World Health Organization

Development of medical devices policies

Second edition

WHO medical device technical series

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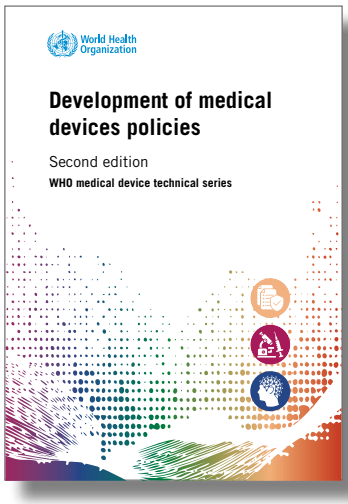

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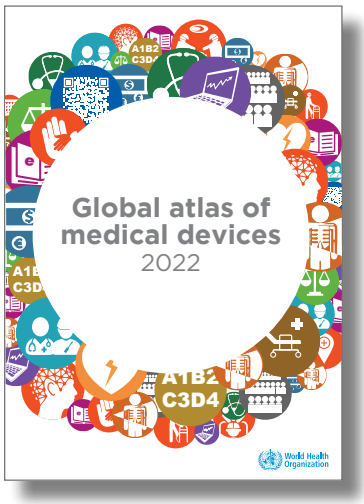

2022

2017

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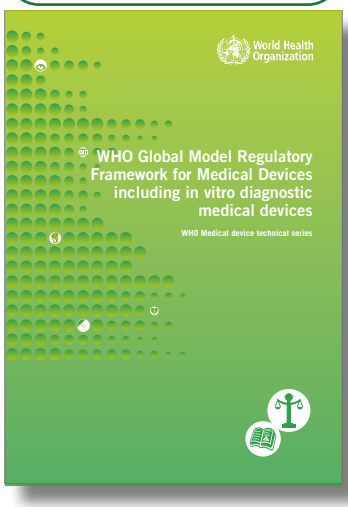
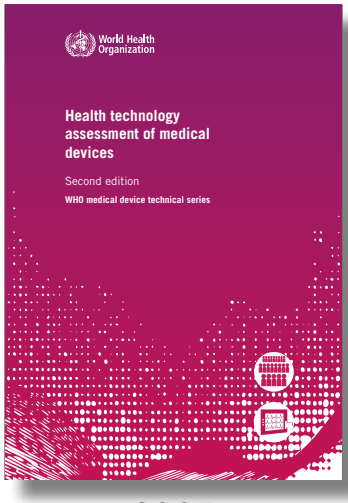
Regulation



2023

Assessment

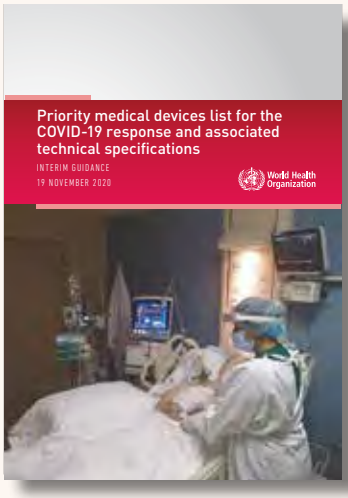


2025

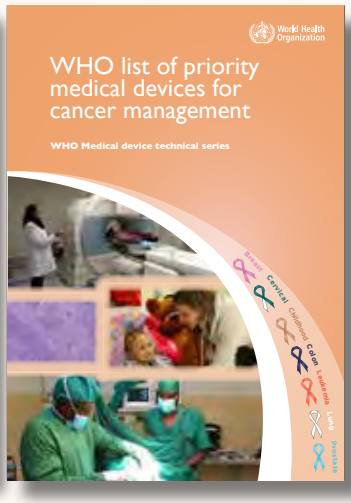
Priority/Essential lists

2019–2023

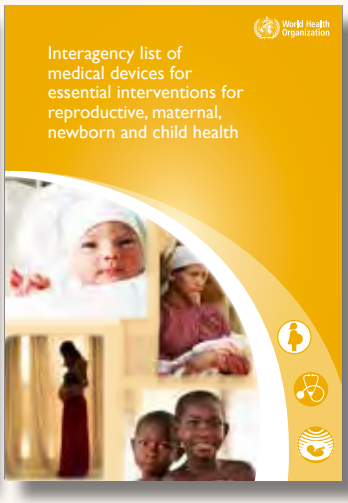
2021



2020



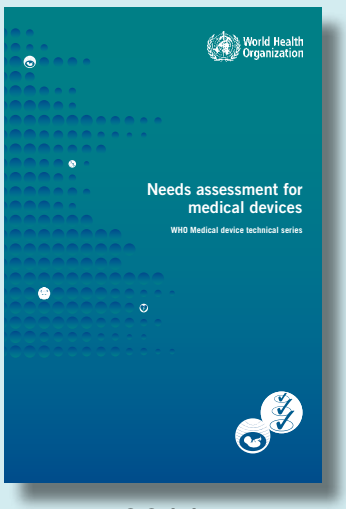
2017



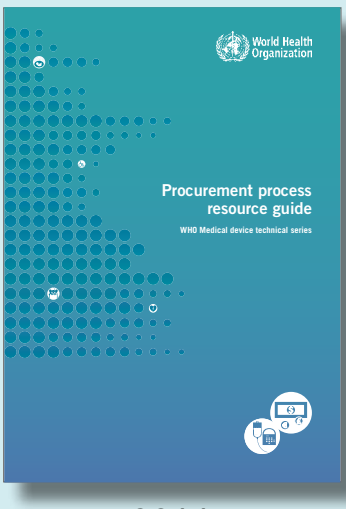
2015

To ensure improved access, quality and use of medical devices

Management



2011



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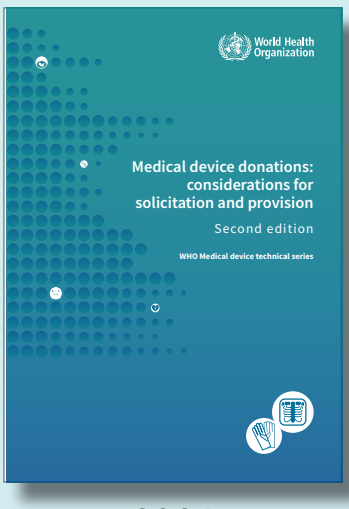
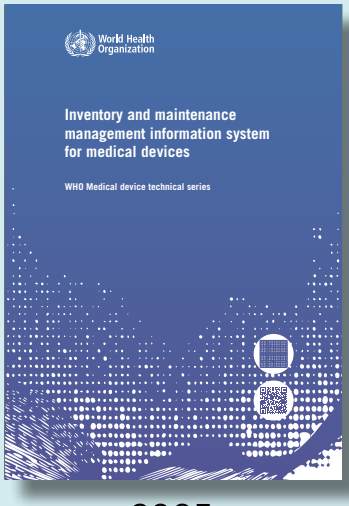


2024



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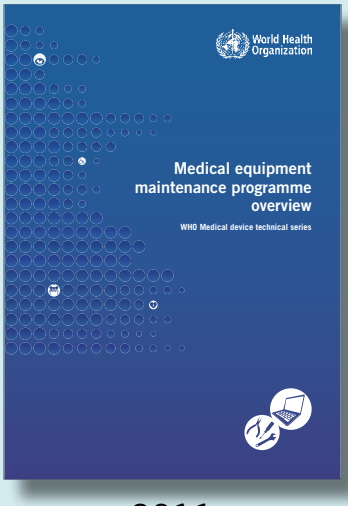
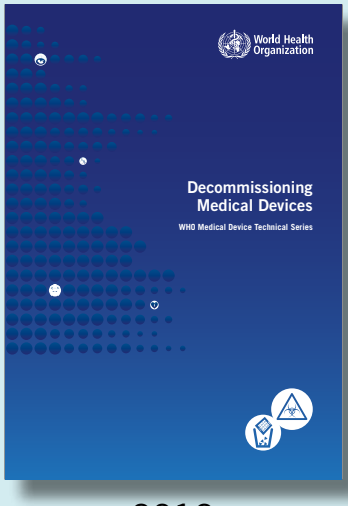


2011



2019

Technical specifications

2019–2021

Compendiums

2011–2024

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Preface

Health technologies are essential for effective functioning and advancement of health-care systems. Medical devices, which are a type of health technology, are crucial for the prevention, diagnosis, and treatment of disease and health conditions. In recognition of the important role of health technologies, the Sixtieth World Health Assembly in May 2007 adopted resolution WHA60.29, in which Member States acknowledged the importance of medical devices for achieving health-related development goals; urged expansion of expertise into the field of health technologies; and addressed issues arising from inappropriate deployment and use. In adopting this resolution, Member States requested that WHO establish priorities in selecting medical devices that would support them in this regard.

To support the implementation of the WHA60.29 resolution, WHO and partners devised an agenda, action plan, tools and guidelines to increase access to medical devices, as appropriate. This document is one of the reference documents developed for use at country level, as part of the WHO Medical device technical series, which address the following subjects:

- Development of medical devices policies (2011, of which this document is the second edition) *(1)*
- Global model regulatory framework for medical devices, including in-vitro devices (IVDs) (2017, 2023) *(2,3)*
- Health technology assessment of medical devices (2025) *(4)*
- Health technology management:
  - Needs assessment for medical devices (2011) *(5)*;
  - Medical devices donations: considerations for solicitation and provision (2024) *(6)*;
  - Procurement resource guide (2011) *(7)*;
  - Inventory and maintenance management information system for medical devices (2025) *(8)*;
  - Medical equipment maintenance management programme overview (2011) *(9)*; and
  - Computerized maintenance management system (2012) *(10)*
- Decommissioning medical devices (2019) *(11)*
- WHO lists of priority medical devices in the Medical Devices Information System (MeDevIS):
  - for reproductive, maternal, newborn and child health (2016) *(12)*;
  - for cancer management (2017) *(13)*;
  - for management of cardiovascular diseases and diabetes (2021) *(14)*;
  - for the COVID-19 response and associated technical specifications (2020) *(15)*;
  - for eye care (2022) *(16)*; and
  - for trauma and emergency surgery (2019) *(17)*; and
- WHO model list of essential in vitro diagnostics (2019, 2020, 2021, 2023) *(18–21)*.

These documents are intended for use by any district, national, regional or global organization, expert or practitioner involved in the regulation and life cycle of medical devices, including health workers, biomedical engineers (BMEs), health managers, policy-makers, donors, nongovernmental organizations and academic institutions which have been developed and updated in order to achieve the Sustainable Development Goals (SDGs) as well as to address the World Health Assembly resolutions related to medical devices..

The purpose of this document is to describe the importance of efficient, legally appropriate medical devices policies, including regulatory frameworks, health technology management (HTM), health technology assessment (HTA) and sustainable research and innovation, within a national health plan. Emphasis is placed on policies to ensure the safe, appropriate, sustainable use of medical devices, a critical subset of health technology.

Policies, strategies and action plans for health technologies, particularly medical devices, could be essential components of any national health plan. WHO has prepared the guidance in this publication to support development and implementation of medical device policies. This document includes sections on enhancing access to safe, effective, cost-effective, sustainable, high-quality devices for screening, prevention, diagnosis, treatment, rehabilitation and end-of-life management, ultimately contributing to better health outcomes and quality of life while respecting the environment. Implementation of policies requires an interdisciplinary approach to ensure adherence of the guidance to the many international and regional legal frameworks, to foster their harmonization and maximize their societal impact.

The first edition of this book was published in 2011 to describe the importance of integrating health technology policies into national health systems. This second edition was prepared to reflect the transition from the Millennium Development Goals to the SDGs, thus ensuring its relevance to current global health priorities. New sections have been added to address more recent pressing public health issues, such as sustainability, digital health, participatory governance and public health emergencies. The policies encompass regulatory frameworks, HTA and HTM, focusing on prioritizing needs, implementing effective strategies and measuring progress with defined indicators and evaluation systems.

By addressing the role of medical devices and other medical products in global health care, these guidelines provide a framework for designing comprehensive, effective national health strategies. When reviewing the data in the Global atlas of medical devices *(22)*, it was noted that, although many WHO Member States have dedicated departments, agencies or authorities for medical device regulations and some for medical device assessment, few have dedicated departments, agencies or authorities for HTM. This publication provides elements for development of a national policy on medical devices, including innovation, regulation, assessment and management, with the aim of increasing access of populations to medical devices.

Acknowledgements

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The principal writers were, from WHO, Adriana Velazquez Berumen, Team lead, Medical Devices, WHO, Switzerland; from UCBM, Leandro Pecchia and Marianna Zarro, Italy, and their collaborators: Lemlem Degafu Abate, Ethiopia; Nahimiya Husen Ibrahim, Ethiopia; Joseph Lovecchio, Italy; Luca Martinalli, United Kingdom; Maria Elisabetta Pagnano, Italy; Karina Ovejero Paredes, Spain; Martina Sassi, Italy; Nathan Samuel Ullman, United States of America (USA); and Spilios ZIsimopoulos, Greece.

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All collaborators involved in development of this document completed declarations of interest, which were assessed by WHO staff, who found no conflicts.

Abbreviations

ACS	accessories, consumables and spare parts
AI	artificial intelligence
ASEAN	Association of Southeast Asian Nations
BME	biomedical engineer
CMMS	computerized maintenance management system
COVID-19	coronavirus disease 2019
EMDN	European Medical Device Nomenclature
GMDN	Global Medical Device Nomenclature
GPW	General Programme of Work
HTA	health technology assessment
HTM	health technology management
IFMBE	International Federation of Medical and Biological Engineering
IMDRF	International Medical Device Regulators Forum
ISO	International Standards Organization
IVD	in-vitro device
LMIC	low- and middle-income countries
M&E	monitoring and evaluation
MeDevIS	Medical Devices Information System
NRA	national regulatory authority
PHC	primary health care
R&D	research and development
SaMD	software as a medical device
SDG	Sustainable Development Goal
STAG MEDEV	Strategic and Technical Advisory Group on Medical Devices
UHC	universal health coverage
UDI	unique device identification
UN	United Nations
UNEP	United Nations Environment Programme
USA	United States of America
WHO	World Health Organization

Glossary

Glossary terms were taken from internationally accepted references, including WHO and IMDRF documents and the glossaries of professional associations.

Biomedical engineering: The profession

> responsible for innovation, research and development, design, selection, management and safe use of all types of medical devices, including single-use and reusable medical equipment, prosthetics, implantable devices, wearables, and bionics *(23)*.

According to the IFMBE, a nongovernmental organization in official relations with WHO that represents the professional and scientific interests of 59 national member societies, a biomedical engineer (BME) is defined as follows *(24)*:

> Medical and biological engineering integrates physical, mathematical and life sciences with engineering principles for the study of biology, medicine and health systems and for the application of technology to improving health and quality of life. It creates knowledge from the molecular to organ systems levels, develops materials, devices, systems, information approaches, technology management, and methods for assessment and evaluation of technology, for the prevention, diagnosis, and treatment of disease, for health care delivery and for patient care and rehabilitation.

BMEs include medical and clinical engineers and those in related fields as categorized in countries. Clinical engineers include those who manage medical devices in health-care settings.

Clinical engineering: Clinical engineering supports and advances patient care by applying engineering and managerial skills to health-care technology and by implementing health-care technologies and strategies in hospitals and other health-care settings. The selection, installation and ongoing support of appropriate technologies and associated equipment used by health-care professionals, also called HTM, are critical to delivery of safe, effective health care. Clinical engineers require not only engineering expertise but also considerable financial, planning and management skills *(23)*.

Diagnostics: are those medical devices* intended by the manufacturer to be used, either in vitro or non in vitro, alone or in combination, for human beings, for providing information for one or more of the specific medical purposes: Diagnosis or monitoring of disease, Investigation; diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction or determination of physiological status.

Health technology: Application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems to solve a health problem and improve the quality of life. The term is used interchangeably with "health-care technology" *(23)* Resolution WHA60.29.

* In alignment with IMDRF essential principles of safety and performance of Medical Devices and IVD Medical devices *(25)*. Following the mandate by Resolution WHA76.5 to develop definition through a group of experts and public consultations. https://www.who.int/news-room/articles-detail/call-for-public-consultation-defining-the-term--diagnostics

Medical device: Any instrument, apparatus, implement, machine, appliance, implant, reagent for in-vitro use, software, material or other similar or related article intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury;
- investigation, replacement, modification or support of the anatomy or of a physiological process;
- supporting or sustaining life;
- control of conception;
- cleaning, disinfection or sterilization of medical devices; or
- providing information by in-vitro examination of specimens derived from the human body.

It does not achieve its primary intended action by pharmacological, immunological or metabolic means in or on the human body, but may be assisted in its intended function by such means *(25)*.

Medical equipment: Medical devices that require calibration, maintenance, repair, user training and decommissioning, which are usually managed by clinical and BMEs. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation after disease or injury. It can be used alone or in combination with any accessory, consumable or other piece of medical equipment. Medical equipment excludes implantable, disposable or single-use medical devices *(9)*.

Executive summary

The WHO secretariat and the STAG MEDEV considered it important to update WHO's published guidance on the development of medical devices policies *(1)*, which was issued in 2011. This revised document reflects the transition from the Millennium Development Goals to the SDGs, with strengthening of primary health care (PHC) and achievement of universal health coverage (UHC), as medical technology has evolved exponentially. The coronavirus disease 2019 (COVID-19) pandemic demonstrated the importance of medical devices in responding to emergencies and pandemics.

Data from the 2022 edition of the Global Atlas of Medical Devices *(22)* show that 46% of countries still do not have a comprehensive national policy on medical devices and that, often, even if one is available, it is not integrated into a national health plan.

This book consists of 13 sections.

Section 1 outlines the development of medical devices policies in the context of the SDGs and the WHO goals for UHC and PHC. It also introduces the potential of artificial intelligence (AI) in advancing health-care innovation and delivery. Additionally, it outlines the foundation for action based on World Health Assembly resolutions, which serves as a critical framework for addressing patient safety, advancing health technologies, combating infectious diseases and improving diagnosis and surgical care. It emphasizes the importance of an action plan to ensure access to safe, effective, quality-assured health products and technologies, in alignment with the SDG targets. The section also provides an overview of WHO tools and guidance documents on essential and priority medical devices.

Section 2 is a guide for effective integration of medical device policies into health systems. It emphasizes the importance of assessing public health needs to ensure their alignment with policy while upholding the principles of equity, diversity and inclusion. The section describes WHO's work in accelerating access to safe, high-quality, effective medical devices for all.

Section 3 describes the nomenclature systems for identification of medical devices and their relevance for ensuring access to medical devices, from manufacturing to use, informing health policies and ensuring the involvement of ministries of health in defining the national system.

Section 4 addresses research and development (R&D), one of the four areas essential for implementing health technology policies. It describes the responsibility of researchers and academia for addressing public health needs and priorities while driving innovation in the medical device sector. R&D are key elements in improving access to safe, high-quality, affordable medical devices, ultimately enhancing the quality of health care.

Section 5 describes medical device regulation, the second of the four important areas in implementing health technology policies. It describes the basic principles of pre-market and post-market surveillance and an overview of the WHO Model regulatory framework for medical devices *(2)*. It is particularly useful for WHO Member States with limited or no medical device regulation, as it guides them from instituting basic to advanced regulatory controls, according to their resources.

Section 6 addresses HTA, the third of the four main areas in implementing health technology policies. It includes systematic evaluation of the characteristics, effects and impacts of HTA, including both direct and indirect outcomes. HTA is essential for informing health-care policy and decision-making, particularly for optimizing the allocation of limited resources for health interventions *(4)*. It includes an overview of the WHO model list of priority medical devices and how countries can use it as a reference to select devices for their national medical devices lists to be presented to ministries of health.

Section 7 addresses HTM, also known as clinical engineering, the fourth of the four areas essential for implementing health technology policies. It includes the last stages of the medical device life cycle, after needs assessments, procurement, inventories, safe use and maintenance, until decommissioning, highlighting best practices and relevant WHO guidance.

Section 8 presents a list of the resources necessary to ensure integration of safe, effective medical devices into health systems. It addresses physical and informational infrastructure, financial resources, challenges and international initiatives for fair pricing of medical devices. The section also emphasizes the critical importance of human resources, highlighting the essential role of biomedical and clinical engineers.

Section 9 provides an overview of digital health, with six main themes: patient data privacy, AI, software as a medical device, wearables, cybersecurity and integrated electronic health records.

Section 10 addresses the cross-cutting role of sustainability, describing how various aspects of medical devices impact the environment. Promotion of sustainable manufacturing practices, effective waste management and sustainable supply chain models at national level can significantly reduce the environmental footprint of the medical device lifecycle.

Section 11 emphasizes the importance of preparedness for health emergencies and the critical role of medical devices in such scenarios. It also describes WHO resources for health emergency preparedness and response.

Section 12 describes engagement of stakeholders at various levels of decision-making to enhance medical device policies. It shows that the ultimate goal of every health system intervention is to improve health outcomes, which cannot be achieved without proper monitoring and evaluation (M&E). It provides guidance on relevant indicators and key performance indicators for medical device policies, from planning to implementation, as well as M&E.

Section 13 offers a brief guide on setting effective, relevant goals for planning medical device policy.

Introduction

National health policies are government strategies that guide prevention, service delivery, the health workforce, financing, governance, health information and access to health products to improve population health and well-being. National health plans must include policies, strategies, guidelines and action plans for health technologies, particularly medical devices, to ensure access to safe, effective, high-quality prevention, diagnosis, treatment and rehabilitation.

Medical devices range from simple tools used in health care, such as syringes, to advanced systems such as imaging and radiotherapy equipment. Globally, there are an estimated 2 million types of medical devices on the market, categorized into more than 7000 generic device groups. Medical devices are used in health-care settings by health care workers and some by the final user, such as glucometers.

The complexity of medical devices necessitates comprehensive policies tailored to health sector functions and population needs. Effective policies must be aligned with national health priorities and maximize resources, budgeting and use.

The World Health Assembly has repeatedly emphasized the importance of policies for health technology and specifically medical devices.

- Resolution WHA60.29 on health technologies (2007) urges Member States

  “to formulate as appropriate national strategies and plans for the establishment of systems for the assessment, planning, procurement and management of health technologies in particular medical devices, in collaboration with personnel involved in health-technology assessment and biomedical engineering ”.

- Resolution WHA69.1.11 (2016), on Health in the 2030 Agenda for Sustainable Development to align WHO health-related goals with the 2030 Agenda for Sustainable Development, identifies integration of health as a central element in achieving sustainable development

  “in particular for achieving access for all to quality, safe, effective, and affordable vaccines and medicines and diagnostics for communicable and noncommunicable diseases ”.

- Resolution WHA67.20 (2014), on Regulatory system strengthening for medical products urges Member States

  “to identifying and developing a core set of regulatory functions to meet country and/or regional needs, such as market control and postmarket surveillance ”.

  It also requests WHO secretariat

  “to *(4)* prioritize support for establishing and strengthening regional and subregional networks of regulatory authorities, as appropriate, including strengthening areas of regulation of health products that are the least developed, such as regulation of medical devices, including diagnostics ”.

- Resolution WHA67.23 (2014) on Health intervention and technology assessment in support of universal health coverage, urges Member States

  “to consider establishing national systems of health intervention and technology assessment, (...) in support of universal health coverage to inform policy decisions”.

  and also,

  “to strengthen the link between health technology assessment and regulation and management, as appropriate”.

- Resolution WHA76.5 (2023), on Strengthening diagnostics capacity, urges Member States

  “to consider the establishment of national diagnostics strategies, as part of their national health plans, that include regulation, assessment and management of diagnostics and development of integrated networks to tackle all diseases and medical challenges, avoiding current silos often observed”.

  and

  “to take policy measures for equitable and timely access for all to diagnostics technologies and products”.

- Resolution WHA76.3 (2023), on Increasing access to medical oxygen urges Member States

  “to develop national, regional and local health regulations, policies and plans that are informed by but not limited to WHO guidelines and technical specifications that relate to medical oxygen and associated medical devices”.

- Resolution WHA78.13 (2025), on Strengthening medical imaging capacity, urges Member States

  “to develop strategies to improve medical imaging capacity and promote the inclusion of medical imaging services in national health sector strategic plans to achieve universal health coverage”.

Key aspects of medical device policies cover their entire lifecycle:

- fostering ethical research and innovation to address user-specific needs and health system-specific demands;
- defining regulatory frameworks to minimize risks for patients and health-care workers;
- assessing needs for resource allocation;
- developing HTA programmes to inform decision-makers;
- ensuring the affordability of medical devices to extend their coverage;
- developing HTM policies and guidelines for safe, effective, sustainable use and their environment-friendly disposal; and
- ensuring the safe use and availability of medical devices to enhance health-care delivery

Moreover, in view of the complexity of the lifecycle of medical devices, it is recommended that national policies are developed in collaboration with stakeholders such as academia, professional organizations, patient groups, policy-makers, health-care professionals and BMEs and at the same time ensuring independent, ongoing dialogue with medical device manufacturers.

This document demonstrates the importance of medical devices in strengthening health systems. It provides guidance on innovation, regulation, assessment, management and use throughout their lifecycle to ensure safe, effective, affordable, sustainable, accessible technologies that address population needs and optimize resources for better health outcomes.

Methods

This book is a revision of the WHO publication Development of medical devices policies *(1)*, published in 2011 in the WHO medical device technical series, to align it with the Sustainable Development Goals *(26)* and the recently approved 4th WHO Global Programme of Work *(27)*, which call for "promoting, providing, and protecting health and well-being for all" and "substantially improving access to quality-assured health products". Where "health products consists of medicines, vaccines, blood and products of human origin; and medical devices including diagnostics and assistive products" *(27)*

The following sections provide a description of the method used for drafting and review, including the search framework, inclusion criteria, evidence appraisal, validation and development.

Objectives

This document describes the current landscape of medical device policies, outlines current practices and provides guidance on development of effective policies. The review was conducted by searching the grey literature in relevant databases for general concepts of medical device policy. Relevant documents were screened for inclusion, and additional sources were identified from citations. The objective was to identify and synthesize current best practices, policy approaches and methodological recommendations for developing medical device policies. The aim was to support the creation of evidence-based, context-appropriate policies aligned with current global health priorities.

Literature search

A targeted search of the grey literature and publicly available publications and policy documents on medical devices, including references from the Global atlas of medical devices *(22)*, was conducted by a team of experts from UCBM. The scope of the search was guided by the objectives of the updated publication, as follow:

- guidance from WHO and national authorities on health technologies;
- institutional policy recommendations relevant to medical device regulations, assessment and management; and
- emerging themes in global governance of health technology.

The sources consulted were:

- grey and institutional literature: WHO Institutional Repository for Information Sharing (IRIS);
- ministry of health websites; and
- WHO publications, the journal of the Global Clinical Engineering Alliance and publications of the Advanced Association for Medical Instrumentation, the International Standards Organization (ISO), the IMDRF, the US Food and Drug Administration and other regulatory agencies; and normative frameworks: WHO guidelines and tools, reports from the Organisation for Economic Co-operation and Development and the Pan American Health Organization and policy documents and guidelines from authoritative global health actors.

The search strategies were developed collaboratively and adapted to the interface and scope of each repository or website.

The inclusion criteria were

- relevance to the updated scope and themes of the report;
- institutional credibility and authorship by recognized authorities;
- publication format: official guidelines, policy briefs, technical reports; and
- publication date between 2010 and 2025.

Decisions on inclusion were made by team consensus. In view of the nature of the sources – primarily grey literature and institutional documents – no formal quality appraisal or risk of bias tools were applied.

The collected materials were synthesized thematically and used to revise chapters of theoriginal report. The key elements extracted were regulatory models, implementation guidance, institutional roles and recommendations for practice.

