World Health Organization

WHO list of priority medical devices for management of cardiovascular diseases and diabetes

WHO medical device technical series

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The project was developed under the overall coordination of Adriana Velazquez Berumen, Team Lead, Medical Devices and In Vitro Diagnostics, with the guidance from Clive Ondari, Director of the Health Product Policy and Standards Department and under the leadership of Mariangela Simao, Assistant Director General of the Access to Medicines and Health Products Division, WHO. Strategic and technical guidance was received from Cherian Varghese, Coordinator, and Taskeen Khan and Gojka Roglic from the Noncommunicable Diseases Management Department, and Walter Johnson from the Health Service Delivery Department, WHO. Technical input for emergency chapter was received from Pryanka Relan and Teri Reynolds; for Rehabilitation chapter and assistive products from Alarcos Cieza, Alexandra Rauch, Emma Tebbutt, Giulia Oggero and Louise Puli; and for clinical Laboratory by Ana Aceves and Nikhil Moorchung†, WHO.

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Abbreviations

ABPM	ambulatory blood pressure monitoring
ACR	albumin–creatinine ratio
AED	automated external defibrillator
APTT	activated partial thromboplastin time
BMI	body mass index
BNP	B-type natriuretic peptide
BPAP	bi-level positive airway pressure
cath lab	catheterization laboratory
CCU	coronary care unit
CPAP	continuous positive airway pressure
CPG	Clinical Practice Guideline
CRPS	chronic regional pain syndrome
CRT	cardiac resynchronization therapy
CSF	cerebrospinal fluid
CT	computed tomography
DICOM	Digital Imaging and Communications in Medicine
DSA	digital subtraction angiography
EEG	electroencephalograph
EMG	electromyography
ESR	erythrocyte sedimentation rate
EVD	extraventricular drain
GDG	Guideline Development Group
GFR	glomerular filtration rate
Hb	haemoglobin
HbA1c	haemoglobin A1c
Hct	haematocrit
ICD-11	International Classification of Diseases, 11th Revision
ICHI	International Classification of Health Interventions
ICT	information and communication technology
ICU	intensive care unit
IT	information technology
IV	intravenous
MRI	magnetic resonance imaging
NCD	noncommunicable disease

NEATS	National Guideline Clearinghouse Extent of Adherence to Trustworthy Standards
NIV	non-invasive ventilation
OCT	optical coherence tomography
PACS	picture archiving and communication system
PEEP	positive end expiratory pressure
PEG	percutaneous endoscopic gastrostomy
PEN	package of essential noncommunicable disease interventions for primary health care in low-resource settings
PET	positron emission tomography
PT/INR	prothrombin time and international normalized ratio
PTT	partial thromboplastin time
SDG	Sustainable Development Goal
SPECT	single photon emission computed tomography
T3	triiodothyronine
T4	thyroxine
TRIP	Turning Research into Practice
TRUST	Transparency and Rigour Using Standards of Trustworthiness
TSH	thyroid-stimulating hormone
UV	ultraviolet
VEGF	vascular endothelial growth factor
WHO	World Health Organization

Glossary

The definitions have been standardized across WHO publications, including the *WHO list of priority medical devices for cancer management.*

Accessibility: 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 device related or not.

Affordability: In the context of this report, the extent to which the intended recipients of a service can pay for it, be it a public, governmental or private service.

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

Assistive products: Any external product (including devices, equipment, instruments or software), specially produced or generally available, the primary purpose of which is to maintain or improve an individual's functioning and independence, and thereby promote their well-being. Assistive products are also used to prevent impairments and secondary health conditions.

Capital medical devices: Medical equipment and devices that providers of health services have acquired during the accounting period and that are used repeatedly or for more than one year in the provision of health services.[1]

Clinical guideline: Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.

Consumables/single-use medical devices: Supplies required for the use of the equipment but allowing only limited, or no, reuse.

e-health: The use of information and communication technologies for health.

General medical devices: Indispensable medical devices for basic use of the clinical unit to perform a majority of interventions for a wide scope of diseases. Range of specification may vary depending of the level of healh.

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

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, implantable medical devices, in vitro diagnostics, solutions and disinfection substances, clothing, accessories and single-use devices.

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 interventions provided during 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.

1 A system of health accounts: 2011 edition. OECD, European Union and World Health Organization; 2011 (https://www.who.int/health-accounts/methodology/sha2011.pdf).

Medical furniture: Furniture used in medical settings (hospitals, or any other health care units) for medical purposes (for example, cabinets to store medical equipment).

Personal protective equipment and clothing: 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, lead aprons and full body suits. This category includes the equipment used to cover and protect the patient, such as gowns and face masks.

Priority assistive products: Those assistive products that are highly needed, an absolute necessity to maintain or improve an individual's functioning and which need to be available at a price the community/ state can afford.

Priority medical devices: Those medical devices that are indispensable to perform a health intervention, of an evidence based clinical practice guideline of a priority diseases or health condition. These medical devices need to be of good quality, effective, appropriate, affordable, accessible and acceptable to the final user. They 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. 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. Those devices have specific intended use from prevention and protection to diagnosis, monitoring, treatment or palliation, to inform the development of national priority lists.

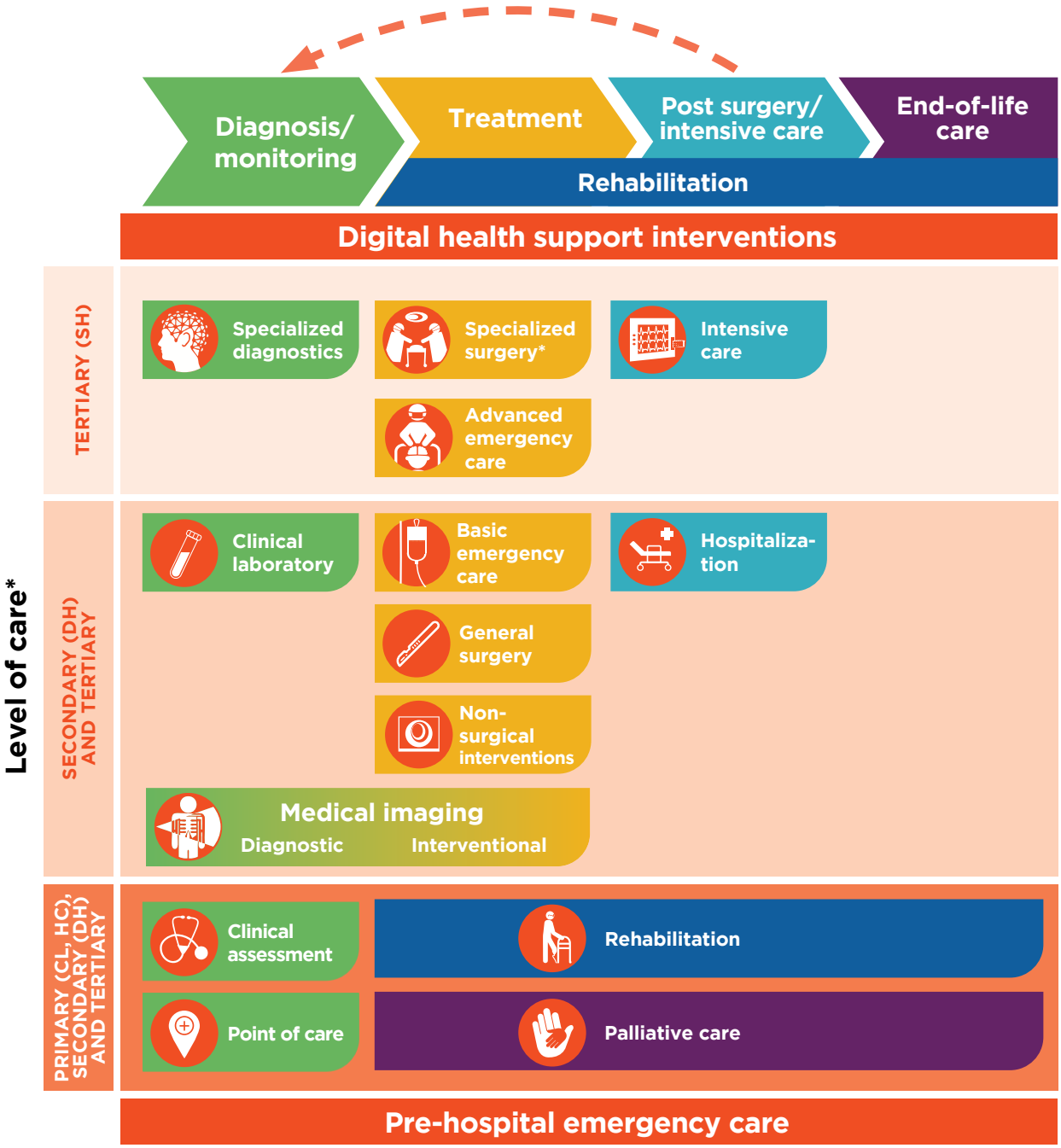
Quality assurance equipment: Equipment clinically relevant to carry out a calibration process needs to meet international standards considering calibration factors. Also called auxiliary dosimetry equipment, for example ionization chambers, phantoms and chamber sleeves.

Specific medical devices: Medical devices for diagnosis or treatment of a specific type of condition or disease and used for specific clinical intervention.

Navigation diagram

In this publication, the priority medical devices that are discussed, selected and presented are organized by clinical unit in a health service provision. The navigation diagram in Figure 1 represents the range of health-related interventions, from pre-hospital activities to highly specialized tertiary hospital-based care. The selected clinical interventions, and thus the medical devices, are required throughout the continuum of care, from prevention, diagnosis and monitoring, treatment, intensive care, rehabilitation, to palliative care, in any of the following clinical areas: clinical assessment, emergency care, clinical laboratory, surgery, non-surgical interventions, intensive care, hospitalization, rehabilitation and palliative care. It should be noted that the navigation diagram represents the units required for diagnosis and treatment of cardiovascular diseases and diabetes.

Click on the diagram to navigate to any section.



Key:

* Including cardiovascular, neurological, ophthalmic and nefrology.

CL community level; health post

DH district/general hospital; interventions can also be offered in a first referral outpatient clinic

HC health centre/outpatient clinic

SH specialized/regional/national hospital; specialized care outpatient unit

Colour codes for diseases

Since this publication covers different diseases, throughout the listing of medical devices, the intervention are general, used for various diseases or health conditions, or specific for either cardiovascular diseases (except stroke), stroke or diabetes. The tables will obey the following code of colour to facilitate the identification of the disease they are aimed for:

General

Cardiovascular except stroke

Stroke

Diabetes

Executive summary

Medical devices are required to provide health care and to improve the health of individuals and populations. They are indispensable for prevention, diagnosis, treatment, rehabilitation, palliative care, and are used along the continuum of health service provision from primary care to specialized hospitals. Of the thousands types of medical devices currently available,[2] the current challenge for health care providers and government institutions is to select which specific technologies are needed for the management of health conditons or high-burden diseases, at a given health care level and in a given context, to include in their national list.

The increase in the prevalence of noncommunicable diseases (NCDs) demanded that the World Health Organization (WHO) identify appropriate and relevant medical devices and develop a prioritized list that can serve as a reference for Member States to develop or update their national lists of medical devices for public procurement, reimbursement, and tracking availability. The final goal of this publication is to guide on the selection, in order to increase access to medical devices required to prevent, diagnose and treat cardiovascular diseases and diabetes, especially in low and middle resource settings.

Objectives of this publication were to:

- determine and select the medical devices required for priority interventions to manage cardiovascular diseases and diabetes aligned with WHO guidance, policies and evidence-based guidelines;
- expand the WHO Priority Medical Devices lists, these now include reproductive, maternal, new born and child health, the ones for cancer management and the most recent ones for COVID-19, to those for cardiovascular diseases and diabetes, which will become global guidances that Member States can use as a reference to define their national medical devices lists;
- provide guidance to countries, national and regional health departments, and health facilities to prioritize medical devices for procurement or reimbursement to manage NCDs in their settings.

For an overview of country implementation, the next steps are suggested:

- define a system to undertake a medical device needs assessment in each target country, in conjunction with other United Nations and international organizations, with the aim of identifying the medical equipment required to address the national disease burden for NCD care at country level;
- organize local workshops on health technology regulatory frameworks, assessments and management for relevant national health officials, academics and other stakeholders in target countries, using existing WHO tools and resources to strengthen regional or national health deliver capacity.

The first section of this publication introduces the Sustainable Development Goals (SDGs), universal health coverage, and the WHO Global Action Plan for the Prevention and Control of NCDs 2013–2020, and presents global statistics for non communicable diseases.

The second section presents the methodology used to select priority medical devices for the clinical interventions required to diagnose, treat and monitor patients living with those conditions.

The third section lists priority medical devices required to manage all three conditions in different units of health care services, as follows:

- clinical assessment
- emergency care
- clinical laboratory
- specialized diagnostics
- medical imaging
- surgery
- non-surgical interventions
- hospitalization
- intensive care unit (ICU)
- rehabilitation
- palliative or end-of-life care

2 Standardization of medical devices nomenclature: http://apps.who.int/gb/ebwha/pdf_files/EB145/B145_3-en.pdf

The lists include technologies required to support general clinical interventions (some of which were presented in previous WHO documents), as well as specific priority medical devices to manage cardiovascular diseases and diabetes. To facilitate budget planning and procurement, medical devices are classified either as capital equipment or as accessories, consumables, software or single-use devices. In addition, each section provides information on the clinical unit.

The fourth section proposes the strategies required in settings where the presented lists of priority medical devices are to be implemented. The activities include performing a needs assessment, cross-referencing and adjusting medical device lists according to country priorities, infrastructure, specialized human resources available, and budget. It is important to note that high-impact technologies (for example, those with high cost or requiring radical organizational changes) for specialized hospitals may require a comprehensive health technology assessment considering contextual variables and local settings.

The annexes include the expert information, search terms and the National Guideline Clearinghouse (NGC) Extent of Adherence to Trustworthy Standards (NEATS) instrument for selection of clinical guidelines, as well as the list of clinical interventions selected in this study.

This publication is intended for ministries of health, public health planners, health technology managers, disease managers, researchers, policy-makers, funding and procurement agencies, and support and advocacy groups for patients suffering from cardiovascular diseases and diabetes. It serves to inform policy-makers and technical decision-makers on the selection of medical devices required for the package of benefits and interventions for a target population in the context of universal health coverage, to be considered in their national medical devices list.

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 improve management of patients worldwide, and especially in low-resource settings.

I. Background

I.I. Sustainable development goals (SDG)

In 2015, all States Members of the United Nations adopted the 2030 Agenda for Sustainable Development. The Agenda is based on 17 Sustainable Development Goals (SDGs), which are an urgent call for action by all countries, at all stages of development, to cooperate in a global partnership for sustainable development (Figure 1).[3] The SDGs recognize that ending poverty must go hand in hand with strategies that build economic growth and address a range of social needs, including education, health, social protection and job opportunities, while tackling climate change and environmental protection.

Figure 1. Sustainable Development Goals

Health is directly connected to many of the SDGs, most importantly SDG 3: Ensure healthy lives and promote well-being for all at all ages. That is why the World Health Organization (WHO) has made the SDGs the focus of its new and future projects to support efforts towards universal health coverage, including the Global Action Plan for Healthy Lives and Well-being for All (SDG 3 Global Action Plan).

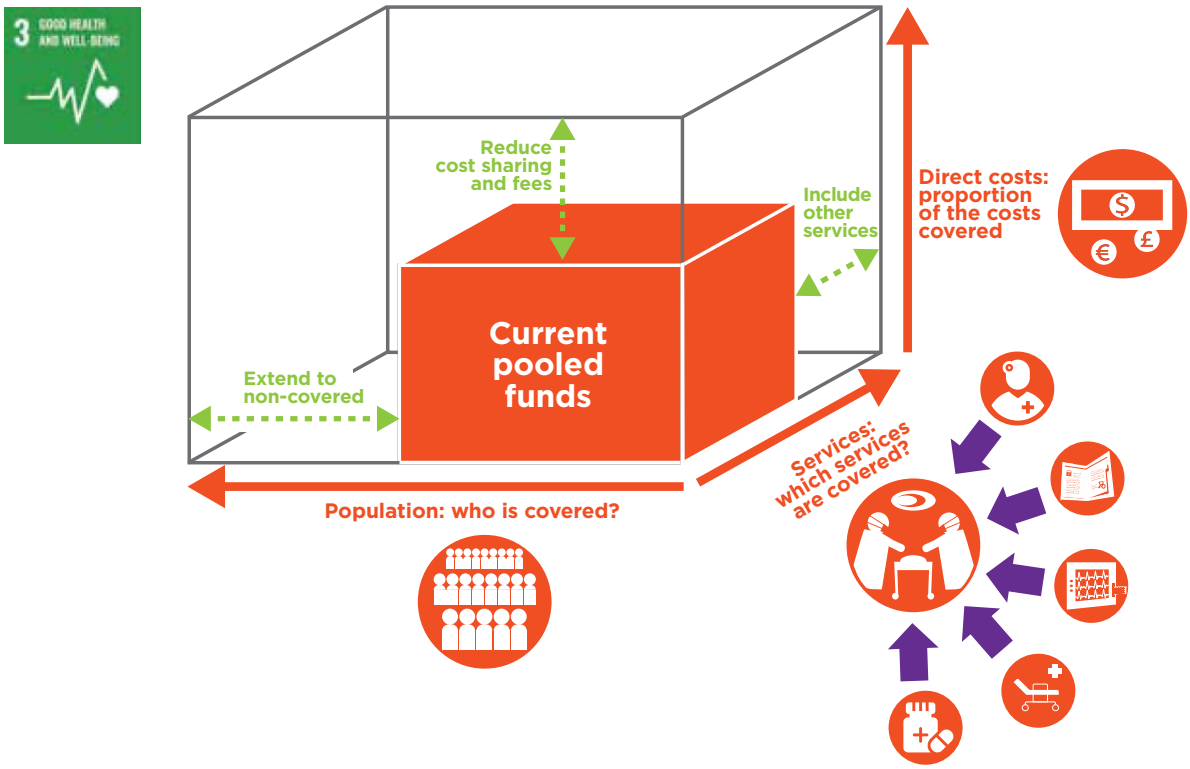
I.II Universal health coverage

Universal health coverage means that all people and communities can use the promotive, preventive, curative, rehabilitative and palliative health services they need, of sufficient quality to be effective, while also ensuring that the use of these services does not expose the user to financial hardship. In 2019, WHO set out its new five-year strategic plan in the Thirteenth General Programme of Work 2019–2023, which includes the "triple billion" goal – ensuring that 1 billion more people benefit from access to universal health coverage, 1 billion more people are better protected from health emergencies, and 1 billion more people enjoy better health and well-being (Figure 2) *(1, 2).* Reaching this goal will require addressing the threats to health from a variety of angles.

Figure 2. The triple billion goal of the WHO Thirteenth General Programme of Work

Importantly, universal health coverage, the first of the three goals, depends in large part on access to essential medicines, vaccines and health products, including medical devices, as well as the quality of the health workforce, health facilities and information (Figure 3) *(3)*.

Figure 3. The dimensions of universal health coverage



This publication is the outcome of a project developed by WHO in response to the need for a model reference list of basic and priority medical devices required for noncommunicable diseases (NCDs) based on the Global Status Report on noncommunicable diseases 2014 *(4)*, with the goal of increasing access to these medical devices, especially in low- and middle-income countries to complement the Priority Medical devices for Cancer management (2017).

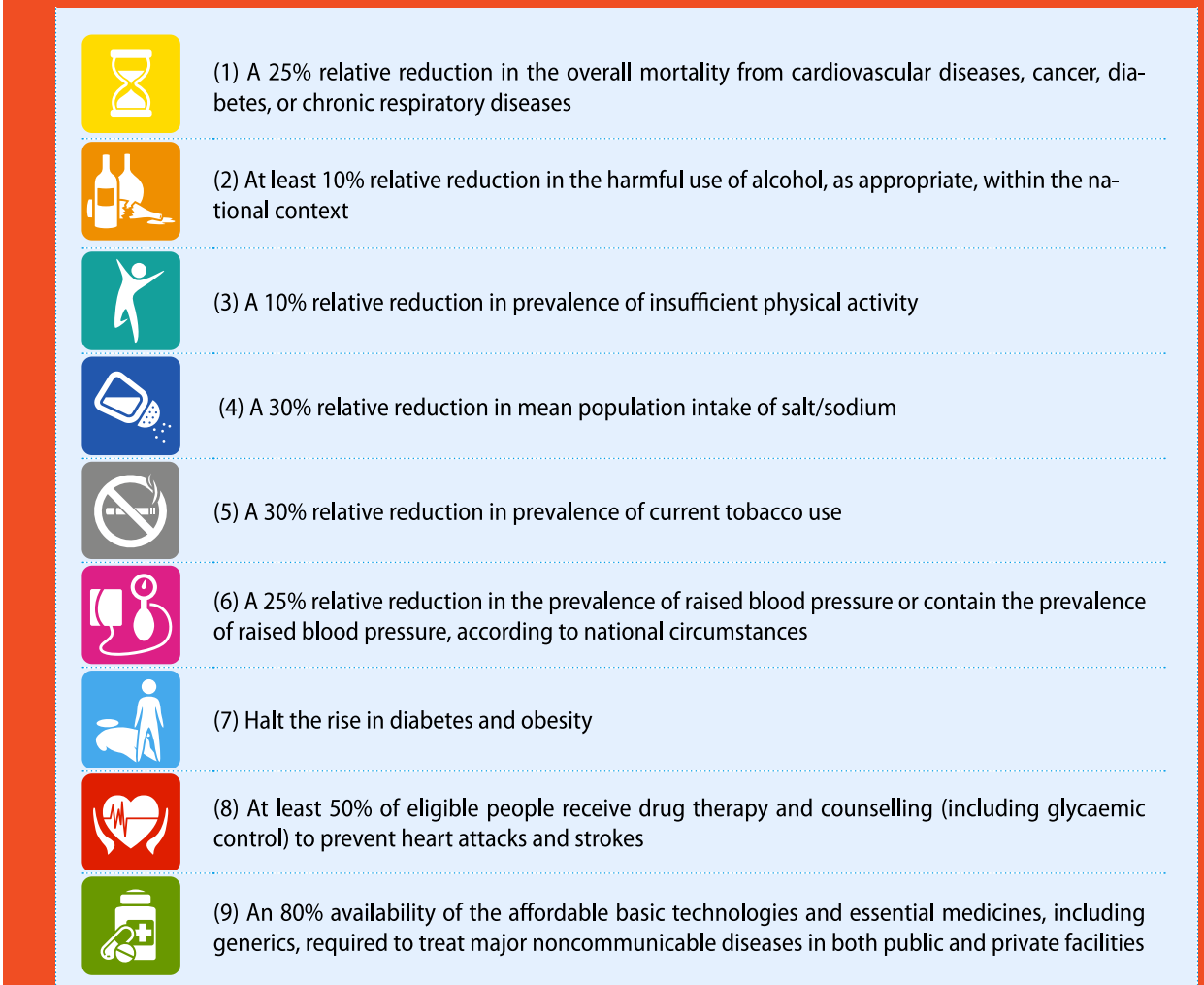
I.III WHO Global NCD Action Plan

NCDs – including cardiovascular diseases, cancers, chronic respiratory diseases and diabetes – are the world's biggest killers. More than 40 million people die annually from NCDs (74% of global deaths), including more than 15 million people who die too young between the ages of 30 and 70. Low- and middle-income countries already bear 85% of the burden of these premature deaths. *(5).*

Most of these premature deaths from NCDs are largely preventable by enabling health systems to respond more effectively and equitably to the health care needs of people with NCDs and influencing public policies in sectors outside health that tackle shared risk factors, including tobacco use, unhealthy diet, physical inactivity and the harmful use of alcohol.

To strengthen national efforts to address the burden of NCDs, the World Health Assembly endorsed the WHO Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013–2020 in May 2013 *(5)*. The Global NCD Action Plan provides Member States, international partners and WHO with a roadmap and menu of policy options that, when implemented collectively between 2013 and 2020, would contribute to progress on nine global NCD targets to be attained in 2025. One of these nine targets specifically address the issue of access to medical technologies and aims at an increase up to "an 80% availability of the affordable basic technologies and essential medicines, including generics, required to treat major noncommunicable diseases in both public and private facilities" (Figure 4) *(6)*.

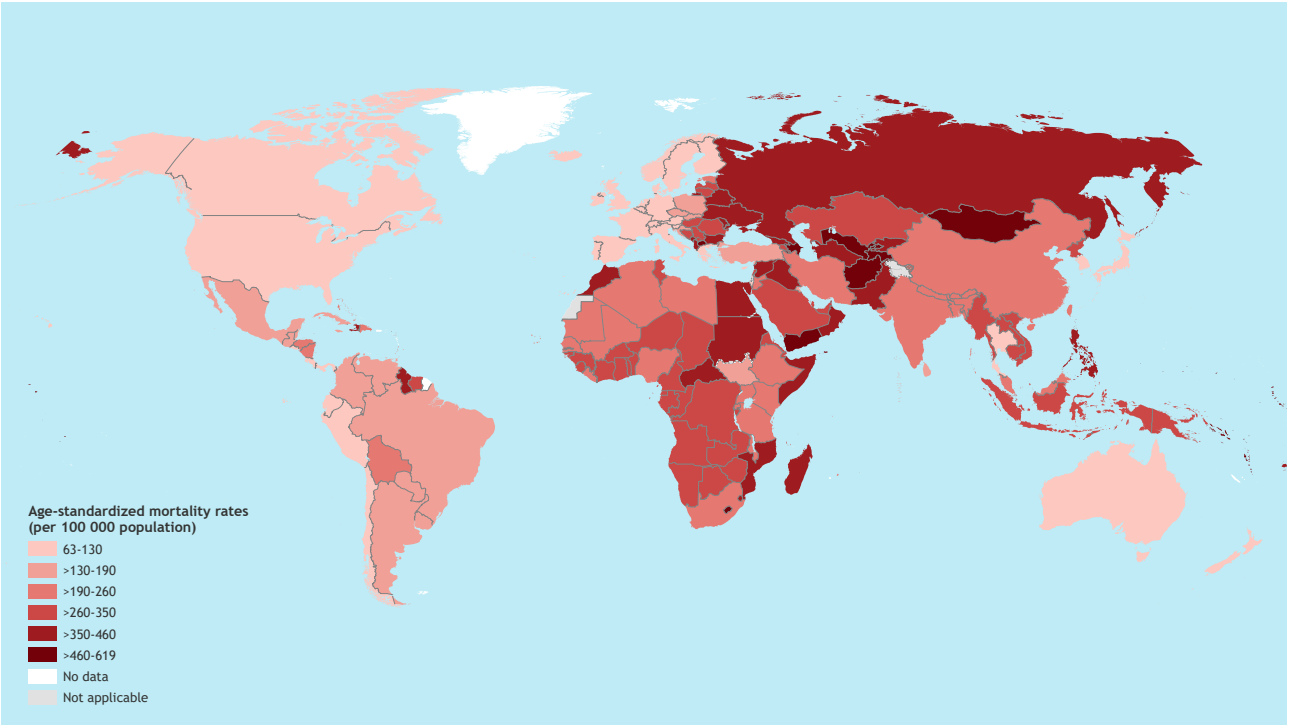
Figure 4. Voluntary global targets for prevention and control of NCDs to be attained by 2025



Cardiovascular diseases: global situation

Cardiovascular diseases are a group of diseases of the heart muscle, valves, conduction system and blood vessels, which manifest primarily as heart attacks and strokes (about 80% of all deaths form cardiovascular disease) *(7)*. Of less prevalence but major importance are heart failure, valvular disease and arrhythmia. Cardiovascular diseases are a major cause of disability and premature death throughout the world, taking the lives of 17.9 million people in 2019, of which 81% occur in developing countries and over one third are premature deaths (Figure 5) *(8)*. The underlying pathology is atherosclerosis, a build-up of fatty deposits on the inner walls of the blood vessels, which reduces blood flow to the heart muscle through an acutely obstructive process or over many years. It is usually advanced by the time symptoms occur. Acute coronary events (heart attacks) and cerebrovascular events (strokes) frequently occur suddenly and are often fatal before medical care can be given *(9)*.

Figure 5. Age-standardized cardiovascular disease mortality rates (per 100 000 population) for both sexes by country, 2019



Source: Global Health Estimates (GHE) *(17)*.

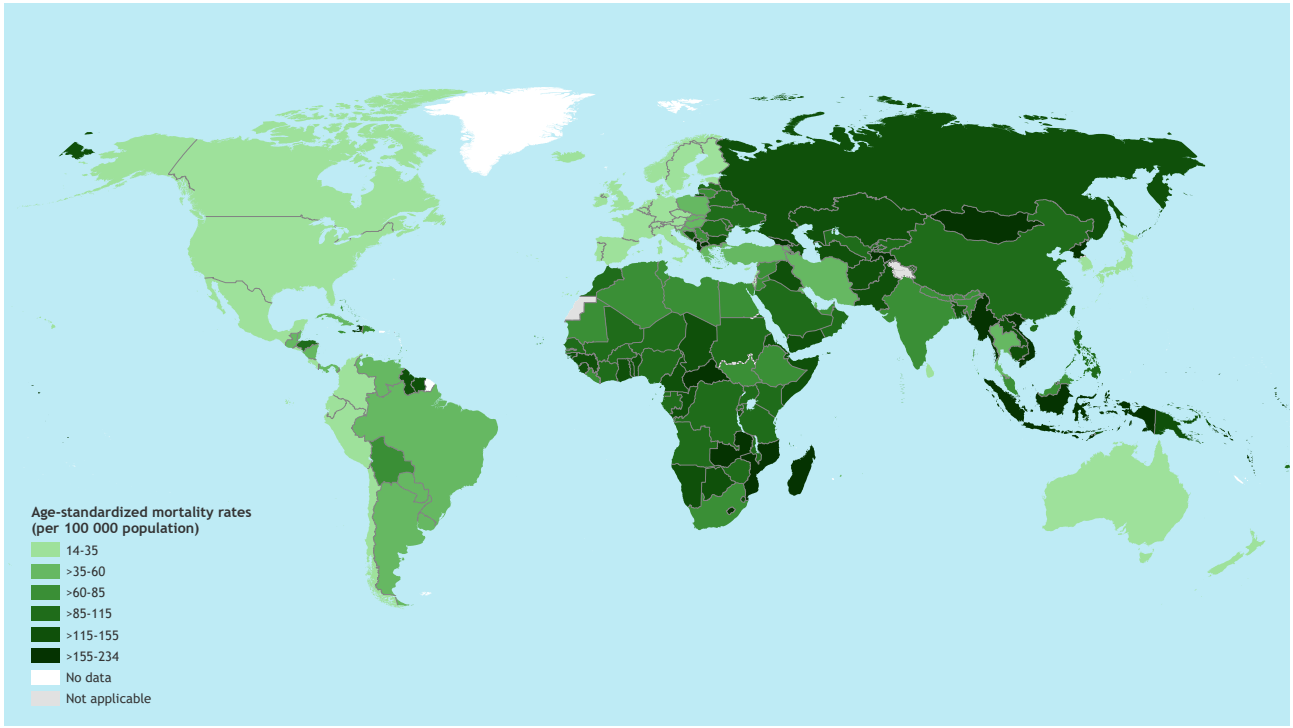
Stroke: global situation

Stroke was the second leading cause of death in 2019, with 6.2 million lives lost globally. It has occupied a high spot on the list of the leading causes of death worldwide for the past 20 years *(10)*. Stroke also causes significant morbidity and is the second-leading cause of disability-adjusted life-years *(11)*. Early recognition of the symptoms of a stroke and access to medical care are crucial to saving patients' lives and improving outcomes *(12)*. Rehabilitation is often necessary to address residual functional deficits following a stroke to achieve and maintain optimal levels of functioning.

A stroke occurs when blood flow to the brain is interrupted. There are two types of stroke. Ischaemic strokes are caused by a blockage in an artery, usually created by a clot; haemorrhagic strokes occur when a blood vessel bursts. The symptoms of stroke vary depending on the area of the brain that is affected. Often the symptoms occur on one side of the body and result in weakness and loss of sensation. Other signs may include severe headache, confusion or difficulty speaking. The symptoms can range from mild to severe or even result in sudden death *(13)*. Diagnostic testing to distinguish the type of stroke that the patient is experiencing is a key factor in saving lives and improving post-stroke quality of life.

Strokes are on the rise in low- and middle-income countries, with rates more than doubling over the past 40 years *(14)*. Mortality attributed to stroke by country is depicted in Figure 6. Differences between sexes in stroke incidence, prevalence, mortality, and outcomes have been documented worldwide. Although men are at higher risk of stroke for most age groups, women older than 85 are at higher risk. In addition, women have worse post-stroke recovery than men. *(15)*. Effective stroke prevention involves management of hypertension, diabetes and high cholesterol in addition to lifestyle changes such as smoking cessation, increased exercise and a healthy diet. Treatment and rehabilitation relies on the availability of medical devices used to diagnose the condition promptly, technologies to aid health care providers in the delivery of care, and staff that are trained to use these tools appropriately. Low- and middle-income countries are disadvantaged in their level of access to such resources *(16)*.

Figure 6. Age-standardized stroke mortality rates (per 100 000 population) for both sexes by country, 2019



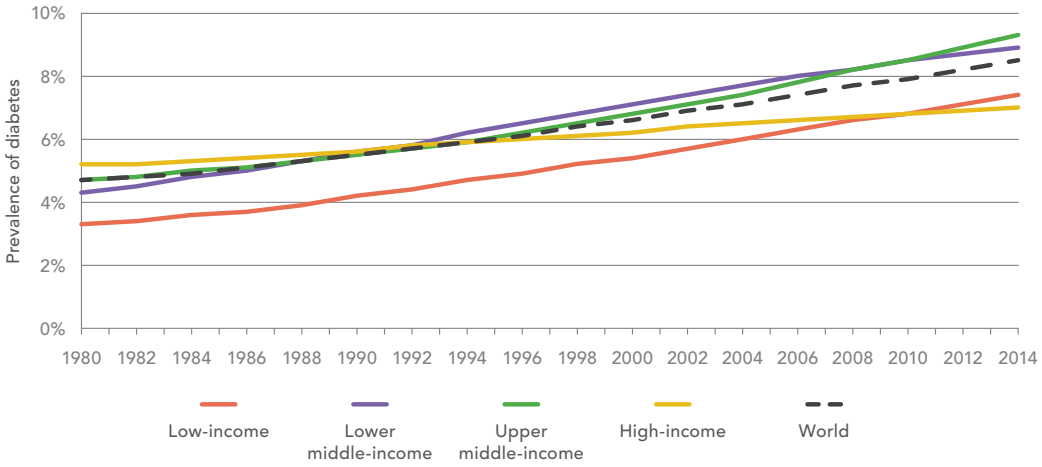
Source: Global Health Estimates (GHE) *(17)*.

Diabetes: global situation

Approximately 422 million adults had diabetese in 2014. *(18)*. A study in 2013 suggests that almost half of all diabetes cases in adults were undiagnosed. *(19)*. Diabetes has detrimental effects throughout the body and the impacts accumulate over time *(20)*. If diabetes is not effectively managed, debilitating and life-threatening complications can arise.

Diabetes was the ninth most common cause of death worldwide in 2019 *(10)*. Of the 1.5 million deaths due to diabetes, 48% occur before the age of 70 years *(20)*. Low- and middle-income countries experience higher premature mortality from diabetes due to reduced access to the resources necessary to successfully identify and manage the disease *(21)*. Unfortunately, these are the same areas where diabetes rates are increasing the most rapidly (Figure 7). The global distribution of Diabetes mellitus mortality is depicted in Figure 8. The prevalence of diabetes has nearly quadrupled over the past three decades. This is partly due to an ageing population (as age is a risk factor), but in large part also due to the increasing prevalence of preventable risk factors, such as obesity and physical inactivity. In 2015, low- and middle-income countries lost an estimated US$ 507 billion to diabetes costs *(20)*, and had significantly higher mortality rates than high-income countries *(22)*.

