specimen bottles
			Collection tube/sterile plastic tubes
			Skin-cover adhesive strip
			Spinal needle
			Spinal anaesthesia needle, single-use
			Syringes
			Hypodermic needles: gauge 25 G, 23 G, 21 G
			Gauze strip antimicrobial
			First aid gauze/bandage
	Solutions and reagents		Antiseptic skin cleansing agent
	Utensils		Skin marker pen
Comprehensive flow cytometric immunopheno-typing	Laboratory and pathology equipment	Flow cytometer Microscope, binocular	

4.2.2.5 Prostate

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devicess/ single use devices
PCA3 test, Prostate specific antigen PSA	Laboratory and pathology equipment	Immunoassay unit, automated	Sample diluent and reagents (ie.PSA test)

4.3 Priority medical devices for pathology

The following tables present general medical devices for pathology, which can be used for screening, diagnosis, staging, and follow-up of many diseases including several cancers, and specific medical devices, which are used for interventions for specific cancer types.

The following tables present the priority medical devices required to perform the following health interventions:

Cancer type	Interventions
All cancers	• General pathology procedures: morphological assessment of tumour biopsy and surgical resection specimens, including assessment of surgical margins (includes histopathology, cytopathology, immunohistochemistry and histochemical stains)

4.3.1 General medical devices for pathology

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devicess/ single use devices
Pathology procedures	Personal protective equipment		Glasses, safety, regular size
			Heat-resistant gloves
			Disposable apron or heavy duty plastic apron (washable, reusable)
			Medical scrubs
			Face masks N95
			Plastic face shield
			Gloves, examination, non-sterile, single use (various sizes)
			Coat, medical, woven (various sizes)
	Single use devices/ disposables/medical supplies		Cover glass/cover slips
			Microscope slides frosted
			Markers, fine point, permanent black, for glassware and slides
			Compress, gauze, sterile & non-sterile, single use
			Pipette tip
			Sponges

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devicess/ single use devices
			Syringes and needles (various sizes, G) [3]
			Swab-pad, alcohol
			Tape, medical, roll (various sizes)
			Tube, push cap, 0.2 ml, PCR, sterile
			Tube, push cap, 5.0 ml, non-sterile
			Tube, screw cap, conic, 15/50 ml, non-sterile
			Tube, screw cap, 0.2 ml / 0.5 ml / 2.0 ml / 5.0 ml, non-sterile
			Tube, screw cap, 0.2 ml / 0.5 ml / 2.0 ml / 5.0 ml, sterile
			Wooden or plastic applicator sticks
			Cassettes
			Micro-vial tubes
	Other		Label, self-adhesive, different sizes

4.3.2 General medical devices for histopathology

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
Reception	Laboratory and pathology equipment	Table Label printer attach with LIS (optional but very useful)	Date chop/stamp Stamp pad Baskets Record book Laboratory registration labels
	Software		Laboratory information system (LIS) (optional but very useful)
Grossing/ Prosection	Laboratory and pathology equipment/medical equipment	Professional grossing bench with sink and exhaust system/ grossing station Refrigerator/freezer laboratory Cassette printer (Optional) Permanent marker pen (for cassette) Strainer Organ balance, Ruler or measuring tape Cutting board	Magnifier Dictation machine Tapes Biohazard Bin
	Instruments	Forceps, Knife for specimens, Rotary saw (optional), Scissors, Spatula, Scalpel handle with blades,	
	Solution and reagents	Inks (for surgical margins)	
	Single use devices		Paper lens
Fixation of specimens	Solution and reagents		10% Neutral Buffered Formalin adjusted for specimen volume 5% 20% Formic Acid
	Medical furniture	Cabinet, Table	Container for specimen immersion (various sizes) Universal bottle for small specimens

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
Tissue processing	Laboratory and pathology equipment, medical equipment	Tissue Processor	
	Solutions and reagents		10% Neutral Buffered Formalin 100% 95% Alcohol Xylene Melted Paraffin Wax
Embedding	Laboratory and pathology equipment	Tissue embedding unit or station	Heated forceps Mould (various sizes) Paraffin Wax
Microtomy	Laboratory and pathology equipment	Microtome, Water bath, Slide label printer (optional)	Cooling device Low Profile Blades Forceps Glass slides Hot Plate Brush
Frozen Sections	Laboratory and pathology equipment	Cryostat, Stool Chair (optional)	Histofreezer OCT Compound Chuck Forceps Small Paint Brush Slides High/Low Profile Blades Racks
H&E staining	Laboratory and pathology equipment	Autostainer Fume Hood Chamber	
	Solutions and reagents		100%, 95%, 80%, 70% Alcohol Xylene Harris's Haematoxylin Eosin 0.25% Acid Alcohol 20% Sodium Acetate Distilled water (Running Water)
	Utensils		Staining racks Slide tray DPX mounting media Filter paper Coverslips (various sizes)
	Glassware		Graduated cylinder Funnel Graduated pipettes Pasteur pipettes Beaker Bottle reagent Flat Bottom Boiling Flask Erlenmeyer flask Coplin jar
	Surgical instruments	Forceps	
Reporting	Laboratory and pathology equipment	Binocular light microscope, Immunofluorescence microscope, Computer and printer	
	Software		Laboratory Information System (LIS) (optional but very useful)
Materials archive	Laboratory and pathology equipment	Block or cassette cabinet, Slides cabinet, - 20 °C and - 80°C freezer for frozen specimens	
Chemical Reagents	Medical furniture	Flammable storage cabinet	

4.3.3 General medical devices for cytology

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
Sample processing	Laboratory and pathology equipment	Biosafety cabinet Class II, Cytocentrifuge, Slide label printer (optional), Centrifuge, Refrigerator	
	Instruments		Forceps Glass slides ThinPrep slides Pasteur pipette Coplin jar Racks Screw cap tube 15 ml / 20 ml Biohazard bin
	Solutions or reagents		Plasma Throbim Methanol
	Single use devices		Paper, lens
Staining	Laboratory and pathology equipment	AutoStainer	
	Solutions and reagents		50%, 70%, 80%, 95% ,100% Alcohol Distilled water (running water) Haematoxylin Eosin Orange Gelb-6 0.5% Acid Alcohol May Grunewald Stain Giemsa Stain Methanol Xylene
	Utensils		Staining racks Slide Tray DPX mounting media Filter Paper Coverslips (various sizes)
	Glassware		Graduated Cylinder Funnel Graduated pipettes Pasteur pipettes Beaker Bottle reagent Flat Bottom Boiling Flask Erlenmeyer flask Coplin jar
	Surgical instruments	Forceps	
Reporting	Laboratory and pathology equipment	Binocular light microscope, Computer and printer	
	Software		Laboratory Information System (LIS) (optional but very useful)
Materials archives	Laboratory and pathology equipment	Refrigerator, Slides cabinet,	
Chemical Reagents	Medical furniture	Flammable storage cabinet	

4.3.4 General medical devices for immunohistochemistry

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
IHC staining	Laboratory and pathology equipment	Gravity-convection laboratory oven Refrigerator -20˚C Freezer Oven 37˚C and 60˚C Mechanical balance Scale precision digital 500 g/0.01 g Mechanical and Digital Timer Microwave oven Pressure cooker pH meter Immunohistochemistry (IHC) / In situ hybridization (ISH) staining platform Slides label printer for Immunohistochemistry (IHC) / In situ hybridization (ISH) staining platform	Micropipettes (different microliters) Staining Rack
	Instruments	Forceps	
	Solutions and reagents		Distilled water Xylene 100% 95 % 80% 70 % Alcohol Washing Buffer Peroxidase Blocking protein solution Antibodies diluents Primary antibodies Secondary antibodies Harris's Haematoxylin Bluing Reagent DAB Enzyme solution Antibodies detection kit / Amplification Kit and Prep Kit dispenser or similar for IHC staining platform Immunohistochemistry (IHC) / In situ hybridization (ISH) staining platform reagents and buffers
	Other		Slide Tray Biohazard Bin Markers / fine point / permanent black for glassware Rack for drying glassware and plastic ware Rack for drying slides Rack for tubes Cover plates Cover slip (various sizes)
	Glassware		Beaker Bottle Reagent Funnel Graduated cylinder Graduated pipette Coplin Jar Dropper bottle
Chemical Reagents	Medical furniture	Flammable storage cabinet	

4.3.5 Special stain (histochemical)

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
Special staining	Laboratory and pathology equipment	Gravity–convection laboratory oven Refrigerator -20˚C and - 80˚C Freezer Oven 37˚C and 60˚C Mechanical balance Precision electronic balance pH meter Mechanical and Digital Timer Hot plate Magnetic stirrer Microwave oven Pressure cooker	Micropipettes (different microliters)
	Instruments	Forceps Spatula	
	Solutions and reagents		Harris's Haematoxylin Eosin 0.5 % Periodic Acid Schiff's Reagent Carbol Fuchsin 0.5% Acid alcohol 10% Sulphuric Acid Methylene Blue 3% Acetic Acid Alcian Blue Sodium Chloride Conge Red Potassium Permanganate Sodium Hydroxide 2% Oxalic Acid Fouchet's Reagent Nuclear Fast Red 5% Chromic Acid Sodium Metabisulfite Methenamine Silver Gold Chloride Sodium Thiosulphate Bouin's Fixative Celestine Blue Acid Fuchsin 5% Phosphotungstic acid Light Green
	Other		Staining Rack Magnetic stirrer Markers / fine point / permanent black for glassware Rack for drying glassware and plastic ware Rack for drying slides Cover plates Cover slip (various sizes)
	Glassware		Beaker Bottle Reagent Funnel Graduated cylinder Graduated pipette Coplin Jar Filter paper Laboratory mortar Erlenmeyer Flask Flat Bottom Boiling Flask Pasteur pipette Dropper bottle
Chemical Reagents	Medical furniture	Flammable storage cabinet	

4.4 Other health system components

4.4.1 Human resources for clinical laboratory and anatomic pathology

The personnel required depend on the anticipated volume of material and process to be handled by the specific laboratory unit.

Depending on national context including workforce availability and models, different occupations can fulfil the roles that may be required for clinical laboratory and anatomic pathology. A prerequisite is having the required competencies to perform these roles and being officially recognized for it as per the scope of practice. The ISCO[2] codes are added as illustrative examples based on current practice for further reference. This should not be interpreted as guidance on occupations that should perform each role but rather indicative occupations that are currently performing these roles in different country contexts.

Sample role	Sample occupations (ISCO-08 codes)
Tissue handling/transportation, tissue assessment, sectioning and staining, analysis of tissue sections	Biomedical Laboratory Scientist, Medical and pathology laboratory technicians (3212)
Gross and microscopic analysis of tissue and cytologic specimens with diagnosis	Specialist medical practitioner (2212) Anatomic Pathologist/ Cytopathologist (2212)
Review Pap smears and non-gynaecologic cytology preparations	Cytotechnologist (3212)
Management of medical devices: planning, procurement, Supervision or performance of: installation, users training, maintenance and decommissioning.	Biomedical Engineer (2149) Biomedical technician / physical and engineering science technician (3119) under supervision of biomedical engineer (2149)
Ensure Quality of all Procedures, that relevant Standard Operating Procedures (SOPs) are followed, and that all staff maintain professional standards and certification Ensure that sufficient internal and external quality control procedures are in place and followed. • Provide employees with orientation and training. • Include policies relevant to personnel in the quality manual.	Specialist medical practitioner (2212) Anatomic Pathologist (2212), Biomedical Laboratory Scientist, Medical and pathology laboratory technicians (3212) Laboratory quality manager
Administrative tasks	Clerical support workers (4412)

4.4.2 Infrastructure

Even at the most primary or basic level, the pathology laboratory facility must meet the ISO certification and local building criteria required for its type of use and equipment, structure, ventilation and storage capacities.

Layout distribution

The laboratory should have the essential infrastructure for the collection and safe handling of the specimens (tissue, blood and other human samples), tissue processing, and diagnosis of the lesion and in the case of pathology (cytology and haematology), the appropriate storage of paraffin blocks and slides to ensure their future use for the benefit of the patient and as required by local laws.

It is important to consider procurement of the sample, which is likely performed offsite from the central institution, with subsequent transportation of the sample to the pathology laboratory. The personnel from remote sites must be instructed about the need for appropriate and timely fixation of the tissues, and appropriate handling of the tissues in the appropriate fixative solutions.

The size of the facility (area) should be commensurate with the volume of material handled, the equipment needed, and the staff to be accommodated on site at any given time. The area must have the capacity to accommodate all of the equipment needed for the unit (see the list of devices necessary for the laboratory), and also appropriate and adequate space for storage of pathological specimens.

The laboratory premises should be appropriately identified and should comply with local/national building regulations. There must be sufficient space and facilities for the safe and satisfactory operation of the laboratory service. Specifically, there should be facility for:

2 *International Standard Classification of Occupations, http://www.ilo.org/public/english/bureau/stat/isco/docs/publication08.pdf*

1. the reception and handling of specimens
2. the handling of hazardous materials
3. space for performance of all licensed tests
4. space for maintenance of all equipment
5. the safe storage of reagents
6. the storage of tissues including blood and other body fluids
7. storage of residual tissues from specimens, tissue blocks and glass slides
8. space for administrative staff and professional staff to work comfortably.

Safety equipment including eye wash/shower, hand basins and personal protective equipment must be available.

Considerations for pre-analytical and analytical phases of specimen handling:

Adequate and clean facilities are required with clean water supply and adequate electrical outlets, with surge protection and/or universal power supply systems to support analyzers and tissue processors All specimens received in the laboratory must be immediately and appropriately labelled. A written policy should be developed for the management and handling of inadequately-labelled specimens or incomplete request forms. All specimens coming to pathology laboratories or being transported from one laboratory to another must be packaged appropriately with appropriate labels and must ensure the integrity of the specimen as well as the safety of the public. If a specimen's integrity is compromised, this must be recorded and the appropriate individuals informed immediately.

Considerations for post-analytical phase of specimen handling:

The post-analytical phase involves the transfer of information back to the appropriate physician and patient. Failure to have a post-analytical phase policy in place can result in adverse events and patient harm.

Electrical systems

Most tissue handling equipment runs on electric power and this makes an adequate electrical system essential. To facilitate the functionality of the devices, a continuous and uninterrupted electrical supply of the appropriate electrical voltage is required. The continuous electrical supply for equipment should be reinsured by a backup electrical supply for essential equipment, in case of power failure.

Heating, ventilation and air conditioning systems

Laboratories should have appropriate ventilation and adequate humidity and temperature conditions. In tropical and subtropical climates, air conditioning would be an asset. All these should conform to national guidelines.

The area requires ambient temperature comfortable for all staff including those who don protective materials (at a minimum, a gown and a plastic apron). Additionally, specific ventilation must be installed in areas where surgical specimens fixed in preservatives, such as formalin (10%), are being examined and sectioned. For this, an appropriate workstation (see list of devices) is necessary.

Air from this suite may need to be exhausted externally, to prevent recirculation with the rest of the facility. The pressure should be negative in relationship to adjacent areas.

Safety and security

Special safety and security considerations should be taken into account as biohazardous materials, flammable materials, toxic materials and waste and excess formalin tissues within the laboratory can be reactive and potentially cause harm to personnel in and surrounding the laboratory.

Considering these potential dangers, special criteria for fire protection should be installed within the facility.

Special Systems

The walls, ceilings and floors should be of a material suitable for regular cleaning and resistant to a potential biohazardous material spill. Moreover, the area should have adequate systems to provide both water and drainage. Lighting and noise levels should conform to national guidelines and all of the above materials and equipment should be securely stored. There should also be appropriate toilet facilities for staff.

4.4.3 Quality management

Quality assurance promotes the safe, effective and appropriate functioning of a laboratory, and the safety of staff and patients. With the intention of ensuring personnel, public and patient safety, the appropriate functioning of a laboratory will be greatly enhanced by the availability of a good laboratory information system, one which can track specimens from arrival to final report and which can be integrated into the wider electronic patient records system. There are many purveyors of these systems and the choice of an appropriate one would help in many ways, as will be described later in this section. A good system ensures that all specimens are appropriately labelled with at least two patient identifiers. The unique identifier applied to a patient's tissue sample follows the sample from the beginning to the end. An example of this is the bar code system. Quality assurance standards should be based on local standards for Quality and Competence. If not available, standards can be based on the quality assurance recommendations of the RCPA (Royal College of Pathologists of Australasia) or the CAP (College of American Pathologists).

Basic requirements:

All patient specimens or body parts must be treated with respect at all times, with adherence to and compliance with the highest ethical standards and with appropriate consideration of patient safety. In all cases, there must be an appropriate patient consent for the examination of the tissues and the performance of special studies (example HIV and molecular testing). It is the responsibility of the treating physician to ensure that a consent is obtained.

Governance:

Each laboratory must have documented systems of governance, including guidelines for patient and staff safety and the control/regulation of risks involved in the delivery of laboratory services. The laboratory must have appropriate supervision, by qualified individuals and appropriately trained certified laboratory directors. The training of all laboratory staff must include safe and ethical laboratory practice. They must be given the authority to ensure that the standards are met. The standards may be the ISO 15189 Medical Laboratory Standards or equivalent standards set by a National Association or a national government of that jurisdiction, e.g. National Association of Testing Authorities (NATA), Australia; South African National Accreditation System, South Africa (SANAS); United Kingdom Accreditation Service, United Kingdom (UKAS); International Accreditation New Zealand, New Zealand (IANZ); or those set by other authorities, such as: National Accreditation Board for Testing and Calibration Laboratories (NABL), India; Bureau of Laboratory Quality and Standards (BLQS), Thailand; Department of Standards Malaysia (DSM), Malaysia.

The standards must take into account the volume of work and set operational practices and requirements for staffing, staff training, and continuing professional development. The standards must plan and regulate the tests to be provided either at the laboratory or off site, as well as safeguard quality assurance via organization of a referral program. These requirements for the above tests must document the methods and the procedures to be followed and ensure that the personnel are trained appropriately in these procedures. The personnel's competence to perform these tests should be determined on an ongoing basis. If the laboratory performs services during one shift per working day, it should be appropriately staffed for this. If it has more than one shift, a shift supervisor must be appointed, trained and empowered to make appropriate decisions.

Internal Quality Assurance:

As previously stated, appropriate procedures must be in place for the handling of tissues sent to the laboratory from the time that they are removed from the patient by the surgeon/practitioner and sent to the laboratory.

Procedures for the appropriate fixation, storage, and disposal of tissues, must be in place, and a log maintained of these practices, detailing when and which patients' tissues were "discarded".

All tests that laboratory personnel are required to perform must have documented standard operating procedures (SOP) in place, which are readily accessible and strictly followed. The materials needed for the appropriate performance of these tests must be easily accessible (day or night).

Since many potentially toxic chemicals are used in the laboratory for tissue fixation, processing and staining, their appropriate storage is essential (prior to use and when they are ready for discard). There must be policies, protocols and documentation for chemicals as they come in and are ultimately destroyed. Areas where these materials are used must have appropriate exhaust systems.

There must be a tracking system to monitor the movement of tissue from the operating room or the physicians' office to the pathology laboratory, including the removal of slides and storage of the residual tissues (until they are discarded). All of the above materials and equipment should be securely stored. This paper trail (or electronic trail) is essential.

The above pertains to the first two stages of tissue handling – preanalytic and analytic. The final stage is the evaluation of the tissues and the making of an appropriate diagnosis. The professional staff must be appropriately trained, qualified, certified and have the opportunity for adequate continuous professional development.

External Quality Assurance:

A good external quality assurance (EQA) system provides an interlaboratory comparison of technical testing and interpretations of shared batches of samples by participating laboratories on a regular basis. For laboratories providing services for cancer management, the EQA program participated should have neoplastic tissues represented. EQA serves as an early warning system when the laboratory performs out-of-range of the majority of other participating laboratories. A good EQA program also provides educational instruction to help laboratories address areas of weaknesses. A log of this practice should be maintained.

Immunohistochemistry:

Where a laboratory performs immunohistochemical stains, it should be part of a quality assurance system, such as the NordiQC (Nordic immunohistochemical Quality Control), NEQAS, RCPA-QAP or other similar proficiency testing systems. To ensure staff qualifications and competence, all qualified staff should be given the opportunity to participate in ongoing professional development to ensure that their skills are maintained and updated regularly. Where a laboratory offers consulting services to smaller laboratories, an information system that allows for tracking of cases from the time they come in to the time the final report is issued, must be available.

Critical alert:

Where there is a significant result (convergent with the clinical or especially one divergent from the clinical diagnosis) the result should be treated as a critical incident and a system in place to report it to the appropriate staff. This effort should be recorded. All diagnosis of malignancy, whether suspected or not, should be reported immediately to the requesting physician and treated as a critical result.

Employee Relations:

It is the responsibility of the institution and the laboratory director, to ensure that the work environment is appropriate for hassle-free work. Staff should have appropriate work clothes and footwear while inside the laboratory (open footwear such as sandals should be prohibited). Clothes (outerwear such as lab coats) worn inside the laboratory should preferably not be worn outside the lab. An appropriate facility to handle the outerwear should be available. Hazardous materials must be appropriately stored and handled. Staff should be aware of the handling of hazardous materials spills. Regular training in this procedure should be offered to all laboratory staff.

4.4.4 Guidance documents

Title	Link	Description
Laboratory Quality Management System	https://globalhealthlaboratories.tghn.org/site_media/media/articles/WHO_Laboratory_quality_management_system_1.pdf	Achieving, maintaining and improving accuracy, timeliness and reliability are major challenges for health laboratories. This handbook is intended to provide a comprehensive reference on Laboratory Quality Management Systems for all stakeholders in health laboratory processes, from management, to administration, to biomedical laboratory scientists. This handbook covers topics that are essential for quality management of a public health or clinical laboratory. They are based on both ISO 15189 and CLSI GP26-A3 documents.
Laboratory Assessment Tool	https://globalhealthlaboratories.tghn.org/site_media/media/articles/WHO_Laboratory_Assessment_Tool_1.pdf	This document offers guidance to assess individual laboratories and the national laboratory system. It describes a general process for assessing laboratories and provides questionnaires to help assess laboratories. The document and its questionnaires can be used as is or after an adaptation to meet local requirements or specificities to better fit the assessment context. The intended audience of the document is any stakeholder performing laboratory assessments, including: national health authorities, multilateral agencies, non-governmental organizations (NGOs), laboratory managers, etc.
The Pathology Request-Test-Report Cycle - Guidelines for Requesters and Pathology Providers	https://www.rcpa.edu.au/getattachment/cb14bc34-0a01-4c09-839c-614e098c84b6/Pathology-Request-Test-Report-Cycle-Guidelines.aspx	These guidelines have been developed for use by medical practitioners when requesting pathology tests and by Pathology Providers operating in both public and private practice.
Australian Commission on Safety and Quality in Healthcare, National Safety and Quality Service Standards, 2011, Government of Australia	http://www.safetyandquality.gov.au/wp-content/uploads/2011/01/NSQHS-Standards-Sept2011.pdf	Contains safety and quality standards for various topics, including handling of blood and blood products.
Quality Systems for Medical Laboratories. Guidelines for Implementation and Monitoring. WHO Regional Publications, Eastern Mediterranean Series. (1995)	http://applications.emro.who.int/dsaf/dsa33.pdf	The document provides guidance for laboratories to introduce, maintain and improve appropriately specified levels of service quality, and to provide a basis for assuring an adequate quality of services, quality system and its specifications.

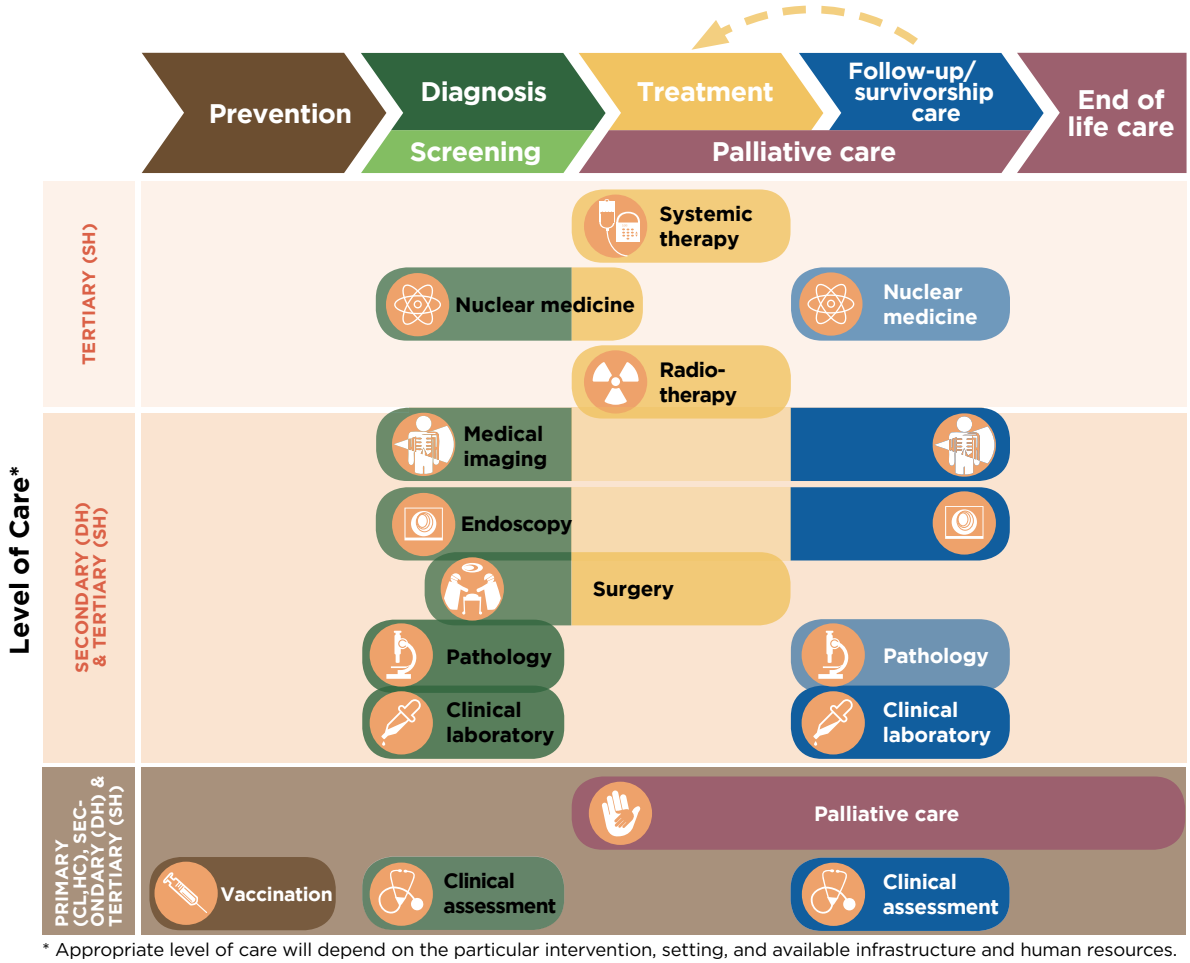
References

Warner LC. Lab-in-a-Box: a guide to building anatomic pathology networks in resource-limited settings. Am J Clin Pathol 2017;147(1):8-14. doi: 10.1093/ajcp/aqw217

5. Radiotherapy

Health service delivery sequence overview:

This diagram expresses the flow of cancer patient to and from the radiotherapy unit, and the elements to consider as support for the unit (Fig. 10.5).



* Appropriate level of care will depend on the particular intervention, setting, and available infrastructure and human resources.
CL Community Level health post DH District Hospital HC Health Centre SH Specialized Hospital

Fig. 10.5 Health care service delivery overview – radiotherapy

5.1 General description of the unit

Radiation therapy is a clinical modality that uses ionizing radiation in the treatment of patients with malignant neoplasia (and occasionally benign disease). It is an important component of multimodality cancer therapy, surgery and chemotherapy. More than 50% of new cancer cases require radiotherapy as their definitive or adjuvant therapy *(1)*.

Radiotherapy services should be available at specialized oncology hospitals, and it should be noted that they require very specialized infrastructure and human resources. It is important to analyse which cancer centres will have the radiation oncology unit, depending on the human, financial and technical resources available, as well as the local demand. Although linear accelerators are the preferred technology, Cobalt 60 unites can be used in limited resource settings as they are easier to operate and maintain.

Radiation safety must always be considered for patients, workers and the public. The role of imaging in radiation therapy is a determinant of the success of the therapy, and the targeting, particularly when there is motion (e.g. diaphragmatic or breast tumors), which affects the location of the tumour relative to healthy tissue, makes imaging a determinant to enhance the therapy and reduce the collateral damage.

Radiotherapy cannot be delivered without a treatment planning system, which is used to determine target volumes and other critical structures, and, subsequently, to determine how the radiotherapy system will deliver the treatment as required. Additionally, oncology information systems combine all oncology data pertaining to a patient for easy access and reference. This enables clinicians to perform essential quality assurance measures in order to facilitate best outcomes for patient care.

5.2 Priority medical devices

The following tables present general medical devices, which can be used for the treatment, follow-up and/or palliative care of many diseases including several cancers, and specific medical devices, which are used for interventions for specific cancer types.

The following tables present the priority medical devices required to perform the following health interventions:

Cancer type	Interventions
All cancers	• Imaging and treatment planning • External beam radiotherapy • Brachytherapy
Cervical cancer & prostate cancer	• High dose rate brachytherapy

5.2.1 General medical devices for external radiotherapy

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
Radiotherapy treatment delivery	Medical equipment	Linear Accelerator (LINAC) (otherwise, Cobalt-60 Unit)	• 3D Conformal therapy • At least 6 MV with multileaf collimator and electronic portal imaging.
			Patient positioning/tracking system
		Single-patient physiologic monitoring system	• Blood pressure cuffs for adults and infants • Thermometer probes (in case it is needed)
		Resuscitation trolley, equipped with medicines and defibrillator	• Laryngoscope for adults and infants
	Radiation safety devices	Personal Dosimeter	
		Geiger–Müller (GM) survey meter	
		Large volume ionization chamber (consider requirements from IAEA)	

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
	Quality assurance equipment	Two Farmer type cylindrical ionization chambers (listed in the IAEA TRS-398), 0.6 cm3 volume, at least one calibrated at a standards laboratory (in terms of absorbed dose to water in Co-60 beam) with graphite walls or plastic walls	
		Reference class electrometer compliant with IEC60731 and compatible with ionization chambers	
		Additional electrometer with varying voltage bias (V1/V2 ratio equal to or greater than 3), and the possibility to reverse the polarity	
		Extension cables for ionization chambers as needed	
		Thermometer calibrated at a standards laboratory	
		Barometer calibrated at a standards laboratory	
		Waterproof plane-parallel ionization chamber calibrated at a standards laboratory (only if electron beams are available)	
		CT number-electron density calibration phantom (if CT simulator is available)	
		Quality assurance phantom for CT positioning lasers evaluation (if CT simulator is available)	
		Phantom for daily mechanical and light field checks on teletherapy unit	
		Plastic slab phantom with holes for ionization chambers for beam output verification	
		Radioactive source for checking the stability of ionization chambers	
		Water phantom for calibration, size at least 30 x 30 x 30 cm^3, with PMMA walls, including a holder for ionization chambers with manual steps or an automatic system to vary the position of the chamber	
		Radiation field analyser to measure isodose distributions, of 50 x 50 x 40 cm3 volume approximately, with a water tank, a phantom trolley with vertical movement, a water pump and water reservoir	• Precision spirit level • Laptop computer • Radiation field analyser software for data collection and data management
		Two waterproof cylindrical ionization chambers, of 0.1 – 0.3 cm3 volume	
		Phantom for mechanical and light field checks on teletherapy unit	Callipers and metal ruler

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
		In-vivo dosimetry system (for example, diode dosimeters, thermoluminescent dosimetry (TLD), or optically stimulated luminescence dosimetry (OSLD))	
		Array of diodes or ion chambers for routine quality assurance checks	
		Film dosimetry system including radiochromic film, film scanner and dedicated software	Radiochromic film
		EPID image quality phantom	
	Radiation safety devices	Area radiation monitor with audible alarm (only if Co-60 teletherapy is available)	
		Survey meter	
Imaging and Treatment Planning	Medical equipment	Computed Tomography (CT) System (16 slices minimum)	
		CT Overlay flat table	
		Laser patient positioning system	
		Contrast media injection system (optional)	
		Conventional simulator (only if a CT simulator is not available)	
		Computerized treatment planning systems (three-dimensional) including	Colour printer
		Hardware and software, virtual simulation software, and plan review software	
		Digitiser	
Mould make process (Immobilization and patient positioning system)	Equipment	Hot water bath for thermoplastic immobilization system	
		Hot wire cutter	
		Drill	
		Pot for cerrobend cadmium free low melting point alloy (if needed according to the technique and the type of accelerator)	
	Furniture	Adequate furniture for the moulding process	
	Instruments		Tray, dressing, stainless steel
	Personal protective equipment and clothing		Apron, protection, plastic
			Eye protection glasses, safety, regular size
			Gloves, examination, latex, non-sterile, single use (various sizes)
			Coat, medical, woven (various sizes)
	Other		Receptacle, waste, stainless steel, pedal action
			Safety box for used syringes/needles
			Brush
			Acetate sheets
			Rubber hammer
		Mould materials	Bolus
			Chosen material for the mould: Foam blocks/Styrofoam/Polystyrene, Thermoplastic, vacuum bag or similar as needed

5.2.2 General medical devices for brachytherapy

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
Treatment delivery, brachytherapy	Medical equipment	Anaesthesia unit, mobile, basic	Face mask for anaesthesia administration Patient circuit
		Equipment for source applicator localization, Portable X-ray equipment (dedicated X-ray equipment e.g. C-arm fluoroscopy is preferred)	
		General-purpose suction system, vacuum	
		Pharmacy refrigerator	
		Operating light, light source (lamp & flashlight)	
		Resuscitation trolley, equipped with medicines and defibrillator with laryngoscope	
		Single-patient physiologic monitoring system	
		Infusion pump (optional)	Infusion pump administration set
		Oxygen humidifier with flowmeter, with pipeline or oxygen cylinder connector	
		Remote-afterloading brachytherapy system, at least 12 channels	• Radioactive seeds • Transfer tubes • Device for fixation of a connector between the transportation applicator tubes to the patient • Flexiguides • Radio-opaque catheter • Afterloading catheter
	Quality Assurance Equipment	Well-type ionization chamber or an isotope calibrator with source holding inserts calibrated at a standards laboratory Reference class electrometer compliant with IEC60731 and compatible with ionization chamber Thermometer calibrated at a standards laboratory	Extension cables for ionization chamber as needed
		Barometer calibrated at a standards laboratory	
		Film dosimetry system including radiochromic film, film scanner and dedicated software	Radiochromic film (consumable)
		Measurement marker clip	
		Measurement marker wire	
		Tool to verify source homogeneity and source position	Callipers and a metal ruler
		Ultrasound unit and vagina/ vaginal vault, which requires applicators (cylinder types)	
	Radiation safety devices	Area radiation monitor (audible alarm)	
		Personal dosimeter	
		Dummy sources	
		Ion chamber survey meter	
		Portable radiation monitor/ Geiger-Müller counter radiation survey meter	

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
	Medical Furniture	Hospital stretcher, with side rails	
		Reclining chair	
		Stand, infusion, double hook, on casters	
		Trolley, dressing, stainless steel, 2 trays	
		Trolley, medicines	
		Trolley, soiled linen	
		Wheelchair, adult	
		Table, instruments, Mayo type, stainless steel, on casters	
		Cabinet for the necessary instruments, equipment, treatment aid and the required documents	
		Cabinet, medicines, double door	
	Instruments	Dressing set	
		General-purpose surgical scissors, reusable	
		Measurement ruler	
		Metzenbaum scissors	
		Suture set	
			Rectal probe or rectal catheter
	Personal protective equipment and clothing		Gloves, examination, non-sterile, single use (various sizes)
			Gown, patient, woven
			Non-conductive shoe cover
			Operating room gown, reusable
			Surgical cap for patients and healthcare worker
			Surgical face mask
			Surgical gloves
	Single use devices/ disposables/medical supplies		Compress, gauze, sterile & non-sterile, single use
			Infusion giving set, sterile, single use
			Prongs, nasal, oxygen, non-sterile, single use (various sizes)
			Radiographic or radiochromic film
			Safety box, for used syringes/needles
			Silicone adhesive tape
			Skin-cleaning wipe
			Surgical scrub brush, single-use
			Sutures
			Syringes with needles (disposable)
			Tape, medical, roll (various sizes)
			Catheter, Foley, sterile, single use (sizes G)[3]
			Skin-cover adhesive strip
			General-purpose sterile drape

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
	Solutions and reagents		Aqueous antibacterial solution
			Contrast media
			Hydrogen peroxide
			Saline solution
			Lubricating jelly (K-Y)
			Iodine povacrylex and isopropyl alcohol solution or similar
	Other	Arm/leg tourniquet	
			Basin, kidney, stainless steel/ polypropylene
			Bowl (dressing changes), stainless steel/polypropylene
			Kick bucket
			Manual brachytherapy source, temporary placement
	Radiation protection devices		Clamps for the source management
			Emergency container and emergency source handling instruments (Retrieval instrument)
			Portable radiation protection barriers
			Radioactive waste storage
			Source handling instruments and accessories (in source preparation room and patient loading room)
			Source loading and cutting devices
			Source storage and transport containers within the department
Imaging and treatment planning	Medical equipment	Imaging X-Ray or Computed tomography (CT) (if not available in external radiotherapy)	
			Include appropriate brachytherapy software

3. Components of all surgical instrument sets as well as needle and catheter gauge sizes (G) are listed in the chapter annex at the end of the Surgery chapter

5.2.3 Specific medical devices for brachytherapy by cancer type

5.2.3.1 Cervical

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
Treatment delivery, High dose rate Brachytherapy	Medical equipment	Universal operating table- radiopaque, (leg rests, anaesthesia requirements, etc) or Brachytherapy table	If patients are prepared in a separate room, then movable, interchangeable patient tables are generally supplied so that the patient is not moved unnecessarily between applicator insertion and treatment delivery
	Instruments		Gynaecologic applicators sets (for intracavitary and interstitial treatments e.g. Henschke, Fletcher–Suit, Manchester or Delouche type) / Cervical/intrauterine brachytherapy system applicator
			Scissors
			Hysterometer
			Manual expandable cervical dilator
			Ring forceps
			Uterine forceps
			Vaginal Speculum, reusable

5.2.3.2 Prostate

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
Treatment delivery, High dose rate Brachytherapy	Medical equipment	Ultrasound unit with biplanar transducer	
		Stepping unit and stabilizer	
	Instruments	Needle cradle	

5.3 Other health system components

5.3.1 Human resources for radiotherapy

The staff would include the following or related areas : radiation oncologists, medical physicists, dosimetrists, radiographers/radiation therapy technologists (RTT),nurses, and other professionals involved in the preparation and delivery of treatment as biomedical engineers, equipment technicians and administrative personnel. In some countries and in larger radiotherapy departments, the additional roles of physician assistants and medical physics assistants might be found effective.