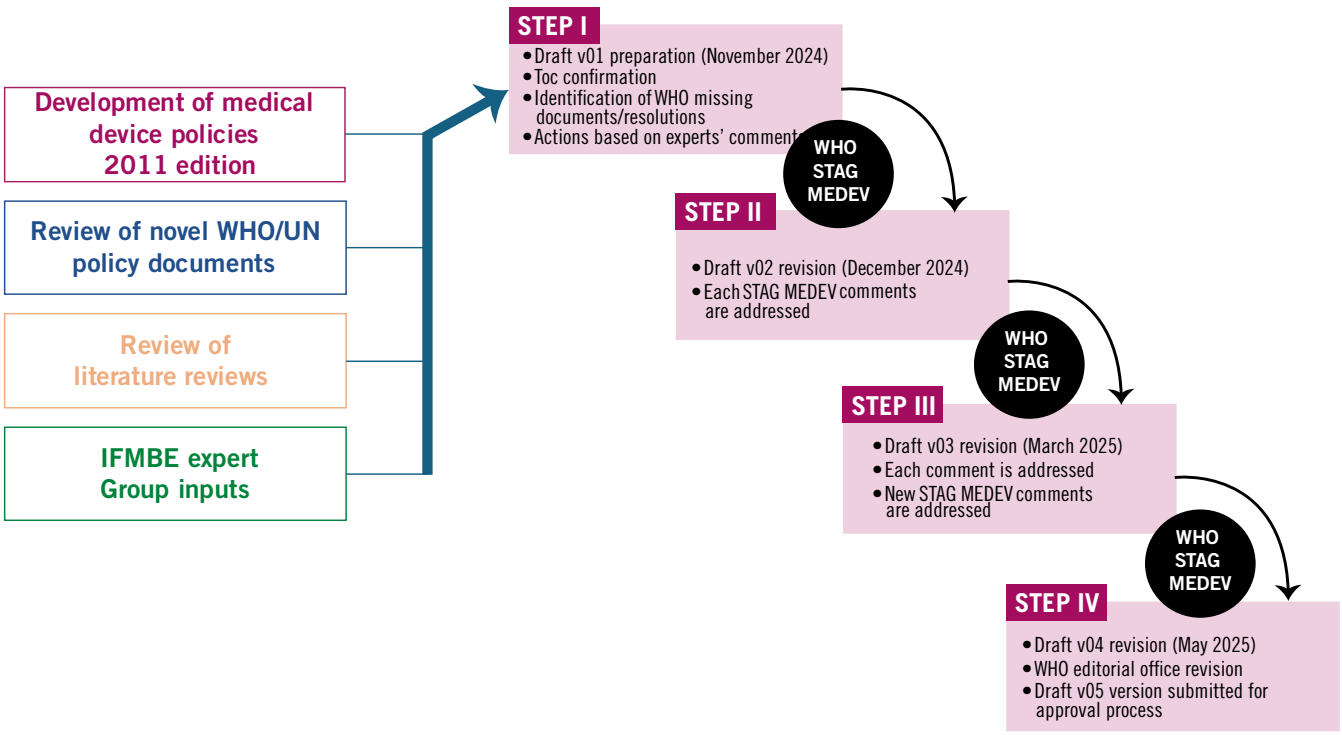
The first draft of the revised document was prepared by the UCBM–IFMBE team in collaboration with WHO and submitted for expert review. An iterative peer-review process involved members of the STAG-MEDEV policy subgroup.

A total of 214 individual comments were received from international experts and institutional stakeholders. All comments were reviewed, categorized and addressed on structured response tables, which guided revisions to the text and documented the actions taken. Feedback was discussed collectively by UCBM collaborators, IFMBE experts, WHO staff and STAG MEDEV and integrated into drafts.

The final version of the document was approved by the multidisciplinary STAG-MEDEV group, edited by WHO technical staff and submitted to the WHO publication team and senior management for approval.

The method is illustrated in Fig. 1.

Fig. 1. Method used to update Development of medical devices policies



The composition of the group of expert consultants, including their names, affiliations and geographical regions, is provided in the acknowledgements section.

The proposal to update the 2011 edition was discussed and approved in September 2024 by the WHO STAG MEDEV, which also prepared the initial table of contents. The first edition (2011), was written by Adriana Velazquez-Berumen, WHO, Geneva, Switzerland, with support from Yadin David, Biomedical Engineering Consultants, LLC, Houston (TX), USA; Paul Rogers, WHO Regional Office for the Western Pacific, Manila, Philippines; and Rhona MacDonald, Ross-Shire, United Kingdom, as part of the Global Initiative on Health Technologies project funded by the Bill & Melinda Gates Foundation.

WHO launched a request to a number of organizations for proposals to draft the second edition. The technical proposals received were assessed by WHO staff and five members of the STAG MEDEV, each from a different region. In a second stage, they reviewed the financial proposals and selected that from UCBM. Therefore, in November 2024, the WHO commissioned the Intelligent Health Technology laboratory team at the UCBM to draft the first version, according to the table of contents proposed by WHO and STAG MEDEV. Two meetings were then held, and the team worked in collaboration with experts from the IFMBE, a non-state actor in official relations with WHO.

The first draft prepared by the UCBM team was reviewed and commented on by international experts from IFMBE in an in-person meeting in Rome. The draft was then presented to STAG MEDEV members in December 2024 for initial input and then opened for consultation.

The WHO secretariat shared the link to the consultation with collaborators and reviewers identified by WHO regional advisors and STAG MEDEV members to ensure input from various regions and professionals with no conflicts of interest. The technical writer, the WHO secretariat and the STAG MEDEV working group addressed the 214 comments received during these sessions to produce a second draft. In early 2025, additional experts were invited to review the draft to ensure that all topics were covered and appropriate regional representation. The third draft was reviewed by the STAG MEDEV edited by WHO technical staff, before submission for WHO executive publication clearance.

1. Global health and medical devices

Medical devices are essential for the effective functioning and advancement of health-care systems. Depending on their intended purpose, can be used for prevention, diagnosis, treatment of disease or health condition and also being used for palliative care, assistive care or rehabilitation, among other uses *(25).*

It is important that a national health plan explicitly identify medical devices as a key component of the health system. Once the national health plan is established, medical device policies could be aligned with it to ensure that national priorities and indicators are in conformity with the overarching national health strategy. Correct development, implementation and evaluation ensure safe, effective, cost-effective, sustainable, high-quality devices for better health outcomes and stronger health systems.

1.1 Scope of medical devices

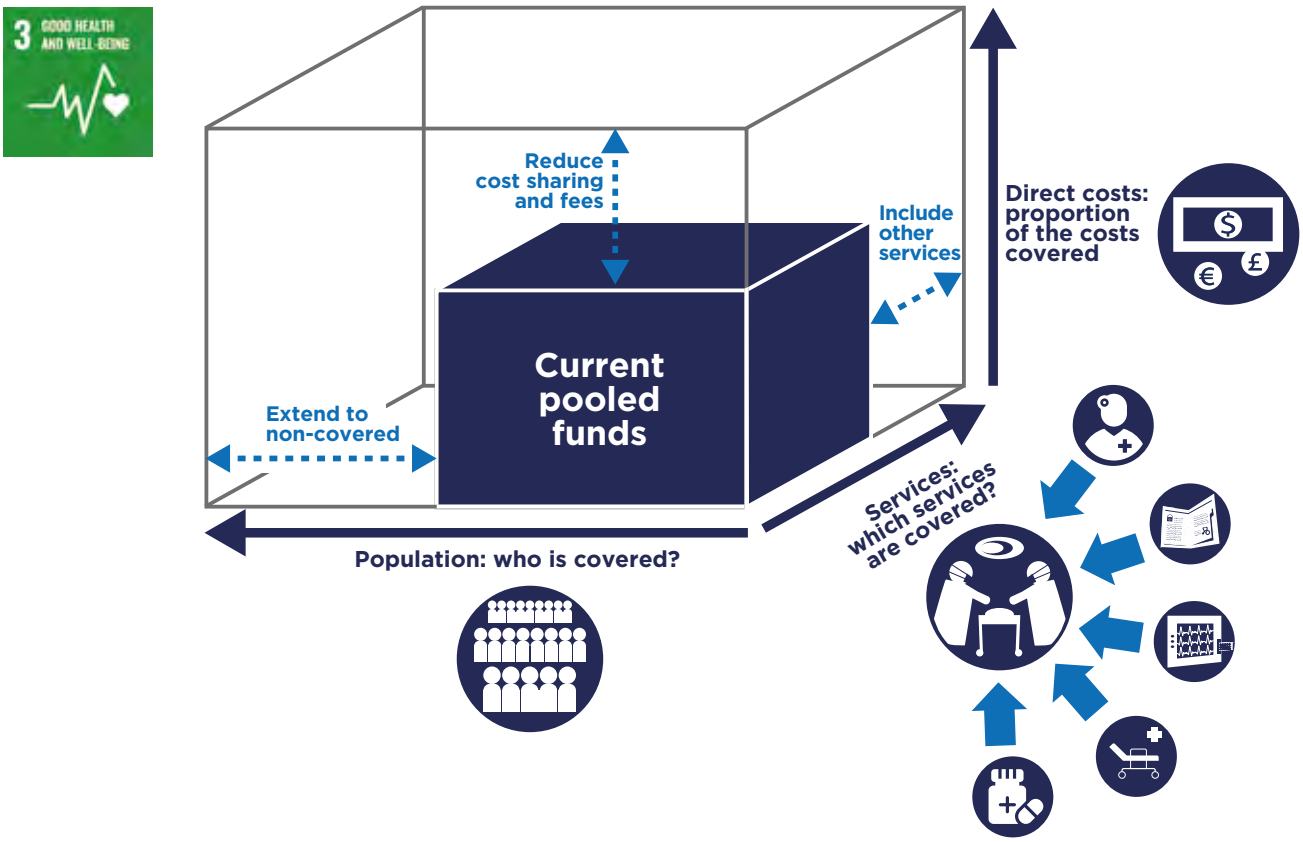
Medical devices comprise a wide range of non-pharmacological health products, such as instruments, implants, diagnostics and software, and are used at all levels of care *(25).* They are classified by risk according to their invasiveness, duration of contact and interaction with vital organs, which guides their safe, effective use *(2)*. In order to ensure their safety and effectiveness, it is crucial to regulate, assess and manage them. The types of medical devices are displayed in MeDevIS *(38)* or the Essential in vitro diagnostics lists databases *(37).*

They are essential components of health-care systems, helping to meet health needs, improve clinical outcomes and, more broadly, to support achievement of the 2030 SDGs.

1.2 United Nations 2030 Sustainable Development goals and forthcoming goals

Policies for medical devices could be aligned with the global health agenda, namely the SDGs, in particular SDG 3 – Ensure healthy lives and promote well-being for all at all ages. On 25 September 2015, the United Nations (UN) adopted the 2030 Agenda for Sustainable Development, outlining 17 SDGs grouped into five key areas – People, Planet, Prosperity, Peace and Partnership – to promote global equity, health and sustainability. Health is central to SDG 3 and linked to nearly all the other goals *(26)*. In 2016, the World Health Assembly approved resolution WHA69.11 for alignment of all WHO health-related goals. The resources necessary to achieve universal health coverage as stated in SDG3, *(28)*, are illustrated in Fig. 2.

Fig. 2. Three dimensions to consider when moving towards universal coverage *(28)*



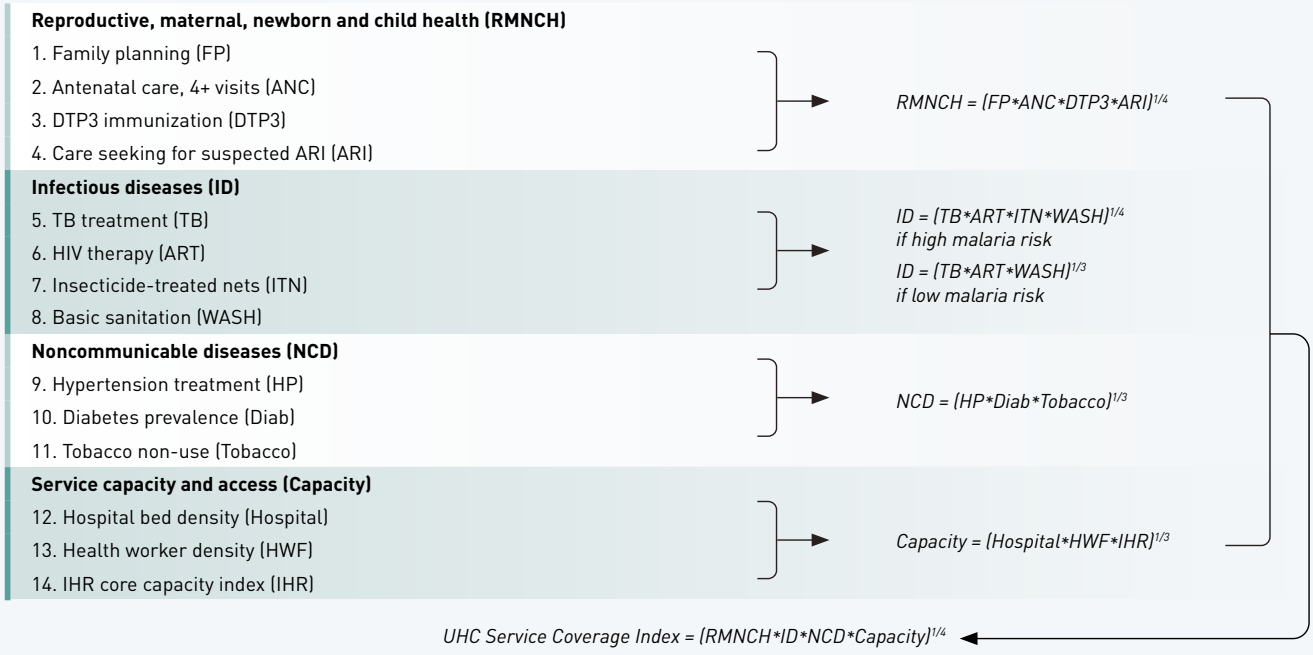
Source: modified from WHO *(28)*

1.3 Universal health coverage

Medical devices could be considered during development and implementation of strategies to ensure UHC, as safe, effective medical devices are critical for ensuring good-quality health care and optimal patient outcomes. As the field of public health shifts gradually from a disease-centred approach to a more patient-centric approach, it is important that public officials also adopt a wider approach, in which health systems – and therefore medical device planning – address not only the most pressing health needs but extend to PHC for achieving UHC *(29-31)*. Fig. 3 shows the UHC service coverage index SDG 3.8.1.

To advance UHC, policy-makers and public officials must prioritize medical devices as essential tools for prevention, diagnosis, treatment and care.

Fig. 3. Schematic of UHC service coverage index components *(31)*



Note: DTP3, three doses of the combined diphtheria, tetanus toxoid and pertussis vaccine; ARI, acute respiratory infection; HIV, human immunodeficiency virus; TB, tuberculosis; IHR, International Health Regulations.

Source: WHO *(31)*

The UHC service coverage index combines 14 tracer indicators of service coverage into a single summary measure, as a measure of SDG Indicator 3.8.1.

1.4 Primary health care

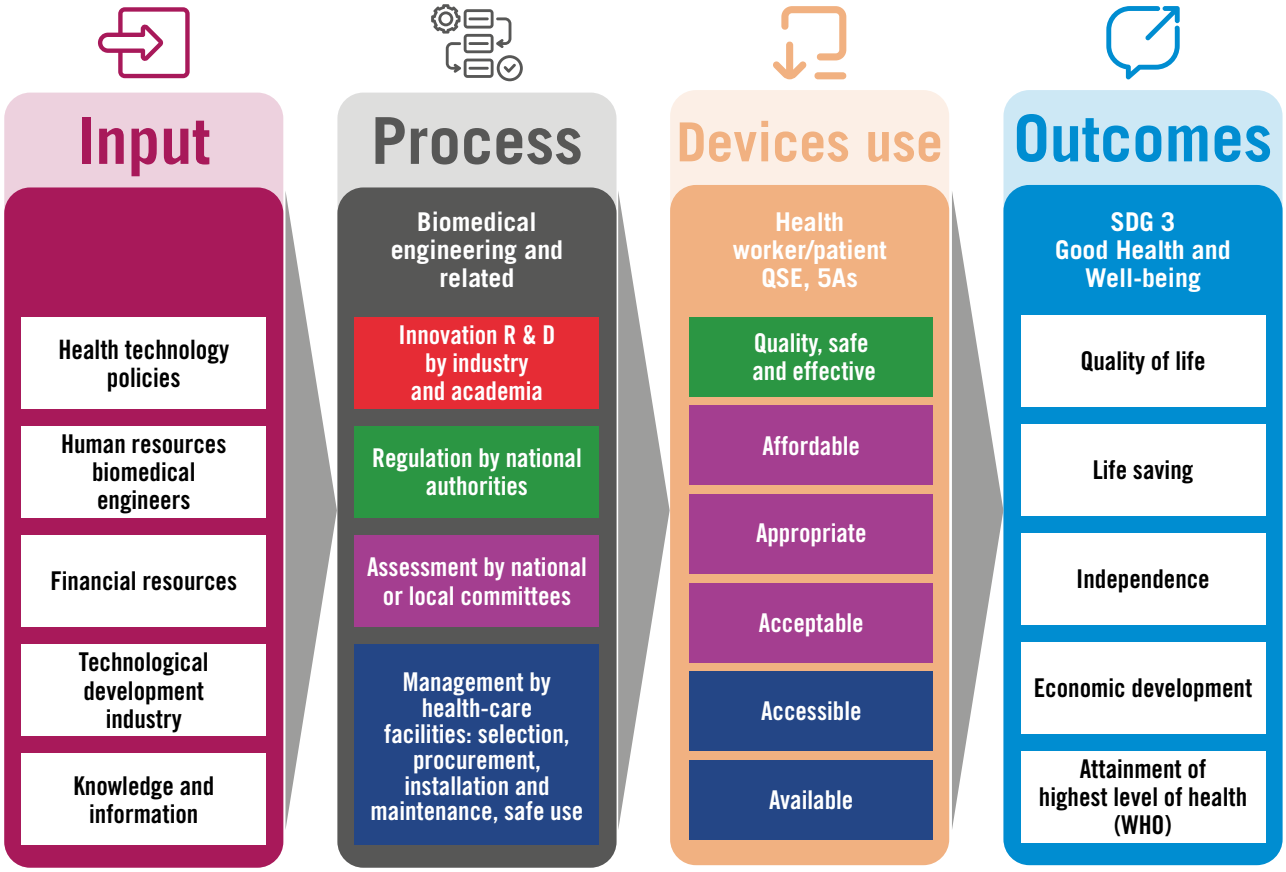
PHC is central to achieving UHC and the SDGs, as reaffirmed at the Conference on PHC in Astana, Kazakhstan, in 2018 *(32)* and in subsequent World Health Assembly resolutions. PHC could be accessible, of high quality, people-centred *(33)* and supported by trained, motivated health workers, including community health workers *(34)*. Strengthening PHC by ensuring equitable access, financial protection and high-quality service could save 60 million lives and increase global life expectancy by 3.7 years by 2030 *(35)*. Therefore, plans for medical devices could include their safe, effective, sustainable allocation in PHC centres where they are required and continuous training and engagement of PHC workers with medical device experts, BMEs *(23)*.

1.5 Input, process and outcomes for medical devices

As shown in Fig. 4, policies are a key element for ensuring a positive impact on the target population, such as improving quality of life, saving lives or achieving additional outcomes such as economic development in support of SDG 3. The inputs also include knowledge and information, the health workforce, financial resources and technological development.

The process involves R&D, regulatory assessment and management, which correspond to the four stages described in sections 4–7. The goal is to ensure the quality, safety and effectiveness of medical devices, while ensuring that they are affordable, appropriate, accessible and available. This contributes to improved health outcomes, such as increased quality of life and life expectancy, as well as to economic development, supporting attainment of the highest possible standard of health.

Fig. 4. Medical devices, from policies to well-being



1.6 Impact of AI on medical devices and related human resources

AI has the potential to transform health care by improving patient outcomes in all phases of care and promoting equity in line with global health goals. AI is a type of software and therefore, by definition, is regarded as a medical device only when its intended use is for medical purposes. To harness its benefits and mitigate its risks, such as bias, violations of privacy and inequality, strong governance, ethical frameworks and inclusive global collaboration are essential, as well as the involvement of medical device experts – BMEs – in the regulation, design, development, validation, assessment, selection and management *(23)*.

1.7 Political support

The Priority Medical Devices Project calls on national strategies to align use of medical devices with essential public health goals *(36)*. Political leadership plays a key role in strengthening infrastructure, workforce training and maintenance systems, as outlined in technical documents on HTM *(5)*. Member States are encouraged to assess needs at national, regional and local levels to identify gaps and to direct investments strategically. Political backing not only drives integration of medical devices into health systems but also ensures that they address public health challenges effectively and sustainably.

1.8 Foundations for action: World Health Assembly resolutions

The importance of medical devices for health systems has also been highlighted by the World Health Assembly, which has adopted many relevant resolutions, providing a framework for action. Some of the resolutions are listed in Table 1. Detailed explanations are provided in Annex 1.

Table 1. Selected World Health Assembly and United Nations General Assembly resolutions relative to medical devices

Resolution and reference	Year and aim
WHA78.13	2025, Strengthening medical imaging capacity
A/RES78/265	2024, Seizing the opportunities of safe, secure and trustworthy artificial intelligence systems for sustainable development
WHA76.5	2023, Strengthening diagnostic capacity
WHA76.3	2023, Increasing access to medical oxygen
WHA75.25	2022, Standardization of medical devices nomenclature
WHA74.8	2021, Strengthening WHO's work on noncommunicable diseases and addressing risk factors
WHA73.1	2020, COVID-19 response
WHA71.8	2018, Improving access to assistive technology
WHA71.7	2018, Digital health
WHA70.12	2017, Cancer prevention and control
WHA69.11	2016, Health in the 2030 Agenda for Sustainable Development
WHA68.20	2015, Draft global action plan on antimicrobial resistance
WHA68.15	2015, Strengthening emergency and essential surgical care and anaesthesia as a component of universal health coverage
WHA67.22	2014, Access to essential medicines
WHA67.23	2014, Health intervention and technology assessment in support of universal health coverage
WHA67.20	2014, Regulatory system strengthening for medical products
WHA60.29	2007, Health technologies

1.9 WHO tools and guidance documents

WHO provides various tools to support Member States in strengthening policies for medical devices in health systems. The Global atlas of medical devices 2022 *(22)* provides a comprehensive overview of the availability of national policies, lists and agencies on medical devices worldwide, providing evidence for decision-making.

WHO develops a number of model lists, including of priority medical devices and essential in-vitro diagnostics to support countries in improving access to and the safety and quality of care. The Electronic model list of essential in-vitro diagnostics *(37)* identifies priority in-vitro diagnostic tests essential for patient care and public health. The MeDevIS *(38)* offers structured information on medical devices, linking them to health interventions and levels of care; and the UHC compendium *(39)* supports countries in prioritizing and implementing health interventions aligned with UHC goals.

The following guidance on essential medical devices can be downloaded from the WHO website:

- The selection and use of essential in vitro diagnostics (18 October 2023)
- Eye care in health systems: guide for action (20 May 2022)
- Selection of essential in vitro diagnostics at country level (30 July 2021)
- WHO list of priority medical devices for management of cardiovascular diseases and diabetes (30 June 2021)
- Priority medical devices list for the COVID-19 response and associated technical specifications (19 November 2020)
- List of priority medical devices in the context of COVID-19 (11 May 2020)
- WHO list of priority medical devices for cancer management (17 February 2017)
- Personal protective equipment for use in a filovirus disease outbreak (16 November 2016)
- Interagency list of priority medical devices for essential interventions for reproductive, maternal, newborn and child health (15 June 2016)
- Priority assistive products list (1 February 2016)
- Systematic review of needs for medical devices for ageing populations (1 June 2015)
- Core medical equipment (12 May 2011)
- Medical devices: managing the mismatch: an outcome of the priority medical devices project (11 July 2010)

As described in the WHO Global Health Strategy for 2025-2028 *(27)*: "WHO's integrated, end-to-end approach aims to ensure good practice across the value chain, ranging from research and development to use by the patient. This includes support for increasing the capacity of regulatory authorities to review and approve health products that meet safety, efficacy and quality standards; increased capacity for local production; improved nomenclature systems; better selection and use through WHO's essential and priority lists of health products; improved affordability; and more efficient procurement and supply systems. The work in this area will evolve to meet the changing health needs of countries, especially to deliver more timely and equitable access to medical countermeasures in emergencies" *(27)*

1.9.1 Equitable access to medical devices

Equitable access to health products, including medical devices, is a global priority. It is a multidimensional challenge that requires comprehensive national policies and strategies that could be aligned with public health needs and economic and social development objectives and promote collaboration with other sectors, partners and stakeholders. They could also be aligned with legal and regulatory frameworks and cover the entire product life cycle.

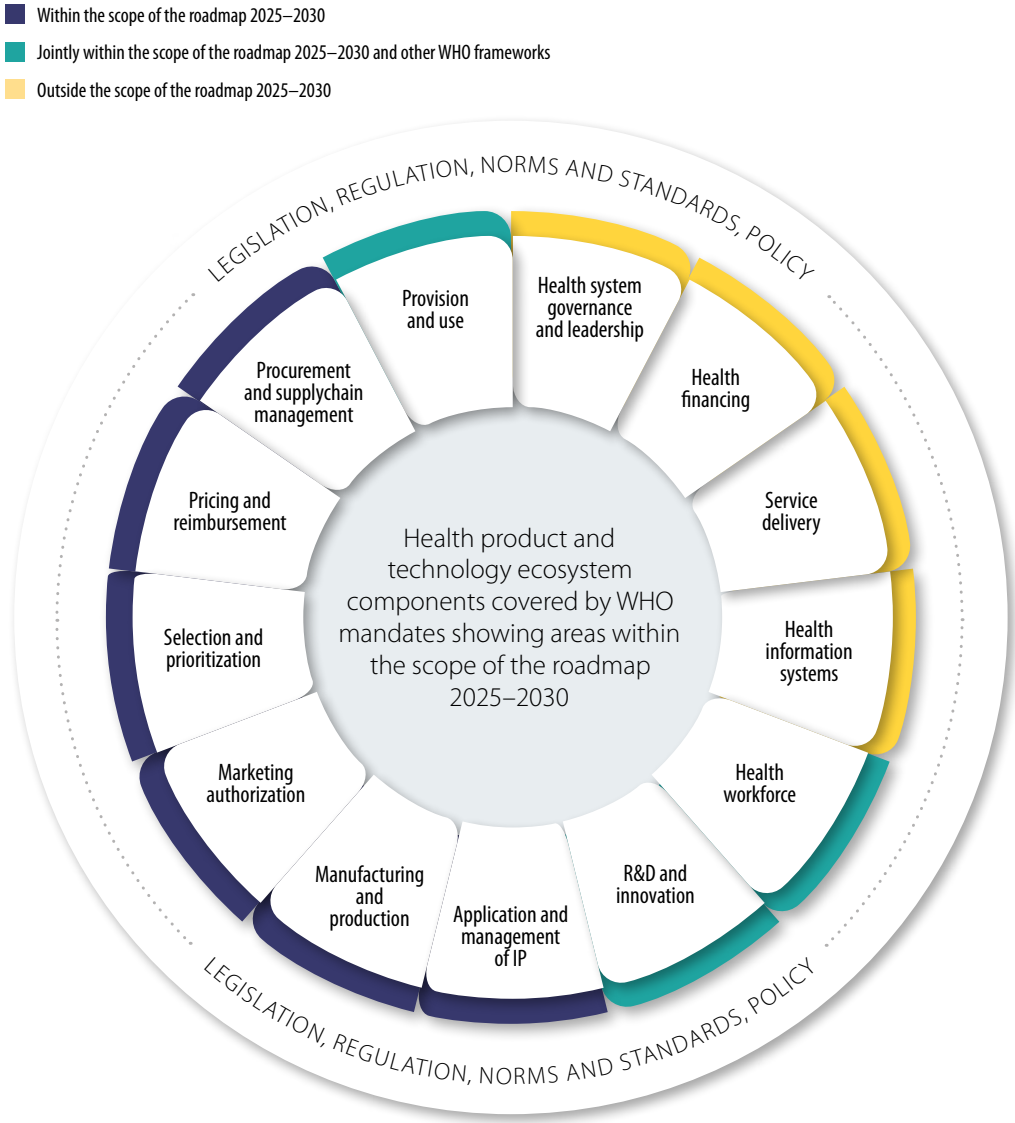
Table 2 lists a number of challenges and solutions for equitable access to medical devices.