Figure 7. Age-adjusted trends in prevalence of diabetes, 1980–2014, by World Bank country income group



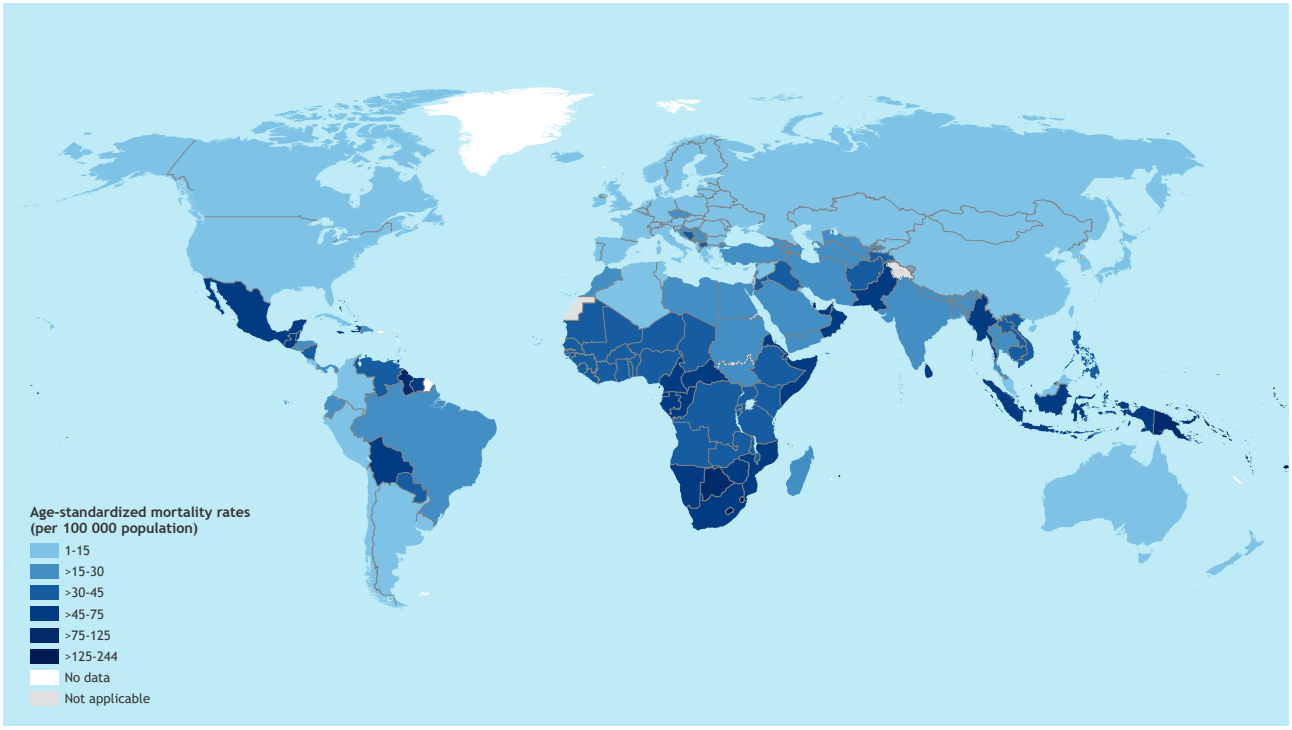
Source: WHO *Global report on diabetes (20).*

Diabetes impairs the body's ability to convert food or caloric beverages into energy. It is a complex metabolic disorder characterized by chronic hyperglycaemia, with disturbances of carbohydrate, fat and protein metabolism. Poorly managed diabetes increases the risk of cardiovascular disease, infection, kidney failure, vision loss, depression and dementia. A combination of commonly occurring peripheral nerve damage and arterial disease is the pathway to non-healing foot ulcers, often leading to infection and limb amputation *(23)*.

Two common types of diabetes are type 1 diabetes, which requires insulin for survival, and type 2 diabetes, which develops over time as the resistance to insulin within the cells increases and insulin production decreases *(20)*. There is no preventive intervention for type 1 diabetes, but the onset and progression of type 2 diabetes to complications can be slowed or even halted through lifestyle modification and adherence to proper health care interventions. Approximately 95% of diabetes cases are type 2 diabetes *(23)*. Rehabilitation becomes important to those who experience complications related to diabetes. In people following amputation, rehabilitation helps to achieve the best possible level of functioning and independence.

Lack of resources is a common barrier to early diagnosis and effective management of diabetes. No data exist to reflect the extent of the problem across all levels of health care delivery. However, in low-income countries, less than half of all primary health care facilities have basic supplies for glucose measurement. Primary health care facilities in low-, middle-, and upper middle-income countries struggle to screen for serious complications that are common in diabetes, because less than 50% have the necessary equipment. While is it likely that tests and devices for monitoring diabetes and diagnosing and treating its complications are available in a few specialized institutions, it is important to make some of them more widely available. Countries hoping to reduce health care expenditure will need to invest both in procuring evidence-based medical devices and in training the health care workforce to use them safely and effectively *(21)*.

Figure 8. Age-standardized Diabetes mellitus mortality rates (per 100 000 population) for both sexes by country, 2019



Source: Global Health Estimates (GHE) *(17)*.

I.IV Availability of and access to medical devices for NCDs

Medical devices are indispensable for effective diagnosis, treatment, monitoring and rehabilitation of illness and disease. An estimated 1.5 million different medical devices exist, in more than 20 000 types of generic device groups *(24, 25)*. Assistive devices are essential to ensure functioning, independence, and well-being of individuals living with stroke, diabetes, and other chronic conditions. In 2008, WHO initiated the first global effort to identify global needs for medical devices, with the aim of prioritizing and selecting the essential and affordable medical devices of greatest importance, taking into account the disease burden of individual countries. In 2010, a first global survey on medical devices revealed major gaps in the availability of and access to medical devices in countries *(26)*, as well as vast discrepancies between countries regarding the existence of regulatory capacities, national policies, national lists, and technical specifications for procurement and reimbursement of medical devices. The update of these data was presented in the WHO *Global atlas of medical devices 2010 (28)*. Examples of global availability of high-cost medical devices per 1 million population are available in the *Global atlas of medical devices (28)*.

WHO estimates that 1 billion people need assistive devices globally, but only 1 in 10 people has access to the devices they need *(27)*. WHO published the Priority Assistive Products List with the goal to improve the availability and affordability of assistive devices in countries.

Many basic technologies for the early detection, diagnosis and monitoring of NCDs were reported as being generally available in primary care facilities in the public health sector: 98% for blood pressure measurement, 92% for height and weight measurement, and 88% for blood glucose measurement *(29)*. Urine strips for albumin assay, and total cholesterol measurement were also reported as being generally available (69%) in most countries. However, for the remainder of the basic technologies, fewer than half of countries reported them as being generally available: for example, HbA1c (53% of countries) and remaining tests (such as dilated fundus examination, foot vibration perception by tuning fork and peak flow measurement spirometry were reported as being generally available in 45–50% of countries.

The six essential technologies for the early detection, diagnosis and monitoring of NCDs comprise devices for measurement of height, weight, blood glucose, blood pressure, and total cholesterol, and urine strips for albumin assay. The general availability of the six essential basic technologies is shown in Figure 9 by WHO region and World Bank income group (height and weight are combined). Total cholesterol measurement was highly variable across regions and income groups with significantly lower availability reported in the South-East Asia (45% of countries) and African regions (32% of countries), and countries of the low income (26%) and low-middle-income (37%) groups. By contrast, blood pressure measurement was consistently available in 90% or more of countries across all regions and income groups. Just over half of countries (53%) reported all six essential tests and procedures (measurement of height, weight, blood pressure, blood glucose, and total cholesterol, as well as urine strips for albumin assay) being generally available. Marked disparities were evident across the income groups: 96% of high-income countries reported all six tests and procedures were generally available compared with 16% (or just five) low-income countries. Figure 10 shows the percentage of countries with procedures generally available for treating NCDs in the public health care system, by World Bank income group. Disparities across income groups are marked: all but 10 high-income countries reported six or seven of the seven procedures as being generally available, while 55% of low-income countries reported no procedures as being generally available, and a further third reported just one.

s defined as reaching at least (“generally available” was defined as reaching at least (68–98% of countries) and least widely available in (68–98% of countries) a

e; retinal photocoagulation, being generally available; retinal photocoagulation,

acement by transplantation (Figure 45). Renal replacement by transplantation

Figure 9. Percentage of countries with availability of essential technologies for early detection, diagnosis and monitoring of NCDs in the primary care facilities of the public and private health sectors, by WHO region and World Bank income group

in the primary care facilities of the public and private health sectors, by WHO region and World Bank income group

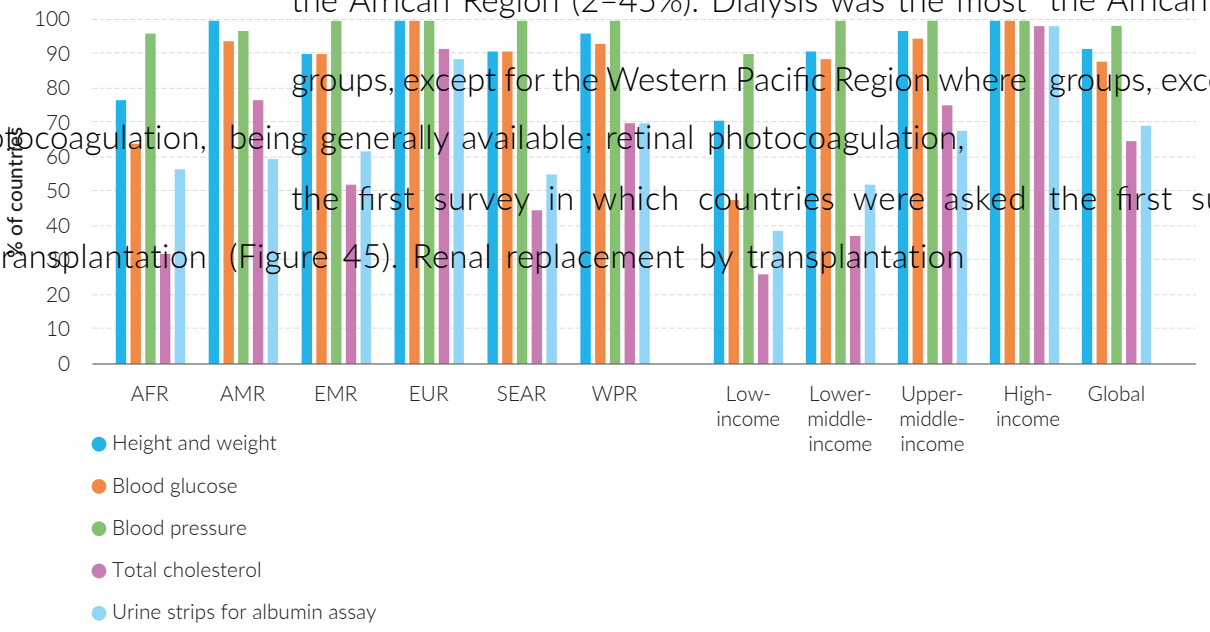


Figure 44

Source: World Health Organization (29).

Figure 10. Percentage of countries with procedures generally available for treating NCDs in the public

region and World Bank income group, by WHO region and World Bank income group

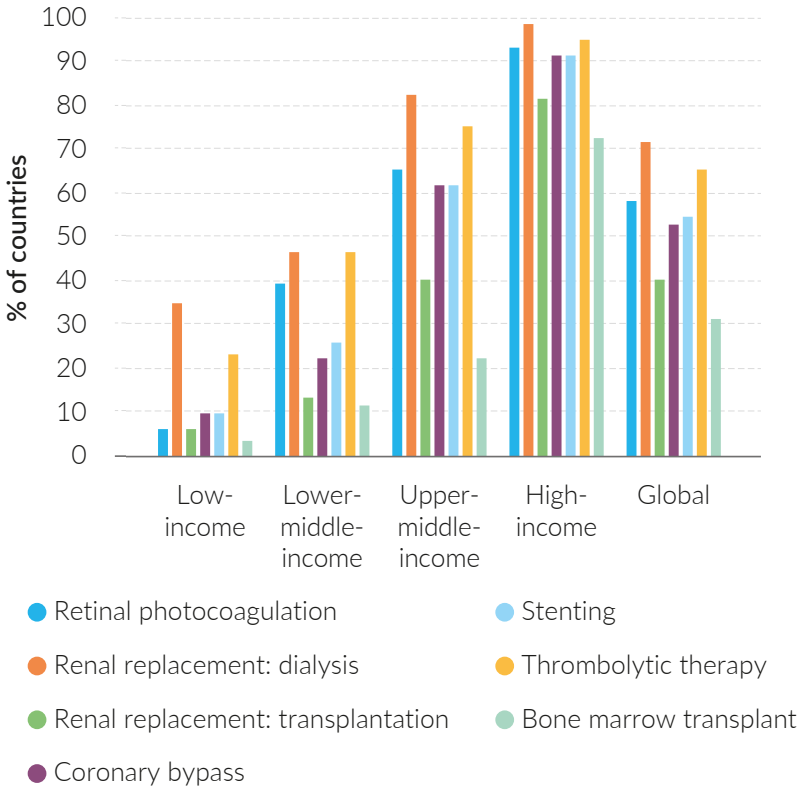


Figure 45

Source: World Health Organization (29).

Further reading

The sources shown in Figure 11 lists WHO's guidelines for cardiovascular disease management, they were used to compile the present publication. Other sources will be listed in each specific section.

Figure 11. WHO sources for cardiovascular disease management

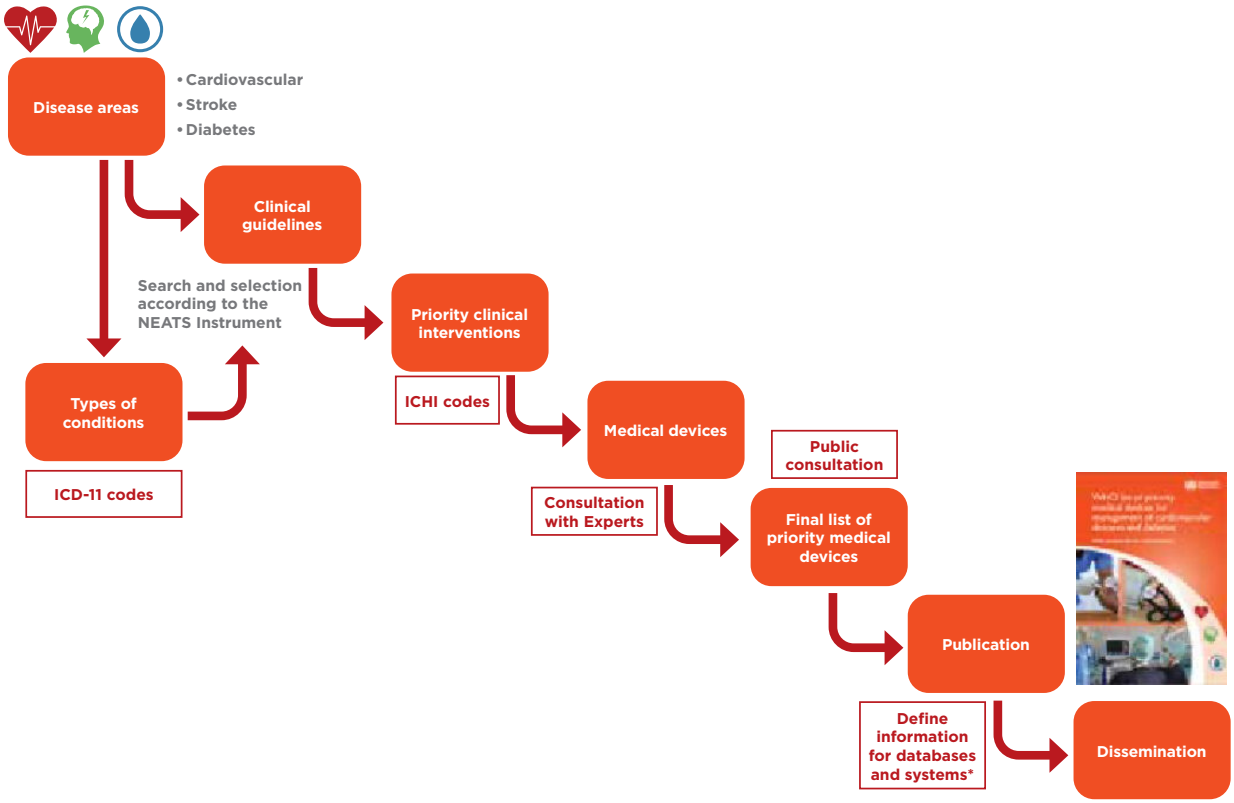
In chronological order:

1. Intergrated management of cardiovascular risk. Report of a World Health Organization meeting,
2. Avoiding heart attacks and strokes. Don't be a victim, protect yourself,
3. Prevention of cardiovascular disease. Guidelines for assessment and management of cardiovascular risk,
4. Prevention of cardiovascular disease (CVDs). Pocket guidelines for assessment and management of CVD risk,
5. World Health Organization/ International Society of Hypertension Risk Prediction Charts,
6. Package of essential NCD interventions for primary health care: cancer, diabetes, heart disease and stroke, chronic respiratory disease,
7. Guidelines for primary health care in low-resource settings. Cancer, diabetes, heart disease and stroke, chronic respiratory disease,
8. Implementation tools. Package of Essential Noncommunicable (PEN) disease interventions for primary health care in low-resource settings,
9. A global brief on hypertension. Silent killer, global public health crisis,
10. HEARTS: Technical package for cardiovascular disease management in primary health care.
11. Six modules that make up the HEARTS Technical package. Healthy-lifestyle counseling, Evidence-based treatment protocols, Access to essential medicines and technology, Risk-based charts, Team-based care and, Systems for monitoring.
12. WHO package of essential noncommunicable (PEN) disease interventions for primary health care.

II. Methodology

The methodology used to select the priority medical devices for cardiovascular diseases and diabetes was based on the methodology defined by WHO to select the previously published lists of priority medical devices *(30, 31)*. The process involves a review of clinical guidelines to define interventions and identification of medical devices required to perform each intervention by level of care. However, there were very few WHO guidelines available for the management of cardiovascular diseases and diabetes; the methodology therefore had to be modified accordingly. The following overview presents the milestones and the adaptation of the methodology throughout the process that led to the present publication.

Figure 12. Methodology: from disease identification to dissemination of information



2017

The first draft selection of medical devices for cardiovascular diseases, including different clinical services, took place. This project was done in parallel with work carried out by the WHO PAHO, following the methodology and structure of the priority medical devices for cancer management *(30)*.

2018

In a meeting to review the progress made in developing the list of priority medical devices for cardiovascular interventions, it was confirmed that many devices used for the management of cardiovascular diseases and their complications are also used in the management of stroke and diabetes complications. As a result, it was decided that the priority interventions and according medical devices for all three diseases were to be combined in a single publication using ad hoc methodology.

In the next step, medical conditions arising from cardiovascular diseases and diabetes were identified using WHO publications and available evidence based clinical guidelines. The selected types of conditions were matched with the WHO International Classification of Diseases, 11th Revision (ICD-11) *(32)*, while the clinical interventions were matched with the WHO International Classification of Health Interventions (ICHI) codes. The types of conditions included the following (colour coded by category – see introductory section).

* https://medevis.test.evidenceprime.com

Cardiovascular disease (except stroke)

- essential hypertension
- coronary atherosclerosis
- heart failure
- cardiomyopathy
- valvular disease
- congenital heart disease
- arrhythmia
- arterial disease
- deep vein thrombosis
- pulmonary embolism

Stroke

- cerebrovascular disease with no acute symptoms
- cerebral ischaemia, including transient ischaemic attack
- retinal vascular occlusion
- intracerebral haemorrhage
- subarachnoid haemorrhage
- certain specified cerebrovascular diseases
- cerebrovascular abnormalities

Diabetes

- diabetes mellitus type unspecified
- hypoglycaemic emergency
- hyperglycaemic emergency
- diabetic nephropathy
- diabetic retinopathy
- diabetic neuropathy
- diabetic foot

WHO staff prepared an initial list of interventions for each condition based on the ICHI codes and proposed a list of medical devices for each of them, to be reviewed by experts. This first draft was presented in a workshop and session at the fourth WHO Global Forum on Medical Devices in India, December 2018 *(33)*.

2019

Step 1. Selection of evidence based clinical guidelines for cardiovascular diseases and diabetes was performed by Cochrane Netherlands (see Annex 2).

Step 2. A multidisciplinary group of experts in cardiovascular diseases, diabetes and medical devices was assembled to review the draft list of clinical interventions and priority medical devices. Each clinical intervention was grouped based on the level of care: primary, secondary or tertiary level.

Step 3. Systematic reviews of selected international guidelines were performed to identify clinical interventions. The selected clinical interventions were classified into different units of health care services: 1. clinical assessment, 2. emergency care, 3. clinical laboratories, 4. other specialized diagnostic services, 5. medical imaging, 6. surgery, 7. non-surgical interventions, 8. hospitalization, 9. intensive care unit, 10. rehabilitation, 11. palliative care**.**

Step 4. The list of clinical interventions was validated using evidence based clinical guidelines as a reference standard.

Step 5. A group of interdisciplinary experts was selected and invited to attend a consultation meeting on 11 and 12 July 2019 in Geneva, Switzerland. Depending on the individual expertise, participants joined one of the three working groups formed to discuss topics relevant to cardiovascular diseases or diabetes. After the two days of discussions, the following meeting outcomes were achieved.

- The project timeline was reviewed and approved.
- The methodology for selection of evidence based clinical guideliness to support the identification of priority medical devices was presented and approved.
- Experts identified and agreed on a draft list of priority clinical interventions for cardiovascular diseases and diabetes.
- Experts identified and agreed on a draft list of priority medical devices for cardiac and vascular diseases and diabetes.
- Next steps and country implementation strategies were discussed in the context of different health care settings.

Step 6. A draft document including background, methodology, and lists of clinical interventions and priority medical devices was developed and reviewed by an extended group of experts. Medical devices were grouped as either general or specific, depending on their applicability to more than one disease.

2020

Step 1. Global on-line consultations took place on the list of priority medical devices for cardiovascular diseases and diabetes.

Step 2. Expert group teleconferences were organized to review comments and finalize the list of priority medical devices.

Step 3. Technical editing and design were completed.

Step 4. Digital publication was completed.

II.I Search and selection of clinical guidelines

Due to the lack of clinical guidelines developed by WHO for the management of cardiovascular diseases and diabetes, WHO commissioned Cochrane Netherlands to identify and select good-quality clinical guidelines addressing the diseases within the scope of this project.

A broad search was performed to identify English language clinical guidelines on prevention, diagnosis, treatment or rehabilitation for cardiovascular diseases and diabetes published between 2017 and 2019. Guidelines from international organizations as well as guidelines developed at national level, including in low- and middle-income countries, were of interest.

The following guideline resources were searched to identify guidelines from North America, Europe, Australia, Canada, and low- and middle-income countries:

- Emergency Care Research Institute Guidelines Trust
- Turning Research into Practice database
- Global Health Library
- Guidelines International Network: International Guidelines Library
- Canadian Agency for Drugs and Technologies in Health reports
- National Institute for Health and Care Excellence evidence search
- World Heart Federation
- International Diabetes Federation
- World Stroke Organization.

A two-step search approach was taken. The information specialist of Cochrane Netherlands performed an initial search using general terms for the conditions of interest (cardiovascular and diabetes) and selected guidelines based on relevance to the topics. Search terms used are reported in Annex 2.

The preselected clinical guidelines were assessed according to the following aspects:

- whether the guideline contained details regarding interventions or medical devices for specific categories of disease;
- whether the guideline addressed prevention, diagnosis, treatment or rehabilitation;
- items of the National Guideline Clearinghouse Extent of Adherence to Trustworthy Standards (NEATS) instrument (Annex 3).

Based on these assessments, the most recent and highest-quality clinical guideline addressing a specific category of disease was selected.

For specific categories of disease that were not covered by one of the selected guidelines, an additional search was performed using terms and synonyms for that specific category of disease. The identified clinical guidelines were assessed as described above.

II.II Selected clinical guidelines

Cardiovascular diseases (except stroke)

Seventeen guidelines were assessed after the initial searches (Table 1). Additional searches were performed for the disease categories of "coronary atherosclerosis" and "arterial disease", which led to the assessment of three additional guidelines.

Of the 20 guidelines assessed, 14 were selected based on an average score of 3 points or higher on the NEATS items (Annex 3).

Table 1. List of selected clinical guidelines for cardiovascular diseases

ICD-11 code	Type of condition	Guidelines [click to open link]
BA00	Essential hypertension	American College of Cardiology, American Heart Association (2017) Hypertension Canada (2018) American College of Cardiology, American Heart Association (2016)
BA80	Coronary atherosclerosis	European Society of Cardiology, European Association for Cardio-Thoracic Surgery (2019) American College of Cardiology, American Heart Association (2016)
BD1Z	Heart failure	American College of Cardiology, American Heart Association, Heart Rhythm Society (2017) American College of Cardiology, American Heart Association, Heart Failure Society of America (2017) National Institute for Health and Care Excellence (2018) National Institute for Health and Care Excellence (2017)
BC43.Z	Cardiomyopathy	American College of Cardiology, American Heart Association, Heart Rhythm Society (2017)
BC0Z	Valvular disease	American College of Cardiology, American Heart Association, Heart Rhythm Society (2017) American College of Cardiology, American Heart Association (2018)
LA8Z	Congenital heart disease	American College of Cardiology, American Heart Association, Heart Rhythm Society (2017) American College of Cardiology, American Heart Association (2018)
BC9Z	Arrhythmia	American College of Cardiology, American Heart Association, Heart Rhythm Society (2017) European Society of Cardiology, European Association for Cardio-Thoracic Surgery (2019) Healthcare Improvement Scotland (2018) National Institute for Health and Care Excellence (2017)
BD52.7	Arterial disease	American College of Cardiology, American Heart Association (2016)
BD71	Deep vein thrombosis	Korean Society for Vascular Surgery (2016) National Institute for Health and Care Excellence (2019) National Institute for Health and Care Excellence (2018)
BB00	Pulmonary embolism	British Thoracic Society (2018) National Institute for Health and Care Excellence (2018)

Stroke

Twelve guidelines were assessed after the initial searches (Table 2). Additional searches were performed for the disease categories of "retinal vascular occlusion" and "subarachnoid haemorrhage", which led to the assessment of two additional guidelines.

Of the 14 guidelines assessed, nine were selected based on an average score of 3 points or higher on the NEATS items (Annex 3).

Table 2. List of selected clinical guidelines for stroke

ICD-11 code	Type of condition	Guidelines [click to open link]
8B21	Cerebrovascular disease with no acute symptoms	Stroke Foundation (2017) European Stroke Organisation (2018)
8B10, 8B11	Cerebral ischaemia including transient ischaemic attack	American Heart Association, American Stroke Association (2018) Stroke Foundation (2017) British Medical Journal (2018) European Stroke Organisation, European Society for Minimally Invasive Neurological Therapy (2019) European Stroke Organisation (2018) Korean Stroke Society (2016) National Institute for Health and Care Excellence (2019) Heart and Stroke Foundation of Canada (2018) European Academy of Neurology, European Stroke Organisation (2018)
8B00	Intracerebral haemorrhage	Stroke Foundation (2017) European Stroke Organisation (2018) National Institute for Health and Care Excellence (2019) European Academy of Neurology, European Stroke Organisation (2018)
8B01	Subarachnoid haemorrhage	European Stroke Organisation (2018) European Academy of Neurology, European Stroke Organisation (2018)

Diabetes

WHO staff provided a list of 25 diabetes guidelines (Table 3) of a previous commissioned guideline search, of which 13 guidelines published from 2017 onwards were assessed. An additional 15 guidelines were identified by the guideline search. As all specific disease categories were covered by the identified guidelines, no additional searches were performed.

Of the 28 guidelines assessed, nine were selected based on an average score of 3 points or higher on the NEATS items (Annex 3). The guideline marcked with a "*" in the following table are meant for diabetes type two only.

Table 3. List of selected clinical guidelines for diabetes

ICD-11 code	Type of condition	Guidelines [click to open link]
5A14	Diabetes mellitus, type unspecified	Diabetes Canada (2018) National Institute for Health and Care Excellence (2017)* Healthcare Improvement Scotland (2017)* Department of Veterans Affairs, Department of Defense (2017) World Health Organization (2018) American College of Physicians (2017)* American Diabetes Association (2019)
5A21	Hypoglycaemic emergency	Healthcare Improvement Scotland (2017)* World Health Organization (2018) American College of Physicians (2017)* American Diabetes Association (2019)
5A20, 5A22	Hyperglycaemic emergency	Diabetes Canada (2018) World Health Organization (2018) American College of Physicians (2017)* American Diabetes Association (2019)
GB61.Z	Diabetic nephropathy	Healthcare Improvement Scotland (2017)* Department of Veterans Affairs, Department of Defense (2017) World Health Organization (2018) American College of Physicians (2017)* American Diabetes Association (2019)
9B71.0	Diabetic retinopathy	Healthcare Improvement Scotland (2017)* Department of Veterans Affairs, Department of Defense (2017) American College of Physicians (2017)* American Diabetes Association (2019)
8C03.0, 8D88.1	Diabetic neuropathy	Diabetes Canada (2018) National Institute for Health and Care Excellence (2018) Healthcare Improvement Scotland (2017)* Department of Veterans Affairs, Department of Defense (2017) American College of Physicians (2017)* American Diabetes Association (2019)
BD54, FA38.10	Diabetic foot	Diabetes Canada (2018) Healthcare Improvement Scotland (2017)* World Health Organization (2018) American Diabetes Association (2019)

II.III Additional clinical guidelines

After the clinical guideline search and selection using specified criteria, gaps in the coverage of certain types of conditions were identified. To fill in the gaps, the working group experts proposed the list of guidelines set out in Table 4, including guidelines published before the period selected for the initial search (2017–2019).

Table 4. List of additional clinical guidelines

Disease	Provider organization	Publication year	Title [click to open link]
Diabetes	International Council of Ophthalmology	2017	International Council of Ophthalmology guidelines for diabetic eye care
Diabetes	Ministry of Health, Colombia	2016	Guía de práctica clínica para el diagnóstico, tratamiento y seguimiento de la diabetes mellitus tipo 2 en la población mayor de 18 años [Clinical practice guide for the diagnosis, treatment and monitoring of type 2 diabetes mellitus in the population over 18 years of age]
Stroke	World Stroke Organization	2016	Global stroke guidelines and action plan: a road map for quality stroke care
Stroke	American Heart Association Stroke Council	2015	Guidelines for the management of spontaneous intracerebral haemorrhage
Stroke	European Stroke Organisation	2014	European Stroke Organisation guidelines for the management of spontaneous intracerebral haemorrhage
Stroke	European Stroke Organisation	2012	European Stroke Organisation guidelines for the management of intracranial aneurysms and subarachnoid haemorrhage
Stroke	South African Stroke Society	2010	South African guideline for management of ischaemic stroke and transient ischaemic attack 2010: a guideline from the South African Stroke Society (SASS)
Cardio-vascular diseases	European Society of Cardiology, European Society of Hypertension	2018	Guidelines for the management of arterial hypertension

II.IV Relevant WHO publications

Relevant documents published by WHO in relation to the diseases targeted in the present project were also consulted and referred to. The list of WHO documents is presented in Table 5.

Table 5. Relevant WHO publications

Publication title	Publication year	Interest
Package of essential noncommunicable (PEN) disease interventions for primary health care in low-resource settings *(16)*	2010	Cardiovascular diseases, diabetes
Prevention of cardiovascular disease (CVDs): pocket guidelines for assessment and management of CVD risk *(9)*	2007	Cardiovascular diseases, stroke
Interagency list of priority medical devices for essential interventions for reproductive, maternal, newborn and child health *(31)*	2015	General assessments, surgery
WHO list of priority medical devices for cancer management *(30)*	2017	General laboratory, imaging, surgery
Second WHO model list of essential in vitro diagnostics *(34)*	2019	Laboratory tests, point-of-care diagnostics
Prevention of blindness from diabetes mellitus: report of a WHO consultation *(35)*	2006	Blindness from diabetes mellitus
HEARTS: technical package for cardiovascular disease management in primary health care *(36)*	2016	Cardiovascular diseases

II.V Selection of the clinical interventions

Whenever possible, the selected clinical interventions were matched with the WHO International Classification of Health Interventions (ICHI) *(37)*. The selected clinical interventions were classified into different units of health care services: 1. clinical assessment, 2. emergency care, 3. clinical laboratories, 4. other specialized diagnostic services, 5. medical imaging, 6. surgery, 7. non-surgical interventions, 8. hospitalization, 9. intensive care unit, 10. rehabilitation, 11. palliative care. A full list of selected priority clinical interventions can be found in Tables 6–9.

III. Priority medical devices by clinical area

III.I Priority intervention lists

The following table lists the general priority clinical interventions. Each intervention was matched with the WHO International Classification of Health Interventions (ICHI) *(37)* if existing. On the level of care column, it is presumed that 1, 2, and 3 indicate primary, secondary and tertiary level of care accordingly, and the space is ticked when the intervention should take place under that level.

Table 6. General priority clinical interventions

ICHI codes [clickable]	Clinical interventions	Level of care		
		1	2	3
Clinical assessment				
PZA.AB.ZZ	Anthropometric measurement (height, weight, body mass index, waist and hip circumference)	X	X	X
HT2.AA.ZZ	Assessment of cardiovascular functions	X	X	X
JTB.AA.ZZ	Assessment of respiratory functions	X	X	X
BZZ.AA.AH	Direct and indirect ophthalmoscopy	X	X	X
ITA.AB.AF	Measurement of blood pressure	X	X	X
ETG.AB.ZZ	Measurement of body temperature	X	X	X
BZZ.AA.AH	Test for visual acuity	X	X	X
Clinical laboratory				
DIA.JH.AF	Erythrocyte sedimentation rate (ESR)	X	X	X
DIA.JH.AF	Haemoglobin (Hb)	X	X	X
DIA.JH.AF	Haematocrit (Hct)	X	X	X
DIA.JH.AF	Platelet count	X	X	X
DIA.JH.AF	Complete blood count automated		X	X
DIA.JH.AF	White blood cell count/differential leucocyte count		X	X
NTC.AA.ZZ	Renal function tests (albumin, blood urea nitrogen, creatinine, phosphate, urine chemistry)		X	X
DIA.JH.AF	Peripheral blood film examination		X	X
DIA.JH.AF	Glucose/point-of-care analyser	X	X	X
DTA.AB.ZZ	Serum bicarbonate/blood pH and gases		X	X
DIA.JH.AF	Lipid profile		X	X
DIA.JH.AF	Electrolytes (sodium, potassium, chloride)		X	X
DIA.JH.AF	Creatinine and albumin to estimate glomerular filtration rate (GFR) and albumin–creatinine ratio (ACR)	X	X	X
DIA.JH.AF	Tests for serum triiodothyronine (T3), thyroxine (T4), thyroid-stimulating hormone (TSH)		X	X
NTC.AB.ZZ	Tests for urinary creatinine, urinary urea, urinary electrolytes (sodium, potassium, chloride) and urinary osmolarity		X	X
Medical imaging				
PZA.BA.BA	X-ray imaging		X	X
	Fluoroscopic imaging			X
PAK.BA.BJ; IZZ.BA.BJ; KMA.BA.BJ; PAK.BA.BJ	Ultrasound scan		X	X
PAK.BA.BC	Computed tomography (CT) scan			X
MZZ.BA.BH	Magnetic resonance imaging (MRI)			X

ICHI codes [clickable]	Clinical interventions	Level of care		
		1	2	3
Hospitalization				
	Inpatient admission		X	X
	Clinical and paraclinical monitoring (scheduled tests)		X	X
	Medical treatment and wound care	X	X	X
	Administration of medication (administration of oral and parenteral treatment)	X	X	X
Intensive care unit				
JTB.DE.AC	Mechanical ventilation		X	X
PZA.DD.AC	Oxygen therapy	X	X	X
HT2.AA.ZZ; ITA.AI.AF	Continuous multiparametric cardiac monitoring with non-invasive/invasive blood pressure monitoring and ambulatory blood pressure monitoring		X	X
JTB.AI.ZZ	Monitoring of oxygen saturation	X	X	X
HTB.SC.AH	Defibrillation and external pacemaker/resuscitation	X	X	X
PAK.BA.BJ; IZZ.BA.BJ; KMA.BA.BJ	Ultrasound scan		X	X
JZZ.DL.AC	Intubation		X	X
PZX.DB.AE PZX.DB.AF	Continuous infusion and application of supportive drugs		X	X
PZX.AH.XA	Blood gas analysis		X	X
JCH.BA.BA	Imaging of the chest	X	X	X
PZX.AH.XA	Point-of-care glucose test	X	X	X

The following tables lists the specific priority clinical interventions by disease following the colour code. Each intervention was matched with the WHO International Classification of Health Interventions (ICHI) *(37)* if existing. On the level of care column, it is presumed that 1, 2, and 3 indicate primary, secondary and tertiary level of care accordingly, and the space is ticked when the intervention should take place under that level. The type of conditions column gives more specificality about what conditions each intervention covers.