Depending on national context including workforce availability and models, different occupations can fulfil the roles that may be required for radiotherapy. A prerequisite is having the required competencies to perform these roles and being officially recognized for it as per the scope of practice. The ISCO[2] codes are added as illustrative examples based on current practice for further reference. This should not be interpreted as guidance on occupations that should perform each role but rather indicative occupations that are currently performing these roles in different country contexts.

2 *International Standard Classification of Occupations, http://www.ilo.org/public/english/bureau/stat/isco/docs/publication08.pdf*

Sample role	Sample occupations (ISCO-08 codes)
Sets up the overall policy for the radiation therapy programme and implementation; Participates in the evaluation of the proposed departmental clinical load; Participates in multidisciplinary cancer team; Responsible for the overall care of the patient including: • Clinical evaluation • Therapeutic decision making • Establishment of treatment plan, including dose prescription, contouring volumes, OAR and restrictive doses, plan evaluation, treatment execution • On-treatment evaluations and patient monitoring • Treatment summary • Follow-up and response assessment of overall treatment	Radiation Oncologist, Specialist medical practitioner (2212)
Provides clinical physics service and supervision. Responsible for: • Specification of therapy equipment (external beam, brachytherapy, simulators, CT and imaging systems, and treatment planning systems) and assuring their radiation safety • Acceptance testing, commissioning and quality assurance (including calibration) of therapy equipment • Measurement and analysis of beam data, and tabulation of beam data for clinical use • Establishment of dose calculation procedures • Establishment of technical aspects of treatment planning and treatment procedures • Supervision, evaluation and optimization of treatment planning • Establishment and supervision of quality assurance procedures in radiotherapy regarding delivery of the treatment, radiation safety, quality control and regulatory compliance • Supervision of maintenance of radiotherapy equipment • Education of staff in radiation safety principles.	Medical Physicist (2111)
• Management of the daily workload of the treatment units and simulators; • Operates simulator and other imaging devices for therapy purposes (CT scan, C-arm, and simulators); • Operates HDR brachytherapy machines; • Records and checks all the parameters needed to repeat or reconstruct the activities undertaken; • Explanation of treatment and daily checking of patients undergoing radiation treatment and reporting new or unusual conditions of patient to radiation oncologist; • Acquisition and verification of images consistent with departmental protocols.	Radiation Therapy Technologist (RTT), medical radiation therapist, medical imaging and therapeutic equipment technicians (3211)
• Provides nursing assistance to radiation oncologist in clinic and brachytherapy room; • Provides nursing intervention for the actual and potential problems that the patient and family may experience related to the disease process, treatment course and follow-up period; • Provides teaching, counselling and support functions needed to assist the patient and family to cope with and adjust to the diagnosis and treatment of cancer	Oncology Nurse, Nursing professional (2221) Nursing associate professional (3221), supervised: healthcare assistant (5321)
Responsible for general management of equipment including: • Procurement specifications, planning of bunker and special infrastructure along with physicists and facilities engineer; • Supervision of installation, compliance with requirements, relations with manufacturer on preventive and corrective maintenance; • Participation in installation of new radiotherapy equipment or major reparation of radiotherapy equipment by vendor.	Biomedical Engineer (2149)
• Designs the radiation protection and safety programme, and evaluates compliance with it; • Prepares the licence application, especially the safety assessment for radiotherapy sources; • Measures accident prevention and mitigation.	Radiation protection officer, Radiation protection expert , environmental and occupational health and hygiene professionals (2263)
Provides administrative support to radiotherapy team in maintaining radiotherapy programme, patients appointments, etc.	Admission/, administrative Staff , Clerical support workers (4412) Technologists (3211),
Support medical physics procedures	Physics assistant, technician (3111)

A quality radiotherapy service is a multifaceted process involving several distinct groups of health experts and supporting staff. In order to improve radiotherapy service, continuous development is essential. Staff/human resource development is aimed to achieve two objectives as follows:

1. Match staff headcount with radiotherapy unit requirement analysis
2. Enhance staff competency in accordance with advancements in technology and science through training and education

The education and training programmes are intended for all staff: radiation oncologists, medical physicists, dosimetrists, physics assistants, RTTs, in house technicians, and nurses.

5.3.2 Infrastructure

A radiotherapy centre usually comprises an admission area, administrative offices, clinics, CT simulation room, a treatment aid fabrication mould room, a treatment planning room, an operating theatre or procedure room for brachytherapy, and one or more treatment rooms for external radiotherapy and brachytherapy. The radiotherapy unit placement should be carefully planned and designed to provide good patient flow, radiation safety and be supported by a well-established information technology (IT) system. It should include physician work room and meeting room, which will be used to conduct vital quality assurance meetings and other staff meetings.

The housing for a linear accelerator is very specific and requires long term planning for construction to meet the requirements of the shielding for the specific equipment to ensure the safety of people in surrounding areas *(3, 8)*. This bunker is an expensive setting that requires radiation calculations and specialized studies. It is important to consider all recommendations from IAEA to set up a radiotherapy unit *(4)*, as well as follow local national laws and guidelines regarding radiotherapy services (if available).

In reference to the equipment, contracts for maintenance by vendors are beneficial to provide ongoing sustainability of the treatment, simulation and planning equipment. Routine maintenance should be scheduled in order to reduce the risk of equipment downtime, which causes patient treatment delays and lost revenue.

The infrastructure of the radiotherapy and brachytherapy unit is discussed generally in this section but further information should be consulted in the IAEA references mentioned below.

Layout distribution

Reception and waiting area

The reception should be located at the main entrance to the department and act as distribution point for all the different sections in the department.

- Sufficient waiting areas should be provided for patients attending clinics and those awaiting treatment (in larger departments, smaller waiting areas should be provided close to the treatment machines).
- An area should be provided for patients on stretchers with electrical power and medical gas connections.

Examination room (clinics)

- A patient changing area should be provided.
- The examination rooms should be large enough to include standard and gynaecological examination tables, appropriate examination instruments and medical supplies.

External beam radiotherapy - Simulator or CT Simulator room

- A door interlock or other suitable means to prevent unauthorized access is needed.
- A sign should be posted at the entrance warning of the radiation hazard.
- The room should be large enough to accommodate the simulator, allowing the full range of motion of the treatment table.
- Secure mounting of patient positioning lasers to the wall at points appropriate for projection of lines through the isocentre should be included in the plans. Adjustable lasers intersecting at a known distance from the reference plane are required for CT simulators.
- A means for dimming the room lights is essential.

- Enough space should be provided for storage of treatment devices and quality assurance equipment.
- If the immobilization devices are to be made in the simulator room, cabinet space to store supplies for their fabrication will be required. A sink and counter-top space for a heated water bath should be provided in this room.
- The control/console area should be of adequate size to accommodate the RTT, a physician and at least one additional person. It should have access to both the simulator room and the hallway.
- A viewing window for the control room is required.

External beam radiotherapy - Mould room

- Space for tools, a block cutter and counter-top is needed, along with adequate workspace for pouring and mounting the blocks.
- Large enough space for storage of Styrofoam, trays and shielding material for custom blocking is also required.
- If immobilization devices are fabricated in the mould room, space for a patient couch will be required, and lasers mimicking those in the treatment and simulator rooms should be provided.

External beam radiotherapy - Treatment planning room

- Large enough space is required to house the treatment-planning computer with its video monitors, a printer, a plotter and a digitizer (if used) and other required computer equipment.
- Space is also needed for supplies of paper and pens or ink for the printer and plotter (if required).

External beam radiotherapy – Treatment room

- The room should be large enough to accommodate the treatment machine, allowing the full range of motion of the treatment table and access for beds if necessary.
- A heavy, electrically operated door should be provided at the entrance to the room or an appropriately designed extended corridor (called a maze or labyrinth) leading into the room, and a sign should be posted at the entrance warning of the radiation hazard.
- A means for dimming the room lights should be included.
- Adequate space should be provided for storage of treatment devices, immobilization devices, blocks and quality assurance equipment.
- A wash hand basin should be installed in all treatment rooms.
- A ‘last man out’ button should be installed.
- A door interlock must be provided.

High Dose Rate (HDR) Brachytherapy - Operating theatre/treatment room and radiographic imaging system

- A brachytherapy unit should include the shielded treatment room, a control area, a procedure/ preparation room, a recovery area, and an imager or film processing area.
- An independent radiation monitor should be provided that indicates, through a measurement of radiation levels, whenever the source is moved out of the shielded safe zone.
- A door interlock must be provided.
- A sign should be posted at the entrance warning of the radiation hazard, in accordance with local or national regulations and the Basic Safety Standard (BSS) (2).

High Dose Rate Brachytherapy - Treatment planning room (TPS)

- Treatment planning for HDR brachytherapy could be performed on a general TPS room for teletherapy and brachytherapy using a separate brachytherapy planning system, or in a separate TPS room more convenient to the HDR brachytherapy suite.

Shielding

- The shielding of the simulator room and the treatment room should be designed according to the requirements of the national regulatory body, paying due regard to the requirements of the BSS *(2)*.
- The brachytherapy treatment room should have adequate shielding for a high dose rate remote afterloading unit, designed in accordance with the recommendations of IAEA SRS No 47 *(3)*, paying due regard to the requirements of the BSS *(2)* and the regulatory authority

Heating, ventilation and air conditioning systems

- The mould room should have adequate ventilation and there should be adequate temperatures to keep equipment running as specified by the manufacturer. The treatment and control rooms as well, as this is something that can be planned ahead, even if the equipment provider has not been selected. Certain equipment needs direct cooling (linear accelerators).

Communication systems

- Provision for the system management of the IT equipment is critical, but control of the system must be retained by the radiotherapy department.
- The console/control area for the treatment room should be provided with a patient intercommunication system and at least two closed circuit television monitors. Sufficient space should be provided for two operators, a physician and at least one additional person to be present.
- It is important to have a patient information system (or treatment record and verify system).

Electrical systems

In countries where power is not readily available, installation of uninterrupted power systems (UPS), stabilizers or generators should be considered (for the linear accelerator circuit). This would guarantee that ongoing treatments can be finished in the event of a loss of power. Special electrical systems for radiotherapy equipment need to be considered.

Special systems

- Sufficient washroom facilities should be strategically placed throughout the facility.
- A supply of medical gasses should be considered in the treatment room.

5.3.3 Quality management

Most of the information in this section on Quality Management comes directly from the following publications:

- Comprehensive Audits of Radiotherapy Practices: A tool for Quality Improvement *(5)*
- Practical Guidelines for implementation of a quality system in Radiotherapy *(6)*
- Setting Up a Radiotherapy Programme *(7)*

Quality Assurance and Quality Control in Radiotherapy

Radiotherapy is a specialized discipline using complex equipment and involving interlinked stages and processes, which require careful and accurate application. Hence, quality assurance is vital to ensure the delivery of safe and effective treatment. Quality assurance in radiotherapy consists of procedures that ensure a consistent and safe fulfilment of the dose prescription to the target volume with minimal dose to normal tissues and minimal exposure to personnel and the public. It involves both clinical and physics aspects. The main aspects include clinical policies, maintenance and review of records, treatment planning and delivery, a quality control programme for machine and equipment performance, maintenance programmes and investigative procedures for accidental medical exposures. The establishment of such a comprehensive quality assurance programme shall be in accordance with the Basic Safety Standard (BSS) and the guidelines given by the WHO and PAHO *(2)*.

Quality control in a radiation therapy department covers a wide range of activities, and the treatment process can be viewed in many different ways. Four main areas have been identified, which are: external beam treatments, brachytherapy treatments, measurement equipment, and clinical aspects of the treatments. In

many countries, the specification, performance and quality control of teletherapy units may be subject to government regulations. If this is the case, these government regulations must be adhered to.

Independent external audits are a necessary part of a comprehensive quality assurance (QA) programme in radiation oncology. Quality audits can be of various types and levels, either reviewing specific critical parts of the radiotherapy process (partial audits) or assessing the whole process (comprehensive audits). The objective of a comprehensive clinical audit is to review and evaluate the quality of all of the components of the practice of radiotherapy at an institution, including its professional competence, with a view to quality improvement. A multidisciplinary team, comprising a radiation oncologist, a medical physicist and a RTT, carries out the audit.

Radiation Protection and Safety

Radiation safety should be provided for all radiotherapy centres from the beginning of building the infrastructure until the very end of patient treatments, including considerations for staff and general public. In order to achieve that safety, there are many standards that have been developed around the world, most of them provided by IAEA.

1. Patient Safety

The objective of patient safety is to manage the radiation dose to the patient commensurate with the medical purpose. The measures to ensure quality of a radiotherapy treatment inherently provide for patient safety and for the avoidance of accidental exposure. The safety of the patient is integrated, therefore, with the quality assurance of the radiotherapy treatments.

2. Healthcare worker

a. Healthcare investigation levels for staff exposure in radiotherapy

The establishment of investigation levels is a tool used to provide a 'warning' of the need to review procedures and performance, to investigate what is not working as expected and to take timely corrective action. In radiotherapy, a suitable quantity for use as the investigation level is the monthly effective dose itself, but the dose to the hands can be used as a quantity to establish the investigation level for staff in manual brachytherapy. In addition, the limitation dosage for health worker will vary for each country; reference should be made to each country's regulations.

b. Pregnant workers

The BSS establishes that "A female worker should, on becoming aware that she is pregnant, notify the employer in order that her working conditions may be modified if necessary." The notification of pregnancy shall not be considered a reason to exclude a female worker from work; however, the employer shall adapt the working conditions in respect of occupational exposure so as to ensure that the embryo or foetus is afforded the same broad level of protection as required for members of the public. The limitation of the dose to the conceptus does not mean that it is necessary for pregnant women to avoid work with radiation, but it does imply that it is necessary for the employer to carefully review the exposure conditions with regard to both normal exposure and potential exposure.

3. Public Safety

Public exposure is controlled by proper design of shielding and, in large part, by ensuring that radiation sources are shielded and secured (e.g. located in a locked area), and that keys to equipment control panels are secured to prevent unauthorized access or use. Presence of members of the public in and near the radiotherapy department should be taken into account when designing the shielding of storage and treatment facilities.

Relevant areas of a practice can be classified as controlled or supervised. A controlled area is defined as an area in which specific protection measures and safety provisions are needed to control normal exposure and to prevent potential exposure. In radiotherapy practice, the department may be divided into three areas:

- Controlled areas (areas requiring specific protection measures) include:
  i. External beam therapy room
  ii. Remote afterloading brachytherapy
  iii. Operating rooms during brachytherapy procedures using real sources
  iv. Brachytherapy patient rooms
  v. Radioactive source storage and handling areas.

It is preferable to define controlled areas by physical boundaries such as walls or other physical barriers marked or identified with 'radiation area' signs. The area of the control panel could be considered a controlled area, not because of normal exposure, which can be reduced by shielding, but rather for reasons of preventing accidental exposure of patients, by restriction of access to non-related persons, to prevent distraction of the operator of a radiotherapy. Note that in some countries, national regulations define the term controlled area differently, and do not use the term supervised area.

- A *supervised* area is any area not already designated as a controlled area but where occupational exposure conditions need to be kept under review even though specific protection measures and safety provisions are not normally needed. Supervised areas may involve areas surrounding brachytherapy patients' rooms or around radioactive source storage and handling areas.
- All areas not designated as controlled or supervised areas should be such that persons in them are afforded the same level of protection as members of the public.

5.3.4 Guidance documents

Title	Link	Description
Commissioning of Radiotherapy Treatment Planning Systems? Testing for Typical External Beam Treatment Techniques IAEA-TECDOC-1583	http://www-pub.iaea.org/MTCD/publications/PDF/te_1583_web.pdf	This publication is intended as a guide for the clinical commissioning of radiotherapy treatment planning systems (RTPSs) and provides a simple protocol for these tasks. The procedures for clinical commissioning tests cover typical treatment techniques used in radiotherapy hospitals and are based on the use of a specific phantom. The purpose of this testing is twofold. Firstly, the tests will provide an educational opportunity for the user to become familiar with the operation of the RTPS. Secondly, the tests will demonstrate to the user that the logistic chain starting from CT scanning, anatomic modelling, treatment planning and MU calculation is operable and leads to the desired results with sufficient accuracy.
Setting Up a Radiotherapy Programme: Clinical, Medical Physics, Radiation Protection and Safety Aspects	http://www-pub.iaea.org/books/iaeabooks/10740/Setting-Up-a-Radiotherapy-Programme	This publication provides guidance for designing and implementing radiotherapy programmes, taking into account clinical, medical physics, radiation protection and safety aspects. It reflects current requirements for radiotherapy infrastructure in settings with limited resources. It will be of use to professionals involved in the development, implementation and management of radiotherapy programmes.
Planning National Radiotherapy Services: A Practical Tool IAEA Human Health Series No. 14	http://www-pub.iaea.org/books/IAEABooks/8419/Planning-National-Radiotherapy-Services-A-Practical-Tool	The current and future burden of cancer incidence in developing countries requires the planning, establishment and upgrading of radiotherapy services at the national level. This publication is a practical guide outlining the main issues at stake when planning national radiotherapy services. It provides an assessment of the cancer burden, evaluates the existing resources, and determines what is needed and how to cover the gap in a resource oriented rational way. The publication will be of practical value to decision makers and programme managers in public health facing the organization or reorganization of radiotherapy services in their countries.
Radiotherapy Facilities: Master Planning and Concept Design Considerations IAEA Human Health Reports No. 10	http://www-pub.iaea.org/books/IAEABooks/10561/Radiotherapy-Facilities-Master-Planning-and-Concept-Design-Considerations	The current and future burden of cancer incidence in developing countries requires the planning, establishment and upgrading of radiotherapy services at the national level. This publication is a practical guide outlining the main issues at stake when planning national radiotherapy services. It provides an assessment of the cancer burden, evaluates the existing resources, and determines what is needed and how to cover the gap in a resource oriented rational way. The publication will be of practical value to decision makers and programme managers in public health facing the organization or reorganization of radiotherapy services in their countries.

Title	Link	Description
Quality Assurance in Radiotherapy IAEA TECDOC No. 989	http://www-pub.iaea.org/books/IAEABooks/5644/Quality-Assurance-in-Radiotherapy	Major efforts have been made to develop and implement QA methodologies, aimed at reducing various sources of errors to ensure not only a high standard of radiation treatment, but first and foremost to prevent radiation accidents. One of the main goals of this publication was to deal with the design, harmonization and structures of QA programmes in different countries, as well as with implementation of these programmes at the institutional, national, regional and international levels.
Applying Radiation Safety Standards in Radiotherapy Safety Reports Series No. 38	http://www-pub.iaea.org/books/IAEABooks/7114/Applying-Radiation-Safety-Standards-in-Radiotherapy	The International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS), jointly sponsored, inter alia, by the IAEA, ILO, WHO and PAHO, establish requirements on the legal persons responsible for designing, running and decommissioning practices involving ionizing radiation. These requirements are basic and general in nature. This report is intended to be of assistance to both regulators and users of radiation sources in radiotherapy in applying the BSS to this practice. Regulators will find it useful for reviewing applications for authorization and for inspection of the practice. Users of radiation in radiotherapy may follow the guidance provided in order to comply with BSS requirements or equivalent national requirements. Experts recruited on IAEA missions to advise on the implementation of the BSS for the practice of radiotherapy are expected to use the guidance given in this report rather than their own national regulations and guidance.
Staffing in Radiotherapy: An Activity Based Approach IAEA Human Health Reports (CD-Rom) No. 13	http://www-pub.iaea.org/books/IAEABooks/10800/Staffing-in-Radiotherapy-An-Activity-Based-Approach	Radiotherapy requires competent professional staff to ensure safe and effective patient treatment and management. There is a need to provide guidelines that recommend appropriate staffing levels to support the initiation of new services as well as the expansion or upgrade of existing services as even simple upgrades or replacement of existing equipment may have a significant impact on staffing needs. Similarly, the introduction of education and training programmes will require staffing adjustments. A calculation algorithm was developed to predict staffing levels based on the inputs that are known or can be easily estimated. This publication complements other IAEA publications used to support the initiation of basic radiation medicine services including setting up a Radiotherapy Programme: Clinical, Medical Physics, Radiation Protection and Safety Aspects.
IAEA Syllabus for the Education and Training of Radiation Oncologists Endorsed by the American Society for Radiation Oncology (ASTRO) and the European Society for Therapeutic Radiology and Oncology (ESTRO) Training Course Series No. 36	http://www-pub.iaea.org/books/IAEABooks/8159/IAEA-Syllabus-for-the-Education-and-Training-of-Radiation-Oncologists-Endorsed-by-the-American-Society-for-Radiation-Oncology-ASTRO-and-the-European-Society-for-Therapeutic-Radiology-and-Oncology-ESTRO	The lack of sufficiently trained staff is a critical problem for the establishment of adequate radiotherapy services in the developing world. The importance of addressing and eventually solving this problem cannot be overemphasized. The appropriate training and subsequent retention of professionals is essential for planned radiotherapy services to be effective in dealing with this 'silent crisis' of cancer in the developing world. This publication is aimed at programme directors of radiation oncology training programmes, as well as institution managers and teaching staff involved in the planning and implementation of educational activities.
Clinical Training of Medical Physicists Specializing in Radiation Oncology Training Course Series No. 37	http://www-pub.iaea.org/books/IAEABooks/8222/Clinical-Training-of-Medical-Physicists-Specializing-in-Radiation-Oncology	The application of radiation in human health, for both diagnosis and treatment of disease, is an important component of the work of the IAEA. The responsibility for the increasingly technical aspects of this work is undertaken by the medical physicist. To ensure good practice in this vital area, structured clinical training programmes are required to complement academic learning. This publication is intended to be a guide to the practical implementation of such a programme for radiation therapy.

Title	Link	Description
A Syllabus for the Education and Training of Radiation Oncology Nurses Training Course Series No. 28	http://www-pub.iaea.org/books/IAEABooks/7757/A-Syllabus-for-the-Education-and-Training-of-Radiation-Oncology-Nurses	This publication provides the basic contents of an education course for radiation oncology nurses. It is a minimally essential syllabus, which can and should be adapted to the particular needs and characteristics of the centre and country. This syllabus provides specific guidelines for the education of nurses new to radiation oncology and for the practice of quality radiation oncology nursing care. This manual can assist with the organization and implementation of a course for the training of radiation oncology nurses in resource limited settings. It can also assist with articulation of the role of the radiation oncology nurse, justification of nursing staff positions in the department of radiation oncology, and with the evaluation of radiation oncology nurses' performance.
A Handbook for the Education of Radiation Therapists (RTTs) Training Course Series No. 58	http://www-pub.iaea.org/books/IAEABooks/10720/A-Handbook-for-the-Education-of-Radiation-Therapists-RTTs	This publication outlines recommendations on the professional education of RTTs and has been developed within the Training Course Series. This publication is intended to provide a framework for the planning and implementation of education programmes for RTTs. It is aimed at professionals and administrators involved in the planning of education programmes in radiotherapy, medical technology schools and RTTs in general.
Transition from 2-D Radiotherapy to 3-D Conformal and Intensity Modulated Radiotherapy IAEA TECDOC No. 1588	http://www-pub.iaea.org/books/IAEABooks/7907/Transition-from-2-D-Radiotherapy-to-3-D-Conformal-and-Intensity-Modulated-Radiotherapy	This publication is intended as a guide for radiotherapy centres making the transition from 2-D radiotherapy through 3-D conformal to intensity modulated radiation therapy (IMRT) and takes into account training, equipment, and other considerations necessary for the safe installation of a modern radiation oncology programme. Although the initial costs of implementing 3-D conformal radiotherapy treatment are high, the transition mapped out in these guidelines can significantly improve patients' medical outcomes and quality of care
Implementation of High Dose Rate Brachytherapy in Limited Resource Settings IAEA Human Health Series No. 30	http://www-pub.iaea.org/books/IAEABooks/10355/Implementation-of-High-Dose-Rate-Brachytherapy-in-Limited-Resource-Settings	Brachytherapy is an essential component of the curative treatment of cervical cancer, a disease with high incidence in many developing countries. The IAEA supports the use of high dose rate brachytherapy for centres with a large number of patients with this disease. HDR brachytherapy is also used in other common cancers such as breast cancer, lung, oesophagus and prostate. This publication provides guidance to radiation oncologists, medical physicists and planners on establishing and operating a high dose rate brachytherapy unit with modern standards and presents the main issues to be addressed for its effective and safe operation.
The Transition from 2-D Brachytherapy to 3-D High Dose Rate Brachytherapy IAEA Human Health Reports No. 12	http://www-pub.iaea.org/books/IAEABooks/10705/The-Transition-from-2-D-Brachytherapy-to-3-D-High-Dose-Rate-Brachytherapy	Brachytherapy is a major treatment modality in the treatment of common cancers including cervical cancer. This publication addresses the recent technological change in brachytherapy treatment planning with better access to 3-D volumetric patient imaging modalities including computed tomography (CT) and magnetic resonance (MR) as opposed to traditional 2-D planar images. In the context of 2-D and 3-D brachytherapy, the publication provides definitions, clinical indications, transitioning milestones, commissioning steps, quality assurance measures and a related questionnaire. Staff training and resourcing are also addressed. The publication will serve as a guide to radiotherapy departments in Member States who wish to make the transition from 2-D to 3-D brachytherapy.
On-site Visits to Radiotherapy Centres: Medical Physics Procedures Quality Assurance Team for Radiation Oncology (QUATRO) IAEA TECDOC No. 1543	http://www-pub.iaea.org/books/IAEABooks/8832/On-site-Visits-to-Radiotherapy-Centres-Medical-Physics-Procedures-Quality-Assurance-Team-for-Radiation-Oncology-QUATRO	The Quality Assurance Team for Radiation Oncology (QUATRO) provides independent quality audits both proactive (comprehensive reviews of the radiotherapy practices) and reactive (focused investigations in response to suspected or actual incidents during radiotherapy). The QUATRO methodology for proactive audit is described in the IAEA publication Comprehensive Audits of Radiotherapy Practices: A Tool for Quality Improvement. This publication describes the audit technique for medical physics aspects of the operation of radiotherapy hospitals with the purpose of helping to identify and rectify problems in the area of radiotherapy physics. It includes the follow-up of inconsistent results detected with the thermoluminescent dosimetry postal service operated jointly by the IAEA and WHO as well as problems found during the radiation treatment planning process for both tele- and brachytherapy. Reactive QUATRO audits help hospitals at a very early stage in the problem solving process, focusing on the prevention of incidents or accidents in radiotherapy.

Title	Link	Description
Absorbed Dose Determination in External Beam Radiotherapy IAEA Technical Report Series No. 398	http://www-pub.iaea.org/books/IAEABooks/5954/Absorbed-Dose-Determination-in-External-Beam-Radiotherapy	This Code of Practice, which has also been endorsed by WHO, PAHO and ESTRO, fulfils the need for a systematic and internationally unified approach to the calibration of ionization chambers in terms of absorbed dose to water and to the use of these detectors in determining the absorbed dose to water for the radiation beams used in radiotherapy. It provides a methodology for the determination of absorbed dose to water in the low, medium and high energy photon beams, proton beams and heavy ion beams used for external radiation therapy.
"Safety is no accident"	https://www.astro.org/uploadedFiles/Main_Site/Clinical_Practice/Patient_Safety/Blue_Book/SafetyisnoAccident.pdf	The document provides guidance on the requirements and processes needed to run a modern radiotherapy department.
European Higher Education Area Level 6 Benchmarking Document for Radiation TherapisTs (RTTs)	http://www.estro.org/binaries/content/assets/estro/about/rtt/rtt-benchmarking.pdf	The ESTRO, through the Radiation TherapisT (RTT) Committee has sought, over a twenty - five year period, to address the educational and professional issues of the group of healthcare professionals responsible for the delivery of the radiotherapy prescription accurately and safely. This document defines the competences that RTTs should have on graduation from their basic education programme.
Roles and Responsibilities, and Education and Training Requirements for Clinically Qualified Medical Physicists	http://www-pub.iaea.org/books/iaeabooks/10690/Roles-and-Responsibilities-and-Education-and-Training-Requirements-for-Clinically-Qualified-Medical-Physicists	This publication addresses the shortfall of well trained and clinically qualified medical physicists working in radiation medicine. The roles, responsibilities and clinical training requirements of medical physicists have not always been well defined or well understood by health care professionals, health authorities and regulatory agencies. To fill this gap, this publication provides recommendations for the academic education and clinical training of clinically qualified medical physicists, including recommendations for their accreditation certification and registration, along with continuous professional development. The goal is to establish criteria that support the harmonization of education and clinical training worldwide.

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3) IAEA SRS No. 47. Radiation Protection in the Design of Radiotherapy Facilities. Available at http://www-pub.iaea.org/books/IAEABooks/7197/Radiation-Protection-in-the-Design-of-Radiotherapy-Facilities

4) Radiotherapy Facilities: Master Planning and Concept Design Considerations. IAEA Human Health Reports No. 10. Available at: http://www-pub.iaea.org/books/IAEABooks/10561/Radiotherapy-Facilities-Master-Planning-and-Concept-Design-Considerations

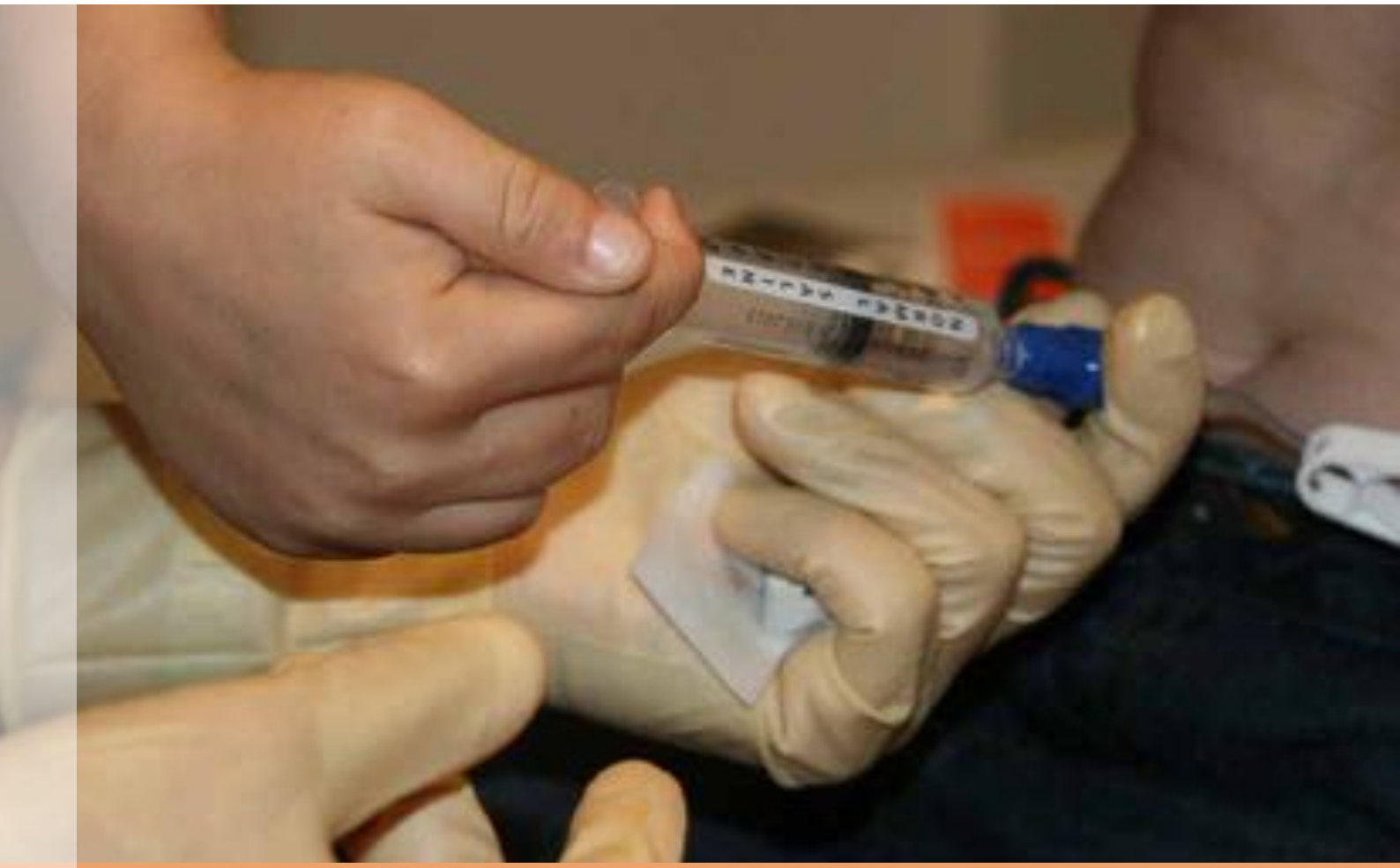
5) Comprehensive Audits of Radiotherapy Practices: A Tool for Quality Improvement. Available at: http://www-pub.iaea.org/books/IAEABooks/7680/Comprehensive-Audits-of-Radiotherapy-Practices-A-Tool-for-Quality-Improvement-Quality-Assurance-Team-for-Radiation-Oncology-QUATRO

6) Practical Guidelines for the Implementation of A Quality System in Radiotherapy. Available at: http://www.estro.org/binaries/content/assets/estro/school/publications/booklet-4---practical-guidelines-for-the-implementation-of-a-quality-system-in-radiotherapy.pdf

7) Setting Up a Radiotherapy Programme: Clinical, Medical Physics, Radiation Protection and Safety Aspects. Available at: http://www-pub.iaea.org/books/IAEABooks/7694/Setting-Up-a-Radiotherapy-Programme

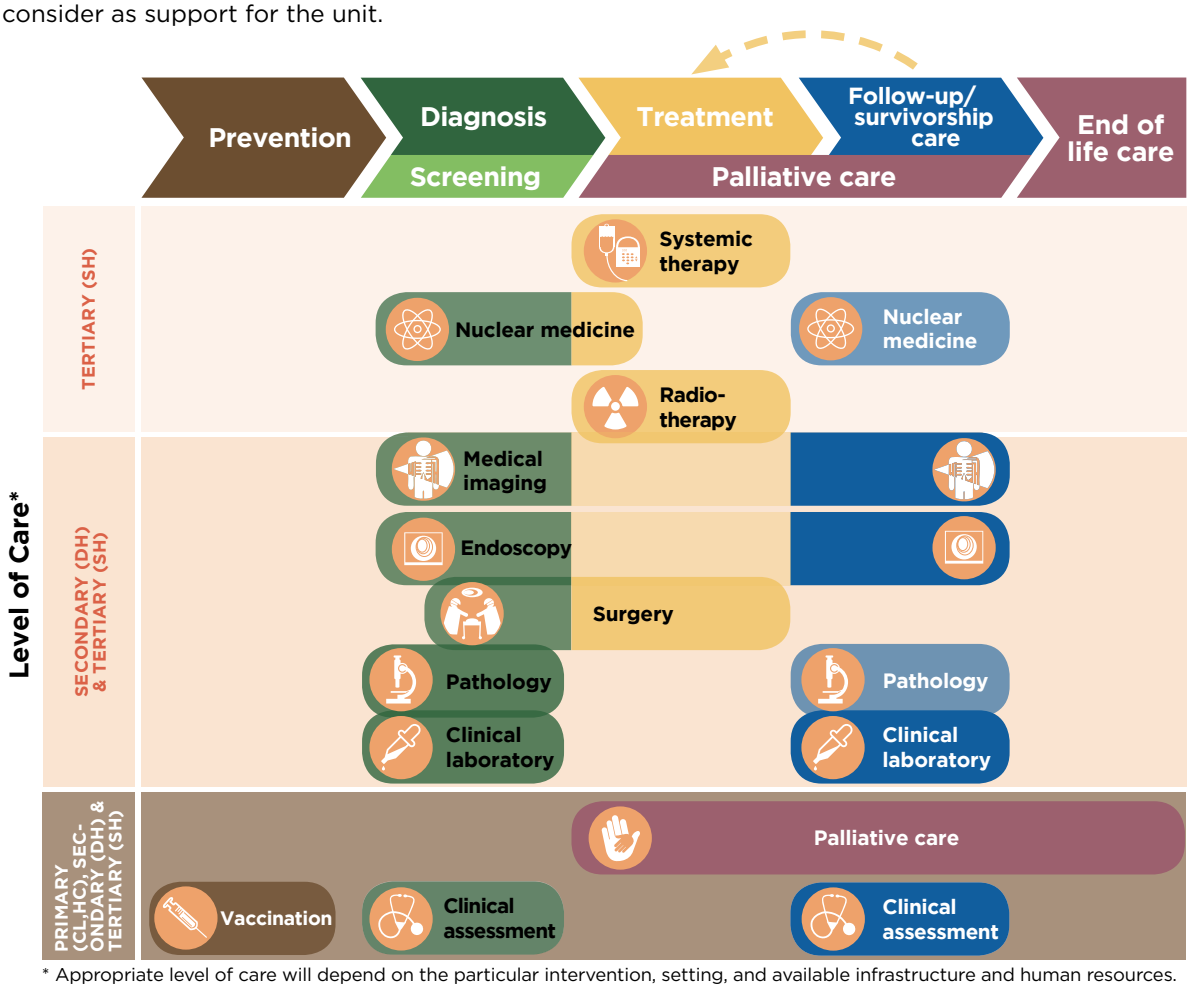
8) NCRP Report No. 151 - Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities (2005); http://www.ncrppublications.org/Reports/151.