Table 2. Challenges and solutions for equitable access to medical devices

Main challenges	• growing disease burden, • limitations and disparities in access to health care, • insufficient investment in R&D, • lack of qualified human resources (biomedical and clinical engineers and health workforce), • inappropriate device selection and management, • weak procurement and supply chain systems and • few national departments for medical devices management.
Possible solutions	• a national policy that would include all stages, from R&D to naming, regulatory approval, assessment selection and management until effective use; • collaboration among entities performing regulation, assessment and management at national level; • promoting R&D aligned with public health priorities; • ensuring evidence-based selection of medical devices; • assessment of medical devices by the national regulatory agency; • evaluation of medical devices by the national HTA unit; • including medical devices in the national HTM system for needs assessments and managing each supply chain until safe, appropriate use; • improving procurement and supply chain management to ensure good-quality, fair pricing and after-sales support; and • ensuring funding for training, maintenance and operational costs to ensure safe, appropriate use.

The document Road map for access to medicines, vaccines and health products 2019–2023 *(40)* responds to the World Health Assembly's request for WHO to describe its activities, actions and deliverables for improving access to medicines and vaccines for the period 2019–2023. These included medical devices related deliverables like priority medical devices list, essential in vitro diagnostics and nomenclature which were addressed until 2023. WHO has updated its road map for 2025–2030 *(41)* to address enhancing access to safe, effective, quality-assured health products and technologies aligned with SDG targets for UHC, financial protection and access to essential health services, medicines and vaccines. The updated road map supports the WHO Fourteenth GPW *(27).* Fig. 5 illustrates the health products and technology addressed by WHO mandates and represented in the road map. The topics related to medical devices have been considered and aligned in the present document on policy development *(41).*

Fig. 5. Health product and technology ecosystem components covered by WHO mandates showing areas within the scope of the Road map 2025–2030



Source: WHO *(41)*

The Roadmap *(41)* presents the how the work of WHO aligns with and contributes to WHO's 14th GPW, for Strategic objective 3: on WHO's 5 programmatic priority areas for access to safe, effective and quality-assured health products and technologies and includes the priorities for medical devices including in vitro diagnostics, for the 5 following areas:

- research, development and production;
- safety, efficacy, and quality assurance;
- policy and prioritization;
- procurement and supply chain management, provision and use; and
- cross cutting like nomenclature.

1.9.2 Global atlas of medical devices

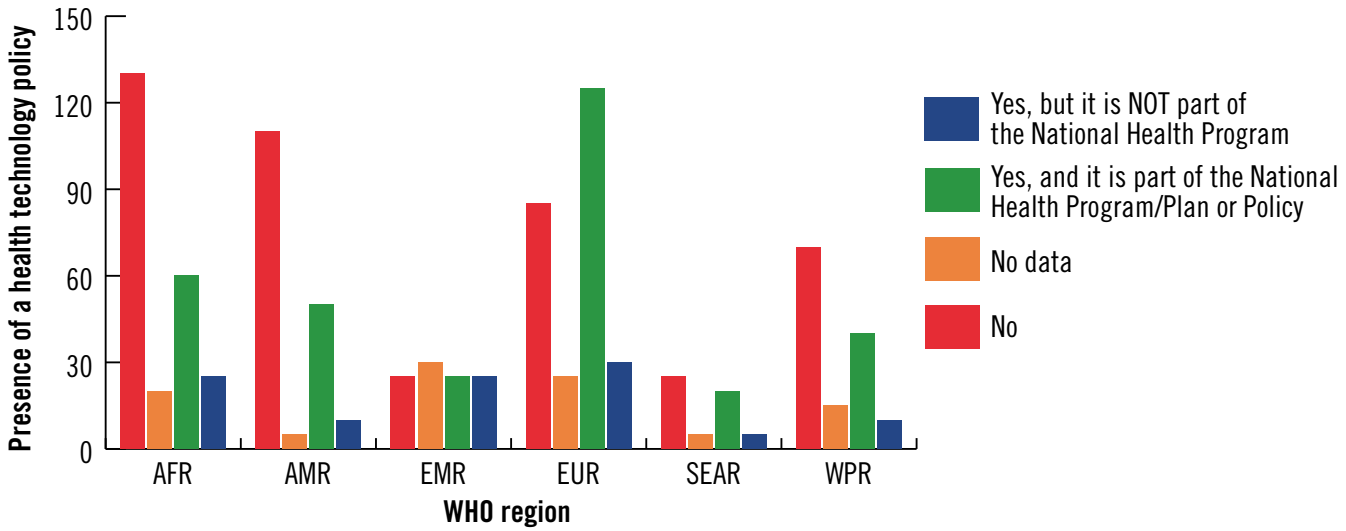
The Global atlas of medical devices 2022 *(22)* presents country profiles that indicate the status of medical devices policies and includes the availability of agencies to assess, regulate and manage medical devices. The country profiles also include comments on advances or challenges. WHO conducted the first baseline survey on medical devices in 2010 and updated 3 times before 2022. The 2020–2022 survey contained 194 country profiles and extensive outreach to update data and verify links to published documents, policies or guidelines.

1.9.3 Global status of medical devices policy

The analyses cited in this section are derived from the Global atlas of medical devices 2022 *(22)*. The data were obtained from a desk survey conducted by WHO in 2021–2022 to assess the status of policies for medical devices in its 194 Member States. Data on whether countries had legal frameworks for medical devices were collected from online sources and by direct communication with WHO focal points and country representatives. Only officially published policies of Member States and their agencies were included. The collected data were translated, reviewed and organized into key components of medical device policies.

The current geographical spread of medical device policies is illustrated in Fig. 6.

Fig. 6. Distribution of health technology (medical device) policies by WHO region, 2021



AFR, African Region; AMR, Americas Region; SEAR, South-East Asia Region; EUR, European Region; EMR, Eastern Mediterranean Region; WPRO, Western Pacific Region

More information can be found on the Global Health Observatory website *(42)*, on which data are updated after every edition of the Global atlas of medical devices.

2. Medical devices in the health systems of Member States

National medical device policies play a crucial role in shaping a country's health-care strategy and could be integrated into the broader national health plan. Thus, medical devices policies must:

- be integrated into national health policies;
- be aligned with overarching government policy objectives;
- respond to public health needs;
- improve equity, diversity and inclusion;
- be discussed with relevant stakeholders;
- be aligned with the evolving national health-care strategy and policies; and
- be aligned with international policies on medical devices and global health.

2.1 Alignment of medical device policies with the national health plan

The national health plan is the basis for development of national policies on medical devices. Effective policies require not only careful planning but also strong management systems for successful implementation, as well as periodic revisions on the basis of achievements. To implement policies, appropriate organizational structures, sufficient resources and continuous monitoring are necessary to ensure that policies are adapted as necessary *(43)*. When policies are well executed, they contribute to improved health outcomes and the long-term sustainability of health systems.

For the development and implementation of evidence-informed policies in health systems, the reader is recommended to consult Evidence, policy, impact: WHO guide for evidence-informed decision-making *(43)* and the Handbook for national quality policy and strategy: a practical approach for developing policy and strategy to improve quality of care *(44)*.

2.1.1 Policy-making

Policy-making is inherently complex, especially in the realm of health technologies, such as medical devices *(44)*. In view of the variety of stakeholder interests, successful policy development requires adherence to clear guiding principles, including:

- the core values of PHC,
- government support,
- inclusive consultation and
- evidence-based, transparent decision-making.

For national health policies to be effective, all the steps of the technology lifecycle must be coordinated. Policies could be designed to remain current over time, especially for rapidly evolving technologies such as medical devices.

Table 3 outlines the constituents of a national health policy framework

Table 3. National health policy framework

Policy framework	National health policy and strategy	National health system	Interventions and programmes	Improvement in health outcomes
National • National development policy and plan • Poverty reduction strategy • Legislative framework Global • 2030 Agenda (SDGs) • PHC and UHC commitments • Astana Declaration (2018) • WHO Global Action Plan for Healthy Lives	A comprehensive plan that includes: • context, needs and priorities; • structure and governance; • functions and financing; • targets and monitoring • of "three ones": one plan. one coordinating framework, one monitoring system Effective elements: • vision and guiding principles; • strategic objectives and priorities; • defined interventions and services; • budgeting and resource allocation; • roles and responsibilities; • stakeholder engagement; • indicators and targets; • monitoring, evaluation, accountability.	• service delivery and infrastructure • health workforce • health information systems • medical products and technologies • health financing • leadership and governance	• counselling and education • clinical interventions (e.g. diagnosis, treatment) • protective interventions (e.g. vaccination) • enabling environment (e.g. water, sanitation, public health laws) • socioeconomic interventions (e.g. housing, education)	• reduced mortality and morbidity • reduced health risks and threats • reduced health inequity • improved health of women, children and vulnerable groups

Source: Modified from WHO *(1)*

2.1.2 Planning

Effective planning for health technology must prioritize public health needs to ensure that it addresses the most pressing health challenges. This approach could be used in broader health sector planning, outputs and cycles at national, regional and local levels. A well-structured health technology plan must be comprehensive, addressing all activities, and coherent, ensuring compatibility with subnational health initiatives *(44)*.

Planning for medical devices could be dynamic, include ongoing monitoring and be aligned with public health priorities and global goals such as UHC and equity, to ensure that it drives innovation and improves health outcomes.

2.1.3 Policy implementation and management

Effective implementation of policies requires evaluation of the available economic resources and health workforce and the epidemiological situation. The outcome could be defined, such as:

- integration of national, regional and local health service governance;
- adequate funding, with a well-defined financing system and clear, long-term budget planning;
- alignment with evolving population needs and health goals;
- alignment with evolving international regulations and health challenges;
- sufficient number of skilled personnel;
- commitment to quality and continuous improvement; and
- continuous monitoring and revision over time, triggered by severe events when relevant.

2.1.4 Policy revision

A best practice in defining national policies is establishment of evidence-based, systematic, periodic monitoring to assess their real-world impact. Governments could regularly engage with stakeholders, including citizens and their representative organizations, in structured consultations and through feedback channels. It is essential to track not only common outcomes but also rare or unforeseen adverse events, which may not be prevented even by well-drafted regulations. Policy-makers could ensure transparent data collection, invest in early warning systems and remain open to adapting policy when evidence suggests a gap between the intended and actual effects.

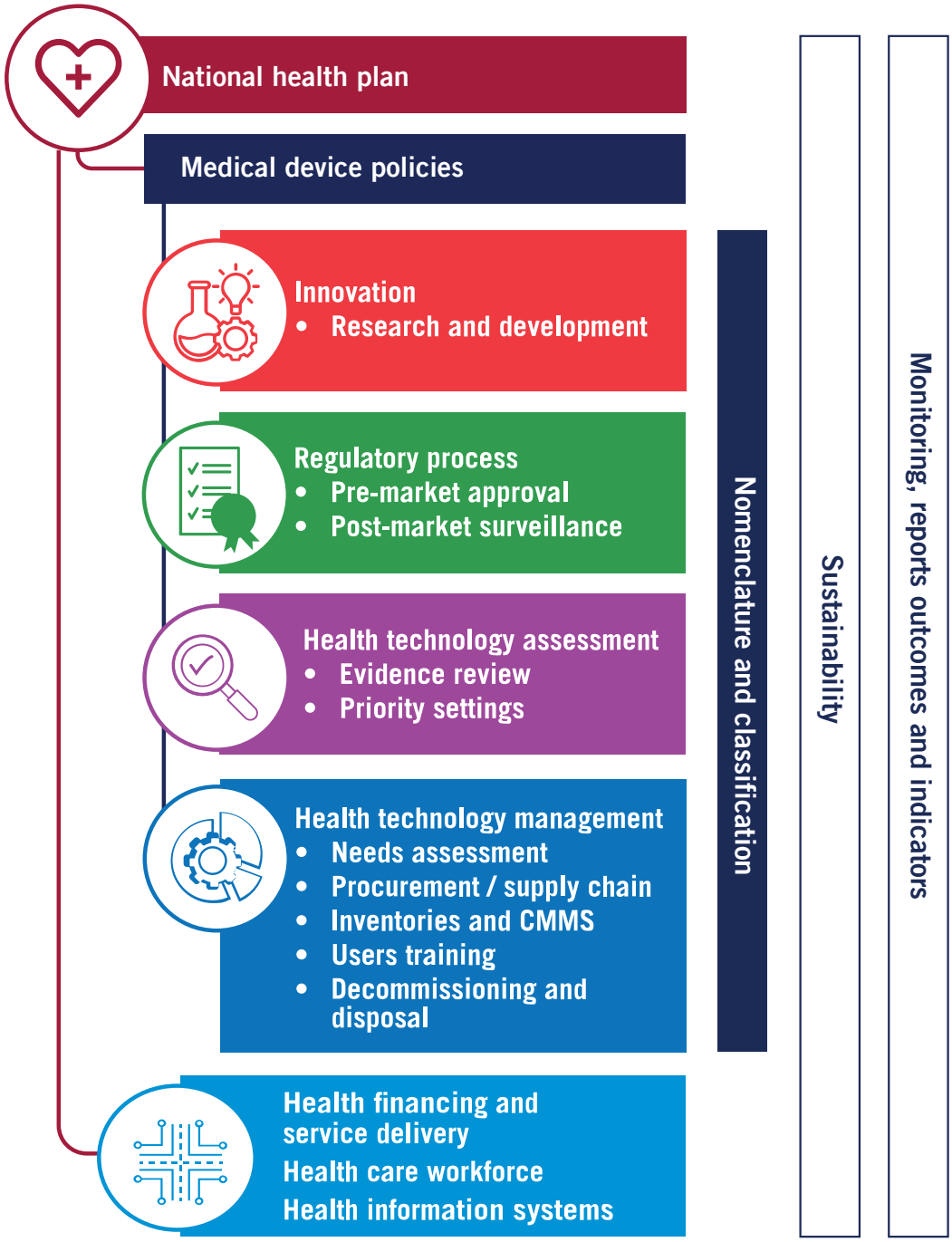
Developing a policy is a complex, ongoing process that adapts to a country's specific political, socio-economic, and historical context and often involve multiple stakeholders *(45).*

In the context of ongoing comprehensive health sector development, strategic planning is an iterative process that could be conducted every 3–5 years (medium-term). Most health sectors work with long- and/or medium-term strategic plans, as well as with annual and quarterly operational plans. The strategic planning exercise generally comes after the phase of priority-setting and precedes operational planning *(44).*

2.2 Elements of medical devices policies

Organizational structures are necessary at various levels to implement policies and strategies for medical devices. Depending on the government structure, the units responsible for the four phases of health technologies are either centralized or decentralized. Fig. 7 illustrates the four primary areas of health technology policies: research and innovation, regulation, HTA and HTM. Moreover, safe, effective, sustainable use of medical devices requires nomenclature system, adequate infrastructure, an adequate health-care workforce and good data management. These topics are explored in greater detail below; however, it is important to stress that dialogue among all areas must be peer-with-peer, substantive and not merely formal, and endorsed by dedicated resources at the levels of the ministry of health and regional and local levels.

Fig. 7. Implementation of medical device policies



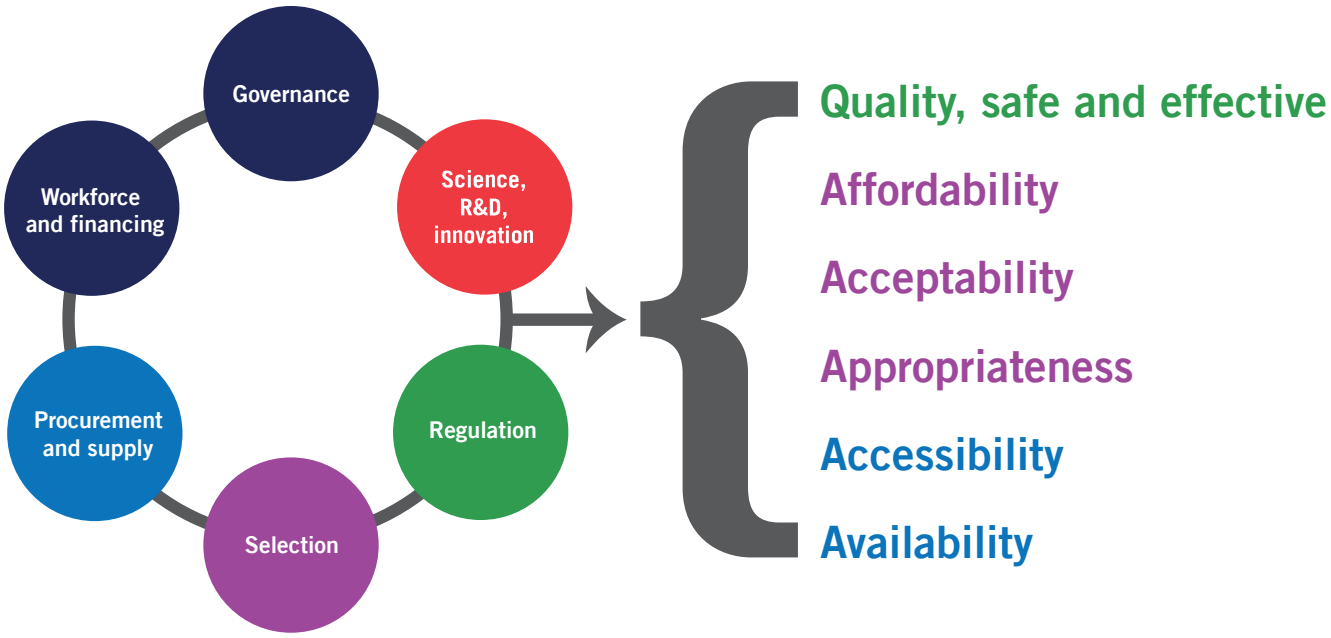
2.3 Alignment of medical device policy with national health policies

Such alignment could be part of the overall vision and aims but could also be considered at each step of national policies for health-care services to aim for equitable access to medical devices (Fig. 8). As discussed in section 1.5 and figure 4.

To be aligned with the national health plan, a medical devices policy could ensure:

- quality and safety: guaranteed quality and safety, approved by a regulatory agency;
- affordability: economic accessibility;
- availability: consistent obtainability;
- accessibility: physical and logistical access for all; and
- acceptability: correspondence to cultural, clinical and social needs.

Fig. 8. Equitable access to medical devices



2.3.1 Alignment at all levels

In order to achieve these aims, medical devices could be considered at all levels of national health policies.

- Governance: Governance of medical devices could be more complex than that for other health products. For instance, medical equipment, a sub-type of medical devices, must be properly installed and maintained regularly, require consumables and must be disposed of appropriately at end of life, often requiring complex infrastructure. To ensure the safety, effectiveness and sustainability of medical devices, countries could establish a dedicated function, department or agency to oversee their full lifecycle.
- R&D and innovation: National health-care policies could include all health products, with priority to those that offer the most benefit to the population needs.
- Regulation: Continuously evolving regulation could consider the lifecycle of medical devices to ensure the safety of patients and health-care workers.
- Assessment, selection, procurement and supply: Approaches to medical devices are different from those to other health products. For example, medical devices are often very sensitive to user skills and local infrastructure. Such complexity could be reflected in the vision, procedures and human resources involved in HTA, selection, procurement and supply of medical devices.

- Workforce: For the functions and reasons listed above, the health-care workforce could include experts in medical device lifecycles, namely well-trained biomedical or clinical engineers, at national (e.g. ministry of health), regional or local level (e.g. hospital or local health-care facility). Furthermore, the health workforce, such as radiologists, laboratory scientists, surgeons and intensive care nurses, must be trained in appropriate, safe use of medical devices.
- Manufacture and local distribution: The requirements, responsibilities, rights and duties of international and national manufacturers could be clearly defined in national health-care policies. They could be extended to local distributors when manufacturers have no legal representation in a country.

2.3.2 Alignment of stakeholders, actors and areas

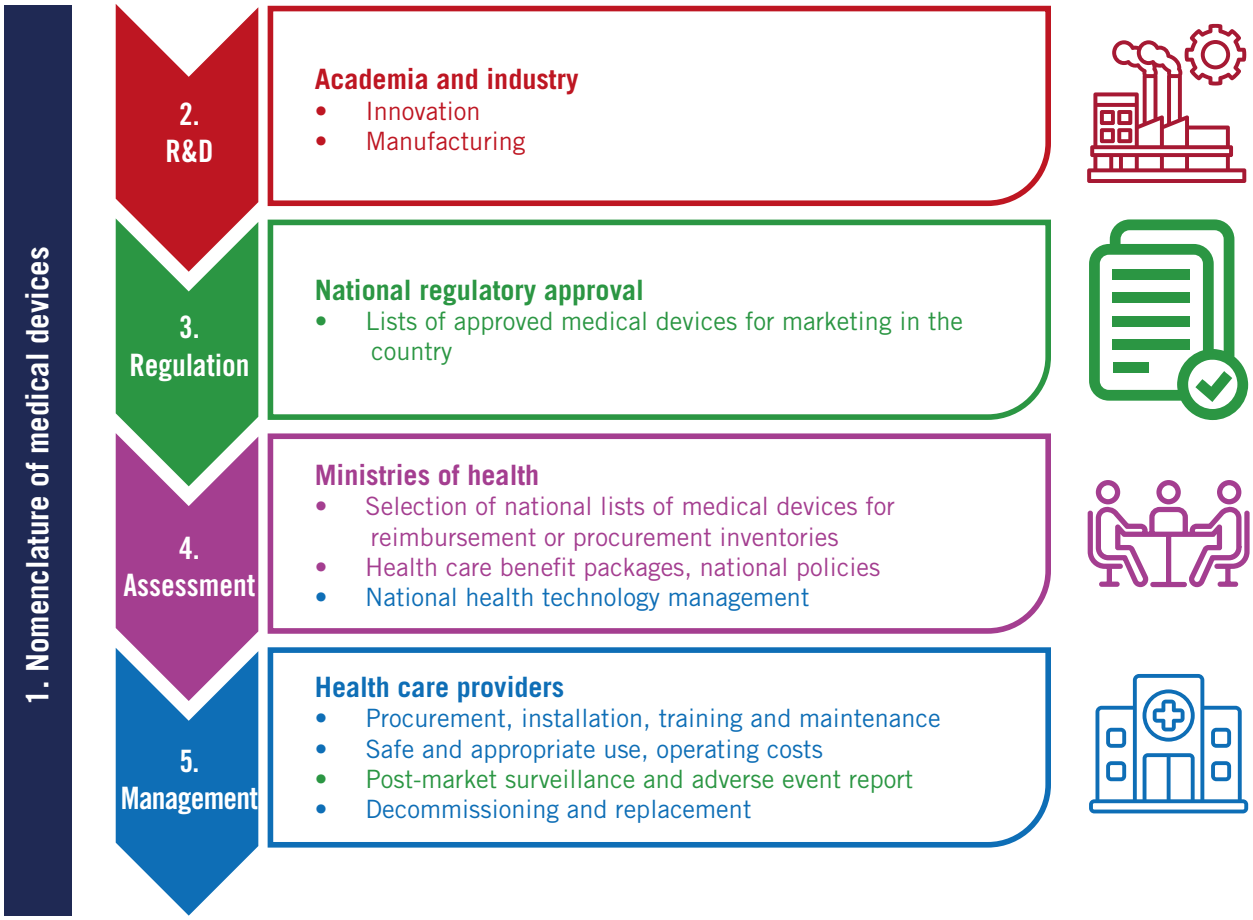
The stakeholders, actors and areas that could be considered in medical device policies are shown in Fig. 9 and Table 3.

Once a new medical technology has been developed and named, a coordinated approach is necessary to connect the functions involved in guiding its integration into the health system (Fig. 9). These functions include:

- nomenclature;
- R&D and manufacture;
- regulatory approval for market access, with evidence differing by function (Table 3);
- HTA of medical devices, to inform policy decisions on coverage, reimbursement or inclusion in benefits packages; and
- management of use of the medical technology throughout its lifecycle, from procurement to decommissioning or disinvestment.

Each step plays a complementary role in ensuring that medical technologies are safely, effectively, appropriately introduced and used in a health system.

Fig. 9. Areas to be included in national medical device policies



Source: WHO *(4)*

Evidence differs by function, as illustrated in Table 3. Regulatory approval focuses on risk and safety, while coverage decisions depend on comparative effectiveness. Local implementation requires a needs assessment, consideration of affordability, training and ongoing management.

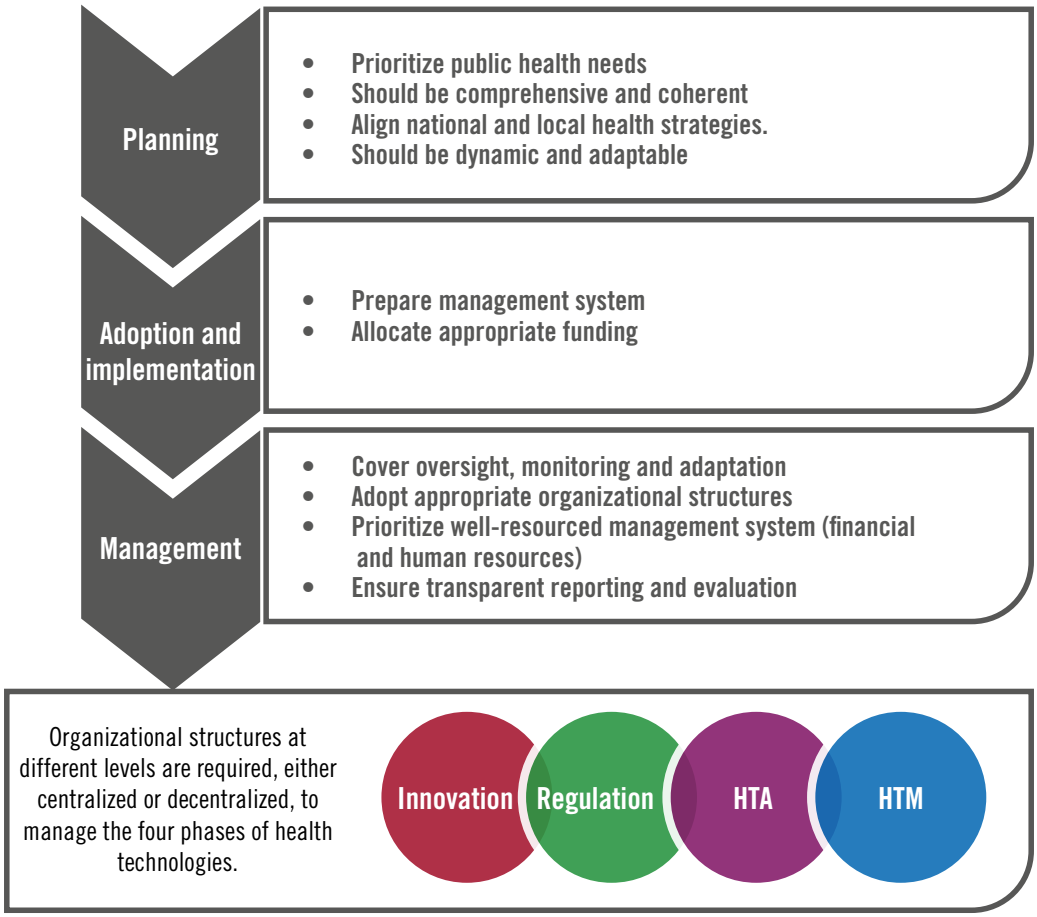
Table 3. Regulation, assessment and management of health technology

Characteristics	Health technology regulation	Health technology assessment	Health technology management
Perspective	Market access: considerations include quality, safety, performance and efficacy	Population-level: considerations include efficacy, relative effectiveness, safety, patient-relevant outcomes, appropriateness (including ethics, social and legal issues) and accessibility	Local-level health facilities: considerations include needs analysis, procurement, affordability, training and alternative technologies towards quality of care
Requirement	Mandatory	National recommendation on complex technologies	National and local implementation of recommended technologies
Role	Prevent harm	Maximize clinical and cost-effectiveness, value-based decision-making	Management across the lifecycle of the device, from adoption to decommissioning to enhance appropriate and safe use

Source: WHO *(4)*

Best practice for national, regional and local policies is also relevant for medical devices. To develop effective policies, policy-makers could follow the steps outlines in Fig. 10.