Table 7. Priority clinical interventions for cardiovascular diseases except stroke

Types of conditions

A – BA00 Essential hypertension
B – BA80 Coronary atherosclerosis
C – BD1Z Heart failure
D – BC43.Z Cardiomyopathy
E – BC0Z Valvular disease (including infectious endocarditis)
F – LA8Z Congenital heart disease
G – BC9Z Arrhythmia
H – BD52.7 Arterial disease
I – BD71 Deep vein thrombosis
J – BB00 Pulmonary embolism

Cardiovascular diseases

ICHI codes [clickable]	Clinical interventions	Type of condition										Level of care		
		A	B	C	D	E	F	G	H	I	J	1	2	3
Clinical assessment														
HTB.AC.AH	Electrocardiography test	X	X	X	X	X	X	X	X	X	X	X	X	X
Clinical laboratory														
DTA.AB.ZZ	Prothrombin time and international normalized ratio (PT/INR), point-of-care testing					X		X		X	X	X	X	X
DTA.AB.ZZ	Partial thromboplastin time (PTT), also known as activated partial thromboplastin time (APTT)					X		X		X	X		X	X
HZZ.ZZ.AZ	B-type natriuretic peptide (BNP) test, point-of-care testing			X	X	X	X				X		X	X
HZZ.ZZ.AZ	Test for cardiac biomarkers (troponin T/I), point-of-care testing		X	X	X	X	X	X			X		X	X
HZZ.ZZ.AZ	Test for cardiac biomarkers (troponin, CK-MB)		X	X	X	X	X	X					X	X
DTA.AB.ZZ	D-dimer, point-of-care testing									X	X		X	X
Other specialized diagnostics														
HTM.AF.ZZ	Exercise cardiac stress test device		X		X	X	X	X					X	X
Medical imaging														
HFD.BA.BG	Positron emission tomography (PET) of myocardium		X	X	X	X								X
HFD.BA.BF	Stress and rest test – single photon emission computed tomography (SPECT)		X		X						X			X
HZZ.BA.BJ	Stress and rest – transthoracic echocardiography with or without contrast	X	X	X	X	X	X	X	X	X	X			X
HZZ.BA.AC	Transoesophageal echocardiography	X	X	X	X	X	X	X	X	X	X			X

ICHI codes [clickable]	Clinical interventions	Type of condition										Level of care		
		A	B	C	D	E	F	G	H	I	J	1	2	3
HIA.BA.BB; ICA.BA.BB; IFA.BA.BB; IDA.BA.BB; IEA.BA.BB; HZA.BA.BB; HZB.BA.BB; IDB.BA.BB; ICD.BA.BB; IED.BA.BB; IFD.BA.BB; IZD.BA.BB	X-ray imaging (cardiac and peripheral angiography)		X	X	X	X	X	X	X	X	X			X
HIA.BA.BB; ICA.BA.BB; IFA.BA.BB; IDA.BA.BB; IEA.BA.BB; HZA.BA.BB; HZB.BA.BB; IDB.BA.BB; ICD.BA.BB; IED.BA.BB; IZD.BA.BB	Digital subtraction angiography (DSA)		X	X	X	X	X	X	X	X	X			X
HIA.LG.AF; HIA.LH.AF	Coronary angioplasty with or without stenting		X		X		X							X
HDG.LG.AF; HDF.LG.AF; HDE.LG.AF; HDH.LG.AF	Percutaneous balloon valvuloplasty (aortic, mitral, pulmonary and tricuspid)					X	X							X
IFA.LG.AF; IFA.LH.AF; ICA.LG.AF; ICA.LH.AF	Peripheral angioplasty with or without stenting								X	X				X
IZZ.BA.BJ; IAA.BA.BJ	Doppler ultrasound of peripheral vascular system									X	X		X	X
Surgery														
HAD.LG.AF	Balloon atrial septostomy						X							X
HIK.LG.AF	Balloon dilatation for coarctation						X							X
HFC.DN.AA; HFC.DN.AF	Cardiac pacemaker implantation							X						X
HFC.DN.AA; HFC.DN.AF	Cardiac resynchronization therapy (CRT), defibrillator implantation			X	X			X						X
IZA.LG.AF; IZA.LH.AF	Angioplasty with or without stenting		X						X	X	X			X
HIA.LI.AA	Coronary artery bypass grafting		X											X
HFC.AF.AF; HFC.GA.AF	Cardiac electrophysiology and catheter ablation						X	X						X
HZM.ML.AA	Correction of congenital heart disease						X							X
HDE.MK.AA; HDF.MK.AA; HDG.MK.AA; HDH.MK.AA	Repair of heart valve					X	X							X
HZB.AB.AF	Right heart cardiac catheterization			X	X	X	X	X			X			X
Intensive Care Unit														
IZA.DB.AF; IZD.DB.AF	Thrombolysis		X						X	X	X		X	X
HZZ.DN.AF	Intra-aortic counterpulsation		X	X										X
HFC.DL.AF	Temporary transvenous pacing							X						X

Table 8. Priority clinical interventions for stroke

Types of conditions

A – 8B21 Cerebrovascular disease with no acute symptoms

B – 8B10, 8B11 Cerebral ischaemia including transient ischaemic attack

C – 9B74 Retinal vascular occlusion

D – 8B00 Intracerebral haemorrhage

E – 8B01 Subarachnoid haemorrhage

F – 8B22, 8B23 Certain specified cerebrovascular diseases

Stroke

ICHI codes [clickable]	Clinical intervention	Type of condition						Level of care		
		A	B	C	D	E	F	1	2	3
Clinical assessment										
AZZ.AA.AH	Neurological assessment	X	X	X	X	X	X		X	X
Clinical laboratory										
AZZ.ZY.AZ	Cerebrospinal fluid (CSF) bilirubin spectrophotometry					X				X
DTA.AB.ZZ	Prothrombin time and international normalized ratio (PT/INR), point-of-care testing	X	X	X	X	X	X		X	X
Other specialized diagnostics										
AAA.AF.AH	Electroencephalography	X	X		X	X	X			X
Medical imaging										
IAA.BA.BJ	Doppler imaging of extracranial vessels	X	X	X		X	X			X
IBA.BA.BJ	Doppler imaging of intracranial vessels	X	X	X	X	X	X			X
BAM.BA.BC	Optical coherence tomography			X					X	X
BZA.BA.BJ	Eye and orbit ultrasound scan	X	X	X	X	X	X			X
BCA.BA.BE	Fluorescein angiography or angioscopy of posterior chamber of eye			X						X
IBA.LH.AF	Dilatation with insertion of stent or prosthesis of artery of head and neck	X	X				X			X
IBA.LA.AF	Endovascular coiling				X	X	X			X
IBA.JE.AF	Endovascular extraction of obstruction from head and neck vessel (e.g. thrombectomy)	X	X				X			
IBB.LG.AF	Percutaneous angioplasty of carotid artery, extracranial									
Surgery										
MAA.JJ.AA	Craniectomy		X		X	X	X			X
MAA.FA.AA	Craniotomy				X	X	X			X
AAG.JB.AA	Extraventricular drain placement		X		X	X	X			X
IBA.LA.AF	Endovascular embolization or occlusion of head and neck vessels				X	X	X			X
HAA.DN.AF	Implantation of left atrial appendage device	X	X	X						X
HAD.ML.AA	Repair of atrial septal defect of heart with graft or prosthesis	X	X	X	X					X
IBA.LA.AF	Surgical aneurysm clipping	X				X	X			X
IBA.DB.AF	Thrombolysis of artery of head and neck (percutaneous transluminal)		X				X			X
IAA.DB.AF	Thrombolysis of intracranial artery (percutaneous transluminal)		X				X			X

ICHI codes [clickable]	Clinical intervention	Type of condition						Level of care		
		A	B	C	D	E	F	1	2	3
Non-surgical interventions										
IZZ.ZY.ZZ	Intermittent pneumatic lower limb compression		X		X	X	X		X	X
KBF.DL.AJ	Percutaneous endoscopic gastrostomy (PEG)		X		X	X	X		X	X
Hospitalization										
IAA.DB.AF	Emergency or ICU procedure - patients admitted to stroke unit after thrombolysis		X				X		X	X
PZZ.ZY.ZZ	Physical therapy/rehabilitation		X	X	X	X	X		X	X
Intensive care unit										
AAA.AI.AE	Intracranial pressure monitoring		X		X	X	X			X
AAA.AI.AE	Near-infrared spectroscopy monitor		X		X	X	X			X

Table 9. Priority clinical interventions for diabetes

Types of conditions

A – 5A14 Diabetes mellitus, type unspecified

B – 5A21 Hypoglycaemic emergency

C – 5A20, 5A22 Hyperglycaemic emergency

D – GB61.Z Diabetic nephropathy

E – 9B71.0 Diabetic retinopathy

F – 8D88.1 Diabetic neuropathy

G – BD54 Diabetic foot

Diabetes

ICHI codes [clickable]	Clinical intervention	Type of condition							Level of care		
		A	B	C	D	E	F	G	1	2	3
Clinical assessment											
AVE.AA.ZZ	Examining vibration perception in the feet, motor function and sensory perception testing	X					X	X	X	X	X
IZZ.AA.ZZ	Measuring ankle-brachial pressure index	X					X	X	X	X	X
KAZ.AE.AC	Periodontal examination	X							X	X	X
PZX.AH.XA	Point-of-care blood glucose test	X	X	X	X	X	X	X	X	X	X
PZX.AH.XA	Point-of-care blood ketone test	X	X	X					X	X	X
Clinical laboratory											
NAM.AA.ZZ	Urinalysis test strips plus microscopy	X			X				X	X	X
NAM.AA.ZZ	Spot urine test for urinary infection	X		X	X				X	X	X
	Haemoglobin A1c (HbA1c), point-of-care testing	X	X	X	X	X	X	X		X	X
PZX.AH.XB; NTC.AB.ZZ	Urine glucose and ketones	X	X	X	X				X	X	X
Other specialized diagnostics											
BZZ.AA.AH	Direct or indirect Ophthalmoscopy	X	X			X				X	X
Medical imaging											
IZZ.BA.BJ	Doppler ultrasound of peripheral vascular system	X						X			X
BCA.BA.BE	Fluorescein angiography	X				X					X
BCA.BA.AH	Fundus photography with a non-mydriatic camera and interpretation of results (locally or remotely)	X				X					X
BZZ.AA.AH	Optical coherence tomography (OCT) and interpretation of results	X				X					X
IEA.BA.BB	Renal angiography function study				X						X
NAA.BA.BE	Renal scan and radioisotope function study				X						X
Surgery											
MOJ.JN.AA	Amputation of lower limb							X		X	X
BCD.DB.AE	Intravitreal injection of anti-vascular endothelial growth factor (VEGF)					X					X
IFA.LG.AF; IFA.LH.AF; IFA.LI.AF; IFA.LI.AA	Lower limb vascular intervention (bypass or angioplasty)							X			X
NAA.KD.AA	Renal transplantation				X						X
BCC.MK.AA	Repair of retina (retinal laser photocoagulation)					X					X
LZZ.JG.AH	Ulcer debridement surgery							X	X	X	X

ICHI codes [clickable]	Clinical intervention	Type of condition							Level of care		
		A	B	C	D	E	F	G	1	2	3
Non-surgical interventions											
MRS.DB.AE	Blood glucose management, including self-monitoring and insulin injections	X	X	X	X	X	X	X	X	X	X
LT2.ZY.ZZ	Foot ulcer management	X	X	X	X	X	X	X	X	X	X
NAA.JC.AF; KMA.JC.AE	Renal replacement therapy				X					X	X
KAZ.AE.AC	Periodontal treatment	X							X	X	X
Hospitalization											
PZB.ZZ.ZZ	Emergency medical treatment		X	X	X			X			

III.II Introduction to listing of priority medical devices for cardiovascular diseases and diabetes

The delivery of health care services, today more than ever, has a close relationship with the use of health technologies. The development and incorporation of these technologies have enabled effective access to quality care and improved capacity to screen, diagnose, treat, rehabilitate and palliate diseases. However, deaths occur as a result of lack of accessible, affordable and available technologies, as well as specialized human resources.

The Priority Medical Devices project, convened by WHO, has the purpose of improving global access to medical devices. The project aims to produce a list of priority medical devices needed for the management of high-burden diseases at a given health care level and in a given context *(38)*.

Priority medical devices are health products that respond to priority health interventions. These medical devices need to be safe, of good quality, effective, appropriate, affordable, accessible and acceptable. They 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. The devices listed in this publication are presented using only generic names (trademarks or commercial names were not included).

Medical devices that are manufactured, selected, purchased or used need to be assessed and evaluated locally by authorities to respond to local regulatory requirements, and selected to be affordable by the health care system. Moreover, the users must be trained for appropriate and safe use of specific medical devices, whenever this applies. In addition, medical devices must be used by the appropriate user, as most of them are developed for use by health professionals, but others are intended for use directly by the patient. Depending on the user, special training or familiarization with the medical device is needed. This also affects directly the level of care at which some interventions can be performed, depending on the level of specialization of the staff. Priority medical devices are options that further need to be assessed considering the diverging needs of countries of differing income levels or other contexts, including appropriate infrastructure, design factors, and specialized human resources.

Levels of health care

In this document, three different levels are considered. These three levels of health care are referred in the tables of priority medical devices as "level of care" 1, 2 and 3. They are defined as follows.

Primary health care (level of care 1). This includes (a) essential health care made accessible at a cost that a country and community can afford, with methods that are practical, scientifically sound and socially acceptable; and (b) the first level of contact with people acting to improve health in a community, including through health promotion, disease prevention, screening, rehabilitation, provision of assistive devices and palliative care *(39)*. This level includes self-testing, self-treatment and personal care; and health posts, health centres or equivalent health care facilities that have outpatient care.

Secondary health care (level of care 2). This includes ambulatory medical services and commonplace general hospital care (outpatient and inpatient services). Access is often via referral from primary health care services. This level generally includes the following medical specialties: general or family medicine, internal medicine, paediatrics, gynaeco-obstetrics and general surgery *(39)*.

Tertiary health care (level of care 3). This refers to specialized medical and related services of high complexity and usually high cost technologies that require a specialized health care workforce. These services are used by those referred from secondary care for diagnosis and treatment not available in primary or secondary care. Tertiary care is generally only available at specialized, regional or national health care facilities with both inpatient and outpatient referral centres *(39)*.

Types of medical devices, according to use

Tables will divide the list of priority medical devices in each unit by general or specific use for a disease:

- **general medical devices** for basic use of the clinical unit to perform a majority of interventions for a big scope of diseases. Range of specification may vary depending on the level of healh.
- **specific medical devices** aimed for diagnosis, treatment and rehabilitation interventions of a specific type of disease. Range of specification may vary depending on the level of health and specialization of the condition.
- **kits or sets,** group of instruments, single-use devices and consumables used together for a particular medical purpose. They are intemised at the end of the intervention table in which they were first mentioned (or see Annex 5 for a compilation of all kits and sets).

1. Clinical Assessment

Navigation diagram

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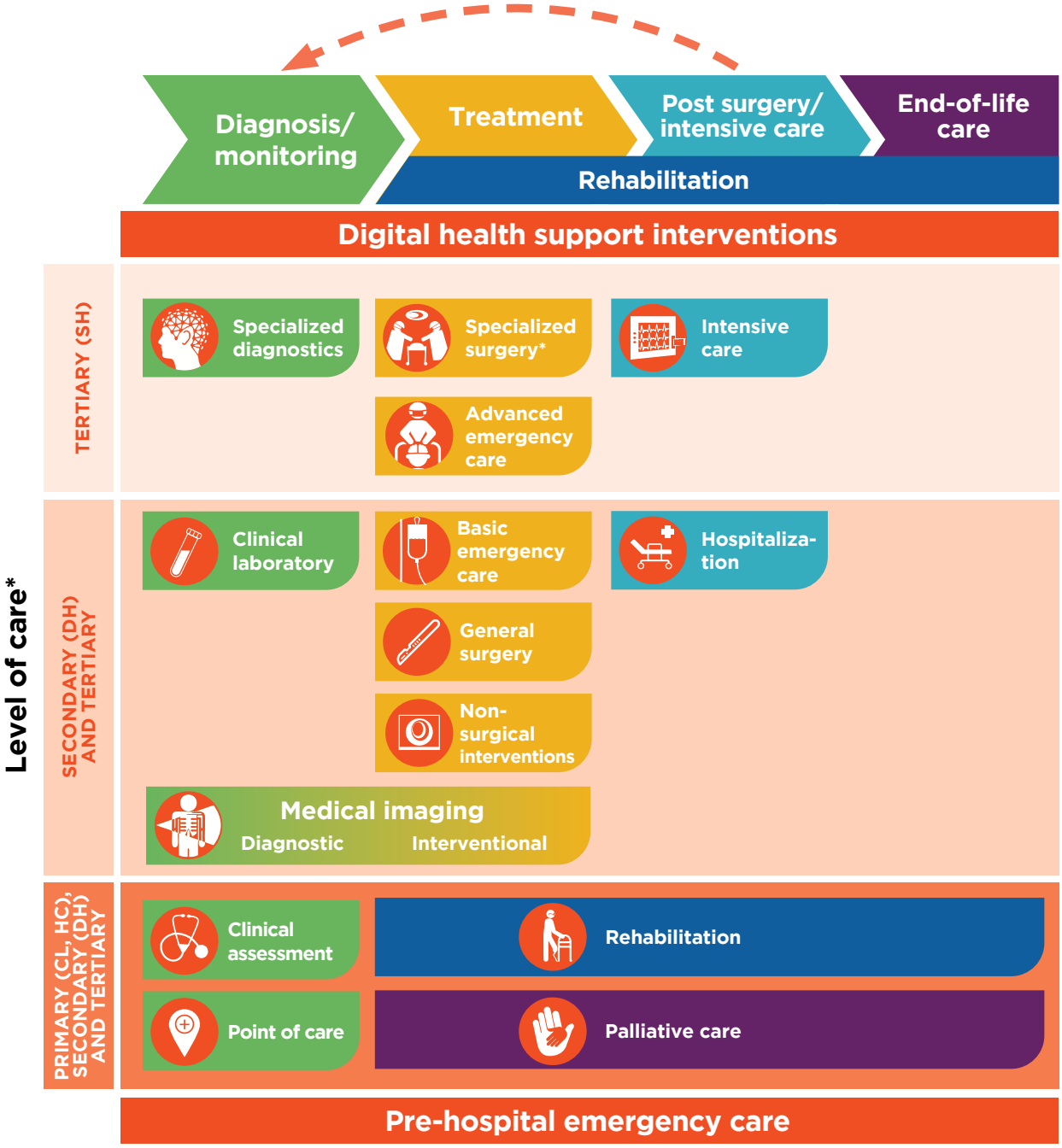


Key:

* Including cardiovascular, neurological, ophthalmic and nefrology.
CL community level; health post
DH district/general hospital; interventions can also be offered in a first referral outpatient clinic
HC health centre/outpatient clinic
SH specialized/regional/national hospital; specialized care outpatient unit

Most premature deaths related to NCDs can be avoided through a combination of early detection and preventive interventions. The clinical interventions listed in this chapter include simple, affordable tools for early detection, treatment and risk assessment (Table 10). The aim is to prevent cardiovascular diseases and diabetes by ensuring equitable access to continuous, standardized, high-quality care for people at high risk.

Table 10. List of clinical assessment interventions

Disease	Interventions	Level of care		
		1	2	3
All	Anthropometric measurement (height, weight, body mass index, waist and hip circumference)	X	X	X
	Assessment of cardiovascular functions	X	X	X
	Assessment of respiratory functions	X	X	X
	Direct ophthalmoscopy	X	X	X
	Measurement of blood pressure	X	X	X
	Measurement of body temperature	X	X	X
	Test for visual acuity	X	X	X
Cardiovascular diseases	Electrocardiography test		X	X
Stroke	Neurological assessment		X	X
Diabetes	Examining vibration perception in the feet; motor function and sensory perception testing	X	X	X
	Measuring ankle-brachial pressure index	X	X	X
	Periodontal examination	X	X	X
	Point-of-care blood glucose test	X	X	X
	Point-of-care blood ketone test	X	X	X

Table 11 present priority general medical devices that can be used for general assessment of patients for early diagnostics of various conditions, including cardiovascular diseases and diabetes. Tables 12–14 present the specific medical devices that are used for disease-specific interventions.

1.1 General priority medical devices for clinical assessment interventions

General medical devices can be used for various conditions and diseases. They are organized here by clinical procedure.

Table 11. List of general priority medical devices for clinical assessment interventions

Clinical intervention	Level of care			Capital medical devices	Consumables, single-use medical devices
	1	2	3		
Anthropometric measurement (height, weight, body mass index, waist and hip circumference)	X	X	X	Scale weight	
	X	X	X	Body mass index calculator	
	X	X	X	Measuring tape	
Assessment of cardiovascular functions	X	X	X	Stethoscope, binaural	Electrodes Electrolytic gel
	X	X	X	Electrocardiography system[a]	
Assessment of respiratory functions	X	X	X	Pulse oximeter	Disposable nozzles
	X	X	X	Peak flow meter	
Direct and indirect ophthalmoscopy	X	X	X	Direct ophthalmoscope	Bulbs
		X	X	Indirect ophthalmoscope	
Measurement of blood pressure	X	X	X	Blood pressure measurement device	Cuffs (various sizes)
Measurement of body temperature	X	X	X	Thermometer[a]	
Test for visual acuity	X	X	X	Illiterate vision chart	

a. These capital medical devices are described in the table on generic equipment in Annex 4.

1.2 Specific priority medical devices for clinical assessment interventions, by disease

1.2.1 Cardiovascular diseases

Table 12. List of specific priority medical devices for clinical assessment interventions for cardiovascular diseases

Clinical intervention	Level of care			Capital medical devices	Consumables, single-use medical devices
	1	2	3		
Electrocardiography test		X	X	Electrocardiography system[a] (3, 6 or 12 leads, depending on level of care)	Electrodes Electrolytic gel

a. This capital medical device is described in the table on generic equipment in Annex 4.

1.2.2 Stroke

Table 13. List of specific priority medical devices for clinical assessment interventions for stroke

Clinical intervention	Level of care			Capital medical devices	Consumables, single-use medical devices
	1	2	3		
Neurological assessment (visual acuity chart, dermatome chart, Modified Rankin scale, Glasgow coma scale, Functional Assesment Staging (FAST) scale, National Institutes of Health stroke scale)	X	X	X	Examination light	Tongue depressor
				512 Hz and 128 Hz tuning fork	
				Reflex hammer	
				10 g monofilament	

1.2.3 Diabetes

Table 14. List of specific priority medical devices for clinical assessment interventions for diabetes

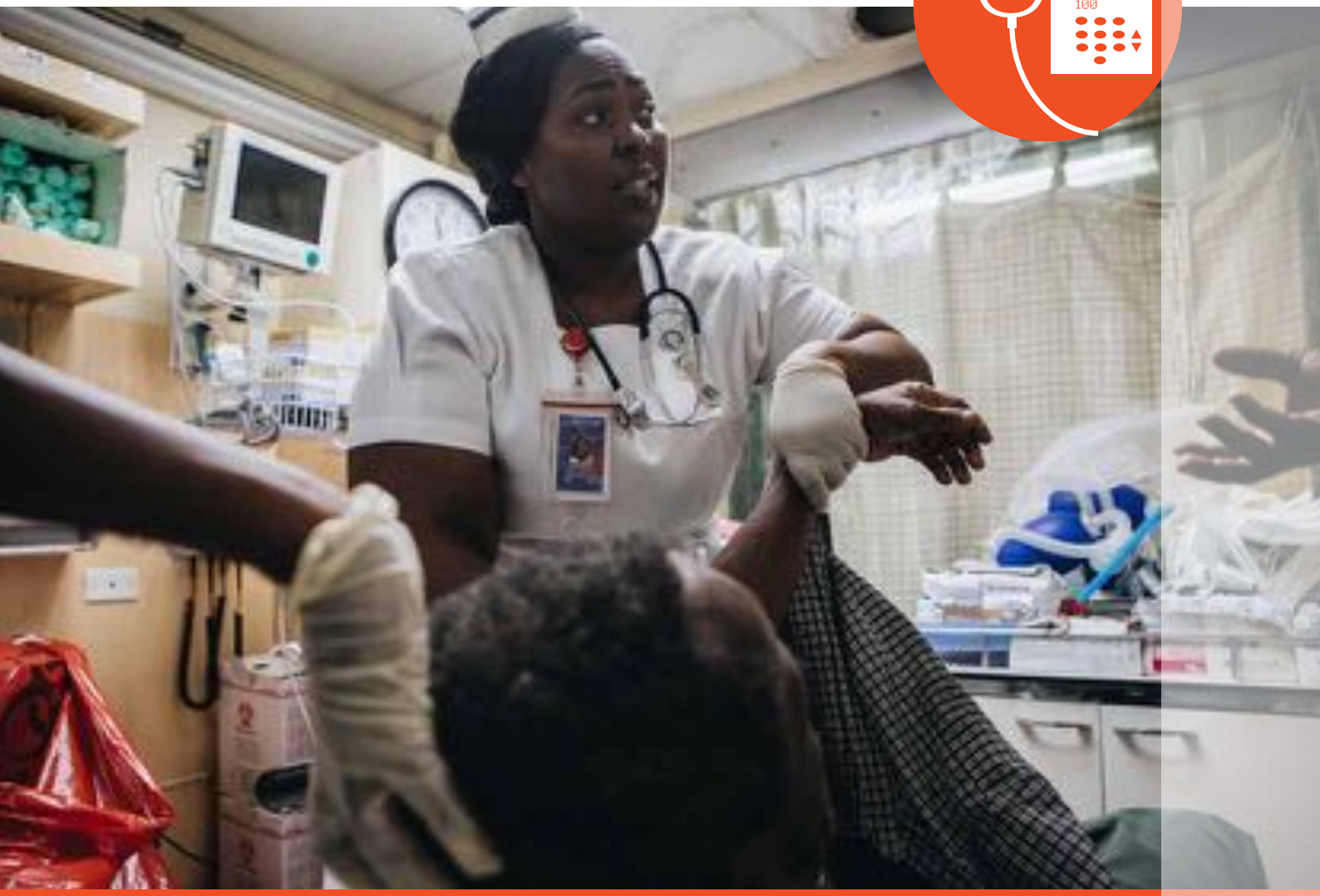
Clinical intervention	Level of care			Capital medical devices	Consumables, single-use medical devices
	1	2	3		
Examining vibration perception in the feet, motor function and sensory perception testing	X	X	X	128 Hz tuning fork	
				Reflex hammer	
				10 g monofilament	
				Diabetic foot ulcer risk scales	
Measuring ankle-brachial pressure index	X	X	X	Blood pressure measurement device	Cuffs (various sizes)
				Doppler ultrasound blood flow measurement system	
Periodontal examination 1. Gingival inflammation (redness) 2. Tooth mobility 3. Gingival bleeding 4. Depth of gingival pocket 1 and 2 as basic exam, and 3 and 4 as clinical standard exam	X	X	X	Examination light	Dental mirror Tweezers (for 2) Periodontal probe (for 3 and 4)
Point-of-care blood glucose test	X	X	X	Blood glucose meter[a]	Single-use sterile lancets for capillary blood collection Blood glucose test strips
Point-of-care blood ketone test	X	X	X	Blood ketone meter	Single-use sterile lancets for capillary blood collection Blood ketone test strips

a. This capital medical device is described in the table on generic equipment in Annex 4.

Guidance documents

- WHO list of priority medical devices for cancer management. Geneva: World Health Organization; 2017 (https://www.who.int/publications/i/item/9789241565462).
- Interagency list of priority medical devices for essential interventions for reproductive, maternal, newborn and child health. Geneva: World Health Organization; 2016 (https://www.who.int/publications/i/item/9789241565028).
- The selection and use of essential in vitro diagnostics: report of the second meeting of the WHO Strategic Advisory Group of Experts on In Vitro Diagnostics, 2019 (including the second WHO model list of essential in vitro diagnostics). WHO Technical Report Series 1022 (https://apps.who.int/iris/bitstream/handle/10665/329527/9789241210317-eng.pdf).

2. Emergency care



Navigation diagram

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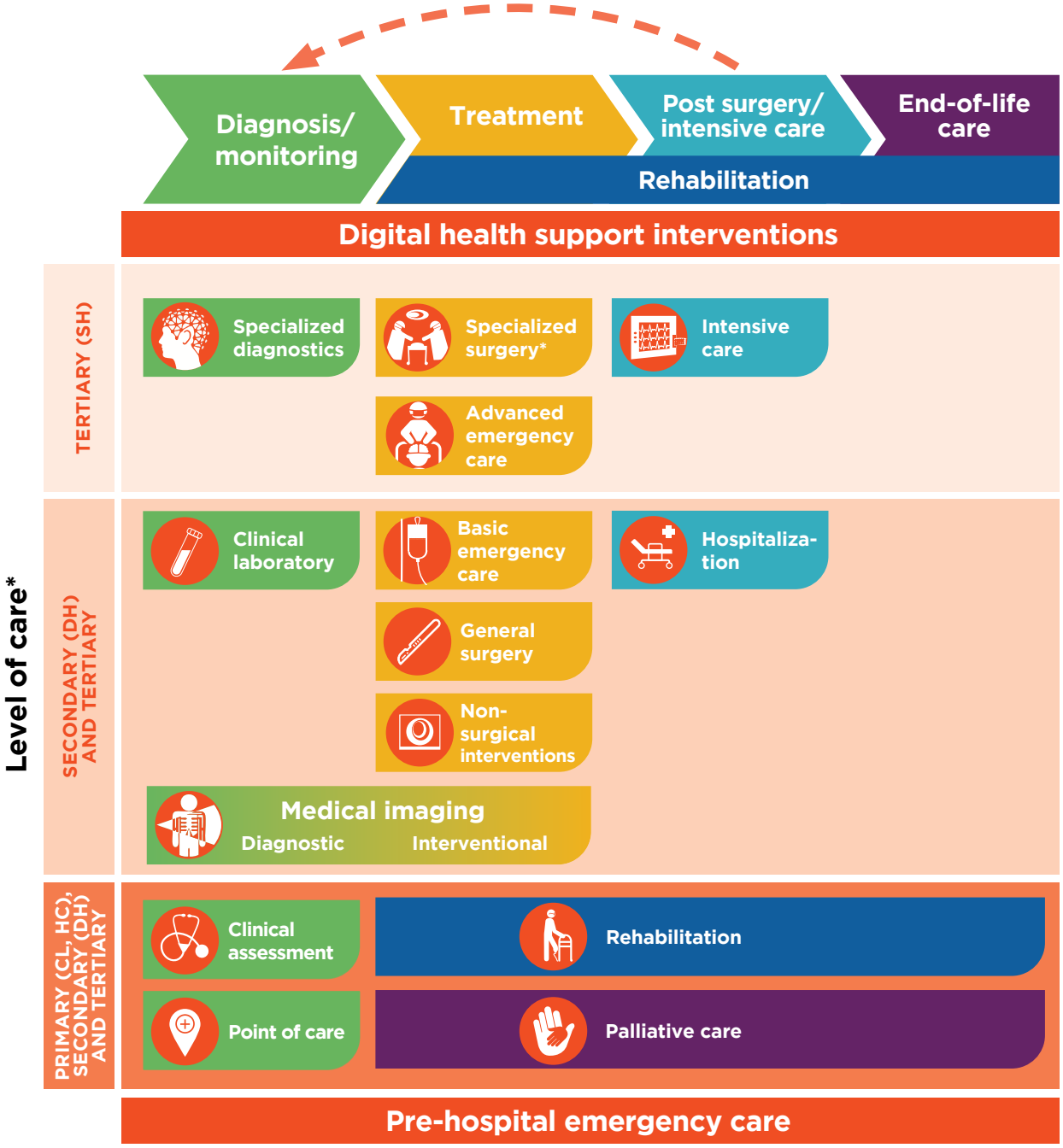

Key:

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Emergency care is an essential part of an effective health system, ensuring timely access to care for all patients. Well organized emergency care provides timely recognition, resuscitation and referral for severely ill patients, and definitive care for many others. In many settings, especially where resources are limited, emergency care is the first point of contact with the health system.

The WHO Emergency Care System Framework defines a series of essential functions for an emergency care system, ranging from pre-hospital care, to care during transport, to facility-based emergency unit care and inpatient operative and critical care as needed. Each of the functions described in the WHO Emergency Care System Framework can be achieved in many ways, depending on available resources, and each is essential to the delivery of effective emergency care.

Emergency care systems address cardiovascular emergencies such as heart attack and stroke, as well as metabolic emergencies such as acute complications of diabetes. Emergency care represents a cross-cutting investment that delivers benefits across other NCDs, injuries, complications of pregnancy and communicable diseases. It is estimated that over half of deaths in low- and middle-income countries are from conditions that can be addressed by emergency care *(40)*.

The WHO Essential Resources for Emergency Care describes essential minimum equipment for ambulances and emergency units at various levels of the health system. Acute cardiovascular diseases, diabetes or stroke may present with difficulty breathing, shock or altered mental status. Tables 15 and 16 describe emergency medical devices generally used in such situations. Clinical guidance for front-line emergency providers on assessment and treatment of acute presentations, such as difficulty breathing, shock, trauma and altered mental status, can be found in the WHO Basic Emergency Care course *(41)*.

2.1 General priority medical devices for emergency care

Medical devices used for emergency care are divided into two categories:

- Basic (B): paramedics, nurse stations, ambulances, stretcher and others, related to level 2 of health care provision.
- Advanced (A): emergency units in clinics or hospitals, specialized ambulances, related to level 3 of health care services.

Table 15. List of general priority medical devices for emergency care

Emergency care level		Capital medical devices	Consumables, single-use medical devices
2	3		
X	X	Blood glucose meter[a]	Glucose meter test strips
X	X		Control solutions
X	X	Oxygen cylinder or concentrator with flow meter and masks	Oxygen tubing and connectors
X	X	Stethoscope, binaural	
X	X	Thermometer	*If digital*, disposable tips
X	X	Pulse oximeter	Probes various sizes
X	X	Blood pressure measurement device	Cuffs (various sizes)
X	X	Examination light	
	X	Fluid warmer	
	X	Pressure bag for intravenous (IV) infusion	
	X	Automated external defibrillator (AED)	
	X	Laryngoscope	Intubation kit
X	X	Point-of-care haemoglobin/haematocrit testing	
	X	Ophthalmoscope	
	X	Peak flow meter	
X	X	IV infusion flow regulator, manual with dial	
X	X	Intravenous pole	
X	X	Minor surgical set	
	X	Scalpel handle	Blades, reusable/single-use
	X	Intraosseous needle driver, electric or manual	
X	X	Stretchers	
X	X	Patient slide for stretcher transfers	
X	X	Clock	
X	X	Surgery suction system[a]	
			Syringes, various sizes
X	X		Needles (various gauges and lengths; safety single-use)
X	X		Oral medication supplies (e.g. cups, droppers)
X	X		Cotton wool
X	X		Sutures, poliglecaprone
X	X		Vaseline or paraffin gauze
X	X		Tongue depressors
X	X		Finger-stick lancets
X	X		Elastic bandages
X	X		Suction catheters
X	X		Yankauer or other stiff suction tip
X	X		Nasal prongs (adult, paediatric and neonatal sizes)
X	X		Oral airways kit
X	X		Nasal airways

Emergency care level		Capital medical devices	Consumables, single-use medical devices
2	3		
X	X	Bag-valve-mask (adult, paediatric and neonatal)	
X	X		Metered-dose inhaler spacer
X	X		Ethanol 70% solution
	X		Rapid infusion catheter
	X		Nasogastric tubes
	X	Positive end expiratory pressure (PEEP) valve for bag-valve-masks	
	X		Endotracheal tubes
X	X		Urine dipstick
X	X		Urine pregnancy test
X	X		HIV rapid testing kits
X	X		Chlorhexidine 5% solution
X	X		Povidone-iodine solution
X	X		Aquatabs (or equivalent)
X	X		Safe final disposal of biological waste
X	X		Safe final disposal of sharps
X	X		Registration forms with patient contact information
X	X		Physical restraints
X	X		Rescue blankets
X	X		Patient tags (e.g. bracelets)
X	X		Adhesive tape
X	X	Automated external defibrillator (AED), manual external defibrillator	
X	X	Patient physiological monitor[a]	Electrodes
X	X		Sheathed needles
X	X		Tubing or connectors for needle drainage
X	X		Fluid collection vessel
X	X		Fluid collection bag
X	X		Nasal tampons or equivalent
X	X		Insulin needles and syringes, various sizes, safety, single-use
X	X		Heimlich valve and catch bags
X	X		Maps of local area

a. These capital medical devices are described in the table on generic equipment in Annex 4.

Table 16. List of general priority medical devices for medicalized ground transportation

Pre-hospital emergency care	Capital medical devices	Consumables, single-use medical devices
X	Ambulance	
X	Stretcher	
X	Resuscitation bag	
X	Oxygen supply system	Oxygen mask, patient interface (cannula, mask, non-rebreather) and oxygen tank
X	Patient physiological monitor[a]	Electrodes, leads, different size cuffs, electrolytic gel
X	Aspirator, electric portable	Single-use tubing
x	Mechanical ventilator (adult, paediatric)	Intubation kit
X	Infusion pump	Infusion set
X	Automated external defibrillator (AED), manual external defibrillator	Conductive gel, defibrillator pads
X	Stethoscope, binaural	Stethoscope covers, alcohol swabs
X	Emergency cabinet or container	
X	Communication system (phone, radio)	*

a. This capital medical device is described in the table on generic equipment in Annex 4.

** Consider to add consumables of table 15*

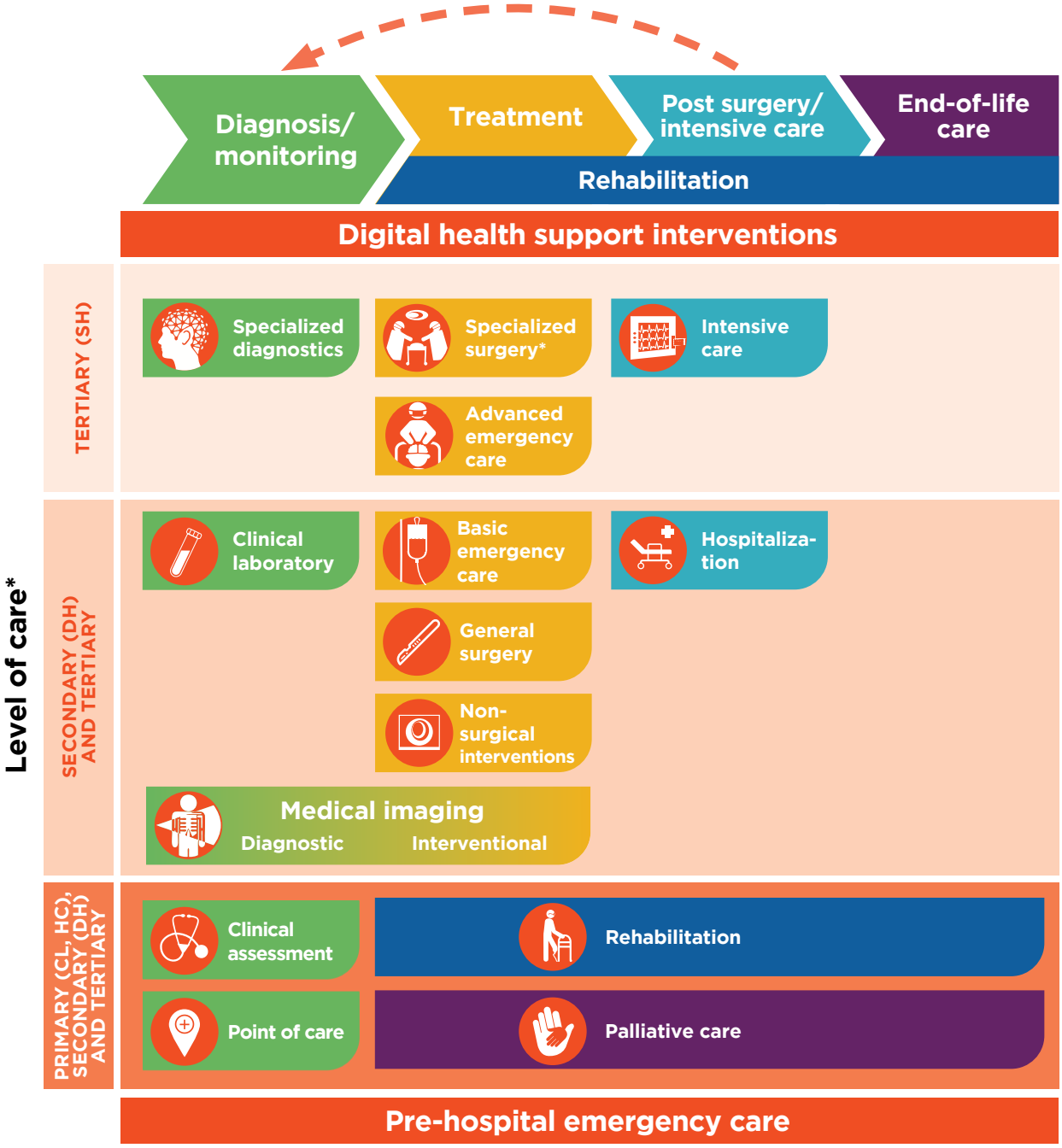
Guidance documents

- Jamison DT, Gelband H, Horton S, Jha P, Laxminarayan R, Mock CN et al. Disease control priorities, third edition: volume 9. Improving health and reducing poverty. Washington (DC): World Bank; 2017 (https://openknowledge.worldbank.org/handle/10986/28877).
- WHO-ICRC basic emergency care: approach to the acutely ill and injured. World Health Organization and International Committee of the Red Cross; 2018 (https://www.who.int/emergencycare/publications/Basic-Emergency-Care/en/).
- Emergency care. Geneva: World Health Organization (https://www.who.int/emergencycare/systems/en/).
- Guidelines for essential trauma care. Geneva: World Health Organization; 2012 (https://www.who.int/publications-detail/guidelines-for-essential-trauma-care).