6. Systemic therapy



Health service delivery sequence overview:

This diagram expresses the flow of cancer patients to and from the systemic therapy unit, and the elements to consider as support for the unit.



* Appropriate level of care will depend on the particular intervention, setting, and available infrastructure and human resources.
CL Community Level health post DH District Hospital HC Health Centre SH Specialized Hospital

Fig. 10.6. Health care service delivery overview – systemic therapy

6.1 General description of the unit

Chemotherapy units (or oncology units) are required to administer systemic therapies to patients with cancer, both in adjuvant and metastatic settings. The usual route of chemotherapy administration is intravenous (bolus or continuous infusion); other routes of infusion include intramuscular or subcutaneous injection. Although less common, intraperitoneal, intrathecal, intra-arterial may also be used. Oral formulations are generally used for outpatients.

The side effects of anticancer drugs are well known. Patient safety and occupational risks to health care workers who prepare, handle or dispose of cytotoxic agents must be considered in the design and operation of medical oncology units. Internal distribution and disposal of waste must also be planned for carefully. Activities within the unit include:

- Managing the scheduling of patient appointments;
- Medication administration;
- Documenting the patients' demographic information; and
- Documenting all treatments administered, including date, time, treatments, drugs, doses, and patient response.

Additionally, an assessment of how the patient tolerated the prior therapy should be documented in case there is a need to reduce the dose of chemotherapy due to unacceptable toxicity. Some chemotherapy agents may cause an immediate reaction; all units should have an emergency box so response to the immediate reaction can be mitigated by a rapid response.

6.2 Priority medical devices

The following tables contain general medical devices, which can be used for preparation and treatment/ infusion of chemotherapy of several cancers, and specific medical devices, which are used for interventions for specific cancer types. The use of central venous catheters versus peripheral is discussed at the end of the list. It is important to include, if applicable, the medical devices for paediatric patients as recommended below. If the chemotherapy is delivered in an outpatient unit, purchasing an ambulance for transportation of patients in case of an emergency is desirable.

The main intervention addressed in this chapter is the systemic therapy infusion of the different specialized treatments, for all cancer types. Other interventions specific to Leukaemia are also addressed, as listed below:

Cancer type	Interventions
All cancers	• Drug infusion, chemotherapy administration • Hazardous drug preparation • Intrathecal chemotherapy

6.2.1 General medical devices for systemic therapy

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
Drug Infusion, chemotherapy administration	Medical equipment	Fixed examination/treatment light	
		Pharmacy refrigerator	
		Stethoscope, adult, binaural and paediatric	
		Thermometer, clinical, digital 32–43°C	Tympanic probe covers (if tympanic thermometers are used)
		Resuscitation trolley, equipped with medicines and defibrillator	With laryngoscope (for adult and paediatric patients)
		Sphygmomanometer (include paediatric size tubes if applicable)	Infant/paediatric blood pressure cuffs
		Basic vital signs monitor (availability in the setting)	Vein finder device (optional) Monitoring electrodes
		General physical examination set	Ophthalmoscope, Otoscope, Lamp)
		Adult stand up scale	
		Stadiometer (wall mounted)	
		Oxygen therapy flowmeter, dial-type (if pipeline available)	
		Suction availability (accessories for wall or portable equipment)	
		Infusion pump (optional)	Infusion pump administration set
		Elastomeric pump (optional)	
		Tympanic thermometer	
		Infant scale	
	Medical furniture	Reclining chair	
		Patient lifting hoist	
		Hospital stretcher with side rails	
		General cabinet	
		Stand, infusion, double hook, on casters	
		Table, instruments, Mayo, stainless steel, on castors	
		Trolley, dressing, stainless steel, 2 trays	
		Trolley, soiled linen	
		Wheelchair, adult/child	
		Cabinet, medicine, with lock (consider national regulations)	
		Cribs	
		Bedside tables/commodes	
	Instruments		Dressing set
	Personal protective equipment and clothing		Glasses, safety, regular size
			Gloves, nitrile non-sterile, single-use
			Gloves, non-sterile, single-use
			General purpose sterile drape
			Surgical face mask
			Gown, impermeable single use
			Apron impermeable

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
	Single use devices/ disposables/medical supplies		Bandage, adhesive, 3.0 cm, 100/box
			Bandage, elastic, 7.5 cm x 5 m, roll
			Compress, gauze, sterile and non-sterile, single-use
			Infusion giving set, sterile, single use
			Needles, luer, sterile, single-use (sizes G)[3]
			Oxygen mask (child or adult, appropriate sizes)
			Oxygen therapy flowmeter, dial-type
			Prongs, nasal, oxygen, non-sterile, single use (various sizes)
			Safety box, for used syringes/needles
			Skin-cleaning wipe/swab-pad, alcohol
			Tape, medical, roll (various sizes)
			Tube, suction, L50 cm, catheter tip, sterile, single use (sizes G)[3]
			IV line extensor
			Syringes (various capacities)
			IV burettes
			Paediatric foley catheters and nasogastric tubes
			IV catheters #22 and #24
			Paediatric spinal needles
			Suction catheters (sizes G)[3]
			Intravenous catheter (sizes G)[3]
	Solutions and reagents		IV solutions provided (Sodium chloride solution for infusion 0.9%, dextrose, NaCl)
			Isopropyl alcohol 70%
			Iodine povacrylex and isopropyl alcohol solution or similar
			Sodium hypochlorite solution
			Aqueous antibacterial solution/ Aqueous cleaning and decontaminating solutions, alkaline detergent solution
			Hand/body hygiene products
	Other		Arm/leg tourniquet
			Bag, disposable for biohazardous waste
			Basin, kidney, stainless steel/ polypropylene
			Bedpan, stainless steel/ polypropylene
			Cytotoxic waste receptacle
			Receptacle, waste, stainless steel, pedal action
			Urinal
			Hazardous drug spill kits

3. Components of all surgical instrument sets as well as needle and catheter gauge sizes (G) are listed in the chapter annex at the end of the Surgery chapter

Procedure	Medical devices category	Capital equipment (for specialized hospitals)	Accessories/hardware/software/ consumables/single use devices
Hazardous drug preparation (pharmacy, special isolated room inside or outside the facility to provide the chemotherapy)	Medical equipment	Class-II biological safety cabinet (the cabinet is needed in cases when the reconstitution of chemo is done in the unit)	
		Respirators (If reconstitution is done in the unit)	
	Furniture		Adequate furniture to prepare the hazardous drugs including chairs, tables, cabinets
	Personal protective equipment and clothing		Coat, medical, woven (various sizes)
			Glasses, safety, regular size
			Gloves, nitrile non-sterile, single-use
			Gloves, non-sterile, single-use
			Non-conductive shoe cover
			Protective head cover
			General-purpose sterile drape
			Surgical face mask
			Gown, impermeable single-use
	Single use devices/ disposables/medical supplies		Bag, disposable for biohazardous waste
			Filter Discs (if available)
			Needles, luer, sterile, single-use (sizes G)[3]
			Scalp vein intravenous administration set
			Secondary set with drip chamber
			Closed system drug transfer devices (if available)
			Filter needles (if available)
			Filter Venting devices (if available)
			Syringes, luer lock, sterile, single-use (various capacities)
			IV fluid and blood giving sets
	Solutions and reagents		Isopropyl alcohol 70%
	Other		Compress, gauze, sterile and non-sterile, single use
			Labels for the drugs identification
Intrathecal chemotherapy			Lumbar puncture set
	Single use devices/ disposables/medical supplies		Needles, spinal, sterile, single-use (sizes)[3]
			Sterile culture tube

6.2.2 Specific medical devices for systemic therapy by cancer type

Discussion

The use of central venous catheters is an important topic worthy of discussion and analysis for specific types of cancer. In most upper and middle income countries (LMIC), the chemotherapy dosage for some treatments (e.g. six cycles) as well as for patients with metastatic diseases who need to be treated at several different time points is done by implantable central venous catheters or peripherally inserted central catheters (PICC). Due to increased risk of infection associated with central lines, patients who develop fever in the setting of neutropenia must have access to timely administration of empiric intravenous antibiotics

Special consideration is required in these instances as each device involves specific personal training (nurses, surgeons, radiologist), patient training pre- and post-implant, maintenance (regular flushing: for totally implantable devices monthly flushing is advised, whereas weekly flushing and dressing for peripherally inserted PICC lines is recommended) and specific infrastructure and equipment (e.g. ultrasound).

Peripheral or central catheters require different sets of devices and each day technology is improving to make possible the availability and affordability of these devices to be used in LMIC.

6.3 Other health system components

6.3.1 Human resources for systemic therapy

To operate the unit, the following personnel can be considered: oncologists, physicians, nurses, pharmacists and administrative assistant(s). The physician in charge should be present in the unit when chemotherapy is being administered, to treat potential adverse drug reactions.

Ideally, there should be trained pharmacists on the oncology team to receive the chemotherapy prescriptions and perform a secondary check of all chemotherapy doses and schedules, days, route and preparation of the chemotherapy. Many LMICs do not have trained pharmacists; therefore, nurses are often relied on to reconstitute the chemotherapy agents, administer the chemotherapy and care for patients with cancer.

Depending on national context including workforce availability and models, different occupations can fulfil the roles that may be required for systemic therapy. A prerequisite is having the required competencies to perform these roles and being officially recognized for it as per the scope of practice. The ISCO[2] codes are added as illustrative examples based on current practice for further reference. This should not be interpreted as guidance on occupations that should perform each role but rather indicative occupations that are currently performing these roles in different country contexts.

The list below presents different occupations that could fulfil the roles and competencies required for systemic therapy. These would depend on national context and local regulations as long as the specific staff has the competency and it fits within their scope of practice . codes are added for further reference.

Sample role	Sample occupations (ISCO-08 codes)
Counsels, prescribes, ensures safe administration, manages toxicity	Haematology, clinical oncologist, Specialist medical practitioner (2212)
Counsels, prescribes, ensures safe administration and manages toxicity in paediatric patients	Paediatric oncologist, Specialist medical practitioner (2212)
Counsels, ensures safe administration and early detection of toxicity and manages simple toxicity, assesses patient response to treatment, manages vascular access devices	Oncology Nurse, Nursing professional (2221), nursing associate professional (3221), supervised: healthcare assistant (5321)
Maintain clean environment and assist patients during chemotherapy sessions	Nursing associate professional (3221),
Ensures and checks prescription and dosage for accurate reconstitution	Oncology pharmacist, pharmacist (2262)

2 *International Standard Classification of Occupations, http://www.ilo.org/public/english/bureau/stat/isco/docs/publication08.pdf*

Sample role	Sample occupations (ISCO-08 codes)
Reconstitutes chemotherapy drugs for administration under supervision of pharmacist	Pharmaceutical technician or assistant (3213)
Management of medical devices: planning, procurement, Supervision or performance of: installation, users training, maintenance and decommissioning.	Biomedical Engineer (2149) Biomedical technician / physical and engineering science technician (3119) under supervision of biomedical engineer (2149)
Scheduling, reception of patients, filing patient data, and all other administrative tasks	Clerical support workers (4412) Technologists(3211), Nurses (2221)
Cleaners need specific training for cleaning systemic therapy area and pharmacy where chemotherapies are prepared.	Cleaning personnel (9112)

An ideal unit will have all the personnel listed above to improve the efficiency and safety of chemotherapy administration.

The minimum requirement for a chemotherapy unit is to have a combination that includes:

1. A consulting oncologist (may be non-residential, but must be reachable in all cases)
2. Physician with experience in prescribing chemotherapy, ensuring safety, monitoring and managing toxicity
3. Pharmacist or registered nurse with experience in reconstitution of chemotherapy
4. A registered nurse with proper training and experience in administering chemotherapy.

6.3.2 Infrastructure

A patient care area where chemotherapy is administered must have a patient waiting area; a treatment room with comfortable reclining chairs and television set (if possible); a clinical area equipped with a refrigerator; clinical supplies for mixing drugs (syringes, needles, etc.); a containment cabinet or hood for mixing chemotherapy; designated containers and area for disposal of cytotoxic waste and pharmacy for the storage of drugs. According to the level of complexity of the unit it may have a unit for storage of the medication, a central pharmacy in the hospital, or optional drug preparations provided by external suppliers.

The facility could be integrated with an oncology or general hospital or it could be a specialized outpatient unit.

Layout distribution

Basic requirements for a facility would include:

1. A pharmacy
2. Consulting room for patient evaluation
3. Access to laboratory diagnostic tests such as haematology test and clinical chemistry
4. Chemotherapy mixing room with vents/extractors and ability to maintain aseptic conditions (controlled area)
5. Chemotherapy suite for administration or a ward
6. Nurse station
7. Toilet facilities

In the ward there should be sufficiently clear dimension between beds and lounge chairs used for chemotherapy treatment/infusion and during administration. Access to the area should be limited to patients receiving therapy and essential personnel.

Electrical systems

If infusion pumps are used to infuse chemotherapy, stable power supply and back-up systems should be installed. Emergency and standby power systems should be considered.

Heating, ventilation and air conditioning systems

The mixing room inside the pharmacy or the ward should maintain aseptic conditions but a contained environment where air pressure is negative to the surrounding areas or that is protected by an airlock or anteroom, is preferred *(1)*. Ideally, a biological safety cabinet should be available.

Ventilation and air conditioning systems are important particularly with patients with an extreme susceptibility of infection.

Communication systems

Communication systems linking the pharmacy and the oncology unit should be installed if they are located a considerable distance apart.

Special systems

The availability of an oxygen supply for example via an oxygen concentrator, oxygen cylinder or pipeline, is highly recommended.

Cleaning and decontamination of hazardous chemotherapy drug equipment and work surfaces

Decontamination may be defined as cleaning or deactivating. Deactivating a hazardous substance is preferred, but no single process has been found to deactivate all currently available hazardous drugs (HDs). The use of alcohol for disinfecting a primary engineering control or other contaminated surface will not deactivate any hazardous chemotherapy drugs and may result in the spread of contamination rather than in any actual cleaning. Many recommend sodium hypochlorite solution as an appropriate deactivating agent. Research has shown that strong oxidizing agents, such as sodium hypochlorite, are effective deactivators of many hazardous chemotherapy drugs. A 2% sodium hypochlorite solution with detergent may be wiped onto contaminated surfaces, and then rinsed; this is followed by a neutralizing solution of 1% sodium thiosulfate, wiped on and off, followed by a rinse solution of water, then alcohol. Surface contact for each solution should be at least 30 seconds. Some studies have shown good analytical results with this technique. The hazardous chemotherapy drugs may not be fully deactivated, but the wiping action followed by rinsing appears to be effective in cleaning. This technique may be used on any surface that will not be harmed by a bleach solution. All cleaning solutions, wipers, and rinsates must be contained and discarded as hazardous *(2)*.

Extravasation management

In terms of cancer therapy, extravasation refers to the inadvertent infiltration of chemotherapy into the subcutaneous or subdermal tissues surrounding the intravenous or intra-arterial administration site. The risk is lower in experienced institutions with well-trained personnel. In general hospitals or when non-trained nurses or physicians apply infusions, the risk is much higher. Most extravasations can be prevented with the systematic implementation of careful, standardized, evidence-based administration techniques. In order to minimize the risk of extravasation, the staff involved in the infusion and management of cytotoxic drugs must be trained to implement several preventive protocols. Regardless of the chemotherapy drug, early initiation of treatment is considered mandatory. In this context, patient education is crucial for a prompt identification of the extravasation.

An extravasation kit containing instructions, materials and medication to handle any incidence should be available. An early multidisciplinary evaluation by nurses, physicians and surgeons is recommended.

Various suggestions have been published with possible topical or injected pharmacologic methods for certain vesicant chemotherapy drugs. One should be aware that many are considered ineffective or further damage the extravasated area. It should be noted that many of these substances are not available or at best have limited access for use in many countries.

Local injection or topical corticosteroids are not recommended due to the increased need for surgical debridement. Topical dimethyl sulfoxide (DMSO) is a treatment option in extravasations occurred during anthracyclines, mitomycin C or platin salts infusions. The application must be repeated every 8 hours for 1 week and the first administration of DMSO performed in the first 10 minutes after extravasation.

Dexrazoxane prevented severe tissue damage following anthracycline extravasation, but is not available in many countries. Hyaluronidase might be efficacious in preventing skin necrosis by extravasation due to vinca alkaloids *(3)*.

Others

The design of this area must include surfaces that are compatible with cleaning and decontaminating agents. Upholstered and carpeted surfaces should be avoided.

6.3.3 Quality management

Patient safety

There are several published guidelines ensuring safety for patients undergoing chemotherapy. All patients should be fully informed about their condition, indication for use of specific drugs, expected side effects and outcomes as well as treatment options. These should be captured in a signed consent form. Record keeping is of high priority to cross check prescriptions, make sure patients have been evaluated for toxicity, review laboratory parameters and document any dose adjustments prior to the next cycle. The labelling of drugs, cross checking of labels and use of appropriate infusion mixture by several other health care workers are important to avoid misadministration such as over dosage. A secondary check system should be put in place and should include a double check of the order to assure right cycle, day, drug, height, weight, body surface area (BSA), dose, route and patient. Additional checks should be performed during the reconstitution and mixing of the drug and upon administration, to assure the right patient is receiving the right drugs and dose, on the right day and time. Accidental exposure can occur in patients as well during administrations. The best patient safety outcomes are achieved with adequate and quality staffing as well as adherence to safety recommendations.

Oncology nurses need specialized training to assure the proper administration techniques for drugs that are called vesicants. If not administered properly accidental extravasation can happen causing severe harm, if these drugs infiltrate into the patient subcutaneous tissue. This can be a devastating occurrence, highlighting the importance of training and skill development.

Public safety

Chemotherapy drugs are prescribed by physicians only for use by a specific patient. The general public should not be exposed to these drugs during or following administration. Exposure to bodily fluids of a patient immediately or a few days following administration may have adverse consequences. Patients need to be educated about the effect of their medication on others close to them. Topics such as the use of washroom facilities, vomitus, sweat and sperm or vaginal fluids should be discussed to ensure appropriate measures are in place to prevent contamination. Most importantly, the safety of pregnant women and young children is paramount.

If a patient receiving chemotherapy requires care, care givers, including health care professionals, should wear gloves and wash their hands with soap and water before donning and after removing gloves. All reusable and disposable containers for bodily fluids should be washed several times with detergent prior to disposal into designated plastic bags. Used needles and blades should be placed into puncture proof, labelled containers. All other tubing and containers containing medication should be placed in hazardous waste labelled bins to be disposed of appropriately.

These recommendations apply to oral chemotherapy as it applies to the home environment.

Health care workers

Pharmacists, pharmacy technicians and oncology nurses are at risk of direct contact with chemotherapy agents during preparation and administration. Use of impermeable gloves, gowns, goggles and shoes should be mandatory without any exceptions. Most commonly, skin and eye contamination can occur as well as needle stick injuries. In case of external exposure, immediate washing with soap and water several times is recommended and the incident should then be reported to a physician. Institutions should enforce that only highly skilled and qualified staff operate the chemotherapy administration suite. Continuous education programmes on the safe preparation and administration and awareness and management of exposure should

be mandatory. A log should be kept of the incidences of accidental exposures in order to improve procedures to reduce such incidents.

Competencies relating to administering cytotoxic and biotherapy agents to paediatric oncology patients

The advent and use of chemotherapy tremendously impacted the survival of children with cancer. In the past 60 years, the survival rates of children with cancer have dramatically improved with 5-year survival rates of the most common types of childhood cancer nearing 90% in high income countries. In low and mid income countries, however, survival rates continue to be much lower. Use of chemotherapeutic agents is not without risk as they are administered in a variety of routes and doses. It is important for nurses to have the knowledge needed to safely administer antineoplastic agents to all patients, but in particular paediatric oncology patients *(4-7).*

Competencies: To administer cytotoxic and biotherapy agents to oncology paediatric patients, the nurse must:

- Possess knowledge of safe handling guidelines for cytotoxic agents and waste products;
- Familiarize self with actions, administration guidelines, and side effects of cytotoxic medications as outlined in pharmacy manual and other resources;
- Be able to provide patient/family teaching in relation to side effects and management of side effects;
- Be knowledgeable about paediatric cancer diagnosis and treatment, haematopoiesis and immune response, treatment modalities, and psychosocial issues in paediatric oncology, attained through education and experience;
- Be able to teach patients/families about their diagnosis, treatment and the cancer experience; and
- List and describe chemotherapy and biotherapy agents and classifications and their mode of action, administration considerations, toxicity and symptom management, and late effects.

Related competencies include:

- Care of central venous catheters and venous access devices; and
- Administration of intravenous, intramuscular, subcutaneous and oral medications to paediatric patients.

6.3.4 Guidance documents

Title	Link	Description
Central venous access in oncology: ESMO Clinical Practice Guidelines	http://www.esmo.org/Guidelines/Supportive-Care/Central-Venous-Access-in-Oncology	Central venous access plays a critical role in the management and care of cancer patients. These new ESMO Clinical Practice Guidelines apply to central venous access in adult cancer patients and cover the use of peripherally inserted central catheters, tunnelled central catheters and totally implantable devices. The guidelines cover diagnosis and treatment of infections as well as complications requiring the removal of central venous access devices.
ASCO-ONS Standards for Safe Chemotherapy Administration	http://www.instituteforquality.org/asco-ons-standards-safe-chemotherapy-administration	The ASCO/ONS chemotherapy safety standards are intended to reduce the risk of errors when providing adult patients with chemotherapy, and to provide a framework for best practices in cancer care. Specifically, they can inform practice policies and procedures, internal quality assessment, and external quality monitoring.

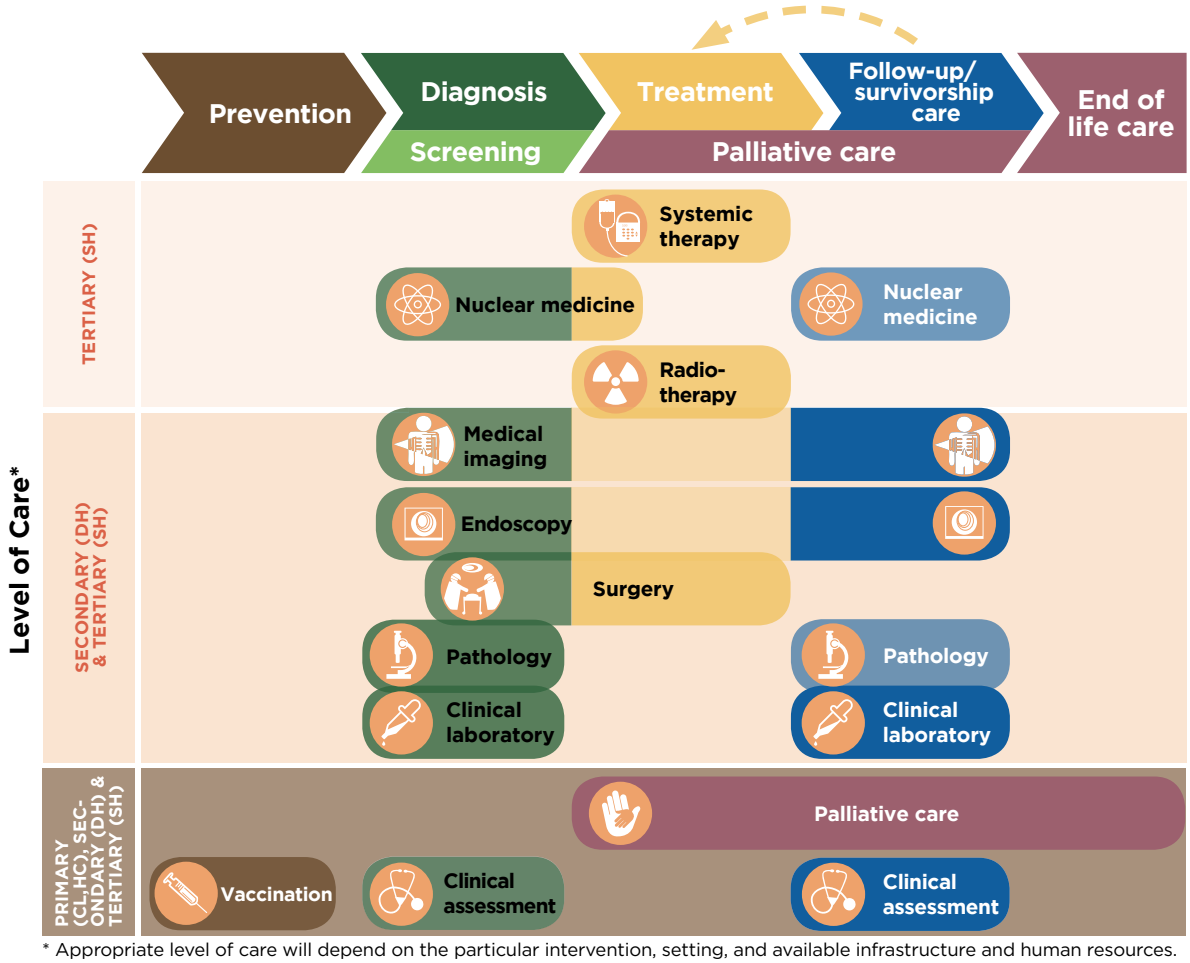
Bibliography:

1) https://www.ashp.org/DocLibrary/BestPractices/PrepGdlHazDrugs.aspx
2) Safe Handling Of Hazardous Chemotherapy Drugs In Limited-Resource Settings, PAHO; Touzin et al. 2010; Zock, Soefje, and Rickabaugh 2011
3) J. A. Pérez Fidalgo et al; Management of chemotherapy extravasation: ESMO–EONS Clinical Practice Guidelines-Annals of Oncology 23 (Supplement 7): vii167–vii173, 2012
4) http://www.bcchildrens.ca/Oncology-Site/Documents/ChemotherapyAdministrationCompetenciesforCommunity.pdf
5) Bertram, Leslee A., "Pediatric Oncology Nurses' Knowledge of Safe Administration of Chemotherapy/ Biotherapy" (2015). DNP Practice Inquiry Projects. Paper 60.
6) http://www.asco.org/international-programs/multidisciplinary-cancer-management-courses
7) http://www.asco.org/international-programs/global-curriculum

7. Palliative care & end of life care

Health service delivery sequence overview:

This diagram expresses the flow of cancer patient to and from the palliative care and end of life care unit, and the elements to consider as support for the unit.



* Appropriate level of care will depend on the particular intervention, setting, and available infrastructure and human resources.
CL Community Level health post DH District Hospital HC Health Centre SH Specialized Hospital

Fig. 10.6. Health care service delivery overview – Palliative care and end of life care

7.1 General description of the unit

7.1.1 Definition

"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 suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual *(1)*." (Definition of Palliative Care adopted by WHO)

7.1.2 Purposes

- Provides relief from pain and other distressing symptoms
- Affirms life and regards dying as a normal process
- Intends neither to hasten nor postpone death
- Integrates the psychological and spiritual aspects of patient care
- Offers a support system to help patients live as actively as possible until death
- Offers a support system to help the family cope during the patient's illness and in their own bereavement
- Uses a team approach to address the needs of patients and their families, including bereavement counselling, if indicated
- Will enhance quality of life, and may also positively influence the course of illness
- Is applicable early in the course of illness, in conjunction with other therapies that are intended to prolong life, such as chemotherapy or radiation therapy, and includes those investigations needed to better understand and manage distressing clinical complications.

In some countries there is recognition of the difference between general palliative care and specialist palliative care; for example, the United Kingdom *(2)* differentiates between:

- *General palliative care* which "is provided by the usual professional carers of the patient and family with low to moderate complexity of palliative care need", and
- *Specialist palliative care services* which "are provided for patients and their families with moderate to high complexity of palliative care need. They are defined in terms of their core service components, their functions and the composition of the multi-professional teams that are required to deliver them."

Terminology in palliative care is somewhat controversial and varies across and even within countries. Recommended definitions of common terms used in palliative care have been offered by the European Association for Palliative Care *(3,4)* and other organizations. General palliative care can and should be delivered throughout any cancer hospital or clinic, wherever a patient is. Within a hospital, in-patient specialist palliative care units (with dedicated beds) can be provided. Alternatively, a multidisciplinary specialist palliative care team may provide consultations throughout the hospital to patients who remain in their wards/rooms under the primary care of their treating physician. Hospice may mean a separate service involving a range of components including: an in-patient unit, home care, day care, out-patient clinics and bereavement support service.

7.1.3 Palliative treatment

There is a wealth of clinical literature to support the role of radiotherapy, brachytherapy, and surgery in the palliation of cancer to relieve symptoms including pain, bleeding, and obstruction and to improve quality of life for cancer patients *(5-8)*. Please refer to the Radiotherapy and Surgery subchapters for interventions and corresponding medical devices. There are also many pharmacological and non-pharmacological interventions for symptom management and psychosocial problem management

7.2. Priority medical devices

The following tables contain general medical devices, which can be used for the general palliative care needs of many diseases including cancers, and specific medical devices, which are used for palliative care needs of specific cancer types.

7.2.1 General medical devices for palliative care and end of life care

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables /single use devices
Palliative care delivery	Medical equipment	Blood glucometer (used after chemotherapy), with accessories	Micro cuvettes or strips according to manufacturer.
		Fixed examination/treatment light	
		Nebulizer, with accessories	
		Pulse oximeter, portable, with accessories	Sensors
		Refrigerator	
		Fridge freezer	
		Stethoscope, adult and paediatric, binaural	
		Thermometer, clinical, digital 32–43°C	
		Sphygmomanometer	Blood pressure cuffs for adults and paediatrics
		General physical examination set	Include Ophthalmoscope, Otoscope, Lamp)
		Oxygen therapy flowmeter, dial-type (if pipeline available)	Oxygen supply (cilinder, oxygen concentrator or pipeline)
		Suction availability (accessories for wall or portable equipment)	
		Electrocardiograph (optional)	
		Syringe pump or elastomeric pumps, battery-operated (optional)	
		Infusion pump for enteral nutrition (optional)	
		Hammer for neurological examination	Tape measurement
		Non-heated respiratory humidifier	
	Medical furniture	Hospital stretcher, with side rails	
		General cabinet	
		Stand, infusion, double hook, on casters	
		Trolley, dressing, stainless steel, 2 trays	
		Lifting device for patient	
		Wheelchair, adult/child	
		Cabinet, medicine, with lock (consider national regulations)	
		Walking frame/mobility walking aids	
		Table, instruments, Mayo type, stainless steel, on castors	
	Instruments	Forceps, dressing, Cheron, 250 mm	
		Surgical instruments, dressing set	
		Scalpel with blades	
		Basic Surgery set, Minor tray	
	Personal protective equipment and clothing		Glasses, safety, regular size
			Gloves, non-sterile, single use
			Gloves, surgical, single use

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables /single use devices
			Surgical face mask
			Gown, impermeable single use (impervious, and consider impervious coat)
			General-purpose sterile drape
	Single use devices/ disposables/medical supplies		Adult/children diapers (incontinence pads)
			Asepto syringe
			Bandage, elastic, 7.5 cm x 5 m, roll
			Cannulas, Intra Venous (IV) short, sterile, single use (sizes G)[3]
			Catheter bag
			Catheter, Foley, sterile, single use (sizes G)[3]
			Catheter, urethral, sterile, single use (sizes G)[3]
			Collector, urine, adhesive, 10–100 ml
			Combined spinal epidural anaesthesia trays (spring-wound catheter, spinal epidural needles)
			Compress, gauze, sterile & non-sterile, single use
			Dressing retention roll
			Lancet, blood, safety, sterile (various sizes)
			Monitoring electrodes
			Nasogastric tube
			Nasogastric tube fixator
			Needles, luer, sterile, single use (sizes G)[3]
			Needles, scalp vein, sterile, single use (sizes G)[3]
			Needles, spinal, sterile, single use (sizes G)[3]
			Ostomy bag
			Parenteral/enteral solution bag
			Partial-rebreathing oxygen face mask
			Prongs, nasal, oxygen, non sterile, single use (various sizes)
			Skin-cleaning wipe/Swab-pad, alcohol
			Surgical scrub brush, single-use
			Suture, synthetic, non-absorbable (sizes USP/DEC) with needle (sizes G)[3], sterile, single use, nylon, catgut, silk
			Tape, medical, roll (various sizes)
			Three-way-stopcock
			Tube, suction, L 50 cm, catheter tip, sterile, single use (sizes G)[3]
			Intravenous catheter (sizes G)[3]

3. Components of all surgical instrument sets as well as needle and catheter gauge sizes (G) are listed in the chapter annex at the end of the Surgery chapter

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables /single use devices
			Syringes (various capacities)
			Syringes, luer lock, sterile, single use (various capacities)
			Syringes for drug preparation/ formulation
			Absorbent tipped applicator
			Compression bandages (for Deep Vein Thrombosis)
			Medication cups
			Tracheostomy kit with adult-child T-tube and ties
			Thoracentesis set
			Paracentesis set
	Solutions and reagents		Alcohol
			Distilled water
			Hand/body hygiene products
			Isopropyl alcohol 70%
			IV Solutions
			Iodine povacrylex solution or similar Petroleum jelly
	Other	Arm/leg tourniquet	
			Basin, kidney, stainless steel/ polypropylene
			Bedpan, stainless steel/ polypropylene
			Bowl (dressing changes), stainless steel/polypropylene
			Bowl (hygiene), stainless steel/ polypropylene
			Brush, hand, scrubbing, plastic
			Receptacle, waste, stainless steel, pedal action
			Sterile container sample
			Urinal
			Oxygen availability (Oxygen concentrator, Oxygen/gas pipeline, cylinder)
			Pressure relief products (e.g. Cushions, mattresses

7.2.2 Specific medical devices for palliative care and end of life care by cancer type

7.2.2.1 Breast

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
Palliative care delivery	Single use devices/ disposables/medical supplies		Dressing sets for malodours/ fungating wounds (carbon pads/silver impregnated pads, compression bandages for lymphoedema etc.)