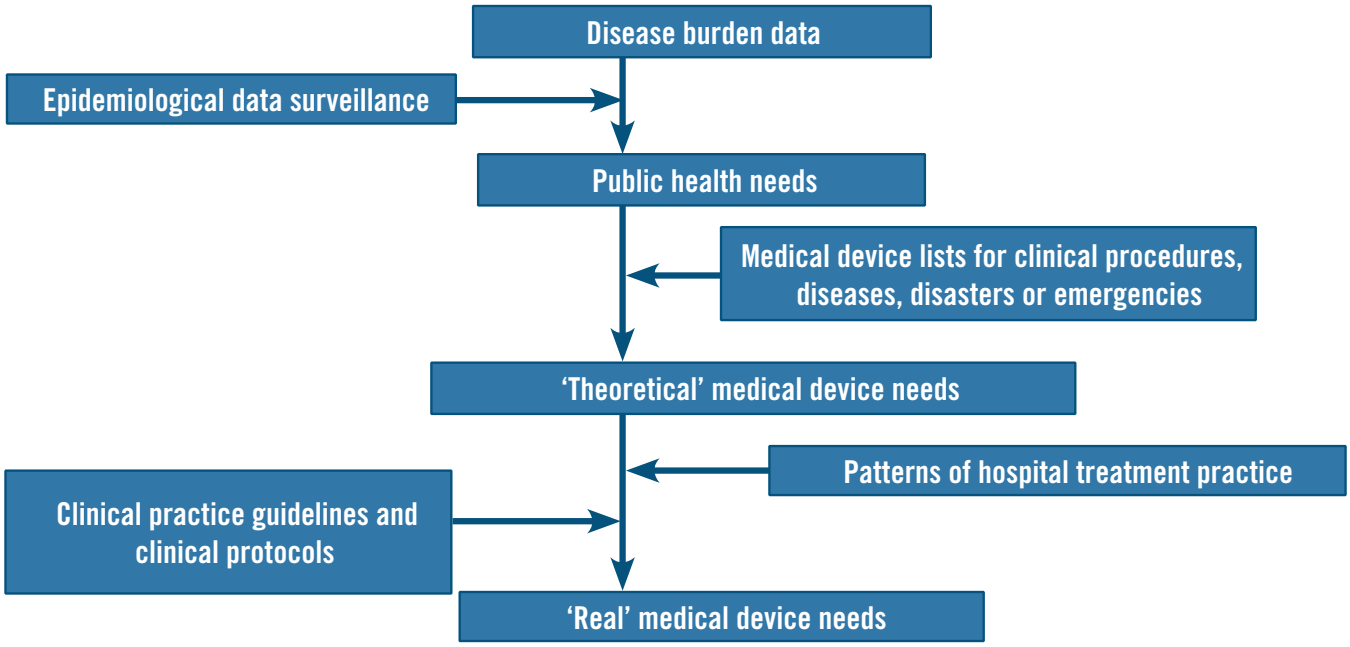
Fig. 10. Best practice for developing policies for medical devices



2.4 Prioritization of public health needs

Effective prioritization of public health needs requires a comprehensive, context-specific approach and diverse, reliable data sources. As health systems face different challenges in different regions, systematic assessments of needs are indispensable, with alignment of national strategies and action plans for medical devices (Fig. 11).

Fig. 11. Setting priorities for medical devices according to public health needs



Source: WHO *(1)*

Data on disease burden are essential for such assessments, as they demonstrate the prevalence and impact of health conditions *(47)*. WHO supports linkage by providing guidelines on aligning medical technologies with health needs *(35)*. Another essential component is gap analysis, in which the availability of medical devices is compares with the needs, identified from patterns of disease burden and treatment.

2.5 Equity, diversity and inclusion

Ensuring equity, diversity and inclusion means that medical devices will serve the needs of diverse populations and reduce health disparities. Equitable access to medical devices is a fundamental component of achieving UHC and advancing health equity (Fig. 11). Disparities in the availability and accessibility of medical devices must be removed, particularly in low-resource settings where unmet health needs are most pronounced.

Strategies are necessary to bridge gaps in access and ensure that devices are distributed according to public health priorities. The principles of equity, diversity and inclusion could also be considered throughout the lifecycle of medical devices, including during research, innovation and design.

3. Nomenclature

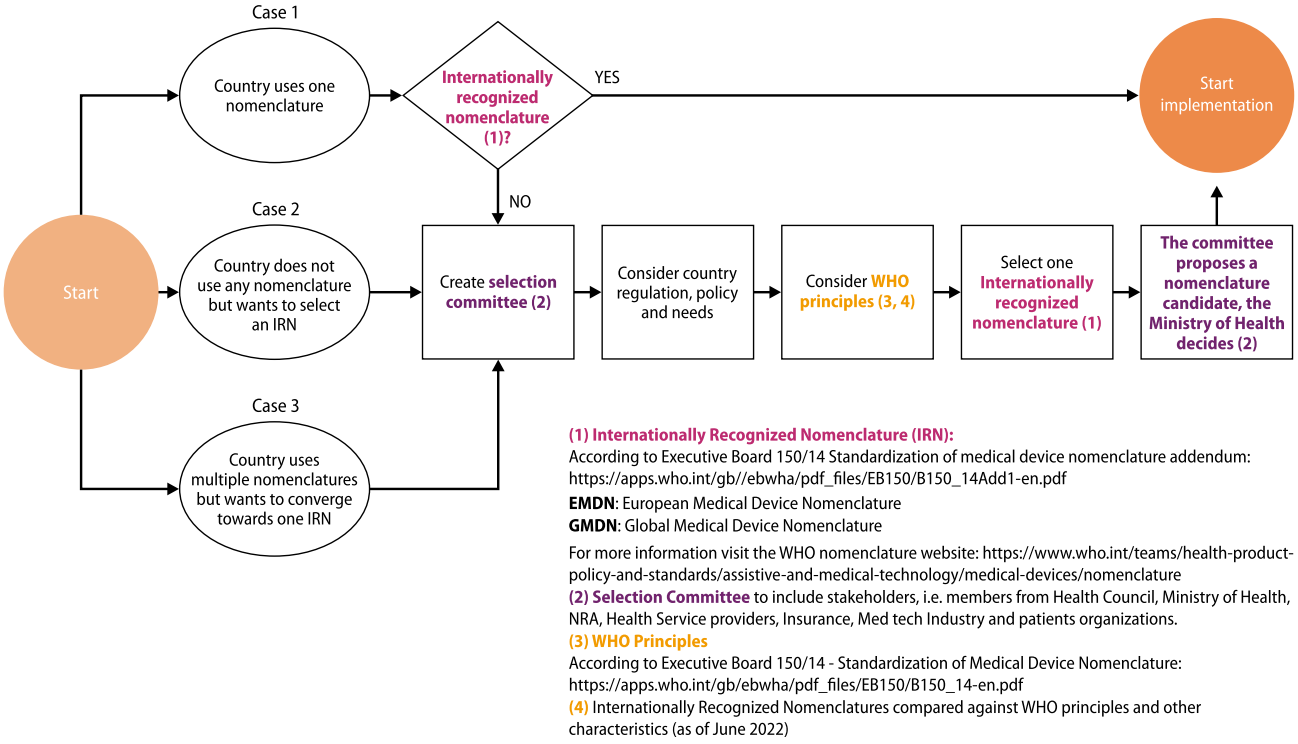
Medical device nomenclature consists of standardized codes and names for classifying and identifying them and related health products. Use of several nomenclature systems complicates exchanges of essential information among individuals and organizations and can have negative health, economic and social consequences. A standardized classification and naming system for medical devices provides a common language for documenting and reporting devices throughout the health system, at all levels of care and for all purposes. WHO supports having globally accessible, transparent, harmonized nomenclature system *(48,49)* including terms, codes and definitions.

Nomenclature could be included in the national medical devices policy to harmonize its use locally, regionally and nationally and for regulation, assessment, supply, management and reporting. As stated in the Global model regulatory framework *(3)*:

> "The benefits of a nomenclature system can only be realized when the same nomenclature system is used consistently and accurately by all relevant stakeholders and that nomenclature is globally harmonized. To this end, the selection of an internationally recognized nomenclature could reflect the needs of each stakeholder both individually (for example, the ministry of health, regulator, manufacturer, health-care industry, health-care providers, trade and customs officials and patients)".

In line with decision WHA75.25 (2022), WHO has adopted European Medical Device Nomenclature (EMDN) codes and terms since 2023. As of March 2024, WHO has also been authorized to use Global Medical Device Nomenclature (GMDN) terms, codes and definitions in its documents and databases. Consequently, the Priority medical devices information system (MeDevIS) *(38)* now includes both nomenclature systems and has progressively extend their use to other WHO databases and publications *(48,49)*. WHO encourages Member States to use any of these nomenclature systems, to advance harmonization and to avoid creation or development of other nomenclature systems, which would complicate correct identification of medical devices at local, regional and national levels and for international benchmarking. Selection of an internationally recognized nomenclature is illustrated in Fig. 12.

Fig. 12. Selection of an internationally recognized nomenclature

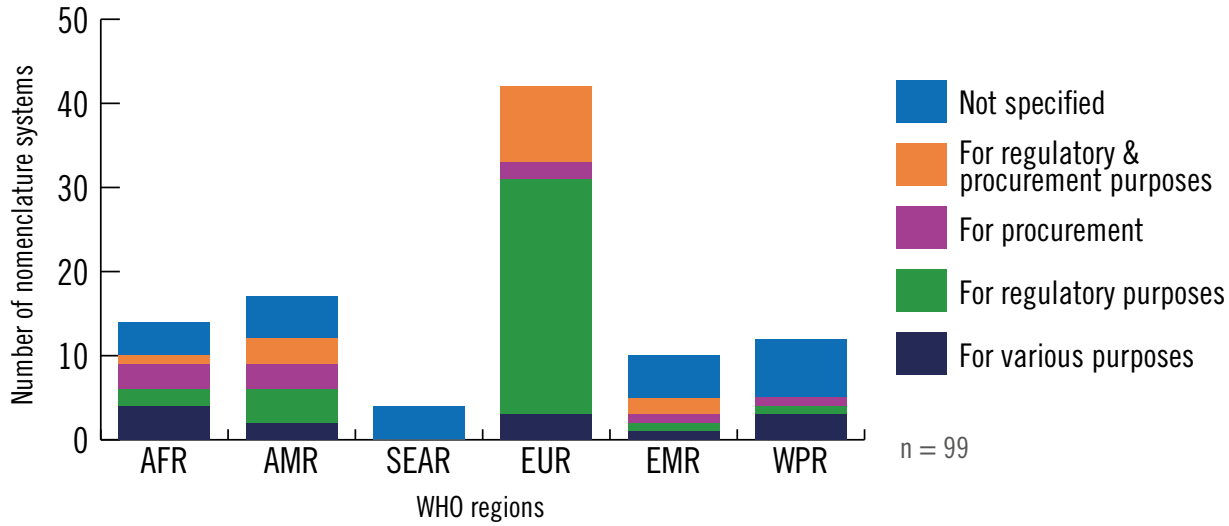


Source: Adapted from Annex 3 in WHO *(3)*

The two approaches to naming medical devices are nomenclature systems. Nomenclature systems such as GMDN and the Universal Medical Device Nomenclature System are multi-hierarchical, whereas classification systems such as the Classificazione Nazionale Dispositivi medici in Italy and the EMDN are hierarchical. Each approach has advantages and limitations *(50,51).*

WHO's Global atlas of medical devices 2022 *(22)* provides information on use of nomenclature systems for medical devices by country (Fig. 13).

Fig. 13. Purpose of use of nomenclature systems by WHO region in 2022 survey



Source: WHO *(22)*

3.1 European Medical Device Nomenclature

The EMDN is used in the European Union regulatory framework for medical devices. It is designed to be accessible and transparent *(52)*. The system is alphanumeric and includes a hierarchical tree of up to seven levels. Medical devices are classified into three main levels: category, group and type, with a maximum of 13 digits. More information on the structure of the EMDN and the full database are available on the website of the European Commission *(52)*.

3.2 Global Medical Device Nomenclature

The GMDN is an internationally recognized system for naming and grouping medical devices *(53)*. It provides standardized terms for use in global trade, regulatory activities and health-care delivery. It is used by regulatory authorities, including the Therapeutic Goods Administration in Australia and the Medicines and Healthcare Products Regulatory Agency in the United Kingdom *(54)*. The database is not, however, fully accessible to the public, and an institution or other user is obliged to register with the GMDN agency in order to use it.

3.3 Unique device identification

The unique device identification (UDI) system provides standardized identification of medical devices to improve patient safety, supply chain management and device tracking. It consists of assignment of a globally recognized alphanumeric code consisting of a fixed device identifier and a variable production identifier. Data are stored in national public databases. Information about the structure, function and issuing bodies of UDI is available *(55,56)*. IMDRF has created a framework for regulatory authorities and manufacturers to develop and implement their UDI systems in a globally harmonized way *(57)*.

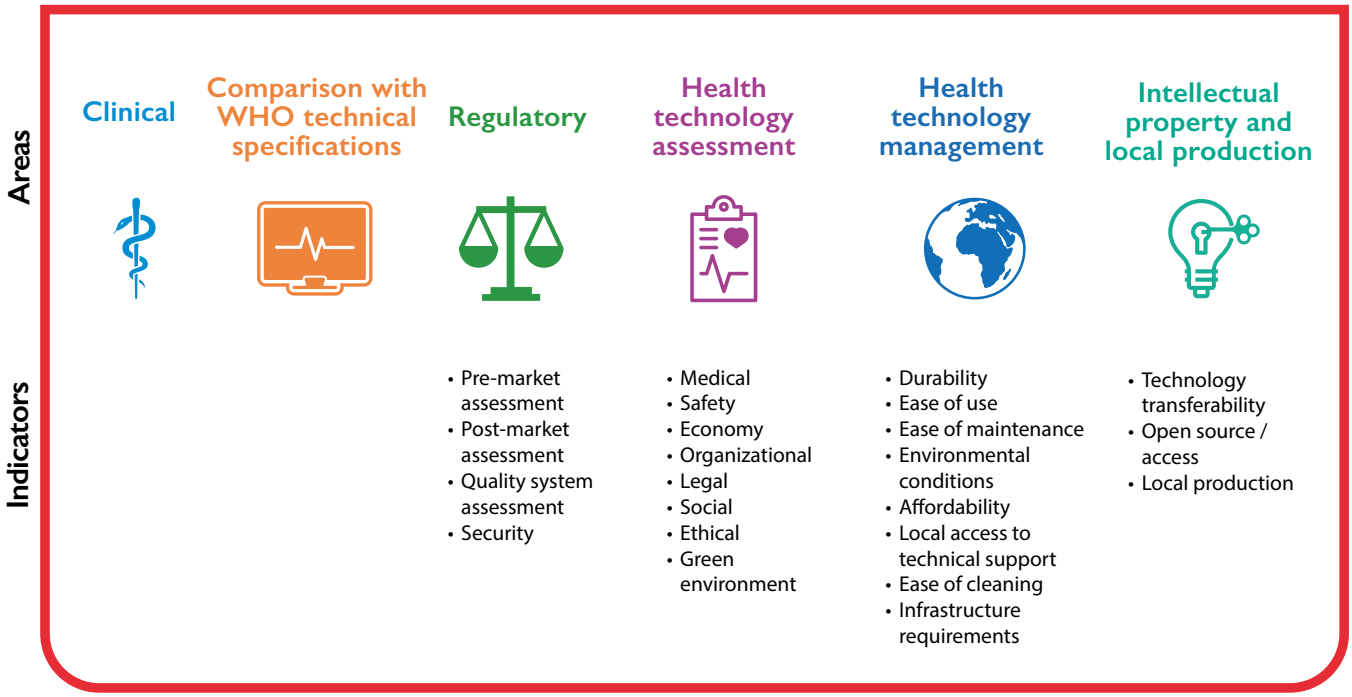
In order to benefit fully from a UDI system, health-care managers could also use data in the associated UDI databases, such as the European database on medical devices UDI and device registration module *(58)* and the Global Unique Device Identification Database of the US Food and Drug Administration *(55)*. Examples of regulatory authorities that have implemented UDI standards or regulations are listed in Table A2.1 in Annex 2.

4. Research, innovation, manufacture of and trade in medical devices

R&D in health is usually performed in high-level research institutions, such as national institutes of health, or in the academic sector, in networks of universities, or in the private sector, including industry and innovative startups. It is usually coordinated by a national science or research council. In order to address national needs effectively, academic and research strategies must correspond to the health priorities of the population. When researchers are developing innovative technologies, they must identify the health challenge properly and address it by priority and target population.

An overview of innovative health technologies for low-resource settings and a validated method for guiding R&D is provided in the WHO compendium of innovative health technologies for low-resource settings 2024 *(59)*, which offers a robust, validated framework for assessing the appropriateness of technologies and cites innovative technologies that have been assessed for clinical effectiveness, compliance and the feasibility of local production. The elements used to assess innovative technologies are illustrated in Fig. 4.

Fig. 14. Elements used to evaluate the appropriateness of alternative technologies

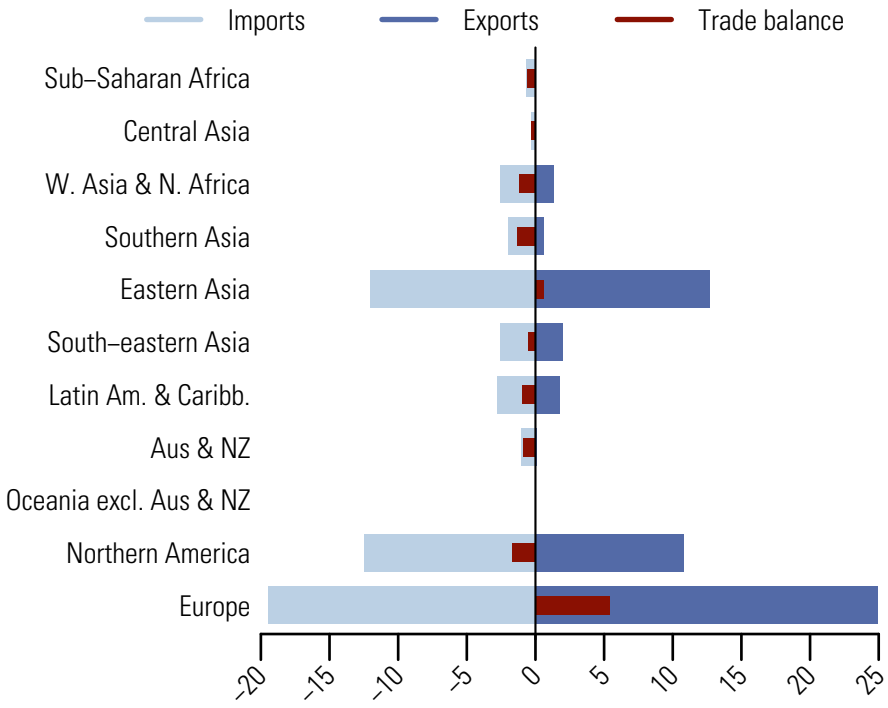


Source: WHO *(59)*

4.1 Global market for medical devices

The International Trade Statistics Yearbook, Vol. I. Trade by country, and Vol. II, Trade by product *(60)* provide an overview of the latest trends in global trade, with country profiles and data on the exchange of specific goods and services. In 2022, the value of exports of electro-medical and radiological equipment was US$ 54.4 billion, representing 0.7% of global exports of machinery and transport equipment of the Standard International Trade Classification and 0.2% of total merchandise exports (Fig. 15). The value of imports was US$ 56.0 billion.

Fig. 15. Trade balance of electro-medical and radiological equipment by SDG region, 2022



Source: United Nations *(60)*

4.2 Harmonized commodity description and coding system

The Harmonized System is an international product classification system developed by the World Customs Organization, which consists of over 5000 commodity groups identified by six-digit codes. The System is used by more than 100 countries as a basis for customs tariffs, trade statistics and various economic and trade policies. It helps to harmonize customs procedures and reduce trade costs and is used for purposes such as taxation, trade monitoring and economic research. The system is governed by the International Convention on the Harmonized Commodity Description and Coding System and is updated periodically by decisions of the World Customs Organization's Harmonized System Committee *(61)*. Ideally, an association could be established with the medical devices nomenclature system to ensure harmonization.

4.3 Access and intellectual property

Intellectual property encourages innovation but can limit access to affordable health technologies in low-demand markets. Flexible policies, such as those included in the Doha Declaration of the World Trade Organization *(62)*, balance innovation with public health needs. WHO, the World Trade Organization and the World Intellectual Property Organization support countries in aligning intellectual property with health goals, although major disparities remain.

4.4 Trade agreements

Since 2009, WHO, the World Trade Organization and the World Intellectual Property Organization have strengthened their collaboration and coordination on matters concerning public health, intellectual property and trade *(63)*.

4.5 Industrial manufacture

Medical device manufacture differs from other sectors in a number of ways. Due consideration could be given to building and supporting sustainable local manufacturing. The sector is dominated by small and medium-sized enterprises and trade secrecy; long training is necessary for technological transfer; manufacture must comply with good manufacturing practice and meet ISO standards; production changes frequently due to innovations; and strict traceability is essential. Manufacturing volumes vary widely, some devices are culturally sensitive, and most require after-sales support for maintenance and software updates.

5. Medical device regulation

Another element of medical device policy is a regulatory process to ensure the quality and safety of medical devices that will enter the market and be distributed in a country, administered by a medical devices unit in the national regulatory agency. As stated in the WHO Global model regulatory framework for medical devices including in vitro diagnostic medical devices, Annex 3 *(3)*:

> The regulation of medical devices including in vitro diagnostics is critical in assuring their quality, safety and performance. In May 2014, the World Health Assembly adopted resolution WHA67.20 on regulatory system strengthening for medical products. This underscored the importance of effective regulatory systems as an essential component of health system strengthening and contributor to public health. WHO decided to develop guidance to support countries that had yet to develop and implement, or that were revising, their national regulatory controls for medical devices.

A stepwise approach, from basic to extensive controls, is recommended in establishing a regulatory system for medical devices. The regulatory framework must be sustainable and extendable and accommodate advances in clinical practice, public health need and evolving technology. Basic controls form the foundation for extended controls. To ensure international regulatory convergence and harmonization, countries are encouraged to integrate the principles of internationally harmonized technical guidance into their legislation.

WHO recommends that a medical devices unit be part of the national regulatory authority (NRA), which could be independent and can exercise autonomous decision-making within the legal framework. Guidance on regulation of medical devices is summarized in Table 4.

Table 4. Policies for regulation of medical devices

Level	Component
National	Create or maintain a medical device unit as part of the NRA. Ensure at least the core level of control and enforcement for pre-market approval and post-market surveillance. Clearly define exemptions for exceptional pre-market situations. Maintain good relationships with authorities in other jurisdictions, manufacturers, health systems, users and patient groups. Provide training in assessing compliance with regulations and in evaluating regulatory data submitted by manufacturers and importers. Join an audit programme. Ensure that medical device laws include a classification scheme based on internationally harmonized guidance.
Regional level	Adopt the national guidance, particularly on decisions for pre-market approval, and adapt to the regional or local situation. Provide information on adverse events to the national entity,
Manufacturers	Draw up, hold and, as required, submit or make available a written declaration of conformity, attesting that the device complies fully with all regulatory requirements. Implement a quality management system. Report adverse events to the NRA, as required by the national law.

5.1 Global model regulatory framework

The WHO Global model regulatory framework for medical devices was originally published in 2017 *(2)*, and an updated version was published in 2021 *(3)*. It provides principles, definitions and attributes for effective, efficient regulation that is aligned with international frameworks such as the IMDRF. It is particularly useful for WHO Member States with limited or no medical device regulation, as it can be used to guide them from basic to advanced regulatory controls, according to their resources. See Annex 3 of the Framework for guidance on national regulation of medical devices aligned to international standards.

5.2 Global Benchmarking Tool Plus Medical Devices

The WHO Global Benchmarking Tool Plus Medical Devices (GBT+MD) Revision VI+MD version 2 *(64)*, published in December 2024, is the latest version of the GBT for benchmarking medical devices in national regulatory systems. It is designed to support evaluation and strengthening of regulatory systems for medical devices. It comprises six regulatory functions in the framework of a national regulatory system and includes a glossary and fact sheet to explain terms and definitions.

5.2.1 Recognition and reliance

Reliance and recognition support convergence of international regulation on medical devices. Reliance allows an NRA to use the assessments of a trusted reference authority, such as another NRA, a conformity assessment body or WHO, in making its own regulatory decisions. The approach can be applied to both market authorization and post-marketing activities and may involve abridged assessments such as the WHO prequalification process *(3)*. Recognition is a more comprehensive form of reliance, in which an NRA fully accepts the regulatory decisions of a reference authority, obviating duplicate assessments.

Reliance and recognition must be consistent with national legislation. If they are not explicitly permitted, they may be adopted through policy interpretation or legislative revision. These mechanisms require mutual understanding, confidence and, if necessary, agreements on confidential information exchange. They may not be appropriate for country-specific aspects or when products differ in their configuration in different markets.

Use of reliance has led to faster approval and simplified submissions *(65)*.

Resolution WHA67.20 (2014) encourages international collaboration, regulatory convergence and participation in global and regional networks.

Table 5 lists elements of the regulatory control of medical devices for which regulatory guidance is available and those for which reliance or recognition may be used.

Table 5. Regulatory control of medical devices

Expanded level controls and enforcement		
Premarket	**Placing on the market**	**Postmarket**
Create oversight of clinical investigations	Perform in-country quality management systems audits	Establish within the regulatory authority a postmarket surveillance and vigilance reporting system
Appoint and have oversight of CABs	Perform review of submissions for compliance with Essential Principles	
Recognize standards		Require mandatory reporting by manufacturers of adverse events
Adopt a medical device nomenclature system		
Control advertising and promotion		Inspections of registered establishments
		Provide for testing laboratories

Basic level controls and enforcement		
Premarket	**Placing on the market**	**Postmarket**
Publish law, including definition, and regulations with transition period Establish medical device classification for regulatory purposes Establish Essential Principles of safety and performance Establish basis for reliance and recognition Establish requirements for declaration of conformity Establish requirement for manufacturers for a QMS Establish requirements for labels and labelling Prohibit deceptive, misleading and false advertising Establish provisions for exceptional premarket situations	• Registration of establishments • Listing of medical devices • Import controls	• Establish a system for vigilance reporting • Require mandatory notification by the manufacturer of field safety corrective actions • Establish a procedure to withdraw unsafe medical devices from the market • Establish procedure to issue safety alerts to users • Undertake market surveillance

Sources: WHO *(3)*
The empty boxes indicate activities that an NRA can decide according to national priorities,

5.2.2 Audit programmes

Audit programmes for medical devices are crucial in ensuring their safety and compliance with global regulatory standards. The Medical Device Single Audit Programme from IMDRF is an example of a global initiative designed to streamline auditing *(66)*. Countries are encouraged to join audit programmes to ensure the effectiveness of their regulatory frameworks.

5.2.3 National competent authority report

Medical devices may fail to perform as expected due to issues in design, manufacture, use or maintenance. A regulatory authority could establish a system for reporting complaints, including malfunction and adverse events, and ensure that the reports are forwarded to the manufacturers for investigation. Vigilance reports can lead to corrective actions, further investigation or sharing of information with other authorities. Guidance on reporting failures is provided by the IMDRF *(67)*.