3. Clinical laboratory

Navigation diagram

Click on the diagram to navigate to any section of this document.



Key:

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CL community level; health post
DH district/general hospital; interventions can also be offered in a first referral outpatient clinic
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Clinical laboratory testing plays an essential role in the delivery of health care. The purpose of a laboratory for clinical diagnostics is to perform accurate testing on patient samples and to analyse and interpret the results, thereby guiding the diagnosis, treatment, management and monitoring of the patient. The process for a laboratory diagnostic test comprises the correct identification of the patient, the right test selection in order to collect the sample of blood or other biological matter from the patient by the nurse, doctor or phlebotomy technician, and then transfer the sample to the clinical laboratory where the required tests will be performed by trained laboratory personnel. *(42)*. Some tests are performed manually, and others are done using automated or semi-automated instrumentation. Therefore, it is crucial that skilled or specially trained human resources (biomedical laboratory scientists) are available to perform the required tests and provide clinical advice where needed. The laboratory provides a report of the test results to the referring clinician, who will then interpret them and decide on the diagnosis and treatment of the patient. Timeliness, accuracy of results, good-quality management and universal safety are critical elements in the safe functioning of the clinical laboratory. Quality control tests and external quality assessment schemes should be carried out regularly as part of laboratory quality assurance *(43)*.

The personnel required depends on the anticipated volume of samples and processes to be handled by the specific laboratory unit. Depending on the national context and factors, including workforce availability, different occupations can fulfil the roles that may be required for clinical laboratory testing and pathology. Prerequisites for that include having the required competencies to perform those roles, and official recognition in accordance with the scope of practice.

Selection of the equipment for laboratory services depends mainly upon volume and available resources. The type of equipment selected (for example, automated or semi-automated) should take into account the facility capacity and the options for purchasing, leasing or renting the equipment and devices, along with the relevant consumables, accessories and software.

Detailed recommendations for the type of infrastructure required for a clinical laboratory can be found in *ISO 15189:2012 Medical laboratories – requirements for quality and competence, and the WHO list of priority medical devices for cancer management,* Chapter 4: Clinical laboratory & pathology (pages 91–96), including the following procedures of interest:

- pre-analytical procedure: phlebotomy, sample reception and distribution, page 91
- general analytical procedures, pages 92–96.

The diagnosis tests listed in this chapter are those belonging to the clinical laboratory setting (Table 17). Tables 18–22 then present general medical devices that can be used for diagnosis of many diseases, including cardiovascular diseases and diabetes, and specific medical devices that are used for disease-specific interventions.

The interventions and tests listed in the tables are, aligned with the *WHO model list of essential in vitro diagnostics (34)*.

Table 17. List of clinical laboratory interventions

Disease	Interventions	Level of care		
		1	2	3
All	Erythrocyte sedimentation rate (ESR)	X	X	X
	Haemoglobin (Hb)	X	X	X
	Haematocrit (Hct)	X	X	X
	Platelet count	X	X	X
	White blood cell count, differential leucocyte count		X	X
	Renal function tests (albumin, blood urea nitrogen, creatinine, phosphate, urine chemistry)		X	X
	Peripheral blood film examination		X	X
	Tests for urinary creatinine, urinary urea, urinary electrolytes (sodium, potassium, chloride) and urinary osmolarity		X	X
	Complete blood count (automated)		X	X
	Glucose, point-of-care testing	X	X	X
	Glucose		X	X
	Serum bicarbonate, blood pH and gases		X	X
	Lipid profile		X	X
	Liver function tests (alanine aminotransferase, albumin, alkaline phosphatase, aspartate aminotransferase, direct and indirect bilirubin, gamma-glutamyl transferase)		X	X
	Tests for serum triiodothyronine (T3), thyroxine (T4), thyroid-stimulating hormone (TSH)		X	X
	Electrolytes (sodium, potassium, chloride)		X	X
	Creatinine and albumin to estimate glomerular filtration rate (GFR) and albumin–creatinine ratio (ACR)		X	X
Cardiovascular diseases	Prothrombin time and international normalized ratio (PT/INR)		X	X
	Partial thromboplastin time (PTT), also known as activated partial thromboplastin time (APTT)		X	X
	Prothrombin time and international normalized ratio (PT/INR), point-of-care testing	X	X	X
	B-type natriuretic peptide (BNP) test, point-of-care testing	X	X	X
	B-type natriuretic peptide (BNP) test		X	X
	Tests for cardiac biomarkers (troponin T/I), point-of-care testing	X	X	X
	Tests for cardiac biomarkers (troponin T/I)		X	X
	D-dimer, point-of-care testing	X	X	X
	D-dimer		X	X
Stroke	Prothrombin time and international normalized ratio (PT/INR), point-of-care testing	X	X	X
	Prothrombin time and international normalized ratio (PT/INR)		X	X
	Cerebrospinal fluid (CSF) bilirubin spectrophotometry			X
Diabetes	Urinalysis test strips plus microscopy		X	X
	Urinalysis test strips	X	X	X
	Haemoglobin A1c (HbA1c)		X	X
	Haemoglobin A1c (HbA1c), point-of-care testing	X	X	X
	Urine glucose and ketones	X	X	X
	Urine glucose	X	X	X

3.1 General priority medical devices for clinical laboratory interventions

Table 18. List of general priority medical devices for clinical laboratory interventions

Clinical intervention	Level of care			Capital medical devices	Consumables, single-use medical devices
	1	2	3		
Clinical intervention	Level of care			Capital medical devices	Consumables, single-use medical devices
	1	2	3		
Erythrocyte sedimentation rate (ESR)	X	X	X	Westergren tubes, Wintrobe tubes, racks for holding tubes, stopwatch	Disposable ESR pipettes, venipuncture kit, anticoagulated tubes (sodium citrate for Westergren method and EDTA for Wintrobe method)
		X	X	ESR analyser	Reagent kit, calibrators, controls, venipuncture kit, anticoagulated tubes (sodium citrate for Westergren method and EDTA for Wintrobe method)
Haemoglobin (Hb)	X	X	X	Sahli's haemoglobinometer	Hydrochloric acid solution (N/10 HCl), Pasteur pipette, stirring rod, disposable graduated tubes, venipuncture kit, anticoagulated tubes
	X	X	X	Colorimeter, racks for test-tubes, autopipette	Drabkin's solution, test-tubes, pipette tips, venipuncture kit, anticoagulated tubes
Haematocrit (Hct)	X	X	X	Clinical chemistry analyser[a]	Reagent kit, calibrators, controls, venipuncture kit
				Colorimeter, racks for test-tubes, autopipette	Test-tubes, pipette tips, venipuncture kit, anticoagulated tubes
Platelet count	X	X	X	Haemocytometer and microscope, or automated full blood counters	Commercial diluting system
				Colorimeter, racks for test-tubes, autopipette	Solution, test-tubes, pipette tips, venipuncture kit, anticoagulated tubes
Peripheral blood film examination or Romanowsky staining		X	X	Staining rack, dropper, microscope, stopwatch, slide spreader, slide marker, Neubauer chamber (cell counter); or automated haematology analyser	Buffer, methanol (for fixation in case water-based stains are used), dropper, cover slips, pipette tips, test-tubes, venipuncture kit, anticoagulated tubes, reagent kit, calibrators, controls
				Automated slide staining system	Venipuncture kit, anticoagulated tubes, reagent kit
Tests for urinary creatinine, urinary urea, urinary electrolytes (sodium, potassium, chloride) and urinary osmolarity		X	X	Clinical chemistry analyser[a]	Reagent kit, calibrators, controls, venipuncture kit Urine collection kit
Complete blood count, automated		X	X	Automated haematology analyser	Reagent kit, calibrators, controls, venipuncture kit
Glucose, point-of-care testing	X	X	X	Point-of-care analyser	Reagent strips, lancets, finger puncture kit
Glucose		X	X	Clinical chemistry analyser[a]	Reagent kit, calibrators, controls, venipuncture kit, anticoagulated tubes

Clinical intervention	Level of care			Capital medical devices	Consumables, single-use medical devices
	1	2	3		
Serum bicarbonate, blood pH and gases		X	X	Clinical chemistry analyser[a]	Reagent kit, calibrators, controls, venipuncture kit
Lipid profile		X	X	Clinical chemistry analyser[a]	Reagent kit, calibrators, controls, venipuncture kit
Liver function tests (alanine aminotransferase, albumin, alkaline phosphatase, aspartate aminotransferase, direct and indirect bilirubin, gamma-glutamyl transferase)		X	X	Clinical chemistry analyser[a]	Reagent kit, calibrators, controls, venipuncture kit
Tests for serum triiodothyronine (T3), thyroxine (T4), thyroid-stimulating hormone (TSH)		X	X	Immunoassay analyser[a]	Reagent kit, calibrators, controls, venipuncture kit
Electrolytes (sodium, potassium, chloride)		X	X	Clinical chemistry analyser[a]	Reagent kit, calibrators, controls, venipuncture kit
Creatinine and albumin to estimate glomerular filtration rate (GFR) and albumin–creatinine ratio (ACR)		X	X	Clinical chemistry analyser[a] (with software to convert serum creatinine to estimate GFR)	Reagent kit, calibrators, controls, venipuncture kit Urine collection kit

a These capital medical devices are described in the table on generic equipment in Annex 4.

The dangers of direct manipulation with bodily fluids in a clinical laboratory setting or in any other clinical unit are higly important. As in all areas, it is important to have a high-quality washing and sterilization station for medical devices to ensure quality and safety for patients, doctors, nuerses and technicians.

Table 19. List of general priority medical devices for washing and sterilizing

Priority medical devices for washing and sterilizing
Washer, ultrasonic
Autoclave
Chemical desinfectant

3.2 Specific priority medical devices for clinical laboratory interventions, by disease

3.2.1 Cardiovascular diseases

Table 20. List of specific priority medical devices for clinical laboratory interventions for cardiovascular diseases

Clinical intervention	Level of care			Capital medical devices	Consumables, single-use medical devices
	1	2	3		
Prothrombin time and international normalized ratio (PT/INR), point-of-care testing	X	X	X	Point-of-care analyser	Test-tubes, reagent kit, controls, anticoagulated tubes, venipuncture kit
	X	X	X	Water bath	
	X	X	X	Stopwatch	
	X	X	X	Pipette	Pipette tips
Prothrombin time and international normalized ratio (PT/INR)		X	X	Coagulation analyser or incubator (tilt tube method)	Reagent kit, calibrators, controls, reaction cuvettes, anticoagulated tubes, venipuncture kit
Partial thromboplastin time (PTT), also known as activated partial thromboplastin time (APTT)		X	X	Coagulation analyser or incubator (tilt tube method)	Reagent kit, calibrators, controls, reaction cuvettes, anticoagulated tubes, venipuncture kit
B-type natriuretic peptide (BNP) test, point-of-care testing	X	X	X	Point-of-care analyser	Reagent kit, controls, venipuncture kit
B-type natriuretic peptide (BNP) test		X	X	Immunoassay analyser	Reagent kit, calibrators, controls, venipuncture kit
		X	X	Clinical chemistry analyser[a]	
Tests for cardiac biomarkers (troponin T/I), point-of-care testing	X	X	X	Point-of-care analyser	Reagent kit, controls, venipuncture kit, pipette tips
Tests for cardiac biomarkers (troponin T/I)		X	X	Clinical chemistry analyser[a]	Reagent kit, calibrators, controls, venipuncture kit
D-dimer, point-of-care testing	X	X	X	Point-of-care analyser	Reagent kit, test card, calibrators, venipuncture kit, pipette tips
D-dimer		X	X	Coagulation analyser	Reagent kit, calibrators, controls, venipuncture kit

a. This capital medical device is described in the table on generic equipment in Annex 4.

3.2.2 Stroke

Table 21. List of specific priority medical devices for clinical laboratory interventions for stroke

Clinical intervention	Level of care			Capital medical devices	Consumables, single-use medical devices
	1	2	3		
Prothrombin time and international normalized ratio (PT/INR), point-of-care testing	X	X	X	Point-of-care analyser, water bath, stopwatch, pipette	Test-tubes, reagents, controls, anticoagulated tubes, venipuncture kit, pipette tips
Prothrombin time and international normalized ratio (PT/INR)		X	X	Coagulation analyser or incubator (tilt tube method)	Reagent kit, calibrators, controls, reaction cuvettes, anticoagulated tubes, venipuncture kit
Cerebrospinal fluid (CSF) bilirubin spectrophotometry			X		Cerebrospinal fluid puncture kit

3.2.3 Diabetes

Table 22. List of specific priority medical devices for clinical laboratory interventions for diabetes

Clinical intervention	Level of care			Capital medical devices	Consumables, single-use medical devices
	1	2	3		
Urinalysis test strips plus microscopy		X	X	Light microscope, tabletop centrifuge, dipstick analyser	Urine collection kit, slides, cover slips, sterile test-tubes, dipsticks, controls
Haemoglobin A1c (HbA1c)		X	X	Clinical chemistry analyser	Reagents, calibrators, controls, venipuncture kit
Haemoglobin A1c (HbA1c), point-of-care testing	X	X	X	Point-of-care analyser	Finger puncture kit, controls, dipsticks
Urine glucose and ketones	X	X	X	Clinical chemistry analyser	Urine collection kit, dipsticks, colour scale guide, reagents, calibrators, controls, test-tubes

Sets and kits

Venipuncture kit
Tourniquet
Needles, various sizes
Syringes, various sizes
Safety needles
IV catheter
IV saline fluid packages
IV lines
Glass and plastic vials
Vacuum blood collection tubes, with or without anticoagulant
Vacuum container hub and needles
Lancets
Alcohol and swabs or prep swabs
Clean gauze squares
Cotton swabs
Roll of strapping
Gloves, non-latex
Waste container for sharps

Reagent kit
Diluent
Distilled water
Reservoir bottle

Cerebrospinal fluid puncture kit
Sterile universal specimen bottle, grey
Cerebrospinal fluid manometer
Lumbar puncture set, adult and child
Collection tube, sterile plastic tubes
Skin-cover adhesive strip
Spinal needle
Spinal anaesthesia needle, single-use
Syringes, various sizes
Hypodermic needles: 25G, 23G, 21G
Gauze strip, antimicrobial
Antiseptic skin cleansing agent
Skin marker pen

Urine collection kit
Urine collection device (graduated cylinder, specimen cup)
Urine dipsticks
Scale
Sample tubes
Funnel

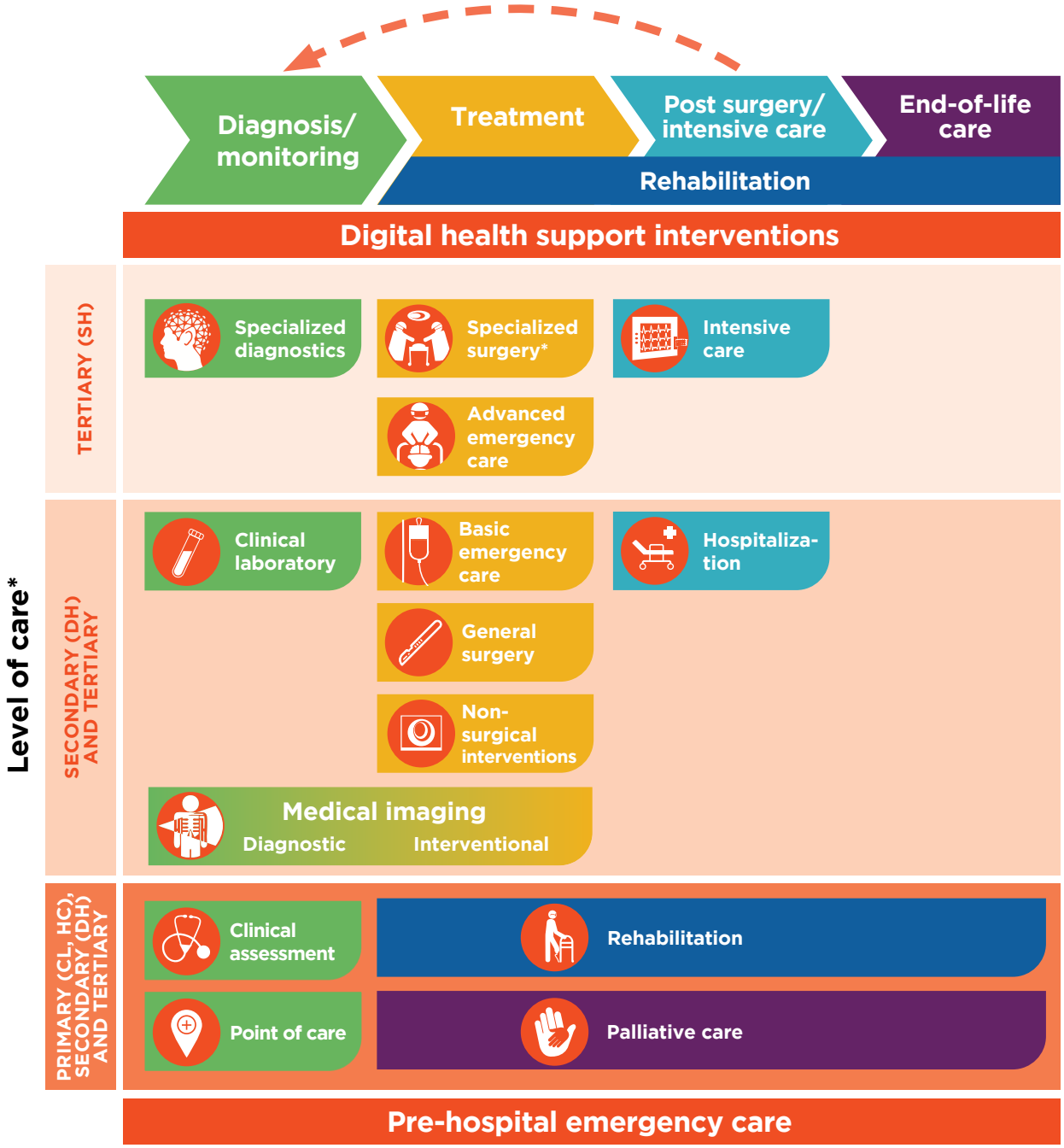
Guidance documents

- The selection and use of essential in vitro diagnostics: report of the second meeting of the WHO Strategic Advisory Group of Experts on In Vitro Diagnostics, 2019 (including the second WHO model list of essential in vitro diagnostics). WHO Technical Report Series 1022 (https://apps.who.int/iris/bitstream/handle/10665/329527/9789241210317-eng.pdf).
- ISO 15189:2012 Medical laboratories: requirements for quality and competence. International Organization for Standardization (https://www.iso.org/standard/56115.html).
- WHO list of priority medical devices for cancer management. Geneva: World Health Organization; 2017 (https://www.who.int/medical_devices/publications/priority_med_dev_cancer_management/en/).
- Laboratory Quality Management System: handbook. Geneva: World Health Organization; 2011 (https://www.who.int/ihr/publications/lqms_en.pdf).
- WHO Prequalification Team: Diagnostics. WHO manual for organizing a national external quality assessment programme for health laboratories and other testing sites. Geneva: World Health Organization; 2016 (https://apps.who.int/iris/bitstream/handle/10665/250117/9789241549677-eng.pdf?sequence=1, accessed 20 May 2020).

4. Other specialized diagnostics

Navigation diagram

Click on the diagram to navigate to any section of this document.



Key:
* Including cardiovascular, neurological, ophthalmic and nefrology.
CL community level; health post
DH district/general hospital; interventions can also be offered in a first referral outpatient clinic
HC health centre/outpatient clinic
SH specialized/regional/national hospital; specialized care outpatient unit

This section includes those diagnostics that are not performed in a clinical laboratory (Chapter 3) or medical imaging unit (Chapter 5). After ordering the clinical laboratory tests listed, and before ordering a medical imaging intervention, doctors may request other specialized diagnostics. Medical complications from cardiovascular diseases and diabetes can also lead to patient referral for more specialized diagnostics, such as the ones described on this chapter.

Table 23. List of specialized diagnostic interventions

Disease	Intervention	Level of care		
		1	2	3
Cardiovascular diseases	Cardiac exercise stress test device			X
Stroke	Electroencephalography			X
Diabetes	Direct or indirect ophthalmoscopy		X	X

4.1 Specific priority medical devices for clinical assessment interventions by disease

4.1.1 Cardiovascular diseases

Table 24. List of specific priority medical devices for specialized diagnostics interventions for cardiovascular diseases

Clinical intervention	Level of care			Capital medical devices	Consumables, single-use medical devices
	1	2	3		
Exercise cardiac stress test device			X	Stress test treadmill, bicycle ergometer[a, b]	
				Electrocardiographic system[a, b] (12 leads)	Electrodes, electrolytic gel
				Stress exercise monitoring system[b]	Printer, paper for printer
				Patient physiological monitor[a, b]	
				Automated external defibrillator (AED), manual external defibrillator	
				Stretcher	

a. These capital medical devices are described in the table on generic equipment in Annex 4.

b. These capital equipment devices may be integrated into a single unit.

4.1.2 Stroke

Table 25. List of specific priority medical devices for specialized diagnostics interventions for stroke

Clinical intervention	Level of care			Capital medical devices	Consumables, single-use medical devices
	1	2	3		
Electroence-phalography			X	Electroencephalo-graph (EEG) unit	Electrolytic gel
					Reusable spider-type electrode, silver/silver chloride
					Reusable electrode-type ear clip, silver or gold
					Washable and reusable cable cover
					Electro-cap with positioned electrodes according to the International 10-20 system
					Original templates (baby, children, adult), allowing complete placement in the skull with 13 or 19 locations for the recording electrodes
					Abrasive gel
					Photo stimulator
					Electrodes, teflon lightweight with gold or silver disc, length 1 m or 1.5 m
					Electrodes, high cupula reusable, gold disc with con-nectors at 90 degrees
					Electrodes, disposable, adult for patient with sensitivi-ty to silver/silver chloride
					Disposable EEG disc electrodes

4.1.3 Diabetes

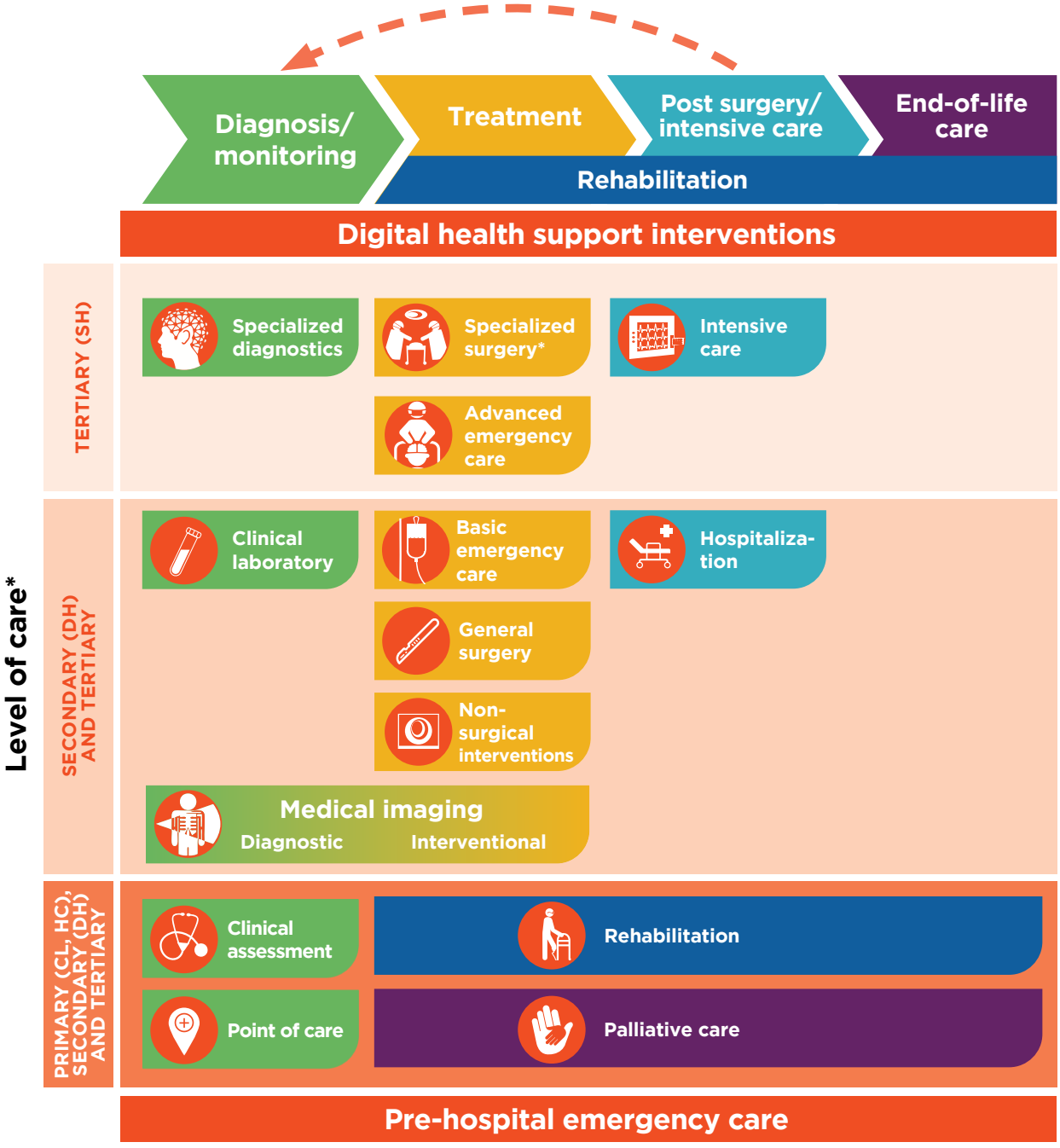
Table 26. List of specific priority medical devices for specialized diagnostics interventions for diabetes

Clinical intervention	Level of care			Capital medical devices	Consumables, single-use medical devices
	1	2	3		
Direct or indirect ophthalmoscopy	X	X	X	Direct ophthalmoscope	Bulbs
		X	X	Indirect ophthalmoscope	

5. Medical imaging

Navigation diagram

Click on the diagram to navigate to any section of this document.



Key:

* Including cardiovascular, neurological, ophthalmic and nefrology.
CL community level; health post
DH district/general hospital; interventions can also be offered in a first referral outpatient clinic
HC health centre/outpatient clinic
SH specialized/regional/national hospital; specialized care outpatient unit

Medical imaging encompasses different imaging modalities and processes to image the human body for diagnostic and treatment purposes and therefore plays an important role in initiatives to improve public health for all population groups. The complexity of infrastructure, equipment and human resources for medical imaging services should be consistent with the capabilities of the health care level in which they are placed (primary, secondary or tertiary).

Medical imaging devices have very specific infrastructure requirements related to safety and the physical resources they need to function properly, for example, building requirements for radiation protection and magnetic safety, three-phase electric power supplies, and correct viewing conditions. Detailed recommendations on the type of infrastructure required for a medical imaging unit can be found in the *WHO list of priority medical devices for cancer management.*

The use of the following devices in coordination with defined, evidence-based, clinical procedures and protocols is important to achieve the best patient outcomes and to use equipment efficiently and effectively. Existing imaging referral guidelines can be used to enhance appropriateness of referral. The minimum technical equipment required to respond to the clinical needs are described in the tables, but detailed technical specifications should be developed according to local needs. Compliance with the Digital Imaging and Communications in Medicine (DICOM) standard is required when developing a functional network of medical imaging devices, along with visualization devices and printers as needed. Digital information can be used in teleradiology applications, and this should be clear in the specification for the particular service or unit. It is important to note that besides the capital expenses of the building, room infrastructure and equipment, the expense of DICOM and other information technology (IT) licences, plus the expected cost of maintaining and updating the licence, should be considered when setting up a medical imaging unit.

A coordinated team of health care professionals (for example, radiographers, radiologists, nuclear medicine specialists, ultrasonographers and technologists) is essential to 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 to establish and maintain teleradiology systems. Guidance on education and training in radiation protection of health professionals is available elsewhere *(44–46).* Depending on national context, including workforce availability and models, different occupations can fulfil the roles that may be required for medical imaging. Prerequisites for that include having the required competencies to perform those roles, and official recognition in accordance with the scope of practice.

Detailed recommendations for the type of infrastructure required for a medical imaging unit can be found in the WHO list of priority medical devices for cancer management.

Because of the detailed specifications of each item of imaging equipment, this chapter is structured differently from the rest. After listing the medical imaging procedures (Table 27), the following tables (Tables 28–35) give a thorough description of the main imaging capital equipment, such as X-rays, ultrasound scans, computer tomography scans and magnetic resonance images. Tables 36–38 then list specific imaging interventions for each disease, and the extra equipment or consumables needed for that purpose.

Table 27. List of medical imaging procedures

Disease	Interventions	Level of care		
		1	2	3
All	Ultrasound scan			X
	X-ray imaging		X	X
	Fluoroscopic imaging		X	
	Computed tomography (CT) scan		X	X
	Magnetic resonance imaging (MRI)			X
Cardiovascular diseases	Positron emission tomography (PET) of myocardium			X
	Stress and rest test (SPECT)			X
	Transthoracic echocardiography, stress and rest, with or without contrast			X
	Transoesophageal echocardiography			X
	X-ray imaging (cardiac and peripheral angiography)			X
	Digital subtraction angiography (DSA)			X
	Coronary angioplasty with or without stenting			X
	Percutaneous balloon valvuloplasty (pulmonary, mitral and aortic)			X
	Peripheral angioplasty with or without stenting			X
Stroke	Doppler imaging of extracranial vessels		X	X
	Doppler imaging of intracranial vessels			X
	Optical coherence tomography		X	X
	Eye and orbit ultrasound			
	Fluorescein angiography or angioscopy of posterior chamber of eye			X
	Dilatation with insertion of stent or prosthesis of artery of head and neck			X
	Endovascular coiling			X
	Endovascular extraction of obstruction from head and neck vessel (e.g. thrombectomy)			X
	Percutaneous angioplasty of carotid artery, extracranial			
Diabetes	Doppler ultrasonography of the lower extremity arteries		X	X
	Fluorescein angiography			X
	Fundus photography with non-mydriatic camera and interpretation of results (locally or remotely)			X
	Optical coherence tomography (OCT) and interpretation of results			X
	Renal angiography function study			X
	Renal scan and radioisotope function study			X

5.1 General priority medical devices for medical imaging interventions

Table 28 presents general devices that should be integral to medical imaging facilities and can be used for various diseases, including cardiovascular diseases and diabetes.

Table 28. List of general medical devices for ultrasound medical imaging

Imaging techniques	Medical device category	Capital medical devices	Consumables, single-use medical devices
For ultrasound technique	Medical equipment	Ultrasound scanner[a] with convex probes Middle-frequency (3–5 MHz) and linear, high-frequency (10–12 MHz) probes Colour Doppler probe (optional)	Gel
			Consumable for dry printer
			Disposable probe drapes
			Antimicrobial solution to disinfect probes
	Medical furniture	Patient examination couch	
		Positioning aids	
	Quality control equipment	Quality control test objects and software, ultrasound	
For contrast media injection procedure	Medical equipment	Contrast media injector[a]	Injection syringes with accessories
		Emergency cart[a]	
		Surgery suction system[a]	
		Patient physiological monitor[a]	
	Medical furniture	Mobile infusion pole	
		Warming cabinet for contrast media	
Software	Software systems	Workstation with storage capacity	
		Radiology information system	
		Picture archiving and communication system (PACS)	
		Dry printer[a]	Ink cartridge Paper
		Digital storage media	Data storage device (CD, DVD, memory stick)

a. These capital medical devices are described in the table on generic equipment in Annex 4.

Table 29. List of general medical devices for X-ray radiography medical imaging (levels of care 2 and 3)

Imaging techniques	Medical device category	Capital medical devices	Consumables, single-use medical devices
For basic X-ray radiography technique	Medical equipment	General-purpose X-ray system, digital	X-ray tube, radiography
		Dry printer[a]	Ink cartridge Paper
		Workstation with storage capacity	Data storage device (CD, DVD, memory stick)
	General radiation protection devices	Radiation shielding apron	
		Radiation shielding gloves	
		Thyroid shielding	
		Gonad shielding	
		Breast shielding	
	Personal dosimetry equipment	Dosimeter	
		Software system, electronic dosimeter	
	Quality control devices	Quality control test objects and software, X-ray	

a. This capital medical device is described in the table on generic equipment in Annex 4.

Table 30. Medical devices for general X-ray radiography medical imaging (only for interventions at level of care 2 and 3)

Imaging techniques	Medical device category	Capital medical devices	Consumables, single-use medical devices
Interventional fluoroscopy	Medical equipment for fluoroscopy	X-ray system (C-arm), analogue/ digital	X-ray tube, fluoroscopy
		Dry printer[a]	Ink cartridge Paper
		Storage media, digital	Data storage device (CD, DVD, memory stick)
		Workstation with storage capacity	
	Radiation protection devices	Radiation shielding apron	
		Radiation shielding goggles	
		Radiation shielding gloves	
		Thyroid shielding	
		Gonad shielding	
		Breast shielding	
	Personal dosimetry equipment	Dosimeter Software system, electronic dosimeter	
	Quality control devices	Quality control test objects and software, X-ray fluorography	
For contrast media injection procedure	Medical equipment	Contrast media injector[a]	Injection syringes with accessories
		Emergency cart[a]	
		Surgery suction system[a]	
		Patient physiological monitor[a]	

a. These capital medical devices are described in the table on generic equipment in Annex 4.

Table 31. List of general medical devices for angioscopy and angiography

Imaging techniques	Medical device category	Capital medical devices	Consumables, single-use medical devices
Angioscopy and angiography	Medical equipment for angiography	X-ray angiography unit	X-ray tube, angiography
	General radiation protection devices	Radiation shielding apron	
		Radiation shielding gloves	
		Thyroid shielding	
		Gonad shielding	
		Breast shielding (optional)	
	Radiation protection devices for angiography	Radiation shielding screen, ceiling suspended	
		Radiation shielding curtains, patient table mounted	
		Radiation shielding screen, mobile	
		Radiation shielding goggles	
	Personal dosimetry equipment	Dosimeter	
		Software system, electronic dosimeter	
	Quality control equipment	Quality control test objects and software Fluoroscopic X-ray system (C-arm) X-ray angiography	
For contrast media injection procedure	Medical equipment	Contrast media injector[a]	Injection syringes with accessories
		Emergency cart[a]	
		Surgery suction system[a]	
		Patient physiological monitor[a]	
Software	Software systems	Workstation with storage capacity	
		Radiology information system	
		Picture archiving and communication system (PACS)	
		Dry printer[a]	Ink cartridge Paper
		Digital storage media	Data storage device (CD, DVD, memory stick)

a. These capital medical devices are described in the table on generic equipment in Annex 4.

Table 32. List of general medical devices for CT

Imaging techniques	Medical device category	Capital medical devices	Consumables, single-use medical devices
For computed tomography (CT) technique	Medical equipment	Computed tomography system[a] (slice configuration according to level of care)	X-ray tube, scanner
	General radiation protection devices	Radiation shielding apron	
		Radiation shielding gloves	
		Thyroid shielding	
		Gonad shielding	
		Breast shielding (optional)	
	Personal dosimetry equipment	Dosimeter	
		Software system, electronic dosimeter	
	Quality control equipment	Quality control test objects and software, CT	
For contrast media injection procedure	Medical equipment	Contrast media injector[a]	Injection syringes with accessories
		Emergency cart[a]	
		Surgery suction system[a]	
		Patient physiological monitor[a]	
	Medical furniture	Mobile infusion pole	
		Warming cabinet for contrast media	
	Software systems	Workstation with storage capacity	
		Radiology information system	
		Picture archiving and communication system (PACS)	
		Dry printer[a]	Ink cartridge Paper
		Digital storage media	Data storage device (CD, DVD, memory stick)

a. These capital medical devices are described in the table on generic equipment in Annex 4.