7.2.2.2 Colorectal

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
Palliative care delivery (including colostomy)	Single use devices/ disposables/medical supplies		Stoma/ostomy bags and adhesive
			Gastrostomy material for skin medication and use
			Devices to deliver enemas through stomas

7.2.2.3 Lung

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
Palliative care delivery	Single use devices/ disposables/medical supplies		Sputum containers

7.2.2.4 Leukaemia

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
Palliative care delivery	Single use devices/ disposables/medical supplies		Blood giving sets and cannulas

7.2.2.5 Cervical

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
Palliative care delivery	Single use devices/ disposables/medical supplies		Female sanitary products
			Devices to manage genital fistulae

7.2.2.6 Prostate

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
Palliative care delivery (Suprapubic catheterization)	Single use devices/ disposables/medical supplies		Suprapubic catheter

In addition to all of the above-mentioned medical devices, it is important to have the following available in a palliative care setting:

- Tools for assessment (approved and validated pain and other symptoms tools)
- Bed sets: Sheets, pillows, pillowcases, blankets/duvets, bed with protective barriers
- Patient's hygiene tools: Soft toothbrush – not pink swabs for mouth care, hair combs and brushes, manicure and pedicure sets, towels of different sizes and colours, single use sponges, soap, shampoo, skin cream, incontinence pads, wipes, tissues

- Food provision utensils: dishes, plates, glasses, sipping cups, straws, cutlery, food processors and modifying consistency agents for dysphagia
- Other furniture and devices: table with light, fan, radio/music device
- If relatives stay overnight option to provide a recliner chair and/or a sofa bed
- Aromatherapy

The palliative care unit should have access to X-Ray, CT scan and echographe and blood laboratory test equipment, moreover the devices and furniture should be adapted for adults' and children's needs and proper patient identification through ID tags or similar is recommended.

7.3 Other health system components

7.3.1 Human resources for palliative care and end of life care

Depending on national context including workforce availability and models, different occupations can fulfil the roles that may be required for palliative care. A prerequisite is having the required competencies to perform these roles and being officially recognized for it as per the scope of practice. The ISCO[1] codes are added as illustrative examples based on current practice for further reference. This should not be interpreted as guidance on occupations that should perform each role but rather indicative occupations that are currently performing these roles in different country contexts.

The list below presents different occupations that could fulfil the roles and competencies required for palliative care. These would depend on national context and local regulations as long as the specific staff has the competency and it fits within their scope of practice . The ISCO[2] codes are added for further reference.

Sample role	Sample occupations (ISCO-08 codes)
Medical care	Specialist Palliative Care Physician, , Clinical Oncologist, Specialist medical practitioner (2212)
Nursing care	Specialist Palliative Care Nurse, Nursing professional (2221), Nursing associate professional (3221)
Patient navigator, support patient follow up during all cancer treatment	Social worker and counselling professionals (2635)
Social work including financial welfare and family support, bereavement support	Specialist Palliative Care Social Worker, social work and counselling professionals (2635)
Psychological assessment and treatment for patient and family, bereavement support	Psychologist (2634)
Nutritional advice and support	Dietician and nutritionist (2265)
Spiritual and existential support/religious support	Religious professional (2636)
Physiotherapy, rehabilitation	Physical therapist, physiotherapist (2264)
Rehabilitation, diversional therapies	Occupational therapist (2269)
Help with swallowing, speech	Speech and language Therapist (2266)
Creative arts therapies	Arts therapists , other health professionals(2269)
Massage, well-being support	Massage therapist (3255)
Domestic/cleaning/ laundry/catering	Domestic/cleaning/ laundry/catering, Cleaning personnel (9112)
Manager or unit and administrative support	Health service manager (1342) and Clerical support workers (4412)
Management of medical devices	Biomedical Engineer (2149) Biomedical technician , physical and engineering science technician (3119)

2 *International Standard Classification of Occupations, http://www.ilo.org/public/english/bureau/stat/isco/docs/publication08.pdf*

Palliative care work occurs within a multidisciplinary team, and involves the following:

- Engagement with medical oncologists, radiotherapists and palliative care teams to use chemotherapy and radiotherapy with palliative intent
- Engagement with surgical teams to deal with intestinal obstruction, and other emergencies; insert PEG tubes
- Engagement with neurologists, anaesthetists and pain specialists for pain management such as nerve blocks and intrathecal procedures
- Engagement with urologists to insert or manage suprapubic catheters

7.3.2 Infrastructure

Layout distribution

The palliative care service should include the following rooms:

- treatment room for patients (private /semi private rooms)
- room for interdisciplinary meetings/family meetings
- family room with kitchen, dining room (quiet space)
- space for children to play
- double lockable cupboard with drawers and shelves for opioid storage and controlled medications
- rooms reserved for barrier nursing (HIV AIDS, MRSA, C Difficile)
- washing/bathing room (ideally a toilet and shower room for each patient)
- airborne infection isolation room(s) (if it is considered necessary by an infection control risk assessment).

The healthcare facility should have:

- a mortuary
- a prayer room with washing facilities (if not already in the facility add this space within the unit).

Electrical systems

The room utility requirements include enough electrical sockets and other services. Emergency electrical system should be considered in the treatment area for critical care devices and illumination. To ensure continuity of services, stable power supply and backup systems should be installed.

Heating, ventilation and air conditioning systems

If an airborne infection isolation room(s) is considered, it should comply with the architectural requirements and have adequate ventilation.

Communication systems

The following considerations should be taken into account:

- an intercom between patient rooms and nursing station
- a manually triggered alarm system allowing immediate notification of the staff
- internet access and telephone
- mobile phone access.

Special systems and other considerations

The list of the team members should be visible to visitors.

The area shall be adapted for disabled access

It is mandatory to provide open visiting access 24/7 for family members.

When and where allowed, pet therapy

7.3.3 Quality management

The safe storage of opioids, controlled medicines and other substances must be ensured to comply with country specific legislation and procedures.

Policies and procedures for infection control as well as for the reporting of risks, incidents and accidents to patients, visitors and staff must be put in place.

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IV.Implementation strategy

The lists presented in this document include a selection of medical devices of different categories (from single use devices to medical equipment and consumables) for selected interventions extracted from clinical guidelines addressing the cancer management continuum of care, including prevention, diagnosis, therapy and palliative care. The lists presented herein are nonexclusive, however serve as guidance for countries seeking to develop or implement a management policy/strategy for cancer specific medical devices.

It is of utmost importance to consider the critical interdependence of these technologies. Best outcomes in cancer cannot be achieved by investing in one set of technologies alone. Diagnostic methods must be combined with therapeutic capability in order to have meaningful impact.

This chapter includes a general implementation strategy and additional considerations to reach pragmatic decisions.

IV.I Approach for adapting the WHO list of priority medical devices for cancer management in each setting

As mentioned, it is important for each country to define an implementation plan that will take into account country-specific needs, epidemiological situation, and availability of infrastructure, related human resources and finances, and affordability to patients, among others.

These lists of priority medical devices for cancer management consider those devices best suited to the management of the priority health problems defined herein (breast, cervical, colorectal, lung, leukaemia, and prostate cancer), and the selected procedures/interventions for each clinical area. Therefore, it should be noted that in order to select them and be able to use these technologies at country level, further steps are required:

1. Perform a needs assessment of in-country resources for cancer management

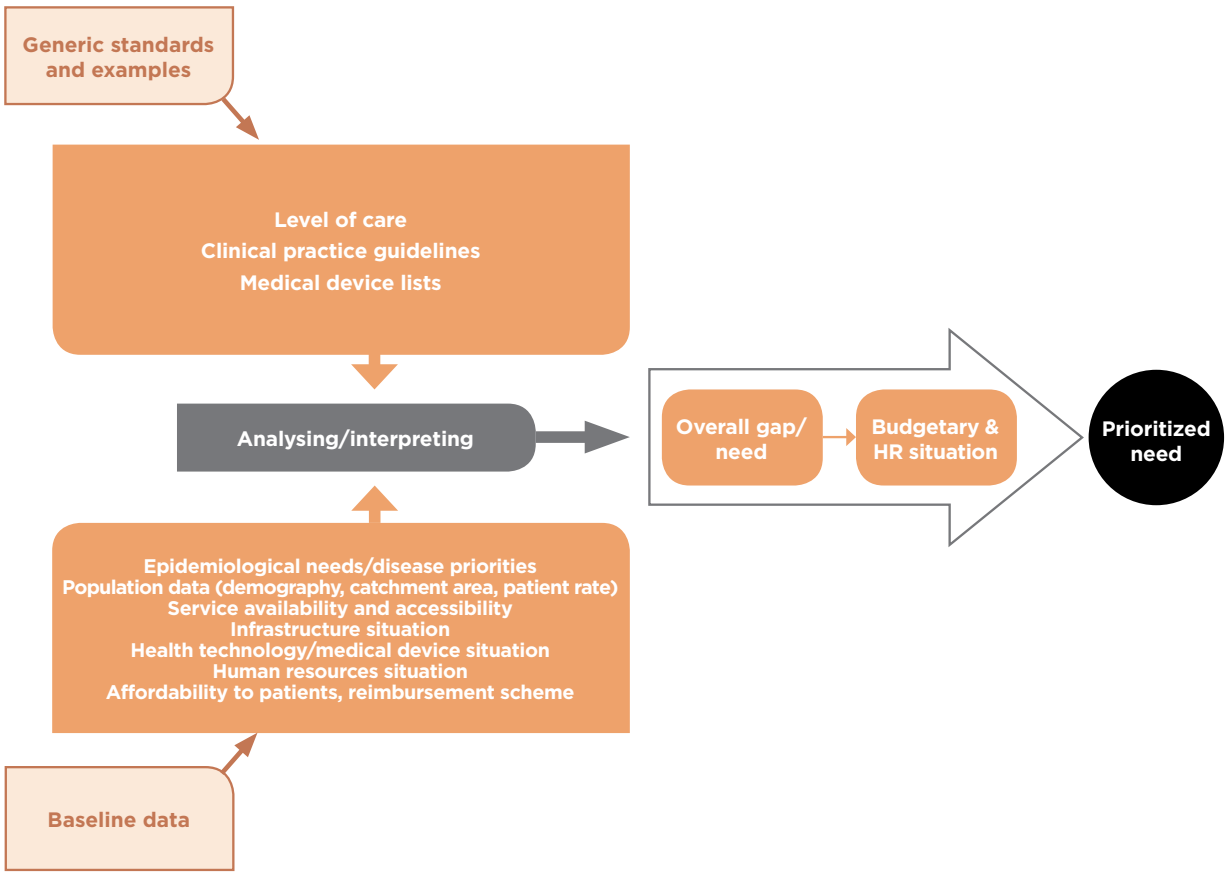

Fig. 11. General Needs Assessment Process (1)

a. Firstly consider National Health Plan and any available Cancer Control Programme priorities, strategies or objectives.
   i. Review country data, epidemiology and registries
   ii. Consider if indicators or evaluation criteria are already in place regarding resources and specifically medical devices.
b. Define the scope of the implementation plan: national, regional, only specialty hospital or all health facilities. Including: district hospitals, health centers and community health posts
   i. It is important that all the levels of care are included in the considerations of the implementation plan, from community health centres to specialized oncology hospitals, even if only one or many hospitals are being equipped
   ii. The network has to consider reference to higher levels of care.
c. Review the lists, unit by unit, with local specialists, and compare to your inventory or availability of technologies to manage cancer. Please note the devices that are general and can serve other diseases besides cancer and those specific only to cancer.
d. Compile information about resources available or not yet appropriate or sufficient on the following topics:
   i. Health facilities that could be used for cancer diagnosis or treatment in the scope of the study and related referral services
   ii. Medical devices available per clinical unit, particularly those specified in this document for:
      - Medical imaging
      - Nuclear medicine
      - Laboratory and pathology
      - Surgery
      - Radiotherapy
      - Systemic therapy
      - Palliative care and end of life care
   iii. Specialized human resources, particularly those mentioned in this document:
      - Biomedical Engineers/Equipment Technicians
      - Laboratory Technicians/Biomedical Laboratory Scientists
      - Medical Physicists
      - Oncologists
      - Oncological Nurses
      - Pathologists
      - Radiologists
      - Radiotherapists/Radiation Therapy Technologists
      - Radiographers
      - Surgical Oncologists
   iv. National treatment guidelines/protocols or care pathways
   v. Priority interventions if defined by an insurance package linked to universal health coverage and reimbursement schemes.
   vi. Target population
      - Type of procedures, for type of patients
      - Population distribution in the country
      - Catchment areas for diagnosis,
      - Support for patients transportation and stay in treatment centers.
   vii. Funding allocation
      1. Depending on the country or setting, this funding could be pre-established or will have to be calculated depending on the technology required and then search for approval.
      2. Funding to support the on-going interventions for diagnosis, treatment, monitoring and palliative care required.
      3. Consider other sponsorships and national cancer programmes funds allocation to support patients access and affordability.

2. Once the needs assessment is done and the gaps identified, select an appropriate methodology to prioritize and select which medical devices would be most needed considering some of the following aspects:

a. Target population

b. Type of cancer

c. Equity, gender and ethical issues, if applicable (i.e. Mammography)

d. Equipment complementary to other diseases

e. Available budget for:
   i. Infrastructure, to install equipment (e.g. bunkers for radiotherapy)
   ii. Capital equipment and its life cycle operation, maintenance and consumables
   iii. Procurement and supply of single use medical devices
   iv. Training of health care workers in safe and appropriate use
   v. Other medical devices, i.e., quality control and safety, complementary to the capital equipment.

f. Feasibility and organizational challenges, i.e., where to place the technology, where more resources are available or where most target population is based.

Most of these considerations are part of health technology assessment and health technology management studies, or certificate of need. Most of them should be done in a committee to make informed decisions based on evidence, when and wherever available.

3. If a technology is approved for incorporation into the health care system, the following must be considered and defined, usually within a process of health technology management handled by personnel with relevant technical expertise (i.e. biomedical engineer):

a. Regulatory clearance: The regulatory approval process of the specific technology performed by the national regulatory agency which can be nuclear, radiological in other Ministries or for medical devices in the Ministry of Health, these have to be in agreement and continuous collaboration.

b. Technical specifications that are generic and comply with standards to guarantee the technical quality of the device.

c. Bidding process:
   i. In the case of radiotherapy, nuclear medicine or other diagnostic imaging equipment, the mechanical guidelines of the infrastructure are to be considered
   ii. Bids should include extended warranty, training for users, installation and spare parts
   iii. Budget should include operating costs, including maintenance for the whole life cycle of technologies (around 10 years)

d. Government importation requirements

e. Transportation, insurance, taxes, customs, delivery and installation

f. Reception of the equipment, verification of installation, and training of the users/health care workers by the manufacturer

g. Supply chain of consumables

h. Verification of quality, safety and performance

i. Decommissioning and waste management procedures (2).

More guidance on each of the mentioned steps can be found in the following WHO publications:

Needs assessment for medical devices:
http://apps.who.int/iris/bitstream/10665/44562/1/9789241501385_eng.pdf

Procurement process resource guide:
http://apps.who.int/iris/bitstream/10665/44563/1/9789241501378_eng.pdf

Medical device donations: consideration for solicitation and provision:
http://apps.who.int/iris/bitstream/10665/44568/1/9789241501408_eng.pdf

Introduction to medical equipment inventory management:
http://apps.who.int/iris/bitstream/10665/44561/1/9789241501392_eng.pdf

Medical equipment maintenance programme overview:
http://apps.who.int/iris/bitstream/10665/44587/1/9789241501538_eng.pdf

Computerized maintenance management system:
http://apps.who.int/iris/bitstream/10665/44567/1/9789241501415_eng.pdf

Related WHO websites:

Topic	Website
Overview of Health technology management	http://www.who.int/medical_devices/management_use/en/
Technical specifications of medical devices	http://www.who.int/medical_devices/management_use/mde_tech_spec/en/
Donations of medical devices	http://www.who.int/medical_devices/management_use/manage_donations/
Priority medical devices	http://www.who.int/medical_devices/priority/en/

Further collaboration:

Besides the guidelines and documents mentioned in each of the chapters, additional support to incorporate technologies can be provided by international organizations, NGOs and professional organizations, some of which are listed below:

Type of organization	Entity	Information
UN organizations	Interagency Task force for NCD	http://www.who.int/ncds/un-task-force/en/
	IAEA	www.iaea.org
	IARC	http://www.who.int/ionizing_radiation/research/iarc/en/
	UNICEF	www.unicef.org
	UNOPS	www.unops.org
	WHO	http://www.who.int/medical_devices/en
NGOs in official relations with WHO	DITTA	http://globalditta.org/
	GMTA	http://www.globalmedicaltechnologyalliance.org
	HUMATEM	http://www.humatem.org
	HTAI	http://www.htai.org
	IAPO	https://www.iapo.org.uk
	IFBLS	http://www.ifbls.org
	IFCC	http://www.ifcc.org
	IFHE	https://www.ifhe.org
	IFMBE	http://2016.ifmbe.org/
	IOMP	http://www.iomp.org
	INCTR	http://www.inctr.org
	ISR	http://www.isradiology.org
	ISRRT	http://www.isrrt.org/
	IUA	http://www.uia.archi/en
	RAD AID	http://www.rad-aid.org
	WASPaLM	www.waspalm.org
	WFUMB	www.wfumb.org
NGOs related to cancer in official relations with WHO	ESMO	www.esmo.org
	UICC	www.uicc.org
Other important cancer organizations	AORTIC	www.aortic-africa.org
	ASCO	www.asco.org
	BHGI	www.bhgi.info
	NCCN	www.nccn.org
	NCI	www.cancer.gov
	SLACOM	www.slacom.org
Other networks	EuroScan	www.euroscangroup.com/

Note: Please see Acronyms and Abbreviations for full organization names

IV.II Future activities

The report here presented is a first step towards defining medical devices required for many diseases including cancer, but it has a limited scope and further work has to be done in the future, to support the best implementation in countries, in the following areas:

1. WHO guidelines on cancer management

Only the cervical cancer WHO guidelines are currently available and future work should encompass other types of cancers, considering guidelines already available in middle income countries. Guidelines usually describe medicines and pharmaceuticals required, but almost none specify the medical devices or the related human resources needed to perform the interventions, which would be useful to have in the future.

2. Prioritization

A methodology is needed to prioritize and select medical devices after the needs assessment considerations (integration with other methodologies such as the ones used for HTA). Most health technology assessment analyses are for specific high cost technologies or for innovative ones, but no studies are found on the total cost of radiotherapy units, palliative care units or pathology units in low or middle income countries, and this would be very helpful for those Member States that would like to have more information, especially considering feasibility, organizational issues, planning, etc.

The MCDA methodology used to developed the working tools in order to collect evidence and justification from experts for inclusion on the list can be leveraged by member states by including contextual criteria (such a size of population, country priorities) to prioritize devices based on their unique context.

3. Indicators, quantification

Future WHO work will need to be undertaken to define and recommend the following global, regional and local indicators:

- Number of pieces of equipment per inhabitant (e.g. radiotherapy system per million inhabitants)
- Size and type of equipment required depending on caseload and utilization rate (e.g. automatic versus manual equipment, multiparameter physiological monitors, etc.)
- Consumables (medical supplies) per inhabitants, or
- Consumables per treatment, or
- Consumables per hospital
- Further studies on country situations need to be conducted, especially for low and middle income countries to allow planning of resources and budget allocation.

4. Technical specifications for procurement

Technical specifications need to be developed, or if developed, placed in one single template which will be useful for the user, procurer, industry or donor agencies. Some of the UN agencies have their own, but they still need to be harmonized and widely disseminated to provide the manufacturers with the market needs so as to produce accordingly.

5. Appropriate affordable technologies

More research and development for affordable technologies for cancer management are required. Currently most technologies for cancer management are very expensive, complicated to use and require specialized human resources (for example, point of care diagnostics for cancer would be a major innovation to support early diagnosis).

a. Evidence and studies of the use of innovative technologies for cancer care in low resource settings, especially where there are no specialized human resources

b. Assessment of the technologies (e.g. measurement of health outcomes, problems of the use of the proposed technologies in different settings), as well as the cost of the packages of interventions when using the technologies proposed in this publication.

IV.III Concluding Remarks

Seventy percent of cancer cases occur in low- and middle-income countries. Much work is still needed in order to place the appropriate, good quality medical technology required to screen, diagnose, treat, monitor and palliate cancer disease worldwide, and to develop the human resource competencies of specialized oncology, pathology, nuclear medicine, radiation therapy, and other disciplines, particularly in low resource settings.

This publication was completed thanks to the very important collaboration from interdisciplinary experts around the world, as well as supportive NGO organizations and individuals committed to cancer care.

It is absolutely indispensable to consider the interdependence of these technologies. The outcomes in cancer cannot be achieved by investing in one set of technologies alone. Diagnostics must be combined with therapeutic capability to have meaningful impact and vice versa. It is therefore hoped that these lists of medical devices by clinical unit will assist policy makers, health care managers and technical experts, to define the needs of each setting.

Medical devices run the substantial risk of being unused due to technology misalignment to deployment settings (3). It is important to note that contextually relevant interventions and devices must be selected to improve resource allocation in each country, depending on the local needs and resources available. Financing models are an important topic that should be evaluated as well in order to deliver services within the health care systems.

The lists presented in this publication should be adapted and reviewed according to local epidemiology, national policies, regulatory frameworks, and available specialized health care workforce, infrastructure, budget, and organizational structures.

It is therefore important to consider innovation, regulatory approval of the technologies, and the health technology assessment process to enable informed decision making taking into consideration equity, social, clinical and economic aspects as well as health technology management aspects. Such informed decision making will ensure that the procurement, installation, training and safe use of technologies is done in the most effective way, ensuring the well-being of the patient.

The selection of the technologies required from the lists presented in this publication is just the first step of many to provide best care for cancer patients. These technologies require multidisciplinary expertise to implement.

More information will be available from WHO and other agencies to support selection, procurement and best use of these medical devices for all patients and specifically to target cancer management to those most in need.

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Glossary

Accessibility: refers to people's ability to obtain and appropriately use good-quality health technologies when they are needed.

Adverse event: any untoward medical occurrence in a subject whether it is device-related or not.

Affordability: in the context of this report it is defined as the extent to which the intended clients of a service can pay for it.

Appropriate(ness): refers to medical methods, procedures, techniques, and equipment that are scientifically valid, adapted to local needs, acceptable to both patient and health-care personnel, and that can be utilized and maintained with resources the community or country can afford.

Availability: when a medical device can be found on the medical device market.

Best practice: an examination of the methods by which optimal outcomes are achieved.

Care pathways: one mechanism of putting a protocol into operation. Care pathways determine locally agreed, multidisciplinary practice, based on guidelines and evidence (where available) for a specific patient group. They form all, or part of the clinical record, they document the care given, and they facilitate the evaluation of outcomes for quality improvement purposes.

Clinical evaluation: the assessment and analysis of clinical data pertaining to a medical device in order to verify the clinical safety and performance of the device.

Clinical evidence: the clinical data and the clinical evaluation report pertaining to a medical device.

Clinical guideline: systematically-developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. A clinical guideline is a tool to support clinical decision-making and it covers a specific clinical problem.

Consumables: liquids or supplies required for the use of the equipment but allowing only limited, or no, reuse.

Cost(s): (1) the value of the resources used in an activity; (2) the benefits sacrificed through a particular event or choice of action rather than another.

Cost-effectiveness analysis: analysis that involves the allocation of scarce resources among competing alternative uses, and the distribution of the products from these uses among the members of the society.

Effectiveness: a device is clinically effective when it produces the effect intended by the manufacturer relative to the medical condition for which it was created.

Efficacy: the ability to produce a desired or intended result, as linked to the performance of a device.

eHealth: the use of information and communication technologies (ICT) for health.

Equity in health: where people's needs guide the distribution of resources and opportunities for well-being.

Gamma camera: medical device that detects gamma rays emitted from a person's body after the administration of a radioactive compound, which produces images of the organ being investigated.

Gap: a disparity between health-care need and reality.

Global burden of disease (GBD): the WHO GBD project draws on a wide range of data sources to quantify global and regional effects of diseases, injuries and risk factors on population health.

Hazard: potential cause of harm.

Health care: any type of service provided by professionals or paraprofessionals with an impact on health status.

Health technology: the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life. The term is used interchangeably with "health-care technology" (1).

Health technologies for the purpose of this project include medical devices, assistive devices (e.g. hearing aids, wheelchairs), e-health solutions (e.g. telemedicine) and related health technologies— excluding clinical procedures, medicinal products, vaccines, biological therapeutic products, or tissue engineered medical products.

Health technology assessment (HTA): the systematic evaluation of properties, effects and/or impacts of healthcare technology. HTA defines a multidisciplinary activity that systematically examines technical performance, safety, clinical efficacy and effectiveness, cost, cost-effectiveness, organizational impact, social consequences, and legal and ethical aspects of the application of a health technology.

Hybrid imaging: A fusion of two imaging technologies (typically SPECT or PET merged with CT) into a single new form of imaging. It provides complementary functional and anatomical medical imaging information acquired from the two modalities without patient repositioning, in a workflow efficient manner.

Medical device: An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means.

Medical devices include: medical equipment, surgical instruments, in vitro diagnostics, solutions and disinfection substances, clothing, accessories, and single use devices.

1. **Medical equipment:**

Medical devices requiring calibration, maintenance, repair, user training, and decommissioning – activities usually managed by clinical engineers. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable, or other piece of medical equipment. Medical equipment excludes implantable, disposable or single-use medical devices.

2. **Quality assurance equipment**
   a. Equipment clinically relevant to carry out a calibration process needs to meet international standards considering calibration factors.
   b. Also called auxiliary dosimetry equipment e.g. ionization chambers, phantoms and chamber sleeves.

3. **Laboratory and pathology equipment**
   a. Equipment that like medical equipment, requires calibration, maintenance, repair, user training and decommissioning but is used in laboratory or pathology areas, generally is not in contact with the patient and in some cases the technical characteristics depend on the sample volume to process.

4. **Medical furniture:**
   a. Furniture used in medical settings (hospitals, or any other healthcare units) for medical purposes (e.g. cabinets to store medical equipment or medicines).

5. **Surgical instruments.**
   a. Tools or devices that perform functions such as cutting, dissecting, grasping, holding, retracting, or suturing. Most surgical instruments are made from stainless steel. Other metals, such as titanium, chromium, vanadium and molybdenum, are also used. (2).
   b. Often packed into sets related to the surgical procedures for which they are required.
   c. The sets can often be used for multiple procedures.

6. **Radiation protection devices**
   a. Protective devices which should be readily available for use when an ionizing source is exposed, this devices protect staff and patients from receiving unnecessary radiation doses from the primary beam and from scattered radiation; these devices should also be used to shield members of the public (3).

7. **Personal protective equipment and clothing.**
   a. Personal protective equipment, commonly referred to as “PPE”, is equipment worn by health care workers to minimize exposure to a variety of hazards. Examples of PPE include such items as gloves, foot and eye protection, protective hearing devices (earplugs, muffs) hard hats, respirators and/or full body suits.
   b. This category includes the equipment used to cover and protect the patient such as gowns and facemasks.

8. Single use devices/disposables/medical supply.

a. Generally used only on one patient for a single procedure (4).

b. Some devices listed in this category, depending on the manufacturer advice, could be reusable, reprocessed or resterilisable (if not indicated, do not reuse them) e.g. dressing devices, injection, tubes, catheter, drains, surgical sutures.

c. In this specific publication laboratory supplies are considered in this category.

9. Solutions and reagents

a. Any chemical, biological or immunological components, solutions or preparations intended to have a laboratory or clinical application such as collection, preparation, preservation of specimens, wash or patient infusion.

b. Includes special stains for pathology.

10. Other

a. Includes the reusable devices commonly used for the interventions, and considers that most of these devices shall be properly reprocessed according to manufacturer recommendations and national and international regulations.

b. Also includes glassware products and those devices whose primary intended use does not modify the structure or function of the body for some health purpose.

Medicine: any substance or combination of substances presented as having properties for treating or preventing disease in humans.

National Cancer Control Programme: a public health programme designed to reduce the number of cancer cases and deaths and improve quality of life of cancer patients, through the systematic and equitable implementation of evidence-based strategies for prevention, early detection, diagnosis, treatment, and palliation, making the best use of available resources.

Performance evaluation: review of the performance of a medical device based upon data already available, scientific literature and, where appropriate, laboratory, animal, or clinical investigations.

Physician preference items: implantable items that come in many brands from which a physician can choose, e.g. cardiac stents, pacemakers, orthopaedic implants.

PET scanner: A type of diagnostic imaging procedure which uses positron-emitting radioisotopes, usually labelled to chemical compounds (see radiopharmaceuticals), to produce a three-dimensional image of functional processes in the body.

Primary health care: 1) essential health care made accessible at a cost a country and community can afford, with methods that are practical, scientifically sound, and socially acceptable; 2) the first level contact with people taking action to improve health in a community.

Priority Medical Devices: Health technologies that respond to priority health interventions without considering any other assessment other than clinical appropriateness. These medical devices need to be of good quality, effective, appropriate, affordable, accessible, acceptable and need to be available to respond to the priority health needs of the setting and should be used safely by the health care worker or final user. These devices are defined by a health based approach; they respond to the need for a positive health outcome, considering first of all priority conditions diseases and disabilities, and the medical devices best suited to the management of those priority health problems.

The devices described in this publication are just generic names required for the specified clinical interventions. The particular medical devices that would be manufactured, selected, purchased or used would need to be assessed and evaluated locally by authorities to respond to local regulations, selected to be affordable by the health care system and the users must be trained for appropriate and safe use. Priority medical devices are options that further need to be assessed considering the diverging needs in high income countries or low and middle income countries or other particular contexts including appropriate infrastructure, design and specialized human resources, among other factors (5).

Protocols: local tools that set out specifically what should happen, when and by whom in the care process. They can be seen as the local definition of a particular care process derived from a more discretionary guideline. They are tools that assist in quality improvement and reducing inequalities. Protocols reflect local circumstances, and variation will be due to the differing types of local provision.

Post-market surveillance: proactive collection of information on medical devices carried out by the manufacturers after those devices have reached the market.

Public health: a social and political concept aimed at improving health, prolonging life and improving the quality of life among whole populations through health promotion, disease prevention, and other forms of health intervention.

Radiopharmaceuticals: are radionuclides or radionuclide-labelled chemical compounds that are mainly used for the diagnosis and, to a limited but growing extent, for the therapy of diseases.

Research and development (R&D): creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of humans, culture and society, and the use of this stock of knowledge to devise new items, applications, etc.

Risk: combination of the probability of occurrence of harm and the severity of that harm.

Secondary health care (see also primary/tertiary health care): specialized ambulatory medical services and commonplace hospital care (outpatient and inpatient services). Access is often via referral from primary health care services.

SPECT: An acronym that stands for single photon emission computed tomography, a nuclear medicine procedure in which a gamma camera rotates around the patient and takes pictures from many angles, which a computer then uses to form a tomographic (cross-sectional) image. The calculation process in SPECT is similar to that in CT (X-ray computed tomography) and in PET (positron emission tomography). It differentiates from PET in that it uses single-photon emitting radioisotopes, usually labelled to chemical compounds (see radiopharmaceuticals).

Telehealth: the use of electronic information and communication technologies to support long-distance clinical health care, patient and professional health-related education, public health, and health administration.

Telemedicine: the delivery of health care services through the use of information and communication technologies in a situation where the actors are not at the same location. The actors can either be two healthcare professionals (for example in teleradiology) or a health-care professional and a patient (for example in telemonitoring of patients with diabetes).

Tertiary health care (see also primary/secondary health care): refers to medical and related services of high complexity and usually high cost. Those referred from secondary care for diagnosis and treatment, which is not available in primary and secondary care. Tertiary care is generally only available at national or international referral centres.

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Annex 1. Clinical interventions

For all the clinical interventions in this publication, the following information is provided as an implementation reference to be adapted as needed by country settings.

Field	Definition
General Action	The stage within the continuum of care (prevention, diagnosis, treatment, follow-up and palliative care).
Steps/Actions/Options	The steps, the actions or the clinical options available.
Interventions identified from the recommendations	The medical and surgical procedures to provide.
Sequence (a, b, c, d)	The order in which the interventions are supposed to be performed.
Priority (I, II, III)	Priority interventions for cancer prevention and control, organized by general resource availability (I: low level of resources, II: medium level of resources, III: high level of resource). Level of prioritization are given as an example and must be contextualized according to country- or region-specific context.
Notes	Personal notes (free field).
When to perform it	Indication of special conditions in which the intervention should be performed.
Source	Reference of the information source.
Where to perform by level of care (CL, HC, DH, SH)	CL: Community level/ health post, HC: health centre, DH: district hospital, or first referral hospital, SH: for the purpose of this book is cancer hospital or other tertiary level hospital, teaching hospital or specialized hospital or specialized outpatient unit, like imaging or laboratory.