5.3 Pre-market approval

The purpose of pre-market approval is to ensure that medical devices in any class conform to all relevant essential principles before being placed on the market. The WHO Global Model Regulatory Framework for Medical Devices *(3)* provides a stepwise approach to supporting the regulatory authority. Basic controls for pre-market approval are illustrated in Table 5 and discussed below.

In the pre-market phase, foundational regulatory controls could be established to ensure the safety, quality and oversight of medical devices before they are placed on the market. A law could be published that clearly defines medical devices and relevant regulations, including a transition period to allow stakeholders time to comply with new requirements. It is also important to establish a classification system for medical devices according to their intended use and level of risk, which guide the appropriate level of regulatory oversight. The essential principles of safety and performance must be defined to ensure that all devices meet basic requirements for protecting health and ensuring performance throughout their lifecycle.

A regulatory basis for reliance and recognition could be established, so that the NRA can take into consideration assessments and decisions made by trusted international bodies or reference authorities. Requirements for a declaration of conformity must be set, specifying the manufacturer's responsibility to demonstrate that a device meets applicable regulatory requirements. Manufacturers could also be required to implement a quality management system to ensure consistent production and quality control of medical devices. Clear labelling requirements must be established to ensure that users have access to accurate, complete information on the use and safety of a device.

To protect users and ensure transparency, misleading or false advertising related to medical devices must be prohibited. Provisions for exceptional pre-market situations could be defined, such as emergency use or humanitarian exemptions, to ensure flexible yet controlled responses in certain circumstances.

5.4 Post-market surveillance

Post-market surveillance ensures the safety of medical devices after they enter the market. It involves monitoring device performance, collecting reports of adverse events and analysing user feedback. Manufacturers must implement post-market surveillance systems and report adverse events, especially those that pose a risk to public health. NRAs could oversee the process and enforce actions such as recalls if public health is at risk. NRAs could have systems for audits, inspections and safety alerts *(3)*. Harmonization of global safety standards is encouraged, with international bodies such as WHO and IMDRF supporting consistent vigilance practices.

WHO has published Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics *(68)* and Global benchmarking tool for evaluation of national regulatory system of medical products *(64)* which includes a section for benchmarking post-market surveillance and market surveillance of medical devices in national regulatory systems.

The Global Harmonization Working Party has established a post-market resource centre *(69)*, and the WHO webpage on safety information for medical and IVDs can be used to report incidents. It also provides information on active field safety notices *(70)*. Other countries' NRAs (e.g. Botswana *(71)*, Ethiopia *(72)* and United Republic of Tanzania *(73)*) provide data from post-market surveillance and guidelines and resources. EUDAMED is developing a Vigilance and Market Surveillance module *(74)*, which will include distribution of reports of corrective actions taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident, publishing manufacturer communications to users or customers in relation to one or several such incidents (fully available to the public) and summary reports. The IMDRF has developed standardized terminology (including terms, terminology and codes) for categorized reporting of adverse events *(75)*.

Examples of harmonization groups, regulatory authorities and WHO collaborating centres on regulation of health technology are provided in Annex 2.

5.5 Instructions for use

Instructions for use provide health-care providers and patients with guidance on safe, effective use of medical devices.

The Association of Southeast Asian Nations (ASEAN) Medical Device Directive includes labelling requirements and principles of instruction for use for medical devices *(76)*. To encourage regulatory convergence, the IMDRF has published Principles of labelling for medical devices and IVD medical devices *(77)* to provide globally harmonized principles for labelling.

6. Health technology assessment

It is recommended that national policy for medical devices include a section on HTA for deciding on the medical devices to be listed for national procurement and reimbursement in benefits packages. HTA is used to evaluate the clinical, economic and social impacts of medical devices as a basis for decisions on coverage, reimbursement and benefits packages. Suggested components of policy for HTA are listed in Table 86.

More guidance on HTA is provided in Health technology assessment of medical devices, second edition *(4)*.

Table 6. Suggested components of policy for HTA

Level	Component
National	Create or maintain an HTA unit specifically for medical devices. Provide evidence-based recommendations for public policy on medical devices and technologies aligned with population needs and national health priorities. If a low-resource approach is required that it is still effective, such as rapid HTA, use multi-criteria decision analysis, adaptive HTA and real-world evidence. A national list of priority medical devices could include essential diagnostic tests, based on WHO model lists (Fig. 17). Define health benefit packages (i.e., essential health interventions and technologies that a healthcare system commits to providing to its population). Additional mechanisms are required to ensure effective implementation and coverage, particularly for medical devices, as further discussed in sections 3 and 5.
Regional	Create or maintain an HTA unit. Adapt HTAs to local contexts and needs.
Local health facility	Implement national recommendations at the local level, or to develop local guidance where national recommendations are not available. In this situation hospital based HTA can be reviewed, as well as setting a selection committee including the local clinical specialist, the local biomedical or clinical engineer, local finance manager, and related facility managers to propose a recommendation to the health facility manager on what medical devices to incorporate.

WHO used HTA principles to continuously update priority lists to improve access to suitable medical devices, to improve the quality of care, to address health-care needs and to strengthen health-care systems. The lists provide evidence-based guidance to policy-makers for the development or updating of national lists of priority devices and to promote their availability to support achievement of UHC.

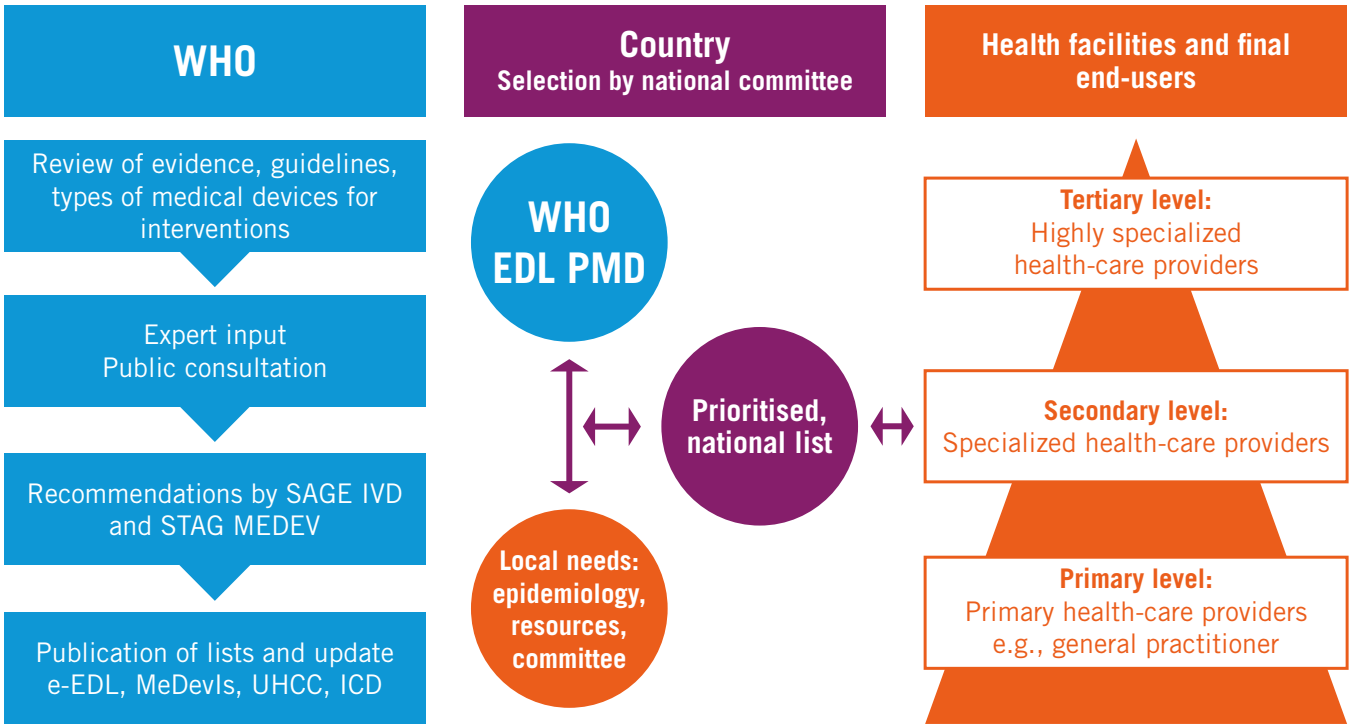
WHO also uses HTA to define medical devices and in-vitro diagnostics. The list of priority medical device identifies medical devices that, when adapted to local contexts, can be used in the management of health-care priorities such as disease elimination and addressing high-burden diseases (e.g. cancer) and those that affect vulnerable populations such as the elderly, pregnant women and newborns.

The WHO lists of priority medical devices list and essential in vitro diagnostics can be used by Member States to develop or update their national medical devices lists for reimbursement or public procurement or to define essential or priority interventions for achieving UHC.

The first column of Fig. 16 shows the process whereby WHO adds new devices or in vitro diagnostics to its lists. Then, it is proposed that a national HTA committee or other decision-making body decide which technology could be prioritized according to factors such as clinical need, burden of disease and available infrastructure and resources *(4)*.

For more information, see the WHO Medical devices information system, MedevIS, which includes terms, codes, definitions, types of medical device, primary use, health care unit, service delivery platform, health-care level, technical specifications and training materials *(38)*. See also the electronic essential in vitro diagnostic list, which includes the IVD purpose, assay format, review of evidence and recommendations by the Advisory Committee *(37)*.

Fig. 16. Updating of WHO lists of priority medical devices and uptake by countries in developing national lists



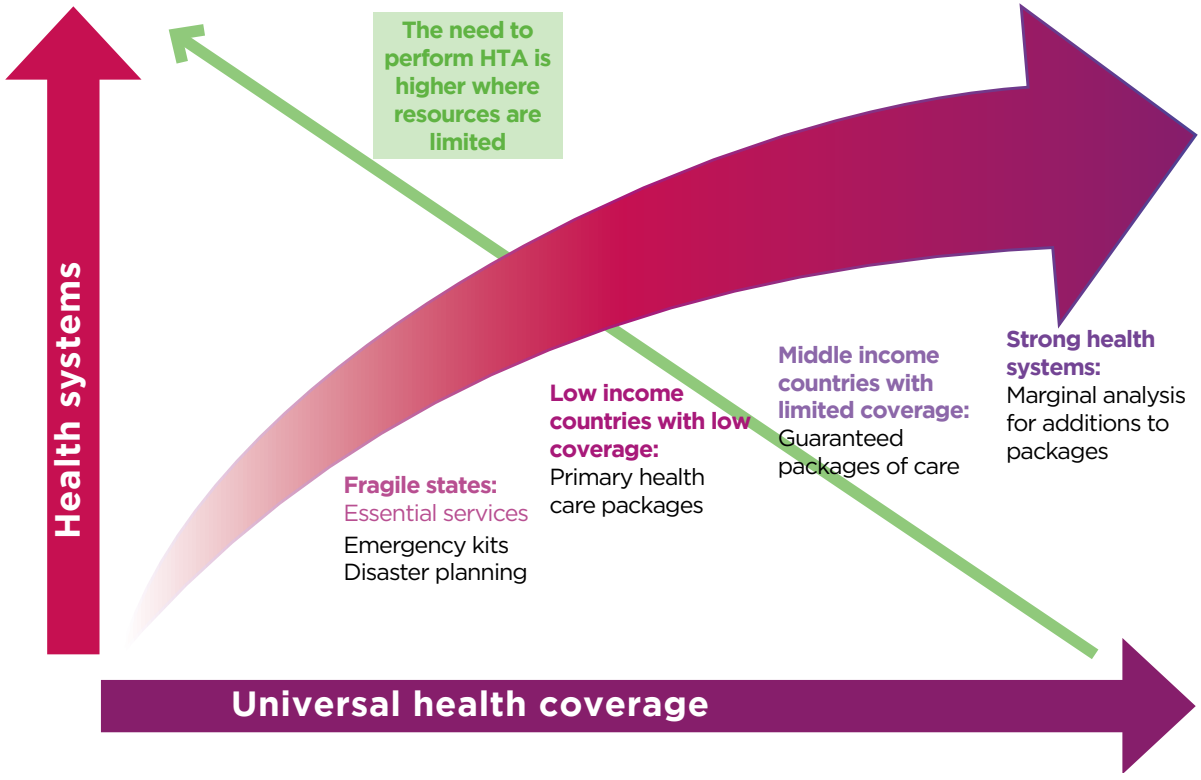
Source: WHO *(4)*

e-EDL, electronic version of the WHO model list of essential in vitro diagnostics; PMD, priority medical devices

6.1 Selection for inclusion

The selection of health technologies is guided by criteria such as effectiveness, safety, cost-effectiveness and local relevance for addressing major health challenges, for supporting UHC and alignment with population needs, particularly in LMIC *(35)*. The political economy of HTA is shaped by a country's legal, financial and social context, in which cost-effectiveness is balanced with ethical and social values, ensuring transparency by allowing stakeholder challenges through legal review *(78)*. In countries with well-established UHC, HTA is a well-recognized tool for setting priorities for public reimbursement and deciding on coverage. In countries where resources are limited, there is an even greater need to conduct HTA (Fig. 17). Integration of HTA into the health systems of LMIC involves building technical capacity, developing regulatory frameworks and ensuring stakeholder engagement. HTA in LMIC also requires data, as estimating the potential costs and health effects of interventions and technologies is challenging in the face of limited access to accurate demographic and epidemiological data. See WHO's guidance to institutionalize HTA *(79)*.

Fig. 17. Levels of HTA application with development of UHC



Source: WHO *(4)*

6.2 Benefits packages

Defining a health benefits package, which consists of the essential health interventions and technologies that a health-care system is committed to providing to its population, ensures equitable, sustainable access to health care. This is integral to achieving UHC *(80)*.

6.3 Priority-setting

Priority-setting is essential for ensuring the fair, efficient allocation of limited health-care resources. Effective priority-setting is based on principles such as inclusivity, evidence-based decision-making, transparency and alignment with national values *(79)*.

6.4 Ethics and social and economic evaluations

Ethical, social and economic aspects must be included in HTA. Active involvement of patients, caregivers, health-care professionals and other stakeholders in HTA is fundamental to ensuring that decisions reflect the diverse perspectives and values of society *(4)*. Examples of HTA agencies, networks and international professional organizations are provided in Annex 2.

7. Health technology management

HTM, also called "clinical engineering", comprises acquiring, implementing, maintaining and optimizing health-care technologies within a health-care organization. HTM units may be at national, regional or hospital level. They oversee needs assessment, device safety and maintenance. National HTM centres set national guidance, offer training and support strategic oversight, although their focus may differ by country. Table 7 lists the suggested components of policy for HTM.

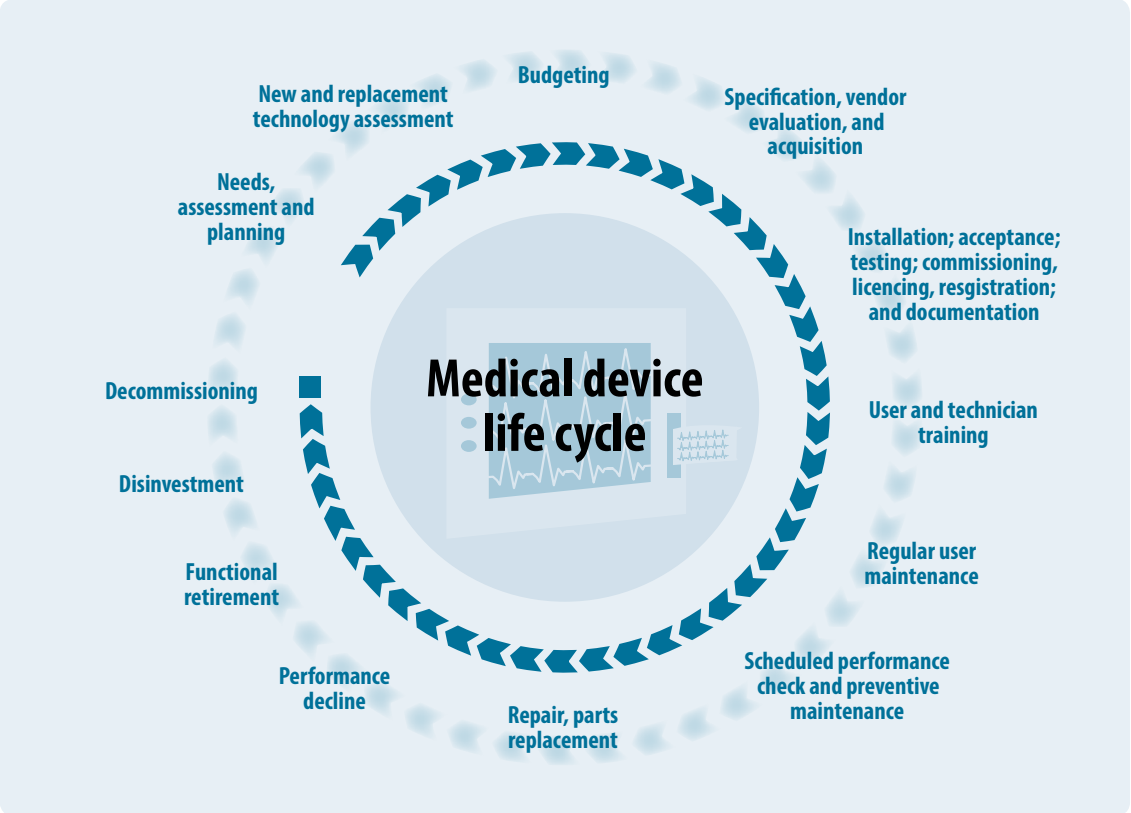
Table 7. Components of HTM

Level	Component
National	Create or maintain an HTM unit in the health ministry. Issue best practices in all areas of HTM, including those of WHO if available. Core functions of HTM: • management of medical devices in each health-care unit and/or required for health interventions; • needs assessment, planning and procurement (including through donations); • inventory and maintenance management information systems to optimize resource allocation and ensure interoperability with other information systems; • training end users; • oversee management of manufacturers or representative vendors services, including maintenance, provision of consumables, spare parts and users training; and • consider integration of new technologies, such as AI, genomics, remote monitoring, mobile health applications and enhanced data analytics.
Regional	Coordinate HTM functions at regional level to ensure best use of resources.
Local health facility	Implement national recommendations at local level, or develop local guidance when national recommendations are not available.

When establishing an HTM system, it is recommended that coordinated HTM teams be formed at all levels, that adequate resources and integration into health management structures are ensured and collaboration is promoted at all levels and with regulatory and assessment bodies. Clear roles and responsibilities could be defined to streamline operations and resource planning.

HTM addresses all phases of the medical device life cycle (Fig. 18).

Fig. 18. Medical device life cycle



Source: WHO *(11)*

At national level, the policy could include provisions for needs assessment and general guidelines on procurement, donations, inventory management, maintenance and decommissioning. While these policies are implemented by health-care facilities, national guidance is essential to ensure more effective resource allocation, transparent procurement and harmonized use of nomenclature for identification of medical devices.

7.1 Needs assessment and planning

Needs assessment consists of identifying and bridging gaps between the current situation and desired outcomes in relation to medical devices. Requirements are prioritized by examining potential impacts on equipment users, service delivery and health system capacity, in alignment with institutional goals. Infrastructure, long-term usage plans and human resource development needs are considered before new devices are acquired.

Needs assessments can be conducted at national, regional, local or facility level and are key in equipment maintenance, inventory updates, service re-evaluations, equipment replacement and planning of new health facilities.

Needs assessment could be conducted according to the guidelines provided in Needs assessment for medical devices *(5)* in the WHO Medical device technical series.

7.2 Procurement and commissioning

Procurement ensures timely, transparent acquisition of good-quality health products and services, guided by clear rules for competition, accountability and prevention of fraud. Procurement consists of:

- development of specifications,
- device evaluation,
- planning and needs assessment,
- procurement,
- installation,
- commissioning and
- inventory update.

Procurement could include consideration of local regulations, quality assurance, replacement of equipment, health information technology, facilities and construction, when required for installation of medical equipment is required, emergencies, sustainability, e-procurement, grievances and ethical considerations.

7.3 Device acceptance in a health service

When a new item of equipment is introduced into a health service, it must be examined to ensure that it is complete, safe, reliable and functioning properly before it is used. Each health facility could have an official process for accepting equipment upon arrival. The HTM working group or its commissioning team oversees arrival, ensuring that:

- the complete order has arrived;
- the equipment is mechanically and electrically safe for use;
- the equipment and supplies are recorded in facility databases; and
- installation, commissioning and initial training are conducted.

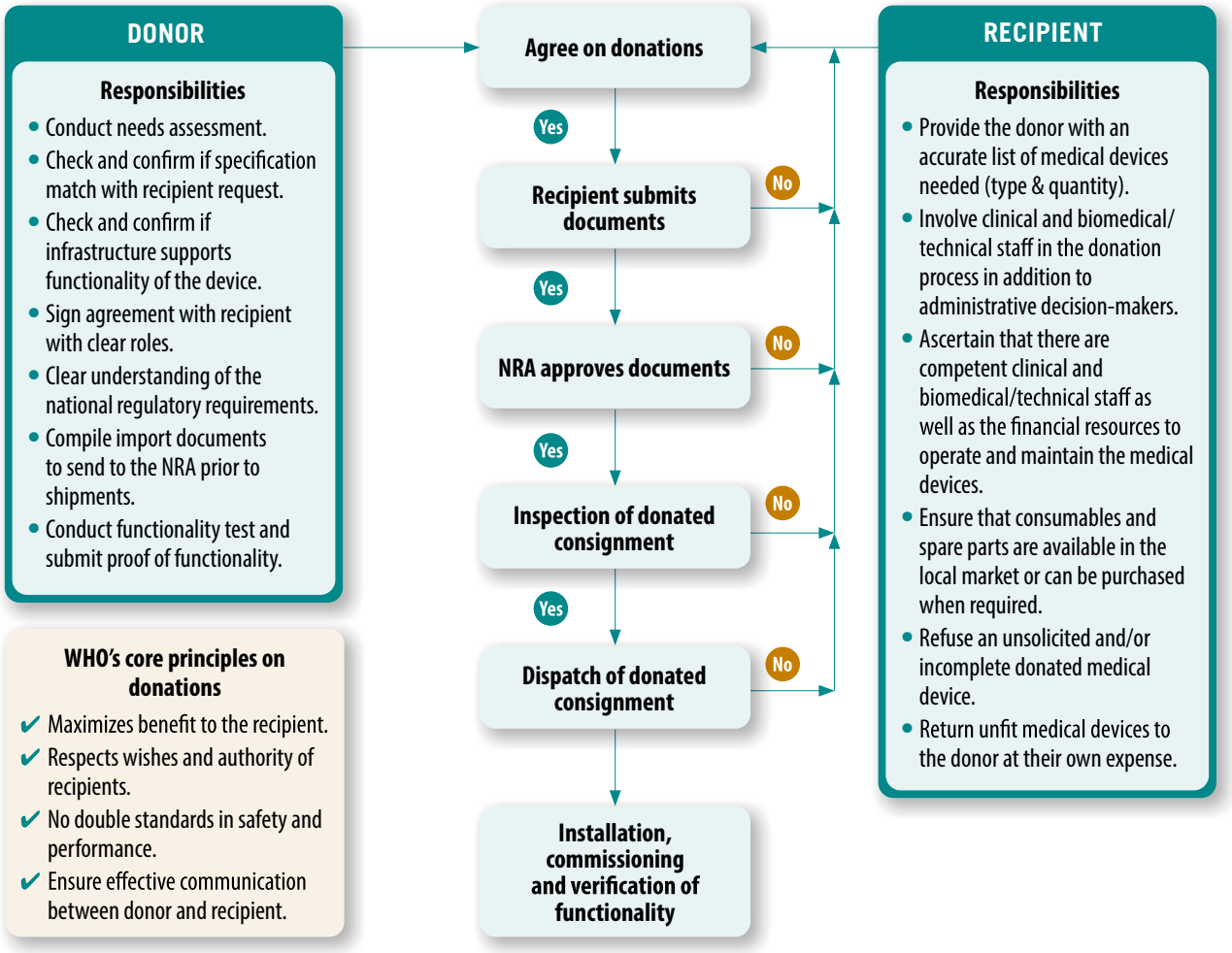
A standard acceptance test log sheet can be used to streamline checks and minimize errors. It serves as the first record in the equipment file and initiates the service history. A sample acceptance test log sheet can be obtained from How to procure and commission your healthcare technology *(81)*.

7.4 Acquisition through donations

Medical devices may be provided free of charge, typically by charities or not-for-profit organizations. If donations are not aligned with the need of recipients and national regulations, however, they can pose safety risks, create burdens and lead to resource and environmental waste. In the absence of local regulations, policies, or guidelines on donations, the involved parties could establish institutional guidelines and standard operating procedures for both donors and recipients, following WHO's Medical device donations: considerations for solicitation and provision, second edition, which includes section on the procedure for regulatory oversight of donated medical devices *(6)*.

Fig. 19 outlines the responsibilities of donors and recipients of medical devices.

Fig. 19. Steps and responsibilities in the donation of medical devices



Source: WHO *(6)*

7.5 Installation

Installation is the process of fixing equipment into place. It also includes the delivery, storage and placement of procured goods in the desired location *(7)*. The steps in installation include:

- preparation of the site,
- inspection before dispatch,
- shipment and clearance by customs,
- receipt and verification,
- installation and
- a user acceptance test.

The installation protocol must include structured inspection and validation to confirm that all the components are correctly assembled and calibrated. This will significantly reduce any risks associated with improper installation. More information on installation is provided in Procurement process resource guide *(7)* in the WHO Medical device technical series.

7.6 Inventories and computerized maintenance management systems

Although such system are established at health facility level, general guidance on naming, inventories and general maintenance policies could be included in the national policy to encourage harmonization.

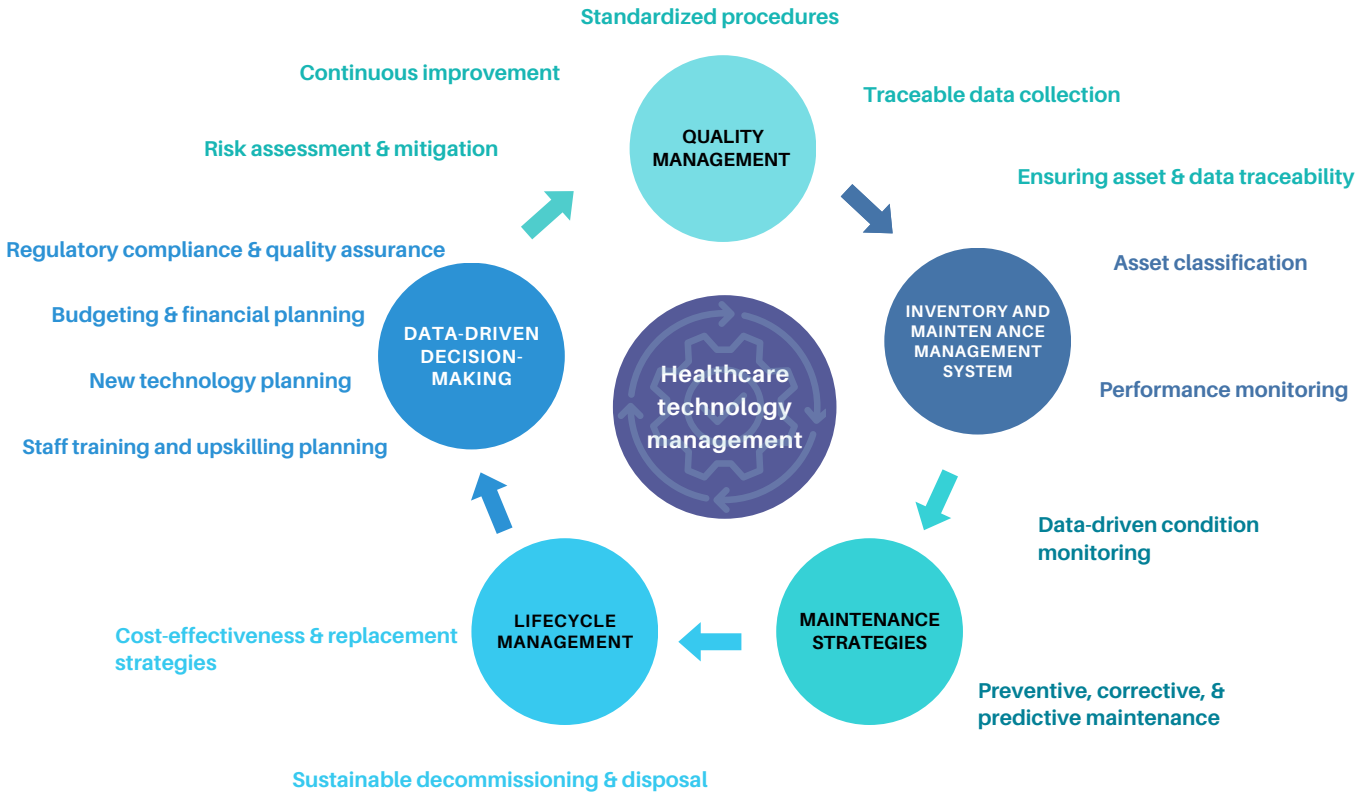
Inventory is essential for effective HTM, as a basis for decision-making and resource allocation. Continuous updating of data on equipment status, from acquisition and retirement to annual audits, allows HTM teams to have an accurate view of all medical equipment and the necessary consumables and spare parts. The inventory, whether managed manually or with software, provides information for critical HTM activities, from budgeting for equipment and maintenance to hiring, training and establishing service contracts.