Table 33. List of general medical devices for SPECT nuclear medical imaging

Imaging techniques	Medical device category	Capital medical devices	Consumables, single-use medical devices
For low- and medium-energy technique	Medical equipment	Gamma camera with SPECT capabilities	
		Collimators and carts	
	Laboratory equipment	High-performance liquid chromatography scanner	Tc-99m, gallium-68 radionuclide generator (if prepared on site)
		Thin layer chromatography scanner	
	Nuclear medicine radiation protection devices	Hot cell, low–medium energy radiation	
		Radiation shielding screen, mobile	
		Vial radiation shield	
		Shielding container	
		Shielding blocks	
		Shielded storage bins	
	Radiation safety instruments	Forceps	
		Needle sheath holder	
		Tongs	
		Trays	
	Quality control devices	Quality control test objects and software, SPECT	
		Dose calibrator	
	Radiation survey, monitoring	Radiation survey meter, Geiger-Müller counter	
		Radiation survey meter, area monitor	
	Personal dosimetry	Dosimeter	
		Software system, electronic dosimeter	
For preparing and dispensing radiopharmaceuticals	Medical equipment	Stethoscope, binaural	
		Blood pressure measurement monitor	
		Infusion pump	Infusion pump administration set
		Tourniquet	
	Medical furniture	Biosafety cabinet, positive pressure	
		Negative pressure fume hood	
		Refrigerator	
		Hot plate with stirrer	
		Water bath	
	Solutions and reagents for radiopharmaceutical components		Labelling kits (MDP, MAA, pyrophosphate, MIBI, MAG3, DMSA, nanocolloids, etc.)
			Distilled water
			Saline solution

Imaging techniques	Medical device category	Capital medical devices	Consumables, single-use medical devices
	Injection devices		Injection set
			Radiation decontamination spill kit
	Radiation protection devices	Syringe shield	
		L-shield	
		Shielding container	
		Radioactive waste receptacle	
	Software systems	Workstation with storage capacity	
		Radiology information system	
		Picture archiving and communication system (PACS)	
		Dry printer[a]	Ink cartridge Paper
		Digital storage media	Data storage device (CD, DVD, memory stick)

a. This capital medical device is described in the table on generic equipment in Annex 4.

Table 34. List of general medical devices for general PET nuclear medical imaging

Imaging techniques	Medical device category	Capital medical devices	Consumables, single-use medical devices
For high-energy technique	Medical equipment	PET, computed tomography (CT) system	
	Nuclear medicine radiation protection devices	Hot cell, high-energy radiation	
		Radiation shielding screen, mobile	
		Vial radiation shield	
		Shielding container	
		Shielding blocks	
		Shielded storage bins	
	Radiation safety instruments	Forceps	
		Needle sheath holder	
		Tongs	
		Trays	
	Quality control devices	Quality control test objects and software, PET	
		Dose calibrator	
	Radiation survey monitoring	Radiation survey meter, Geiger-Müller counter	
		Radiation survey meter, area monitor	
	Personal dosimetry	Dosimeter	
		Software system, electronic dosimeter	
For preparing and dispensing radio-pharmaceu-tical	Medical equipment	Stethoscope, binaural	
		Blood pressure measurement monitor	
		Infusion pump	Infusion set
		Tourniquet	
	Injection devices		Injection set
			Radiation decontamination spill devices
	Radiation protection devices	Syringe shield	
		L-shield	
		Shielding container	
		Radioactive waste receptacle	
	Software systems	Workstation with storage capacity	
		Radiology information system	
		Picture archiving and communication system (PACS)	
		Dry printer[a]	Ink cartridge Paper
		Digital storage media	Data storage device (CD, DVD, memory stick)

a. This capital medical device is described in the table on generic equipment in Annex 4.

Table 35. List of general medical devices for MRI medical imaging

Imaging techniques	Medical device category	Capital medical devices	Consumables, single-use medical devices
Magnetic resonance imaging (MRI) technique	Medical equipment	Magnetic resonance imaging (MRI) system[a]	
		Contrast media injector[a], MRI safe	Injection set
		Patient physiological monitor, MRI safe[a]	Electrodes, MRI safe Electrolytic gel
		Anaesthesia system, MRI safe[a]	Gas (O2, air, N2O, anaesthetic)
			Patient breathing circuit
			Soda lime
		Oxygen devices, MRI safe	Oxygen canisters, MRI safe
		Sphygmomanometer, MRI safe	
		Stethoscope, binaural, MRI safe	
	Medical instruments	Biopsy procedure equipment kit, MRI safe (optional)	
	Medical furniture	Mobile infusion pole, MRI safe	
		Assistive footstool, MRI safe	
		Cart, MRI safe	
		Wheelchair, MRI safe	
		Stretcher, MRI safe	
	Quality assurance devices	Quality control test objects and software system, MRI	
	Others	Magnetic metal detector	
			Foam plugs for ears
For contrast media injection procedure in MRI environment	Medical equipment	Contrast media injector, MRI safe	Injection set
		Emergency cart, MRI safe	
		Surgery suction system[a], MRI safe	
		Patient physiological monitor, MRI safe[a]	
	Medical furniture	Mobile infusion pole, MRI safe	
		Warming cabinet (for contrast media), MRI safe	
Software	Software systems	Workstation with storage capacity	
		Radiology information system	
		Picture archiving and communication system (PACS)	
		Dry printer[a]	Ink cartridge Paper
		Digital storage media	Data storage device (CD, DVD, memory stick)

a. These capital medical devices are described in the table on generic equipment in Annex 4.

5.2 Specific priority medical devices for imaging interventions, by disease

5.2.1 Cardiovascular diseases

Table 36. List of specific priority medical devices for imaging interventions for cardiovascular diseases

Clinical intervention	Capital medical devices	Consumables, single-use medical devices
Positron emission tomography (PET) of myocardium	See 5.1 (Table 34) General priority medical devices for PET medical imaging	Radiopharmaceutical products
Stress and rest test (SPECT)	See 5.1 (Table 33) General priority medical devices for SPECT medical imaging	Radiopharmaceutical products
	Exercise cardiac stress test device[a]	
	Emergency cart	
Transthoracic echocardiography, stress and rest, with or without contrast	See 5.1 (Table 28) General priority medical devices for ultrasound medical imaging Ultrasound scanner[a] with specific cardiac probes	
	Exercise cardiac stress test device[a]	
	Emergency cart	
Transoesophageal echocardiography	Ultrasound scanner[a] with specific transoesophageal probe	Disposable mouthguards
		Local anaesthesia set
X-ray imaging (cardiac and peripheral angiography)	See 5.1 (Table 31) General priority medical devices for angiography medical imaging	
Coronary artery bypass grafting	Cardiopulmonary bypass system, non-roller type and roller type	See cardiac catheterization laboratory set
	Ultrasound scanner[a]	
	Transoesophageal vascular ultrasound probe	
Percutaneous balloon valvuloplasty (pulmonary, mitral and aortic)	Angiography: cath lab system	See cath lab set
		Coronary angioplasty balloon catheters
		Diagnostic and radiofrequency ablation EP catheters
		Percutaneous coronary intervention balloon catheters
		Balloon valvuloplasty catheters
		Electrophysiology catheters
		Introducer sheath
		Crimpers
		Extension tubings
		Crimp stoppers
		Inflation devices
Peripheral angioplasty, with or without stenting	Angiography: cath lab system	See cath lab set

a. These capital medical devices are described in the table on generic equipment in Annex 4.

Injection set
Cannulas, intravenous, short, sterile (sizes G)
Compress, gauze, sterile and non-sterile
Needles, Luer, sterile (sizes G)
Scalp vein needles, sterile (sizes G)
Syringes (various sizes)
Prongs, nasal, oxygen, non-sterile (various sizes)
Skin cleaning wipe
Tape, medical, roll (various sizes)
Transparent film dressings
Sharps container
Instrument or equipment drape, non-sterile
Skin-cover adhesive strip
First aid gauze
Bandage

Specific equipment for haemodynamics	Consumables, single-use medical devices
Resuscitation trolley, equipped	
Catheters, cardiac	Catheters, intra-aortic balloon
Automated external defibrillator (AED), manual external defibrillator	Arterial and venous sheaths, pressure transducers, tubing
Ultrasound scanner[a], cardiovascular	Electrocardiography electrodes[a], reusable/single-use
Haemodynamic monitoring system, multiparametric monitoring system	X-ray contrast medium, injectable (contrast media)
Multipurpose warming cabinet, mobile (contrast media)	
Intravenous pole	
Oxygen terminal unit	
Nitrous oxide/oxygen cylinder (50% nitrous oxide and 50% oxygen)	

a. These capital medical devices are described in the table on generic equipment in Annex 4.

Radiation protection equipment
Radiation shielding aprons
Suitable suspended or movable screens
Radiation shielding goggles or glasses
Radiation shielding collar
Dosimeter and software system, electronic dosimeter
Radiation warning lights/signs

Intubation kit
Laryngoscope
Laryngoscope blades, straight, reusable/single-use, sizes 0, 1, 2, 3, 4; and curved, reusable/single-use, sizes 0, 1, 2, 3, 4 (46829 – flexible-end laryngoscope blade)
Laryngoscope batteries
Spare light bulbs
Cannula or single-use tubing

Infusion set
Infusion pump (if available)
Pressure bag for IV infusion
IV infusion flow regulator (manual or with dial)
Intravenous pole
Catheters, various sizes and types
Instrument set for haemodynamics
General-purpose bowl, reusable/single-use (bowl, stainless steel, 250 ml)

Instrument tray
Scalpel handle with blades, reusable/single-use
Artery forceps with oval rings
Dissecting artery forceps, toothed tip
Dissecting artery forceps, toothless tip (blunt)
Iris artery forceps
Towel clamp
Kelly forceps
Mosquito forceps, curved, haemostatic
Needle holder, reusable/single-use
Rake retractor with prong tips
Rake retractor with prong tips, small
Farabeuf retractor
General-purpose surgical scissors, reusable/single-use

Disposables and healing set for haemodynamic procedures
Cutting scissors
Metzenbaum scissors
Syringe-loaded injector, manual, professional (injector syringe, 150 ml)
Blood pressure transducer set
Angiography kit (includes tubing, manifold, stopcocks, and syringes, and other supportive devices: angiography drapes, covers, dressings)
Cardiac/peripheral vascular guidewire, single-use
Multipurpose surgical adhesive tape, non-sterile/sterile
Hypodermic needles, single-use, non-sterile/sterile (needles: 18, 20, 21, 22, 25 gauge)
Adhesive bandage (adhesive patch, transparent, 10 x 12 cm, 8.5 x 10.5 cm, 5 cm x 5.7 cm)
Catheter, peripheral vascular: 14, 16, 18, 20, 22, 24 gauge
Multipurpose surgical adhesive tape, non-sterile/sterile (micropore tape: 2.5 cm and 5 cm)
Anaesthesia breathing circuit, reusable/single-use, non-sterile/sterile (Bain circuit, universal)

Intravenous line/syringe Luer connector, non-sterile/sterile (double male connector, Luer lock)
Electrocardiography electrodesa, reusable/single-use
General-purpose syringe, reusable/single-use: syringe 20 ml
General-purpose syringe, reusable/single-use: syringe 3 ml
General-purpose syringe, reusable/single-use: syringe 5 ml
Basic intravenous administration set (disposable sterile kit for puncture site)
Electrosurgical handpiece, reusable/single-use
Intravenous line stopcock (three-way stopcock)
Hypothermia prevention whole body suit (paediatric/adult)
Catheter, peripheral vascular
General-purpose infusion pump, battery-powered/line-powered (infusion pump system, with 150 ml burette)
Infusion controller administration set (micro-drip infusion set)
Infusion controller administration set (macro-drip infusion set)
Examination/treatment gloves, sterile (various sizes)
Surgical sterile gloves, sizes 6, 6Ð, , 7, 7Ð, 8
Blade, scalpel, reusable/single-use
Syringe pump or elastomeric pumps
General-purpose syringe, single-use (Syringe, radiopaque, 50 ml)
General-purpose syringe, reusable/single-use: syringe 1 ml
General-purpose syringe, reusable/single-use: syringe 10 ml
Sutures, nylon, calibre 3-0
Sutures, poliglecaprone
Sutures, black silk, braided
Sutures, polypropylene, monofilament
Multipurpose stopper, yellow
Multipurpose stopper, white
Multipurpose surgical adhesive tape, non-sterile/sterile (cloth tape, 2.5 cm)
Multipurpose surgical adhesive tape, non-sterile/sterile (cloth tape, acetate, 50 cm)
Medicine cup, reusable/single-use (polypropylene, 125 ml)
Surgical dressing/drape kit (includes different types of sterile drapes, dressings, covers and towels intended to be used specifically during a surgical procedure)

a. These capital medical devices are described in the table on generic equipment in Annex 4.

Clothing for haemodynamic procedures
Operating room gown, reusable/single-use
Surgical shoes
Surgical/examination garment kit (sterile clothes for haemodynamic procedures)
Surgical face mask, reusable/single-use
General-purpose surgical drape, sterile, reusable/single-use
Operating table sheet, reusable/single-use (cover)

Instruments for airway management and oxygenation
Electronic or mechanical ventilator
Laryngoscope handle, reusable/single-use
Laryngoscope blades, straight, reusable/single-use, sizes 0, 1, 2, 3, 4
Laryngoscope blades, curved, reusable/single-use, sizes 0, 1, 2, 3, 4 (46829 – flexible-end laryngoscope blade)
Oropharyngeal airway, reusable/single-use, sizes 3, 4, 5, 6, 7, 8, 9, 10, 11
Laryngeal airway, reusable/single-use, sizes 1.5, 2, 2.5, 3, 3.5, 4, 5
Basic nasal oxygen cannula
Non-rebreathing/partial rebreathing oxygen face mask
Oxygen cylinder with humidified bottle and regulator
Advanced airway conducts

Local anaesthesia set
Needles and syringes for local anaesthetic
Skin-cover adhesive strip
Skin cleaning wipe

Cath lab set
Bandbag, 36 x 40 in., with tape 1
Bowl, guidewire, 2500 cc 1
Bowl, sponge,16 oz., 500 cc 1
Clamps, towel
Cover, setup
Domebag
Drape, femoral angiography
Forcep, Halstead mosquito
Gowns
Introducer, guidewire
Labels, waterproof
Marker, skin
Medicine cups, graduated
Needle holder
Needles, 18G x and 25G x
Scalpel handle with blades
Scissors
Sponges
Syringes, various sizes
Table cover
Towels
Tray, organizer
Povidone-Iodine Scrub Solutions
Pressure transducer kit
Access sheath(s)
Guidewire, .035 J-tipped, 180/300 cm lengths

Cath lab set
Catheters, diagnostic, femoral/radial
Interventional
Catheters, interventional, femoral/radial
Workhorse guidewire(s), 183/300 cm length
Specialty guidewire(s)
Angioplasty balloons
Cutting balloon(s)
Drug-eluting stent(s)
Bare metal stent(s)
Covered stent(s)
Balloon indeflator

5.2.2 Stroke

Table 37. List of specific priority medical devices for imaging interventions for stroke

Clinical intervention	Level of care			Capital medical devices	Consumables, single-use medical devices
	1	2	3		
Doppler imaging of extracranial vessels			X	Ultrasound scanner[a] with large frequency range probes	
Doppler imaging of intracranial vessels			X	Ultrasound scanner[a] with 1.3–4 MHz small footprint	
Optical coherence tomography				Optical coherence tomography (OCT) platform	
Eye and orbit ultrasound			X	Ultrasound scanner[a.] Mode A and B	Immersion cups for mode A and B, various sizes.
Fluorescein angiography or angioscopy of posterior chamber of eye			X	Fluorescein angiograph	Sodium fluorescein, disposable syringes
Dilatation with insertion of stent or prosthesis of artery of head and neck			X	Dilatation set	
Endovascular coiling			X	Endovascular embolization set	
Endovascular extraction of obstruction from head and neck vessel (e.g. thrombectomy)			X	Endovascular extraction set	
Percutaneous angioplasty of carotid artery, extracranial			X	Percutaneous angioplasty set	

a. These capital medical devices are described in the table on generic equipment in Annex 4.

5.2.3 Diabetes

Table 38. List of specific priority medical devices for imaging interventions for diabetes

Clinical intervention	Level of care			Capital medical devices	Consumables, single-use medical devices
	1	2	3		
Doppler echography of the arteries of the lower extremities			X	General ultrasound scanner[a] with Doppler probe	
Fluorescein angiography			X	Fluorescein angiograph	Sodium fluorescein, disposable syringes
Fundus photography with a non-mydriatic camera			X	Non-mydriatic/fundus camera	
			X	Cards for diagnosis of fundus	
Optical coherence tomography (OCT)			X	Optical coherence tomography (OCT) platform	
Renal angiography function study			X	See 5.1 (Table 31) General priority medical devices for angiography medical imaging	
Renal scan and radioisotope function study			X	See 5.1 (Table 33) General priority medical devices for SPECT medical imaging	Radioactive isotopes

a. This capital medical device is described in the table on generic equipment in Annex 4.

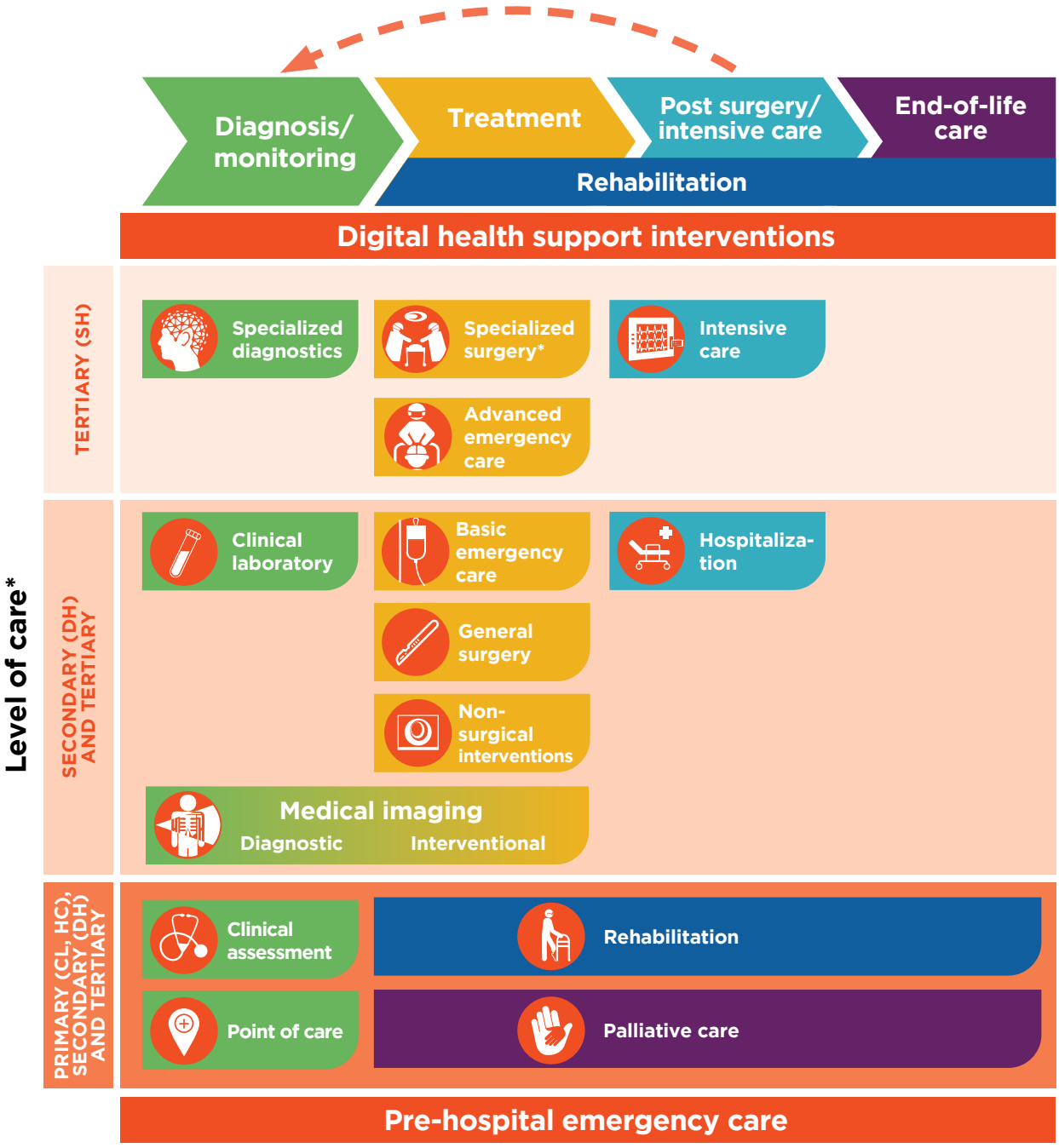
Guidance documents

- Education and training in radiological protection for diagnostic and interventional procedures. ICRP Publication 113. International Commission on Radiological Protection; 2009 (http://www.icrp.org/publication.asp?id=ICRP%20Publication%20113.
- Guidelines on radiation protection education and training of medical professionals in the European Union. Radiation Protection No. 175. International Commission on Radiological Protection and European Commission. European Commission; 2014 (https://ec.europa.eu/energy/sites/ener/files/documents/175.pdf).
- Radiological protection in fluoroscopically guided procedures performed outside the imaging department. ICRP Publication 117. International Commission on Radiological Protection; 2010 https://pubmed.ncbi.nlm.nih.gov/22732420/).

6. Surgery

Navigation diagram

Click on the diagram to navigate to any section of this document.



Key:

* Including cardiovascular, neurological, ophthalmic and nefrology.
CL community level; health post
DH district/general hospital; interventions can also be offered in a first referral outpatient clinic
HC health centre/outpatient clinic
SH specialized/regional/national hospital; specialized care outpatient unit

The objective of a surgical unit is to provide general and specialized surgical care for patients. A central goal of surgical care is interventional curative treatment. While surgical procedures are intended to save lives and prevent disability, unsafe procedures or lack of adequately skilled personnel can cause substantial harm. In 2015, the Lancet Commission on Global Surgery found that 5 billion people do not have access to safe surgery. The issue was recognized by all Member States in World Health Assembly resolution WHA68.15, on strengthening emergency and essential surgical care and anaesthesia as a component of universal health coverage *(47)*. Services provided by a surgical unit must be safe, of high quality, and founded on guidelines or established standards, as highlighted by the second WHO Global Patient Safety Challenge, Safe Surgery Saves Lives *(48)*.

Like other hospital units, 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 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 complications and recognizing changes or deterioration in patient status, escalating levels of care appropriately. At its most basic, a surgical unit needs appropriately trained surgical health care professionals, sufficient physical infrastructure to ensure safe surgery, surgical supplies, and procedures that ensure safety and quality for both patients and staff.

Detailed recommendations for the type of infrastructure required for a surgical unit can be found in the WHO list of priority medical devices for cancer management.

The clinical interventions listed in this chapter are those performed in surgery settings (Table 39). The following tables (Tables 40–43) present general medical devices that can be used for treatment of many diseases, including cardiovascular diseases and diabetes, and specific medical devices that are used for disease-specific interventions.

Table 39. List of surgical interventions

Disease	Interventions	Level of care		
		1	2	3
Cardiovascular diseases	Balloon atrial septostomy			X
	Balloon dilatation for coarctation			X
	Cardiac pacemaker implantation			X
	Cardiac resynchronization therapy (CRT), defibrillator implantation			X
	Coronary artery bypass grafting			X
	Cardiac electrophysiology and catheter ablation			X
	Correction of congenital heart disease			X
	Repair of heart valve			X
	Right heart cardiac catheterization			X
Stroke	Skull neurosurgery			X
	Craniectomy			X
	Craniotomy			X
	Extraventricular drain placement			X
	Endarterectomy of carotid artery, extracranial			X
	Endovascular embolization or occlusion of head and neck vessels			X
	Implantation of left atrial appendage device			X
	Repair of atrial septal defect of heart with graft or prosthesis			X
	Surgical aneurysm clipping			X
	Thrombolysis of artery, head and neck (percutaneous transluminal)			X
	Thrombolysis of intracranial artery (percutaneous transluminal)			X

Disease	Interventions	Level of care		
		1	2	3
Diabetes	Amputation of lower limb		X	X
	Intravitreal injection of anti-VEGF			X
	Lower limb vascular intervention (bypass or angioplasty)			X
	Renal transplantation			X
	Repair of retina (retinal laser photocoagulation)			X
	Ulcer debridement surgery		X	X

6.1 General priority medical devices for surgical interventions

Table 40. List of general priority medical devices for surgical interventions

Category of medical device	Level of care			Capital medical devices	Consumables, single-use medical devices
	1	2	3		
Medical equipment		X	X	Anaesthesia system[a], mobile	Anaesthesia breathing circuit, reusable/single-use, non-sterile/sterile (Bain circuit, universal)
					Electronic ventilator
					Nitrous oxide/oxygen terminal unit (oxygen and nitrous oxide supply)
					Breathing circuit bag, reusable/single-use (breathing bag)
					Carbon dioxide absorber, reusable/single-use (absorber and soda lime)
					Carbon dioxide absorbent (soda lime)
		X	X	Surgery suction system[a]	Suction system tubing (Yankauer suction tube, 270 mm)
					Basic suction tip, reusable/single-use (Yankauer suction tips)
					Suction system tubing (suction tube, L50 cm, catheter tip, sterile, single-use, sizes G)
					Suction system bottle
					Suction system canister, bottle holder
					Suction system filter, microbial (suction trap to collect fluid specimens)
		X	X	Electrosurgical unit	Electrosurgical handpiece, reusable/single-use (electrosurgical pencil, monopolar pen)
					Electrosurgical return electrode, reusable/single-use, non-sterile/single-use, sterile
					Electrosurgical return electrode, reusable Electrosurgical return electrode, single-use, non-sterile/sterile
					Electrosurgical/ultrasonic surgical system generator, Unit for haemostasis by thermocoagulation, Electrocautery system generator, Battery-powered/line-powered

Category of medical device	Level of care			Capital medical devices	Consumables, single-use medical devices
	1	2	3		
		X	X	General-purpose mechanical infusion pump, battery-powered/line-powered/, reusable/single-use	Basic intravenous administration set
		X	X	Fluoroscopic X-ray system (C-arm), analogue or digital	
		X	X	Operating light, double or single	Operating, examination or treatment light handle cover, reusable/single-use
		X	X	Pulse oximeter, line-powered or battery-powered	
		X	X	Thermometer, continuous electronic	
		X	X	Universal operating table (electrohydraulic, electromechanical, hydraulic)	
		X	X	Resuscitation trolley equipped	Intubation kit
		X	X	Cardiopulmonary bypass system, non-roller type or roller type	
		X	X	Cardiopulmonary bypass system heat exchanger	
			X	Temporary pacemaker	
		X	X	Automated external defibrillator (AED)	Pads, contact gel
Medical furniture		X	X	Stretcher	
		X	X	Anaesthetist's trolley	
		X	X	Instrument storage cabinet	
		X	X	Instrument table	
		X	X	Infusion stand, double hook, on casters	
		X	X	Kick bucket	
		X	X	Operating room stool	
		X	X	Surgical scrub station	
		X	X	Utility trolley (dressing trolley, stainless steel, two trays)	
		X	X	Emergency trolley, with drawers	
		X	X	Laundry/linen trolley	
		X	X	Radiographic film view box magazine	
		X	X	Bowl/basin stand (stand, single bowl, on casters)	
		X	X	Surgical tray stand (Mayo stand)	
		X	X	Blanket warmer	
		X	X	Cabinet, medicines, double door	
		X	X	Wheelchair	

Category of medical device	Level of care			Capital medical devices	Consumables, single-use medical devices
	1	2	3		
Personal protective equipment and clothing		X	X		Clogs, plastic
		X	X		Bed sheet, reusable/single-use
		X	X		Eye splash shield
		X	X		Examination gloves, non-sterile, single-use
		X	X		Surgical gloves, sterile
		X	X		Shoe covers, non-conductive, sterile/non-sterile
		X	X		Surgical cap, reusable/single-use
		X	X		Operating room gown, reusable/single-use
		X	X		Surgical apron, reusable/single-use (aprons, impermeable)
		X	X		Surgical face mask, reusable/single-use
		X	X		General-purpose surgical drape, sterile, reusable/single-use
		X	X		Patient gown, reusable/single-use
		X	X		Surgical scrub station (medical scrubs for health care workers or similar)
Single-use devices, disposables, medical supplies		X	X		Anaesthesia breathing circuit, reusable/single-use, non-sterile/sterile (Bain circuit, universal)
		X	X		Gauze roll, non-sterile/sterile
		X	X		Basic endotracheal tube, reusable/single-use
		X	X		Basic intravenous administration set
		X	X		Oxygen administration kit, non-sterile/sterile (mask and tubing for oxygen)
		X	X		Electrocardiography electrodes[a] reusable/single-use (monitoring electrodes)
		X	X		Nasogastric tubes
		X	X		Operating room laundry bag
		X	X		Donor organ preservation/transport bag
		X	X		Skin-cleaning wipe, non-sterile/sterile
		X	X		Sutures
		X	X		General-purpose syringe, single-use
		X	X		Hypodermic needle, single-use, non-sterile/sterile
		X	X		Multipurpose surgical adhesive tape, non-sterile/sterile (medical tape rolls, various sizes)
		X	X		Non-wearable urine collection bag, non-sterile/sterile
		X	X		Surgical scrub sponge
		X	X		Basic intravenous administration set (intravenous cannulas or catheters)
		X	X		Laryngeal mask airways

Category of medical device	Level of care			Capital medical devices	Consumables, single-use medical devices
	1	2	3		
		X	X		Oropharyngeal airway
		X	X		Basic endotracheal tube, reusable/single-use
		X	X		Endotracheal tube introducer, reusable/single-use
		X	X		Operating table sheet, reusable/single-use (cover)
		X	X		Bedmat, absorbable
		X	X	Arm/leg tourniquet, reusable/single-use	Waste disposal container
		X	X	Bedpan	Sponge bowl, reusable/single-use
		X	X	Emesis bowl, reusable/single-use	Skin marker guide
		X	X	Cardiopulmonary resuscitation kit, including resuscitator bag valve and mask (adult and paediatric)	Sharps container

a. These capital medical devices are described in the table on generic equipment in Annex 4.

6.2 Specific priority medical devices for surgical interventions, by disease

6.2.1 Cardiovascular diseases

The purpose of cardiovascular surgery is to prevent, diagnose, treat, or monitor palliative cardiovascular disease. Cardiovascular surgery may be open or minimally invasive, and may involve electrophysiology, endoscopy, laparoscopy, and interventional radiology. Cardiovascular surgery covers multiple procedures ranging from anatomical restructuring – such as coronary angioplasty or grafting to unblock blood vessels – to implantation of mechanical products for cardiac resynchronization, for example. Percutaneous interventions for the coronary and the peripheral vascular system are catheter-based procedures often used to open partially or fully blocked blood vessels in people with cardiovascular disease. These procedures are done by a broad spectrum of specialists highly experienced at performing many traditionally invasive complex procedures, including interventional cardiology, electrophysiology, cardiovascular surgery, interventional radiology, and vascular surgery. Cardiovascular surgeons are clinical specialists aided by teams composed of nurses, interventional radiologists, radiographers and radiological technologists, and surgical technologists.

While some cardiovascular surgery can be performed in a general operating theatre, high-risk procedures must be conducted in a cardiac catheterization laboratory (cath lab). A cath lab is a room with a collection of medical devices that are used together during specific cardiovascular interventions.

Table 41. List of specific priority medical devices for surgical interventions for cardiovascular diseases

Clinical intervention	Level of care			Capital medical devices	Consumables, single-use medical devices
	1	2	3		
Balloon atrial septostomy			X	Angiography: cardiac catheterization laboratory (cath lab) system	See cath lab set
Balloon dilatation for coarctation			X	Angiography: cath lab system	See cath lab set
Cardiac pacemaker implantation			X	Pacemaker, invasive	Double or single chamber pacemaker generator, MRI-compatible or non-compatible
					Cable electrode by atrial or ventricular chambers, transvenous introducers
					Cable analyser and programmer
Cardiac resynchronization therapy (CRT), defibrillator implantation			X	Angiography: cath lab system	Device implantation kit
					See cath lab set
				Implantable cardioverter defibrillator	
				CRT (with/without defibrillation) generator	
				Atrial cable electrode	
				Right ventricle power and pace cable	
				Left ventricle cable electrode	
				Left ventricle access system	
Coronary artery bypass grafting			X	Cardiopulmonary bypass system, non-roller type or roller type	
				Ultrasound scanner[a]	
				Transoesophageal vascular ultrasound probe	See cath lab set
					Catheters, coronary angioplasty balloon
					Catheters, diagnostic and radiofrequency ablation, electrophysiology
					Catheters, percutaneous coronary intervention balloon
					Catheters, balloon valvuloplasty
					Catheters, electrophysiology
					Introducer sheath set
					Crimpers
					Extension tubings
					Crimp stoppers
					Inflation devices
Cardiac electrophysiology and catheter ablation			X	Cardiac ablation unit Echography system	Diagnostic and radiofrequency ablation Catheters, electrophysiology Introducer sheath set

Clinical intervention	Level of care			Capital medical devices	Consumables, single-use medical devices
	1	2	3		
Correction of congenital heart disease			X	Angiography: cath lab system	See cath lab set Metal stent or mesh
Repair of heart valve			X	Angiography: cath lab system	See cath lab set Annuloplasty band
Right heart cardiac catheterization			X	Angiography: cath lab system	See cath lab set

a. This capital medical device is described in the table on generic equipment in Annex 4.

6.2.2 Stroke

Table 42. List of specific priority medical devices for surgical interventions for stroke

Clinical intervention	Level of care			Capital medical devices	Consumables, single-use medical devices
	1	2	3		
Skull neurosurgery			X		Skull neurosurgery set
Craniectomy			X	High-speed surgical drill (craniotome)	Heads of various types, tissue guard, lubricant oil, sterilization case, brush, saw blades, drill bits, nitrogen
			X		Trepanation attachment
Craniotomy			X	High-speed surgical drill (craniotome) Operating microscope Neuronavigation equipment for precision clot evacuation	Craniotomy set
Extraventricular drain (EVD) placement			X	EVD set	EVD close drainage system
Endarterectomy of carotid artery, extracranial			X		Endarterectomy set
Endovascular embolization or occlusion of head and neck vessels			X		Endovascular embolization set
Implantation of left atrial appendage device			X	Implantation of left atrial appendage device set	
Repair of atrial septal defect of heart with graft or prosthesis			X	Apparatus for cardiopulmonary bypass	Atrial septal set
Surgical aneurysm clipping			X	Operating microscope with intraoperative on-table cerebral angiogram	Aneurism set Titanium clips as per the pathological anatomy of the aneurysm (preferable to have the entire set of clips available to have good operative clipping of the aneurysm)
Thrombolysis of artery, head and neck (percutaneous transluminal)			X		Thrombolysis set
Thrombolysis of intracranial artery (percutaneous transluminal)			X		Thrombolysis set

6.2.3 Diabetes

Table 43. List of specific priority medical devices for surgical interventions for diabetes

Clinical intervention	Level of care			Capital medical devices	Consumables, single-use medical devices
	1	2	3		
Amputation of lower limb		X	X	Anaesthesia system[a]	Orthopaedic operative set
				Amputation blade	Rongeur
				Oscillating bone saw or manual saw	Suction drain
				Tourniquet	Clamp
Intravitreal injection of anti-VEGF			x	None	Prefilled anti-VEGF syringe, single-use
Lower limb vascular intervention surgery (bypass or angioplasty)			x	Angiography: cath lab system	See cath lab set
Renal transplantation			x	Anaesthesia system[a]	Clamp Surgery set
Repair of retina (retinal laser photocoagulation)			x	Slit lamp laser system, camera-based photocoagulation system	Contact lens
Ulcer debridement surgery		X	x	Scalpel handle	Dressing set: Forceps, artery Forceps, dressing, standard, 155 mm, straight Scissors, Deaver, 140 mm, straight, sharp/blunt Dishes, kidney Blades, reusable/single-use

a. These capital medical devices are described in the table on generic equipment in Annex 4.