Annex table 1-1. Breast cancer

General action	Steps/Actions/ Options	Interventions identified from the recommendations	Sequence (a, b, c, d)	Priority (I, II, III)	Notes
Prevention	Physical examination (early diagnosis and screening)	Bimanual palpation of breast and locoregional lymph nodes	a	I	Clinical breast examination, a low-cost screening method, seems to be a promising approach for these settings and could be implemented when the necessary evidence from ongoing studies becomes available.
	Breast imaging (screening)	Mammography	b	II	WHO recommends organized, population-based mammography screening programmes for women aged 50-69 years only in well-resourced settings and only if the conditions for implementing an organized programme are met by the healthcare system, and if shared decision- making strategies are implemented so that women's decisions are consistent with their values and preferences. (WHO Position paper on mammographic screening)
		MRI of the breast	b	III	In combination with mammography for screening of certain groups of high-risk patients
Diagnosis	Physical examination	Bimanual palpation of breast and locoregional lymph nodes	a	I	-
	Blood testing	Complete blood count and blood chemistry tests (liver and renal function tests, alkaline phosphatase and calcium)	a	I	-
	Breast imaging	Mammography (bilateral)	a	I	-

Prevention
Diagnosis
Treatment
Follow up
Palliative care

General action	When to perform it	Source	Source	Source	Source
Prevention	There is uncertainty about the appropriate age groups for screening and the steps that should be taken by responsible authorities to commission and implement breast cancer screening programmes of appropriate quality (WHO).	WHO position paper on mammography screening (2014)	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	Early and locally advanced breast cancer. NICE clinical guideline 80 (2014)	-
		WHO position paper on mammography screening (2014)	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	Early and locally advanced breast cancer. NICE clinical guideline 80 (2014)	-
		-	-	-	NCCN. Breast Cancer Screening and Diagnosis. Version 1.2014
Diagnosis	-	-	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	Early and locally advanced breast cancer. NICE clinical guideline 80 (2014)	NCCN. Breast Cancer Screening and Diagnosis. Version 1.2014
	-	-	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	-	NCCN. Breast Cancer Screening and Diagnosis. Version 1.2014
	-	-	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	Early and locally advanced breast cancer. NICE clinical guideline 80 (2014)	NCCN. Breast Cancer Screening and Diagnosis. Version 1.2014

General action	Steps/Actions/ Options	Interventions identified from the recommendations	Sequence (a, b, c, d)	Priority (I, II, III)	Notes
Diagnosis		Breast ultrasound	b	I	-
		Ultrasound of regional lymph nodes	c	I	-
		MRI of the breast	b	III	-
	Biopsy	Ultrasound-guided core needle biopsy of primary tumour	a	I	-
		Stereotactic-guided core needle biopsy of primary tumour	a	I	-
		Core needle biopsy (manual) of primary tumour	a	I	Can consider manual biopsy of primary tumor when image-guided buipsy not available.
		Fine needle aspiration	a	I	FNA can be used in triple test of breast masses.
		Placement of tissue markers during biopsy (e.g. surgical clip, carbon)	b	II	
		Ultrasound guided biopsy of regional lymph nodes (fine needle aspiration or core biopsy)	b	I	-
	Pathological examination	Examination of primary tumour	a	I	-
		Biomarker analysis of surgical specimen	b	I	-
		Histological assessment of resection margins of surgical specimen	c	I	-
	Staging and risk assessment	Sentinel lymph node biopsy (SLNB)	a	II	Used for axillary staging when trained expertise and necessary devices available.
		Chest CT	a	II	Chest x-ray (CXR) can be considered for staging in low resource settings.
		Abdominal ultrasound	b	I	-

General action	When to perform it	Source	Source	Source	Source
Diagnosis	May be in combination with mammography.	-	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	Early and locally advanced breast cancer. NICE clinical guideline 80 (2014)	NCCN. Breast Cancer Screening and Diagnosis. Version 1.2014
	-	-	-	Early and locally advanced breast cancer. NICE clinical guideline 80 (2014)	-
	Not routinely recommended. May be considered in some cases and high-risk groups		BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	Early and locally advanced breast cancer. NICE clinical guideline 80 (2014)	NCCN. Breast Cancer Screening and Diagnosis. Version 1.2014
		-	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	Early and locally advanced breast cancer. NICE clinical guideline 80 (2014)	NCCN. Breast Cancer Screening and Diagnosis. Version 1.2014
		-	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	-	-
	If ultrasound- or stereotactic-guided biopsy cannot be performed.	-	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	-	-
	If core needle biopsy cannot be performed.	-	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	Early and locally advanced breast cancer. NICE clinical guideline 80 (2014)	NCCN. Breast Cancer Screening and Diagnosis. Version 1.2014
	If preoperative systemic therapy is planned.	-	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	-	NCCN. Breast Cancer Screening and Diagnosis. Version 1.2014
	If suspicious lymph nodes have been detected.	-	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	Early and locally advanced breast cancer. NICE clinical guideline 80 (2014)	NCCN. Breast Cancer Screening and Diagnosis. Version 1.2014
	-	-	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	-	NCCN. Breast Cancer. Version 3.2014
	-	-	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	-	NCCN. Breast Cancer. Version 3.2014
	-	-	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	-	NCCN. Breast Cancer. Version 3.2014
	-	-	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	Early and locally advanced breast cancer. NICE clinical guideline 80 (2014)	NCCN. Breast Cancer. Version 3.2014
	-	-	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	-	-
	When CT and MRI are not available.	-	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	-	NCCN. Breast Cancer. Version 3.2014

General action	Steps/Actions/ Options	Interventions identified from the recommendations	Sequence (a, b, c, d)	Priority (I, II, III)	Notes
Diagnosis		CT scan (whole body)	c	II	Staging with CT scan of chest and abdomen done according to symptoms and clinical stage.
		Bone scan (bone scintigraphy)	d	II	X-ray of symptomatic bone sites can be considered in low-resourced settings.
		MRI scan	e	III	-
		Specimen radiography	f	I	Specimen radiograph used to confirm appropriate resection in settings where lumpectomy performed and lesion identifiable or localized on mammogram.
		PET/CT	g	III	-
		SPECT with Technetium (99mTc) sestamibi	h	III	-
Treatment		Mastectomy	a	I	-
	Surgery	Breast-conservation surgery (lumpectomy)	a	I	Lumpectomy can be considered when radiotherapy is generally available for post-lumpectomy radiotherapy.
		Breast reconstruction	b	I	Breast reconstruction can be considered using a variety of techniques with differing levels of complexity and resource requirements.
	Radiation therapy	Postoperative radiation therapy	a	I	-
	Adjuvant systemic treatment	Chemotherapy	a	I	-
		Endocrine therapy	a	I	-
		Biological therapy	a	I	Biological or targeted therapies can be considered according to WHO List of Essential Medicines.

General action	When to perform it	Source	Source	Source	Source
Diagnosis	-	-	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	Advanced breast cancer. NICE clinical guideline 81 (2014)	NCCN. Breast Cancer. Version 3.2014
	-	-	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	Advanced breast cancer. NICE clinical guideline 81 (2014)	NCCN. Breast Cancer. Version 3.2014
	-	-	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	Advanced breast cancer. NICE clinical guideline 81 (2014)	NCCN. Breast Cancer. Version 3.2014
	-	-	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	-	NCCN. Breast Cancer. Version 3.2014
	Assessment with fluorodeoxyglucose (FDG) is considered optional (NCCN).	-	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	Advanced breast cancer. NICE clinical guideline 81 (2014)	NCCN. Breast Cancer. Version 3.2014
	-	-	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	-	-
Treatment	-	-	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	Early and locally advanced breast cancer. NICE clinical guideline 80 (2014)	NCCN. Breast Cancer. Version 3.2014
	-	-	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	Early and locally advanced breast cancer. NICE clinical guideline 80 (2014)	NCCN. Breast Cancer. Version 3.2014
	Should be proposed (immediate or delayed) after mastectomy.	-	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	Early and locally advanced breast cancer. NICE clinical guideline 80 (2014)	NCCN. Breast Cancer. Version 3.2014
	Recommended after breast-conservation surgery. Recommended after mastectomy if high-risk of local recurrence.	-	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	Early and locally advanced breast cancer. NICE clinical guideline 80 (2014)	NCCN. Breast Cancer. Version 3.2014
	Depending on the intrinsic phenotype determined by ER and HER2 assessment.	-	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	Early and locally advanced breast cancer. NICE clinical guideline 80 (2014)	NCCN. Breast Cancer. Version 3.2014
	Depending on the intrinsic phenotype determined by ER and HER2 assessment.	-	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	Early and locally advanced breast cancer. NICE clinical guideline 80 (2014)	NCCN. Breast Cancer. Version 3.2014
	Depending on the intrinsic phenotype determined by ER and HER2 assessment.	-	BHGI Guidelines for International Breast Health and Cancer Control–Implementation. Cancer 2008;113(S8): i–ix, 2215–2371	Early and locally advanced breast cancer. NICE clinical guideline 80 (2014)	NCCN. Breast Cancer. Version 3.2014

General action	Steps/Actions/ Options	Interventions identified from the recommendations	Sequence (a, b, c, d)	Priority (I, II, III)	Notes
Follow up	Imaging	Mammography	a	I	-
		MRI scan	b	III	-
		Bone density scan (bone densitometry)	b	I	-
		Chest CT	b	III	CT scan can be considered according to symptoms.
		Abdominal and/or pelvic CT	b	III	CT scan can be considered according to symptoms.
		Brain MRI	b	III	Brain MRI can be considered according to symptoms and resource availability.
	Blood testing	Complete blood count and blood chemistry tests (liver and renal function tests, alkaline phosphatase and calcium)	b	I	-
	Physical examination	Gynaecological examination	b	I	-
Palliative care	Palliative radiotherapy	Palliative breast irradiation	a	I	-
	Palliative systemic therapy	Biphosphonates therapy	a	I	-

General action	When to perform it	Source	Source	Source	Source
Follow up	-	-	-	Early and locally advanced breast cancer. NICE clinical guideline 80 (2014)	NCCN. Breast Cancer. Version 3.2014
	In case of recurrent disease.	-	-	-	NCCN. Breast Cancer. Version 3.2014
	Recommended for patients on aromatase inhibitor therapy.	-	-	Early and locally advanced breast cancer. NICE clinical guideline 80 (2014)	NCCN. Breast Cancer. Version 3.2014
	In case of recurrent disease for assessment of metastasis.	-	-	-	NCCN. Breast Cancer. Version 3.2014
	In case of recurrent disease for assessment of metastasis.	-	-	-	NCCN. Breast Cancer. Version 3.2014
	In case of recurrent disease for assessment of metastasis.	-	-	-	NCCN. Breast Cancer. Version 3.2014
	In case of recurrent disease.	-	-	-	NCCN. Breast Cancer. Version 3.2014
	For patients on tamoxifen.	-	-	-	NCCN. Breast Cancer. Version 3.2014
Palliative care	-	-	-	-	NCCN. Breast Cancer. Version 3.2014
	-	-	-	-	NCCN. Breast Cancer. Version 3.2014

Annex table 1-2. Cervical cancer

General action	Steps/actions/ options	Interventions identified from the recommendations	Se-quence	Priority	Notes
Prevention	Preventive immunization	Human papillomavirus vaccination (HPV Vaccination)	a	I	WHO has reiterated its recommendation that HPV vaccines should be included in national immunization programmes, provided that: prevention of cervical cancer and/or other HPV-related diseases constitutes a public health priority; vaccine introduction is programmatically feasible; sustainable financing can be secured; and the cost-effectiveness of vaccination strategies in the country or region is considered.
	Management of information and education	Provision of barrier methods	a	I	
	Management of information and education	Male circumcision	a	I	
	Screening of pre-cancerous lesions	Speculum, vaginal examinations	a	I	
	Screening of pre-cancerous lesions	Human papillomavirus test (HPV Test)	a	I	Decisions on which screening and treatment approach to use in a particular country or health-care facility should be based on a variety of factors, including benefits and harms, potential for women to be lost to follow-up, cost and availability of the necessary equipment and human resources.
	Screening of precancerous lesions	Visual Inspection with Acetic Acid (VIA)Test	b	I	

General action	When to perform it	Source	Support Services	Medical devices (without classification)	CL	HC	DH	SH
Prevention		World Health Organization (WHO). Human papillomavirus vaccines: WHO position paper, October 2014.				x		
		World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2017			x	x		
		World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2017						
		World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2017				x		
	A strategy of screening with HPV and treat with cryotherapy (Or leep when not eligible with cryotherapy) over a strategy of screen with VIA and over a strategy of screen with cytology followed by colposcopy (with or without biopsy) and over a strategy of screen with and HPV test followed by colposcopy and treat with cryotherapy (Or leep when not eligible with cryotherapy) or either a strategy of HPV Test followed by VIA and treat with cryotherapy (Or leep when not eligible with cryotherapy)	World Health Organization (WHO). WHO guidelines for screening and treatment of precancerous lesions for cervical cancer prevention. Geneva: WHO; 2013 World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2014	Histology service	Disposable or high level disinfected examination gloves, a small brush or soft swab swabs and a labelled vessel with preservative solution, Hystopathological analysis		x	x	
	In resource constrained settings where screening with an HPV test is not feasible and over a strategy of screen with cytology followed by colposcopy (with or without biopsy) and treat with cryotherapy (Or leep when not eligible with cryotherapy)	World Health Organization (WHO). WHO guidelines for screening and treatment of precancerous lesions for cervical cancer prevention. Geneva: WHO; 2013		A bright light source to examine the cervix, an examination table covered by clean paper or cloth, a speculum, high-level disinfected (need not be sterile), disposable or high-level disinfected examination gloves (need not be sterile, 3-5% acetic acid solution, large cotton swab		x		

General action	Steps/actions/ options	Interventions identified from the recommendations	Se-quence	Priority	Notes
Prevention	Screening of precancerous lesions	Screen with cytology (Pap test)	b	I	
	Screening of precancerous lesions	Screen with cytology (Liquid Based Cytology LBC)	b	I	
	Screening of precancerous lesions	Colposcopy (with or without biopsy)	b	I	
	Screening of pre-cancerous lesions	Screen with cytology followed by colposcopy	b	I	
	Screening of pre-cancerous lesions	HPV followed by colposcopy	b	I	
	Screening of pre-cancerous lesions	HPV followed by VIA	b	I	

General action	When to perform it	Source	Support Services	Medical devices (without classification)	CL	HC	DH	SH
Prevention		World Health Organization (WHO). WHO guidelines for screening and treatment of precancerous lesions for cervical cancer prevention. Geneva: WHO; 2013	Cytology services	A bright light source to examine the cervix, an examination table covered by clean paper or cloth, a speculum, high-level disinfected (need not be sterile), disposable or high-level disinfected examination gloves (need not be sterile, An extended-tip wooden or plastic spatula or a brush for sampling (see Figure PS5.6.1), a glass slide with frosted edge, and fixative spray or solution, a small container of warm water to lubricate and warm the speculum, 0.5% chlorine solution for decontaminating instruments and gloves, the use of a specially design devices that sample the area so the transformation zone is recommended, wooden or plastic spatula, moistened cotton swab or a brush -type endocervical sampler device (cytobrush)		x	x	
		World Health Organization (WHO). WHO guidelines for screening and treatment of precancerous lesions for cervical cancer prevention. Geneva: WHO; 2013	Cytology services	A bright light source to examine the cervix, an examination table covered by clean paper or cloth, a speculum, high-level disinfected (need not be sterile), disposable or high-level disinfected examination gloves (need not be sterile A tube containing a special preservative solution, a small container of warm water to lubricate and warm the speculum, 0.5% chlorine solution for decontaminating instruments and gloves.		x	x	
		World Health Organization (WHO). WHO guidelines for screening and treatment of precancerous lesions for cervical cancer prevention. Geneva: WHO; 2013	Cytology services	A bright light source to examine the cervix, an examination table covered by clean paper or cloth, a speculum, high-level disinfected (need not be sterile), disposable or high-level disinfected examination gloves (need not be sterile, Colposcope, all necessary supplies for infection prevention because biopsies and/or endocervical curettage (ECC) are usually performed during colposcopy, you may also need 3–5% acetic acid; Monsel's paste (see Annex 13); punch biopsy forceps; endocervical curette; ring forceps; cotton swabs; specimen bottles with 10% formalin			x	
		World Health Organization (WHO). WHO guidelines for screening and treatment of precancerous lesions for cervical cancer prevention. Geneva: WHO; 2013	Cytology services				x	
		World Health Organization (WHO). WHO guidelines for screening and treatment of precancerous lesions for cervical cancer prevention. Geneva: WHO; 2013	Cytology services				x	
		World Health Organization (WHO). WHO guidelines for screening and treatment of precancerous lesions for cervical cancer prevention. Geneva: WHO; 2013				x		

General action	Steps/actions/ options	Interventions identified from the recommendations	Se-quence	Priority	Notes
Prevention	Treatment of pre-cancerous lesions	Cryotherapy	c	I	
	Treatment of pre-cancerous lesions	Large loop excision of transformation zone (LEEP/LLETZ)	c	I	
	Treatment of pre-cancerous lesions	Cold knife conization (CKC)	c	I	
Diagnosis	Definitive diagnosis of invasive cervical cancer in second care level	Pelvic examinations	a	I	
	Definitive diagnosis of invasive cervical cancer in second care level	Pregnancy test	b	I	
	Definitive diagnosis of invasive cervical cancer in second care level	HIV Test	c	I	
	Definitive diagnosis of invasive cervical cancer in second care level	Biopsy	d	I	
	Definitive diagnosis of invasive cervical cancer in second care level	Endocervical curettage ECC	d	I	

General action	When to perform it	Source	Support Services	Medical devices (without classification)	CL	HC	DH	SH
Prevention		World Health Organization (WHO). WHO guidelines for screening and treatment of precancerous lesions for cervical cancer prevention. Geneva: WHO; 2013	Histology service	Speculum, high-level disinfected (need not be sterile); disposable or high-level disinfected examination gloves (need not be sterile); cotton swabs for wiping the cervix; normal saline solution; colposcope, if used in the particular venue; cryosurgery unit with adequate gas supply (carbon dioxide or nitrous oxide) and with the equipment components: 1)Probe or Cryoprobe 2) Trigger, 3)Handle grip (fibreglass), 4) Yoke, 5) Inlet of gas from cylinder 6) Tightening knob, 7) Pressure gauge showing cylinder pressure 8) Silencer (outlet) 9) Gas-conveying tube 10) Probe tip		x	x	
		World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013	Histology service	Reliable power supply, electrosurgical generator and electrode handle, colposcope, non-conducting speculum, preferably with side retractors, return electrode, wire electrodes of several sizes (see Figure PS5.11.1), coagulating/ball electrode, smoke evacuator, forceps, local anaesthetic: 1% or 2% lidocaine, with or without 1:100 000 epinephrin, 5-ml syringes with long 27-gauge needles, bottles with normal saline and with 5% acetic acid, Monsel's paste (see Annex 13), large swabs, needles and suture material, specimen containers with 10% formalin, Different types and sizes of electrodes (a) ball electrode, (b) square loop electrode, (c) semicircular loop electrode,			x	
	Recommends against their use in a screen and treat strategy	World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013	Histology service				x	
Diagnosis		World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013				x	x	
	If appropriate for the patient before taking a biopsy	World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013	Clinical Laboratory				x	x
	If appropriate for the patient before taking a biopsy	World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013	Clinical Laboratory	HIV Test			x	x
		World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013	Histology service				x	x
		World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013					x	x

General action	Steps/actions/ options	Interventions identified from the recommendations	Se-quence	Priority	Notes
Diagnosis	Determine the cervical cancer staging	Speculum, vaginal and rectal examinations	a	I	
	Determine the cervical cancer staging	Intravenous pyelogram (IVP)	b	I	Abdominal ultrasound can be used as an alternate staging investigation according to resource and expertise availability.
	Determine the cervical cancer staging	Abdominal Ultrasound	b	I	
	Determine the cervical cancer staging	Cystoscopy (Test to examine the urinary system)	c	I	Used as a supplement for staging according to symptoms, resource availability and expertise.

General action	When to perform it	Source	Support Services	Medical devices (without classification)	CL	HC	DH	SH
Diagnosis	Mandatory for staging May be the only available tools for staging, based on this limited number of tests an experienced specialist will know the location of the tumour, whether it is growing outwards or inwards from the tissues of the cervix, its size, its extension to the tissues next to the uterus and the ligaments holding the uterus in place as well as to the pelvic walls. Involvement of the urinary bladder and rectum can also be determined. At most tertiary level facilities more advanced tests are also available and will be used to obtain a more detailed description of the disease which will assist in determining the best treatments available for the patient.	World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013					x	x
	Mandatory for staging. At many centres CT or MR is now substituted for this evaluation.	World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013					x	x
	Mandatory for staging, it can be used because it says Intravenous pyelogram or abdominal ultrasound.	World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013		Ultrasound			x	x
	Supplementary for staging FIGO May be the only available tools for staging, based on this limited number of tests an experienced specialist will know the location of the tumour, whether it is growing outwards or inwards from the tissues of the cervix, its size, its extension to the tissues next to the uterus and the ligaments holding the uterus in place as well as to the pelvic walls. Involvement of the urinary bladder and rectum can also be determined. At most tertiary level facilities more advanced tests are also available and will be used to obtain a more detailed description of the disease which will assist in determining the best treatments available for the patient.	World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013		Cystoscopy			x	x

General action	Steps/actions/ options	Interventions identified from the recommendations	Se-quence	Priority	Notes
Diagnosis	Determine the cervical cancer staging	Proctoscopy (Test to examine the intestinal system)	d	I	Used as a supplement for staging according to symptoms, resource availability and expertise.
	Determine the cervical cancer staging	Endocervical curettage or smear ECC	e	I	
	Determine the cervical cancer staging	Chest X-Ray	f	I	
	Determine the cervical cancer staging	Skeletal X-Ray or bone scan (if bone pain)	g	I	Used as a supplement for staging according to symptoms, resource availability and expertise.
	Determine the cervical cancer staging	Blood test (including full blood count and haemoglobin levels) in addition to Pregnancy and HIV tests when appropriate.	h	I	The specialists at the hospital may conduct additional tests to further investigate the extent of the cancer.

General action	When to perform it	Source	Support Services	Medical devices (without classification)	CL	HC	DH	SH
Diagnosis	Supplementary for staging FIGO May be the only available tools for staging, based on this limited number of tests an experienced specialist will know the location of the tumour, whether it is growing outwards or inwards from the tissues of the cervix, its size, its extension to the tissues next to the uterus and the ligaments holding the uterus in place as well as to the pelvic walls. Involvement of the urinary bladder and rectum can also be determined. At most tertiary level facilities more advanced tests are also available and will be used to obtain a more detailed description of the disease which will assist in determining the best treatments available for the patient.	World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013		Proctoscopy			x	x
	Supplementary for staging FIGO	World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013					x	x
	Supplementary for staging FIGO	World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013		X-Ray System			x	x
	Supplementary for staging FIGO May be the only available tools for staging, based on this limited number of tests an experienced specialist will know the location of the tumour, whether it is growing outwards or inwards from the tissues of the cervix, its size, its extension to the tissues next to the uterus and the ligaments holding the uterus in place as well as to the pelvic walls. Involvement of the urinary bladder and rectum can also be determined. At most tertiary level facilities more advanced tests are also available and will be used to obtain a more detailed description of the disease which will assist in determining the best treatments available for the patient.	World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013		X-Ray or bone scan			x	x
		World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013	Clinical Laboratory				x	x

General action	Steps/actions/ options	Interventions identified from the recommendations	Se-quence	Priority	Notes
Diagnosis	Determine the cervical cancer staging	Kidney and liver function tests;	a	I	The specialists at the hospital may conduct additional tests to further investigate the extent of the cancer.
	Determine the cervical cancer staging and follow up	CT	a	II	Used for staging according to symptoms, resource availability and expertise. Useful to evaluate the tumour size, correlation with anatomic structures, metastases and nodal involvement.
	Determine the cervical cancer staging and follow up	Nuclear Magnetic Resonance	a	II	Gives high resolution of soft tissues particularly for the cervix, parametrial invasion, bladder or rectal invasion, ureteral obstruction, lymph node enlargement.
	Determine the cervical cancer staging and follow up	PET/CT	a	III	Allows for increased sensitivity in assessing lymphatic invasion.
Treatment	Treatment with Surgery (appropriate to the stage , based on the diagnostic)	Pelvic lymphadenectomy	a	I	
	Treatment with Surgery (appropriate to the stage, based on the diagnostic)	Cone Biopsy	a	I	
	Treatment with Surgery (appropriate to the stage, based on the diagnostic)	Simple Hysterectomy	a	I	
	Treatment with Surgery (appropriate to the stage, based on the diagnostic)	Radical Hysterectomy	a	I	
	Treatment with Surgery (appropriate to the stage, based on the diagnostic)	Salvage Surgery	a	I	

General action	When to perform it	Source	Support Services	Medical devices (without classification)	CL	HC	DH	SH
Diagnosis		World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013					x	x
	Though not part of the clinical staging, evaluation for regional or distant metastases using CT, MR or PET/CT may help guide treatment planning. Routine imaging is not recommended for patients who have completed primary therapy.	World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013	Imaging Services				x	x
		World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013	Imaging Services					x
		World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013	Imaging Services					x
Treatment		World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013	Surgery					x
	For Microinvasive cancers (those that are entirely contained within the cervical epithelium) can be treated with cone biopsy, particularly if retaining fertility is an issue.	World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013	Surgery					x
	Indicated for the treatment of early microinvasive cervical cancers in postmenopausal women and younger women who are not interested in preserving fertility.	World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013	Surgery					x
		World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013	Surgery					x
	When the patient has had primary surgery, but microscopic examination of the removed tissue shows that the margin of normal tissue around the cancer is too thin or when the patient has undergone radiotherapy and/or chemotherapy, but early recurrences or incomplete destruction of the cancer are noted on follow-up.	World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013	Surgery					x

General action	Steps/actions/ options	Interventions identified from the recommendations	Se-quence	Priority	Notes
Treatment	Treatment with Radiation (appropriate to the stage, based on the diagnostic)	External-beam radiotherapy, or tele-therapy.	a	I	
	Treatment with Radiation (appropriate to the stage, based on the diagnostic)	High-dose-rate (HDR) brachytherapy	a	I	
	Treatment with Radiation (appropriate to the stage, based on the diagnostic)	Radiation as adjunctive therapy	a	I	
	Planning Radiotherapy	Computerized tomography (CT) scan	a	I	CT scan or MRI of the abdomen and pelvis (to help plan radiotherapy); however, treatment can be planned in the absence of these procedures if they are not available, affordable or feasible.
	Planning Radiotherapy	Magnetic resonance imaging (MRI) of the abdomen and pelvis	a	I	CT scan or MRI of the abdomen and pelvis (to help plan radiotherapy); however, treatment can be planned in the absence of these procedures if they are not available, affordable or feasible.
	Treatment with Chemotherapy (appropriate to the stage , based on the diagnostic)	Chemotherapy	a	I	
	Treatment with Chemotherapy (appropriate to the stage, based on the diagnostic)	Chemotherapy combined with radio-therapy	a	I	
	Treatment with Chemotherapy (appropriate to the stage, based on the diagnostic)	Chemotherapy combined with surgery	a	I	
	Combined Treat-ments	Teletherapy plus brachytherapy	a	I	

General action	When to perform it	Source	Support Services	Medical devices (without classification)	CL	HC	DH	SH
Treatment	For women with cancer at stage IIA2 or greater. It may be offered to women with cancers greater than 4 cm in diameter confined to the cervix, and for cancers that have spread beyond the cervix. Primary radiotherapy intended to cure earlier cancers.	World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013	Radiotherapy					x
	For women with cancer at stage IIA2 or greater. It may be offered to women with cancers greater than 4 cm in diameter confined to the cervix, and for cancers that have spread beyond the cervix. Primary radiotherapy intended to cure earlier cancers.	World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013	Radiotherapy					x
		World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013	Radiotherapy					x
		World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013	Imaging Services					x
	CT or better yet magnetic resonance imaging (MRI) of the abdomen and pelvis (to help plan radiotherapy); however treatment can be planned in the absence of these procedures if they are not available, affordable or feasible.	World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013	Imaging Services					x
	Chemotherapy is rarely used alone as the primary treatment for cervical cancer; rather; it is used in combination with radiotherapy and less often with surgery.	World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013	Chemotherapy Services					x
	Chemotherapy is used first in women with very large and bulky tumours, to reduce the cancer size, and the followed by radiotherapy. Treatment is done in this sequence because cancer is shown to respond better to radiation when tumour is less bulky.	World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013	Chemotherapy Services and Radiotherapy					x
		World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013	Chemotherapy Services and Surgery					x
		World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013	Radiotherapy Services					x

General action	Steps/actions/ options	Interventions identified from the recommendations	Se-quence	Priority	Notes
Follow up	Special Managing cervical cancer in women living with HIV	Baseline CD4 count test	a	I	
	Follow up care	Speculum, vaginal and rectal examinations	a	I	
		Full examination, including general systems and abdominal examination plus palpation of lymph nodes, with particular attention to the neck and groin;	a	I	
		Cytological smear of the vaginal vault for women	a	I	
		Blood test (including full blood count and haemoglobin levels)	a	I	
Palliative Care	Palliative care	Palliative surgery	a	I	Is sometimes done in advanced cancer to relieve obstruction of the bowel, or to treat fistulae (abnormal channels between the vagina and the urinary organs or rectum) that result from radiation or extension of the primary disease.
		Radiation as palliative therapy	a	I	
		Chemotherapy as palliative care	a	I	
		Nonmedical pain management (massage, acupuncture)	a	I	
		Home-based management of vaginal problems	a	I	
		Treatment of cervical infections and pelvic inflammatory disease (PID)	a	I	

General action	When to perform it	Source	Support Services	Medical devices (without classification)	CL	HC	DH	SH
Follow up		World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013	Clinical Laboratory					x
		World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013				x	x	x
		World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013				x	x	x
	Who have only been treated with surgery	World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013	Histology service				x	x
		World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013	Clinical Laboratory				x	x
Palliative Care		World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013	Surgery Services					x
		World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013	Radiotherapy Services					x
	Palliative chemotherapy is sometimes used, after careful consideration of the expected benefits versus the adverse side effects, to relieve symptoms in women with widespread metastases to liver, lung and bone.	World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013	Chemotherapy services					x
		World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013				x	x	
		World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013			x	x		
		World Health Organization (WHO). Comprehensive Cervical Cancer Control. A guide to essential practice Geneva: WHO; 2013					x	x

Annex table 1-3. Colorectal cancer

General action	Steps/Actions/ Options	Interventions identified from the recommendations	Sequence (a, b, c, d)	Priority (I, II, III)	Notes
Prevention	Dietary modification	Dietary counselling	a	I	Increasing dietary fibre and reducing red and processed meat consumption (NCCN) and alcoholic drinks as well as regular physical exercise for colon cancer prevention (EURECCA)
Diagnosis	Stool-based testing (early diagnosis and screening)	Faecal immunochemical testing (FIT)	a	II	Colon + Rectal. WHO-IARC has not developed official recommendations for colorectal cancer screening at this time.
		Guaiac faecal occult blood test (gFOBT)	a	II	Colon + Rectal. WHO-IARC has not developed official recommendations for colorectal cancer screening at this time.
	Endoscopy (screening)	Colonoscopy	a	II	Colon + Rectal. WHO-IARC has not developed official recommendations for colorectal cancer screening at this time.
		Flexible sigmoidoscopy	a	III	Colon + Rectal. WHO-IARC has not developed official recommendations for colorectal cancer screening at this time.
	Physical examination	Digital rectal examination (just if rectal cancer is suspected) and examination of abdomen, liver and lymph nodes.	a	I	Colon + Rectal
	Endoscopy (early diagnosis)	Colonoscopy	a	I	Colon + Rectal
		Flexible sigmoidoscopy	a	I	Colon + Rectal
		Rectoscopy	a	I	Rectal
	Colorectal imaging	Barium enema	b	II	Colon + Rectal
		CT colonography (early diagnosis or screening)	a	II	Colon + Rectal. WHO-IARC has not developed official recommendations for colorectal cancer screening at this time.

General action	When to perform it	Source	Source	Source
Prevention	-	-	NCCN. Colon Cancer. Version 2.2015 NCCN. Rectal Cancer. Version 2.2015	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.
Diagnosis	As a second choice according to NCCN. No clear indications from EURECCA.	-	NCCN. Colorectal Cancer Screening. Version 1.2014	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.
	As a second choice according to NCCN. No clear indications from EURECCA.	-	NCCN. Colorectal Cancer Screening. Version 1.2014	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.
	As a first choice according to NCCN. No clear indications from EURECCA.	-	NCCN. Colorectal Cancer Screening. Version 1.2014	-
	As a third choice according to NCCN. No clear indications from EURECCA.	-	NCCN. Colorectal Cancer Screening. Version 1.2014	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.
	-	-	NCCN. Colon Cancer. Version 2.2015 NCCN. Rectal Cancer. Version 2.2015	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.
	For patients without major comorbidity	Colorectal cancer. NICE clinical guideline 131 (2014)	NCCN. Colon Cancer. Version 2.2015 NCCN. Rectal Cancer. Version 2.2015	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.
	For patients with major comorbidity followed by barium enema	Colorectal cancer. NICE clinical guideline 131 (2014)	-	-
	-	-	-	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.
	After flexible sigmoidoscopy for patients with major comorbidity (NICE) As a third choice for colon cancer when colonoscopy is not possible or contraindicated and CT colonography is not available (EURECCA)	Colorectal cancer. NICE clinical guideline 131 (2014)	-	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.
	If the local radiology service can demonstrate competency in this technique. Suspicious lesions need to be confirmed by colonoscopy with biopsy (NICE) As a second choice colon cancer diagnostic test for patients with incomplete colonoscopy (EURECCA)	Colorectal cancer. NICE clinical guideline 131 (2014)	-	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.

General action	Steps/Actions/ Options	Interventions identified from the recommendations	Sequence (a, b, c, d)	Priority (I, II, III)	Notes
Diagnosis	Biopsy	Endoscopic biopsy	a	I	Colon + Rectal
	Pathological examination	Examination of biopsy specimen	b	I	Colon + Rectal
	Staging and risk assessment	Complete blood count and blood chemistry tests (liver and renal function tests)	a	I	Colon + Rectal
		Carcinoembryonic antigen (CEA) test	a	I	Colon + Rectal
		CT scan of chest, abdomen and pelvis	a	I	Colon + Rectal
		X-ay of the chest	a	I	X-ray of the chest and ultrasound of the liver can be used an alternate staging test in settings where CT scan is not available.I
		Ultrasonography of the liver	b	I	Ultrasound of the liver and x-ray of the chest can be used an alternate staging test in settings where CT scan is not available.
		MRI scan	a	II	Rectal
		Endoscopic rectal ultrasound (ERUS)	a	II	Rectal

General action	When to perform it	Source	Source	Source
Diagnosis	To perform histological analysis	Colorectal cancer. NICE clinical guideline 131 (2014)	NCCN. Colon Cancer. Version 2.2015 NCCN. Rectal Cancer. Version 2.2015	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.
	To confirm diagnosis of cancer	Colorectal cancer. NICE clinical guideline 131 (2014)	NCCN. Colon Cancer. Version 2.2015 NCCN. Rectal Cancer. Version 2.2015	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.
	Recommended	-	NCCN. Colon Cancer. Version 2.2015 NCCN. Rectal Cancer. Version 2.2015	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.
	Recommended (NCCN) CEA can assist in staging and evaluation of prognosis (EURECCA)	-	NCCN. Colon Cancer. Version 2.2015 NCCN. Rectal Cancer. Version 2.2015	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.
	Contrast-enhanced CT of the chest, abdomen and pelvis to estimate the stage of disease unless it is contraindicated (NICE) (NCCN) For patients with colon cancer (EURECCA)	Colorectal cancer. NICE clinical guideline 131 (2014)	NCCN. Colon Cancer. Version 2.2015 NCCN. Rectal Cancer. Version 2.2015	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.
	For staging of distant metastases if CT scan cannot be performed (EURECCA)	-	-	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.
	When contrast-enhanced CT is not clinically appropriate, not accessible or not acceptable to the person, contrast-enhanced ultrasound is recommended (NICE) If abdominal CT is not possible in diagnosing liver metastases (EURECCA)	Colorectal cancer. NICE clinical guideline 131 (2014)	-	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.
	To assess the risk of local recurrence, as determined by anticipated resection margin, tumour and lymph node staging in rectal cancer patients (NICE) First choice for rectal cancer; second choice for colon cancer (EURECCA) (NCCN)	Colorectal cancer. NICE clinical guideline 131 (2014)	NCCN. Rectal Cancer. Version 2.2015	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.
	As alternative to pelvic MRI.	Colorectal cancer. NICE clinical guideline 131 (2014)	NCCN. Rectal Cancer. Version 2.2015	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.

General action	Steps/Actions/ Options	Interventions identified from the recommendations	Se-quence (a, b, c, d)	Priority (I, II, III)	Notes
Treatment		Open excision/resection	a	I	Colon + Rectal
	Surgery	Laparoscopic excision/resection	a	II	Colon + Rectal
		Stenting	a	III	Colon + Rectal
	Radiation therapy	External beam radiation therapy	a	I	Rectal
		Intraoperative radiation therapy (IORT)	a	III	Rectal
		Brachytherapy	a	II	Rectal
		Arterial embolisation	a	III	Colon + Rectal
	Systemic therapy	Chemotherapy	a	I	Colon + Rectal
		Monoclonal antibodies therapy	a	II	Colon + Rectal. WHO List of Essential Medicines can be used to assist with selection of systemic therapy.