WHO suggests use of a maintenance management system to enhance inventory management by centralizing data and automating processes, including modules for tracking installation and commissioning, scheduling maintenance, management of spare parts management and end-of-life management.

A system can be used on the premises or via a cloud-based setup. Strong data security practices are advised. WHO recommends CMMS for facilities that have the necessary resources to reduce equipment downtime, minimize errors and enhance decision-making, ultimately leading to more effective, patient-focused care. More information on installation, inventory and maintenance is available in Inventory and maintenance management information systems for medical equipment just published by WHO in June 2025 *(8)*.

Fig. 20 proposes a holistic approach to HTM.

Fig. 20. Holistic approach to HTM



Source: WHO *(8)*

7.7 User training

Ensuring that users of medical devices are well trained and aware of potential risks is essential for patient safety and efficient health-care delivery. Periodic training reinforces knowledge, updates users on new features and addresses any gaps since initial training. A combination of in-house training and outside service providers can offer a comprehensive training programme.

7.8 Maintenance

Medical devices are considerable investments, and many have high maintenance costs. A budget for maintenance is therefore essential at both national and subnational levels, especially in the health-care sector. Proper budgeting ensures that medical equipment remains functional, safe and efficient over time. A well-planned and managed maintenance programme keeps the medical equipment in a health-care institution reliable, safe and available for use when it is needed for diagnostic and therapeutic procedures. In addition, such a programme prolongs the equipment's lifetime and minimizes the cost of equipment ownership *(9)*.

A maintenance strategy includes inspections and both preventive and corrective maintenance to ensure equipment performance and safety. While inspections help to detect issues, they cannot fully prevent failures, due to the unpredictable nature of components. Maintenance can be managed in-house, outsourced or in a hybrid approach, depending on resources and facility needs. Use of an inventory system *(8)* in a health-care institution for HTM opens the door to use of AI for predictive maintenance. An effective maintenance programme comprises adequate planning, management and implementation.

7.9 Testing and calibration

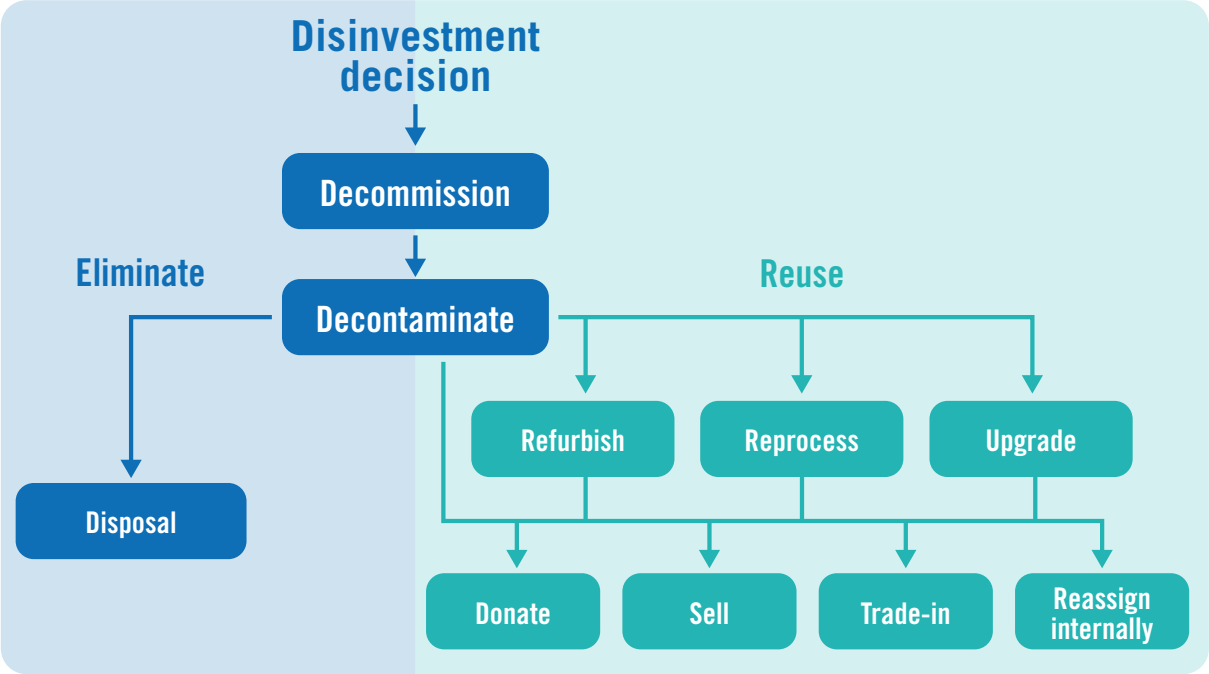
Before medical equipment is put into service, it undergoes an initial inspection to verify compliance with the purchase order, proper installation, functionality and training arrangements. It could be registered in the CMMS, if available. Devices with energy output or measuring functions also require periodic calibration to ensure their safety, accuracy and performance within specifications *(8)*.

7.10 Decommissioning

Decommissioning involves removal of medical devices from their originally intended uses in a health-care facility to an alternative use or their disposal after a decision to disinvest. Decommissioned medical devices can be either eliminated (disposed of) or reused. Reuse of medical devices includes donating, selling, trading-in or internal reassignment *(11)*. All medical devices, whether reusable or non-reusable, must be properly cleaned and decontaminated before decommissioning.

Decommissioning of medical devices that contain ionizing radiation requires special expertise because of the risks associated with exposure and the importance of safe handling and disposal of radioactive materials. A multidisciplinary team with expertise in radiation safety, medical physics, biomedical engineering and regulatory compliance is required. For further guidance, see Decommissioning of medical devices *(11)*, which provides detailed recommendations and procedures for effective, safe decommissioning practices. The steps in decommissioning are illustrated in Fig. 21.

Fig. 21. Decommissioning a medical device



Source: WHO *(11)*

7.11 Decontamination

The decontamination of medical devices is a critical step in ensuring patient safety and maintaining compliance with regulatory standards. According to most guidelines, the process generally includes disassembly, cleaning with an appropriate cleaning agent, manual and mechanical cleaning, and disinfection to remove any articles, dirt or microorganisms that could cause spread of infection from one patient to another. Furthermore, all patient data must be securely erased to safeguard privacy and confidentiality before the device is decommissioned. Each step could be thoroughly documented and reported *(11,83)*.

7.12 Replacement

Medical devices could be replaced when necessary to ensure safety, efficiency and continuity of care when equipment becomes outdated or damaged or reaches the end of its service life. Facilities could have a structured, evidence-based replacement policy that includes consideration of service history, cost-effectiveness and available trade-in or procurement options. A structured approach ensures that replacements are justified, aligned with organizational priorities and compliant with regulatory standards *(11)*.

7.13 Waste management and disposal

Health-care systems produce significant amounts of waste. When a medical device reaches the end of its life, it may become eligible for disposal. Waste generated during its disposal could be managed in accordance with current regulations. This topic is further discussed in section 12.2. Additional guidance on waste management and disposal is provided in Decommissioning medical devices *(11)* and Safe management of wastes from health-care activities *(129)*.

7.14 Maintenance workshops

Ministries of health could develop guidelines for workshops on medical device maintenance for each service level. Hospitals could also provide dedicated medical device maintenance workshops tailored to service-level needs, with the following components *(9,85)*:

- Infrastructure: Include administrative offices, separate electrical and biomechanical work areas, storage for tools and personal protective equipment, optional staff training rooms.
- Equipment and tools: Maintain essential tools and testing devices; share resources when necessary; procure spare parts according to the manufacturer's guidelines, and use generics cautiously.
- Documentation: Secure operation and service manuals at purchase or collaboratively; provide standard operating procedures and technical guides, ideally in the national language.
- Infrastructure: Ensure adequate work space, protection from contamination, ventilation and access for device transport; ensure reliable electricity and digital infrastructure.
- Cost-effective strategies: Invest in technician training and good-quality tools, and consider using centralized depots or shared networks to optimize resources and services.

7.15 Accessories, consumables and spare parts

Accessories, consumables and spare parts (ACS) are essential for ensuring the continuous functionality of medical devices, minimizing downtime, preventing infection and safeguarding both patient safety and the overall lifespan of equipment.

- Accessories are items that support or complement the core function of a device (e.g. blood pressure cuff for a blood pressure monitor).
- Consumables are items that require routine replenishment (e.g. test strips, syringes, printer paper).
- Spare parts are replaceable components required for maintenance or repair (e.g. fuses, batteries).

To ensure the sustainability and functionality of medical devices, ACS could be included in national procurement frameworks bundling them with medical device procurements to cover at least 1–2 years of operation. ACS could be explicitly included on lists of essential medical devices and tender specifications to avoid gaps in their supply. Standardization of ACS specifications and mapping their compatibility with specific device models will improve efficiency and interoperability.

Strengthening the supply chain is equally critical. This can be achieved by setting specific forecasting protocols for ACS, digitized inventory systems with tagging and expiry alerts.

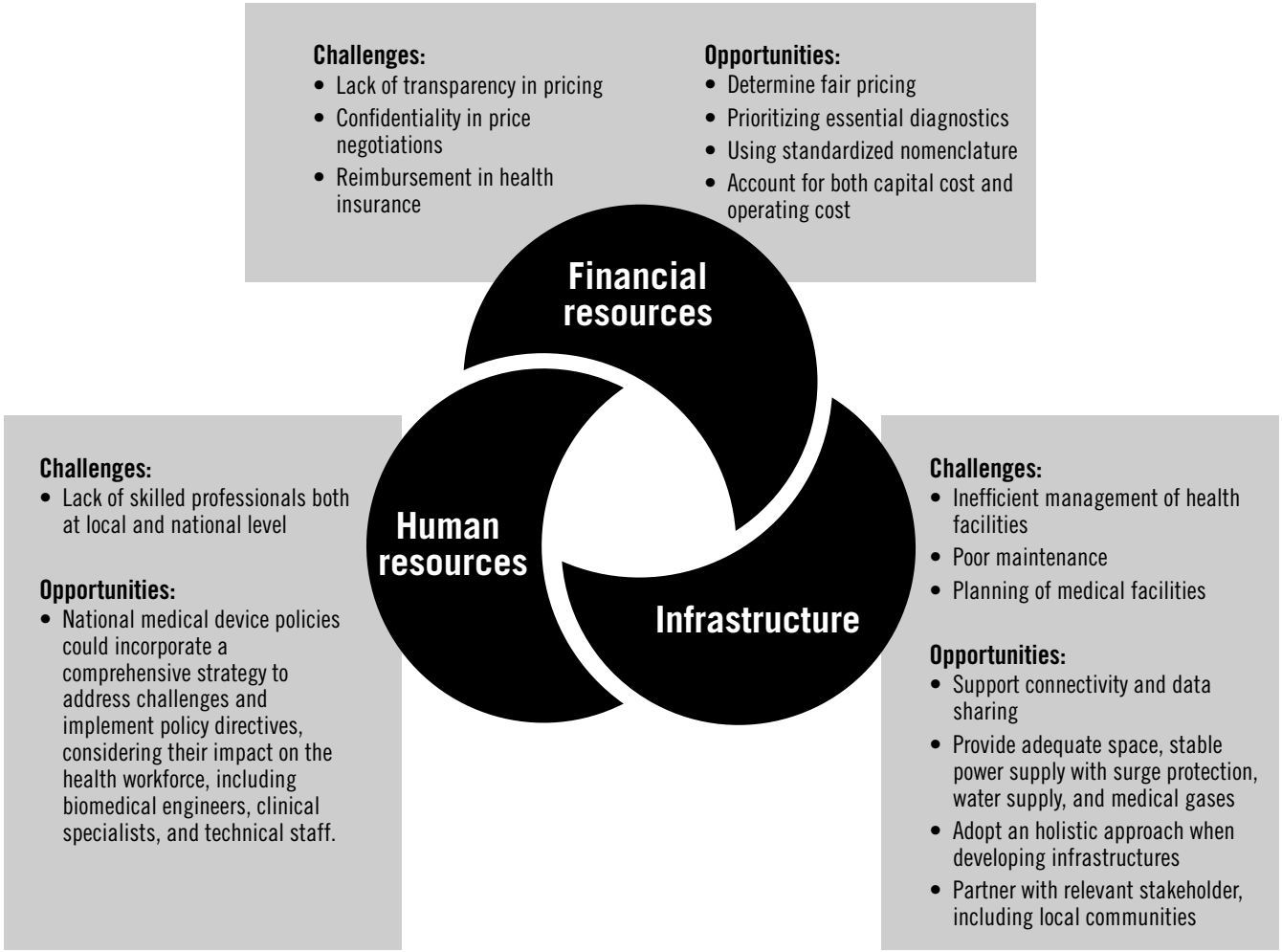
Promoting local and regional sourcing by incentivizing the production of selected consumables and maintaining a vetted supplier list will improve the availability of ACS and reduce lead times. The capacity of biomedical personnel could be built by training on ACS management, maintenance and replacement, with enforcement of regulatory oversight to ensure that all ACS meet approved quality standards. Post-market surveillance could be in place to monitor the performance of ACS to ensure patient safety.

Examples of national HTM units and in WHO collaborating centres are listed in Annex 2.

8. Resources

Adequate infrastructure, an adequate health-care workforce and sustainable financing for medical devices are essential for ensuring effective, safe, equitable delivery of health services in any health system (Fig. 22).

Fig. 22. Resources for medical devices



8.1 Infrastructure and connectivity

Adequate infrastructure is essential for effective use of medical devices. Many health systems, however, have no national guidelines on the minimum requirements for health-care facilities (e.g. technological infrastructure, human resources for each hospital operating unit). Especially in rural areas, they may have poor maintenance, inefficient funding and a shortage of skilled personnel, leading to underused or nonfunctional facilities *(6)*.

Such problems are often exacerbated when infrastructure is provided by multinational corporations that have not assessed local needs and environmental conditions such as humidity, temperature, dust, unstable power supply or a poor supply chain for consumables and spare parts. To maximize the impact of medical devices, a holistic approach is necessary that includes proper facility design, trained staff, interoperable digital systems and strong engagement with local communities *(86)*.

8.2 Health-care workforce

In 2014, the World Health Assembly adopted resolution WHA67.24, on UHC, calling for global human resources for health, later aligned with the SDGs. In 2016, a UN commission called for 40 million new health and social sector jobs by 2030, involving job creation, gender equality, education and reforms to health systems. More information on human resources for medical devices, particularly the role of BMEs, is provided in Human resources for medical devices: the role of biomedical engineers *(22)*.

8.2.1 Biomedical engineers

BMEs are essential in designing, developing, validating and managing medical devices and health-care technologies, although their contributions are often overlooked. They could be involved in every stage of a medical device's lifecycle *(22)*. This includes:

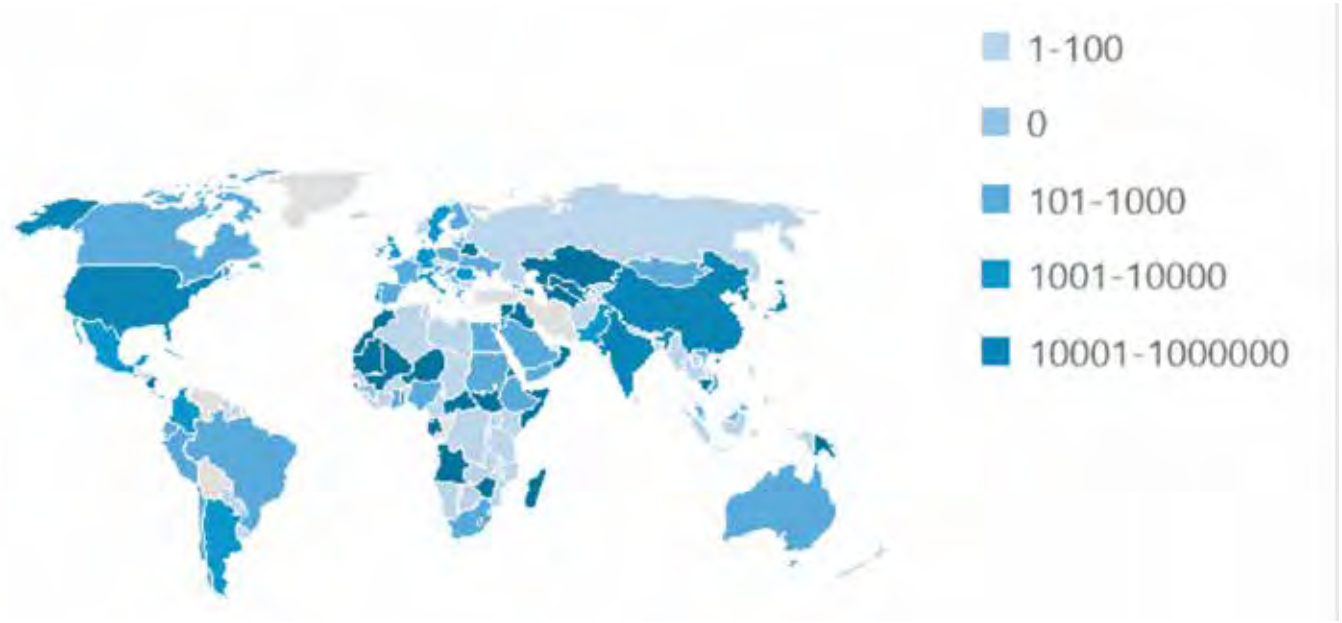
- assessment of needs and R&D;
- innovation in medical devices;
- manufacture;
- coordinating and supporting clinical validation and evaluation;
- regulatory approval and clearance of medical devices;
- HTA, pricing, procurement and disposal of devices;
- HTM of devices, maintaining, ensuring quality and promoting safe use of medical devices in hospitals and other health-care settings;
- post-market surveillance and monitoring; and
- training.

BMEs could be responsible for implementation of national medical devices policies. At regional and local levels, BMEs manage the medical devices in their institution, always in collaboration with other members of the health workforce.

Despite their critical role, BMEs are frequently excluded from decision-making nationally and in health facilities, although global recognition of their value is increasing. WHO surveys and reports provide data on the prevalence and roles of BMEs. Clinical specialists and technical staff are also important for evaluating, managing and replacing medical devices. Collaboration among doctors, nurses, BMEs, technicians and community health care workers ensures optimized device use and improves patient care. Their role in medical device management is described in the WHO publication Human resources for medical devices: the role of biomedical engineers *(22)*. Emerging technologies, especially intangible ones such as AI, are increasing the need for well-trained BMEs. If AI for health is used to diagnose or treat a patient then it could be regarded as a medical device, qualified BMEs could be involved and lead AI development, regulation, clinical trialling, HTA and maintenance.

In January 2015, WHO conducted a global survey of the professional and academic profiles of BMEs and technicians to assess the prevalence of BME departments in hospitals *(22)*. Further data on the number of BMEs, identified from their university degrees, have been collected from the WHO Global Health Observatory and a report on the status of medical devices by country in 2021 *(26)*. The numbers of BMEs in each country are provided on a WHO website *(87)* and illustrated in Fig. 23.

Fig. 23. Numbers of BMEs by country, 2015



Source: WHO *(87)*

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

8.2.2 Clinical medical specialists

BMEs could work with physicians, nurses and other clinical health workers in the management and evaluation of medical devices in health-care settings. Clinical specialists determine when medical devices no longer meet clinical needs and provide expert input on their safety, performance and impact on patient care. They collaborate on technology committees with engineers and financial staff to guide the replacement of outdated equipment.

8.2.3 Allied health professionals

Sophisticated equipment is used mainly in laboratory and imaging departments. Technical staff, including laboratory and imaging professionals, as well as oxygen systems specialists, medical gas pipeline systems experts, medical physicists and other technical specialists, evaluate the performance of and manage medical devices and help to identify when equipment could be replaced.

8.2.4 Workforce requirements

At national level, BMEs have the technical competencies and would be the most appropriate to work in the regulatory agency, in HTA and HTM and in the national agency responsible for medical devices policies.

Health-care facilities define their workforce requirements with various organizational models for biomedical and clinical engineering services, their decisions depending on factors such as local organization, cost and institutional constraints. The three main models *(22)* are:

- in-house personnel: BME services managed entirely within the facility;
- third-party multi-vendor: services outsourced to external providers; and
- a combination of in-house teams and external support.

The Lancet Commission on medical oxygen security has recommended 0.4 BMEs per 10 000 people by 2030, or roughly 1 BME per 100 beds or per 250 health-care workers, with equitable distribution in all types of facility *(87)*. The figures could be considered indicative, approximate benchmarks rather than fixed standards, as staffing requirements must be assessed in relation to local health system characteristics and population needs. To meet this target, various staffing models are used at different health-care levels *(87)*:

- tertiary hospitals: more than two onsite BMEs;
- secondary hospitals: at least one onsite BME;
- primary health-care facilities: at least one BME on call.

Advanced models for defining staffing requirements include data on workload, hospital indicators and the complexity of medical equipment. Measurable objectives in terms of health outcomes can drive decisions about the human resources required *(88–92)*.

For assessment of staffing requirements, WHO introduced a method, Workload indicators of staffing need, which is used to calculate health worker requirements according to workload, with standard times for each activity. More details on staffing needs, including guidance for BMEs, are available in the Workload indicators of staffing need: user's manual, second edition *(93)*.

8.2.5 Non-clinical roles of the health workforce

Health systems include not only clinical staff but also experts in regulation, policy, innovation and education with respect to medical devices. A multidisciplinary, diverse workforce is essential for comprehensive, innovative health-care solutions.

8.3 Financing

Financing and pricing of medical devices are challenging due to lack of transparency, complex pricing structures and insufficient budget allocation for operational costs. Capital costs often dominate procurement decisions, overshadowing the long-term financial demands of maintenance, training and ACS. Efforts to address these issues include initiatives by WHO and other organizations to improve market transparency, standardize nomenclature and promote value-based procurement models. Advocacy groups and governments are also promoting strategies to ensure fair pricing and equitable access, particularly in LMIC. Collaborative approaches are essential for achieving sustainable solutions and improving global access to essential medical technologies.

WHO's Fair Pricing Forum *(94)*, launched after the passage of resolution WHA72.8 on market transparency in 2019, addresses the lack of standardized pricing for medical devices. Prices are often opaque due to product diversity, bundled services and confidential negotiations. Mark-ups by distributors, especially in LMIC, can further inflate costs. Challenges and responses include *(95)*:

- capital costs: focus on upfront purchase and installation, often neglecting long-term sustainability;
- operating costs: the costs of maintenance, consumables and repairs are frequently underestimated, although they are significant; and
- budgeting for ACS: underfunding of maintenance leads to equipment breakdown, especially in LMIC.

The 2024 Fair Pricing Forum, included a session on medical devices, specifically addressing recent Resolutions: diagnostics capacity, access to medical oxygen and the standardize nomenclature.

9. Digital health and artificial intelligence

To improve health information systems, ministries of health could establish a legal framework to ensure that data privacy is balanced with use of health data for public benefit, research and policy-making. Laws could clearly define how data are shared, processed and stored to ensure security without restricting access. Such measures will allow secure, efficient health data management, by:

- balancing data privacy with public benefit, research and policy-making;
- clearly regulating data-sharing, processing and storage to ensure security without limiting access;
- providing key health data to public health authorities and statistical offices;
- adopting international standards such as ICD-11 for consistency and reliability; and
- ensuring secure data management through protocols for access, modification and sharing.

More information on health information systems is provided in the WHO publication, Support tool to strengthen health information systems: guidance for health information system assessment and strategy development *(97)*.

9.1 Patient data privacy

A comprehensive framework to ensure the privacy of health-care data could include a dedicated oversight authority, independent data protection officers and mechanisms to ensure compliance, protect patient data and foster public trust *(97)*.

Health data can be classified into two main categories: aggregate data (presented in summary form with no identifying personal information) and personal data.

In line with its data policy, issued in 2017 *(98)*, WHO actively promotes sharing of health data, especially during emergencies. The policy encourages dissemination of anonymized health data while respecting national sovereignty and confidentiality. WHO's commitment to open access, grounded in global standards such as FAIR *(99)* and GDPR *(100)*, ensures that high-quality health data are accessible for public health and scientific advancement, positioning WHO as a global leader in health data governance.

9.2 Artificial intelligence

Development of successful AI systems in health care requires high-quality data for both training and validation. Use of health data can raise ethical concern about safeguarding individual privacy. There are also technical challenges, such as lack of good-quality data and algorithmic bias. Regulation and governance to address these risks are essential to ensure safe, reliable, transparent AI systems.

In 2018, WHO launched the Global Initiative on AI for Health *(101)* to promote safe, effective use of AI technologies in health care. The WHO Focus Group on AI for Health, established with the International Telecommunication Union, provided guidance for addressing patient data privacy and protection when designing, developing and adopting AI systems for health. WHO's comprehensive strategy for AI in health emphasizes global collaboration and capacity-building, robust governance structures, policies, evidence-based guidance and promotion of equitable, ethical, sustainable AI models for health *(102)*.

Data quality must be considered, from selection of datasets to curation and management of data, which could be well documented by the developers to ensure transparency and allow verification and traceability. Developers could design, implement and document their approaches and methods to ensure quality throughout development and to protect data privacy, including good data accountability practices *(103)*. To ensure privacy protection, developers could be aware of the applicable data protection regulations and privacy laws, including special regulatory provisions for sensitive information, such as genetic data *(103)*.

To provide flexible conditions for developers to test innovative products, an increasing number of countries are experimenting with AI regulatory "sandboxes" in various sectors, including health care. Although this approach has raised a few concerns, it could benefit regulators, developers, manufacturers and, potentially, patients. An AI regulatory sandbox can provide better understanding of AI systems during development, before they are placed on the market; can facilitate development of adequate enforcement policies and technical guidelines to mitigate risks and unintended consequences; and foster AI innovation by providing controlled experimentation scenarios and testing environments for innovative AI technologies, products and services for new, potentially safer AI systems, while maximizing inclusivity and minimizing bias.

The opportunities and challenges of AI in health are discussed further on the WHO websites Harnessing artificial intelligence for health *(102)* and Regulatory considerations on artificial intelligence for health *(103)*, which provide guidance on implementation, governance, and policy development. Further information is provided in: Ethics and governance of artificial intelligence for health: guidance on large multi-modal models *(104)* and Generating evidence for artificial intelligence based medical devices: a framework for training validation and evaluation *(105)*.