Skull neurosurgery set
Gouge, Leksell or Leksell-Stille, angulated, wide point, length 229–250 mm
Gouge, Stille-Luer, straight, length 200–230 mm
Gouge, Echlin, wide point, length 230 mm
Gouge, Stille-Luer, curved, length 220–230 mm
Bunnell drill set, manual
Cone driller, 12 mm x 22.9 cm
Cone driller, for skull, children
Protective clamp, with an extreme hole, cross-strips, with zipper, length 150–160 mm
Dandy clamp
Love-Gruenwald clamp, straight, 3 x 10 mm bit, length 180 mm
Kerrison-type clamp
Standard clamp, straight, with 2 x 3 teeth, length 140–150 mm
Potts-Smith clamp, straight, without teeth, with tungsten carbide inserts, length 240–250 mm
Gerald clamp, straight, with teeth, length 170–180 mm
Crile clamp, curved, with 1 x 2 teeth, length 140 mm
DeVilbiss clamp, cranial, length 205–210 mm
Adson clamp, in bayonet, without teeth, length 18.5 cm
Ferris-Smith clamp, straight, 4 mm bit, length 120 mm
Halsey needle holder, straight, with central slot, with tungsten carbide inserts, length 130–135 mm
Crile-Wood needle holder, straight, stretched jaw, length 145–150 mm
Saw, Gigli or Olivecrona, length 500–510 mm, with two grip handles in the form of a T

Craniotomy set
Instrument tray, stainless steel
Scalpel handle with blades, reusable/single-use
Penfield dissector
Handle for bistoury
Backhaus towel clamp, length 130–140 mm
Adson clamp, with 1 x 2 teeth, length 110–125 mm
Foerster or Foerster-Ballenger clamp, straight, crossed, length 180 to 200 mm
Allis clamp, with 4 x 5 teeth, length 150–155 mm
Adson clamp, without teeth, length 110–120 mm
Needle holder
Senn-Mueller separator, round or sharpened point, length 15 cm
Volkmann separator
Farabeuf separator, set of 2, length 150–155 mm
Weitlaner separator, with self-retaining mechanism
Taylor scissors, length 17 cm
Metzenbaum scissors, straight, with tungsten carbide inserts, length 180–185 mm
Mayo scissors, straight, length 150–155 mm
Mayo-Stille scissors, curved, with tungsten carbide inserts, length 145–155 mm
Hudson drill set, 9, 14, 16, 22 mm
McKenzie drill, 13 mm x 9.8 cm
Frazier cannula
Cobb knife, number
Dandy nerve hook
Sachs hook
Gouge, Leksell or Leksell-Stille, angulated, wide point, length 229–250 mm
Gouge, Stille-Luer, straight, length 200–230 mm
Gouge, Echlin, wide point, length 230 mm
Gouge, Stille-Luer, curved, length 220–230 mm
Bunnell drill set
Cone driller, 12 mm x 22.9 cm
Cone driller, for skull, children
Dandy nerve clamp
Ferris-Smith-Kerrison clamp, angle at 40 degrees, 5 mm bit, length 180 mm
Kerrison-type clamp
Standard clamp, straight, with 2 x 3 teeth, length 140–150 mm
Potts-Smith clamp, straight, without teeth, with tungsten carbide inserts, length 240–250 mm
Gerald clamp, straight, with teeth, length 170–180 mm
Crile clamp, curved, with 1 x 2 teeth, length 140 mm
DeVilbiss clamp, cranial, length 205–210 mm
Adson clamp, in bayonet, without teeth, length 18.5 cm
Crile-Wood needle holder, straight, stretched jaw, with tungsten carbide inserts, length 145–150 mm
Saw, Gigli or Olivecrona, length 500–510 mm, with two grip handles in the form of a T
Scissors for wire, universal, length 12 cm

Orthopaedic operative set
Metal ruler (min 15cm)
Scalpel handle with blades, reusable/single-use
Operating scissors
Stitch scissors, standard
Forceps
Bone/cartilage clamp
Rongeur
Bone mallet
Osteotome
Retractor
Suction tube

Surgery set
Scalpel handle with blades, reusable/single-use
Scissors
Forceps, dressing
Forceps, tissue
Needle holder
Forceps, haemostatic
Forceps, towel clamp
Forceps, sponge
Retractor
Forceps, tissue

Dressing set
Forceps, artery, Kocher, 140 mm, straight
Forceps, dressing, standard, 155 mm, straight
Scissors, Deaver, 140 mm, straight, sharp/blunt
Dishes, kidney type

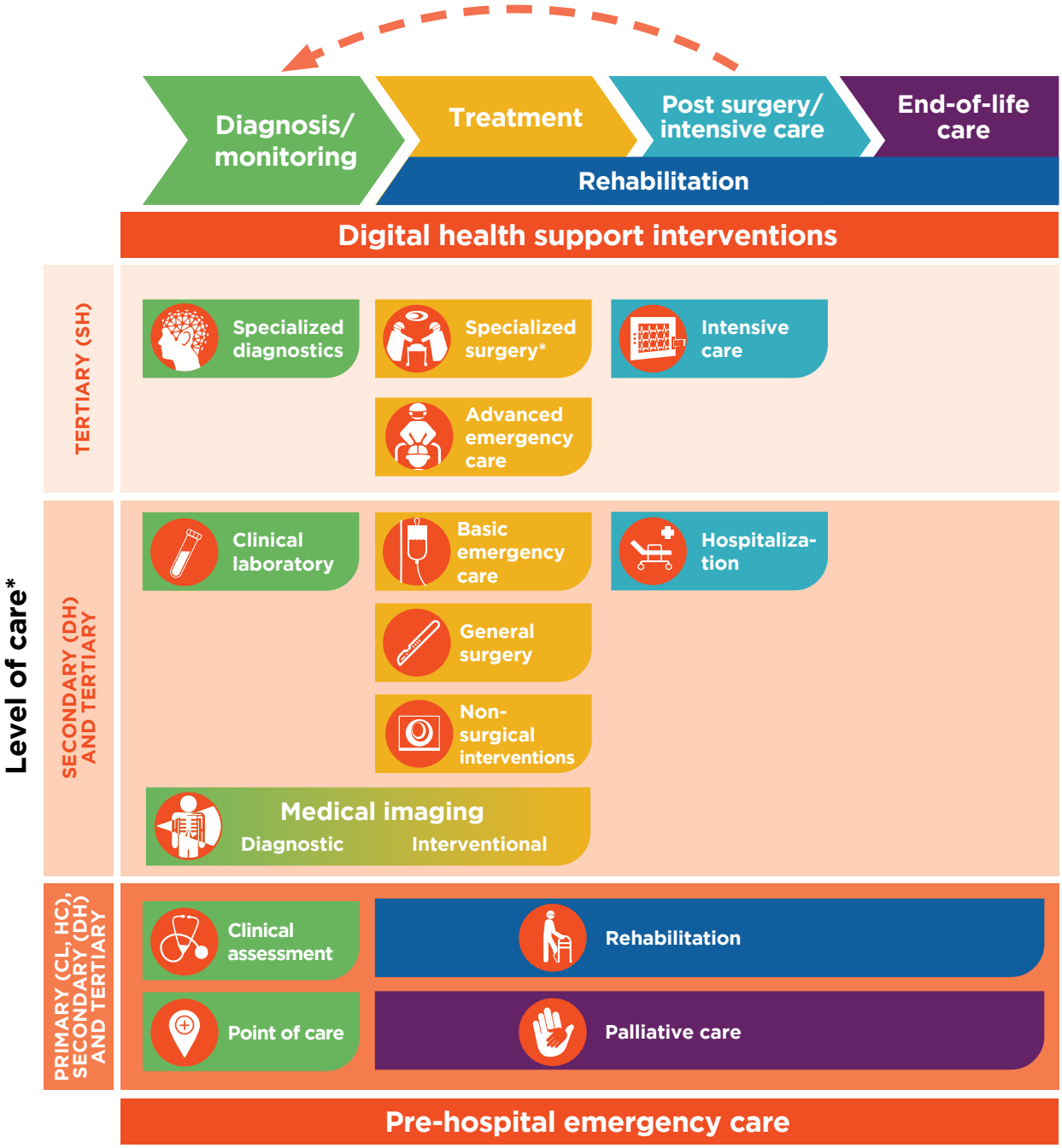
Guidance documents

- Resolution WHA68.15. Strengthening emergency and essential surgical care and anaesthesia as a component of universal health coverage. In: Sixty-eighth World Health Assembly, May 2015. Geneva: World Health Organization; 2015 (http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_R15-en.pdf).
- Safe surgery: why safe surgery is important. Geneva: World Health Organization (https://www.who.int/teams/integrated-health-services/patient-safety/research/safe-surgery).

7. Non-surgical interventions

Navigation diagram

Click on the diagram to navigate to any section of this document.



Key:
* Including cardiovascular, neurological, ophthalmic and nefrology.
CL community level; health post
DH district/general hospital; interventions can also be offered in a first referral outpatient clinic
HC health centre/outpatient clinic
SH specialized/regional/national hospital; specialized care outpatient unit

Once a patient is diagnosed, doctors will prescribe an appropriate treatment. In many cases, that treatment will include medications, surgical interventions, or non-surgical interventions, or a combination of the three. Non-surgical interventions are those that are not necessarily performed under a surgical unit; some can even be done at home. Table 44 presents some priority non-surgical interventions for stroke and diabetes. The following tables (45 and 46) list the medical devices needed for such interventions. Rehabilitation and palliative care interventions will be detailed in Chapters 10 and 11.

Table 44. List of priority non-surgical interventions

Disease	Interventions	Level of care		
		1	2	3
Stroke	Intermittent pneumatic compression		X	X
	Percutaneous endoscopic gastrostomy (PEG)		X	X
Diabetes	Blood glucose management, including self-monitoring and insulin injections	X	X	X
	Foot ulcer management	X	X	X
	Haemodialysis		X	X
	Peritoneal dialysis	X	X	X
	Periodontal treatment	X	X	X

7.1 Specific priority medical devices for non-surgical interventions, by disease

7.1.1 Stroke

Table 45. List of specific priority medical devices for non-surgical interventions for stroke

Clinical intervention	Level of care			Capital medical devices	Consumables, single-use medical devices
	1	2	3		
Intermittent pneumatic compression		X	X	Circulatory assistance unit for peripheral compression	Bed support
					Clamping devices, hand, foot, calf, thigh, abdomen, hip
					Multipurpose devices, hoses
Percutaneous endoscopic gastrostomy (PEG)		X	X	Endoscopy unit	

7.1.2 Diabetes

Table 46. List of specific priority medical devices for non-surgical interventions for diabetes

Clinical intervention	Level of care			Capital medical devices	Consumables, single-use medical devices
	1	2	3		
Blood glucose management, including self-monitoring and insulin injections	X	X	X	Refrigerator	Syringe Needle Vials (of insulin) Swabs Lancet Strips
				Blood glucose meter[a]	
Foot ulcer management	X	X	X	Therapeutic footwear	Forceps, artery
				Orthoses (lower limb)	
					Forceps, dressing, standard, 155 mm, straight
					Scissors, Deaver, 140 mm, straight, sharp/blunt
					Dishes, kidney
Haemodialysis		X	X	Haemodialysis machine Reverse osmosis water treatment equipment Haemodialysis furniture Specialized nurse workstation	Haemodialysis set
					Swabs
Peritoneal dialysis	X	X	X	Peritoneal dialysis machine	Sterile, disposable, PVC multiconnector system for connecting up to four bags of peritoneal dialysis solution; system compatible with brand and model of the equipment Bags of dialysis solution of different concentrations and connectors, compatible with the brand and model to the equipment
Periodontal treatment	X	X	X	Mechanical tooth-cleaning kit for scaling	Plaque control kit (toothbrush, floss, mouth rinse)

This capital medical device is described in the table on generic equipment in Annex 4.

Reverse osmosis water treatment equipment
Hydropneumatics system
Activated carbon tank
Softener tank with brine tank
Reverse osmosis water tank
Reservoir tank of treated water
Recirculation pumps
Ultraviolet (UV) light lamp
Microfilter
Remote alarm system
Pallet to stow goods
Iodine-free pelleted salt sacks
Disinfectant
Input filter of 1.5 microns

Haemodialysis furniture
Haemodialysis chair with Trendelenburg position
Intravenous pole
Oxygen wall outlet
Air wall outlet with surgery suction system[a]
Dialysate conductivity monitor
Sharps container
Container for hazardous medical waste
Diagnostic set or system (includes otoscope, ophthalmoscope and laryngoscope)
Automated, non-invasive blood pressure device, with proper-sized upper arm cuff

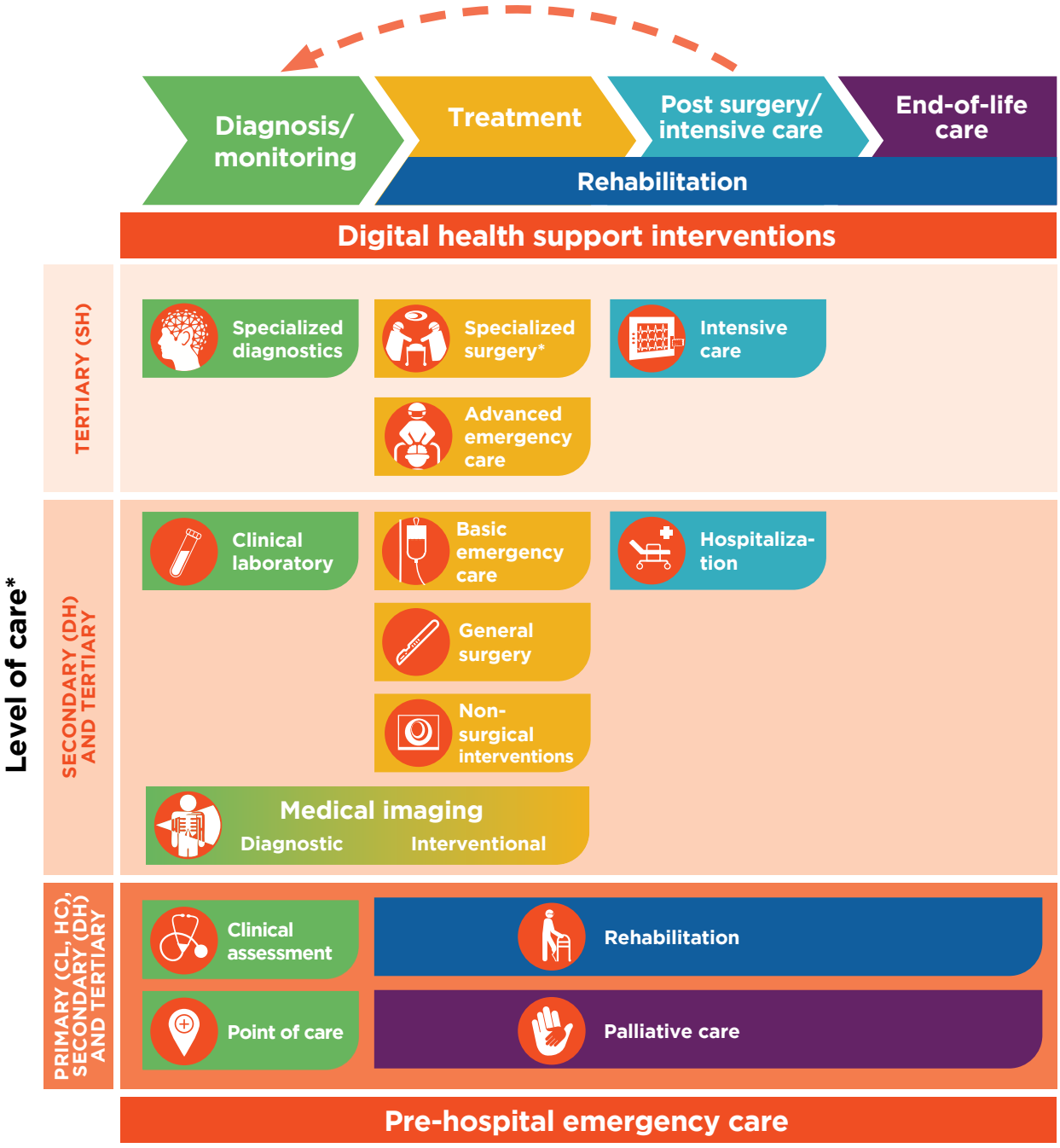
This capital medical device is described in the table on generic equipment in Annex 4.

Haemodialysis set
Solutions for haemodialysis: with variable concentrations of calcium and potassium, according to user requirements, sodium bicarbonate for manual or automatic preparation
Arterial and venous lines with pressure transducer protector, disposable and adaptable or integrated to arterial and venous lines (neonatal, paediatric, adult)
Arteriovenous fistula puncture needles
Filter for haemodialysis or haemodialyser
Disinfectant and descaling agent

8. Hospitalization

Navigation diagram

Click on the diagram to navigate to any section of this document.



Key:

* Including cardiovascular, neurological, ophthalmic and nefrology.
CL community level; health post
DH district/general hospital; interventions can also be offered in a first referral outpatient clinic
HC health centre/outpatient clinic
SH specialized/regional/national hospital; specialized care outpatient unit

A patient can be admitted into a hospital for multiple reasons, including scheduled tests, procedures, or surgery; emergency medical treatment; administration of medication; or to stabilize or monitor an existing condition *(49)*. The inpatient unit is essential and is the most interconnected to all the other hospital units, as it provides a continuum of medical or nursing care plus other hospital services. When admitted, a patient should have a bed assigned either in a private or in a common room with all the required medical equipment and care (including medicines, rehabilitation, treatment and diet), depending on each patient's needs. A hospitalization unit should have a nurse station that can store all the patient's information and needed instrumentation. There should be at least a 1:8 nurse-to-patient ratio.

In most high-income countries, hospitals manage to cover the needs of the inpatient unit. However, around the world, most hospitals are saturated, patients will not always have access to a personal bed, nurses and physicians are overwhelmed, the rehabilitation workforce is not available, and not all the needed medicines, medical and rehabilitation equipment are available. Patient safety is a serious global public health concern; estimates show that one in every 10 patients is harmed while receiving medical care *(50)*.

The table 47 lists priority interventions taking place under a hospitalization setting for the three diseases. The following tables (48 -51) detail the medical devices needed for said interventions.

Table 47. List of hospitalization interventions

Disease	Interventions	Level of care		
		1	2	3
All	Inpatient admission		X	X
	Clinical and paraclinical monitoring (scheduled tests)		X	X
	Medical treatment and wound care		X	X
	Administration of medication (administration of oral and parenteral treatment)		X	X
Cardiovascular diseases	Thrombolysis			X
	Echo Doppler		X	X
	Intra-aortic counterpulsation			X
Stroke	Thrombolysis		X	X
	Kinesiotherapy		X	X
Diabetes	Emergency medical treatment		X	X

8.1 General priority medical devices for hospitalization interventions

Table 48. List of general priority medical devices for hospitalization interventions

Clinical intervention	Level of care			Capital equipment	Consumables, single-use medical devices
	1	2	3		
Inpatient admission		X	X	Stretcher Hospital bed Mattress for bed Bedrail Wheelchair Waste disposal units Resuscitation trolley Nurses' central monitoring station (specified bellow) Sterilization unit	Patient record chart Bed sheets Needles Infusion set
Clinical and paraclinical monitoring (scheduled tests)		X	X	Blood pressure measurement monitor Electrocardiography system[a] or patient physiological monitora	ECG electrodes Electrolytic gel Disposable oxygen saturation with non-invasive haemoglobin sensor and end tidal carbon dioxide sensor Disposable sample lines Cuffs, blood pressure
Medical treatment and wound care		X	X		Medicines Dressing set
Administration of medication (oral and parenteral treatment)		X	X	Intravenous pole Infusion pump	Infusion set

a. These capital medical devices are described in the table on generic equipment in Annex 4.

Nurses' central monitoring station
Crash cart with automated external defibrillator (AED) and monitoring
Electrocardiography system[a]
Wheelchair
Electronic scale
Automated, non-invasive blood pressure device
Stethoscope, binaural
Diagnostic set or system (includes otoscope, ophthalmoscope and laryngoscope)
Flexible LED examination lamp on casters
Thermometer
Pulse oximeter
Blood glucose meter[a], portable
Medication refrigerator
Surgery suction system[a], toraxic
Whole blood coagulation analyser
Haematology analyser
Red bag container for hazardous medical waste
Pasteur table, stainless steel
Point-of-care analyser

a. These capital medical devices are described in the table on generic equipment in Annex 4.

8.2 Specific priority medical devices for hospitalization interventions, by disease

8.2.1 Cardiovascular diseases

Table 49. List of specific priority medical devices for hospitalization interventions for cardiovascular diseases

Clinical intervention	Level of care			Capital equipment	Consumables, single-use medical devices
	1	2	3		
Thrombolysis			X	X-ray system, mobile	Catheters, interventional Thrombolytic medication Contrast media
Echo Doppler		X	X	Ultrasound scanner[a]	Ultrasound gel Ultrasound probes
Intra-aortic counterpulsation			X	Intra-aortic balloon pump unit	Catheters, interventional

a. This capital medical device is described in the table on generic equipment in Annex 4.

8.2.2 Stroke

Table 50. List of specific priority medical devices for hospitalization interventions for stroke

Clinical intervention	Level of care			Capital medical devices	Consumables, single-use medical devices
	1	2	3		
Thrombolysis		X	X	X-ray system, mobile	Catheter, interventional Thrombolytic medication Contrast media
Kinesiotherapy		X	X		Bands, resistance

8.2.3 Diabetes

Table 51. List of specific priority medical devices for hospitalization interventions for diabetes

Clinical intervention	Level of care			Capital medical device	Consumables, single-use medical devices
	1	2	3		
Emergency medical treatment (insulin management)		X	X	Intravenous pole Infusion pump	Needles Insulin Infusion set

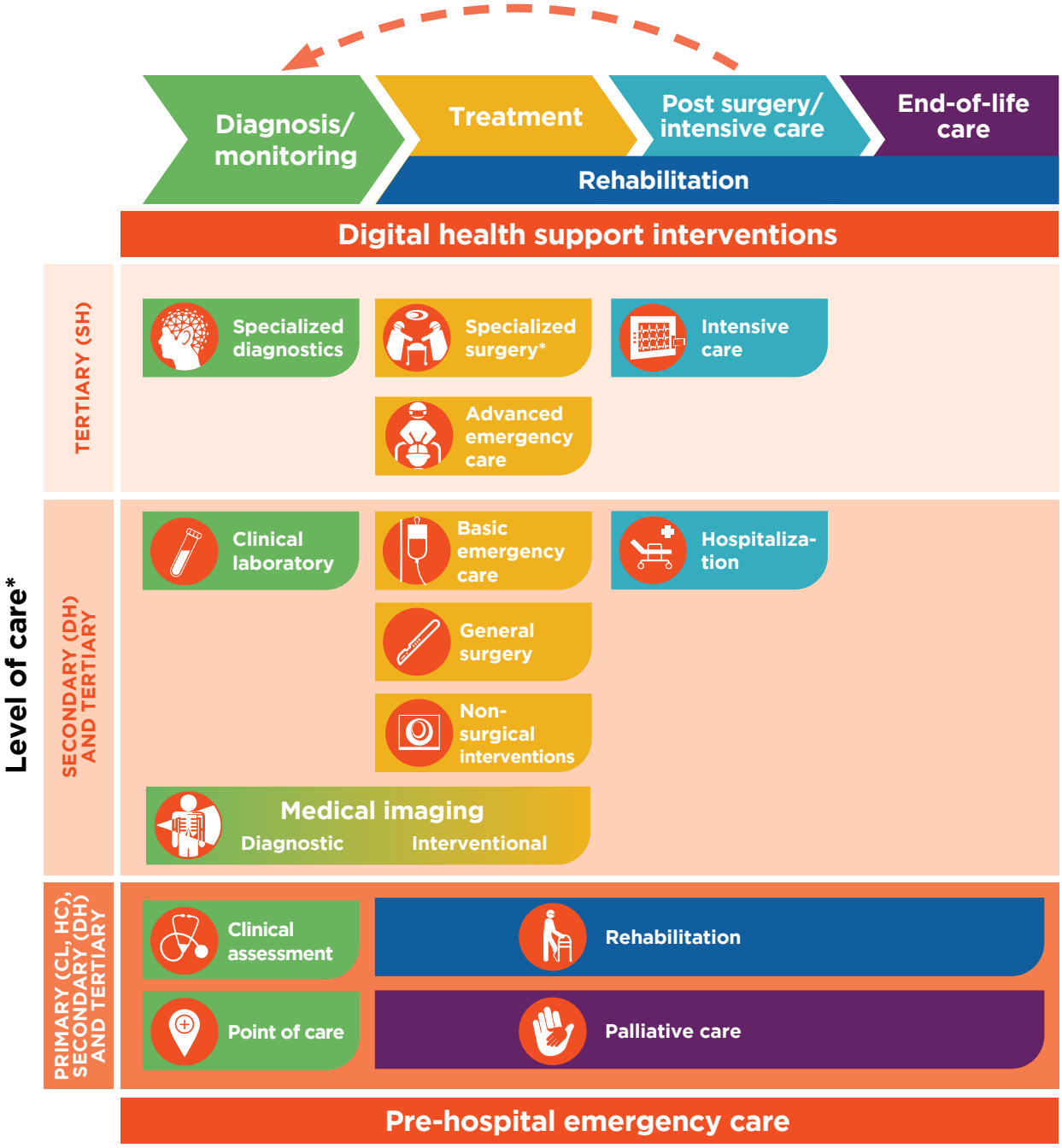
Guidance documents

- WHO, Medical devices by health care facility, (https://www.who.int/activities/prioritizing-medical-devices).

9. Intensive care units

Navigation diagram

Click on the diagram to navigate to any section of this document.



Key:

* Including cardiovascular, neurological, ophthalmic and nefrology.
CL community level; health post
DH district/general hospital; interventions can also be offered in a first referral outpatient clinic
HC health centre/outpatient clinic
SH specialized/regional/national hospital; specialized care outpatient unit

An intensive care unit (ICU) aims to support patients who are at immediate risk of undergoing or developing vital organ failure. It can be understood as a hospitalization unit that includes intensive and specialized medical and nursing care. ICUs offer medical staff who are specialized in caring for critically ill patients. ICUs have the capacity to sustain physiological organ support and are equipped with advanced patient physiological monitors. They are found in high-income countries but are becoming an important part of health structures in low- and middle-income countries as well.

The rooms of ICU units should be large enough to deal with emergencies, and it should be possible to easily move beds and equipment (for example, resuscitation trolleys, oxygen devices or imaging modalities). Subsequently, doors should be wide enough to avoid blockages and the whole unit should benefit from proper ventilation, cooling and heating. Moreover, ICUs need to be connected to oxygen, pressurized air and vacuum outlets, and a proper electricity supply, and need to be secured with a continuous emergency power supply system. Spacious working areas, offices for medical staff, and staff rest areas are highly recommended to increase the efficiency of the department.

The extent, as well as the capacity, of ICUs in hospitals can differ according to the level of specialization. Moreover, some hospitals feature an ICU to deal with specific types of patients or medical requirements. The ICU specialized in dealing with cardiovascular diseases, for example, can be termed a coronary care unit (CCU). CCUs are specifically designed and equipped to deal with life-threatening cardiovascular conditions. Most patients will be transferred to a ward when intensive care is no longer needed.

Some hospitals feature a stroke unit or a neurology intensive unit, which is entirely devoted to care for patients with stroke and its complications. Stroke units and neurology intensive units are staffed with highly trained medical personnel, educated in specialized stroke care.

The clinical interventions listed in this chapter are those applicable to the ICU (Table 52). The extent of possible interventions depends on the level and degree of specialization of the ICU (for example, whether a CCU or stroke unit is present).

Table 52. List of intensive care unit interventions

Disease	Interventions	Level of care		
		1	2	3
All	ICU admission			X
	Intubation		X	X
	Continuous infusion and application of supportive drugs		X	X
	Continuous multiparametric cardiac monitoring with non-invasive or invasive blood pressure monitoring		X	X
	Blood gas analysis		X	X
	Ultrasound scan	X	X	X
	Mechanical ventilation			X
	Oxygen therapy		X	X
	Imaging of the chest		X	X
	Point-of-care glucose test	X	X	X
	Suction of fluids		X	X
	Defibrillation and external pacemaker	X	X	X
	Resuscitation	X	X	X
Cardiovascular diseases	Angiography			X
	Temporary transvenous pacing			X
	Intra-aortic balloon pump			X
Stroke	Intracranial pressure monitoring			X
	Near-infrared spectroscopy monitor			X
Diabetes	Dialysis	X	X	X
	Haemodialysis		X	X
	Renal replacement therapy			X
	Continuous glucose monitoring		X	X

9.1 General priority medical devices for the intensive care unit

Table 53 presents general medical devices that are used for interventions in ICUs. The extent and availability of medical devices depend on the level of the ICU and whether a specialized unit (for example, CCU or stroke unit) is present.

Table 53. List of general priority medical devices for intensive care unit interventions

Clinical intervention	Level of care			Capital equipment	Consumables, single-use medical devices
	1	2	3		
ICU admission			X	Stretcher Hospital bed Pressure relief mattress for bed Bedrail Wheelchair Waste disposal units Resuscitation trolley Nurse's station Sterilization unit Autoclave, washer, disinfectors Respirometer Blood warmer Vascular duplex scanner Pneumatic compression machine Continuous positive airway pressure (CPAP) machine Apheresis machine	Chart, patient record Bed sheets Needles Infusion set Chemical supplies for autoclave/washer
Intubation		X	X	Laryngoscope	Intubation kit
Continuous infusion and application of supportive drugs		X	X	Infusion pump, precise graduation Infusion stand, double hook, on casters Patient-controlled analgesia pumps Rapid infusion device	Infusion set
Continuous multiparametric monitoring with non-invasive/invasive blood pressure monitoring		X	X	Patient physiological monitor[a] (ECG five channel, NIBP, EEG headset SpO_2 and $etCO_2$, temperature, cardiac output, non-invasive haemoglobin, SpHb, CVP, MAP)	ECG electrodes EEG headset Electrolytic gel Disposable oxygen saturation sensor Cuffs, blood pressure
Blood gas analysis		X	X	Blood gas analyser, automated or semi-automated Electrolyte analyser	Reagents Calibration fluids
Ultrasound scan	X	X	X	Ultrasound scanner[a]	Ultrasound gel Ultrasound probes
Mechanical ventilation			X	Ventilator, different interfaces; should include continuous positive airway pressure (CPAP) and bi-level positive airway pressure (BPAP), $etCO_2$ monitor	Ventilator set
Oxygen therapy		X	X	Oxygen devices	Oxygen masks and tubes
Imaging of the chest		X	X	X-ray system, mobile	Film or digital detector Protective equipment
Point-of-care blood glucose test	X	X	X	Blood glucose meter[a]	Glucometer strips Spare batteries for the glucometer
Suction of fluids		X	X	Surgery suction system[a]	Surgery suction system set[a]
Defibrillation, external pacemaker and resuscitation	X	X	X	Automated external defibrillator (AED)	Defibrillator electrodes Electrolytic gel Spare battery
	X	X	X	Resuscitation trolley, equipped Cardiopulmonary resuscitation kit, including resuscitator bag valve and mask Emergency trolley, with drawers Utility trolley (dressing trolley, stainless steel, two trays) Stretcher Laundry/linen trolley Instrument table Instrument storage cabinet Kick bucket	Resuscitator bag valve Resuscitator mask Stretcher linen Tearproof bags

a. These capital medical devices are described in the table on generic equipment in Annex 4.

Ventilator set
Expiratory valve assemblies
Flow sensors
Non-invasive ventilation (NIV) mask
Ventilator tubes

Surgery suction system set
Suction system tubing (Yankauer suction tube, 270 mm)
Basic suction tip, reusable/single-use (Yankauer suction tips)
Suction system tubing (suction tube, L50 cm, catheter tip, sterile, single-use, sizes G)
Suction system bottle
Suction system canister, bottle holder
Suction system filter, microbial (suction trap to collect fluid specimens)

9.2 Specific priority medical devices for monitoring and intensive care unit, by disease

9.2.1 Cardiovascular diseases

Cardiovascular monitoring after a cardiovascular event is carried out in the cardiovascular intensive care unit. The length of time in the unit will depend on the particular heart problem that the patient has. The professionals that work in the unit will have had advanced training on how to take care of patients with vascular problems and special training on all of the equipment available for treating cardiovascular emergencies. The cardiovascular intensive care unit is specialized in the care of patients with cardiovascular conditions that require continuous monitoring. Table 54 details the medical devices listed for each intensive care unit intervention for cardiovascular diseases.

Table 54. List of specific priority medical devices for intensive care unit interventions for cardiovascular diseases

Clinical intervention	Level of care			Capital equipment	Consumables, single-use medical devices
	1	2	3		
Angiography			X	Angiography system	Angiography equipment (cushions, protective equipment)
Temporary transvenous pacing			X	Temporary external transvenous pacing generator	Central venous access kit Pacing lead
Intra-aortic balloon pump			X	Angiography: cath lab system Balloon pump	Cath lab set

9.2.2 Stroke

Table 55 details the medical devices listed for each intensive care unit intervention for stroke.

Table 55. List of specific priority medical devices for intensive care unit interventions for stroke

Clinical intervention	Level of care			Capital equipment	Consumables, single-use medical devices
	1	2	3		
Intracranial pressure monitoring			X	Intracranial pressure monitor	Catheter (filter, needle with luer lock, case and cap)
Near-infrared spectroscopy			X	Infrared spectrometer system	Headband

9.2.3 Diabetes

Table 56 details the medical devices listed for each intensive care unit intervention for diabetes.

Table 56. List of specific priority medical devices for intensive care unit interventions for diabetes

Clinical intervention	Level of care			Capital equipment	Consumables, single-use medical devices
	1	2	3		
Dialysis	x	X	X	See 7.1.2. (Table 47)	See 7.1.2. (Table 47)
Haemodialysis		X	X	See 7.1.2. (Table 47)	See 7.1.2. (Table 47)
Continuous renal replacement therapy			x	Continuous renal replacement therapy system Anaesthesia system[a]	Set for kidney therapy continues, according to doctor's prescription Effluent collecting bag, 5 litres Bicarbonate-based dialysis and replacement solution, bagged Anaesthesia set
Continuous glucose monitoring		X	X	Blood glucose meter[a], continuous monitor	

a. These capital medical devices are described in the table on generic equipment in Annex 4.

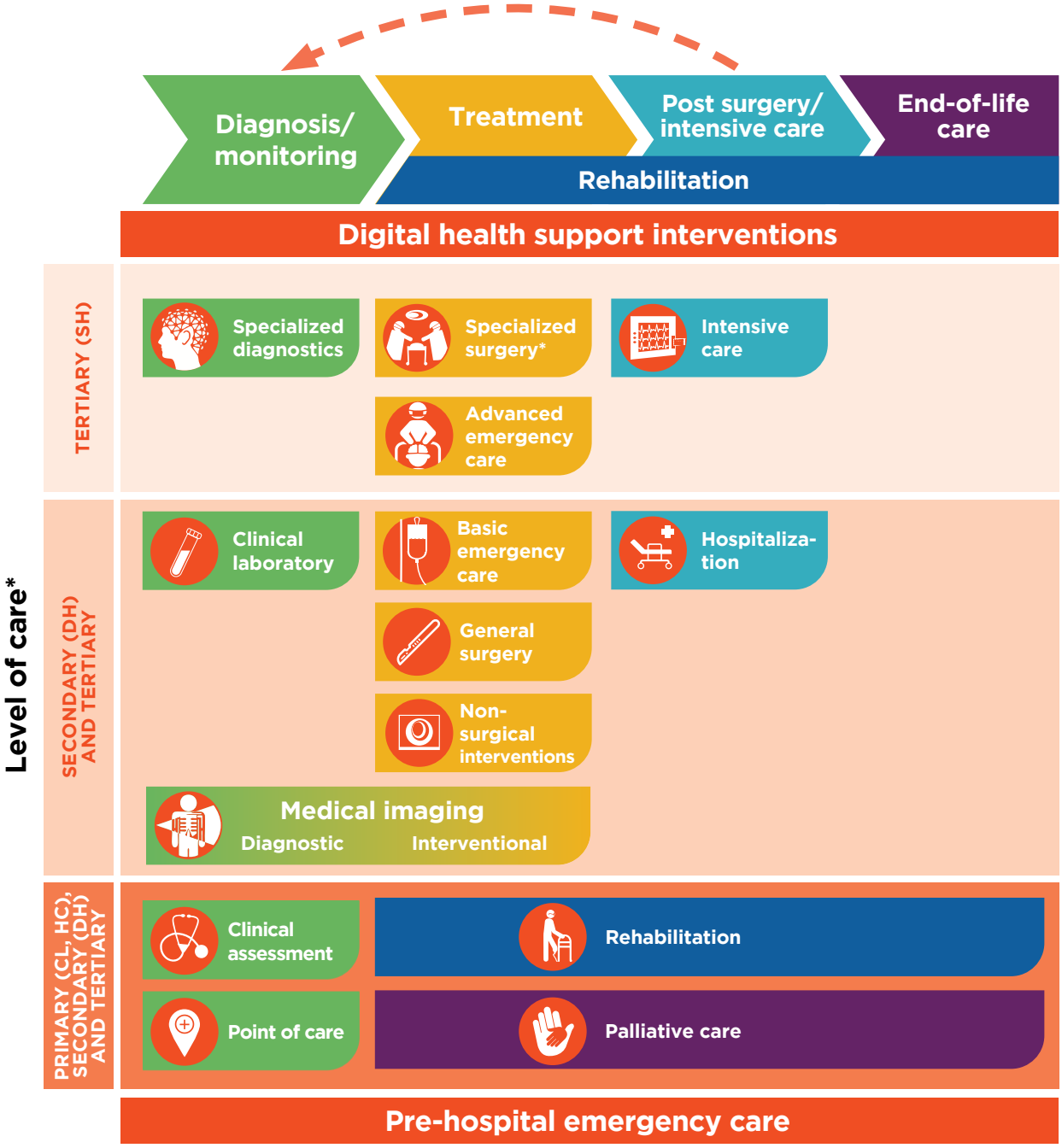
Guidance documents

- WHO, Medical devices by health care facility, (https://www.who.int/activities/prioritizing-medical-devices).

10. Rehabilitation

Navigation diagram

Click on the diagram to navigate to any section of this document.



Key:

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Rehabilitation is the set of interventions needed when a person is experiencing or is likely to experience limitations in everyday functioning due to aging or a health condition, including chronic diseases or disorders, injuries, or traumas. It is an essential component of universal health coverage along with promotion, prevention, treatment, and palliative care, and it can help to prevent complications associated with many health conditions, such as spinal cord injury, stroke, or a fracture. Rehabilitation can also help to minimize or slow down the disabling effects of chronic health conditions, such as cardiovascular disease, cancer, and diabetes, by equipping people with self-management strategies and the assistive products they require, or by addressing pain or other complications. There is a broad range of health professionals who provide rehabilitation interventions, including physiotherapists, occupational therapists, speech and language therapists, orthotic and prosthetic technicians, and physical medicine and rehabilitation physicians (51).