General action	When to perform it	Source	Source	Source
Treatment	-	Colorectal cancer. NICE clinical guideline 131 (2014)	NCCN. Colon Cancer. Version 2.2015 NCCN. Rectal Cancer. Version 2.2016	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.
	For early colon cancer, endoscopic techniques such as endoscopic mucosal resection (EMR), endoscopic submucosal dissection (ESD) or even endoscopic mucosal ablation (EMA) can be considered as alternatives to colectomy (EURECCA) Laparoscopic resection of rectal cancer is safe with similar oncological outcomes and short term advantages compared to open surgery (EURECCA) Laparoscopic resection of rectal cancer is preferred in the setting of a clinical trial (NCCN)	Colorectal cancer. NICE clinical guideline 131 (2014)	NCCN. Colon Cancer. Version 2.2015 NCCN. Rectal Cancer. Version 2.2015	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.
	In selected cases.	Colorectal cancer. NICE clinical guideline 131 (2014)	NCCN. Colon Cancer. Version 2.2015 NCCN. Rectal Cancer. Version 2.2015	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.
	Recommended, depending on the stage.	Colorectal cancer. NICE clinical guideline 131 (2014)	NCCN. Rectal Cancer. Version 2.2015	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.
	For very close or positive margins after resections, an additional boost, especially for patients with T4 or recurrent cancer (NCCN) To be considered for non-responders or in expected R1-R2 (EURECCA)	-	NCCN. Rectal Cancer. Version 2.2015	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.
	If IORT is not available (NCCN) To be considered for non-responders or in expected R1-R2 (EURECCA)	-	NCCN. Rectal Cancer. Version 2.2016	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.
	In patients with large or multiple liver metastasis to shrink the affected liver lobes and induce growth of the later remnant liver (EURECCA)	-	NCCN. Colon Cancer. Version 2.2015 NCCN. Rectal Cancer. Version 2.2015	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.
	Recommended, with different indications, depending on stage	Colorectal cancer. NICE clinical guideline 131 (2014)	NCCN. Colon Cancer. Version 2.2015 NCCN. Rectal Cancer. Version 2.2016	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.
	Recommended mainly in advanced stages	Colorectal cancer. NICE clinical guideline 131 (2014)	NCCN. Colon Cancer. Version 2.2015 NCCN. Rectal Cancer. Version 2.2016	-

General action	Steps/Actions/ Options	Interventions identified from the recommendations	Se-quence (a, b, c, d)	Priority (I, II, III)	Notes
Follow up	Physical exami-nation	Digital rectal examination	a	I	Rectal
		Examination of abdomen, liver and lymph nodes	a	I	Colon
	Blood testing	Carcinoembryonic antigen (CEA) test	b	I	Colon + Rectal
	Endoscopy	Sigmoidoscopy	a	I	Rectal
		Colonoscopy	a	I	Colon
	Imaging	CT scan	a	I	Colon + Rectal. X-ray of chest and liver ultrasound can be considered in low resource settings where CT scan may not be available
Palliative Care	Systemic therapy	Palliative chemotherapy	a	I	Colon + Rectal
	Surgery	Palliative resection or diversion	a	I	Colon + Rectal. Palliative stenting can be considered in select cases and according to resource availability.

General action	When to perform it	Source	Source	Source
Follow up	Recommended but with moderate consensus (EURECCA)	-	NCCN. Rectal Cancer. Version 2.2016	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.
	Physical examination is recommended as post-treatment surveillance (NCCN)	-	NCCN. Colon Cancer. Version 2.2015	-
	Recommended periodically with different frequency and duration	Colorectal cancer. NICE clinical guideline 131 (2014)	NCCN. Colon Cancer. Version 2.2015 NCCN. Rectal Cancer. Version 2.2015	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.
	Recommended but with moderate consensus (EURECCA).	-	-	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.
	Recommended periodically with different frequency and duration	Colorectal cancer. NICE clinical guideline 131 (2014)	NCCN. Colon Cancer. Version 2.2015 NCCN. Rectal Cancer. Version 2.2015	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.
	CT scan of chest abdomen and pelvis is recommended periodically (NICE)	Colorectal cancer. NICE clinical guideline 131 (2014)	NCCN. Colon Cancer. Version 2.2015 NCCN. Rectal Cancer. Version 2.2015	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.
Palliative Care	According to the disease characteristics and patients' preference regarding toxicity and efficacy	Colorectal cancer. NICE clinical guideline 131 (2014)	NCCN. Colon Cancer. Version 2.2015 NCCN. Rectal Cancer. Version 2.2015	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.
	Chemotherapy is mostly active in eliminating local tumour related symptoms (EURECCA)	Colorectal cancer. NICE clinical guideline 131 (2014)	NCCN. Colon Cancer. Version 2.2015 NCCN. Rectal Cancer. Version 2.2015	van de Velde CJ, Boelens PG, Borras JM, et al. EURECCA colorectal: multidisciplinary management: European consensus conference colon & rectum. Eur J Cancer. 2014 Jan;50(1):1.e1-1.e34.

Annex table 1-4. Leukaemia

General action	Steps/Actions/ Options	Interventions identified from the recommendations	Sequence (a, b, c, d)	Priority (I, II, III)	Notes	When to perform it
Diagnosis	Physical examination	General assessment of symptoms	a	I	-	-
	Blood testing	Complete blood count, platelets, differential, chemistry profile	a	I	-	-
		Disseminated intravascular coagulation (DIC) panel: D-dimers, fibrinogen, prothrombin time (PT), partial thromboplastin time (PTT);	b	I	Measurement for D-dimers only recommended for ALL	-
		Tumour lysis syndrome panel: lactate dehydrogenase (LDH), uric acid, potassium (K), Calcium (Ca), Phosphore	c	I	-	-
	Cardiac function assessment	Echocardiography	a	I	-	-
		Radionuclide angiography	b	III	-	-
		CT of the heart	b	III	-	-
	Imaging	X-Ray scan	a	I	-	To assess bones according to clinical symptoms.

General action	Source	Source	Source	Source	Source	Source
Diagnosis	NCCN. Acute Lymphoblastic Leukemia. Version 2.2014	NCCN. Acute Myeloid Leukemia. Version 1.2015	NCCN. Chronic Myelogenous Leukemia. Version 1.2015	-	Eichhorst B, Dreyling M, Robak T, et al., on behalf of the ESMO Guidelines Working Group. Chronic lymphocytic leukemia: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2011;22(6): vi50–vi54	Baccarani M, Pileri S, Steegmann JL, et al.; ESMO Guidelines Working Group. Chronic myeloid leukemia: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2012;23(7): vii72-7
	NCCN. Acute Lymphoblastic Leukemia. Version 2.2014	NCCN. Acute Myeloid Leukemia. Version 1.2015	NCCN. Chronic Myelogenous Leukemia. Version 1.2015	Fey MF, Buske C, on behalf of the ESMO Guidelines Working Group. Acute myeloblastic leukaemias in adult patients: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6): vi138–vi143	Eichhorst B, Dreyling M, Robak T, et al., on behalf of the ESMO Guidelines Working Group. Chronic lymphocytic leukemia: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2011;22(6): vi50–vi54	Baccarani M, Pileri S, Steegmann JL, et al.; ESMO Guidelines Working Group. Chronic myeloid leukemia: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2012;23(7): vii72-7
	NCCN. Acute Lymphoblastic Leukemia. Version 2.2014	NCCN. Acute Myeloid Leukemia. Version 1.2015	-	-	-	-
	NCCN. Acute Lymphoblastic Leukemia. Version 2.2014	-	-	-	Eichhorst B, Dreyling M, Robak T, et al., on behalf of the ESMO Guidelines Working Group. Chronic lymphocytic leukemia: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2011;22(6): vi50–vi54	-
	NCCN. Acute Lymphoblastic Leukemia. Version 2.2014	NCCN. Acute Myeloid Leukemia. Version 1.2015	NCCN. Chronic Myelogenous Leukemia. Version 1.2015	-	-	-
	-	NCCN. Acute Myeloid Leukemia. Version 1.2015	-	-	-	-
	NCCN. Acute Lymphoblastic Leukemia. Version 2.2014	-	-	-	-	-
	NCCN. Acute Lymphoblastic Leukemia. Version 2.2014	NCCN. Acute Myeloid Leukemia. Version 1.2015	-	Fey MF, Buske C, on behalf of the ESMO Guidelines Working Group. Acute myeloblastic leukaemias in adult patients: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6): vi138–vi143	-	-

General action	Steps/Actions/ Options	Interventions identified from the recommendations	Sequence (a, b, c, d)	Priority (I, II, III)	Notes	When to perform it
Diagnosis		CT scan	a	I	-	In case of involvement of head, chest, mediastinal or other site and according to symptoms.
		MRI scan	a	II	-	In case of involvement of head, chest, mediastinal or other site and according to symptoms
	Staging and risk assessment	Bone marrow aspirate	a	I	-	-
		Bone marrow biopsy	b	I	-	-
		Comprehensive flow cytometric immunophenotyping	c	I	-	-
		Lumbar puncture	d	I	-	-
	Genetic characterisation	Cytogenetics	a	I	-	Cytogenetics and FISH testing are important components of treatment for leukemia and can be considered according to resource availability.
		Fluorescence in situ hybridisation (FISH) testing	b	I	-	Cytogenetics and FISH testing are important components of treatment for leukemia and can be considered according to resource availability.

General action	Source	Source	Source	Source	Source	Source
Diagnosis	NCCN. Acute Lymphoblastic Leukemia. Version 2.2014	NCCN. Acute Myeloid Leukemia. Version 1.2015	-	Fey MF, Buske C, on behalf of the ESMO Guidelines Working Group. Acute myeloblastic leukaemias in adult patients: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6): vi138–vi143	-	-
	NCCN. Acute Lymphoblastic Leukemia. Version 2.2014	NCCN. Acute Myeloid Leukemia. Version 1.2015	-	-	-	-
	NCCN. Acute Lymphoblastic Leukemia. Version 2.2014	NCCN. Acute Myeloid Leukemia. Version 1.2015	NCCN. Chronic Myelogenous Leukemia. Version 1.2015	Fey MF, Buske C, on behalf of the ESMO Guidelines Working Group. Acute myeloblastic leukaemias in adult patients: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6): vi138–vi143	-	Baccarani M, Pileri S, Steegmann JL, et al.; ESMO Guidelines Working Group. Chronic myeloid leukemia: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2012;23(7): vii72-7
	NCCN. Acute Lymphoblastic Leukemia. Version 2.2014	NCCN. Acute Myeloid Leukemia. Version 1.2015	NCCN. Chronic Myelogenous Leukemia. Version 1.2015	Fey MF, Buske C, on behalf of the ESMO Guidelines Working Group. Acute myeloblastic leukaemias in adult patients: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6): vi138–vi144	Eichhorst B, Dreyling M, Robak T, et al., on behalf of the ESMO Guidelines Working Group. Chronic lymphocytic leukemia: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2011;22(6): vi50–vi54	Baccarani M, Pileri S, Steegmann JL, et al.; ESMO Guidelines Working Group. Chronic myeloid leukemia: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2012;23(7): vii72-7
	NCCN. Acute Lymphoblastic Leukemia. Version 2.2014	NCCN. Acute Myeloid Leukemia. Version 1.2015	NCCN. Chronic Myelogenous Leukemia. Version 1.2015	Fey MF, Buske C, on behalf of the ESMO Guidelines Working Group. Acute myeloblastic leukaemias in adult patients: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6): vi138–vi145	Eichhorst B, Dreyling M, Robak T, et al., on behalf of the ESMO Guidelines Working Group. Chronic lymphocytic leukemia: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2011;22(6): vi50–vi54	-
	NCCN. Acute Lymphoblastic Leukemia. Version 2.2014	NCCN. Acute Myeloid Leukemia. Version 1.2015	-	-	-	-
	NCCN. Acute Lymphoblastic Leukemia. Version 2.2014	NCCN. Acute Myeloid Leukemia. Version 1.2015	NCCN. Chronic Myelogenous Leukemia. Version 1.2015	Fey MF, Buske C, on behalf of the ESMO Guidelines Working Group. Acute myeloblastic leukaemias in adult patients: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6): vi138–vi145	-	Baccarani M, Pileri S, Steegmann JL, et al.; ESMO Guidelines Working Group. Chronic myeloid leukemia: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2012;23(7): vii72-7
	NCCN. Acute Lymphoblastic Leukemia. Version 2.2014	NCCN. Acute Myeloid Leukemia. Version 1.2015	NCCN. Chronic Myelogenous Leukemia. Version 1.2015	Fey MF, Buske C, on behalf of the ESMO Guidelines Working Group. Acute myeloblastic leukaemias in adult patients: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6): vi138–vi145	Eichhorst B, Dreyling M, Robak T, et al., on behalf of the ESMO Guidelines Working Group. Chronic lymphocytic leukemia: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2011;22(6): vi50–vi54	-

General action	Steps/Actions/ Options	Interventions identified from the recommendations	Sequence (a, b, c, d)	Priority (I, II, III)	Notes	When to perform it
Diagnosis		Reverse trascriptase-polimerase chain reaction (RT-PCR) testing	c	I	-	-
		Human leukocyte antigen (HLA) typing	d	II	-	-
Treatment	Systemic therapy	Chemotherapy	a	I	-	-
		Intrathecal chemotherapy	a	I	-	-
	Radiation therapy	Cranial irradiation	a	II	-	Cranial or testicular irradiation is recommended for patients with ALL when these districts are involved
	Transplantation	Haematopoietic stem cell transplantation	a	II	-	-
Follow up	Physical examination	General assessment of symptoms	a	I	-	-
	Blood testing	Complete blood count with differential and platelets	a	I	-	Platelets counts is recommended in AML patients

General action	Source	Source	Source	Source	Source	Source
Diagnosis	NCCN. Acute Lymphoblastic Leukemia. Version 2.2014	NCCN. Acute Myeloid Leukemia. Version 1.2015	NCCN. Chronic Myelogenous Leukemia. Version 1.2015	Fey MF, Buske C, on behalf of the ESMO Guidelines Working Group. Acute myeloblastic leukaemias in adult patients: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6): vi138–vi145	Yeoh AE, Tan D, Li CK, Hori H, Tse E, Pui CH; Asian Oncology Summit 2013. Management of adult and paediatric acute lymphoblastic leukaemia in Asia: resource-stratified guidelines from the Asian Oncology Summit 2013. Lancet Oncol. 2013 Nov;14(12):e508-23.	Baccarani M, Pileri S, Steegmann JL, et al.; ESMO Guidelines Working Group. Chronic myeloid leukemia: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2012;23(7): vii72-7
	NCCN. Acute Lymphoblastic Leukemia. Version 2.2014	NCCN. Acute Myeloid Leukemia. Version 1.2015	NCCN. Chronic Myelogenous Leukemia. Version 1.2015	Fey MF, Buske C, on behalf of the ESMO Guidelines Working Group. Acute myeloblastic leukaemias in adult patients: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6): vi138–vi145	Eichhorst B, Dreyling M, Robak T, et al., on behalf of the ESMO Guidelines Working Group. Chronic lymphocytic leukemia: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2011;22(6): vi50–vi54	-
Treatment	NCCN. Acute Lymphoblastic Leukemia. Version 2.2014	NCCN. Acute Myeloid Leukemia. Version 1.2015	NCCN. Chronic Myelogenous Leukemia. Version 1.2015	Fey MF, Buske C, on behalf of the ESMO Guidelines Working Group. Acute myeloblastic leukaemias in adult patients: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6): vi138–vi145	Eichhorst B, Dreyling M, Robak T, et al., on behalf of the ESMO Guidelines Working Group. Chronic lymphocytic leukemia: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2011;22(6): vi50–vi54	Baccarani M, Pileri S, Steegmann JL, et al.; ESMO Guidelines Working Group. Chronic myeloid leukemia: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2012;23(7): vii72-7
	NCCN. Acute Lymphoblastic Leukemia. Version 2.2014	NCCN. Acute Myeloid Leukemia. Version 1.2015	-	-	-	-
	NCCN. Acute Lymphoblastic Leukemia. Version 2.2014	NCCN. Acute Myeloid Leukemia. Version 1.2015	-	-	-	-
	NCCN. Acute Lymphoblastic Leukemia. Version 2.2014	NCCN. Acute Myeloid Leukemia. Version 1.2015	NCCN. Chronic Myelogenous Leukemia. Version 1.2015	Fey MF, Buske C, on behalf of the ESMO Guidelines Working Group. Acute myeloblastic leukaemias in adult patients: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6): vi138–vi145	Eichhorst B, Dreyling M, Robak T, et al., on behalf of the ESMO Guidelines Working Group. Chronic lymphocytic leukemia: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2011;22(6): vi50–vi54	Baccarani M, Pileri S, Steegmann JL, et al.; ESMO Guidelines Working Group. Chronic myeloid leukemia: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2012;23(7): vii72-7
Follow up	NCCN. Acute Lymphoblastic Leukemia. Version 2.2014	-	-		Eichhorst B, Dreyling M, Robak T, et al., on behalf of the ESMO Guidelines Working Group. Chronic lymphocytic leukemia: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2011;22(6): vi50–vi54	-
	NCCN. Acute Lymphoblastic Leukemia. Version 2.2014	NCCN. Acute Myeloid Leukemia. Version 1.2015	-	Fey MF, Buske C, on behalf of the ESMO Guidelines Working Group. Acute myeloblastic leukaemias in adult patients: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6): vi138–vi145	Eichhorst B, Dreyling M, Robak T, et al., on behalf of the ESMO Guidelines Working Group. Chronic lymphocytic leukemia: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2011;22(6): vi50–vi54	Baccarani M, Pileri S, Steegmann JL, et al.; ESMO Guidelines Working Group. Chronic myeloid leukemia: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2012;23(7): vii72-7

General action	Steps/Actions/ Options	Interventions identified from the recommendations	Sequence (a, b, c, d)	Priority (I, II, III)	Notes	When to perform it
Follow up		Liver function test	b	I	-	-
	Biopsy	Bone marrow aspirate	a	I	-	-
		Cerebrospinal fluid aspirate	b	I	-	-
		Bone marrow biopsy	c	I	-	-
	Cardiac function assessment	Echocardiography	a	I	-	-
	Genetic characterisation	Fluorescence in situ hybridisation (FISH) testing	a	I	-	-
		Flow cytometry	b	I	-	-
		Quantitative reverse trascriptase-polimerase chain reaction (QPCR) testing	c	I	-	-
Palliative Care	-	-	-	-	-	-

General action	Source	Source	Source	Source	Source	Source
Follow up	NCCN. Acute Lymphoblastic Leukemia. Version 2.2014	-	-	Fey MF, Buske C, on behalf of the ESMO Guidelines Working Group. Acute myeloblastic leukaemias in adult patients: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6): vi138–vi145	-	-
	NCCN. Acute Lymphoblastic Leukemia. Version 2.2014	NCCN. Acute Myeloid Leukemia. Version 1.2015	-	Fey MF, Buske C, on behalf of the ESMO Guidelines Working Group. Acute myeloblastic leukaemias in adult patients: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6): vi138–vi145	-	Baccarani M, Pileri S, Steegmann JL, et al.; ESMO Guidelines Working Group. Chronic myeloid leukemia: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2012;23(7): vii72-7
	NCCN. Acute Lymphoblastic Leukemia. Version 2.2014	-	-	-	-	-
	-	NCCN. Acute Myeloid Leukemia. Version 1.2015	-	Fey MF, Buske C, on behalf of the ESMO Guidelines Working Group. Acute myeloblastic leukaemias in adult patients: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6): vi138–vi145	-	Baccarani M, Pileri S, Steegmann JL, et al.; ESMO Guidelines Working Group. Chronic myeloid leukemia: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2012;23(7): vii72-7
	NCCN. Acute Lymphoblastic Leukemia. Version 2.2014	-	-	Fey MF, Buske C, on behalf of the ESMO Guidelines Working Group. Acute myeloblastic leukaemias in adult patients: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6): vi138–vi145	-	-
	NCCN. Acute Lymphoblastic Leukemia. Version 2.2014	-	-	-	-	-
	NCCN. Acute Lymphoblastic Leukemia. Version 2.2014	-	-	-	Eichhorst B, Dreyling M, Robak T, et al., on behalf of the ESMO Guidelines Working Group. Chronic lymphocytic leukemia: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2011;22(6): vi50–vi54	-
	-	-	NCCN. Chronic Myelogenous Leukemia. Version 1.2015	-	-	Baccarani M, Pileri S, Steegmann JL, et al.; ESMO Guidelines Working Group. Chronic myeloid leukemia: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2012;23(7): vii72-7
Palliative Care	-	-	-	-	-	

Annex table 1-5. Lung cancer

General action	Steps/Actions/ Options	Interventions identified from the recommendations	Se-quence (a, b, c, d)	Priority (I, II, III)	Notes
Prevention	Smoking cessation	Smoking cessation counselling	a	I	-
Diagnosis	Lung imaging (screening)	CT scan of the chest	a	-	WHO has not reviewed low-dose CT as a modality for cancer screening at this time because of insufficient data.
	Physical examination	Assessment of symptoms that may suggest lung cancer (check breathing, lymph nodes, etc.)	a	I	-
	Lung imaging (early diagnosis)	Chest X-Ray	a	I	-
		CT scan of the chest	b	I	Contrast-enhanced CT scan of the chest is recommended by NICE.
	Pulmonary function test	Spirometry	a	I	-
	Staging and risk assessment	Haematology, renal and hepatic func-tion, and bone biochemistry tests	a	I	-
		Abdominal ultrasound	c	I	Abdominal ultrasound can be considered as an alternate staging test in setting where CT scan may not be available.

General action	When to perform it	Source	Source	Source	Source
Prevention	-	Lung cancer. NICE clinical guideline 121 (2011)	NCCN. Non-small cell lung cancer. Version 3.2015	Vansteenkiste J, De Ruysscher D, Eberhardt WE, Lim E, Senan S, Felip E, Peters S; ESMO Guidelines Working Group. Early and locally advanced non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi89-98.	-
Diagnosis	For selected and high-risk smokers or former heavy smokers according to NCCN and ESMO.	-	NCCN. Lung Cancer Screening. Version 1.2015	Vansteenkiste J, De Ruysscher D, Eberhardt WE, Lim E, Senan S, Felip E, Peters S; ESMO Guidelines Working Group. Early and locally advanced non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi89-98.	-
	-	Lung cancer. NICE clinical guideline 121 (2011)	NCCN. Non-small cell lung cancer. Version 3.2015	Vansteenkiste J, De Ruysscher D, Eberhardt WE, Lim E, Senan S, Felip E, Peters S; ESMO Guidelines Working Group. Early and locally advanced non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi89-98.	-
	When lung cancer is suspected at physical examination.	Lung cancer. NICE clinical guideline 121 (2011)	-	-	-
	When lung cancer is highly suspected from X-Ray results.	Lung cancer. NICE clinical guideline 121 (2011)	NCCN. Non-small cell lung cancer. Version 3.2015	-	
	-	Lung cancer. NICE clinical guideline 121 (2011)	-	Vansteenkiste J, De Ruysscher D, Eberhardt WE, Lim E, Senan S, Felip E, Peters S; ESMO Guidelines Working Group. Early and locally advanced non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi89-98.	-
	-	-	-	-	Reck M, Popat S, Reinmuth N, De Ruysscher D, Kerr KM, Peters S; ESMO Guidelines Working Group. Metastatic non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2014;25(3):iii27-39
	When abnormal-looking areas in the liver that are noticed.	Lung cancer. NICE clinical guideline 121 (2011)	-	-	-

General action	Steps/Actions/ Options	Interventions identified from the recommendations	Sequence (a, b, c, d)	Priority (I, II, III)	Notes
Diagnosis		PET/CT	a	II	-
		CT scan chest and upper abdomen including adrenals	a	I	-
		Ultrasound-guided transthoracic needle biopsy (TNB)	a	II	-
		Endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-guided TBNA)	a	II	Negative results need to be confirmed by surgical staging if clinical suspicion of mediastinal malignancy is high.
		Endoscopic ultrasound-guided fine needle aspiration (EUS-guided FNA)	a	II	Negative results need to be confirmed by surgical staging if clinical suspicion of mediastinal malignancy is high.
		Non-ultrasound-guided transbronchial needle aspiration (TBNA)	a	II	Negative results need to be confirmed using EBUS-guided TBNA or EUS-guided FNA.
		Neck ultrasound with visible lymph nodes biopsy	a	I	Negative results can be confirmed using non-ultrasound-guided TBNA, EBUS-guided TBNA or EUS-guided FNA.
		Surgical staging	a	I	-

General action	When to perform it	Source	Source	Source	Source
Diagnosis	First choice after CT showing a low probability of mediastinal malignancy for patients who are potentially suitable for treatment with curative intent.	Lung cancer. NICE clinical guideline 121 (2011)	NCCN. Non-small cell lung cancer. Version 3.2015	Vansteenkiste J, De Ruysscher D, Eberhardt WE, Lim E, Senan S, Felip E, Peters S; ESMO Guidelines Working Group. Early and locally advanced non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi89-98.	Reck M, Popat S, Reinmuth N, De Ruysscher D, Kerr KM, Peters S; ESMO Guidelines Working Group. Metastatic non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2014;25(3):iii27-39
	To patients with peripheral lung lesions when treatment can be planned on the basis of this test.	Lung cancer. NICE clinical guideline 121 (2011)	NCCN. Non-small cell lung cancer. Version 3.2015	Vansteenkiste J, De Ruysscher D, Eberhardt WE, Lim E, Senan S, Felip E, Peters S; ESMO Guidelines Working Group. Early and locally advanced non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi89-98.	Reck M, Popat S, Reinmuth N, De Ruysscher D, Kerr KM, Peters S; ESMO Guidelines Working Group. Metastatic non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2014;25(3):iii27-39
	To patients with peripheral lung lesions when treatment can be planned on the basis of this test.	Lung cancer. NICE clinical guideline 121 (2011)	NCCN. Non-small cell lung cancer. Version 3.2015	-	-
	As the first test for patients with an intermediate probability of mediastinal malignancy who are potentially suitable for treatment with curative intent.	Lung cancer. NICE clinical guideline 121 (2011)	NCCN. Non-small cell lung cancer. Version 3.2015	Vansteenkiste J, De Ruysscher D, Eberhardt WE, Lim E, Senan S, Felip E, Peters S; ESMO Guidelines Working Group. Early and locally advanced non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi89-98.	-
	As the first test for patients with an intermediate probability of mediastinal malignancy who are potentially suitable for treatment with curative intent.	Lung cancer. NICE clinical guideline 121 (2011)	NCCN. Non-small cell lung cancer. Version 3.2015	Vansteenkiste J, De Ruysscher D, Eberhardt WE, Lim E, Senan S, Felip E, Peters S; ESMO Guidelines Working Group. Early and locally advanced non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi89-98.	-
	As the first test for patients with an intermediate probability of mediastinal malignancy who are potentially suitable for treatment with curative intent.	Lung cancer. NICE clinical guideline 121 (2011)	NCCN. Non-small cell lung cancer. Version 3.2015	-	-
	To patients with a high probability of mediastinal malignancy.	Lung cancer. NICE clinical guideline 121 (2011)	-	-	-
	To confirm negative results obtained by non-ultrasound-guided TBNA, EBUS-guided TBNA or EUS-guided FNA (if clinical suspicion of mediastinal malignancy is high).	Lung cancer. NICE clinical guideline 121 (2011)	NCCN. Non-small cell lung cancer. Version 3.2015	Vansteenkiste J, De Ruysscher D, Eberhardt WE, Lim E, Senan S, Felip E, Peters S; ESMO Guidelines Working Group. Early and locally advanced non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi89-98.	Reck M, Popat S, Reinmuth N, De Ruysscher D, Kerr KM, Peters S; ESMO Guidelines Working Group. Metastatic non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2014;25(3):iii27-39

General action	Steps/Actions/ Options	Interventions identified from the recommendations	Sequence (a, b, c, d)	Priority (I, II, III)	Notes
Diagnosis		MRI of the head	a	II	-
		CT of the head	a	II	Needs to be followed by MRI of the head if normal.
		Localised X-Ray exams	a	I	Negative or inconclusive results can be confirmed by bone scan or MRI as resources permit.
		Bone scan	b	II	-
		Epidermal growth factor receptor tyrosine kinase (EGFR-TK) mutation test	a	II	EGFR-TK mutation testing done according to availability and accesibility of targetted therapy. WHO List of Essential Medicines can be used to assist with selection of systemic therapy.

General action	When to perform it	Source	Source	Source	Source
Diagnosis	To patients with features suggestive of intracranial pathology.	Lung cancer. NICE clinical guideline 121 (2011)	NCCN. Non-small cell lung cancer. Version 3.2015	-	Reck M, Popat S, Reinmuth N, De Ruysscher D, Kerr KM, Peters S; ESMO Guidelines Working Group. Metastatic non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2014;25(3):iii27-39
	To patients with features suggestive of intracranial pathology.	Lung cancer. NICE clinical guideline 121 (2011)	NCCN. Non-small cell lung cancer. Version 3.2015	-	Reck M, Popat S, Reinmuth N, De Ruysscher D, Kerr KM, Peters S; ESMO Guidelines Working Group. Metastatic non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2014;25(3):iii27-39
	To patients with localised signs or symptoms of bone metastasis.	Lung cancer. NICE clinical guideline 121 (2011)	-	-	Reck M, Popat S, Reinmuth N, De Ruysscher D, Kerr KM, Peters S; ESMO Guidelines Working Group. Metastatic non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2014;25(3):iii27-39
	To confirm negative or inconclusive results from X-Ray exams.	Lung cancer. NICE clinical guideline 121 (2011)	NCCN. Non-small cell lung cancer. Version 3.2015	-	Reck M, Popat S, Reinmuth N, De Ruysscher D, Kerr KM, Peters S; ESMO Guidelines Working Group. Metastatic non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2014;25(3):iii27-39
	To identify patients who might benefit from treatment with EGFR–TK inhibitors rather than chemotherapy.	Lung cancer. NICE clinical guideline 121 (2011)	NCCN. Non-small cell lung cancer. Version 3.2015	-	Reck M, Popat S, Reinmuth N, De Ruysscher D, Kerr KM, Peters S; ESMO Guidelines Working Group. Metastatic non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2014;25(3):iii27-39

General action	Steps/Actions/ Options	Interventions identified from the recommendations	Se-quence (a, b, c, d)	Priority (I, II, III)	Notes
Treatment	Surgery	Open lobectomy	a	I	-
		Thoracoscopic lobectomy	a	II	-
	Radiotherapy	Conventionally fractionated radiother-apy	a	I	-
		Accelerated fractionated radiotherapy	a	I	-
		Stereotactic ablative radiotherapy (SABR)	a	II	-
	Systemic therapy	Chemotherapy	a	I	Agents and regimens vary according to clinical pathway, cancer type, and cancer stage.
	Tissue ablation	Percutaneous radiofrequency ablation	a	III	-
		Photodynamic therapy	a	II	-

General action	When to perform it	Source	Source	Source	Source
Treatment	Treatment of first choice.	Lung cancer. NICE clinical guideline 121 (2011)	NCCN. Non-small cell lung cancer. Version 3.2015	Vansteenkiste J, De Ruysscher D, Eberhardt WE, Lim E, Senan S, Felip E, Peters S; ESMO Guidelines Working Group. Early and locally advanced non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi89-98.	-
	Treatment of first choice.	Lung cancer. NICE clinical guideline 121 (2011)	NCCN. Non-small cell lung cancer. Version 3.2015	Vansteenkiste J, De Ruysscher D, Eberhardt WE, Lim E, Senan S, Felip E, Peters S; ESMO Guidelines Working Group. Early and locally advanced non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi89-98.	-
	When CHART is not available.	Lung cancer. NICE clinical guideline 121 (2011)	NCCN. Non-small cell lung cancer. Version 3.2015	-	Reck M, Popat S, Reinmuth N, De Ruysscher D, Kerr KM, Peters S; ESMO Guidelines Working Group. Metastatic non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2014;25(3):iii27-39
	For patients who are not suitable for surgery.	Lung cancer. NICE clinical guideline 121 (2011)	-	-	-
	First choice for non-surgical treatment of stage I NSCLC	-	NCCN. Non-small cell lung cancer. Version 3.2015	Vansteenkiste J, De Ruysscher D, Eberhardt WE, Lim E, Senan S, Felip E, Peters S; ESMO Guidelines Working Group. Early and locally advanced non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi89-98.	Reck M, Popat S, Reinmuth N, De Ruysscher D, Kerr KM, Peters S; ESMO Guidelines Working Group. Metastatic non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2014;25(3):iii27-39
	To be performed after surgery (adjuvant chemotherapy), after radiotherapy (chemoradiotherapy) or for advanced and metastatic cancer.	Lung cancer. NICE clinical guideline 121 (2011)	NCCN. Non-small cell lung cancer. Version 3.2015	Vansteenkiste J, De Ruysscher D, Eberhardt WE, Lim E, Senan S, Felip E, Peters S; ESMO Guidelines Working Group. Early and locally advanced non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi89-98.	Reck M, Popat S, Reinmuth N, De Ruysscher D, Kerr KM, Peters S; ESMO Guidelines Working Group. Metastatic non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2014;25(3):iii27-39
	-	Lung cancer. NICE clinical guideline 121 (2011)	NCCN. Non-small cell lung cancer. Version 3.2015	-	-
	For localised inoperable endobronchial cancer.	Lung cancer. NICE clinical guideline 121 (2011)	NCCN. Non-small cell lung cancer. Version 3.2015	-	-

General action	Steps/Actions/ Options	Interventions identified from the recommendations	Sequence (a, b, c, d)	Priority (I, II, III)	Notes
Follow up	Physical examination	Assessment of symptoms that may suggest lung cancer	a	I	-
	Lung imaging	CT scan of the chest	a	I	With or without contrast.
		Chest X-Ray	a	I	-
Palliative Care	Palliative cancer treatment	Radiotherapy	a	I	-
	Management of pleural effusions	Pleural aspiration or drainage	a	I	-
		Pleurodesis	a	I	-
	Management of endobronchial obstructions	External beam radiotherapy	a	I	-

General action	When to perform it	Source	Source	Source	Source
Follow up	Recommended periodically.	Lung cancer. NICE clinical guideline 121 (2011)	NCCN. Non-small cell lung cancer. Version 3.2015	Vansteenkiste J, De Ruysscher D, Eberhardt WE, Lim E, Senan S, Felip E, Peters S; ESMO Guidelines Working Group. Early and locally advanced non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi89-98.	Reck M, Popat S, Reinmuth N, De Ruysscher D, Kerr KM, Peters S; ESMO Guidelines Working Group. Metastatic non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2014;25(3):iii27-39
	Recommended periodically.	-	NCCN. Non-small cell lung cancer. Version 3.2015	Vansteenkiste J, De Ruysscher D, Eberhardt WE, Lim E, Senan S, Felip E, Peters S; ESMO Guidelines Working Group. Early and locally advanced non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi89-98.	Reck M, Popat S, Reinmuth N, De Ruysscher D, Kerr KM, Peters S; ESMO Guidelines Working Group. Metastatic non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2014;25(3):iii27-39
	Recommended periodically.	-	-	Vansteenkiste J, De Ruysscher D, Eberhardt WE, Lim E, Senan S, Felip E, Peters S; ESMO Guidelines Working Group. Early and locally advanced non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi89-98.	Reck M, Popat S, Reinmuth N, De Ruysscher D, Kerr KM, Peters S; ESMO Guidelines Working Group. Metastatic non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2014;25(3):iii27-39
Palliative Care	-	Lung cancer. NICE clinical guideline 121 (2011)	NCCN. Non-small cell lung cancer. Version 3.2015	-	Reck M, Popat S, Reinmuth N, De Ruysscher D, Kerr KM, Peters S; ESMO Guidelines Working Group. Metastatic non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2014;25(3):iii27-39
	-	Lung cancer. NICE clinical guideline 121 (2011)	-	-	Reck M, Popat S, Reinmuth N, De Ruysscher D, Kerr KM, Peters S; ESMO Guidelines Working Group. Metastatic non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2014;25(3):iii27-39
	-	-	-	-	Reck M, Popat S, Reinmuth N, De Ruysscher D, Kerr KM, Peters S; ESMO Guidelines Working Group. Metastatic non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2014;25(3):iii27-39
	-	Lung cancer. NICE clinical guideline 121 (2011)	NCCN. Non-small cell lung cancer. Version 3.2015	-	-

General action	Steps/Actions/ Options	Interventions identified from the recommendations	Sequence (a, b, c, d)	Priority (I, II, III)	Notes
Palliative Care		Endobronchial debulking	a	II	-
		Endobronchial stenting	a	II	-
	Management of symptomatic brain metastases	Palliative whole-brain radiotherapy	a	II	-
	Management of superior vena cava obstructions	Chemotherapy	a	II	-
		Radiotherapy	a	II	-
		Stenting	a	II	-
	Management of bone metastases	Radiotherapy	a	II	-
	Managing treatment-resistant recurrent ascites	Peritoneal catheter drainage	a	II	Palliative peritoneal drainage can be considered.