9.3 Software as a medical device

The term "software as a medical device" (SaMD) defines software that is intended to be used for one or more medical purposes but is not part of a hardware medical device *(106)*. Development of SaMD based on AI and machine learning is advancing rapidly; however, there is no globally recognized framework for benchmarking evidence generated by these devices. Training for validation and evaluation for digital health products are evolving *(105)*.

AI-based models require extensive, high-quality, inclusive datasets, which are particularly difficult to collect in LMIC. Datasets must reflect the demographics of the target populations to avoid bias and defects in AI SaMD. International datasets often do not represent lower-resource settings and marginalized groups. Data management and sources must be evaluated in assessing evidence from clinical trials and ensuring replication of safety and performance metrics *(105)*. Another source of inequality may be the environmental impact of AI systems and their downstream effects on human health. Member States could develop mechanisms and frameworks for mandatory reporting and disclosure of the direct environmental impacts of AI by companies that offer AI products and services, with the support of the UN Environment Agency (UNEP) *(107,108)*.

The minimum standards for data management are:

- data sources and selection (including missing data);
- data curation, processing and augmentation;
- data quality and demographic distribution; and
- methods for splitting data and overlaps in use of data.

Robust data management is important in post-market monitoring, including audits of integration of AI SaMD into workflows *(111)*.

9.4 Wearables

Wearables allow real-time personal health monitoring. Their global adoption is, however, limited by variation among devices, lack of standardization and the absence of clear guidelines. WHO intends to address these issues in its digital health strategy.

9.5 Cybersecurity

Cybersecurity is essential for protecting health data and digital systems. WHO promotes strong safeguards and international collaboration to ensure data integrity, privacy and resilience in global digital health infrastructure.

9.6 Integration into electronic health records

Electronic health records, digital systems that store and manage patient information in real time, provide authorized users with secure access to information such as medical history, diagnoses, treatments, medications, allergies, vaccinations, laboratory results and images. Electronic health record systems are often managed at national level. They are designed to connect health-care professionals in different facilities, including pharmacists, laboratory personnel and specialists. Electronic health records are essential for modern health care, as they improve communication, streamline workflows and provide both providers and patients with accurate, accessible information *(97)*.

In advanced health information systems, electronic health records completely replace paper records and centralize all information on patient care, including laboratory results, diagnostic images, referrals, surgical operations, prescriptions and billing. They also include tools to support clinical decisions, professional guidelines and electronic signatures for secure authorization.

In fully developed information health systems, electronic health records provide high-quality, standardized data that are easy to analyse. The data can be used for planning, policy-making and public health initiatives. With international coding standards such as ICD, they ensure consistent, reliable information for both patient care and secondary uses.

10. Sustainability

Health-care systems generate significant waste, posing environmental and health risks. WHO promotes climate-resilient, sustainable health-care facilities. Key policy considerations include the following.

- sustainable manufacture and procurement;
- medical devices designed to be reusable, durable, easy to clean and resilient to reduce their environmental impact;
- phasing out of hazardous chemical wastes (e.g. mercury), in alignment with global agreements (such as the Minamata, Basel, Rotterdam and Stockholm Conventions), and plastics, a major pollutant, which are under regulatory scrutiny *(109)*;
- reducing, reusing and recycling health-care waste, about 15% of which is hazardous, which can lead to toxic exposures and emissions;
- reducing the environmental impact of health-care supply chains by promoting sustainable procurement and efficient resource use; and
- inclusion of sustainability in medical device regulations, enforcement of circular economy models and enhancement of green procurement to reduce the environmental footprint of health care.

This section addresses the sustainability of medical devices, as every phase of a medical device's lifecycle can cause environmental damage without appropriate regulations. In recognition of the vulnerability of health-care systems to climate change, WHO has published WHO guidance for climate-resilience and environmentally sustainable health care facilities *(110)*.

10.1 Manufacture

Manufacture is defined by WHO as "the process of designing, producing, packaging, and labelling a device in preparation for its placement on the market" *(11)*.

Local production and distribution networks reduce dependence on international shipping, which contributes significantly to the carbon footprint of health care. In LMIC, resilient local manufacture and local "last-mile" delivery can lower costs and ensure faster access while decreasing emissions. Decentralized models with solar-powered cold chains and electric logistics can drastically reduce the carbon impact of distributing temperature-sensitive medical devices. Further, digital tracking systems with blockchain or AI-enhanced logistics improve transparency, minimize waste and forecast demand accurately, reducing oversupply and stockouts.

10.1.1 Design for reuse

Sustainable design and manufacture ensure the long-term viability of medical devices. Adoption of and adherence to eco-friendly design principles and sustainable manufacturing practices significantly reduce the environmental impact of medical devices.

10.1.2 Toxic substances, plastics and other concerns

Chemicals, which are ubiquitous in health-care facilities *(111)*, present serious risks to human health and the environment. In May 2017, the Seventieth World Health Assembly adopted a road map on chemicals *(112)*, which provides a framework for strengthening the role of the health sector in safe management of chemicals, including advice to choose environmentally friendly products and avoid hazardous chemicals when purchasing equipment and supplies.

The most recent (2024) Compendium of WHO and other UN guidance on health and environment *(113)* recommends adherence to multilateral environmental agreements on chemicals and waste, including:

- the Minamata Convention on Mercury;
- the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal;
- the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade; and
- the Stockholm Convention on Persistent Organic Pollutants.

In addition, the carbon footprint of raw material extraction and component sourcing in medical device manufacture must be addressed. A growing body of literature highlights the environmental impact of mining for rare earth elements and metals for use in high-tech medical equipment. Sustainable sourcing policies must ensure traceability and ethical mining practices. For instance, the Sustainable Procurement Platform *(114)* and initiatives of the Organisation of Economic Co-operation and Development advocate for conflict-free minerals and reduced energy-intensive processes *(115)*. Manufacturers could align their processes with ISO 14001 *(116)* and adopt life-cycle assessment *(117)* methods to evaluate the "cradle-to-grave" environmental impacts of devices to improve design and production.

10.1.3 Regulatory frameworks and incentives for green innovation

Governmental and international regulatory bodies can ensure sustainability by providing incentives and requiring compliance. Policies such as green public procurement, tax incentives for low-emission technologies and mandatory disclosure of carbon footprints can encourage manufacturers to innovate sustainably. Regulations could also require manufacturers to participate in "take-back" programmes or extended producer responsibility schemes, such as the ISO 14024 eco-labelling standard *(118)*. Alignment of national regulation with such a framework would ensure accountability and incite the industry to use circular design principles.

10.1.4 Packaging

Packaging is important in ensuring the sustainability of medical devices; however, it not only protects a device during transport and storage but has significant environmental implications. WHO advocates for sustainable packaging with minimal environmental impact while ensuring the safety and integrity of medical devices. A strategy for sustainable packaging includes selection of materials, packaging design and end-of-life management. When possible, manufacturers could use recyclable, biodegradable or compostable materials that meet health and safety standards. Use of environmentally friendly materials for packaging reduces the environmental footprint of packaging waste and meets the principles of a circular economy. Examples include use of a paper sterile barrier systems instead of layers of plastics and use of post-consumer recycled content (material made from items that consumers recycle, such as aluminium, cardboard boxes, paper and plastic bottles).

Digital labelling, QR codes and electronic instructions for use can reduce use of paper. Regulatory compliance remains paramount, although digital transformation in labelling is increasing globally. "Extended producer responsibility" and eco-labelling, which have been adopted in many countries, shift responsibility for disposal and recycling of packaging to manufacturers. Such practices are part of strategies for a circular economy, promoted by organizations such as Health Care Without Harm *(119)* and UNEP *(120)*. To ensure that packaging materials and designs are compliant with relevant regulatory requirements and standards includes development of national guidelines.

10.1.5 Viability, guaranteed spare parts and consumables

The long-term viability of medical devices is essential for sustainable HTM. Much medical equipment becomes obsolescent due to lack of spare parts and consumables. Ensuring a steady supply of such components is crucial for maintaining the functionality and safety of medical devices throughout their lifecycles, particularly in low-resource settings, where equipment downtime can severely compromise patient care and increase costs. Activities for ensuring the viability of reusable medical devices include:

- supply chain management,
- quality assurance,
- inventory management,
- training and support and
- regulatory compliance.

Spare parts and consumables could be included in analyses of the total cost of ownership during procurement. WHO Technical Report 1025 *(121)* and publications of PATH *(122)* and the UNICEF Supply Division *(123,124)* describe the critical role of lifecycle service support and spare parts planning in medical device management in LMIC. A framework to ensure robust maintenance and the availability of parts is essential for ensuring the functionality, reliability and sustainability of health-care technology.

10.1.6 Climate-resilient medical device strategy

The increasing frequency of events related to extreme climate, such as floods, extreme heat and power outages, poses direct threats to medical infrastructure and device functionality. In LMIC, where power is often poorly reliable, this can cause devastating disruptions in care. Planning for resilience planning could prioritize climate-proofing of health-care technology, such as using devices with "ingress protection" casings, off-grid solar compatibility and rugged designs suitable for volatile conditions. The WHO publication Operational framework for climate-resilient health systems *(125)* calls for hazard mapping, climate risk assessments and integration of adaptation strategies in planning health infrastructure.

Policies for medical equipment procurement could require certification of resilience and scenario-based stress testing, particularly for essential technologies such as cold chain units, oxygen generator and digital monitoring devices.

10.1.7 HTA for environmental sustainability

Although HTA is usually used clinically and for cost-effectiveness analysis, it is increasingly being used to evaluate sustainability. Environmental HTA consists of including data from analysis of life cycles, emissions, material toxicity and end-of-life recyclability into procurement decisions. Adoption of green HTA methods will ensure that selected devices meet both public and planetary health goals.

10.2 Sustainable waste management

Health-care waste management is a policy priority, as improper handling can lead to health hazards such as infections, toxic exposures and environmental pollution. Effective waste management practices are essential to mitigate such risks. An often-overlooked aspect of sustainable waste management is end-of-life processing of electronic medical devices, particularly in LMIC. E-waste from obsolete or non-functional diagnostic equipment contributes significantly to local environmental contamination when improperly disposed. According to the Global E-Waste Monitor 2024 *(126)*, less than 20% of global e-waste is formally recycled, and LMIC are disproportionately affected by unregulated dumping. Strengthening of reverse logistics, establishment of regional e-waste recycling hubs and adoption of WHO's guidance on decommissioning medical devices are critical *(11).* National health systems could adopt extended producer responsibility schemes for electronic health technologies to ensure responsible disposal and possible recovery of materials.

10.2.1 Reusable and single-use devices

Medical devices can be classified as reusable or for single use. Reusable devices can be used many times on different patients according to the manufacturer's instructions on safe reprocessing *(83)*, which comprises all the actions necessary to prepare a contaminated reusable medical device for its intended use. The steps include cleaning, functional testing, packaging, labelling, disinfection and sterilization *(83)*.

Numerous medical devices are, however, for one use only or on a single patient during a single procedure; accordingly, they could not be reused. Reuse of single-use medical devices could be avoided even as donations and in emergency situations. If their reuse is considered, the associated risks, ethical concerns and legal responsibilities must be carefully assessed, as many countries prohibit or regulate this practice *(6)*. The document Decontamination and reprocessing of medical devices for health-care facilities *(83)* provides best-practice recommendations on safe, effective reprocessing of reusable medical devices to ensure patient safety and to prevent infections.

10.2.2 Plastics

Plastic pollution is a global challenge, with well-documented consequences for the environment and potential risks to human health. Each year, over 430 million tonnes of plastic are produced worldwide, with social and environmental costs estimated to be US$ 300–600 billion per year *(127)*. Plastics are associated with potential risks and harms at every step of their lifecycle.

In March 2022, during the resumed fifth session of the UN Environment Assembly *(127),* Member States voted to establish an intergovernmental negotiating committee that will develop an internationally legally binding instrument designed to combat plastic pollution throughout its lifecycle *(127,128)*.

Considerations for addressing plastic pollution in the health-care sector include *(127,128)*:

- strategies to reduce the use of single-use plastics in health-care settings;
- sustainable procurement practices;
- improved waste management systems;
- encouraging R&D of alternative materials; and
- ensuring compliance with international and national regulations such as an internationally legally binding instrument designed to combat plastic pollution throughout its lifecycle *(128).*

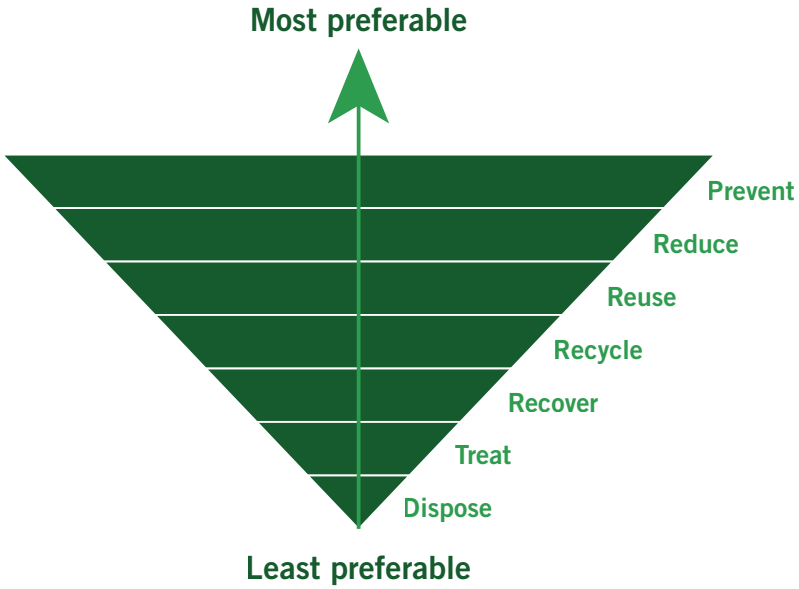
10.2.3 Waste management

Health-care waste includes infectious waste, pathological waste, sharps, chemicals, pharmaceutical and cytotoxic waste, radioactive waste and non-hazardous (general) waste. Lack of proper separation of hazardous from non-hazardous waste results in a higher proportion of hazardous waste *(129)*. Despite its critical importance, there are few effective health-care waste management systems. The COVID-19 pandemic exacerbated the problem, with a sharp increase in health-care waste that placed additional stress on waste management systems *(130)*. Additionally, transport of health-care waste and improper processing (e.g. incineration) can result in significant greenhouse gas emissions and release of toxic substances into the environment *(110)*.

WHO has issued the publication Safe management of wastes from health-care activities *(129)*, which includes minimization of waste. Recommended practices include "environmentally preferable purchasing", green procurement, safe reuse, recycling and recovery and environmental management systems. Proper separation and recycling of non-hazardous health-care waste are essential to mitigate environmental impacts *(129)*. Advanced waste treatment technologies such as autoclaving, microwave treatment and chemical disinfection could significantly reduce the volume and hazardous nature of health-care waste. These technologies, combined with proper waste segregation practices, can improve the overall efficiency and sustainability of health-care waste management systems *(130).*

Overall, the concept of reduce, reuse and recycle could be considered in waste management (Fig. 24) to achieve a sustainable waste management system *(113).* More information on waste management in health care can be found in the second edition of Safe management of wastes from health-care activities *(129).*

Fig. 24. Hierarchy of waste management



Source: Adapted from WHO *(113)*

10.2.4 Water and energy footprints of medical devices

Many medical devices, such as sterilizers, imaging equipment, dialysis machines and heating, ventilation and air-conditioning systems, consume large amounts of water and energy, which could compromise the trade-off between clinical need and resource availability, especially in off-grid or drought-prone areas. The WHO publication Guidance for climate-resilient and environmentally sustainable healthcare facilities *(110)* recommends assessment of water and energy use during both procurement and operations. Use of solar-powered systems, LED surgical lighting and energy-efficient sterilizers can significantly reduce emissions and running costs. Analysis of life-cycle inventories by UNEP *(117)* and Health Care Without Harm *(111)* show that the energy used during operation of devices often exceeds that used in their manufacture. This information could guide policy reforms that include mandatory labelling of energy and water and incentives for green equipment procurement.

10.2.5 Digital health technologies and e-waste

Rapid expansion of digital health technologies, including mobile health applications, wearable diagnostic devices and telemedicine platforms, has revolutionized health-care delivery, especially in LMIC. These innovations are, however, accompanied by new challenges to sustainability, particularly in the form of e-waste. Obsolete tablets, smartphones, sensors, routers and batteries are increasingly found in health settings, often with no viable strategy for end-of-life disposal.

According to the Global E-Waste Monitor 2024 *(126)*, over 62 million tonnes of e-waste were generated globally in 2023, of which only 17.4% was documented as properly collected and recycled. LMICs face higher risks of unregulated dumping and burning, and the lack of formal recycling systems results in unsafe informal processing, exposing workers to toxic metals such as lead and cadmium.

Sustainable strategies include digital device lifecycle planning, procurement contracts that include take-back clauses and partnerships with certified e-waste recyclers. The WHO Digital Health Strategy 2020–2025 *(131)* encourages integration of the principles of green information and communication technology, while the "mobile for development" programme of the GSM Association, which represents mobile network operators, supports circular solutions for health-related mobile tech.

10.3 Supply chain and sustainable models for medical device distribution

Integration of sustainability into the supply chain of medical devices is critical for reducing health-care-associated greenhouse gas emissions and promoting environmental, social and economic progress. Sustainable procurement practices, use of renewable energy and collaboration could contribute significantly to global sustainability goals.

The supply chain of medical products is responsible for approximately 70% of health-care-associated greenhouse gas emissions *(132)*. Strategies could therefore be adopted to decarbonize the supply chain for sustainable procurement of medical products. WHO is working toward achievement of these goals by launching the Alliance for Transformative Action on Climate and Health (ATACH) *(133)*. One of the five working groups of the Alliance specifically addresses the sustainability of supply chains.

WHO has also introduced sustainability as the main criterion for procurement of medical products *(134)*. It defines sustainable procurement as

> "a series of practices that integrate requirements, specifications and criteria that are compatible and in favour of the protection of the environment, of social progress and in support of economic development, namely by seeking resource efficiency, improving the quality of products and services and ultimately optimizing costs".

This definition includes three types of sustainability: environmental, social and economic. To further increase the sustainability of medical device distribution, the following strategies are recommended *(134)*:

- Adopt environmentally preferable purchasing practices.
- Encourage use of renewable energy sources and energy-efficient technologies.
- Promote development and use of medical devices that are designed to be durable and can be reused and recycled.
- Use robust tracking and monitoring systems.
- Foster collaboration with suppliers and other stakeholders.

10.4 Sustainability of software as medical devices and AI

SaMD, especially when powered by AI, can be used to redesign health-care delivery, as it allows earlier diagnosis closer to the patient and reduces reliance on centralized facilities. While it offers some benefits, it also raises concern about sustainability. Scientific evidence of the full impact of AI on the life cycle of medical devices is still limited, and the available studies often lack transparency. The main areas of concern are energy consumption, water use, greenhouse gas emissions and electronic waste. Studies could therefore address its direct impacts, such as energy use during training and the environmental costs of hardware production. UNEP encourages the development of standardized reporting frameworks for the environmental footprint of AI and adoption of sustainable practices such as green data centres and renewable energy for more sustainable digital transformation of health care *(107,108)*.

11. Use of medical devices during emergencies and the International Health Regulations (2005)

Medical devices are needed in the response for humanitarian emergencies in public health, pandemics, natural disasters, war, terrorism and industrial accidents (such as nuclear accidents) which are becoming more frequent. Prompt, effective medical responses to emergencies and preparedness are crucial for safeguarding lives and optimizing health outcomes. Guidelines and regulations must ensure that medical devices are safe, reliable and suitable for emergency contexts, thus reducing the risks associated with untested or inappropriate equipment.

To ensure effective emergency preparedness and response with respect to medical devices, health ministries might:

- adopt a national policy and regulatory framework for emergency medical devices.
- establish or designate a medical device regulatory authority;
- use transparent processes to assess and update national lists of priority medical devices;
- set procurement and quality standards for emergency contexts;
- enable fast-track approval mechanisms for emergency use of medical devices;
- maintain strategic reserves of essential medical devices;
- train health-care workers in use of medical devices in emergencies;
- monitor the performance and safety of medical devices that are deployed;
- coordinate with international partners for rapid support and device mobilization; and
- ensure clear communication among all levels of the health system.

The International Health Regulations (2005) (IHR) provide an overarching legal framework that defines States Parties' (countries') rights and obligations in managing public health risks, events and emergencies that have the potential to cross borders. There have been 3 amendments to the IHR, in 2014, 2022 and the last one in 2024, applicable 19 September 2025. Such amendments to the International Health Regulations (2005), third edition *(135)*, lay the foundation for later resolutions for strengthening global health systems.

The WHO European Regional Office has continued to advance emergency preparedness through initiatives such as the Preparedness 2.0 strategy and the Emergency Medical Teams action plan for 2024–2030 *(136)*. Furthermore, at the 29th Conference of the Parties to the UN Framework Convention on Climate Change in late 2024, high-income nations agreed to provide a package of US$ 300 billion annually by 2035 to low-income countries to tackle the effects of climate change *(137)*, including those on health-care systems. The aim for health care is to strengthen infrastructure to withstand climate-related health emergencies, including improving access to essential medical services, building adaptive capacity to address climate-induced health risks (such as heatwaves, floods and disease outbreaks) and ensuring that health systems continue to function under stress.

On 20 May 2025, the World Health Assembly adopted the Pandemic Agreement *(138)*, which reinforces the essential role of medical devices in pandemic prevention, preparedness and response. Medical devices, as vital tools for diagnostics, treatment and infection control, are the first line of defence in health emergencies. Amendments to the Agreement include the following.

Article 1 - defines "relevant health products" means those health products needed to respond to public health emergencies of international concern, including pandemic emergencies, which may include medicines, vaccines, diagnostics, medical devices, vector control products, personal protective equipment, decontamination products, assistive products, antidotes, cell- and gene-based therapies, and other health technologies (referred to in amended Articles 13, 15, 16, 17, 18 and 44).

The agreement calls for equitable access to pandemic-related health products, including medical devices, as outlined in Chapter II:

Article 8. Regulatory strengthening,

Article 9. Research and development.

Article 10. Sustainable and geographically diversified local production,

Article 11. Transfer of technology and cooperation on related know-how for the production of pandemic-related health products,

Article 12. Pathogen access and benefit-sharing system,

Article 13. Supply chain and logistics,

Article 14. Procurement and distribution and

Article 13. on supply chains and logistics.

These amendments are aligned with those made to the International Health Regulations (2005) in May 2024 *(135)*, particularly Article 2, which promotes preparedness and equity, and Article 13, which guarantees equitable access to essential health technologies.

WHO has also issued other documents, frameworks and kits for humanitarian emergencies. During an emergency, both rapid deployment and the availability of medical devices are essential. WHO has called for standardization of emergency health kits, such as the Interagency Emergency Health Kit *(139)*, which is designed to serve the needs of up to 10 000 people for 3 months. The kits provide pre-packaged essential medicines, renewable supplies and reusable medical equipment to ensure swift, efficient responses. WHO also releases special kits, such as for trauma and emergency surgery *(17)* and for cholera *(140)*, for use in crises such as armed conflict and infectious disease outbreaks. The kits are updated regularly to include new material and to adapt to evolving emergency needs.

WHO continually reviews and updates its lists of essential medical devices for specific conditions, such as priority medical devices for maternal health, child health, emergency care, surgery and infectious diseases. The lists are part of WHO's broader initiative to ensure that countries have access to the most effective life-saving medical technologies, especially during health emergencies or humanitarian crises. The medical devices are evidence based selected, according to global health priorities and emerging health trends, with particular consideration of lower-resource settings to ensure equity in the availability and accessibility of these devices. The medical devices selected are displayed in MeDevIS *(38)* or the Essential in vitro diagnostics lists databases *(37).*

12. Participatory governance and measurement of outcomes

12.1 Engagement in participatory governance, social participation and governance

Governments are recognizing the value of inclusive decision-making in health and of stakeholder involvement to ensure effective implementation. Social participation accelerates progress toward UHC by ensuring that health systems are responsive and people-centred. Effective social participation in health requires diverse, well-designed mechanisms such as forums, consultations and digital platforms, with capacity-building for both governments and civil society. Inclusive, participatory approaches in setting policy for medical devices ensures relevance and equity, especially when marginalized voices and feedback mechanisms like "regulatory sandboxes" are used. Empowering citizens and removing power imbalances are essential for building more responsive, just health systems. The results of participation must be clearly reflected in policy decisions. Mechanisms could be available for providing feedback to participants, monitoring implementation and ensuring the sustainability of participatory spaces.

Policy-makers could create a supportive legal and regulatory framework for social participation, with transparent, inclusive mechanisms for citizen engagement in health decisions. They could allocate resources for such initiatives, strengthen the capacity of both government and civil society and monitor the impact on health policies. To avoid fragmentation, policy-makers could promote coordination and collaboration among stakeholders.

The WHO Voice, agency, empowerment *(33)* handbook provides guidance on creating and strengthening social participation mechanisms. In recognition of the potential of young people, the Youth declaration on creating healthy societies *(141)* by the WHO Youth Council calls for encouragement and facilitation of the active engagement of young people in the design, implementation and evaluation of policies and programmes. A technical paper, Meaningful social participation in health decision-making for universal health coverage describes actions that policy-makers can take to enable meaningful social participation in health policy-making to promote UHC *(33)*.

12.2 Measuring progress: outcomes and indicators

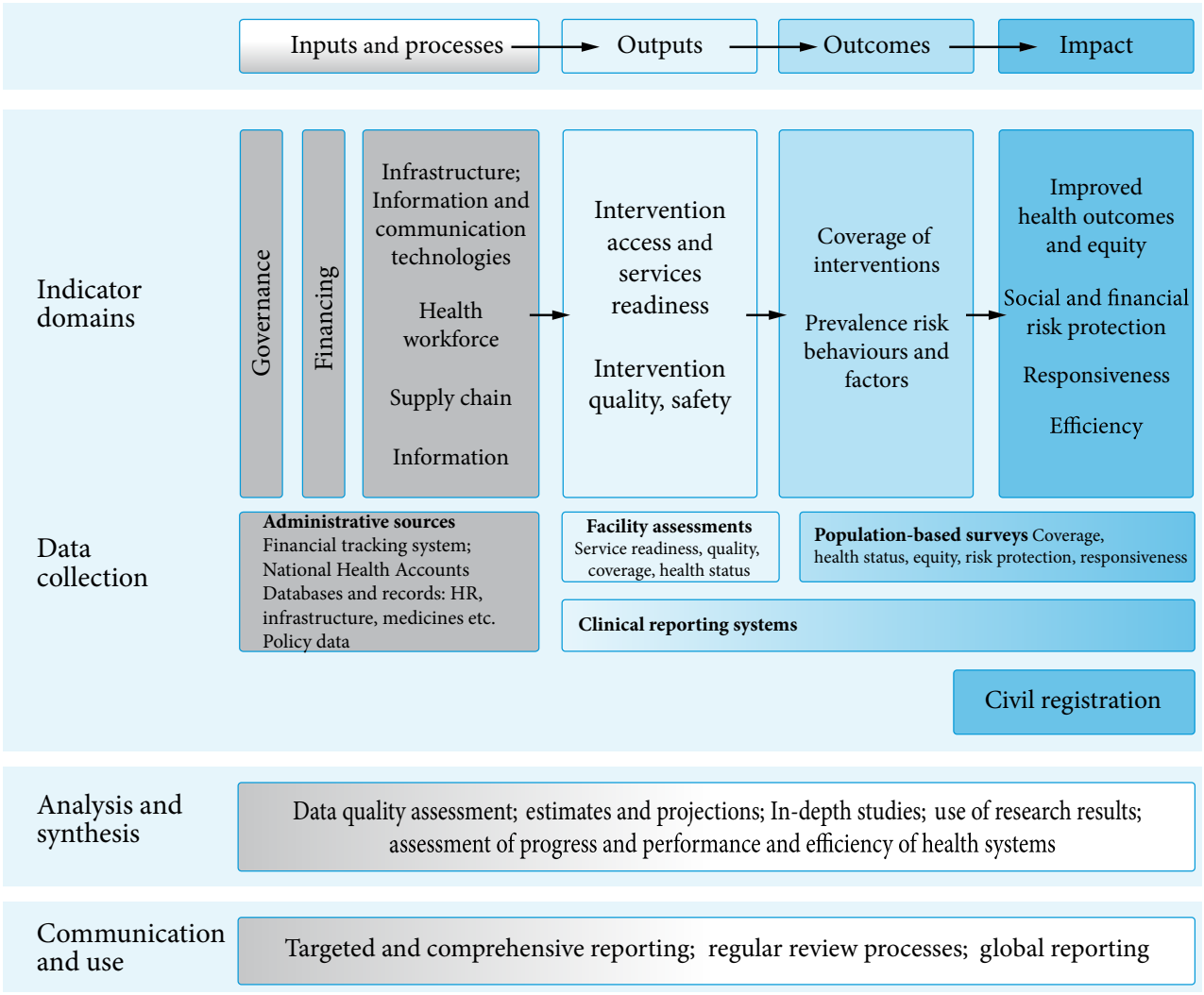
Indicators and outcomes provide insight into whether a policy or programme is effective, to assess performance and to establish benchmarks for modifications and future action. A well-designed national health plan could include sections dedicated to medical devices and government entities policies in four areas: R&D (innovation), regulation, assessment and management.