The type of rehabilitation varies depending on the disease or health complication of each patient. There is a wide range of innovations and medical devices that can assist a person's recovery and resumption of everyday life. Therefore, in this chapter medical devices will not be specified by disease but will be considered more generally, with usage to be determined by a health professional. Cardiovascular diseases and diabetes rehabilitation is achieved through medically supervised programs that involve adopting a heart-healthy lifestyle to address risk factors (52), for example through:

- exercise counseling and training
- education for heart-healthy living
- counseling to reduce stress.

As mentioned above, because rehabilitation interventions are meant to help minimize or slow down the disabling effects of chronic health conditions, they are not separated by disease but by the rehabilitation domain. The following tables (Tables 57–68) describe the assistive products, equipment, service delivery platforms, and health workers needed for each intervention and domain.

Service delivery platforms

For each assessment or intervention, the DG members are asked to confirm the pre-selected service delivery platforms at which the assessment or intervention should be available. Assessments and interventions can be assigned to one or more service delivery platforms, depending on where they should be available.

The service delivery platforms are described as follows:

Rehabilitation at First Level Clinical (outpatient health clinics in the community)

First level clinics include the first access point for patients with acute health problems or the continuous delivery of discrete services for patients with chronic conditions. The rehabilitation service is available at a single-professional practice (e.g. OT practice), or integrated in a general primary health clinic (e.g. GP practice or primary healthcare centers and clinics). Interventions for rehabilitation are person-centered and are provided by trained rehabilitation workers or by other health workers either under the supervision of trained rehabilitation workers or trained in rehabilitation and who may follow rehabilitation protocols (level of care 1).

Rehabilitation at General Referral Clinical (inpatient general hospital, emergency unit)

Patients are referred to a general clinic from a first level clinic or admitted through emergency. The rehabilitation service is integrated in the emergency or acute care (e.g. cardiovascular unit in acute hospital) or general inpatient service. In such services, multi-professional teams composed of different health professions work together. Interventions for rehabilitation are person-centered and are provided by trained rehabilitation workers or by health workers under supervision of trained rehabilitation workers or trained in rehabilitation and who may follow rehabilitation protocols (level of care 2).

Rehabilitation at Specialized Referral Clinical (inpatient or outpatient rehabilitation centers/unit)

Patients are referred to a specialized rehabilitation center, or unit from a first level clinic or a general referral clinic. Such centers or units may be specialized for the care of people with specific health conditions with complex rehabilitation needs (e.g. spinal cord injury rehabilitation center) or provide rehabilitation for people with a range of health conditions in a dedicated rehabilitation centre. In such in- or outpatient centers, multi-disciplinary teams composed of different rehabilitation professions (PRM physician, physiotherapist, occupational therapist, prosthetist&orthotist, rehabilitation nurse, etc.) work together, these centers and programmes commonly have capacity for longer-stay and high intensity delivery of rehabilitation interventions. Interventions for rehabilitation are person-centered and provided by trained rehabilitation workers specialized for the care of people with specific health conditions or by health workers under supervision of trained rehabilitation workers or trained in rehabilitation and who may follow rehabilitation protocols (level of care 3).

The list of rehabilitation interventions and assistive products, equipment and consumables required for general rehabilitation are presented in tables 57 and 58 by level of care: 1st, 2nd or 3rd, as described above.

Table 57. List of rehabilitation interventions

Disease	Intervention	Level of care		
		1	2	3
General	Assessment of cognitive functions	X	X	X
	Provision and training in the use of assistive devices for walking	X	X	X
	Assessment of exercise capacity	X	X	X
Ischemic heart disease	Screening for sleep apnea	X	X	X
	Respiratory muscle strengthening		X	X
	Monitoring of heart rhythm		X	X
	Measurement of blood pressure functions	X	X	X
	Resistance training	X	X	X
	Assessment of muscle stiffness	X	X	X
	Balance training	X	X	X
	Physical fitness training (including aerobic exercises, walking, non-weight bearing exercises)	X	X	X
	Assessment of work and employment	X		X
	Assessment of work capacity (treadmill test, 6-min walk test)	X	X	X
	Vocational rehabilitation	X		X
	Stress management training (incl. cognitive behavioral training, relaxation therapy)	X	X	X
	Assessment of body composition (body weight)	X	X	X
Diabetes (lower limb amputation)	Epidural treatment	X	X	X
	Skin care	X	X	X
	Removable Rigid Dressing		X	X
	Assessment of blood vessel functions	X	X	X
	Assessment of edema	X	X	X
	Compression therapy (incl. Removable Rigid Dressing)	X	X	X
	Assessment of joint mobility	X	X	X
	Therapeutic interventions (incl. range of motion exercises, stretching)	X	X	X
	Assessment of muscle strength	X	X	X
	Muscle strengthening	X	X	X
	Assessment of gait and walking	X	X	X
	Therapeutic interventions (incl. balance training, gait training)	X	X	X
	Assessment of mobility	X	X	X
	Mobility training (incl. transfer training)	X	X	X
	Provision and training in the use of assistive devices for mobility (other than walking)	X	X	X
	Assessment of risk for falls	X		X
	Assessment of driving	X		X
	Driving training			X
	Assessment of activities of daily living	X	X	X
	ADL Training	X	X	X
	Provision and training in the use of assistive products incl. environmental modification for ADLs	X		X
	Physical fitness training	X		X
	Assessment of education, work and employment	X		X
	Educational/Vocational training	X		X
	Environmental modification			
	Training for recreation and leisure activities (incl. sports)	X		X

Disease	Intervention	Level of care		
		1	2	3
Stroke	Cognitive training (incl. awareness raising, mnemonic strategies, errorless learning, cueing)	X	X	X
	Physical exercise training	X	X	X
	Provision and training in the use of assistive products (incl. environmental modification) for cognition	X	X	X
	Provision and training in the use of assistive products (incl. environmental modification) for perception	X	X	X
	Environmental modification			
	Assessment of visual functions	X	X	X
	Eye movement therapy	X	X	X
	Provision and training in the use of assistive products for vision	X	X	X
	Assessment of mental functions of language	X	X	X
	Speech and language therapy (incl. verbal strategies, non-verbal strategies, group conversation therapy)	X	X	X
	Provision and training in the use of assistive products for communication	X	X	X
	Assessment of swallowing (incl. videofluoroscopy)	X	X	X
	Compensatory and restorative techniques (incl. positioning, biofeedback, nasogastric tube feeding)	X	X	X
	Assessment of body composition (body weight)	X	X	X
	Enteral nutrition support		X	X
	Assessment of pain	X	X	X
	Intraarticular injections	X	X	X
	Therapeutic interventions (incl. range of motion exercises, mirror therapy, positioning, active motor training)	X	X	X
	Provision and training in the use of assistive products for joint protection	X	X	X
	Assessment of bowel functions	X	X	X
	Assessment of bladder functions	X	X	X
	Rectal medications	X	X	X
	Therapeutic interventions (incl. muscle strengthening, biofeedback, electrical stimulation, emotional support, diet management)	X	X	X
	Intermittent catheterization	X	X	X
	Provision and training in the use of assistive products for incontinence management	X	X	X
	Oral hygiene	X	X	X
	Assessment of vascular functions	X	X	X
	Heparin injections	X	X	X
	Therapeutic interventions (incl. range of motion exercises, retrograde massage, positioning, intermittent pneumatic compression)	X	X	X
	Physical fitness training (incl. walking)	X	X	X
	Assessment of joint mobility and stability	X	X	X
	Therapeutic interventions (incl. range of motion exercises, antispastic pattern positioning)	X	X	X
	Provision and training in the use of assistive products for joint protection	X	X	X
	Therapeutic interventions (incl. electrical stimulation, muscle strengthening, range of motion exercises, antispastic pattern positioning, repetitive task training)	X	X	X
	Botulinum toxin injections			X

Disease	Intervention	Level of care		
		1	2	3
	Provision and training in the use of assistive products for joint protection		X	X
	Assessment of balance, control of voluntary movement, gait pattern/ walking, hand and arm use	X	X	X
	Therapeutic interventions (incl. biofeedback, electrical stimulation, repetitive task training, treadmill training, aquatic therapy, mirror therapy, constraint induced movement therapy, gait/walking training, escorted walking practice, physical fitness training, virtual reality training, electromechanically assisted training)	X	X	X
	Assessment of driving			X
	Assessment of activities of daily living	X	X	X
	ADL Training (incl. virtual reality training)	X	X	X
	Provision and training in the use of assistive products (incl. environmental modification) for ADLs (self-care)	X	X	X
	Assessment of risk for falls	X	X	X
	Provision and training in the use of assistive devices (incl. environmental modification) for safe mobility	X	X	X
	Assessment of work and employment	X		X
	Vocational training	X		X
	Work place visits (incl. environmental modification)	X		X
	Leisure therapy	X		X

10.1 General assistive products for rehabilitation

Table 58 presents general assistive products, equipment and consumables required for general rehabilitation.

Table 58. General assistive products, equipment and consumables required for general rehabilitation

General intervention	Level of care			Assistive devices	Equipment	Consumables
	1	2	3			
Interventions for cognitive functions (intellectual, memory and attention functions)						
Assessment of cognitive functions (incl. intellectual, memory and attention functions)	X	X	X		• Standardized and Norm-Referenced Tests; Intelligence/ cognitive tests or batteries	
Provision and training in the use of assistive products for walking	X	X	X	• Early Walking Aids (EWA) • Canes/Sticks • Prostheses, lower limb Crutches, axillary/elbow • Orthoses (lower limb) Rollators • Standing frames, adjustable Walking frames/walkers	• Casting kit • Orthoses kit • Splinting kit (static/ dynamic) • Parallel bars • Prosthetic kit	Tubular
Interventions for exercise and fitness						
Assessment of exercise capacity	X	X	X	• Prostheses, lower limb (for limb amputation)	• Automated external defibrillator (AED) • Blood pressure measurement device • Cycle ergometer (arm or leg) • Pedometer • ECG monitor (with or without telemetry) Parallel bars • Pulse oximeter • Timer • Tape measure • Treadmill	Electrodes (Replaceable sticky)

10.2.1 Specific assistive products for rehabilitation in people with heart disease

Table 59 presents the specific assistive products, equipment and consumables required for rehabilitation of people with heart disease.

Table 59. Assistive products, equipment and consumables required for rehabilitation in people with cardiovascular disease (ischemic heart disease)

Intervention	Level of care			Assistive devices	Equipment	Consumables
	1	2	3			
Interventions for respiration functions						
Screening for sleep apnea	X	X	X		• Tape measure	
Respiratory muscle strengthening		X	X		• Resistance bands • Respiratory resistance training devices	
Interventions for cardiovascular and heamatological functions						
Monitoring of heart rhythm		X	X		• ECG monitor (with or without telemetry)	Electrodes (Replaceable sticky)
Measurement of blood pressure functions	X	X	X		• Blood pressure measurement device	
Interventions for muscle functions (muscle power functions)						
Resistance training	X	X	X		• Heart rate monitor • Pulley machine • Resistance bands Weights	
Interventions for movement functions (muscle stiffness, involuntary movement reaction functions, gait pattern/walking)						
Assessment of muscle stiffness	X	X	X		• Goniometer Tape measure	
Balance training	X	X	X		• Exercise mats	
Interventions for exercise and fitness						
Physical fitness training (including aerobic exercises, walking, non-weight bearing exercises)	X	X	X		• Blood pressure measurement device • Cycle ergometer (arm or leg) • ECG monitor (with or without telemetry) • Exercise balls Exercise mats • Heart rate monitor • Pulse oximeter • Resistance bands • Stop watch Treadmill Weights	Electrodes (Replaceable sticky)
Interventions for work and employment						
Assessment of work and employment	X		X		• Computer/tablets with software	
Assessment of work capacity (treadmill test, 6-min walk test)	X	X	X		• Blood pressure measurement device • ECG monitor (with or without telemetry) • Pulse oximeter • Stop watch Treadmill	Electrodes (Replaceable sticky)
Vocational rehabilitation	X		X		• Computer/tablets with software	
Interventions for self-management (stress management)						
Stress management training (incl. cognitive behavioral training, relaxation therapy)	X	X	X		• Exercise mats Pillow	

Interventions for lifestyle modification						
Assessment of body composition (body weight)	X	X	X		Scale Tape measure	

10.2.2 Specific assistive products for rehabilitation in people with stroke disease

Table 60 presents the specific assistive products, equipment and consumables required for rehabilitation of people with stroke disease.

Table 60. Assistive products, equipment and consumables required for rehabilitation in people with stroke

Intervention	Level of care			Assistive devices	Equipment	Consumables
	1	2	3			
Interventions for cognitive functions (intellectual, memory and attention functions)						
Cognitive training (incl. awareness raising, mnemonic strategies, errorless learning, cueing)	X	X	X	• Communication board/ books/cards Communication software (incl. electronic device)	• Calendar • Timer	
Physical exercise training	X	X	X	• Body belt (for wheelchair) • Canes/Sticks Crutches, axillary/elbow Walking frames/walker	• Cycle ergometer (arm or leg) Exercise ball Resistance bands Wall bars • Parallel bars Pulley machine • Steps (stackable) Weights	
Provision and training in the use of assistive products (incl. environmental modification) for cognition	X	X	X	• Alarm signalers with light/ sound/vibration Communication software (incl. electronic device) Orientation board • Personal emergency alarm systems (PDA) Pill organizers • Recorders		
Interventions for perceptual functions (neglect)						
Provision and training in the use of assistive products (incl. environmental modification) for perception	X	X	X	• Alarm signalers with light/ sound/vibration • Prism glasses		
Interventions for prevention of emotional functions/psychological health						
Environmental modification				• Lighting control device		
Interventions for seeing functions						
Assessment of visual functions	X	X	X	• Spectacles; low vision, short distance, long distance, filters and protection	• Color perception charts • Eye testing booklets • Ophthalmoscope • Snellen chart	
Eye movement therapy	X	X	X	• Magnifiers, digital hand-held Spectacles; low vision, short distance, long distance, filters and protection	• Color perception charts Eye patches	

Intervention	Level of care			Assistive devices	Equipment	Consumables
	1	2	3			
Provision and training in the use of assistive products for vision	X	X	X	• Magnifiers, digital hand-held Prism glasses • Screen readers Spectacles; low vision, short distance, long distance, filters and protection		
Interventions for speech, language and communication						
Assessment of mental functions of language	X	X	X	• Communication boards/ books/cards In-line speaking valves	• Timer	
Speech and language therapy (incl. verbal strategies, non-verbal strategies, group conversation therapy)	X	X	X	• Augmentative and alternative communication devices Communication boards/ books/cards Communication software (incl. electronic device) • Keyboard and mouse emulation software Recorders	• Metronome • (Mobile) mirror Reading materials • Timer	• Gloves Straws Tongue depressor Tissues
Provision and training in the use of assistive products for communication	X	X	X	• Augmentative and alternative communication devices • Communication boards/ books/cards Communication software (incl. electronic device)		
Interventions for dysphagia management						
Assessment of swallowing (incl. videofluoroscopy)		X	X		• Camera Flexible laryngoscopy Fluoroscope Laryngoscope Led apron • Stethoscope Suction Machine • Videofluoroscopic equipment Wall-mounted x-ray viewer • X ray machine	• Barium • Food dye Gloves Modified liquids and solids Oral anesthetic spray Oral Swabs Straws Tongue depressor
Compensatory and restorative techniques (incl. positioning, biofeedback, nasogastric tube feeding)	X	X	X	• Adapted eating and drinking products	• Biofeedback device Feeding cup Foam rollers Foam wedges • Pillows Spoon	• Carbonated water • Food thickeners Gauze • Gloves • Hydration/ nutrition bags • Iced sour suckers • Lubricant Medical tape • Modified liquids and solids Nasogastric tubes • Replaceable sticky electrodes • Straws

Intervention	Level of care			Assistive devices	Equipment	Consumables
	1	2	3			
Interventions for prevention of malnutrition						
Assessment of body composition (body weight)	X	X	X		• Fat caliper Scale • Tape measure	
Enteral nutrition support		X	X		• Feeding machine (pump) • Feeding tubes (in-cluding PEG tubes)	• Food thickeners Syringes
Interventions for sensation of pain						
Assessment of pain	X	X	X		• X-ray machine	
Intraarticular injections	X	X	X			• Injection set
Therapeutic interventions (incl. range of motion exercises, mirror therapy, positioning, active motor training)	X	X	X		• Foam rollers Foam wedges • (Mobile) Mirror Pillow Pulley machine Resistance bands Upper limb workstation Weights	
Provision and training in the use of assistive products for joint protection	X	X	X			
Interventions for bowel and bladder management						
Assessment of bowel functions		X	X		• Anorectal physiological studies (CT, MRI, rectosigmoidoscopy exam) • Stethoscope, Ultrasound • Wall-mounted x-ray viewer X-ray system	• Gloves Lubricant
Assessment of bladder functions		X	X		• Bladder Scanner portable • EMG • Fluoroscope Ultrasound • Urine collection device (incl. graduated cylinder) specimen cup) • Urodynamic System Video fluoroscopic equipment Wall-mounted x-ray viewer • X-ray system	• Catheters Gloves Lubricant
Rectal medications	X	X	X		• Suppository inserter	• Gloves
Therapeutic interventions (incl. muscle strengthening, biofeedback, electrical stimulation, emotional support, diet management)	X	X	X		• Biofeedback device Exercise ball • (Functional) electrical stimulation kit	• Gloves • Lubricant Pads/Diaper • Replaceable sticky elec-trodes

Intervention	Level of care			Assistive devices	Equipment	Consumables
	1	2	3			
Intermittent catheterization	X	X	X		• Foam wedges • Mirror Pillows	• Catheters Gloves Lubricant
Provision and training in the use of assistive products for incontinence management	X	X	X			• Gloves Lubricants
Interventions for the prevention of pneumonia						
Oral hygiene	X	X	X		• Gargle cup • (Mobile) Mirror • Assisted cough devices	• Oral swabs Mouth wash • Tissues Tongue depressor
Interventions for prevention of venous thromboembolism						
Assessment of vascular functions	X	X	X		• Doppler ultrasound • Tape measure	
Heparin injections	X	X	X			• Injection set
Interventions for edema control						
Therapeutic interventions (incl. range of motion exercises, retrograde massage, positioning, intermittent pneumatic compression)	X	X	X		• Foam rollers Foam wedges Intermittent pneumatic compression • Pillows	• Compression bandages (incl. stump, tubular) Massage lotion
Interventions for exercise and fitness						
Physical fitness training (incl. walking)	X	X	X		• Assistant support belt • Cycle ergometer (arm or leg) Exercise ball Exercise mats Hoist and sling • Parallel bars • Pulley machine • Resistance bands Steps (stackable) Timer • Training stairs Weights	
Interventions for joint functions (mobility and stability)						
Assessment of joint mobility and stability	X	X	X		• Goniometer • Wall-mounted x-ray viewer • X-Ray system	
Therapeutic interventions (incl. range of motion exercises, antispastic pattern positioning)	X	X	X		• Foam rollers Foam wedges • Pillows	
Provision and training in the use of assistive products for joint protection	X	X	X			

Intervention	Level of care			Assistive devices	Equipment	Consumables
	1	2	3			
Interventions for muscle functions (muscle power and muscle tone functions)						
Therapeutic interventions (incl. electrical stimulation, muscle strengthening, range of motion exercises, antispastic pattern positioning, repetitive task training)	X	X	X		• Exercise mats • Foam rollers Foam wedges (Functional) electrical stimulation kit • Pillow Pulley machine Resistance bands Upper limb workstation • Weights	• Replaceable sticky electrode pads
Botulinum toxin injections			X		• Ultrasound scanner	• Injection set • Ultrasound gel
Provision and training in the use of assistive products for joint protection		X	X		• Casting kit Splinting kit (static/dynamic)	• Gauze Gloves
Interventions for movement functions (involuntary movement reaction functions, control of voluntary movement functions, gait pattern/walking, hand and arm use)						
Assessment of balance, control of voluntary movement, gait pattern/walking, hand and arm use	X	X	X		• Assistant support belt • Balance board Parallel bars Steps (stackable)	
Therapeutic interventions (incl. biofeedback, electrical stimulation, repetitive task training, treadmill training, aquatic therapy, mirror therapy, constraint induced movement therapy, gait/walking training, escorted walking practice, physical fitness training, virtual reality training, electromechanically assisted training)	X	X	X		• Assistant support belt • Balance board • Biofeedback devices Cycle ergometer (arm or leg) • Elastic bandages • Electromechanical devices • Exercise ball Exercise mats • (Functional) electrical stimulation kit Harness Hoist and sling Mittens • Trampoline Metronome (Mobile) Mirror • Parallel bars Pulley machine • Resistance bands • Steps (stackable) Training stairs Treadmill Upper limb workstation Virtual reality equipment • Water equipment Water floats Wet vests	• Replaceable sticky electrode pads
Interventions for driving						
Assessment of driving			X		• Modified vehicle	

Intervention	Level of care			Assistive devices	Equipment	Consumables
	1	2	3			
Interventions for activities of daily living						
Assessment of activities of daily living	X	X	X			
ADL Training (incl. virtual reality training)	X	X	X		• Assistant support belt Stools/Small benches of varying height Virtual reality equipment	
Provision and training in the use of assistive products (incl. environmental modification) for ADLs (self-care)	X	X	X			
Interventions for prevention of falls						
Assessment of risk for falls	X	X	X		• Balance board Blood pressure measurement device • Stools/Small benches of varying height Timer	
Provision and training in the use of assistive devices (incl. environmental modification) for safe mobility	X	X	X			
Interventions for work and employment						
Assessment of work and employment	X		X		• Computer/tablets with software	
Vocational training	X		X		• Calculation workbooks Computer/tablets with software	

Intervention	Level of care			Assistive devices	Equipment	Consumables
	1	2	3			
Work place visits (incl. environmental modification)	X		X			
Interventions for recreation and leisure						
Leisure therapy	X		X		• Books • Crafting supplies Cue (e.g. timer, log, alarm) • Music • Toys	

10.2.3 Specific assistive products for rehabilitation in people with lower limb amputation due to complication of diabetes.

Table 61 presents the specific assistive products, equipment and consumables required for rehabilitation of people with with lower limb amputation due to diabetes.

Table 61. Assistive devices, equipment and consumables for rehabilitation in people with lower limb amputation due to diabetes

Intervention	Level of care			Assistive devices	Equipment	Consumables
	1	2	3			
Interventions for pain management						
Epidural treatment		X	X			Injection set
Interventions for skin and stump care						
Skin care	X	X	X			Alcohol wipes Dressings Gauze Gloves Lubricant
Removable Rigid Dressing		X	X			Alcohol wipes Dressings Gloves Plaster
Interventions for cardiovascular functions						
Assessment of blood vessel functions	X	X	X		Doppler ultrasound Plethysmograph	
Interventions for edema control						
Assessment of edema	X	X	X		Tape measure	

Intervention	Level of care			Assistive devices	Equipment	Consumables
	1	2	3			
Compression therapy (incl. Removable Rigid Dressing)	X	X	X			Alcohol wipes Dressings Elastic and non-elastic bandages Gloves Plaster Powder Stump socks
Interventions for joint functions (mobility of joints)						
Assessment of joint mobility	X	X	X		Goniometer	
Therapeutic interventions (incl. range of motion exercises, stretching)	X	X	X		Exercise mats Foam rollers Pillow	
Interventions for muscle functions (muscle power functions)						
Assessment of muscle strength	X	X	X		Resistance bands Weights	
Muscle strengthening	X	X	X		Pulley machine Resistance bands Upper limb workstation Weights	
Interventions for movement functions (involuntary movement reaction functions, gait pattern functions/walking)						
Assessment of gait and walking	X	X	X		Parallel bars	
Therapeutic interventions (incl. balance training, gait training)	X	X	X		Balance board Exercise mats (Mobile) mirror Parallel bars Steps (stackable) Training stairs Trampoline	
Interventions for Mobility						
Assessment of mobility	X	X	X		Balance board Exercise mats Parallel bars Stools/Small benches of varying height Training stairs	
Mobility training (incl. transfer training)	X	X	X		Balance board Cycle ergometer (arm or leg) Exercise mats (Mobile) mirror Parallel bars Steps (stackable) Stools/Small benches of varying height Training stairs	
Provision and training in the use of assistive devices for mobility (other than walking)	X	X	X		Wheelchair training assistant strap	

Intervention	Level of care			Assistive devices	Equipment	Consumables
	1	2	3			
Interventions for prevention of falls						
Assessment of risk for falls	X		X		Balance board Foam mat	
Interventions for driving						
Assessment of driving	X		X		Modified vehicle	
Driving training			X		Modified vehicle	
Interventions for activities of daily living						
Assessment of activities of daily living	X	X	X			
ADL Training	X	X	X		Stools/Small benches of varying height	
Provision and training in the use of assistive products incl. environmental modification for ADLs	X		X			
Interventions for exercise and fitness						
Physical fitness training	X		X		Cycle ergometer (arm or leg) Exercise mats Pedometer Stop watch Treadmill	
Interventions for education, work and employment						
Assessment of education, work and employment	X		X	Prostheses, lower limb	Computer/tablets with software	
Educational/ Vocational training	X		X		Computer/tablets with software Basic manual work tools	
Environmental modification				Hand rail/grab bars Ramps, portable		
Interventions for recreation and leisure (including sport)						
Training for recreation and leisure activities (incl. sports)	X		X	Canes/Sticks Crutches, axillary/ elbow Prostheses, lower limb Rollators Walking frames/ walkers	Cycle ergometer (arm or leg) Crafting supplies Treadmill Toys	

Guidelines:

Cardiovascular disease (Ischemic heart disease)

The interventions included in these lists have been selected by a development group from the following clinical practice guidelines:

- National Institute for Health and Care Excellence (NICE): MI - Secondary prevention in primary and secondary care for patients following a myocardial infarction. Partial update of NICE CG48; 2013
- Scottish Intercollegiate Guidelines Network (SIGN): Cardiac rehabilitation - A national clinical guideline, SIGN; 2017
- International Council of Cardiovascular Prevention and Rehabilitation's Consensus statement: Cardiac rehabilitation delivery model for low-resource settings; 2016

Stroke

The interventions included in these list have been selected by a development group from the following clinical practice guidelines:

- Scottish Intercollegiate Guidelines Network (SIGN): Management of patients with stroke: Rehabilitation, prevention and management of complications, and discharge planning; 2010
- National Clinical Guideline Center (NICE): Stroke Rehabilitation - Long term rehabilitation after stroke; 2013
- Canadian stroke best practice recommendations: Stroke rehabilitation practice guidelines, update 2015
- Australian stroke foundation: Clinical guidelines for stroke management: Chapter 5 (Rehabilitation), 6 (Managing complications) and 8 (Community participation); 2017

Lower limb amputation

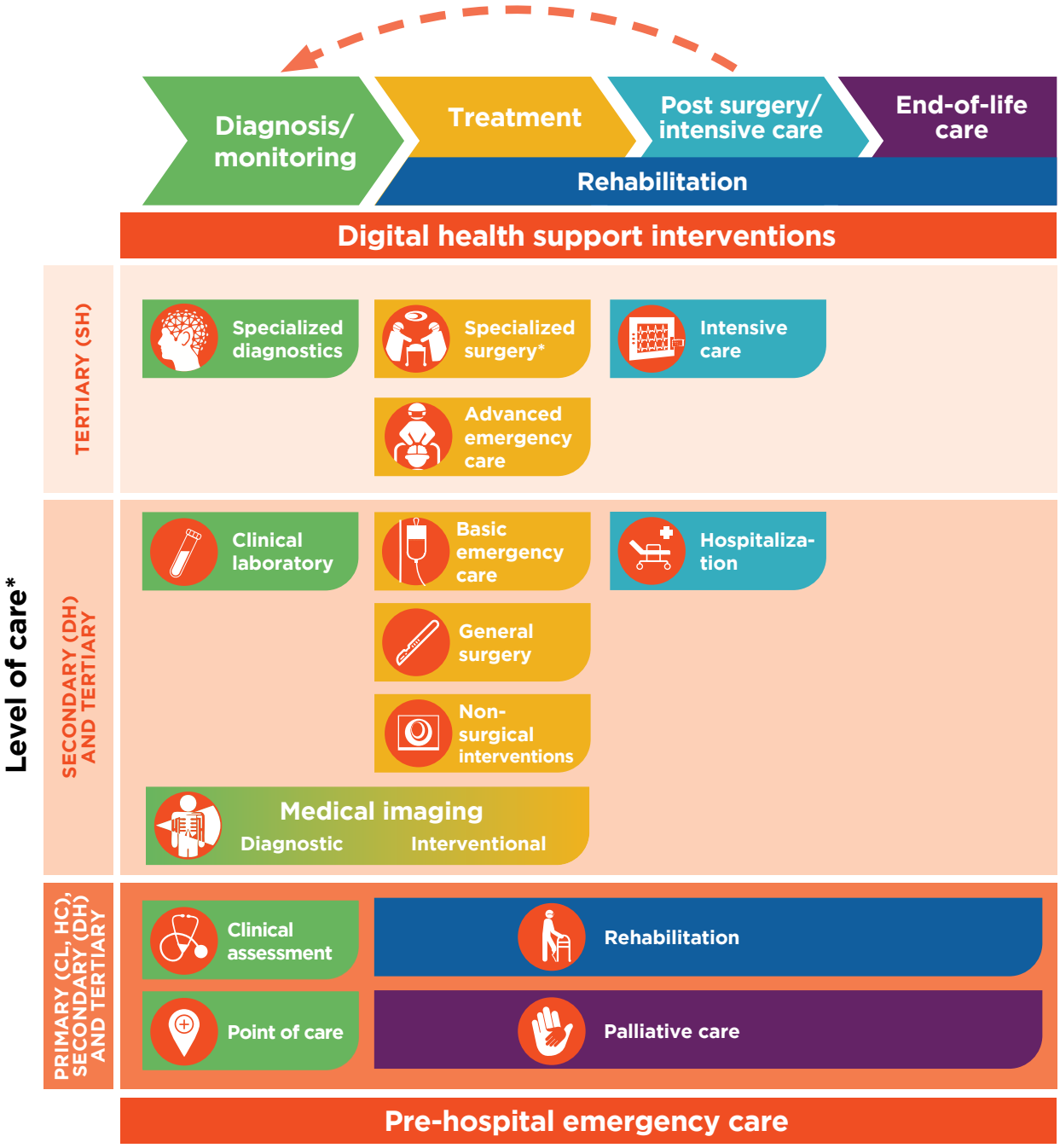
The interventions included in these lists have been selected by a development group from the following clinical practice guidelines:

- Netherlands Society of Physical and Rehabilitation Medicine, ISPO international: Guideline Amputation due to vascular reasons and prosthetics of the lower limb; 2012
- British Association of Chartered Physiotherapists in Amputee Rehabilitation: Clinical guidelines for the pre- and post operative physiotherapy management of adults with lower limb amputations; 2016
- Department of Veteran Affairs, Department of Defense: Va/DoD Clinical practice guideline for rehabilitation of individuals with lower limb amputation; 2017

11. Palliative care

Navigation diagram

Click on the diagram to navigate to any section of this document.



Key:
* Including cardiovascular, neurological, ophthalmic and nefrology.
CL community level; health post
DH district/general hospital; interventions can also be offered in a first referral outpatient clinic
HC health centre/outpatient clinic
SH specialized/regional/national hospital; specialized care outpatient unit

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 *(53)*. Palliative care:

- provides relief from pain and other distressing symptoms;
- affirms life and regards dying as a normal process;
- intends neither to hasten nor to 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;
- enhances 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, in the United Kingdom, the National Council for Hospice and Specialist Palliative Care Services *(54)* 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 multiprofessional 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 *(55, 56)* and other organizations. Within a hospital, inpatient 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 or rooms under the primary care of their treating physician. A hospice may mean a separate service involving a range of components, including an inpatient unit, home care, day care, outpatient clinics and bereavement support service.

Detailed recommendations for the type of infrastructure required for palliative care can be found in the WHO list of priority medical devices for cancer management.

11.1 General priority medical devices for palliative care

Tables 69 and 70 present general medical devices that can be used for the general palliative care needs of many diseases, including cardiovascular diseases and diabetes, and specific medical devices.

Table 62. List of general priority medical devices for palliative care interventions

Procedure	Medical devices category	Capital equipment	Consumables, single-use medical devices
Palliative care delivery	Medical equipment	Blood glucose meter[a], portable	Micro cuvettes or strips, according to manufacturer
		Fixed examination/treatment light	
		Nebulizer, with accessories	
		Pulse oximeter, portable, with accessories	Sensors
		Refrigerator	
		Fridge freezer	
		Stethoscope, binaural	
		Thermometer, clinical, digital 32–43°C	
		Sphygmomanometer	Cuffs, blood pressure
		General physical examination set	Includes ophthalmoscope, otoscope, lamp)
		Oxygen therapy flowmeter, dial type (if pipeline available)	Oxygen supply (cylinder, oxygen concentrator or pipeline)
		Suction availability (accessories for wall or portable equipment)	
		Electrocardiography system[a] (optional)	
		Syringe pump or elastomeric pumps (optional)	
		Infusion pump for enteral nutrition (optional)	
		Hammer for neurological examination	Tape measurement
		Non-heated respiratory humidifier	
	Medical furniture	Stretcher	
		General cabinet	Infusion set
		Dressing trolley, stainless steel, two trays	
		Lifting device for patient	
		Wheelchair	
		Cabinet, medicine, with lock (consider national regulations)	
		Walking aids	
		Table, instruments, Mayo type, stainless steel, on castors	
		Pressure relief mattress	
		Pressure relief cushion	
	Instruments	Forceps, dressing, Cheron, 250 mm	
		Surgical instruments, dressing set	
		Scalpel handle	Blades, reusable and single-use
		Basic surgery set, minor tray	
	Personal protective equipment and clothing		Glasses, safety, regular size
			Gloves, non-sterile, single-use
			Gloves, surgical, single-use

a. These capital medical devices are described in the table on generic equipment in Annex 4.

Table 63. List of general priority medical and assistive devices for pain management, by domain

Domain, intervention category	Assistive products	Capital equipment	Service delivery platform	Health worker
Interventions for pain: chronic regional pain syndrome (CRPS), neuropathic pain, shoulder pain				
Screening and assessment		Visual analogue scale X-ray system	First level clinic General referral clinic Specialized referral clinic Outreach level	General medical practitioner Specialist medical practitioner PRM physician Nursing professional Occupational therapist Physical therapist Psychologist Community health worker
Pharmacological agents			First level clinic General referral clinic Specialized referral clinic Outreach level	General medical practitioner Specialist medical practitioner PRM physician Nursing professional
Preventive, promotive, restorative and compensatory approaches	Slings	Mirror, mobile Activity kit for arm function Pulley machine Resistance bands Upper limb workstation Weights Pillows Foam rollers Foam wedges	First level clinic General referral clinic Specialized referral clinic Outreach level	Nursing professional Occupational therapist Physical therapist Community health worker
Self-management approaches	Slings	Pillows Foam wedges	First level clinic General referral clinic Specialized referral clinic Outreach level	General medical practitioner Specialist medical practitioner PRM physician Nursing professional Occupational therapist Physical therapist Community health worker

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

- tools for assessment (approved and validated tools for pain and other symptoms);
- bed sets: sheets, pillows, pillowcases, blankets, duvet, pressure relief mattress, and 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 agents for modifying the consistency of food in cases of dysphagia;
- other furniture and devices: table with light, fan, radio or music device;
- if relatives stay overnight, option to provide a recliner chair or sofa bed;
- aromatherapy.

The palliative care unit should have access to an X-ray system, computed tomography system and echographer, and blood laboratory test equipment. The devices and furniture should be adapted for adults' and children's needs. Proper patient identification through ID tags or similar is recommended.