General action	When to perform it	Source	Source	Source	Source
Palliative Care	-	Lung cancer. NICE clinical guideline 121 (2011)	-	-	Reck M, Popat S, Reinmuth N, De Ruysscher D, Kerr KM, Peters S; ESMO Guidelines Working Group. Metastatic non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2014;25(3):iii27-39
	-	Lung cancer. NICE clinical guideline 121 (2011)	NCCN. Non-small cell lung cancer. Version 3.2015	-	Reck M, Popat S, Reinmuth N, De Ruysscher D, Kerr KM, Peters S; ESMO Guidelines Working Group. Metastatic non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2014;25(3):iii27-39
	-	Lung cancer. NICE clinical guideline 121 (2011)	NCCN. Non-small cell lung cancer. Version 3.2015	-	Reck M, Popat S, Reinmuth N, De Ruysscher D, Kerr KM, Peters S; ESMO Guidelines Working Group. Metastatic non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2014;25(3):iii27-39
	-	Lung cancer. NICE clinical guideline 121 (2011)	NCCN. Non-small cell lung cancer. Version 3.2015	-	-
	-	Lung cancer. NICE clinical guideline 121 (2011)	NCCN. Non-small cell lung cancer. Version 3.2015	-	-
	-	Lung cancer. NICE clinical guideline 121 (2011)	NCCN. Non-small cell lung cancer. Version 3.2015	-	Reck M, Popat S, Reinmuth N, De Ruysscher D, Kerr KM, Peters S; ESMO Guidelines Working Group. Metastatic non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2014;25(3):iii27-39
	-	Lung cancer. NICE clinical guideline 121 (2011)	NCCN. Non-small cell lung cancer. Version 3.2015	-	Reck M, Popat S, Reinmuth N, De Ruysscher D, Kerr KM, Peters S; ESMO Guidelines Working Group. Metastatic non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2014;25(3):iii27-39
	-	Lung cancer. NICE clinical guideline 121 (2011)	-	-	-

Annex table 1-6. Prostate cancer

General action	Steps/Actions/ Options	Interventions identified from the recommendations	Se-quence (a, b, c, d)	Priority (I, II, III)	Notes
Diagnosis	Blood testing	Prostate-specific antigen (PSA) test	a	I	WHO-IARC does not have an official position on prostate cancer screening at this time. Consideration must be made for resource availability, potential benefits and potential harms"
	Blood testing	Prostate-specific antigen (PSA) test	a	I	-
	Urine testing	PCA3 test	b	III	-
	Physical examination	Digital rectal examination	b	I	-
	Biopsy	TRUS-guided prostate biopsy	a	II	-
		Transperineal template biopsy	a	III	-
	Pathological examination	Examination of biopsy specimen	b	I	-
	Pelvic imaging	MRI scan	a	II	Pelvic MRI or CT can be considered for diagnostic and staging purposes according to clinical context and resource availability.
	Staging and Risk Assessment	Digital rectal examination	a	I	-
		Endorectal MRI	b	III	-
		Bone scintigraphy	b	II	X-ray and CT scan can also be considered for staging according to clinical context and resource availability.

General action	When to perform it	Source	Source	Source
Diagnosis	Frequency and age groups are still under debate.	-	NCCN. Prostate Cancer Early Detection. Version 1.2014	Horwich A, Parker C, de Reijke T, Kataja V; ESMO Guidelines Working Group. Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi106-14.
		Prostate cancer. NICE clinical guideline 175 (2014)	NCCN. Prostate Cancer Early Detection. Version 1.2014	Horwich A, Parker C, de Reijke T, Kataja V; ESMO Guidelines Working Group. Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi106-14.
	In case of elevated PSA and negative initial biopsies, to determine whether re-biopsies are indicated (ESMO) (NCCN)	-	NCCN. Prostate Cancer Early Detection. Version 1.2014	Horwich A, Parker C, de Reijke T, Kataja V; ESMO Guidelines Working Group. Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi106-14.
		Prostate cancer. NICE clinical guideline 175 (2014)	NCCN. Prostate Cancer Early Detection. Version 1.2014	Horwich A, Parker C, de Reijke T, Kataja V; ESMO Guidelines Working Group. Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi106-14.
	.	Prostate cancer. NICE clinical guideline 175 (2014)	NCCN. Prostate Cancer Early Detection. Version 1.2014	Horwich A, Parker C, de Reijke T, Kataja V; ESMO Guidelines Working Group. Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi106-14.
	In patients with suspected prostate cancer who have had negative or equivocal results from other biopsy methods (NICE) At present not recommended (NCCN)	Prostate cancer. NICE clinical guideline 175 (2014)	-	-
	Recommended.	Prostate cancer. NICE clinical guideline 175 (2014)	NCCN. Prostate Cancer Early Detection. Version 1.2014	Horwich A, Parker C, de Reijke T, Kataja V; ESMO Guidelines Working Group. Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi106-14.
	Consider multiparametric MRI for men with a negative biopsy to determine whether another biopsy is needed (NICE)	Prostate cancer. NICE clinical guideline 175 (2014)	NCCN. Prostate Cancer Early Detection. Version 1.2014	Horwich A, Parker C, de Reijke T, Kataja V; ESMO Guidelines Working Group. Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi106-14.
	Recommended for low-, intermediate- or high-risk patients.	-	NCCN. Prostate Cancer. Version 1.2015	Horwich A, Parker C, de Reijke T, Kataja V; ESMO Guidelines Working Group. Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi106-14.
	To increase resolution of MRI in the pelvis	-	NCCN. Prostate Cancer. Version 1.2015	-
	For high-risk disease, bone scintigraphy should be carried out and an MRI of the pelvis should be considered (ESMO)	Prostate cancer. NICE clinical guideline 175 (2014)	NCCN. Prostate Cancer. Version 1.2015	Horwich A, Parker C, de Reijke T, Kataja V; ESMO Guidelines Working Group. Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi106-14.

General action	Steps/Actions/ Options	Interventions identified from the recommendations	Se-quence (a, b, c, d)	Priority (I, II, III)	Notes
Treatment	Surgery	Radical prostatectomy	a	I	-
		Pelvic lymph node dissection	a	I	-
		Bilateral orchiectomy	a	I	-
	Radiation therapy	Brachytherapy	a	I	-
		External beam radiation therapy	a	I	-
		Radiopharmaceutical therapy	a	II	Radiopharmaceutical therapy can be used in setting of metastases or bulky nodal disease according to clinical context and resource availability.
	Systemic treatment	Hormonal therapy	a	I	-
		Chemotherapy, immunotherapy and targetted therapy	a	I	WHO List of Essential Medicines can be used to assist with selection of systemic therapy.
Follow up	Blood testing	PSA test	a	II	-
	Physical examination	Digital rectal examination	a	I	-

General action	When to perform it	Source	Source	Source
Treatment	Optimal treatment of prostate cancer requires assessment of risk and depends on: patient age, expected patient survival, TNM, PSA level, Gleason score, symptoms, patient's preferences. Treatment options can be offered as stand-alone or in combination	Prostate cancer. NICE clinical guideline 175 (2014)	NCCN. Prostate Cancer. Version 1.2015	Horwich A, Parker C, de Reijke T, Kataja V; ESMO Guidelines Working Group. Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi106-14.
		-	NCCN. Prostate Cancer. Version 1.2015	Horwich A, Parker C, de Reijke T, Kataja V; ESMO Guidelines Working Group. Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi106-14.
		Prostate cancer. NICE clinical guideline 175 (2014)	NCCN. Prostate Cancer. Version 1.2015	Horwich A, Parker C, de Reijke T, Kataja V; ESMO Guidelines Working Group. Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi106-14.
		Prostate cancer. NICE clinical guideline 175 (2014)	NCCN. Prostate Cancer. Version 1.2015	Horwich A, Parker C, de Reijke T, Kataja V; ESMO Guidelines Working Group. Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi106-14.
		Prostate cancer. NICE clinical guideline 175 (2014)	NCCN. Prostate Cancer. Version 1.2015	Horwich A, Parker C, de Reijke T, Kataja V; ESMO Guidelines Working Group. Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi106-14.
		-	NCCN. Prostate Cancer. Version 1.2015	Horwich A, Parker C, de Reijke T, Kataja V; ESMO Guidelines Working Group. Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi106-14.
		Prostate cancer. NICE clinical guideline 175 (2014)	NCCN. Prostate Cancer. Version 1.2015	Horwich A, Parker C, de Reijke T, Kataja V; ESMO Guidelines Working Group. Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi106-14.
		Prostate cancer. NICE clinical guideline 175 (2014)	NCCN. Prostate Cancer. Version 1.2015	Horwich A, Parker C, de Reijke T, Kataja V; ESMO Guidelines Working Group. Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi106-14.
Follow up	Recommended routinely	Prostate cancer. NICE clinical guideline 175 (2014)	NCCN. Prostate Cancer. Version 1.2015	Horwich A, Parker C, de Reijke T, Kataja V; ESMO Guidelines Working Group. Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi106-14.
	Not always required	Prostate cancer. NICE clinical guideline 175 (2014)	NCCN. Prostate Cancer. Version 1.2015	Horwich A, Parker C, de Reijke T, Kataja V; ESMO Guidelines Working Group. Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi106-14.

General action	Steps/Actions/ Options	Interventions identified from the recommendations	Se-quence (a, b, c, d)	Priority (I, II, III)	Notes
	Biopsy (sample collection)	TRUS-guided prostate biopsy	b	I	-
	cardiovascular examination	Assessment for cardiovascular disease	a	I	-
	Blood testing	Assessment for diabetes	a	I	-
	Gastroenterologi-cal examination	Assessment of chronic bowel symptoms	a	I	-
	Bone assessment	Assessment of osteoporosis symptoms	a	I	-
Palliative Care	Systemic treatment	Palliative androgen deprivation therapy and hormonal manipulation	a	I	-
		Palliative chemotherapy	a	I	-
		Palliative immunotherapy	a	III	Clinical trials are ongoing to assess impact of immunotherapy in metastaic prostate cancer. WHO List of Essential Medicines can be used for reference.
	Radiation therapy	Palliative radiation therapy	a	I	-
		Radiopharmaceutical therapy	a	II	-
	Management of obstructive uropathy	Percutaneous nephrostomy	a	II	
		Insertion of a double J stent	a	II	

General action	When to perform it	Source	Source	Source
	Not always required	-	NCCN. Prostate Cancer. Version 1.2015	Horwich A, Parker C, de Reijke T, Kataja V; ESMO Guidelines Working Group. Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi106-14.
	Recommended for patients receiving androgen deprivation therapy.	-	NCCN. Prostate Cancer. Version 1.2015	-
	Recommended for patients receiving androgen deprivation therapy.	-	NCCN. Prostate Cancer. Version 1.2015	-
	Recommended for patients received radiation therapy	-	-	Horwich A, Parker C, de Reijke T, Kataja V; ESMO Guidelines Working Group. Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi106-14.
	Recommended for patients on long-term androgen deprivation therapy	-	NCCN. Prostate Cancer. Version 1.2015	Horwich A, Parker C, de Reijke T, Kataja V; ESMO Guidelines Working Group. Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi106-14.
Palliative Care	Palliative approaches are offered within some approaches (e.g. observation) and tumour stages (e.g. metastatic castration-resistant prostate cancer).	Prostate cancer. NICE clinical guideline 175 (2014)	NCCN. Prostate Cancer. Version 1.2015	Horwich A, Parker C, de Reijke T, Kataja V; ESMO Guidelines Working Group. Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi106-14.
		Prostate cancer. NICE clinical guideline 175 (2014)	NCCN. Prostate Cancer. Version 1.2015	Horwich A, Parker C, de Reijke T, Kataja V; ESMO Guidelines Working Group. Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi106-14.
		-	NCCN. Prostate Cancer. Version 1.2015	Horwich A, Parker C, de Reijke T, Kataja V; ESMO Guidelines Working Group. Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi106-14.
		Prostate cancer. NICE clinical guideline 175 (2014)	NCCN. Prostate Cancer. Version 1.2015	Horwich A, Parker C, de Reijke T, Kataja V; ESMO Guidelines Working Group. Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2013;24(6):vi106-14.
		-	NCCN. Prostate Cancer. Version 1.2015	-
		Prostate cancer. NICE clinical guideline 175 (2014)	-	-
		Prostate cancer. NICE clinical guideline 175 (2014)	-	-

Annex 2. Experts information

All experts provided conflict of interest statements, which were reviewed in accordance to WHO requirements. The declared interests are listed in tables below.

Imaging and Nuclear Medicine

NAME	AFFILIATION	COUNTRY	CONTACT EMAIL	JUSTIFICATION	CONFLICT OF INTEREST
Sizar Akoum	Biomedical Engineering Consultant Ministry of Public Health	LEBANON	sizarak@gmail.com	Biomedical Engineer	None
Angelika Bischof Delaloye	Nuclear Medicine Physician	SWITZERLAND	angelika.bischofdelaloye@chuv.ch	Nuclear medicine specialist, focal point for the World Federation of Nuclear Medicine and Biology (WFNMB). Professeur honoraire, Faculté de Biologie et de Médecine, Université de Lausanne	None
Cecil Chow Robilotta	Institute of Physics of University of São Paulo (IFUSP), Nuclear Medicine Physicist	BRAZIL	cecilcr@if.usp.br	Medical physicist specialist in nuclear medicine. Long term experience in nuclear medicine in Latin America and collaboration with the IAEA, senior professor at IFUSP	None
Tobey Clark	University of Vermont/ IFMBE/ American College of Clinical Engineering	USA	tobey.clark@uvm.edu	Director, Clinical Engineering - Imaging equipment consultation; Adjunct Faculty, Nursing & Health Sciences/ Engineering – developed & teach courses on medical equipment technology and management	None
Gloria Soto Giordani	Inter-American College of Radiology/International Society of Radiology (CIR/ISR)	CHILE	gloria.soto@gmail.com	Paediatric radiologist who was president of Inter American College of Radiology and is elected president of the World Federation of Paediatric Imaging, has contributed as external expert to a number of WHO projects/activities	None
Michael Kawooya	African Society of Radiology/International Society of Radiology (ASR/ISR)	UGANDA	kawooyagm@yahoo.co.uk	Radiologist, Imaging specialist with vast experience in radiology and ultrasound, has contributed as external expert to a number of WHO projects/ activities	Member of the Uganda Ministry of Health National Advisory Committee on Medical Equipment 1998-2007
Melissa Martin	Member States of WHO	USA	melissa@therapyphysics.com;melissacarolmartin@yahoo.com	Medical physicist	None
Manuel Antonio Munoz	UNOPS	EL SALVADOR	manuelmu@unops.org	Biomedical Engineer	None
Donna Newman	International Society of Radiographers and Radiological Technologists (ISRRT)	USA	donnaenewman@gmail.com	Nuclear Medicine Technologist with experience in PET/CT, has contributed as external expert to a number of WHO projects/ activities	None
Dieter Nuernburg	World Federation for Ultrasound in Medicine and Biology (WFUMB)	GERMANY	nuernbergdieter@gmx.de	Sonographer	None
Graciano Paulo	Coordinator, Professor of Medical Imaging & Radiotherapy department of Escola Superior de Tecnologia da Saúde do Instituto Politécnico de Coimbra (Portugal)	PORTUGAL	graciano@estescoimbra.pt	Radiographer	None

NAME	AFFILIATION	COUNTRY	CONTACT EMAIL	JUSTIFICATION	CONFLICT OF INTEREST
Madan Rehani	International Organization for Medical Physics (IOMP), Harvard Medical School, Massachusetts General Hospital and Duke University	USA	madan.rehani@gmail.com	Medical physicist	None
Shuvro H Roy-Choudhury	FRCS (London), FRCR (London), CCST (UK), FCIRSE, EBIR (Interventional Radiologist)	INDIA	shuvrorc@googlemail.com	Interventional radiologist, LMIC	None
Satchithanantham Somanesan	Nuclear Medicine, Physicist Singapore General Hospital	SINGAPORE	somanesan@sgh.com.sg	Nuclear medicine physicist Long term experience in nuclear medicine in Asia and collaboration with the IAEA	None
Rathan Subramaniam	Nuclear Radiology Prof. Associate Professor in the Division of Nuclear Medicine, Russell H Morgan Department of Radiology and Radiological Sciences at the Johns Hopkins University School of Medicine, Baltimore, MD	USA	rsubram4@jhmi.edu	Nuclear medicine specialist Long term experience in establishing nuclear medicine and diagnostic imaging facilities	None

Surgery

NAME	AFFILIATION	COUNTRY	CONTACT EMAIL	JUSTIFICATION	CONFLICT OF INTEREST
Nicholas Adjabu	Deputy director, clinical engineering department, Ghana health service	GHANA	adjabu95@yahoo.com	Medical Practitioner and Biomedical Engineer with extensive experience in health technology management especially in Ghana and other developing countries. Has been a health technology consultant in WHO-AFRO. Also the Deputy Director for Clinical Engineering Department of the Ghana Health Service.	None
Benjamin O. Anderson	MD, Professor of Surgery and Global Health Medicine, University of Washington, Seattle, Washington, USA	USA	banderso@uw.edu	Chair and Director, Breast Health Global Initiative (BHGI), Fred Hutchinson Cancer Research Center, Seattle, Washington, USA	Unrestricted educational grant support from Pfizer and Roche
Ainhoa Costas-Chavarri	MD, MPH, FACS General Surgeon, Human Resources for Health Rwanda, Boston Children's Hospital/Harvard Medical School	RWANDA	noabelles@gmail.com	Extensive experience in Rwanda and Haiti; Very experienced on the ground with breast cancer in very low-income countries.	None.
Serigne Gueye	Professor of Urology at University Cheikh Anta DIOP, Dakar, Senegal and Chair of Urology and Andrology, Grand Yoff General Hospital. Adjunct Dean for Research at School of Medicine St Christopher-Iba Mar Diop, University El Hadj Ibrahima Niasse, Dakar, Senegal	SENEGAL	drsmgueye@gmail.com	Professor of urology in Senegal	None
Tom Judd	IFMBE	USA	tom.judd@kp.org	Biomedical engineer	None

NAME	AFFILIATION	COUNTRY	CONTACT EMAIL	JUSTIFICATION	CONFLICT OF INTEREST
Guy Maddern	Professor of Surgery, University of Adelaide	AUSTRALIA	guy.maddern@adelaide.edu.au	Surgical technology assessment	None
C.S. Pramesh	Professor and Chief, Thoracic Surgery, Department of Surgical Oncology at Tata Memorial Hospital	INDIA	prameshcs@tmc.gov.in	Professor of Surgery	Research support from Ethicon Endosurgery
Judith Shamian	International Council of Nurses	CANADA	shamianjudith@gmail.com	Nursing specialist	None
Richard Sullivan	Director , Institute of Cancer Policy and King's Health Partners Comprehensive Cancer Centre	UK	richard.sullivan@kcl.ac.uk	Onco-urologist. Expertise in global cancer policy, implementation science and health services research. Led Lancet Oncology Commission on Global Cancer Surgery. Member of Global Surgery 2030 team	None
Audrey Tsunoda	MD, PhD (oncology) Hospital Erasto Gaertner and Instituto de Oncologia do Paraná	BRAZIL	atsunoda@gmail.com	Surgical Oncologist - Gynaecologic Oncology Department Medical Director at IRCAD Latin America, for minimally invasive surgery	Received educational support for lectures, from Roche, in 2015
David Watters	Deakin University, Australia. Professor of Surgery at Deakin University and Director of Surgery at University Hospital Geelong; President, Royal Australasian College of Surgeons	AUSTRALIA	watters.david@gmail.com	Professor of Surgery	None
Cheng-Har Yip	Department of Surgery, Faculty of Medicine, University of Malaya	MALAYSIA	chenghar.yip@gmail.com	Nearly 30 years' experience working as a general surgeon, paediatric surgeon and now a breast surgeon in a low resource setting. Co-author in the chapter on Surgical Services for Cancer Care in DCP3 Cancer Volume.	None

Pathology

NAME	AFILIATION AND DEGREE	COUNTRY	CONTACT EMAIL	JUSTIFICATION	CONFLICT OF INTEREST
Jagdish Butany	MBBS, MS, FRCPC	CANADA	jagdish.butany@uhn.ca	Consultant Pathologist and substantial experience in laboratory services planning	None
Kirti Chadha	M.D.(Pathology), PDDC (Oncopathology & Oncohematopathology)	INDIA	kirti.chadha@metropolisindia.com	Hematopathologist, Histopathologist/Oncopathologist, and Oncohematopathologist in LMIC	None
Patrick Fitzgibbons	ASCO and CAP/Expert to review medical devices for cancer care	US	patrick.fitzgibbons@stjoe.org	Pathologist	None
John Flanigan	Senior Adviser for NCDs	USA		Internist and Emergency Physician	Employed by the United States Government
Ken Fleming	Senior adviser for Pathology, Centre for Global Health NCI. MB ChB, DPhil FRCPath	UK	kenneth.fleming@medsci.ox.ac.uk	A pathologist with many years of experience. Dean of the Oxford University Medical School and recently finished a term as global health lead for the Royal College of Pathologists U.K.	Owns a consultancy business. Currently contracted by the United States Government

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Héctor A Maldonado-Martínez	M.D. (Pathology), MSc, Ph.D. Head of the Pathology Department, Insituto Nacional de Cancerologia (National Cancer Institute), México	MEXICO	hmaldonado@incan.edu.mx, arzhaus@yahoo.com	Pathologist	Consultant and receives research support from Roche-Ventana
Lai-Meng Looi	MBBS BSc FRANZCR. Liverpool and Macarthur Cancer Therapy Centres, Ingham Institute for Applied Medical Research, University of New South Wales, Western Sydney University	MALAYSIA	looilm@ummc.edu.my	Anatomical pathologist with long practice experience, including pathology laboratory planning and capacity building in low & middle income countries. Past-President of WASPaLM and Co-Chair of the InterAcademy Partnership for Health.	None
Danny A. Milner, Jr.	M.D., MSc(Epi)	US	dmilner@bwh.harvard.edu	Pathologist Extensive experience in Rwanda and Haiti. Very experienced on the ground in very low-income countries with successful implementation.	None
James Pepoon	Administrative Director, Clinical Operations & Planning, Anatomic Pathology - Brigham and Women's Hospital, Boston, MA. Appointed Advisor, Global Cancer Diagnostic Outreach - Partners in Health, Inc., Boston, MA. Appointed Advisor, Global Cancer Diagnostic Outreach - Partners in Health, Inc., Boston, MA	US	jpepoon@partners.org. jpepoon@gmail.com	Pathology Administrator of Anatomic Pathology clinical and research operations with extensive technical background. Substantial experience in global healthcare diagnostic outreach including procurement, construction, operations and human resource needs. Primary projects in Rwanda and Haiti. Very experienced on the ground in very low income countries with successful implementation.	None
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Michael L. Wilson	M.D; Editor of the AJCP Professor of Pathology, University of Colorado African Strategies for Advancing Pathology group	USA	michael.wilson@dhha.org	Substantial experience working in LMIC and in building capacity for Pathology and Laboratory Services	Received research support from NCI, USA for a non-profit organization African Strategies for Advancing Pathology
Ms Gabrielle Wolff	BSc, MLT; Dept of Pathology, Toronto General Hospital	CANADA	gabrielle.wolff@uhn.ca	Pathology technician	None

Radiotherapy

NAME	AFILIATION AND DEGREE	COUNTRY	CONTACT EMAIL	JUSTIFICATION	CONFLICT OF INTEREST
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Surbhi Grover	MD	Botswana, USA	surbhi.grover@uphs.upenn.edu	Radiation oncologist Extensive experience on the ground in Botswana	None
Geoffrey Ibbott	International Organization for Medical Physics (IOMP)	USA	gibbott@mdanderson.org	Medical Physicist	None
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Scott Triedman	MD	USA	scott_triedman@brown.edu	Radiation oncologist Extensive experience planning radiation implementation in Kenya and Rwanda Extensive planning with considerable detail all that is needed for radiation implementation – external beam and brachytherapy	None
Jacob Van Dyk	DSc. Professor Emeritus, Western University, London, Ontario, Canada. Former head of Physics and Engineering, London Regional Cancer Program, London, Ontario, Canada.	CANADA	vandyk@uwo.ca	Medical Physicist. Chairman of UICC/GTFRCC Work Group 2 which determined infrastructure requirements (facilities, equipment, personnel). Worked as consultant in the Dosimetry and Medical Radiation Physics Section at the IAEA from 2009-2011.	JVD has a license agreement for development of QUASAR quality assurance phantoms for radiation therapy treatment planning, sold commercially throughout the world; JVD has received honoraria and travel support for being a consultant and lecturer for the IAEA.
Mei Ling Yap	MBBS BSc FRANZCR. Liverpool and Macarthur Cancer Therapy Centres, Ingham Institute for Applied Medical Research, University of New South Wales, Western Sydney University	AUSTRALIA	mei.yap@sswahs.nsw.gov.au	Radiation oncologist. UICC Global Task force on Radiotherapy for Cancer Control, Lancet Commission Paper on global radiotherapy, co-chair RANZCR Asia-Pacific Radiation Oncology Special Interest Group and GlobalRT.org	None

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Eduardo Cazap	President, Latin American and Caribbean Society of Medical Oncology (SLACOM)	ARGENTINA	ecazap@slacom.org	Medical oncologist Both, Latin America, Europe, Middle East, Global Past President of UICC, Expert in Global cancer control and Global health	Honoraria, Consultant or Advisory: Bayer; Bristol-Myers Squibb; Roche, Fresenius, Pfizer; Research Funding: Paid to Institution: Poniard Pharmaceuticals; Daiichi Sankyo Pharma; Breast Cancer Research Foundation (BCRF); Leadership Position (No honoraria). SLACOM, SIS.
Laura Cedro	Dana Farber Cancer Institute/Operations Manager, IDS Pharmacy	US	lcedro@partners.org, cedro.laura@gmail.com	Oncology pharmacist	None
Ahmed Elzawawy	MD, PHD	EGYPT	worldcooperation@gmail.com	Medical oncologist, Professor of Clinical Oncology, Egypt & Chairs of three Departments of Clinical and Radiation Oncology, Port Said and Ismailia, Egypt , President of ICEDOC (International Campaign for Establishment and Development of Oncology Centers) www.icedoc.net & President of AORTIC & Director of SEMCO	None
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Verna Vanderpuye	FWACS FGCP; National Center for Radiotherapy, Korlebu Teaching Hospital, Accra	GHANA	vanaglat@yahoo.com	Radiation/Medical oncologist. Vast experience in managing cancer patients in Africa.	None

Palliative Care

NAME	AFILIATION AND DEGREE	COUNTRY	CONTACT EMAIL	JUSTIFICATION	CONFLICT OF INTEREST
Claudia Gamondi	Oncology Institute of Southern Switzerland Palliative Care Department	SWITZERLAND	claudia.gamondi@eoc.ch	Clinical director and Palliative medicine specialist	None
Philip Larkin	Professor of Clinical Nursing [Palliative Care], Chair, All-Ireland Institute of Hospice and Palliative Care, UCD School of Nursing, Midwifery and Health Systems and Our Lady's Hospice & Care Services, Head of Subject for Children's Nursing, UCD College of Health Sciences	IRELAND	philip.larkin@ucd.ie	Palliative care nurse specialist	None
Sheila Payne	Emeritus Professor International Observatory on End of Life Care, Lancaster University & Member of WHO ad-hoc technical advisory group on palliative care	UK	s.a.payne@lancaster.ac.uk	Palliative care specialist Palliative care health psychologist and nurse	None

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Annex 3. Terms of reference for experts groups

PURPOSE

The members of the 5 proposed Expert Groups (EGs), will define the medical devices that should be included in the WHO model list of medical devices for cancer management:

COMPOSITION AND WORKING METHODS

Five working groups composed of 7 to 13 members with different disciplines will conduct this exercise. (See below annex table 3-1 the list for a detailed composition)

Annex table 3-1: Experts groups members by specialty

1. SURGERY	2. IMAGING AND NUCLEAR MEDICINE	3. RADIOTHERAPY
1. Oncologic surgeon 2. Anesthetists 3. Surgery manager 4. Biomedical engineer 5. Nurse manager 6. Surgical oncology nurse ** Lancet Surgery commission member(s) for surgery working group*	1. Radiologist 2. Oncologist 3. Oncologic surgeon 4. Radiographer 5. Medical physicist 6. Sonographer 7. Nuclear medicine specialist 8. Nuclear medicine technologist 9. Biomedical Engineer	10. Physicist 11. Radiation oncologist 12. Brachytherapy specialist 13. Radiation technologist 14. Biomedical Engineer ** Lancet Radiotherapy commission member(s)*

4. SYSTEMIC THERAPY AND PALLIATIVE CARE		5. PATHOLOGY AND LABORATORY
1. Medical oncologist 2. Oncology nurse 3. Oncology pharmacist 4. Hematologist 5. Biochemist 6. Pediatric oncologist 7. Pediatric nurse	1. Palliative care specialist 2. Pharmacist/Narcotic specialist 3. Nurse	1. Pathologist 2. Medical oncologist 3. Pathology technician 4. Lab manager 5. Lab technologist 6. Biochemist 7. Biomedical engineer 8. Microbiologist 9. Hematopathologist

A chair will be appointed in the first teleconference and will run the meetings according to the schedule, provide guidance, facilitate and address conflict, delegate and achieve a consensus. A secretariat will be assigned within the group in the first teleconference who will report on progress and the working tools completeness.

An internal WHO staff will provide support to the working groups in terms of WHO-EGs meetings organization, monitoring issues and technical support during the working sessions.

The EGs members will be duly acknowledged in the resulting publication and their contributions will be voluntary.

TIMEFRAME

Annex table 3-2: Schedule for expert groups' work

DATE (WEEK MON-SUN)	DAY AND HOUR	ACTIVITY	RESPONSIBLE/PARTICIPANTS
Week 1 **27 oct-1 nov**	All week	Establish contact with experts	WHO
	1 nov	WHO deliver the information by e mail.	WHO to send to Experts groups
Week 2 **2 nov- 8 nov**	Mo 2 nov (15:00 and 16:30 CET)	Initial TCON (Project explanation, chair and secretariat definition)	GROUP 1: Surgery GROUP 2: Imaging and Nuclear Medicine
	Tu 3 nov (07:00 and 08:30 CET)	Initial TCON (Project explanation, chair and secretariat definition)	GROUP 3: Radiotherapy GROUP 4: Systemic Therapy and Palliative care
	We 4 nov (15:00 and 16:30 CET)	Initial TCON (Project explanation, chair and secretariat definition)	GROUP 5: Laboratory and Pathology
Week 3 **9 nov- 15 nov**	All week	Work and discussion Inside the experts groups	Experts groups

DATE (WEEK MON-SUN)	DAY AND HOUR	ACTIVITY	RESPONSIBLE/PARTICIPANTS
Week 4 16 nov- 22 nov	Mo 16 nov (15:00 and 16:30 CET)	Monitoring TCON	GROUP 1: Surgery GROUP 2: Imaging and Nuclear Medicine
	Tu 17 nov (07:00 and 08:30 CET)	Monitoring TCON	GROUP 3: Radiotherapy GROUP 4: Systemic Therapy and Palliative care
	We 18 nov (15:00 and 16:30 CET)	Monitoring TCON	GROUP 5: Laboratory and Pathology
Week 5 23 nov- 29 nov	All week	Work and discussion Inside the experts groups	Experts groups
Week 6 30 nov- 06 dic	Mo 30 nov	Deliver to WHO completed documents	GROUP 1: Surgery GROUP 2: Imaging and Nuclear Medicine
	Tu 1 dec	Deliver to WHO completed documents	GROUP 3: Radiotherapy GROUP 4: Systemic Therapy and Palliative care
	We 2 dec	Deliver to WHO completed documents	GROUP 5: Laboratory and Pathology
	Fr 4 dec (14:00 CET)	Advisory Committee teleconference to review the outcome of the working groups	Advisory committee and WHO
Dec-Jan 2016		Compile information for final publication	WHO

COMMUNICATION

The communication between members will be held by teleconferences and emails; moreover, the documents for working sessions will be published on a Collaborative Project Website. The secretariat and chair will report back to WHO at least 1 day previous to the teleconference by e mail concerning the main achievements, comments and the meeting agenda.

The EGs should be available to answer their e-mail and be actively involved in the teleconferences. The group has the authority to define their own meeting schedule but it is anticipated that the groups will meet remotely at least 2 times with WHO HQ staff.

GOVERNANCE

The EGs need to decide what is basic when more than one alternative exists and the devices will be rated based upon Multi-criteria decision analysis MCDA, a recommendation will be given whether to include the device or not. The chair should establish consensus regarding discrepancies within the group.

The project will be supervised by WHO headquaters staff.

ACTIVITIES AND DELIVERABLES OF EXPERTS GROUPS:

The EGs will: 1) review the general basic medical devices per service using Working tools 1, 2) identify the basic services, functions/interventions and specific basic medical devices in order to be included in to the WHO Model List of basic medical devices of cancer management using Working tool 2., 3) the EGs will use the Multi-criteria decision analysis (MCDA) tool to complement the selection and prioritization exercise in case of contentious options (or if further information is deemed useful by the EGs to justify inclusion in the list), using Working tool 3 and 4). Develop special notes per type of working group.

The above mentioned activities will be detailed below.

1. Reviewing all the general basic medical devices per services using Working tool 1 considering:
    a. *Pertinence:*
        i. *Are the enounced medical devices considered basic? If so, please highlight with yellow in the list provided of general medical devices whether the devices is listed in the basic column or not.*

- **b.** *Completeness:*
  - **i.** *Are any basic medical devices missing from this list? If so, please ADD at the end of the list.*
- **c.** *Relevance:*
  - **i.** *Are all listed basic medical devices relevant to this list? Please DELETE the device you deem not relevant*
- **d.** *Classification:*
  - **i.** *Are the devices classified accordingly: Medical and QA equipment, instruments, high cost consumables and software, medical furniture, PPE, Clothing, Disposables, Solutions and Reagents and Utensils? If not specify the adequate category in brackets next to the device.*

Refer to annex figure 3-3.

2. Identify the basic services, functions/interventions and specific basic medical devices required for cancer management using the Working tool 2.
   Review the information presented in the working tool 2 about Category, Basic services, Basic functions/ interventions/procedures (by line), Type of Cancer, Basic Specific Medical Devices Devices considering

- **a.** *Pertinence:*
  - **i.** *Is it a BASIC service (column B "Service")? Is the category (column A "category" matching? If so, please leave the information and continue if not highlight with orange) the entire line and all the interventions and devices associated.*
  - ii. *Is it a BASIC/Indispensable intervention (column C "Function/Intervention")? If so*
  - iii. *Is the name and type of cancer adequate for the intervention? If so, please leave the entire line and continue or modify as pertinent.*
  - iv. *Are all the enounced medical devices considered as specific basic devices (column F) If so, please leave the devices in the table.*
- **b.** *Completeness:*
  - **i.** *Are there any basic services or interventions missing from this list? If so, please ADD at the end of the list.*
  - ii. *Are any specific basic devices missing from this list? If so, please ADD in medical devices column.*
- **c.** *Relevance:*
  - **i.** *Are all listed basic services and interventions relevant to this list? Please DELETE the entire line you deem not relevant.*
  - ii. *Are all listed basic devices relevant to this list? Please DELETE the device you deem not relevant.*

Fill in the working tool 2 with the information required.

- **a.** *Fill in the column "Expected outcome".*
- b. *Fill in the column "Contentious option" (Column e and G) in the following cases:*
  - **i.** *In case of doubt as to whether or not a function or a device should be included in this list.*
  - ii. *If the working group considers that further information is needed to justify inclusion in the list.*
- **c.** *Fill in the Key & contextual considerations (Column H)*
- d. *Identify the level of health care system for each intervention/function (Column G)*

Refer to annex table 3-4 for working tool definitions and instructions.

Refer to the example in annex table 3-5.