Resources for guidance on M&E in health systems include Monitoring, evaluation and review of national health strategies: a country-led platform for information and accountability *(142)*, the 2018 global reference list of 100 core health indicators *(143)* and the WHO results framework *(144).*

12.2.1 Monitoring and evaluation

The goal of every intervention is to enhance health outcomes, which requires proper M&E. The International Health Partnership+ offers guidance to countries and partners on enhancing monitoring, evaluation and review of national health plans and strategies and specific programmes or health system strengthening initiatives *(142)* with a common M&E framework (Fig. 25).

Fig. 25. Common M&E framework



Source: International Health Partnership +, WHO *(142)*

M&E of medical device policies are vital for assessing regulatory effectiveness. Clear objectives, performance indicators and regular assessments ensure alignment with goals and transparency and result in data-based decisions, with stakeholder consultations. M&E also ensure adaptable, resource-efficient policies and maintenance of public trust.

12.2.2 Indicators

When developing a policy for medical devices and IVDs, clear goals, regulations and performance indicators (financial, technological and organizational) could be set to assess progress. Progress reports could be shared regularly with policy makers, parliament and the public to ensure alignment with available resources, enhance transparency and guide future decisions. A policy requires realistic, achievable goals.

Indicators must be clearly defined and consistently collected to be effective. The data can be used to identify priorities for intervention, to monitor progress, plan programmes and evaluate effectiveness. Fig. 26 illustrates the 100 core indicators used by WHO for global health priorities, including new and emerging priorities in the health and health-related SDGs *(143)*. WHO also uses these data to customize its expertise and direct programmes and resources to the specific needs of each country.

Fig. 26. 100 core health indicators and health-related SDGs by results chain

Health financing

- Total current expenditure on health as % of gross domestic product *(Also: total capital expenditure on health as % of current + capital expenditure on health)*
- Public domestic sources of current spending on health as % of current health expenditure *(Also: private)*
- External source of current spending on health (% of current expenditure on health)
- Total net official development assistance to medical research and basic health sectors [SDG 3.b.2]

Health workforce

- Health worker density and distribution [SDG 3.c.1]
- Output training institutions

Health infrastructure

- Health facility density and distribution *(Also: access to emergency surgery)*
- Hospital bed density

Health information / governance

- Birth registration [SDG 16.9.1]
- Death registration [SDG 17.19.2]
- Completeness of reporting by facilities *(Also: completeness and timeliness for notifiable diseases)*
- Existence of national health sector policy/strategy/plan

Service access and availability

- Outpatient service utilization *(Also: inpatient admissions and surgical volume)*
- Service-specific availability and readiness
- Access to a core set of relevant essential medicines [SDG 3.b.3]

Service quality and safety

- Perioperative mortality rate
- Obstetric and gynaecological admissions owing to abortion
- Institutional maternal mortality ratio
- Maternal death reviews
- ART retention rate
- HIV test results for TB patients
- TB notification rate
- TB treatment success rate

Health security

- International Health Regulations (IHR) 2005 core capacity index [SDG 3.d.1]

Coverage of interventions

- Demand for family planning satisfied with modern methods [SDG 3.7.1]
- Contraceptive prevalence rate
- Antenatal care coverage
- Births attended by skilled health personnel [SDG 3.1.2] *(Also: institutional delivery – overall and in "baby-friendly" institutions)*
- Postpartum care coverage – women
- Postnatal care coverage – newborn
- Care-seeking for symptoms of pneumonia
- Coverage of diarrhoea treatment
- Vitamin A supplementation coverage
- Immunization coverage rate by vaccine for each vaccine in the national schedule [SDG 3.b.1]
- People living with HIV who know their status
- Prevention of mother-to-child transmission
- Antiretroviral therapy (ART) coverage
- HIV viral load suppression
- Coverage of treatment for latent TB infection (LTBI)
- HIV-positive new and relapse TB patients on ART during TB treatment
- Drug susceptibility testing coverage for TB patients
- TB treatment coverage
- Treatment coverage for drug-resistant TB
- Intermittent preventive therapy for malaria during pregnancy (IPTp)
- Use of insecticide treated nets (ITNs)
- Treatment of confirmed malaria cases
- Indoor residual spraying (IRS) coverage
- Number of people requiring interventions against neglected tropical diseases [SDG 3.3.5]
- Coverage of preventive chemotherapy for selected neglected tropical diseases
- Cervical cancer screening
- Coverage of services for severe mental health disorders
- Treatment coverage for alcohol and drug dependence [SDG 3.5.1]
- Coverage of essential health services [SDG 3.8.1]

Risk factors and behaviours

- Exclusive breastfeeding rate 0–5 months of age
- Early initiation of breastfeeding
- Incidence of low birth weight among newborns
- Children under 5 years who are stunted [SDG 2.2.1]
- Children under 5 years who are wasted [SDG 2.2.2]
- Children aged under 5 years who are overweight [SDG 2.2.2]
- Anaemia prevalence in children
- Anaemia prevalence in women of reproductive age *(Also: severe anaemia)*
- Prevention of HIV in key populations
- Population using safely managed drinking-water services [SDG 6.1.1]
- Population using safely managed sanitation services [SDG 6.2.1a/6.2.1b (forthcoming)] *(Also: population with handwashing facility with soap and water)*
- Population with prirmary reliance on clean fuels and technologies [SDG 7.1.2]
- Air pollution level in cities [SDG 11.6.2]
- Total alcohol per capita (age 15+ years) consumption [SDG 3.5.2]
- Tobacco use among persons aged 15+ years [SDG 3.a.1] *(Also: adolescents)*
- Raised blood pressure among adults
- Overweight and obesity in adults *(Also: school-age children and adolescents)*
- Raised blood glucose/diabetes among adults
- Salt intake
- Insufficient physical activity in adults *(Also: adolescents)*
- Intimate partner violence prevalence [SDG 5.2.1]
- Non-partner sexual violence prevalence [SDG 5.2.2]
- Prevalence of female genital mutilation/cutting [SDG 5.3.2]
- Sexual violence against children [SDG 16.2.3]
- Early marriage [SDG 5.3.1]
- Frequency rates of occupational injuries [SDG 8.8.1]

Health status

- Life expectancy at birth
- Adolescent mortality rate
- Adult mortality rate between 15 and 60 years of age
- Under-five mortality rate [SDG 3.2.1]
- Infant mortality rate
- Neonatal mortality rate [SDG 3.2.2]
- Stillbirth rate
- Maternal mortality ratio [SDG 3.1.1]
- TB mortality rate
- AIDS-related mortality rate
- Malaria mortality rate
- Premature noncommunicable disease (NCD) mortality [SDG 3.4.1]
- Mortality from household and ambient air pollution [SDG 3.9.1]
- Mortality from unsafe water, unsafe sanitation and lack of hygiene [SDG 3.9.2]
- Mortality from unintentional poisoning [SDG 3.9.3]
- Suicide rate [SDG 3.4.2]
- Death rate due to road traffic injuries [SDG 3.6.1]
- Number of deaths, missing persons and persons affected by disaster per 100 000 people [SDG 1.5.1, 11.5.1, 13.1.1]
- Mortality rate due to homicide [SDG 16.1.1]
- Adolescent birth rate [SDG 3.7.2]
- Total fertility rate
- New cases of vaccine-preventable diseases
- New cases of IHR-notifiable diseases and other notifiable diseases
- HIV prevalence rate
- HIV incidence rate [SDG 3.3.1]
- Hepatitis B surface antigen prevalence
- Hepatitis B incidence [SDG 3.3.4]
- Sexually transmitted infections (STIs) incidence rate
- Congenital syphilis rate
- TB incidence rate [SDG 3.3.2]
- Malaria parasite prevalence among children aged 6–59 months
- Malaria incidence rate [SDG 3.3.3]
- Cancer incidence, by type of cancer

Finanical risk protection

- Proportion of the population with impoverishing health expenditure
- Proportion of the population with large household expenditure on health as a share of total household consumption or income [SDG 3.8.2]

Source: WHO *(143)*.

WHO's transformation was based on a core principle: to achieve measurable impact. As stated by the Director-General, "we can make progress only if we measure progress". This focus is reflected in WHO's strategic plans, including the Thirteenth GPW (2018–2024) and the Fourteenth GPW (2025–2028), which are based on a results-driven approach *(27)*.

The Fourteenth GPW provides a strategic road map for global health between 2025 and 2028, for advancing the health-related SDGs and strengthening health systems for the post-SDG era. A draft was considered at the Seventy-seventh World Health Assembly in May 2024, with six strategic objectives and joint outcomes (Table 8). Outcome 3.2 is to substantially improve access to quality-assured health products. The proposed indicators are shown in Table 9 *(27)*. The results framework consists of the results chain and their measurement. Output indicators and the output scorecard are used to measure results at their output. The "delivery for impact" approach and stories of impacts in countries will also be used to communicate results *(27).*

Table 8. Outcome 3.2 in the WHO Fourteenth GPW and indicators *(27)*

3.2. Health and care workforce, health financing and access to quality-assured health products substantially improved	• SDG indicator 3.c.1. Health worker density and distribution (by occupation, subnational, facility ownership, facility type, age group, sex) (Thirteenth GPW) • Resolution WHA64.9. Government domestic spending on health as a share of general government expenditure, and per capita (new) • Access to health product index (new) [a] • Resolution WHA67.20. Improved regulatory systems for targeted health products (medicines, vaccines, medical devices including diagnostics) (new) • Resolution WHA64.9. Government domestic spending on PHC as a share of total PHC expenditure (new)

[a] Replaces SDG indicator 3.b.3, "Proportion of health facilities that have a core set of relevant essential medicines available and affordable on a sustainable basis", which was used in the Thirteenth GPW.

Additional indicators are listed in Primary health care measurement framework and indicators *(146)*, in which health systems are assessed from a PHC perspective. The domain that includes medicines and other health products is used to evaluate the availability and affordability of safe, effective, high-quality, appropriate medicines and products. Countries are encouraged to select a set of indicators according to their context, any identified gaps, national policy priorities and the maturity of their health and information systems. The indicators are listed in Table 9.

Table 9. Indicators for evaluating medicines and other health products in PHC *(146)*

Questions on country context and requirements	Indicators to be selected from the menu	Preferred data source
Are there regulatory mechanisms to ensure the safety, effectiveness and quality of health products?	Regulatory mechanisms for medicines	Qualitative assessment
	Availability of essential medicines (SDG 3.b.3)	Facility survey
	Availability of essential in-vitro diagnostics	Facility survey
Has the availability of medicines, diagnostics, supplies and equipment improved?	Availability of priority medical equipment and other medical devices	Facility survey

If regulatory controls are extended, it may be necessary to measure performance, such as the timeliness of the NRA in monitoring manufacturers' reactions to defects in quality or serious injuries due to use of their medical devices, including IVDs. Other general performance indicators could include periodic consultations with stakeholders such as medical device users, patient representatives and industry groups. The public and legislators will expect the NRA's actions and resource use to be justified *(2)*.

The World Health Statistics Report *(28)*, published annually by WHO since 2005, contains over 50 health-related indicators from the SDGs and WHO's Thirteenth GPW. Data are derived by global monitoring as of May 2024 and are sourced from WHO, other UN partners and peer-reviewed publications.

13. Development of an action plan for a medical device policy

Effective implementation of medical device policies requires a well-defined action plan that involves the units impacted by the policy in the ministry of health and related agencies, including:

- the medical devices unit in the NRA;
- the medical devices section in the HTA agency or a related unit;
- the national HTM unit or equivalent office;
- the public health insurance unit, specifically the benefits packages unit;
- the health services division of the ministry of health; and
- professionals specialized in fields such as biomedical engineering.

M&E are crucial to track progress in these policies, for accountability and for data-driven improvements. For Member States to develop action plans for their medical device policies, this section provides a brief guide on creating an effective action plan. Annex 2 provides examples of national policies and action plans for medical devices.

13.1 Situation assessment

A situation assessment is the foundation of an action plan. It involves collecting data on the current epidemiological situation, the status of medical devices and a general overview of their availability. The activities include:

- assessment of public health needs and potential areas for device intervention, including the burden of disease and conditions that could benefit from medical devices, addressing both current and emerging health challenges;
- evaluation of existing policies, strategies or national plans on nomenclature, regulation, selection and management (including procurement and supply, maintenance and use of medical devices, to identify barriers and areas for improvement;
- assessment of the available technical capacity and workforce in national bodies with activities related to medical devices for effective policy implementation;
- mapping of the general status of inventory and quality of medical devices in health-care facilities; and
- in facilities, cataloguing devices, assessing their functionality and identifying gaps in availability or quality, a highly complex task involving many players.

A general assessment could be conducted to determine whether the population has access to medical devices required for the public health interventions that are part of the benefits programme. This basic assessment clarifies the current state of medical devices and identifies areas that require urgent attention.

13.2 Priority setting

The situation assessment will indicate priorities for addressing the most critical needs in the health-care system. This could be done in consultation with stakeholders including national public health insurance, national health services and other national agencies of the ministry of health. The assessment includes:

- resources for areas with the highest health impact potential, focusing on medical devices that can significantly improve health outcomes, particularly for high-burden diseases;
- disparities among regions, particularly rural and underserved areas, and ensuring equitable access to medical devices to improve overall health equity;
- identifying medical devices that are essential for public health but are currently unavailable or underused, perhaps by consulting health-care providers;
- a priority medical device list for public procurement or reimbursement depending on the health insurance services or benefits package;
- HTA tools to evaluate cost-effectiveness to guide decision-makers in prioritizing medical devices according to their potential impact, cost-effectiveness and public health priorities;
- priorities for procurement of capital equipment;
- the budget required for continued operation of medical equipment, including maintenance;
- the quantities and budget for single-use medical devices and consumables for capital equipment; and
- priorities for replacements due to obsolescence.

By setting clear priorities, stakeholders will allocate resources effectively and focus on interventions that yield the most benefit.

13.3 Identification of effective strategies

Once priorities are defined, strategies could be developed to address each, by:

- establishing regulatory frameworks for medical device approval, safety and quality assurance, including transparent processes for device evaluation and ensuring compliance with international standards;
- forming partnerships with academic institutions, industry and health-care providers to foster innovation and improve access to medical devices, which may lead to shared resources and expertise;
- defining the roles and responsibilities of regulatory authorities, manufacturers and health-care providers to ensure accountability and streamline implementation;
- promoting international and cross-border cooperation and knowledge-sharing to accelerate adoption of best practices and innovations, especially in low-resource settings; and
- reviewing World Health Assembly resolutions that include global initiatives and provide global guidance.

These strategies could be tailored to the context of the health-care system and needs, ensuring that they are both practical and effective.

13.4 Resources required to implement the policy

To ensure financial feasibility, cost could be estimated according to priorities.

At national level, the analysis could include:

- staff required in regulations, nomenclature, assessment or management units at the ministry of health;
- process required or systems to be developed;
- operation of units;
- development of staff competency in units;
- meetings and involvement with stakeholders;
- strengths, weaknesses, opportunities and threats in the national medical device situation;
- the national epidemiological situation; and
- the global landscape, including World Health Assembly resolutions and guidance.

At health service delivery level, the analysis could include:

- estimation of the costs associated with implementing regulatory and administrative frameworks, including expenses for staffing, training and infrastructure development;
- assessment of the financial requirements for the acquisition of capital medical devices and for maintenance, consumables and upgrading, by health-care facility and then by priorities, depending on epidemiology and resources;
- calculation of the total cost of ownership, by health-care facility, to ensure sustainable procurement and funding for the lifetime of the equipment;
- budgeting for training and development of technical staff involved in device management;
- investment in workforce development to ensure that health-care providers use and maintain medical devices effectively; and
- evaluation of cost-sharing models, including opportunities for co-financing and public–private partnerships to mitigate financial barriers to access.

A comprehensive costing approach helps stakeholders to understand the financial implications of their action plan and to secure the necessary funding.

13.5 Resource planning

Resource planning addresses the human, technical and financial resources necessary to achieve both local and national policy goals, depending on the health financing mechanisms and the extent of national control over local implementation. They include:

- developing workforce training programmes to increase local technical expertise, focusing on the operational aspects and regulatory requirements of device management;
- procuring the technologies necessary for device management, including monitoring and data collection systems to improve oversight and facilitate decision-making;
- allocating budgets for periodic assessment and maintenance of devices to ensure their longevity and functionality to prevent device failures and ensure patient safety; and
- establishing a sustainable supply chain for device procurement and maintenance to avoid disruptions.

Effective planning of resources ensures that the necessary tools and personnel are available to implement the action plan successfully.

13.6 Programming and implementation

In this phase, the action plan is converted into concrete programmes and actions. The steps include:

- conducting pilot programmes to test the regulatory and operational frameworks, providing real-world testing and insights into potential challenges;
- engaging health-care facilities and professionals in the early phases of the plan to ensure that the proposed solutions are practical and meet their needs;
- gradually scaling up the programme according to the outcomes and resource availability, which allows time for adjustments and management of risks; and
- establishing a communication plan to ensure that all stakeholders are informed.

Practical programming and implementation are crucial for translating strategic plans into tangible improvements in health-care delivery.

13.7 Monitoring and evaluation

A strong M&E framework ensures that the action plan has an impact and is adaptable. M&E could:

- define measurable indicators to measure policy implementation, device use and outcomes, with clear metrics to allow stakeholders to assess progress and identify areas for improvement;
- establish a feedback mechanism for regular updates and adjustments to the action plan according to its performance, enabling stakeholders to respond to emerging challenges and opportunities;
- document lessons learnt for future iterations of the policy, which are useful for planning and decision-making; and
- conduct regular audits.

With a strong M&E framework, stakeholders can ensure that their work leads to meaningful improvements in health-care outcomes and that the policies remain relevant and effective over time. More information on M&E and WHO guidance documents on the topic are provided in section 11.

A comprehensive action plan for developing and implementing a medical device policy is essential to improve health-care delivery. By following these steps, stakeholders can create a framework that addresses the unique challenges of their health-care systems, ultimately improving patient outcomes and resulting in more efficient resource use.

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Annex 1. Selected World Health Assembly resolutions related to medical devices during health emergencies

Resolution	Title	Intent	Focus	Relevance to medical devices
WHA65.20 (2012)	Role of the health sector in humanitarian emergencies	Establishes WHO as the lead agency in coordinating health sector responses during humanitarian crises. Addresses improving preparedness, response and recovery while strengthening national health systems.	Humanitarian crisis coordination; national health system preparedness	Ensures that medical devices and supplies are appropriately deployed during emergencies, while addressing readiness and health system strengthening.
WHA73.8 (2020)	Strengthening preparedness for health emergencies	Provides an all-hazards, multisectoral approach to health emergency preparedness. Promotes coordination to detect, assess and respond to health emergencies globally. Requires full compliance with the International Health Regulations (2005)	Strengthening health emergency response capacities	Ensures timely access to medical devices and other health resources during emergencies, while strengthening health system capacity for rapid response.
WHA74.7 (2021)	Strengthening WHO preparedness for and response to health emergencies	Enhances WHO's capacity for global health emergency response by ensuring that the Organization and its Member States are prepared to respond effectively to emergencies.	Health systems readiness; WHO Health Emergencies Programme	Strengthens WHO's ability to coordinate emergency responses, including ensuring the availability of medical devices.
WHA74.8 (2021)	Health sector preparedness for public health emergencies	Ensures that preparedness for health emergencies is inclusive, with the involvement of marginalized groups (e.g. people with disabilities, women) at all stages of emergency response.	Disability, inclusivity, gender balance; community participation	Stresses the importance of including marginalized groups in emergency planning and response, ensuring that medical devices are accessible and effective for vulnerable populations.
WHA75.11 (2022)	Strengthening health systems and addressing noncommuni-cable diseases in humanitarian emergencies	Strengthening policies to improve health system resilience, particularly for the prevention and control of noncommunicable diseases in emergencies.	Resilient health systems; non-communicable diseases preven-tion and control in emergencies	Addresses the need for medical devices to manage chronic diseases and noncommunicable disease risk factors during crises, ensuring that health systems are equipped to handle these health needs.
WHA76.2 (2023)	Integrated emergency, critical and operative care	Calls for integration of emergency, critical and operative care services into health systems to ensure equitable access and service delivery during health emergencies.	Critical care integration; service delivery equity	Ensures that medical devices are a core part of integrated emergency services, particularly for critical care, trauma and surgery during emergencies.

Annex 2. Tables providing national initiatives of medical device related policies

Table A2.1. Examples of national UDI guidance and database

Country	Regulatory authority	Regulation or UDI database	Website
Australia	Therapeutic Goods Administration	UDI hub (in progress)	https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/unique-device-identification-udi-hub
Brazil	Health Regulatory Agency	UDI guidelines *(83)*	https://in.gov.br/en/web/dou/-/resolucao-rdc-n-591-de-21-de-dezembro-de-2021-370622845
China	National Medical Products Administration	Rules for UDI system, national UDI database	https://english.nmpa.gov.cn/2022-06/30/c_785636.htm https://udi.nmpa.gov.cn/
Egypt	Egyptian Drug Authority	Guidance on Requirements for UDI for Medical Devices	https://www.edaegypt.gov.eg/media/v23hklih/udi-guideline-13-12-2021_nancy-fateen.pdf
European Union	European Database on Medical Devices	Regulation 2017/745 on medical devices *(85)*	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32017R0745 https://ec.europa.eu/tools/eudamed/#/screen/home
Republic of Korea	Ministry of Food and Drug Safety	Regulation, IMDIS	https://law.go.kr/admRulLsInfoP.do?admRulSeq=2100000073289&vSct=%EC%9D%98%EB%A3%8C%EA%B8%B0%EA%B8%B0
Saudi Arabia	Saudi Food and Drug Authority	Requirements for UDI for medical devices *(84)*, Saudi-DI	https://udi.sfda.gov.sa/ https://www.sfda.gov.sa/sites/default/files/2022-06/RequirementsUDI_0.pdf
Singapore	Health Sciences Authority	Guidance on Medical Device UDI System (July 2022) *(82)*	https://www.hsa.gov.sg/medical-devices/guidance-documents
USA	Food and Drug Administration	UDI System Rule *(80)*, GUDID *(78)*	https://accessgudid.nlm.nih.gov/about-gudid#what-is-udi

Table A2.2. Examples of WHO collaborating centres, harmonization groups and regulatory authorities that work on regulation of medical devices

Group	Country	Website
WHO collaborating centres		
Subdirección de Equipos Médicos; Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Médicos	Cuba	http://www.cecmed.cu
Medical Devices Sector; Saudi Food and Drug Authority	Saudi Arabia	http://https//www.sfda.gov.sa/en/overview-medical
Harmonization groups		
International Medical Device Regulators Forum (IMDRF)	Global	https://www.imdrf.org/
Regulatory authorities		
Australia		http://www.tga.gov.au/industry/devices.htm
Brazil		https://www.gov.br/anvisa/pt-br
European Commission		https://health.ec.europa.eu/medical-devices-sector_en

Table A2.3. Examples of regulations on instructions for use

Country	Regulatory authority	Regulation	Website
Australia	Therapeutic Goods Administration	Electronic instructions for use for professional users of medical devices (including IVDs)	https://www.tga.gov.au/sites/default/files/electronic-instructions-use-eifu.pdf
Brazil	Health Regulatory Agency	Resolution of the Collegiate Board of Directors RDC No. 751/2022	https://antigo.anvisa.gov.br/documents/10181/5672055/RDC_751_2022_.pdf/37b2d641-82ec-4e64-bb07-4fc871936735
Canada	Health Canada	Guidance document: Guidance for the labelling of medical devices, not including in-vitro diagnostic devices	https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/guidance-labelling-medical-devices-including-vitro-diagnostic-devices-appendices.html
European Union		Regulation 2017/745 on medical devices, Regulation (EU) 2021/2226	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02017R0745-20230320 https://eur-lex.europa.eu/eli/reg_impl/2021/2226/oj
India	Central Drugs Standard Control organization	Medical Devices Rules 2017	https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/m_device/Medical%20Devices%20Rules,%202017.pdf
Malaysia	Medical Device Authority	Medical Device Guidance Document – Requirements for labelling of medical devices	https://mda.gov.my/index.php/documents/guidance-documents/2295-guidance-document-labelling-requirements-for-medical-device-6th-edition-final-pdf/file

Table A2.3. Examples of regulations on instructions for use (continued)

Country	Regulatory authority	Regulation	Website
Saudi Arabia	Saudi Food and Drug Authority	MDS – G5 Guidance on requirements for medical device listing and marketing authorization	https://www.sfda.gov.sa/sites/default/files/2020-07/MDS-G5.pdf
Singapore	Health Sciences Authority	GN-23: Guidance on labelling for medical devices	https://www.hsa.gov.sg/medical-devices/guidance-documents

Table A2.4. Examples of HTA agencies, networks and professional organization dealing with medical devices

Centre, agency or network	Country	Website
WHO collaborating centres		
Instituto de Efectividad clínica y Sanitaria	Argentina	http://www.iecs.org.ar/
Key Laboratory of Health Technology Assessment, Ministry of Health	China	http://chta.fudan.edu.cn/
Agencies		
Institut national d'excellence en santé et en services sociaux	Canada	http://www.inesss.qc.ca/
Health Intervention and Technology Assessment Programme	Thailand	http://www.hitap.net
Networks		
International Network of Agencies of Health Technology Assessment	52 member agencies	http://www.inahta.org/
Health Technology Assessment Network	European Commission	https://health.ec.europa.eu/health-technology-assessment/behind-hta-regulation/health-technology-assessment-network_en
Health Technology Assessment Network of the Americas	Americas	https://redetsa.bvsalud.org/en/
Professional organizations		
Health Technology Assessment International	International	http://www.htai.org/

Table A2.5. Examples of WHO collaborating centers and professional organizations on health technology management

WHO collaborating centres and professional organizations	Website
WHO collaborating centres	
Clinical Engineering Department, S. Matteo Hospital Foundation, Italy	http://www.sanmatteo.org/site/home/il-san-matteo/organizzazione/scheda4129.html
Technical Services Partnership, University of Vermont, USA	http://www.tsp-uvm.org/
Centro Nacional de Excelencia Tecnológica en Salud, Mexico	http://www.gob.mx/salud/cenetec
Professional organizations	
International Federation of Medical and Biological Engineering	https://ifmbe.org/
Global Clinical Engineering Alliance	https://www.globalcea.org/home

World Health Organization
Medical devices team
Health Products Policy and Standards Department
20 Avenue Appia
1211 Geneva 27
Switzerland

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