Guidance documents

- WHO list of priority medical devices for cancer management (palliative care chapter). Geneva: World Health Organization; 2017 (https://www.who.int/publications/i/item/9789241565462).
- WHO Priority Assistive Products List. Geneva: World Health Organization; 2016 (https://apps.who.int/iris/bitstream/handle/10665/207694/WHO_EMP_PHI_2016.01_eng.pdf?sequence=1)

IV.Implementation strategy

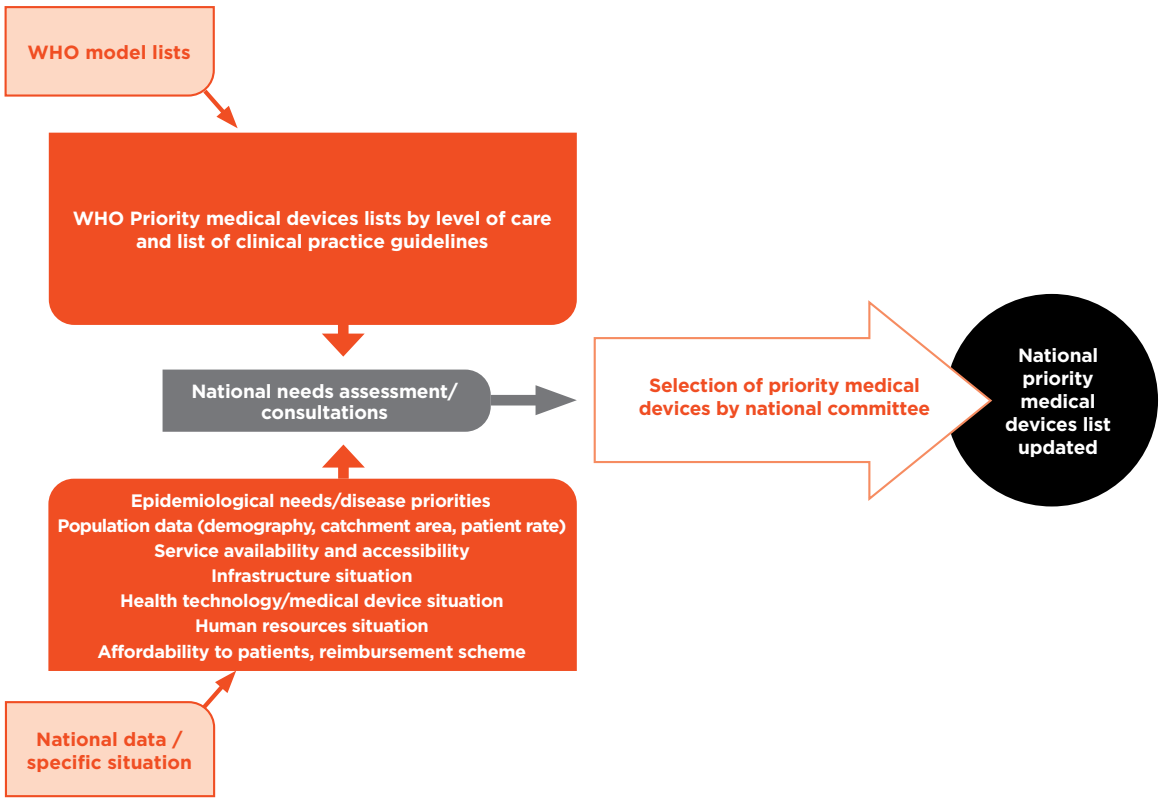
IV.I Needs assessment for policy and strategy development

The lists presented in this document define priority medical devices for clinical interventions extracted from guidelines addressing selected NCDs: cardiovascular diseases and diabetes. Although the lists are not exclusive, they can serve as guidance for countries seeking to develop or implement a management policy or strategy for medical devices specific to these diseases. It is important to note the interdependence of these technologies: best outcomes cannot be achieved by investing in only one set of technologies. Diagnostic methods must be combined with therapeutic capability to achieve meaningful impact. This chapter includes a general implementation strategy and additional considerations to reach pragmatic decisions.

As mentioned, it is important for each country to define an implementation plan that will consider their country-specific needs, epidemiological situation, availability of infrastructure, and related human resources and finances, as well as affordability to patients.

The WHO model lists can be used by countries to develop or update their national medical devices list, to support universal health coverage, address emergencies and ensuring well being of population. Figure 13 illustrates the general process to adapt the WHO model list to the national situation, perform a needs assessment and define the medical devices that would be added to the national list. This procedure can be done at regional or institutional level, as needed. The following section will describe the implementation steps required to increase access to the specific medical devices selected, to meet the population needs.

Figure 13. General needs assessment process to consider the WHO priority lists to develop or update the national medical devices list.



Source: Modified from WHO needs assessment for medical devices *(57)*.

Needs assessment and implementation plan

1. Perform a needs assessment of in-country resources for cardiovascular and diabetes management:
   - **a.** First, consider the national health plan and any available NCD 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 centres and community health posts:
     - **i.** It is important that all levels of care are included in the considerations of the implementation plan, from community health centres to specialized hospitals, even if only one or many hospitals are being equipped.
     - **ii.** The network has to consider reference to higher levels of care, emergency services and outpatient specialized units.
   - **c.** Review the lists, unit by unit, with local specialists, and compare to your inventory or availability of technologies to manage NCDs. Note the devices that are general and can serve other diseases.
   - **d.** Compile information about resources available or not yet appropriate or sufficient on the following topics:
     - **i.** Health facilities that could be used for cardiovascular diseases or diabetes 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
       - » surgery
       - » palliative care and end-of-life care.
     - **iii.** Specialized human resources, particularly those mentioned in this document:
       - » cardiologists, endocrinologists, intensivists, neurologists, specialized nurses
       - » biomedical engineers, equipment technicians
       - » laboratory technicians, biomedical laboratory scientists
       - » medical physicists
       - » radiologists
       - » radiographers.
     - **iv.** National treatment guidelines, protocols or care pathways for cardiovascular diseases or diabetes.
     - **v.** Priority interventions if defined by an insurance package linked to universal health coverage and reimbursement schemes.
     - **vi.** Target population:
       - » types of procedures for types of patients
       - » population distribution in the country
       - » catchment areas for diagnosis
       - » support for patients' transportation to and stay in treatment centres.
     - **vii.** Funding allocation
       - » Depending on the country or setting, this funding could be pre-established or will have to be calculated depending on the technology required, followed by search for approval.
       - » Funding to support the ongoing interventions for diagnosis, treatment, monitoring and palliative care is required.
       - » Consider other sponsorships and allocation of funds to national cardiovascular diseases or diabetes programmes 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 intervention for ccardiovascular diseases or diabetes disease management.
    c. Equity, gender and ethical issues, if applicable.
    d. Equipment complementary to other diseases.
    e. Available budget for:
        i. Infrastructure, to install equipment (e.g. haemodialysis units, cardiac cath units, stroke units).
        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, for example in the areas of quality control and safety, complementary to the capital equipment.
    f. Feasibility and organizational challenges, such as where to place the technology – where more resources are available or where most of the target population is based.

    Most of these considerations are part of health technology assessment and health technology management studies, subject to a certificate of need. Most of them should be considered by a specially convened committee to make informed, evidence-based decisions.

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:
    a. Regulatory clearance: the regulatory approval process of the specific technology performed by the national regulatory agency – the ministry of health for medical devices, or the nuclear, radiological or similar body for other relevant devices. These entities need to be in 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 haemodialysis, nuclear medicine or other diagnostic and interventional 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 and health care workers by the manufacturer.
    g. Supply chain of consumables.
    h. Verification of quality, safety and performance.
    i. Decommissioning and waste management procedures *(58, 59)*.

WHO database of priority medical devices

WHO has developed a database, clearing house to host all the medical devices listed in this publication and other related publications of selection of priority medical devices. "MeDevIS" is the priority medical devices information systems, webbased, that includes technical information and will be periodically updated. This can be a very helpful tool to search, review and select medical devices by intervention, by delivery platform or by publication.

The beta version, as of June 2021, can be found at https://medevis.test.evidenceprime.com.

Guidance documents

- WHO list of priority medical devices for cancer management. Geneva: World Health Organization; 2017 (https://www.who.int/publications/i/item/9789241565462).
- Needs assessment for medical devices. WHO Medical Device Technical Series. Geneva: World Health Organization; 2011 (https://apps.who.int/iris/bitstream/handle/10665/44562/9789241501385-eng.pdf?sequence=1&isAllowed=y).
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V Concluding remarks

The present publication was completed thanks to a collaboration between interdisciplinary experts from around the world, as well as supportive nongovernmental organizations. It is envisioned that these lists of medical devices classified by clinical unit will assist policy-makers, health care managers and technical experts to define the needs of each setting and to inform the development or update of the national medical devices lists approved for procurement or reimbursement, towards universal health coverage.

Medical devices run the substantial risk of being unused due to technology misalignment with deployment settings *(60)*. 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 also an important consideration, and their ability to deliver services within health care systems should be carefully evaluated. The lists presented in this publication should be adapted by a local committee to different cultural norms and reviewed according to local epidemiology, national policies, regulatory frameworks, and the 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 patients. These technologies require multidisciplinary expertise to be implemented. 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 management of NCDs.

Much work is still needed in order to increase access to the appropriate, good-quality medical technology required to prevent, diagnose, treat, and monitor NCDs worldwide, including cardiovascular diseases and diabetes, and to develop the human resource competencies of specialized interventions and ensure financial resources to provide the services under the universal health coverage initiative.

The recent COVID-19 global situation calls for prioritizing investment in prevention and management of health. It has been noted that population with NCDs are more prone to have COVID-19 complications, therefore the prevention and management of NCDs is of paramount importance and thus, important to have access to the medical devices required for them.

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Annex 1. Expert information

All experts provided conflict of interest statements, which were reviewed and assessed in accordance to WHO requirements and no conflicts were found.

Table A1.1 Experts on cardiovascular diseases and related medical devices

Name	Affiliation	Country	Email	Justification
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Donald DiPette	University of South Carolina	USA	donald.dipette@uscmed.sc.edu	Health Sciences Professor
Keiko Fukuta	Bureau, Ministry of Health, Labour and Welfare	Japan	fukuta-keiko@mhlw.go.jp	Biomedical Engineer
Ganesan Karthikeyan	Cardiothoracic Sciences Centre, All India Institute of Medical Sciences	India	karthik2010@gmail.com	Doctor of Medicine (DM) in Cardiology and Health Sciences Professor
Kamel Abdul Rahim	WHO Iraq Country Office	Iraq	abdulrahimk@who.int	Technical Officer
Laura Patricia Lopez Meneses	Medical devices consultant	Mexico	ing.lplm@gmail.com	Biomedical engineer and patient perspective

Table A1.2 Experts on stroke and related medical devices

Name	Affiliation	Country	Email	Justification
Shrish Naresh Acharya	Colonial War Memorial Hospital	Fiji	shrish.acharya@health.gov.fj	Consultant Physician
Alexander Kostyuk	Joint Commission for Quality Health Care Services, Ministry of Health	Kazakhstan	alex.vl.kostyuk@gmail.com	Chair of HTA Committee
Patrik Michel	World Stroke Organization, CHUV	Switzerland	patrik.michel@chuv.ch	Stroke medical specialist
Isabel Watanabe Ortega	Medical Equipment Division, Planning of Medical Infrastructure, IMSS	Mexico	isabe.wat73@gmail.com	Biomedical Engineer
Alessandro Stievano	International Council of Nurses	Switzerland	stievano@icn.ch	Director for Nursing and Health Policy

Table A1.3 Experts on diabetes and related medical devices

Name	Affiliation	Country	Email	Justification
Dinsie Williams	Consultant	Sierra Leone/ Canada	dinsbw@gmail.com	Biomedical Engineer
Garry John	Norfolk and Norwich University Hospital	United Kingdom	garry.john@nnuh.nhs.uk	Consultant Clinical Biochemist
Ambady Ramachandran	India Diabetes Research Foundation and Dr. A. Ramachandran's Diabetes Hospitals	India	dr.ramachandran@ardiabetes.org	Medical Doctor
Emma English	School of Health Sciences, University of East Anglia	United Kingdom	emma.english@uea.ac.uk	Clinical Biochemist
Babacar Gueye	Ministère de la Santé et de l'Action Sociale	Senegal	bbcar137@gmail.com	Specialist in Public Health
Santiago Hasdeu	Ministry of Health of Neuquén Province, Comahue National University, participated on behalf of PAHO	Argentina	hasdeusanti@gmail.com	Medical Doctor
Belma Malanda	International Diabetes Federation	Belgium	belma.malanda@idf.org	Senior Programme Manager
Gabriele Thumann	Hopitaux Universitaires de Geneve	Switzerland	gabriele.thumann@hcuge.ch	Medical Doctor

Annex 2. Search terms for clinical guidelines by Cochrane Netherland

Table A2.1 Search criteria for guidelines on cardiovascular diseases

Guideline resource	Search terms
Emergency Care Research Institute Guidelines Trust	"Essential Hypertension" OR "Coronary Atherosclerosis" OR "Heart Failure" OR "Cardiomyopathy" OR "Valvular Disease" OR "Congenital Heart Disease" OR "Arrhythmia" OR "Arterial Disease" OR "Deep Vein Thrombosis" OR "Pulmonary Embolism" *Restricted from 2017 to current*
	Full database search, select clinical area: Cardiology *Restricted from 2017 to current*
Turning Research into Practice database	(title: "Essential Hypertension" OR "Coronary Atherosclerosis" OR "Heart Failure" OR "Cardiomyopathy" OR "Valvular Disease" OR "Congenital Heart Disease" OR "Arrhythmia" OR "Arterial Disease" OR "Deep Vein Thrombosis" OR "Pulmonary Embolism"), from 2017
Global Health Library	ti:(ti:("Essential Hypertension" OR "Coronary Atherosclerosis" OR "Heart Failure" OR "Cardiomyopathy" OR "Valvular Disease" OR "Congenital Heart Disease" OR "Arrhythmia" OR "Arterial Disease" OR "Deep Vein Thrombosis" OR "Pulmonary Embolism") AND (instance:"ghl") AND (type_of_study:("guideline") AND la:("en"))) AND (instance:"ghl") AND (year_cluster:("2016" OR "2017" OR "2018")) AND (instance:"ghl")
Guidelines International Network: International Guidelines Library	"Essential Hypertension" OR "Coronary Atherosclerosis" OR "Heart Failure" OR "Cardiomyopathy" OR "Valvular Disease" OR "Congenital Heart Disease" OR "Arrhythmia" OR "Arterial Disease" OR "Deep Vein Thrombosis" OR "Pulmonary Embolism" *Restricted from 2017 to current*
Canadian Agency for Drugs and Technologies in Health reports	Using filters under "Disease and Conditions" (Acute Coronary Syndrome, Heart Failure, Heart Attack, Peripheral Vascular Disease, Thrombosis), and "Publication date" *Restricted from 2017 to current*
National Institute for Health and Care Excellence evidence search	"Essential Hypertension" OR "Coronary Atherosclerosis" OR "Heart Failure" OR "Cardiomyopathy" OR "Valvular Disease" OR "Congenital Heart Disease" OR "Arrhythmia" OR "Arterial Disease" OR "Deep Vein Thrombosis" OR "Pulmonary Embolism" *Filtered on guidance, area is clinical* *Restricted from 2017 to current*
World Heart Federation	*No specific search terms; global search of guidelines*

Note: Current = June 2019.

Table A2.2 Search criteria for guidelines on stroke

Guideline resource	Search terms
Emergency Care Research Institute Guidelines Trust	Full database search, select clinical area: Stroke *Restricted from 2017 to current*
Turning Research into Practice database	(title:stroke) from: 2017
Global Health Library	ti:(ti:(stroke) AND (instance:"ghl") AND (type_of_study:("guideline") AND la:("en"))) AND (instance:"ghl") AND (year_cluster:("2016" OR "2017" OR "2018"))
Guidelines International Network: International Guidelines Library	"Stroke" *Restricted from 2017 to current*
Canadian Agency for Drugs and Technologies in Health reports	Using filters under "Disease and Conditions" (Stroke), and "Publication date" *Restricted from 2017 to current*
National Institute for Health and Care Excellence evidence search	"Stroke" *Filtered on guidance, area is clinical* *Restricted from 2017 to current*
World Stroke Organization	*No specific search terms; global search of guidelines*

Note: Current = June 2019.

Table A2.3 Search criteria for guidelines on diabetes

Guideline resource	Search terms
Emergency Care Research Institute Guidelines Trust	Full database search, select clinical area: Diabetes *Restricted from 2017 to current*
Turning Research into Practice database	(title:diabetes) from: 2017
Global Health Library	ti:(diabetes) AND (instance:"ghl") AND (type_of_study:("guideline") AND la:("en") AND year_cluster:("2016" OR "2017"))
Guidelines International Network: International Guidelines Library	"Diabetes" *Restricted from 2017 to current*
Canadian Agency for Drugs and Technologies in Health reports	Using filters under "Disease and Conditions" (Diabetes), and "Publication date" *Restricted from 2017 to current*
National Institute for Health and Care Excellence evidence search	"Diabetes" *Filtered on guidance* *Restricted from 2017 to current*
International Diabetes Federation	*No specific search terms; global search of guidelines*

Note: Current = June 2019.

Annex 3. Shortened version of the NEATS instrument (built on the framework of the AGREE II tool)

For most items of the NEATS Instrument, there is a 5-point Likert scale from 1 (lowest) to 5 (highest) to score the degree of adherence to the rating criteria. For the items about transparency and Guideline Development Group (GDG) composition, there is a scale consisting of "yes", "no", or "unknown". Good quality was defined as an average score of 3 points or higher (1 = Poor, 2 = Fair, 3 = Good, 4 = Very Good, and 5 = Excellent) combined with clear information on transparency and GDC composition. The Emergency Care Research Institute Guidelines Trust presents TRUST (Transparency and Rigour Using Standards of Trustworthiness) scorecards for guidelines. These TRUST scorecards consist of the items of the NEATS instrument. If a TRUST scorecard was available for a guideline, we used these item scores.

Funding and potential conflicts of interest

- The Clinical Practice Guideline (CPG) discloses and states explicitly its funding source.
- Financial conflicts of interest of GDG members have been disclosed and managed.

Composition of the GDG

- The GDG includes persons from a variety of relevant clinical specialties and other professional groups.
- The guideline states that it included a methodological expert in the GDG, and it identifies the methodologist.

Systematic review of evidence

- The CPG or a related companion document describes a search strategy that includes a listing of databases searched; a summary of search terms used; and the specific time period covered by the literature search, including the beginning date (month and year) and end date (month and year).
- The CPG or a related companion document describes the study selection; description includes the number of studies identified, the number of studies included, and a summary of inclusion and exclusion criteria.
- The CPG or a related companion document provides a synthesis of evidence from the selected studies; i.e., an analysis of individual studies and the body of evidence, in the form of a detailed description or evidence tables, or both.

Foundations for recommendations

- The CPG provides a grading or rating of the level of confidence in or certainty regarding the quality or strength of the evidence for each recommendation.
- The potential benefits and harms of recommended care are clearly described.

Annex 4. Explanations concerning medical devices

To synthesize the lists on each section, equipment, medical devices, consumables and disposable devices are not detailed in the tables. The listed capital equipment is considered complete and ready for operation when purchased. The accessories are the components external to the main unit (for example, cables, sensors, probes, trolley), and they are usually delivered with their corresponding capital equipment along with the internal software, batteries and battery chargers if needed (batteries may be rechargeable or alkaline). Nearly all medical equipment must be able to function on a power grid as well as on a battery in the event of a failure of the public electrical grid, for the safety of the patient and to enable completion of the ongoing procedure.

Some accessories or software can vary from child to adult, by age or by gender (for example, blood pressure cuffs and oximetry sensors). It is advisable to have at least one of each, depending on the patients who will use the equipment in question.

When a device has several functions, such as the anaesthesia system, it can be integrated into a single system or kept in separate units.

Table A4.1 Description of select medical devices

Medical device	Description and principal components	Consumables, single-use
Anaesthesia system	A combination of devices that deliver anaesthesia gases and monitor the vital signs of patients who are anaesthetized. The principal components are: ventilator (mechanical or electronic) patient physiological monitor with analysis of anaesthetic gas and CO2, in one or separate units halogen vaporizers, according to the gas used soda lime tank oxygen, nitrous oxide, air inlets, which feed a mixer-flowmeter.	Single-use patient breathing circuit for gas (O2, air, N20, halogens) Soda lime
Anaesthesia system, MRI safe	Anaesthesia system that does not contain materials sensitive to the magnetic field of the MRI device.	Needs the same consumables as the ordinary unit
Blood gas analyser, automated or semi-automated		Venipuncture kit
Blood glucose meter	A device that measures the amount of sugar (glucose) in blood.[a] Because it is in direct contact with bodily fluids, disinfection and protection equipment is required when it is in use.	Single-use sterile lancets for capillary blood collection Blood glucose test strips Disinfectant pads Alcohol and swabs Batteries Gloves
Cardiac catheterization (cath) lab	A suite within a hospital that houses multiple devices that are used for cardiac and vascular interventions, such as coronary angiography and transcatheter aortic valve replacement. The interventions typically involve the insertion of one or more catheters under image guidance. The devices may be used for diagnostic or interventional (treatment) purposes.	Catheters Contrast agent
Clinical chemistry analyser	A device that measures the amount of biochemicals in a sample of blood serum, urine, saliva, or tissue, using multiple methods. Interaction of a known chemical or reagent with the sample is used for the assessment. The concentration of the biochemical is compared to a known sample.	Reagents Calibrators Controls Venipuncture kit

Medical device	Description and principal components	Consumables, single-use
Computed tomography (CT) system	A radiographic system that generates transveral images of segments of anatomy. Its primary components are: high-voltage X-ray generator X-ray tube detector electronic data acquisition system gantry image processor. Data from a CT scanner may be transferred to an electronic storage device or an image display system. When the X-ray tube is rotating in the gantry, 4, 16, 32, 64 ... slices may be obtained simultaneously per rotation of the tube; 16 slices are enough for imaging nearly all static structures. Cardiac imaging requires at least 32 simultaneous slices. The more simultaneous slices available, the more expensive the equipment, and the more costly its operation and maintenance.	Contrast agent (for select procedures)
Digital storage media	An electronic device that can receive, save, and transmit digital data. This can be a compact disc (CD), a digital video disc (DVD), or a memory stick.	CD DVD Memory stick
Dry printer	A device that does not use liquids to print. It may be: a thermal printer, which uses thermal paper a laser printer, which uses laser films a paper printer, which uses standard paper.	Thermal paper Laser film Standard paper
Electrocardiography system or electrocardiogram (ECG)	A device that measures and displays electrical activity of the heart. It may use 3, 6, 12 data acquisition channels and leads, depending on the procedure.	Electrocardiography electrodes, single-use Gel
Emergency cart	Medical furniture that contains devices and supplies that are most often needed to treat patients with traumatic conditions: blood pressure device automated external defibrillator (AED) contrast reaction kit emergency kit.	
Exercise cardiac stress test device	A device that measures and records a patient's vital signs as they transition between a state of rest and various active states. It comprises: stress test treadmill or bicycle ergometer electrocardiography system with 12 leads stress exercise monitoring system patient physiological monitor automated external defibrillator (AED) stretcher.	Electrodes Gel
Immunoassay analyser	A device that measures the amount of biochemicals in a sample of blood serum, urine, saliva, or tissue. An antibody's interaction with the sample is typically evaluated. The concentration of the biochemical is compared to a known sample.	Reagents Calibrators Controls Venipuncture kit
Magnetic resonance imaging (MRI) system	A system that produces images of anatomy obtained by analysing radiofrequency signals emitted from tissue under a high-intensity uniform magnetic field. Clinical magnetic field strengths range from 0.5 to 3 Tesla. Systems up to 7 Tesla have been tested on humans. Its primary components are: magnet radiofrequency coils.	Contrast agent
MRI-safe medical device	A device that does not contain materials sensitive to the magnetic field of an MRI system.	Same as the regular device
Patient physiological monitor	A device that displays signals and values reflective of vital signs such as heart rate, blood oxygen saturation, non-invasive blood pressure.	Electrodes Cuffs (various sizes) Oxygen saturation sensors

Medical device	Description and principal components	Consumables, single-use
Patient breathing circuit	Tubes, connectors and masks that are connected to a ventilator to help a patient breathe. May be reusable or single-use, non-sterile or sterile, for children or adult patients.	
Surgery suction system	A device that aspirates fluid from body cavities during surgery. It comprises: electrical or mechanical aspirator of liquid two 5 litre collection vessels antimicrobial filter tubing with a sterile tip or catheter.	
Thermometer	A device that measures and displays the temperature of a patient. Commonly used thermometers may be analog and contain gallium, or digital with tympanic or infrared technology.	Alcohol swabs Probe covers Batteries (if digital)
Ultrasound scanner	A device that uses ultrasonic waves to determine the structure of anatomy. Its primary components are probes, a data acquisition system, and a display. The probes send out sounds waves at frequencies ranging from 3 MHz to about 12 MHz and record echoes from within the body. Low-frequency signals target anatomy far below the surface while high-frequency signals target superficial anatomy and produce images with high spatial resolution. Ultrasound scanners are used commonly for fetal monitoring in obstetrics and in gynaecology. Other applications include functional cardiac and vascular imaging, breast imaging, and abdominal imaging. Probes come in three primary shapes: convex, concave, and linear. Data from an ultrasound scanner may be transferred to an electronic data storage device, a network, a dry printer, or an image display system.	Conductive gel Paper for dry printer Disposable probe drapes Antimicrobial solution to disinfect the probes
X-ray system	A radiographic system that produces two-dimensional images of anatomy. The system consists of a high-voltage X-ray generator, an X-ray tube, a flat panel detector, and an image processor (analog or digital). Data from an X-ray system may be transferred to an electronic data storage device, a network, or an image display system.	

a. Blood glucose monitoring devices. U.S. Food and Drug Administration (https://www.fda.gov/medical-devices/vitro-diagnostics/blood-glucose-monitoring-devices).

Annex 5. Instrument kits and sets

Venipuncture kit
Tourniquet
Needles, various sizes
Syringes, various sizes
Safety needles
IV catheter
IV saline fluid packages
IV lines
Glass and plastic vials
Vacuum blood collection tubes, with or without anticoagulant
Vacuum container hub and needles
Lancets
Alcohol and swabs or prep swabs
Clean gauze squares
Cotton swabs
Roll of strapping
Gloves, non-latex
Waste container for sharps

Reagent kit
Diluent
Distilled water
Reservoir bottle

Cerebrospinal fluid puncture kit
Sterile universal specimen bottle, grey
Cerebrospinal fluid manometer
Lumbar puncture set, adult and child
Collection tube, sterile plastic tubes
Skin-cover adhesive strip
Spinal needle
Spinal anaesthesia needle, single-use
Syringes, various sizes
Hypodermic needles: 25G, 23G, 21G
Gauze strip, antimicrobial
Antiseptic skin cleansing agent
Skin marker pen

Urine collection kit
Urine collection device (graduated cylinder, specimen cup)
Urine dipsticks
Scale
Sample tubes
Funnel

Cath lab set
Bandbag, 36 x 40 in., with tape 1
Bowl, guidewire, 2500 cc 1
Bowl, sponge,16 oz., 500 cc 1
Clamps, towel
Cover, setup
Domebag
Drape, femoral angiography
Forcep, Halstead mosquito
Gowns
Introducer, guidewire
Labels, waterproof
Marker, skin
Medicine cups, graduated
Needle holder
Needles, 18G x and 25G x
Scalpel handle with blades
Scissors
Sponges
Syringes, various sizes
Table cover
Towels
Tray, organizer
Povidone-Iodine Scrub Solutions
Pressure transducer kit
Access sheath(s)
Guidewire, .035 J-tipped, 180/300 cm lengths
Catheters, diagnostic, femoral/radial
Interventional
Catheters, interventional, femoral/radial
Workhorse guidewire(s), 183/300 cm length
Specialty guidewire(s)
Angioplasty balloons
Cutting balloon(s)
Drug-eluting stent(s)
Bare metal stent(s)
Covered stent(s)
Balloon indeflator

Skull neurosurgery set
Gouge, Leksell or Leksell-Stille, angulated, wide point, length 229–250 mm
Gouge, Stille-Luer, straight, length 200–230 mm
Gouge, Echlin, wide point, length 230 mm
Gouge, Stille-Luer, curved, length 220–230 mm
Bunnell drill set, manual
Cone driller, 12 mm x 22.9 cm
Cone driller, for skull, children
Protective clamp, with an extreme hole, cross-strips, with zipper, length 150–160 mm
Dandy clamp
Love-Gruenwald clamp, straight, 3 x 10 mm bit, length 180 mm
Kerrison-type clamp
Standard clamp, straight, with 2 x 3 teeth, length 140–150 mm
Potts-Smith clamp, straight, without teeth, with tungsten carbide inserts, length 240–250 mm
Gerald clamp, straight, with teeth, length 170–180 mm
Crile clamp, curved, with 1 x 2 teeth, length 140 mm
DeVilbiss clamp, cranial, length 205–210 mm
Adson clamp, in bayonet, without teeth, length 18.5 cm
Ferris-Smith clamp, straight, 4 mm bit, length 120 mm
Halsey needle holder, straight, with central slot, with tungsten carbide inserts, length 130–135 mm
Crile-Wood needle holder, straight, stretched jaw, length 145–150 mm
Saw, Gigli or Olivecrona, length 500–510 mm, with two grip handles in the form of a T

Craniotomy set
Instrument tray, stainless steel
Scalpel handle with blades, reusable/single-use
Penfield dissector
Handle for bistoury
Backhaus towel clamp, length 130–140 mm
Adson clamp, with 1 x 2 teeth, length 110–125 mm
Foerster or Foerster-Ballenger clamp, straight, crossed, length 180 to 200 mm
Allis clamp, with 4 x 5 teeth, length 150–155 mm
Adson clamp, without teeth, length 110–120 mm
Needle holder
Senn-Mueller separator, round or sharpened point, length 15 cm
Volkmann separator
Farabeuf separator, set of 2, length 150–155 mm
Weitlaner separator, with self-retaining mechanism
Taylor scissors, length 17 cm
Metzenbaum scissors, straight, with tungsten carbide inserts, length 180–185 mm
Mayo scissors, straight, length 150–155 mm
Mayo-Stille scissors, curved, with tungsten carbide inserts, length 145–155 mm
Hudson drill set, 9, 14, 16, 22 mm
McKenzie drill, 13 mm x 9.8 cm
Frazier cannula

Craniotomy set
Cobb knife, number
Dandy nerve hook
Sachs hook
Gouge, Leksell or Leksell-Stille, angulated, wide point, length 229–250 mm
Gouge, Stille-Luer, straight, length 200–230 mm
Gouge, Echlin, wide point, length 230 mm
Gouge, Stille-Luer, curved, length 220–230 mm
Bunnell drill set
Cone driller, 12 mm x 22.9 cm
Cone driller, for skull, children
Dandy nerve clamp
Ferris-Smith-Kerrison clamp, angle at 40 degrees, 5 mm bit, length 180 mm
Kerrison-type clamp
Standard clamp, straight, with 2 x 3 teeth, length 140–150 mm
Potts-Smith clamp, straight, without teeth, with tungsten carbide inserts, length 240–250 mm
Gerald clamp, straight, with teeth, length 170–180 mm
Crile clamp, curved, with 1 x 2 teeth, length 140 mm
DeVilbiss clamp, cranial, length 205–210 mm
Adson clamp, in bayonet, without teeth, length 18.5 cm
Crile-Wood needle holder, straight, stretched jaw, with tungsten carbide inserts, length 145–150 mm
Saw, Gigli or Olivecrona, length 500–510 mm, with two grip handles in the form of a T
Scissors for wire, universal, length 12 cm

Orthopaedic operative set
Metal ruler (min 15cm)
Scalpel handle with blades, reusable/single-use
Operating scissors
Stitch scissors, standard
Forceps
Bone/cartilage clamp
Rongeur
Bone mallet
Osteotome
Retractor
Suction tube

Surgery set
Scalpel handle with blades, reusable/single-use
Scissors
Forceps, dressing
Forceps, tissue
Needle holder
Forceps, haemostatic
Forceps, towel clamp
Forceps, sponge
Retractor
Forceps, tissue

Dressing set
Forceps, artery, Kocher, 140 mm, straight
Forceps, dressing, standard, 155 mm, straight
Scissors, Deaver, 140 mm, straight, sharp/blunt
Dishes, kidney type

Reverse osmosis water treatment area
Hydropneumatics system
Activated carbon tank
Softener tank with brine tank
Reverse osmosis water tank
Reservoir tank of treated water
Recirculation pumps
Ultraviolet (UV) light lamp
Microfilter
Remote alarm system
Pallet to stow goods
Iodine-free pelleted salt sacks
Disinfectant
Input filter of 1.5 microns

Haemodialysis furniture
Haemodialysis chair with Trendelenburg position
Intravenous pole
Oxygen wall outlet
Air wall outlet with surgery suction system[a]
Dialysate conductivity monitor
Sharps container
Container for hazardous medical waste
Diagnostic set or system (includes otoscope, ophthalmoscope and laryngoscope)
Automated, non-invasive blood pressure device, with proper-sized upper arm cuff

a This capital medical device is described in the table on generic equipment in Annex 4.

Haemodialysis set
Solutions for haemodialysis: with variable concentrations of calcium and potassium, according to user requirements, sodium bicarbonate for manual or automatic preparation
Arterial and venous lines with pressure transducer protector, disposable and adaptable or integrated to arterial and venous lines (neonatal, paediatric, adult)
Arteriovenous fistula puncture needles
Filter for haemodialysis or haemodialyser
Disinfectant and descaling agent

Reverse osmosis water treatment area
Hydropneumatics system
Activated carbon tank
Softener tank with brine tank
Reverse osmosis water tank
Reservoir tank of treated water
Recirculation pumps
Ultraviolet (UV) light lamp
Microfilter
Remote alarm system
Pallet to stow goods
Iodine-free pelleted salt sacks
Disinfectant
Input filter of 1.5 microns

Haemodialysis furniture
Haemodialysis chair with Trendelenburg position
Intravenous pole
Oxygen wall outlet
Air wall outlet with surgery suction system[a]
Dialysate conductivity monitor
Sharps container
Container for hazardous medical waste
Diagnostic set or system (includes otoscope, ophthalmoscope and laryngoscope)
Automated, non-invasive blood pressure device, with proper-sized upper arm cuff

a. This capital medical device is described in the table on generic equipment in Annex 4.

Haemodialysis set
Solutions for haemodialysis: with variable concentrations of calcium and potassium, according to user requirements, sodium bicarbonate for manual or automatic preparation
Arterial and venous lines with pressure transducer protector, disposable and adaptable or integrated to arterial and venous lines (neonatal, paediatric, adult)
Arteriovenous fistula puncture needles
Filter for haemodialysis or haemodialyser
Disinfectant and descaling agent

Nurses' central monitoring station
Crash cart with automated external defibrillator (AED) and monitoring
Electrocardiography system[a]
Wheelchair
Electronic scale
Automated, non-invasive blood pressure device
Stethoscope, binaural
Diagnostic set or system (includes otoscope, ophthalmoscope and laryngoscope)
Flexible LED examination lamp on casters
Thermometer
Pulse oximeter
Blood glucose meter[a], portable
Medication refrigerator
Surgery suction system[a], toraxic
Whole blood coagulation analyser
Haematology analyser
Red bag container for hazardous medical waste
Pasteur table, stainless steel
Point-of-care analyser

a. These capital medical devices are described in the table on generic equipment in Annex 4.

Ventilator set
Expiratory valve assemblies
Flow sensors
Non-invasive ventilation (NIV) mask
Ventilator tubes

Surgery suction system set
Suction system tubing (Yankauer suction tube, 270 mm)
Basic suction tip, reusable/single-use (Yankauer suction tips)
Suction system tubing (suction tube, L50 cm, catheter tip, sterile, single-use, sizes G)
Suction system bottle
Suction system canister, bottle holder
Suction system filter, microbial (suction trap to collect fluid specimens)

EVD set
Scalpel Handle 3 no, 13.5 cm
Mayo-Stille Surgical Scissors,Curved, 14 cm
Standart Tissue Forcep, 14.5 cm
Foerster-Ballenger Organ and Tissue Forcep, Straight, 24 cm
Allis Tissue Grasping Forcep, 5x6 teeth, 15.5 cm
Backhaus Towel Clamp, 13.5 cm
Halsey Needle Holder, HM, 13 cm

Micro-Halsted Delicate Haemostatic Forcep, Curved, 12.5 cm
Rochester-Pean Haemostatic Forcep, Curved, 16 cm
Probe, Ø 2.5 mm 14.5 cm
Wire Basket, 255x245x30mm

Endarterectomy set

Lemmon disectors, for intimate.
Universal handles for instrumental management.
Flexible handles, of different point, length and gauge.
Long handles to secure the handles.
Specific case for your storage and sterilization.
Lemmon disectors, for intimate.
Universal handles for instrumental management.

Endovascular embolization set

Introducer, guidewire, 18G x 7cm
Guidewire, .035 J-tipped, 180/300cm lengths
Access sheath(s)
Interventional catheters (Femoral / Radial)
.014 Workhorse guidewire(s) 183/300 length
.014 Specialty guidewire (s)
Angioplasty balloons
Cutting balloon(s)
Drug-eluting stent(s)
Catheter set (filter, needle with luer, case and cap)
Bandbag, 36 x 40 in., with tape 1
Bowl, guidewire, 2500cc 1
Bowl, sponge,16oz., 500cc 1
Embolization material (glue, plastic particles, foeam, metal coil)

Thrombolysis set

Introducer, guidewire, 18G x 7cm
Guidewire, .035 J-tipped, 180/300cm lengths
Access sheath(s)
Interventional catheters (Femoral / Radial)
.014 Workhorse guidewire(s) 183/300 length
.014 Specialty guidewire (s)
Angioplasty balloons
Cutting balloon(s)
Mechanical device to suction or break clot
Catheter set (filter, needle with luer, case and cap)
Bandbag, 36 x 40 in., with tape 1
Bowl, guidewire, 2500cc 1
Bowl, sponge,16oz., 500cc 1

Atrial septal set
Introducer, guidewire, 18G x 7cm
Guidewire, .035 J-tipped, 180/300cm lengths
Access sheath(s)
Interventional catheters (Femoral / Radial)
.014 Workhorse guidewire(s) 183/300 length
.014 Specialty guidewire (s)
Angioplasty balloons
Cutting balloon(s)
Atrial septal occluder
Catheter set (filter, needle with luer, case and cap)
Bandbag, 36 x 40 in., with tape 1
Bowl, guidewire, 2500cc 1
Bowl, sponge,16oz., 500cc 1

Percutaneous angioplasty set
Introducer, guidewire, 18G x 7cm
Guidewire, .035 J-tipped, 180/300cm lengths
Access sheath(s)
Interventional catheters (Femoral / Radial)
Workhorse guidewire(s) 183/300 length
Specialty guidewire (s)
Angioplasty balloons
Cutting balloon(s)
Drug-eluting stent(s)
Catheter set (filter, needle with luer, case and cap)
Bandbag, 36 x 40 in., with tape 1
Bowl, guidewire, 2500cc 1
Bowl, sponge,16oz., 500cc 1

WHO medical device technical series

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https://www.who.int/health-topics/medical-devices

9789240027978