3. Use the Multi-criteria decision analysis (MCDA) tool in case of contentious options (or if further information is deemed useful by the EGs to justify inclusion in the list), using Working tool 3

The MCDA tool allows for the selection and inclusion of optimal devices by accounting for the outcomes (effectiveness, safety, patient dignity and perspective), the type of benefit (therapeutic benefit [e.g. cure vs. symptom alleviation]; applicability to several diseases and several cancers), as well as implementation aspects (ease of use, ease of training, ability to reach remote communities), economic considerations and positive consequences on healthcare resource utilization.

WHO acknowledges that some criteria need to be considered by member states (e.g., size of population, budget associated) however they are beyond the purpose of this exercise. Furthermore, given the methodology adopted for elaborating the list based on clinical guidelines, the criteria "Expert consensus" was omitted from the working tool.

For more information about the MCDA tool, please refer to: EVIDEM Collaboration. Decision criteria of the framework-Conceptual background, definitions, design & instructions. 2015. https://www.evidem.org/components-decision.php. (Accessed 29 Jul 2015).

Note: for all assessments, the reference point is doing nothing (so the "incremental" assessment is versus nothing)

Fill in working tool 3 considering the criteria for assessing/ranking devices: Least beneficial - Most beneficial and the Scores indicating the performance of the intervention/device for each criteria ranges from High (XXX) to Very low (0). If needed, the options NA (not applicable) and ? (Unknown) can also be selected.

Refer annex table 3-6 for working tool definitions and instructions.

Refer to the example in annex table 3-7.

Expert groups will make a recommendation whether to include the intervention and medical devices or not to include them. Highlight with green if the recommendation is positive.

4. Write special notes and references about the clinical service of the specific experts working group (5 to 10 pages)

   a. *The experts groups are asked to provide the following:*
      i. *Service description and functioning. What are the cohesive functions and services the health facility needs to provide in order to make full use of the indicated devices? The groups should describe general criteria for functionality e.g. surgical services for cancer or pathology services for cancer.*
      ii. *Human resources information.*
      iii. *Infrastructure considerations.*
      iv. *Interdependencies.*
      v. *Quality and Safety*
      vi. *Others: i.e. Volume and quantification*

Consider the annex table 3-4 definitions.

2. List relevant references you recommend for further reading.

Annex figure 3-3: First section of working tool 1

Working Tool 1

List of General Medical Devices for Laboratory

Medical Equipment, Furniture, PPE, Disposables, Solutions and Reagents, Utensils , Instruments and Hardware/Software

	OPTIONS DEPENDING ON THE SETTINGS AND RESOURCES AVAILABLE			Optional devices
Procedure	1 (Basic)	2 (Standard)	3 (Advanced)	
Pre-analytical procedure- Phlebotomy, sample reception and distribution	**Equipment**			
		Table top centrifuge		Automated sample processing system
	Furniture			
	Adequate furniture for the laboratory devices			
		Blood Draw Chairs		
		Samples distribution trolley		
	Personal Protective Equipment			
	Coat, medical, woven, white - # sizes			
	Gloves, examination, latex, non-sterile, single use (Sizes*)			
	Biozahard disposal container			
	Disposables/Medical supplies			
	Bandage, adhesive, 3.0 cm, box/100			
	Compress, gauze, anti-septic, 6x3cm, sterile			
	Compress, gauze,sterile & non-sterile, single use			
	Needles, luer, sterile, single use (Sizes G*)			
	Paper towels			
	Swab-pad, alcohol			...

Annex table 3-4: Instruction tool for working tool 2 and definitions.

CRITERIA	DEFINITION
Category	Intended purpose of functions/interventions: Investigational (Diagnostic/Monitoring) and Therapeutic, commonly the category will apply to the devices associated as intended use.
Basic services	Fundamental services absolutely necessary for any cancer health care system to function, attainable with limited financial means and modest infrastructure. i.e. Diagnostic imaging, surgery, histopathology.
Basic interventions/ function	Fundamental interventions absolutely necessary for any cancer health care system to function attainable with limited financial means and modest infrastructure.
Expected outcome	Mention the expected outcome of the intervention if applicable. Therapeutic outcome (e.g., removal of tumour) or diagnostic/investigational outcome of the intervention defined if applicable.
Type of Cancer:	Define the cancer type(s) applicable to the intervention/function. B/Breast cancer, CR/ Colorectal Cancer, P/Prostate cancer, L/Leukaemia, CU Cervical Cancer, L/Lung Cancer.
Specific Basic Medical Devices:	Describe the specific basic medical devices needed to carry out the intervention safely. These devices are components of cancer care (although not necessarily specific to cancer). They are basic (indispensable to provide cancer care), and affordable (low range of overall costs of acquisition and maintenance). This includes medical equipment, instruments, disposables, devices that cannot be included in the basic general devices because they are intervention specific and probably cancer specific. For specific examples, please see provided tool.
Contentious option	Describe whether the working group had a discrepancy or considered it is worthwhile to detail further information about function/interventions or devices.
Interdependencies:	Device to be considered only if pre-requisite intervention/device has been used (e.g., diagnostic before radiation). Interpendencies may also occur with other services.
Human resources requirement	Indicate whether specialized skills are needed. What human resources should be available?
Infrastructure requirements	Indicate whether special infrastructure is needed including utilities (e.g. AC, voltage, power, water, IT, confinement, waste management, temperature control)
Key equipment associated (not stand-alone):	Indicate if other devices are necessary to operate the specific device or to achieve the intended function.
Planning, quality assurance and safety considerations:	Indicate need for planning and quality assessment. How can and should the devices (and their output) be quality assured? What is necessary in order to make safe use of devices?
Other special considerations:	Please specify if there are special considerations to account for, for example, regarding selection and procurement or use of the medical equipment for that service. List any particular issues planners should bear in mind.
Level of Healh care system	Community Level (CL) This level includes individuals and organizations; community-based, faith-based and other nongovernmental organizations; and community and home-based palliative care services. Also included are health posts, which are usually staffed by an auxiliary nurse or community health worker. Health Centre – Primary Care Level (HC) A health centre is a primary care facility with trained staff and regular working hours. Maternity and minimal laboratory services may be available. District Hospital – Secondary Care Level (DH) Typically, a hospital at this level provides general medical, paediatric and maternity services, general surgery, inpatient and outpatient care, and specialized care in some specific areas. Patients may be referred to this level from health centres and private practitioners in the district. Laboratory services may include cytology and histopathology. Central Or Referral Hospital – Tertiary Care Level (RH) Tertiary care hospitals provide specialized care for complex cases and acutely ill patients, including surgery, radiotherapy and multiple outpatient and inpatient services. General medical, acute and chronic care clinics are offered. The most complete public-sector diagnostic and reference laboratory services are available with pathologists and cytotechnologists, radiology and diagnostic imaging.

Annex table 3-5: Working tool 2 (Examples are included below for illustration only. For full working tools, see www.who.int/medical_devices for supplementary annex.)

A: Category	B: Basic Service	C: Basic Function or Intervention	D. Expected Outcomes	E Type of Cancer	E: Contentious Option (function) Y/N	F: Basic Specific Medical devices	G: Contentious Option (device) Y/N	H: Key & contextual considerations (see definitions & guidance for below) Complete as applicable						C: Level of Health Care
								Interdependencies	HR requirements	Infrastructure requirements	Key Associated devices	QA & management	Other	
Investigational	Imaging	Mammography		B	N	Stationary mammographic X-Ray system	N	NA	1. Radiologist 2.Radiographer	Shielded room	Compression devices for additional projections	Radiation shielding apron, Radiation shielding apron rack, Dosimeter	NA	DH,RH
Investigational	NA	Papanicolau		C CU	N	Colposcope	Y	Pathology Lab for biopsy examination	N1A H	NA	NA	NA	NA	HC, DH, RH
Therapeutic	Radiotherapy	External Radiotherapy		B CU,	Y	Telethertherapy unit	Y	Computerized treatment planning systems	1. Physicist 2. Radiation oncologist 3. RTT (Radiation Therapist)	Adequate Network Infrastructure and storage capacity	Resuscitation trolley equipped,- Closed-circuit television system, Advanced Vital Signs Monitor	REFERENCE TO THE RADIOTHERAPY GENERAL DEVICES	NA	DH,RH

HR: human resources; QA: quality assessment

Annex table 3-6: Criteria and scoring instruction for MCDA methodology for working tool 3

DOMAIN Cluster of criteria based on MCDA principle of meaningful clustering	CRITERIA Criteria representing a contribution to the value of the intervention/ device; criteria included are justified by ethical positions for healthcare decision making (adapted from EVIDEM (www.evidem.org)	DEFINITION
Outcomes	Efficacy/effectiveness	A broad notion of effectiveness is used that is adapted to the type of device: For devices performing a therapeutic function, assessment of effectiveness is based on therapeutic outcomes. For devices performing a diagnostic function, assessment of effectiveness is based on sensitivity, specificity and negative/positive predictive value For other types of devices, specify what is considered (e.g., pump type features) Note: If effectiveness varies across cancer types, indicate a range, e.g. X–XXX, and specify as footnote below table OR create a row for each type of cancer (e.g., XXX for breast cancer, 0 for leukaemia)
	Safety	Includes both: risk of patient adverse events with correct operation and risk of errors in operating the device resulting in patient adverse events Note: If safety varies across cancer types, indicate a range, e.g. X–XXX, and specify as footnote below table OR create a row for each type of cancer (e.g., XXX for breast cancer, 0 for leukaemia)
	Patient reported outcomes (PROs)	Quality of patient experience with the device; includes notion of convenience, invasiveness, impact on dignity, autonomy, and tolerability by patient of the application of the device Note: If PROs vary across cancer types, indicate a range, e.g. X–XXX, and specify as footnote below table OR create a row for each type of cancer (e.g., XXX for breast cancer, 0 for leukaemia)
Type of benefit	Type of therapeutic benefit (e.g. cure)	Only for devices which fulfill therapeutic functions (cure is high and symptom relief is low) Note: If type of benefit varies across cancer types, indicate a range, e.g. X–XXX, and specify as footnote below table OR create a row for each type of cancer (e.g., XXX for breast cancer, 0 for leukaemia)
	Applicability across disease areas	Device can be used for multiple diseases
	Applicability across cancers	Device can be used for multiple types of cancer
Implementation	Ease of use	Broad notion of ease of use from the healthcare worker perspective (includes also safety considerations for worker)
	Ease of training	Knowledge and training necessary to apply the device
	Ability to reach remote communities	Device easily portable, easy to use with telemedicine
Economics	Affordability of device	Cost of purchase/acquisition and operation/administration
	Affordability of device maintenance & replacement	Cost of maintenance (repair) & replacement (taking into account the lifespan of the device)
	Positive consequences on healthcare resource utilization	Limited need of physician visits, hospitalization, monitoring etc.
Quality of evidence	Quality of evidence	Extent to which evidence on the intervention is valid with respect to scientific standards. This includes consideration of uncertainty (eg conflicting results/interpretation, limited date). Common sense might be deemed as sufficient evidence.

Annex table 3-7: Working tool 3 (Examples are included below for illustration only. For full working tools, see www.who.int/medical_devices for supplementary annex.) Expert group: Surgery

A: Function/ Intervention	B Contentious Option	C: Specific Medical Devices	D: Contentious Option Yes/No as	E: Value Criteria (see definitions and guidance for scoring in table above) Complete as applicable											
				Effectiveness*	Safety*	PROs*	Therapeutic benefit*	Multi-disease	Multi-cancer	Ease of use	Ease of training	Remote communities	Affordability – device	Affordability – maintenance / replacement	HC resource consequences	Quality of evidence
Colonoscopy	YES (see above)	Colonoscope	YES	xxx	xxx	xxx	NA	x	x	xx	xx	x	x	x	x	xx
Mediastinoscopy	YES (see above)	Other device	YES	xx	xxx	xxx	NA	x	x	xx	xx	xxx	xxx	xxx	x	xx

PROs: patient-reported outcomes; HC: healthcare

Annex 4. List of priority medical devices for cancer management, by categories

Capital equipment

MEDICAL EQUIPMENT
Anaesthesia unit, mobile, basic
Aneroid sphygmomanometer
Biopsy gun
Blood glucometer
Bronchoscope
Cerebrospinal fluid manometer
Colposcope
Computed Tomography (CT) System (multi-slice)
Computerized treatment planning systems (three-dimensional)
Contrast medium injection system
Conventional simulator with digital imaging systems
Cryosurgery unit
Defibrillator
Diagnostic spirometer
Elastomeric pump
Electrocardiography system
Electrosurgical unit
Emergency cart with medicines
Endoscope sterilization/ disinfection support set
Endoscope washer/disinfector
Endoscopy tower system
Examination light
Fixed examination/treatment light
Flexible sigmoidoscope
Floor scale with stadiometer
Gamma camera system
Gamma probes (for intraoperative use)
General physical examination set (Ophthalmoscope, Otoscope, Lamp)
General ultrasound colour Doppler imaging system
General-purpose digital radiography system
General-purpose suction system, vacuum
Gynaecological examination/treatment table
Hammer for neurological examination
Infant scale
Infusion pump
Infusion pump for enteral nutrition
Linear Accelerator (LINAC) 3D Conformal therapy
Magnetic Resonance Imaging (MRI) System (1.5 T)
Mammographic stereotactic biopsy system
Mammographic X-ray system
Mobile diagnostic X-ray digital system (C-arm)
MR-safe stethoscope and sphygmomanometer
MRI compatible anaesthesia machine
MRI compatible biopsy procedure equipment
MRI compatible infusion pump
MRI compatible patient physiologic monitoring system
MRI compatible resuscitation trolley equipped with medicines and defibrillator
Nebulizer
Non-heated respiratory humidifier
Operating light, light source (lamp & flashlight)
Oxygen humidifier with flowmeter
Oxygen therapy flowmeter, dialtype
Patient positioning/tracking system
PET/CT system
Proctoscope
Pulse oximeter
Radionuclide generator
Rectal irrigation system
Remote-afterloading brachytherapy system, at least 12 channels
Respirator
Resuscitation trolley, equipped with medicines and defibrillator with laryngoscope
Resuscitator bag valve and mask (adult and paediatric)
Rigid cystoscope
Rigid sigmoidoscope
Rotary saw (optional)
Single-patient physiologic monitoring system for ECG, Capnography, SpO2, blood pressure
Stadiometer (wall mounted)
Stepping unit and stabilizer
Stethoscope, adult, binaural and paediatric
Suction and irrigation device
Syringe pump
Thermometer, clinical, digital 32–43°C
Thin layer chromatography scanner
Tympanic thermometer
Ultrasonic washer
ultrasound imaging system specific for TRUS
Ultrasound unit with biplanar transducer
Universal operating table
Universal operating table radiotransparent
Vibratory (reciprocating) saw
Video-colonoscope
Weighing scale, range 0 –150 Kg

LABORATORY AND PATHOLOGY EQUIPMENT

- Analyser Laboratory Haematology, Manual or Automated
- Basic laboratory mixer/Laboratory shaker vortex
- Camera (photo microscopy)
- Cassette printer (optional)
- Centrifuge
- Centrifuge, micro - haematocrit
- Class-II biological safety cabinet
- Clinical chemistry Analyser
- Coagulation analyser, manual or automated
- Cover slipper for slides
- Cryostat for intraoperative frozen sections
- Cytocentrifuge
- Distillation unit, 2 L/h, with tank
- Flow cytometer
- Freezer, laboratory
- Gravity-convection laboratory oven
- Grossing table, simple with cutting board and exhaust
- High performance liquid chromatography
- Hot plate, with stirrer
- Humid chamber
- Hygrometer
- iFOB immunochemical analyzer, automated
- Immunoassay analyser, automated
- Immunohistochemistry (IHC)/In situ hybridization (ISH) staining platform, semi-automated
- Immunostaining centre
- Incubator, 30 L, up to 80° C
- Macro digital imaging for pathology (optional)
- Magnetic stirrer plate
- Magnifying glass
- Mechanical balance
- Microscope, binocular
- Microtome
- Microwave oven
- Negative Pressure Fume Hood
- Organ balance
- Oven
- pH meter
- Pharmacy refrigerator
- Positive Pressure Laminar Flow cabinet for radiopharmaceutical preparation
- Professional grossing bench with sink (exhaust system)
- Refrigerator
- Refrigerator/freezer, laboratory
- Rotator, agglutination test
- Scale, digital, 1500 g/0.1 g
- Scale, precision, digital, 500 g/0.01 g
- Shaker, orbital
- Slide label printer (Optional)
- Slide trays or plastic slide carriers for transport
- Spectrophotometer, ultraviolet/ visible
- Stainer
- Staining station/Automated slide stainer
- Sterilizer steam autoclave, 24 L
- Table Lamp
- Table top centrifuge
- Thermometer, glass, min/max -20°C/100°C
- Thermometer, min/max -30°C/60°C
- Timer, 60 min, mechanical
- Timer, digital
- Tissue embedding unit or station
- Tissue processor
- Water bath thermometer
- Water bath, 7 L

QUALITY ASSURANCE DEVICES

- Array of diodes or ion chambers for routine quality assurance checks
- Barometer
- Calibrated radioactive reference sources for quality control of activity measuring systems
- CT phantom and CT quality control devices
- Diagnostic ultrasound phantom
- Dose calibrator
- EPID image quality phantom
- Film dosimetry system
- In-vivo dosimetry system
- Large volume ionization chamber
- Long lived reference source for checking the stability of the welltype ionization chamber
- Measurement marker clip
- Measurement marker wire
- MRI system quality assurance device
- Phantom for daily mechanical and light field checks on teletherapy unit
- Plastic slab phantom with holes for ionization chambers for beam output verification
- QA Phantom for brachytherapy
- QA phantom for CT positioning lasers evaluation
- QA/QC phantoms and accessories for Gamma Camera system
- QA/QC phantoms and accessories for PET /CT System
- Radiation field analyser to measure isodose distributions

Radioactive source for checking the stability of ionization chambers
Survey meter
Thermometer calibrated at a standards laboratory
Water phantom for calibration
Waterproof cylindrical ionization chambers
Waterproof plane-parallel ionization chamber
Well-type ionization chamber or an isotope calibrator with source holding inserts calibrated at a standards laboratory

SURGICAL INSTRUMENTS

Abdominal Hysterectomy set
Aspiration tray
Basic Colon Surgery set
Basic Rectal Surgery set
Basic Surgery set/ Minor tray
Biopsy forceps
Blunt obturator
Bone marrow aspiration set
Catheter placement set
Cervical punch biopsy forceps
Cervix conization set
Cheron forceps
Chest Aspirations set
Chest tube insertion kit
Chest tube set
Clamp, test tubes
Cricothyroidotomy set
Cystoscope sheath
Cystoscopy biopsy forceps
Dressing set
Endo-GIA stapler
Endocervical curette
Endoclip-applicator
Endoscopic hemoclip
Endotracheal tube
Examination/suturing, vaginal/cervical set
Excisional breast biopsy set
Forcep, artery
Forceps
Forceps tissue-long
Forceps, dressing, 155 mm, straight
General-purpose surgical scissors, reusable
Gynaecologic biopsy set
Gynecological and Kidney set
Hysterometer
Internally-anchored endotherapy retractor
Laparoscope holder
Laparoscopic biopsy forceps
Laparoscopic dissection spatula
Laparoscopic electrosurgical blunt dissector
Laparoscopic grasper
Laparoscopic grasping forceps
Laparoscopic irrigation/aspiration cannula
Laparoscopic multi-instrument access port
Laparoscopic needle holder
Laparoscopic swab forceps
Laparotomy ring
Laparotomy set
Laryngoscope handle with Macintosh blades
Lobectomy and segmental lung set
Long needle holders
Lumbar Puncture set, Adult
Lumbar Puncture set, Paediatrics
Manual expandable cervical dilator
Mastectomy set
McGill forceps adult and paediatric
Measurement ruler
Metzenbaum scissors
Needle holders
Pleural Biopsy set
Polypectomy snare
Prostatectomy set
Punch, Dry Blood Spot (DBS), 3.0 mm
Retractors (various sizes)
Ring forceps
Scalpel with blades
Scissors
Spatula, stainless steel (various sizes)
Suture set
Suture set
Thoracentesis set
Thoracotomy set
Tracheostomy set
Trocars with safety sheath (multiple sizes)
Urology set
Uterine forceps
Vaginal hysterectomy set
Vaginal sidewall retractors
Vaginal speculum, Non conducting preferably with side retractors
Vaginal speculum, reusable
Wire oval snare

Single use, accessories, software, consumables, protection devices and reagents

LABORATORY AND PATHOLOGY EQUIPMENT

- Bag, disposable for biohazardous waste
- Bags for contaminated disposable supplies
- Containers for hazardous waste (solutions and others)
- Faecal occult blood test (FOBT) rapid test kit (slides and applicator sticks)
- Graduated pipettes
- HPV DNA Test
- Micropipettes (different microliters)
- Microplate, ELISA, 96 U-well
- Pasteur Pipette
- Pipette, digital, 10–100 ul
- Pipette, digital, 100–1000 ul
- Pipette, digital, 2–20 u
- Pipette, digital, 20–200 ul
- Pipette, digital, 8 channel, 20-200 ul
- Pipette, digital, 8 channel, 5–50 ul
- Pipette, filler, wheel-run, set/2
- Pipette, repeating, 5 volume
- Pipette, stand, 4 positions
- Pipettes, blood graduated, 0.05 ml
- Rack, drying glass & plastic ware
- Rack, staining slides
- Rack, test tubes, 24 positions
- Rack, tubes, 0.5/2.0/5.0 ml, 24 positions
- Safety box for used syringes/needles
- Serological pipette
- Staining rack

PERSONAL PROTECTIVE EQUIPMENT AND CLOTHING

- Apron impermeable
- Clogs, plastic (various sizes)
- Coat, medical, woven, white (various sizes)
- Disposable apron or heavy duty plastic apron (washable, reusable)
- Drawsheet, plastic, approx. 90x180 cm
- Examination/treatment table cover
- Eye protective wear
- Face masks N95
- General-purpose sterile drape
- Glasses, safety, regular size
- Gloves, examination, non-sterile,single use (various sizes)
- Gloves, nitrile, powder-free, nonsterile, single use
- Gown, impermeable single use
- Gown, patient
- Heat-resistant gloves
- Mask, surgical, non-woven
- Medical scrubs for healthcare workers or similar
- Non-conductive shoe cover
- Operating room gown, reusable
- Plastic face shield
- Surgical cap for patients and healthcare worker
- Surgical face mask

RADIATION PROTECTION/MONITORING DEVICES

- Area monitoring devices (area survey meter)
- Area radiation monitor (audible alarm)
- Breast shielding
- Clamps for the source management
- Dosimeter, personal
- Dummy sources
- Emergency container and emergency source handling instruments
- Geiger-Müller counter radiation survey meter and measuring probe
- Gonadal shielding
- Ion chamber survey meter
- Patient radiation shielding
- Portable radiation protection barriers
- Radiation shielding apron
- Radiation shielding apron rack
- Radiation shielding gloves
- Radiation shielding goggles
- Radiation shielding headwear
- Radioactive waste storage
- Ring dosimeter
- Source handling instruments and accessories
- Source loading and cutting devices
- Source storage and transport containers within the department
- Thyroid shielding

SINGLE USE DEVICES/DISPOSABLES/ MEDICAL SUPPLIES

- Absorbent tipped applicator
- Adult/children diapers (incontinence pads)
- Anaesthesia breathing circuit
- Asepto syringe
- Bag, biohazard, 20 L
- Bag, re-sealable, plastic
- Bags for contaminated supplies
- Bandage, adhesive, 3.0 cm, 100/box
- Bandage, elastic, 7.5 cm x 5 m, roll
- Biopsy needle
- Blood collection tube, neonatal cord blood, sterile
- Blood giving sets and cannulas
- Cannulas, Intra Venous (IV) short, sterile, single use (sizes G)
- Cassettes
- Catheter (18 gauge or larger)
- Catheter bag
- Catheter, Foley, sterile, single use (sizes G)
- Catheter, urethral, sterile, single use (sizes G)
- Cervical aspiration catheter
- Cervical cytology brush or cervical cytology scraper
- Chest tube
- Chest tubes drainage
- Closed system drug transfer devices
- Closed-wound drainage reservoir system with closed wound drain connector
- Collection tube/sterile plastic tubes
- Collector, urine, adhesive, 10–100 ml
- Combined spinal epidural anaesthesia trays (spring-wound catheter, spinal epidural needles)
- Compress gauze, sterile & non-sterile, single use
- Compress, gauze, antiseptic, 6x3 cm, sterile
- Compression bandages (for Deep Vein Thrombosis)
- Container, sample, 50 ml
- Cotton wool, 500 g, roll, non-sterile
- Cover glass, slides
- Cover glass/cover slips
- Cryptographic/urethrographic catheter, female
- Devices to deliver enemas through stomas
- Devices to manage genital fistulae
- Drainage bag including gravitational IV tube or connect to suction system
- Dressing retention roll
- Dressing sets for malodours/ fungating wounds (carbon pads/ silver impregnated pads, etc.)
- Dressing strip, adhesive, diameter 3.0 cm, sterile
- Elastic bandage
- Endotracheal tubes adult and paediatric
- Envelope, packing, 27x36 cm
- Epidural catheter
- Examination table paper cover
- Female sanitary products
- Fiducial markers/soft tissue markers
- Film, sealing, flexible, 10 cm x 38 m, roll
- Filter Discs
- Filter needles
- Filter Venting devices
- First aid gauze/bandage
- Flexible silicon catheter with needle
- Gastrostomy material for skin medication and use
- Gauze strip antimicrobial
- Gelfoam (for plugged biopsy)
- General-purpose sterile drape
- Grey bottle, sterile universal specimen bottles
- Hemoclips/clip cartridge or similar for cardiothoracic surgery
- Hypodermic needles: gauge 25 G, 23 G, 21 G
- ICD set / Thoracic tube insertion set
- Infusion giving set, sterile, single use
- Infusion set, sterile, single use
- Inoculation loop, plastic, sterile
- Instrument/equipment drape, single-use, non-sterile
- Intravenous catheters
- Intubating bougies, adult and paediatric
- IV burettes
- IV catheters
- IV infusor bags/sets
- Kato-Katz, kit, stool sample preparation
- Lancet, 2 mm, safety, sterile
- Lancet, blood, safety, sterile (various sizes)
- Laryngeal mask airways
- Lead sharps container according to isotope energy used
- Markers, fine point, permanent black, for glassware and slides
- Mask and tubing for oxygen
- Medication cups
- Micro-vial tubes

Nasogastric tube
Nasogastric tube fixator
Needle cradle
Needle holder, vacuum tubes, sterile
Needle, vacuum tube, 20 G/ 22 G, sterile
Needles, luer, sterile, single use (sizes G)
Needles, scalp vein, sterile, single use (sizes G)
Needles, spinal, sterile, single use (sizes G)
Needles, sterile, single use: • 20–24G (for fine needle aspiration)• 11–14 G (for bone biopsy)• 16–20G (for other tissue biopsy)
Non-implantable needle guide
Non-sterile coupling gel
Operating room laundry bag
Organ bag
Oropharyngeal airway (adult size)
Ostomy bag
Paediatric foley catheters and nasogastric tubes
Paediatric spinal needles
Paper towels
Paper, dry blood spot
Paper, exam table
Paper, filter
Paper, lens
Paper, pH indicator 2.0 to 9.0
Paper, weighing
Paracentesis set
Parafilm paper
Parenteral/enteral solution bag
Partial-rebreathing oxygen face mask
Pipette, repeat, tip 2.5/5.0 ml, 10/25 ml
Pipette, tip, barrier, 200 ul / 1000 ul, sterile
Pipette, tip, blue, 100–1000 ul
Pipette, tip, white, 2–20 ul
Pipette, tip, yellow, 10–100 ul / 20–200 ul
Pipette, transfer, 3 ml, non-sterile
Pipette, transfer, 3 ml, sterile
Pneumonectomy pleurevacs only for Pneumonectomy
Prongs, nasal, oxygen, non sterile, single use (various sizes)
Rack, drying DBS cards, 10 positions
Radiographic or radiochromic film
Rectal probe or rectal catheter
Reservoir, reagent, 60 ml
Sclerotherapy endoscopic needles
Sealant, compound
Secondary set with drip chamber
Septo syringe
Sheet, absorbent, bench, 50x40 cm
Skin-cleansing wipe
Skin-cover adhesive strip
Slide, microscope
Slide, microscope, frosted
Specimen container
Spinal anaesthesia needle, single-use
Sponges
Sputum containers
Staplers (linear and thoracotomy) with staples reloads
Sterile culture tube
Sterile sample container
Sterile ultrasound coupling gel
Stoma/ostomy bags and adhesive
Suprapubic catheter
Surgery table, padded accessories for patient positioning or similar
Surgical clip
Surgical scrub brush, single-use
Surgical scrub sponge
Suture, synthetic, non-absorbable (sizes USP/DEC) with needle (sizes G), sterile, single use, nylon, catgut, silk
Sutures
Swab-pad, alcohol
Swab, cotton-tip, tube, sterile
Syringes (various capacities)
Syringes for drug preparation/ formulation
Syringes for the biopsy and holder (optional)
Syringes with needles (disposable)
Syringes, autodisable (AD), (various capacities)
Syringes, luer, sterile, single use (various capacities)
T-tube and ties
Tape, medical, roll (various sizes)
Three-way-stopcock
Tongue depressor, single use (wooden or plastic spatula)
Transparent film dressings
Transparent film dressings with a gel pad
Tube containing EDTA anticoagulant
Tube suction, Yankauer, 270 mm/Yankauer suction tips

Tube, push cap, 0.2 ml, PCR, sterile
Tube, push cap, 5.0 ml, non-sterile
Tube, screw cap, 0.2 ml / 0.5 ml / 2.0 ml / 5.0 ml, non-sterile
Tube, screw cap, 0.2 ml / 0.5 ml / 2.0 ml / 5.0 ml, sterile
Tube, screw cap, conic, 15/50 ml, non-sterile
Tube, suction, L 50 cm, catheter tip, sterile, single use (sizes G)
Tube, vacuum, EDTA, 2 ml / 4 ml / 6 ml, sterile
Tube, vacuum, Ethylene Diamine
Tube, vacuum, plain/dry, sterile (various capacities)
Tube, vacuum, serum, 4 ml / 6 ml, sterile
Ureteral catheter connector and other connectors as required
Urinary catheter (Foley)
Urine drain bag
Urological irrigation kit
Veress needle (optional, for transperitoneal access only)
Vortex, test tube
Wire localization needle (e.g. Kopan's Needle 21G, 20G)
Wooden or plastic applicator sticks

SOLUTIONS AND REAGENTS

Acetic acid solution
Acetone, bottle
Acid Alcohol 1%
Alcohol
Alcohol isopropyl 70%
Alcoholic Ammonia 1%
Alkaline detergent solution
Ammonium hydroxide/Ammonia
Amplification Kit for IHC staining platform
Antibody detection kit for IHC staining platform
Antibody diluent
Antibody recovery solution
Antimicrobial solution
Antiseptic skin cleansing agent
Aqueous antibacterial solution/ Aqueous cleaning and decontaminating solutions
Blocking protein solution
Bluing Reagent
Bromine solution
Buffer, tablets, pH 7.2, box
Chlorhexidine
Chlorine solution
Contrast medium, injectable
Contrast medium, oral
Cytology stain kit
Detection system based on polymers
Diamine
Diethyl ether, bottle
Dispenser with pre kit for automated staining platform
Distilled water
Endoscope cleaning kit
Enzymatic detergent, test strip to measure the action of enzyme
Enzyme solutions
Eosin
Ethanol
Ethanol, denatured, bottle
Ethyl alcohol
Fixative spray or solution for pap smear (if slides are used)
Formaldehyde, 10%, 10 ml, ampoule
Formalin 10%, or tissue fixation reagents
Gelatin Titanium dioxide (E171) Indigo carmine solution
Gentian violet, solution, bottle
Giemsa Stain
Glutaraldehyde 3.4% (Cidex, Maxicide, Wavicide)
Glycerol, bottle
Haematoxylin
Hand/body hygiene products
Harris's Haematoxylin
Hydrochloric acid, 40%, bottle
Hydrogen peroxide
Immunoassay analyser reagent sample diluent
Immunoassay analyser reagents
Immunohistochemistry (IHC)/In situ hybridization (ISH) staining platform reagents
Indian ink, black, bottle
Ink (for surgical margins)
Iodine povacrylex
Iodine preparation cleansing agent
Isopropyl alcohol
IV solution
KI starch solution
Lubricating jelly (K-Y)
Lugol iodine, bottle

May Grunewald stain (BDH)
Methanol, bottle
Methylene blue, bottle
Monsel's paste
Mounting medium
MRI contrast medium, injectable
Neutral Buffered Formalin 10%
Nitric acid
Oil, immersion, bottle
Orange Gelb-6
Oxidase test
Oxygenated water
Paraffin
Peracetic acid disinfectant anticorrosion additive (for endoscopes or similar)
Peroxidase
Petroleum gel, paraffin, bottle
Phosphate Buffer (pH 6.8)
Pipettes cleaning solution
Potassium iodide
Preservative solutions
Primary antibodies
Rubber cement
Saline solution
Sclerodesis agent (e.g. talc)
Secondary antibodies
Silica gel (desiccant for DBS), pouch
Sodium bicarbonate
Sodium chloride, powder, bottle
Sodium hypochlorite solution
Sodium hypochlorite, tablets
Sodium persulfate
Stain, Field A, solution
Stain, Field B, solution
Stain, Giemsa, solution
Stain, Gram, set
Stain, May-Grunwald Giemsa, set
Stain, Ziehl–Neelsen, solution, bottle
Substrate, adamantyl phosphate oxetane
Sugar fermentation tests
Sulphuric acid, 95%
Test, Nickerson or sabouraud medium, kit
Test, potassium hydroxide KOH, preparation
Transurethral-instrument lubricant
Trichloroacetic acid, crystals, bottle
Wash solution
Washing buffer
Xylene, bottle

OTHER (glassware, utensils, etc.)
Acetate sheets
Arm/leg tourniquet
Basic sedation equipment
Basin, kidney, polypropylene
Beaker, glass, 100 ml / 250 ml
Bedpan
Bolus
Bottle reagent
Bottle, amber, dropper, 30 ml
Bottle, amber, screw cap, 100 ml /250 ml / 1000 ml
Bottle, plastic, 1 L
Bowl, polypropylene
Bowl/Emesis bowl
Box, refill, pipette tips, empty
Box, specimen transport, 2 L/4 L
Box, storage 0.5/2/5 ml tubes, 100 positions
Box, storage, 100 slides
Brush, bottles and flasks (various sizes)
Brush, hand, scrubbing, plastic
Brush, test tubes (various sizes)
Container for specimen immersion
Container for warm water
Coplin jar
Cover plates
Cover slipper - Shandon cover plate
Cylinder, measuring, glass, 10 ml/ 100 ml / 500 ml/ 100 ml
Cytotoxic waste receptacle
Drill
Dropper bottles
Funnel, glass
Funnel, plastic
Glassware Beaker
Hand/body hygiene products
Hazardous drug spill kits
Hot water bath for thermoplastic immobilization system
Hot wire cutter

Jar, Coplin, staining
Knife for specimens
Label or pen for labelling specimen containers
Label, biohazard, adhesive, 3x4 cm
Label, self-adhesive, different sizes
Label, self-adhesive, freezer
Labels for the drugs identification
Magnetic metal detector
Manual brachytherapy source, temporary placement
Marker pen, cryoware
Marker pen, glassware
Marker, diamond
Markers, fine point, permanent black, for glassware
Mould materials (Foam blocks/Styrofoam/Polystyrene, Thermoplastic, vacuum bag or similar as needed)
MRI compatible oxygen canisters
Oxygen/gas pipeline, cylinder
Petri dish, glass, with lid
Pot for cerrobend cadmium free low melting point alloy
Pressure cooker
Pressure relief products (e.g. Cushions, mattresses)
Receptacle, waste, stainless steel,pedal action
Rod, glass
Rubber hammer
Ruler
Sample distribution container
Skin marker pen
Smoke evacuator
Specimen cup
Sponge bowl
Thermic containers
Urinal
Warming cabinet for contrast media
Wash bottle, 250 ml
Waste disposal container

SOFTWARE
Laboratory Information System (LIS)
Picture Archiving Communication System (PACS)
Radiology Information System (RIS)

WHO list of priority medical devices for cancer management

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